Richtlijnmodules Subacromiaal Pijnsyndroom van de schouder (SAPS)

INITIATIEF
Nederlandse Orthopaedische Vereniging

IN SAMENWERKING MET
Koninklijk Nederlands Genootschap voor Fysiotherapie
Nederlands Huisartsen Genootschap
Nederlandse Vereniging voor Anesthesiologie
Nederlandse Vereniging voor Arbeids- en Bedrijfsgeneeskunde
Nederlandse Vereniging voor Radiologie
Nederlandse Vereniging voor Reumatologie
Nederlandse Vereniging van Revalidatieartsen
Nederlandse Vereniging voor Verzekeringsgeneeskunde

MET ONDERSTEUNING VAN
Kennisinstituut van de Federatie Medisch Specialisten

FINANCIERING
De richtlijnontwikkeling werd gefinancierd uit de Kwaliteitsgelden Medisch Specialisten (SKMS).

Colofon

RICHTLIJN SUBACROMIAAL PIJNSYNDROOM VAN DE SCHOUDER (SAPS)

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Inhoud

Samenstelling van de werkgroep

Werkgroep
dr. J.J.A.M (Jos) van Raaij, orthopedisch chirurg Martiniziekenhuis Groningen, NOV (voorzitter)
dr. C.P.J. (Cornelis) Visser, orthopedisch chirurg Alrijne en Eisenhower Kliniek, NOV
dr. F.O. (Okke) Lambers Heerspink, orthopedisch chirurg VieCuri Medisch Centrum, NOV
dr. E.J.D. (Bart Jan) Veen, orthopedisch chirurg Medisch Spectrum Twente, NOV
dr. O. (Oscar) Dorrestijn, orthopedisch Chirurg Sint Maartenskliniek, NOV
dr. M.J.C. Maarten Leijs, orthopedisch chirurg Reinier Haga Orthopedisch Centrum , NOV
dr. D. (Dennis) van Poppel, manueel therapeut, sportfysiotherapeut PECE Zorg, Fontys Paramedisch, KNGF
drs. P.A. (Peter) Stroomberg, radioloog, Isala, NVvR
dr. R.P.G. (Ramon) Ottenheijm, huisarts, vakgroep huisartsgeneeskunde, Universiteit Maastricht, NHG
dr. J.W. (Jan Willem) Kallewaard, anesthesioloog Rijnstate, NVA
drs. T.J.W. (Tjerk) de Ruiter, revalidatiearts De Ruiter Revalidatie, VRA
dr. H.A. (Henk) Martens, reumatoloog Sint Maartenskliniek, NVR

Klankbordgroep
drs. R.J. (René) Naber, Bedrijfsarts arbodienst Amsterdam UMC, NVAB
drs. Y.B. (Yvonne) Suijkerbuijk, Arts-onderzoeker Amsterdam UMC en verzekeringsarts UWV, NVVG

<u>Met ondersteuning van</u>
dr. J.G.M. (Jacqueline) Jennen, adviseur, Kennisinstituut van de Federatie Medisch Specialisten (oktober 2023 tot mei 2024)
drs. T. (Tessa) Geltink, adviseur, Kennisinstituut van de Federatie Medisch Specialisten (tot mei 2024)
drs. F.M. (Femke) Janssen, junior adviseur, Kennisinstituut van de Federatie Medisch Specialisten (tot oktober 2023, vanaf mei 2024)
dr. M.S. (Matthijs) Ruiter, senior adviseur, Kennisinstituut van de Federatie Medisch Specialisten (vanaf mei 2024)

Lijst van afkortingen van PROMS

CMS: Constant Murley Score
DASH: Disability of the Arm, Shoulder and Hand questionnaire
WORC: Western Ontario Rotator Cuff index
ASES: American Shoulder and Elbow Surgeons score
DSST: Dutch Simple Shoulder Test
OSS: Oxford Shoulder Score
VAS: Visual Analogue Score

Startpagina Herziening Richtlijn Subacromiaal Pijnsyndroom van de Schouder (SAPS)

Waar gaat deze richtlijn over?
Het doel van deze herziening is het actualiseren van de bestaande richtlijn op basis van de meest recente medische kennis omtrent de beste zorg voor patiënten met het Subacromiaal Pijnsyndroom van de Schouder (SAPS).

Onder SAPS worden alle niet-traumatische, specifiek niet-inflammatoire of door een reumatologische oorzaak (meestal unilaterale) schouderklachten gerekend die leiden tot pijn, veelal verergerend tijdens of aansluitend aan het heffen van de arm. Primair omvat dit bursitis subdeltoidea/subacromialis en/of problematiek ten aanzien van de rotator cuff. De pathologie kan divers zijn, zoals cuff degeneratie, tendinosis calcarea, en rupturen van de supraspinatuspees.

Deze richtlijn is niet bedoeld voor de behandeling van patiënten met schouderklachten ten gevolge van een primaire of secundaire “frozen shoulder”, geïsoleerde bicepspeespathologie, (posttraumatische en atraumatische) instabiliteit van het glenohumerale of acromioclaviculaire gewricht, artrose van het glenohumerale en acromioclaviculaire (AC) gewricht, irreparabele rupturen van de rotator cuff en evenmin voor de behandeling van patiënten met primaire intra-articulaire pathologie of met schouderklachten ten gevolge van primair neurologisch lijden.

Voor wie is deze richtlijn bedoeld?
Deze richtlijn is bedoeld voor alle leden van de beroepsgroepen die betrokken zijn bij de zorg voor patiënten met SAPS, waaronder orthopedisch chirurgen, fysio- en oefentherapeuten, anesthesiologen, radiologen en huisartsen. De richtlijn is mogelijk ook relevant voor revalidatieartsen, reumatologen, sociaal- en verzekeringsgeneeskundigen en bedrijfsartsen. Aangezien richtlijnen de klinische besluitvorming ondersteunen, is de richtlijn ook bedoeld voor patiënten met schouderklachten.

Voor patiënten
Het Subacromiaal Pijnsyndroom van de Schouder (SAPS) is een veel voorkomend probleem bij volwassenen (40-plussers). Per jaar krijgen ruim 20 op de 1000 patiënten deze klacht; vrouwen meer dan mannen. De schouder is met name pijnlijk bij zijwaartse bewegingen of heffen van de arm, zoals bijvoorbeeld bij bovenhandse werkzaamheden. Ook bij het liggen op de zijde kan deze pijn ontstaan of verergeren. Soms is de schouder ook pijnlijk in rust. Er zijn verschillende oorzaken, zoals een slijmbeursontsteking, een peesontsteking of peesbeschadiging (scheur), veroudering van de pees of kalkafzetting in de pees of een combinatie daarvan.

In deze richtlijn worden meerdere aspecten (modules) van SAPS behandeld, zoals preventieve maatregelen, beeldvorming voor de diagnose, niet-operatieve en operatieve behandelingsmogelijkheden. De aanbevelingen volgen uit literatuuronderzoek en ervaringen van een multidisciplinaire werkgroep bestaande uit experts. De behandelend arts kan in overleg met de patiënt (samen beslissen) bepalen welk advies of welke behandeling het meest geschikt is (passende zorg).

Zie ook Schouderklachten op Thuisarts.nl

Hoe is de richtlijn tot stand gekomen?
Het initiatief voor deze richtlijn is afkomstig van de Nederlandse Orthopaedische Vereniging (NOV). De richtlijn is opgesteld door een multidisciplinaire commissie met vertegenwoordigers vanuit de orthopedisch chirurgen, radiologie, anesthesiologie, revalidatieartsen, huisartsen, en fysiotherapeuten. Er werd aandacht besteed aan het patiëntperspectief door inbreng van Patiëntenfederatie Nederland tijdens de knelpunteninventarisatie en de commentaarfase.

Verantwoording

Leeswijzer
De verantwoording wordt op de Richtlijnendatabase bij elke module opgenomen. Aangezien deze richtlijn gedeeltelijk een herziening betreft, zal het gedeelte 'Autorisatie en geldigheid' per module verschillen.

Autorisatie en geldigheid

Autorisatiedatum:	volgt
Eerstvolgende beoordeling actualiteit	volgt
Geautoriseerd door:	volgt
Belangrijkste wijzigingen t.o.v. vorige versie:	Het betreft de herziening van de richtlijn Herziening Richtlijn Subacromiaal Pijnsyndroom van de Schouder (SAPS) (2013). Deze richtlijn zal worden herzien volgens de vastgestelde adviezen van de adviescommissie richtlijnen van de Raad Kwaliteit. Daar waar de modules nog actueel zijn, worden deze herbevestigd. De overige modules worden herzien.
Herbevestiging:	volgt
Regiehouder(s):	Nederlandse Orthopaedische Vereniging,

Algemene gegevens
De ontwikkeling/herziening van deze richtlijnmodule werd ondersteund door het Kennisinstituut van de Federatie Medisch Specialisten (www.demedischspecialist.nl/kennisinstituut) en werd gefinancierd uit de Kwaliteitsgelden Medisch Specialisten (SKMS).
De financier heeft geen enkele invloed gehad op de inhoud van de richtlijnmodule.

Samenstelling werkgroep
Voor het herzien van de richtlijnmodules is in 2022 een multidisciplinaire werkgroep ingesteld, bestaande uit vertegenwoordigers van alle relevante specialismen (zie hiervoor de Samenstelling van de werkgroep) die betrokken zijn bij de zorg voor patiënten met Subacromiaal Pijnsyndroom van de Schouder (SAPS).

Belangenverklaringen
De Code ter voorkoming van oneigenlijke beïnvloeding door belangenverstrengeling is gevolgd. Alle werkgroepleden hebben schriftelijk verklaard of zij in de laatste drie jaar directe financiële belangen (betrekking bij een commercieel bedrijf, persoonlijke financiële belangen, onderzoeksfinanciering) of indirecte belangen (persoonlijke relaties, reputatiemanagement) hebben gehad. Gedurende de ontwikkeling of herziening van een module worden wijzigingen in belangen aan de voorzitter doorgegeven. De belangenverklaring wordt bevestigd tijdens de commentaarfase.
Een overzicht van de belangen van werkgroepleden en het oordeel over het omgaan met eventuele belangen vindt u in onderstaande tabel. De ondertekende belangenverklaringen zijn op te vragen bij het secretariaat van het Kennisinstituut van de Federatie Medisch Specialisten.

Werkgroep

Werkgroeplid	Functie	Nevenfuncties	Gemelde belangen	Ondernomen actie
Van Raaij (voorzitter)	Voorzitter werkgroep	Orthopedisch chirurg, wetenschappelijk medewerker (stichting orthoresearch noord) Martiniziekenhuis Groningen (onbezoldigd). Bestuurslid werkgroep schouder/elleboog NOV (onbezoldigd) Lid registratie adviesraad (RAR) LROI (Landelijke Registratie Orthopedische Implantaten) (onbezoldigd). Lid LEARN, (Rijksuniversiteit Groningen) (onderzoek naar opleiding/onderwijs) (onbezoldigd). Cursusleider vaardigheidstraining voor aios orthopedie (Techmed Centre, University of Twente) (onbezoldigd). Voorzitter werkgroep herziening richtlijn SAPS (FMS, kennisinstituut). Lid werkgroep richtlijn chronische instabiliteit schouder (FMS, kennisinstituut) Voorzitter cluster richtlijnen bovenste extremiteit (FMS,kennisinstituut) Lid werkgroep ontwikkeling richtlijn schouderklachten, KNGF (fysiotherapie)	Geen	Geen restricties
Visser	Orthopedisch chirurg Alrijne	Orthopedisch chirurg Eisenhowerkliniek; Lid wetenschappelijke adviesraad (WAR) LROI (Landelijke Registratie Orthopedische Implantaten) (onbezoldigd); Lid kascommissie van de NOV (onbezoldigd)	Geen	Geen restricties
Lambers Heerspink	Orthopedisch chirurg VieCuri Medisch Centrum	Commissie van onderzoek VieCuri (onbetaald)] Lid wetenschapscommissie VieCuri (onbetaald) Voorzitter BELG (Bovenste Extremiteit Limburgs genootschap) (onbetaald)	Presentatie orthopedische firma (Arthrex) betreffende proximale humerusfracuur	Geen restricties, onderwerp van extern gefinancierd onderzoek valt

			(betaald) Extern gefinancieerd onderzoek (Financier, (inhoud)): Arthrex en Fons Wetenschap Innovatie Viecuri (optimale positionering glenoid bij revers schouderprothese), Fons wetenschap innovatie Viecuri (Nabehandeling schouderprothese middels app), Fonds Wetenschap Innovatie Viecuri (Voorkomen van cristallopathie bij patienten met een degeneratieve rotator cuff ruptuur).	buiten het bestek van de richtlijn
Veen	Orthopedisch chirurg, Medisch Spectrum Twente	Geen	Geen	Geen restricties
Dorrestijn	Orthopedisch chirurg	Dienstverband Sint Maartenskliniek - echter geen direct financieel voordeel	Geen	Geen restricties
Leijs	Clubarts Excelsior en orthopedisch chirurg	Geen	Geen	Geen restricties
Van Poppel	Manueel therapeut, sportfysiotherapeut, bewegingswetenschapper, docent, onderzoeker bij PECE Zorg, Schouder Expertise Centrum en	Zelfstandig docent, auteur, onderzoeker, betaald. Docent Master Opleiding Sportfysiotherapie Hogeschool Rotterdam, betaald. Lid werkgroep ontwikkeling richtlijn schouderklachten, KNGF (fysiotherapie). Auditeur Health Care Auditing, betaald.	Geen	Geen restricties

	Fontys Hogescholen.	Lid Regionaal Tuchtcollege Gezondheidszorg, betaald.		
Stroomberg *Deelname vanaf 09-10-2023*	*Tot 31-10-2024:* Fellow Radioloog, Rijnstate Ziekenhuis *Vanaf 01-11-2024:* Radioloog Isala	Geen	Geen	Geen restricties
Koen *Deelname t/m 09-10-2023*	Radioloog bij het Meander Medisch Centrum, Screeningsradioloog bevolkingsonderzoek borstkanker.	Geen	Geen	Geen restricties
Ottenheijm	Universitair docent; Vakgroep Huisartsgeneeskunde, Universiteit Maastricht; Kaderhuisarts bewegingsapparaat: werkzaam als ZZPer voor MCC Omnes, Pluspunt MC en ZBC Optimus Orthopedie	Voorzitter Stichting Optimus Klinieken (ZBC) (onbetaald) Medisch Directeur van Optimus Orthopedie BV (onbetaald) Bestuurder van de NHG-expertgroep Het Beweegkader (vereniging van kaderhuisartsen bewegingsapparaat) t/m juni 2022.	Werkzaam als ZZP kaderhuisarts op 1,5 lijnspoli's en in een ZBC orthopedie, waar zorg voor schouderpatienten wordt geleverd. Mede-aandeelhouder Optimus Orthopedie BV Mede-aanvrager van een door ZonMW gefinanceerd doelmatigheidsonderzoek schouderklachten in de huisartspraktijk (Hoofdaanvrager werkzaam bij Erasmus MC)	Geen restricties
Kallewaard	Anesthesioloog, Rijnstate Ziekenhuis	Betrokken bij andere richtlijnen: bbc nva sectie pijn nva hoofd clusterpijn deelnemer	Extern gefinancierd onderzoek (Financier, inhoud): Boston Scientific	Geen restricties, onderwerp van extern

			(Neuromodulatie en endometriose), Saluda (neuromodulatie psps2), Dtm (neuromodulatie virgin back).	gefinancierd onderzoek valt buiten het bestek van de richtlijn
De Ruiter	Revalidatiearts bij De Ruiter Revalidatie	Rotterdam Knowledge Ambassador, Onbetaald. Adviseur Stichting Mobiliteit voor Gehandicapten, Onbetaald. Oprichter Perpetual Prosthetics, Onbetaald. Lid Membership Committee, International Society on Prosthetics and Orthotics, onbetaald.	Geen	Geen restricties
Martens	Reumatoloog bij de Sint Maartenskliniek	Geen	Geen	Geen restricties

Klankbordgroep

Klankbordgroeplid	Functie	Nevenfuncties	Gemelde belangen	Ondernomen actie
Naber	Bedrijfsarts AUMC	Secretaris NVAB werkgroep Bedrijfsartsen in de Zorg (onbetaald) Lid NVAB commissie Richtlijnontwikkeling en Wetenschap (onbetaald) Lid NVAB commissie Intercollegiale toetsing en Deskundigheidsbevordering (onbetaald) Lid Samenwerkingsverband Vroegsignalering Alcoholproblematiek (namens de NVAB, onbetaald) lid werkgroep SRI PBM lid werkgroep SRI BRMO lid werkgroep SRI MRSA	Geen	Geen restricties
Suijkerbuijk	Arts-onderzoeker (promovenda) Kenniscentrum	-Lid commissie wetenschap NVVG: beoordelen en deelname aan ontwikkeling	promotieonderzoek gefinancierd door UWV	Geen restricties

	Verzekeringsgeneeskunde, Amsterdam UMC, locatie AMC (betaald) verzekeringsarts UWV: WIA beoordelingen (betaald)	van richtlijnen. Momenteel deelname aan ontwikkeling multidisciplinaire richtlijn Depressie (Trimbos) (onbetaald) -lid commissie bedrijfs- en verzekeringsartsen Radboud Health Academy: organiseren van symposia: momenteel betrokken bij symposium long-COVID en arbeid (onbetaald) -lid begeleidingscommissie van een door UWV gefinancierd implementatieonderzoek (WerkWeb Autisme UMCG): laagfrequent bijeenkomsten gericht op advies/meedenken, geen uitvoerende rol (onbetaald)		

Inbreng patiëntperspectief

Er werd aandacht besteed aan het patiëntperspectief door het uitnodigen van de Patiëntenfederatie Nederland voor de invitational conference (knelpuntenanalyse). Het verslag hiervan is besproken in de werkgroep. De verkregen input is meegenomen bij het opstellen van de uitgangsvragen, de keuze voor de uitkomstmaten en bij het opstellen van de overwegingen. De conceptrichtlijn is tevens voor commentaar voorgelegd aan Patiëntenfederatie Nederland en de eventueel aangeleverde commentaren zijn bekeken en verwerkt.

Kwalitatieve raming van mogelijke financiële gevolgen in het kader van de Wkkgz
Bij de richtlijnmodule is conform de Wet kwaliteit, klachten en geschillen zorg (Wkkgz) een kwalitatieve raming uitgevoerd om te beoordelen of de aanbevelingen mogelijk leiden tot substantiële financiële gevolgen. Bij het uitvoeren van deze beoordeling is de richtlijnmodule op verschillende domeinen getoetst (zie het stroomschema op de Richtlijnendatabase).

Module	**Uitkomst raming**	**Toelichting**
Secundaire preventie SAPS (herzien)	Geen substantiële financiële gevolgen	Hoewel uit de toetsing volgt dat de aanbeveling(en) breed toepasbaar zijn, volgt ook uit de toetsing dat het geen nieuwe manier van zorgverlening of andere organisatie van zorgverlening betreft, het geen toename in het aantal in te zetten voltijdsequivalenten aan zorgverleners betreft en het geen wijziging in het opleidingsniveau van het zorgpersoneel betreft. Er worden daarom geen substantiële financiële gevolgen verwacht.
Diagnostische testen (herzien/aanvulling op module)	Geen substantiële financiële gevolgen	Hoewel uit de toetsing volgt dat de aanbeveling(en) breed toepasbaar zijn, volgt ook uit de toetsing dat het geen nieuwe manier van zorgverlening of andere organisatie van zorgverlening betreft, het geen toename in het aantal in te zetten voltijdsequivalenten aan zorgverleners betreft en het geen wijziging in het opleidingsniveau van het zorgpersoneel betreft. Er worden daarom geen substantiële financiële gevolgen verwacht.
Beeldvormende diagnostiek SAPS (herzien)	Geen substantiële financiële gevolgen	Hoewel uit de toetsing volgt dat de aanbeveling(en) breed toepasbaar zijn, volgt ook uit de toetsing dat het geen nieuwe manier van zorgverlening of andere organisatie van zorgverlening betreft, het geen toename in het aantal in te zetten voltijdsequivalenten aan zorgverleners betreft en het geen wijziging in het opleidingsniveau van het zorgpersoneel betreft. Er worden daarom geen substantiële financiële gevolgen verwacht.
Niet-chirurgische behandeling tendinosis calcarea	Geen substantiële financiële gevolgen	Hoewel uit de toetsing volgt dat de aanbeveling(en) breed toepasbaar zijn, volgt ook uit de toetsing dat het geen nieuwe manier van zorgverlening of andere organisatie

		van zorgverlening betreft, het geen toename in het aantal in te zetten voltijdsequivalenten aan zorgverleners betreft en het geen wijziging in het opleidingsniveau van het zorgpersoneel betreft. Er worden daarom geen substantiële financiële gevolgen verwacht.
Oefentherapie versus corticosteroïdeinjectie	Geen substantiële financiële gevolgen	Hoewel uit de toetsing volgt dat de aanbeveling(en) breed toepasbaar zijn, volgt ook uit de toetsing dat het geen nieuwe manier van zorgverlening of andere organisatie van zorgverlening betreft, het geen toename in het aantal in te zetten voltijdsequivalenten aan zorgverleners betreft en het geen wijziging in het opleidingsniveau van het zorgpersoneel betreft. Er worden daarom geen substantiële financiële gevolgen verwacht.
Nervus suprascapularis blokkade	Geen substantiële financiële gevolgen	Hoewel uit de toetsing volgt dat de aanbeveling(en) breed toepasbaar zijn, volgt ook uit de toetsing dat het geen nieuwe manier van zorgverlening of andere organisatie van zorgverlening betreft, het geen toename in het aantal in te zetten voltijdsequivalenten aan zorgverleners betreft en het geen wijziging in het opleidingsniveau van het zorgpersoneel betreft. Er worden daarom geen substantiële financiële gevolgen verwacht.
Operatieve versus niet-operatieve behandeling	Geen substantiële financiële gevolgen	Hoewel uit de toetsing volgt dat de aanbeveling(en) breed toepasbaar zijn, volgt ook uit de toetsing dat het geen nieuwe manier van zorgverlening of andere organisatie van zorgverlening betreft, het geen toename in het aantal in te zetten voltijdsequivalenten aan zorgverleners betreft en het geen wijziging in het opleidingsniveau van het zorgpersoneel betreft. Er worden daarom geen substantiële financiële gevolgen verwacht.
Bicepspeestenotomie en tenodese als onderdeel van rotator cuff repair	Geen substantiële financiële gevolgen	Hoewel uit de toetsing volgt dat de aanbeveling(en) breed toepasbaar zijn, volgt ook uit de toetsing dat het geen nieuwe manier van

		zorgverlening of andere organisatie van zorgverlening betreft, het geen toename in het aantal in te zetten voltijdsequivalenten aan zorgverleners betreft en het geen wijziging in het opleidingsniveau van het zorgpersoneel betreft. Er worden daarom geen substantiële financiële gevolgen verwacht.
Prognostische factoren SAPS (herzien/aanvulling op module)	Geen substantiële financiële gevolgen	Hoewel uit de toetsing volgt dat de aanbeveling(en) breed toepasbaar zijn, volgt ook uit de toetsing dat het geen nieuwe manier van zorgverlening of andere organisatie van zorgverlening betreft, het geen toename in het aantal in te zetten voltijdsequivalenten aan zorgverleners betreft en het geen wijziging in het opleidingsniveau van het zorgpersoneel betreft. Er worden daarom geen substantiële financiële gevolgen verwacht.
Duur van immobilisatie als nabehandeling	Geen substantiële financiële gevolgen	Hoewel uit de toetsing volgt dat de aanbeveling(en) breed toepasbaar zijn, volgt ook uit de toetsing dat het geen nieuwe manier van zorgverlening of andere organisatie van zorgverlening betreft, het geen toename in het aantal in te zetten voltijdsequivalenten aan zorgverleners betreft en het geen wijziging in het opleidingsniveau van het zorgpersoneel betreft. Er worden daarom geen substantiële financiële gevolgen verwacht.
Operatieve behandeling versus barbotage	Geen substantiële financiële gevolgen	Hoewel uit de toetsing volgt dat de aanbeveling(en) breed toepasbaar zijn, volgt ook uit de toetsing dat het geen nieuwe manier van zorgverlening of andere organisatie van zorgverlening betreft, het geen toename in het aantal in te zetten voltijdsequivalenten aan zorgverleners betreft en het geen wijziging in het opleidingsniveau van het zorgpersoneel betreft. Er worden daarom geen substantiële financiële gevolgen verwacht.

Werkwijze

AGREE

Deze richtlijnmodule is opgesteld conform de eisen vermeld in het rapport Medisch Specialistische Richtlijnen 3.0 van de adviescommissie Richtlijnen van de Raad Kwaliteit. Dit rapport is gebaseerd op het AGREE II instrument (Appraisal of Guidelines for Research & Evaluation II; Brouwers, 2010).

Knelpuntenanalyse en uitgangsvragen

Tijdens de voorbereidende fase inventariseerde de werkgroep de knelpunten in de zorg voor patiënten met SAPS. Tevens zijn er knelpunten aangedragen door de IGJ, NFU, NHG, NVZ, PF NL, STZ, V&VN, NAPA, ZiNL, ZKN, ZN, VIG, NOV, KNGF, NVvR, NHG, NVA, PFNL, VRA, NVR, NVAB, en Verzekeringsgeneeskundigen, via een knelpuntenanalyse (invitational conference). Een verslag hiervan is opgenomen onder aanverwante producten.

Op basis van de uitkomsten van de knelpuntenanalyse zijn door de werkgroep concept-uitgangsvragen opgesteld en definitief vastgesteld.

Uitkomstmaten

Na het opstellen van de zoekvraag behorende bij de uitgangsvraag inventariseerde de werkgroep welke uitkomstmaten voor de patiënt relevant zijn, waarbij zowel naar gewenste als ongewenste effecten werd gekeken. Hierbij werd een maximum van acht uitkomstmaten gehanteerd. De werkgroep waardeerde deze uitkomstmaten volgens hun relatieve belang bij de besluitvorming rondom aanbevelingen, als cruciaal (kritiek voor de besluitvorming), belangrijk (maar niet cruciaal) en onbelangrijk. Tevens definieerde de werkgroep tenminste voor de cruciale uitkomstmaten welke verschillen zij klinisch (patiënt) relevant vonden.

Methode literatuursamenvatting

Een uitgebreide beschrijving van de strategie voor zoeken en selecteren van literatuur is te vinden onder ‘Zoeken en selecteren’ onder Onderbouwing. Indien mogelijk werd de data uit verschillende studies gepoold in een [random-effects model]. [Review Manager 5.4] werd gebruikt voor de statistische analyses. De beoordeling van de kracht van het wetenschappelijke bewijs wordt hieronder toegelicht.

Beoordelen van de kracht van het wetenschappelijke bewijs

De kracht van het wetenschappelijke bewijs werd bepaald volgens de GRADE-methode. GRADE staat voor ‘Grading Recommendations Assessment, Development and Evaluation’ (zie http://www.gradeworkinggroup.org/). De basisprincipes van de GRADE-methodiek zijn: het benoemen en prioriteren van de klinisch (patiënt) relevante uitkomstmaten, een systematische review per uitkomstmaat, en een beoordeling van de bewijskracht per uitkomstmaat op basis van de acht GRADE-domeinen (domeinen voor downgraden: risk of bias, inconsistentie, indirectheid, imprecisie, en publicatiebias; domeinen voor upgraden: dosis-effect relatie, groot effect, en residuele plausibele confounding).
GRADE onderscheidt vier gradaties voor de kwaliteit van het wetenschappelijk bewijs: hoog, redelijk, laag en zeer laag. Deze gradaties verwijzen naar de mate van zekerheid die er bestaat over de literatuurconclusie, in het bijzonder de mate van zekerheid dat de literatuurconclusie de aanbeveling adequaat ondersteunt (Schünemann, 2013; Hultcrantz, 2017).

GRADE	Definitie
Hoog	• er is hoge zekerheid dat het ware effect van behandeling dichtbij het

	geschatte effect van behandeling ligt; • het is zeer onwaarschijnlijk dat de literatuurconclusie klinisch relevant verandert wanneer er resultaten van nieuw grootschalig onderzoek aan de literatuuranalyse worden toegevoegd.
Redelijk	• er is redelijke zekerheid dat het ware effect van behandeling dichtbij het geschatte effect van behandeling ligt; • het is mogelijk dat de conclusie klinisch relevant verandert wanneer er resultaten van nieuw grootschalig onderzoek aan de literatuuranalyse worden toegevoegd.
Laag	• er is lage zekerheid dat het ware effect van behandeling dichtbij het geschatte effect van behandeling ligt; • er is een reële kans dat de conclusie klinisch relevant verandert wanneer er resultaten van nieuw grootschalig onderzoek aan de literatuuranalyse worden toegevoegd.
Zeer laag	• er is zeer lage zekerheid dat het ware effect van behandeling dichtbij het geschatte effect van behandeling ligt; • de literatuurconclusie is zeer onzeker.

Bij het beoordelen (graderen) van de kracht van het wetenschappelijk bewijs in richtlijnen volgens de GRADE-methodiek spelen grenzen voor klinische besluitvorming een belangrijke rol (Hultcrantz, 2017). Dit zijn de grenzen die bij overschrijding aanleiding zouden geven tot een aanpassing van de aanbeveling. Om de grenzen voor klinische besluitvorming te bepalen moeten alle relevante uitkomstmaten en overwegingen worden meegewogen. De grenzen voor klinische besluitvorming zijn daarmee niet één op één vergelijkbaar met het minimaal klinisch relevant verschil (Minimal Clinically Important Difference, MCID). Met name in situaties waarin een interventie geen belangrijke nadelen heeft en de kosten relatief laag zijn, kan de grens voor klinische besluitvorming met betrekking tot de effectiviteit van de interventie bij een lagere waarde (dichter bij het nuleffect) liggen dan de MCID (Hultcrantz, 2017).

Overwegingen (van bewijs naar aanbeveling)

Om te komen tot een aanbeveling zijn naast (de kwaliteit van) het wetenschappelijke bewijs ook andere aspecten belangrijk en worden meegewogen, zoals aanvullende argumenten uit bijvoorbeeld de biomechanica of fysiologie, waarden en voorkeuren van patiënten, kosten (middelenbeslag), aanvaardbaarheid, haalbaarheid en implementatie. Deze aspecten zijn systematisch vermeld en beoordeeld (gewogen) onder het kopje 'Overwegingen' en kunnen (mede) gebaseerd zijn op expert opinion. Hierbij is gebruik gemaakt van een gestructureerd format gebaseerd op het evidence-to-decision framework van de internationale GRADE Working Group (Alonso-Coello, 2016a; Alonso-Coello 2016b). Dit evidence-to-decision framework is een integraal onderdeel van de GRADE methodiek.

Formuleren van aanbevelingen

De aanbevelingen geven antwoord op de uitgangsvraag en zijn gebaseerd op het beschikbare wetenschappelijke bewijs en de belangrijkste overwegingen, en een weging van de gunstige en ongunstige effecten van de relevante interventies. De kracht van het wetenschappelijk bewijs en het gewicht dat door de werkgroep wordt toegekend aan de overwegingen, bepalen samen de sterkte van de aanbeveling. Conform de GRADE-methodiek sluit een lage bewijskracht van conclusies in de systematische literatuuranalyse een sterke aanbeveling niet a priori uit, en zijn bij een hoge bewijskracht ook zwakke aanbevelingen mogelijk (Agoritsas, 2017; Neumann, 2016). De sterkte van de aanbeveling wordt altijd bepaald door weging van alle relevante argumenten tezamen. De werkgroep

heeft bij elke aanbeveling opgenomen hoe zij tot de richting en sterkte van de aanbeveling zijn gekomen.
In de GRADE-methodiek wordt onderscheid gemaakt tussen sterke en zwakke (of conditionele) aanbevelingen. De sterkte van een aanbeveling verwijst naar de mate van zekerheid dat de voordelen van de interventie opwegen tegen de nadelen (of vice versa), gezien over het hele spectrum van patiënten waarvoor de aanbeveling is bedoeld. De sterkte van een aanbeveling heeft duidelijke implicaties voor patiënten, behandelaars en beleidsmakers (zie onderstaande tabel). Een aanbeveling is geen dictaat, zelfs een sterke aanbeveling gebaseerd op bewijs van hoge kwaliteit (GRADE gradering HOOG) zal niet altijd van toepassing zijn, onder alle mogelijke omstandigheden en voor elke individuele patiënt.

Implicaties van sterke en zwakke aanbevelingen voor verschillende richtlijngebruikers		
	Sterke aanbeveling	*Zwakke (conditionele) aanbeveling*
Voor patiënten	De meeste patiënten zouden de aanbevolen interventie of aanpak kiezen en slechts een klein aantal niet.	Een aanzienlijk deel van de patiënten zou de aanbevolen interventie of aanpak kiezen, maar veel patiënten ook niet.
Voor behandelaars	De meeste patiënten zouden de aanbevolen interventie of aanpak moeten ontvangen.	Er zijn meerdere geschikte interventies of aanpakken. De patiënt moet worden ondersteund bij de keuze voor de interventie of aanpak die het beste aansluit bij zijn of haar waarden en voorkeuren.
Voor beleidsmakers	De aanbevolen interventie of aanpak kan worden gezien als standaardbeleid.	Beleidsbepaling vereist uitvoerige discussie met betrokkenheid van veel stakeholders. Er is een grotere kans op lokale beleidsverschillen.

Organisatie van zorg
In de knelpuntenanalyse en bij de ontwikkeling van de richtlijnmodule is expliciet aandacht geweest voor de organisatie van zorg: alle aspecten die randvoorwaardelijk zijn voor het verlenen van zorg (zoals coördinatie, communicatie, (financiële) middelen, mankracht en infrastructuur). Randvoorwaarden die relevant zijn voor het beantwoorden van deze specifieke uitgangsvraag zijn genoemd bij de overwegingen. Meer algemene, overkoepelende, of bijkomende aspecten van de organisatie van zorg worden behandeld in de module Organisatie van zorg.

Commentaar- en autorisatiefase
De conceptrichtlijnmodule werd aan de betrokken (wetenschappelijke) verenigingen en (patiënt) organisaties voorgelegd ter commentaar. De commentaren werden verzameld en besproken met de werkgroep. Naar aanleiding van de commentaren werd de conceptrichtlijnmodule aangepast en definitief vastgesteld door de werkgroep. De definitieve richtlijnmodule werd aan de deelnemende (wetenschappelijke) verenigingen en (patiënt) organisaties voorgelegd voor autorisatie en door hen geautoriseerd dan wel geaccordeerd.

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Gehandhaafde modules

Meetinstrumenten SAPS

Patiëntenperspectief SAPS

Herziene modules

Leeswijzer
Onderstaande conceptmodules wordt na het doorlopen van de commentaar- en autorisatiefase opgenomen in de Richtlijnendatabase (www.richtlijnendatabase.nl). Verwijzingen naar ‘tabbladen’ zijn in de huidige versie van de richtlijntekst terug te vinden in de ‘bijlagen’ aan het einde van de hoofdtekst. In verband met de modulaire opbouw van richtlijnen in de database wordt verwezen naar modules (i.p.v. hoofdstukken) en aanverwante producten (bijlagen).
Literatuuranalyses (van introductie t/m literatuurconclusies) worden in het Engels geschreven om internationale uitwisseling mogelijk te maken. Bij publicatie op de Richtlijnendatabase kan dit worden uitgeklapt. De overgangen van de ene taal naar de andere zullen daar dus niet worden ervaren.

Module 1 Secundaire preventie van SAPS

Uitgangsvraag
Welke preventieve maatregelen kunnen ingezet worden bij de werkende populatie om een recidief SAPS te voorkomen?

Introduction (English)
Subacromial pain syndrome (SAPS) is a common reason for work disability and limitations in daily activities, accounting for high and enduring social, medical and mental costs. Defining (primary and secondary) prevention measures is therefore very important. This module aims at prevention after recovery from a SAPS episode, considering that the same measures should be applicable in primary prevention as well. Knowing the value of preventive measures makes counseling much easier by the clinician or therapist.

Search and select
A systematic review of the literature was performed to answer the following question: What preventive measures can be used in the working population to prevent recurrent SAPS?

Patients	patients who had SAPS complaints and have recovered
Intervention	preventive measures
Control	no preventive measures
Outcomes	SAPS complaints (pain), return to work or leisure, health care consumption

Relevant outcome measures
The guideline development group considered return to work or leisure as a critical outcome measure for decision making; and SAPS complaints (pain) and health care consumption as important outcome measures for decision making.

A priori, the guideline development group did not define the outcome measures listed above but used the definitions used in the studies.

The working group defined the following clinical relevant differences:
- SAPS complaints (pain): difference of 25% (RR ≤ 0.80 and ≥ 1.25)
- Health care consumption: difference of 25% (RR ≤ 0.80 and ≥ 1.25)
- Return to work or leisure: difference of 25% (RR ≤ 0.80 and ≥ 1.25)

Search and select (Methods)
The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms from 2000 until 19 June 2023. The detailed search strategy is depicted under the tab Methods. The systematic orienting literature search resulted in 683 hits. Studies were selected based on the following criteria:
- Study design: randomized controlled trial, systematic review or observational studies about recurrence of SAPS and preventive measures.
- Describing at least one of the relevant outcomes specified in the PICO.

A systematic search resulted in 683 articles that were selected for title and abstract screening. After the title and abstract screening, none of these articles met the selection criteria. Full-text selection was therefore not performed.

Results
No studies were included in the analysis of the literature.

Summary of literature
Description of studies
No studies were included reporting whether a preventive measure has been considered in terms of intervention in patients with recurrent subacromial pain syndrome.

Results
SAPS complaints, return to work or leisure, and health care consumption
No results could be reported as no studies were included reporting about the effectiveness of a preventive measure on SAPS complaints, return to work or leisure, and health care consumption compared to a wait and see policy in patients with recurrent subacromial pain syndrome.

Level of evidence of the literature
The level of evidence regarding the outcome measure **SAPS complaints, return to work or leisure, and health care consumption** could not be graded as no studies were included about the effectiveness of a preventive measure on these outcome measures compared to a wait and see policy in patients with recurrent shoulder impingement syndrome.

Conclusions

No GRADE	No evidence was found regarding the effective of a preventive measure on **SAPS complaints, return to work or leisure, and health care consumption** compared with a wait and see policy in patients with recurrent shoulder impingement syndrome.

Overwegingen – van bewijs naar aanbeveling

Voor- en nadelen van de interventie en de kwaliteit van het bewijs

Er is een literatuuronderzoek verricht naar de effectiviteit van preventieve maatregelen vergeleken met geen preventieve maatregelen bij patiënten die SAPS klachten hadden en zijn hersteld. Er is echter geen literatuur gevonden die voldeed aan de PICO – en dus waarin er qua interventie gekeken is naar een preventieve maatregel bij een patiëntenpopulatie met een recidief SAPS. Om deze reden kunnen er op basis van de literatuur geen conclusies getrokken worden over het effect van (een) preventieve maatregel(en) ten opzichte van geen preventieve maatregelen op SAPS klachten bij patiënten met recidief SAPS. Er bestaat hier een kennisvraag.

Aanbevelingen op basis van literatuur kunnen dan ook niet worden gegeven. In de klinische praktijk moeten we daarom vertrouwen op algemene literatuur betreffende (pees-)herstel, klinisch redeneren, inzichten uit de biomechanica, en algemener: expert opinie.

Gezien de huidige opinie en kennis over preventieve maatregelen, de rol van overbelasting en een ongezonde leefstijl was het a priori niet te verwachten dat er een “wait and see” controlegroep in de literatuur zou kunnen zijn. Aan leefstijladviezen kleven geen relevante nadelige effecten. Factoren die weefselregeneratie negatief beïnvloeden (zoals een algeheel matige conditie, roken, diabetes, obesitas maar ook langdurig NSAID en steroidgebruik), zullen dat ook doen bij SAPS. Houdingsafwijkingen (zoals protractie of hoogstand van de schouders) en biomechanische factoren die potentieel nadelig zijn, zullen dat ook doen. Dat zal zeker het geval zijn bij langdurige zware belasting (langdurig volgehouden), repeterende bewegingen tegen de begrenzingen van de range of motion (ROM)(met name bij rotaties), en bewegingen waarbij impingement op kan treden. Denk daarbij aan reiken en ante- en lateroflexie boven schouderniveau.

Surmenage is een relatief begrip. Bij een betere houding, controle en coördinatie van de schouderbeweging en bij een betere fysieke belastbaarheid (zoals bijvoorbeeld competitieve sporters) kan dezelfde belasting langdurig en zonder klachten worden volgehouden.

Waarden en voorkeuren van patiënten (en evt. hun verzorgers)

Patiënten willen een recidief van SAPS voorkomen, maar voor hen moeten de maatregelen in verhouding staan tot de klachten die ze bij een terugkerende SAPS ervaren. Het nemen van preventieve maatregelen is iets waar veel patiënten voor open staan, maar de preventieve maatregelen moeten passen binnen het leven en de leefstijl van de patient, oftewel haalbaar zijn voor de patiënt. Voor patiënten is het daarom belangrijk om te horen wat de preventieve maatregelen, zoals training en een verandering van de leefstijl, hen mogelijk kan opleveren en wat er van hen wordt verwacht.

Verandering van leefstijl en trainingsdiscipline vergt geduld en vasthoudendheid, maar nadelen zijn er voor patiënten verder niet. Dit vergt leerbaarheid en veranderbaarheid, maar ook therapietrouw. In de praktijk is anders-taligheid, ernstige psychopathologie of mentale retardatie een relatieve contra-indicatie. Ten aanzien van werk verwijst de werkgroep naar de generieke richtlijnmodule Arbeidsparticipatie voor medisch specialistische richtlijnen.

Kosten (middelenbeslag)

Counseling door de medisch specialist, huisarts, bedrijfsarts (maar ook verzekeringsarts en andere arbo-professionals) of therapeut moet uiteraard betaald worden. Het is daarom essentieel om goedkopere opties te gebruiken c.q. te ontwikkelen, zoals begeleiding vanuit

het gemeentelijke sociale domein, voorlichting door toegewijde verpleegkundigen of therapeuten, groepsvoorlichting, YouTube en instructiefolders. Het is niet bekend of er voor (bepaalde) subgroepen andere argumenten met betrekking tot kosten gelden. Verlies van arbeidsparticipatie is kostbaar voor de samenleving.

Aanvaardbaarheid, haalbaarheid en implementatie
De aanvaardbaarheid en haalbaarheid van deze interventies is niet specifiek voor deze doelgroep uitgevoerd. Over leefstijlinterventie en arbeidsadvisering is echter voldoende geschreven. Gehoorde bezwaren zijn dat de interventie in dit specifieke geval niet mogelijk is. In de regel zijn compensatiestrategieën dan nog onvoldoende geëxploreerd (bijvoorbeeld de was ophangen zonder boven schouderniveau te tillen). In dergelijke situaties is de spreekuurtijd van de arts vaak te kort en is er toegevoegde waarde van bijvoorbeeld een ergotherapeut of oefentherapeut.

Voor leerbaarheid en veranderbaarheid is helaas geen ander middel dan vasthoudendheid, geduld en overredingsvermogen. Helaas zijn biomechanisch zware belastingen (langdurig, zwaar, repeterend, weinig ergonomisch onhandige posities) in lagere sociale klassen oververtegenwoordigd en is de ruimte om voor minder belasting te kiezen vaak niet groot.

Belemmerende factoren op het gebied van implementatie van de interventie kan de benodigde tijd zijn. Counseling kost te veel tijd om te organiseren binnen een normaal artsenspreekuur. Ook kosten zijn een belemmerende factor; oefen-/fysiotherapie is vaak niet verzekerd bij de groepen die dat het hardst nodig hebben. Acceptatie en therapietrouw is in essentie de crux van deze interventie (zie kopje *Waarden en voorkeuren van patiënten).*

Haalbaarheid en veranderbaarheid/veranderbereidheid zijn voorwaarden, net zoals overtuigende diagnostiek, de juiste woordkeuze en aansluiting bij de patiënt. In essentie is de ideale getrapte zorgketen passend in het Integraal Zorg Akkoord.

Aanbevelingen

1. *Voorlichting over leefstijl*

Rationale van de aanbeveling: weging van argumenten voor en tegen de interventies
Veranderen van gedrag staat centraal in preventie van (recidieve) SAPS. Er zijn geen nadelen aan het zoveel mogelijk elimineren van risicofactoren en aan gedoseerd en doelgericht trainen, maar het motiveren daartoe vergt overredingsvermogen (waaronder overtuigende diagnostiek en het juiste taalgebruik) en geduld. Juist bij niet veranderbare factoren (zoals diabetes) is een gezonde leefstijl essentieel.

Aanbeveling

Informeer patiënten over de potentieel positieve effecten van een gezonde leefstijl. Denk hierbij aan:

- terughoudend zijn met langdurig NSAID gebruik en frequente corticosteroïdinjecties.
- blijvend aandacht hebben voor gedoseerd bewegen binnen sport en werk kan de belastbaarheid van de cuff duurzaam vergroten.

2. *Voorlichting omtrent arbeid*

Rationale van de aanbeveling: weging van argumenten voor en tegen de interventie
De bezwaren tegen interventie in biomechanische (en psychosociale) overbelasting zijn relatief. Overbelasting komt frequent voor bij schouderbelastend werk, maar ook daar geldt dat een uitgevallen werknemer duidelijk minder produceert dan een werknemer die zich aan ergonomie en rustpauzes mag houden. Medisch wetenschappelijk onderzoek is in relatie tot

deze onderzoeksvraag niet aanwezig. Biomechanische wetten maken weefselschade echter logisch indien de belasting de belastbaarheid overschrijdt.

Aanbeveling

Adviseer om:

- te bewegen binnen de comfortzone en niet te lang, te zwaar en te vaak.
- bewegingen zoals reiken, ante- en lateroflexie boven schouderniveau, endo- en exorotatie tegen de grenzen van de ROM te beperken.
- de inrichting van de werkplek te optimaliseren, rustpauzes in te lassen en hulpmiddelen te gebruiken.
- voor bovenstaande aanbevelingen te verwijzen naar de desbetreffende experts (bedrijfsarts en paramedici).

Zie ook de module Arbeidsparticipatie voor medisch specialistische richtlijnen.

Kennisvragen

Welke preventieve maatregelen kunnen in de beroepsbevolking worden ingezet om recidiverende SAPS te voorkomen?

Literatuur

Geen

Bijlagen bij module 1 Secundaire preventie van SAPS

Implementatieplan

Aanbeveling	Tijdspad voor implementatie: < 1 jaar, 1 tot 3 jaar of > 3 jaar	Verwacht effect op kosten	Randvoorwaarden voor implementatie (binnen aangegeven tijdspad)	Mogelijke barrières voor implementatie	Te ondernemen acties voor implementatie	Verantwoordelijken voor acties	Overige opmerkingen
Informeer patiënten over de potentieel positieve effecten van een gezonde leefstijl. Denk hierbij aan: • terughoudend zijn met langdurig NSAID gebruik en frequente corticosteroïdinjecties. • blijvend aandacht hebben voor gedoseerd bewegen binnen sport en werk kan de	< 1 jaar	Macro-economisch uiteindelijk positief. Op ziekenhuis niveau afhankelijk van de organisatie	Ontwikkelen van flyers, filmpjes, gebruik van bestaand materiaal op Youtube etc. Herorganiseren van het orthopedisch spreekuur met voorlichting/uitleg meer bij PA tot doktersassistente: duur waar het moet, goedkoop waar het kan	Onvoldoende ontwikkelde website, niet veranderbare taakverdeling op een poli/huisartsenpraktijk	Evaluatie taakherschikking Verzamelen bestaand materiaal in een thesaurus Ontwikkelen eigen voorlichtingsmateriaal en opleiding aan diegenen die het brengen Het verdient aanbeveling om de patiënt na het oefenadvies te helpen een geschikte	In essentie orthopeed en hoofd polikliniek/huisartsenpraktijk	

belastbaarheid van de cuff duurzaam vergroten.					therapeut uit het netwerk (therapeut met affiniteit voor de behandeling van schouderklachten) te vinden.		
Adviseer om: • te bewegen binnen de comfortzone en niet te lang, te zwaar en te vaak. • bewegingen zoals reiken, ante- en lateroflexie boven schoudernivea u, endo- en exorotatie tegen de grenzen van de ROM te beperken. • de inrichting van de	< 1 jaar	Macro-economisch uiteindelijk positief. Op ziekenhuis niveau afhankelijk van de organisatie	Ontwikkelen van flyers, filmpjes, gebruik van bestaand materiaal op Youtube etc. Herorganiseren van het orthopedisch spreekuur met voorlichting/uitleg meer bij PA tot doktersassistente: duur waar het moet, goedkoop waar het kan	Onvoldoende ontwikkelde website, niet veranderbare taakverdeling op een poli/huisartsenpraktijk	Evaluatie taakherschikking Verzamelen bestaand materiaal in een thesaurus Ontwikkelen eigen voorlichtingsmateriaal en opleiding aan diegenen die het brengen Het verdient aanbeveling om de patiënt na het oefenadvies te helpen een geschikte therapeut uit het	In essentie orthopeed en hoofd polikliniek/huisartsenpraktijk	

werkplek te optimaliseren, rustpauzes in te lassen en hulpmiddelen te gebruiken. • voor bovenstaande aanbevelingen te verwijzen naar de desbetreffende experts (bedrijfsarts en paramedici). Zie ook de module Arbeidsparticipatie voor medisch specialistische richtlijnen..					netwerk (therapeut met affiniteit voor de behandeling van schouderklachten) te vinden.		

Table of excluded studies

Reference	Reason for exclusion
-	-

Literature search strategy

Zoekopbrengst

	EMBASE	OVID/MEDLINE	Ontdubbeld
SR	48	55	70
RCT	112	95	159
Observationele studies	251	420	454
Totaal	411	570	**683***

in Rayyan

Zoekstrategie

Embase.com

No.	Query	Results
#13	#10 OR #11 OR #12	411
#12	#5 AND (#8 OR #9) NOT (#10 OR #11) = observationeel	251
#11	#5 AND #7 NOT #10 = RCT	112
#10	#5 AND #6 = SR	48
#9	'case control study'/de OR 'comparative study'/exp OR 'control group'/de OR 'controlled study'/de OR 'controlled clinical trial'/de OR 'crossover procedure'/de OR 'double blind procedure'/de OR 'phase 2 clinical trial'/de OR 'phase 3 clinical trial'/de OR 'phase 4 clinical trial'/de OR 'pretest posttest design'/de OR 'pretest posttest control group design'/de OR 'quasi experimental study'/de OR 'single blind procedure'/de OR 'triple blind procedure'/de OR (((control OR controlled) NEAR/6 trial):ti,ab,kw) OR (((control OR controlled) NEAR/6 (study OR studies)):ti,ab,kw) OR (((control OR controlled) NEAR/1 active):ti,ab,kw) OR 'open label*':ti,ab,kw OR (((double OR two OR three OR multi OR trial) NEAR/1 (arm OR arms)):ti,ab,kw) OR ((allocat* NEAR/10 (arm OR arms)):ti,ab,kw) OR placebo*:ti,ab,kw OR 'sham-control*':ti,ab,kw OR (((single OR double OR triple OR assessor) NEAR/1 (blind* OR masked)):ti,ab,kw) OR nonrandom*:ti,ab,kw OR 'non-random*':ti,ab,kw OR 'quasi-experiment*':ti,ab,kw OR crossover:ti,ab,kw OR 'cross over':ti,ab,kw OR 'parallel group*':ti,ab,kw OR 'factorial trial':ti,ab,kw OR ((phase NEAR/5 (study OR trial)):ti,ab,kw) OR ((case* NEAR/6 (matched OR control*)):ti,ab,kw) OR ((match* NEAR/6 (pair OR pairs OR cohort* OR control* OR group* OR healthy OR age OR sex OR gender OR patient* OR subject* OR participant*)):ti,ab,kw) OR ((propensity NEAR/6 (scor* OR match*)):ti,ab,kw) OR versus:ti OR vs:ti OR compar*:ti OR ((compar* NEAR/1 study):ti,ab,kw) OR (('major clinical study'/de OR 'clinical study'/de OR 'cohort analysis'/de OR 'observational study'/de OR 'cross-sectional	14177310

	study'/de OR 'multicenter study'/de OR 'correlational study'/de OR 'follow up'/de OR cohort*:ti,ab,kw OR 'follow up':ti,ab,kw OR followup:ti,ab,kw OR longitudinal*:ti,ab,kw OR prospective*:ti,ab,kw OR retrospective*:ti,ab,kw OR observational*:ti,ab,kw OR 'cross sectional*':ti,ab,kw OR cross?ectional*:ti,ab,kw OR multicent*:ti,ab,kw OR 'multi-cent*':ti,ab,kw OR consecutive*:ti,ab,kw) AND (group:ti,ab,kw OR groups:ti,ab,kw OR subgroup*:ti,ab,kw OR versus:ti,ab,kw OR vs:ti,ab,kw OR compar*:ti,ab,kw OR 'odds ratio*':ab OR 'relative odds':ab OR 'risk ratio*':ab OR 'relative risk*':ab OR 'rate ratio':ab OR aor:ab OR arr:ab OR rrr:ab OR ((('or' OR 'rr') NEAR/6 ci):ab)))	
#8	'major clinical study'/de OR 'clinical study'/de OR 'case control study'/de OR 'family study'/de OR 'longitudinal study'/de OR 'retrospective study'/de OR 'prospective study'/de OR 'comparative study'/de OR 'cohort analysis'/de OR ((cohort NEAR/1 (study OR studies)):ab,ti) OR (('case control' NEAR/1 (study OR studies)):ab,ti) OR (('follow up' NEAR/1 (study OR studies)):ab,ti) OR (observational NEAR/1 (study OR studies)) OR ((epidemiologic NEAR/1 (study OR studies)):ab,ti) OR (('cross sectional' NEAR/1 (study OR studies)):ab,ti)	6767914
#7	'clinical trial'/exp OR 'randomization'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR 'placebo'/exp OR 'prospective study'/exp OR rct:ab,ti OR random*:ab,ti OR 'single blind':ab,ti OR 'randomised controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	3302394
#6	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	733409
#5	#4 AND [2000-2023]/py	608
#4	#3 NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	718
#3	#1 AND #2	861
#2	'recurrence risk'/exp OR 'recurrent disease'/exp OR recurr*:ab,ti,kw OR relaps*:ab,ti,kw OR recrudesc*:ab,ti,kw	1450947
#1	'shoulder impingement syndrome'/exp/mj OR 'shoulder impingement syndrome':ti,ab,kw OR 'subacromial impingement syndrome':ti,ab,kw OR (('bursitis'/exp/mj OR bursitis:ti,ab,kw OR 'tendinitis'/exp/mj OR tendinitis:ti,ab,kw OR 'impingement':ti,ab,kw) AND ('shoulder'/exp/mj OR 'rotator cuff':ti,ab,kw OR acromion:ti,ab,kw OR acromial:ti,ab,kw OR subacromial:ti,ab,kw OR shoulder*:ti,ab,kw)) OR 'rotator cuff injury'/exp/mj OR 'rotator cuff rupture'/exp/mj OR ((('rotator cuff' OR 'shoulder cuff' OR infraspinatus OR supraspinatus OR subscapularis) NEAR/3 (tear* OR lesion* OR rupture* OR tendinopath* OR	18074

	laceration*)):ti,ab,kw) OR (('full-thickness':ti,ab,kw OR partial:ti,ab,kw) AND 'rotator cuff':ti,ab,kw) OR ('rotator cuff'/exp/mj AND ('rupture'/exp/mj OR 'injury'/mj OR 'laceration'/exp/mj))	

Ovid/Medline

#	Searches	Results
13	10 or 11 or 12	570
12	(5 and (8 or 9)) not (10 or 11) = observationeel	420
11	(5 and 7) not 10 = RCT	95
10	5 and 6 = SR	55
9	Case-control Studies/ or clinical trial, phase ii/ or clinical trial, phase iii/ or clinical trial, phase iv/ or comparative study/ or control groups/ or controlled before-after studies/ or controlled clinical trial/ or double-blind method/ or historically controlled study/ or matched-pair analysis/ or single-blind method/ or (((control or controlled) adj6 (study or studies or trial)) or (compar* adj (study or studies)) or ((control or controlled) adj1 active) or "open label*" or ((double or two or three or multi or trial) adj (arm or arms)) or (allocat* adj10 (arm or arms)) or placebo* or "sham-control*" or ((single or double or triple or assessor) adj1 (blind* or masked)) or nonrandom* or "non-random*" or "quasi-experiment*" or "parallel group*" or "factorial trial" or "pretest posttest" or (phase adj5 (study or trial)) or (case* adj6 (matched or control*)) or (match* adj6 (pair or pairs or cohort* or control* or group* or healthy or age or sex or gender or patient* or subject* or participant*)) or (propensity adj6 (scor* or match*))).ti,ab,kf. or (confounding adj6 adjust*).ti,ab. or (versus or vs or compar*).ti. or ((exp cohort studies/ or epidemiologic studies/ or multicenter study/ or observational study/ or seroepidemiologic studies/ or (cohort* or 'follow up' or followup or longitudinal* or prospective* or retrospective* or observational* or multicent* or 'multi-cent*' or consecutive*).ti,ab,kf.) and ((group or groups or subgroup* or versus or vs or compar*).ti,ab,kf. or ('odds ratio*' or 'relative odds' or 'risk ratio*' or 'relative risk*' or aor or arr or rrr).ab. or (("OR" or "RR") adj6 CI).ab.))	5448124
8	Epidemiologic studies/ or case control studies/ or exp cohort studies/ or Controlled Before-After Studies/ or Case control.tw. or cohort.tw. or Cohort analy$.tw. or (Follow up adj (study or studies)).tw. or (observational adj (study or studies)).tw. or Longitudinal.tw. or Retrospective*.tw. or prospective*.tw. or consecutive*.tw. or Cross sectional.tw. or Cross-sectional studies/ or historically controlled study/ or interrupted time series analysis/ [Onder exp cohort studies vallen ook longitudinale, prospectieve en retrospectieve studies]	4464295
7	exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti,ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind$3 or mask$3)).tw. or Placebos/ or placebo*.tw.	2600532
6	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data	674975

	extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	
5	limit 4 to yr="2000 -Current"	825
4	3 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	965
3	1 and 2	993
2	exp Recurrence/ or (recurr* or relaps* or recrudesc*).ti,ab,kf.	953623
1	Shoulder Impingement Syndrome/ or 'shoulder impingement syndrome'.ti,ab,kf. or 'subacromial impingement syndrome'.ti,ab,kf. or ((exp bursitis/ or exp Tendinopathy/ or bursitis.ti,ab,kf. or tendinitis.ti,ab,kf. or 'impingement'.ti,ab,kf.) and (exp Shoulder/ or 'rotator cuff'.ti,ab,kf. or acromion.ti,ab,kf. or acromial.ti,ab,kf. or subacromial.ti,ab,kf. or shoulder*.ti,ab,kf.)) or Rotator Cuff/ or exp Rotator Cuff Injuries/ or (('rotator cuff' or 'shoulder cuff' or infraspinatus or supraspinatus or subscapularis) adj3 (tear* or lesion* or rupture* or tendinopath* or laceration*)).ti,ab,kf. or (('full-thickness' or partial) and 'rotator cuff').ti,ab,kf.	19733

Module 2 Diagnostische testen voor SAPS

Leeswijzer:
Onderstaande conceptrichtlijntekst wordt na het doorlopen van de commentaar- en autorisatiefase opgenomen in de Richtlijnendatabase (www.richtlijnendatabase.nl). Verwijzingen naar 'tabbladen' zijn in de huidige versie van de richtlijntekst terug te vinden in de 'bijlagen' aan het einde van de hoofdtekst. In verband met de modulaire opbouw van richtlijnen in de database wordt verwezen naar modules (i.p.v. hoofdstukken) en aanverwante producten (bijlagen).

Uitgangsvraag
Welke fysisch diagnostische tests zijn het meest geschikt voor het diagnosticeren van SAPS?

Introduction (English)
Patients presenting with non-traumatic shoulder pain are often seen by care givers in different settings. After anamnesis a thorough physical examination is needed to make a proper differential diagnosis including subacromial pain syndrome. This is done by inspecting the joint and taking note of range of motion. Specific tests are available to provoke pain and influence the subacromial structures. Previous studies suggest the use of a combination of tests (Somerville, 2014; Michener, 2009).

Search and select
A systematic review of the literature was performed to answer the following question:
What is the diagnostic accuracy for using a combination of multiple tests compared to a single test in diagnosing or ruling out of SAPS?

Patients	patients with (suspected) SAPS, with exception of a subscapularis rupture
Index test	combination of multiple tests (for example empty can/neer/painful arc/exorotation againts resistance /Yocum/Hawkins)
Comparator test	solitary test (for example Hawkins)
Reference standard	imaging (ultrasound or MRI) or arthroscopy
Outcomes	pain, functionality, return to work or leisure, diagnostic test accuracy measures (sensitivity, specificity)
Timing and setting	outpatient orthopedic consultation

<u>Relevant outcome measures</u>
The guideline development group considered **diagnostic test accuracy measures** as critical outcome measure for decision making; and **pain, functionality, and return to work or leisure** as important outcome measures for decision making.

A priori, the guideline development group did not define the outcome measures listed above but used the definitions used in the studies.

Due to the diagnostic nature of this question, no minimal clinically (patient) important difference was specified.

<u>Search and select (Methods)</u>

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms from 2008 until February 21th, 2023.The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 629 hits. Studies were selected based on the following criteria:

- Patients with suspected SAPS
- A combination of diagnostic tests for SAPS compared to a single test for the diagnosis of SAPS
- Imaging tests (ultrasound or MRI) or arthroscopy as reference standard
- Pain, functionality, sensitivity and specificity as outcome measures
- Case-control studies were not included

Fifteen studies were initially selected based on title and abstract screening. After reading the full text, thirteen studies were excluded (see the table with reasons for exclusion under the tab Methods), and two studies were included.

Results

Two studies were included in the analysis of the literature. Important study characteristics and results are summarized in the evidence tables. The assessment of the risk of bias is summarized in the risk of bias tables.

Summary of literature

Description of studies

Michener (2009) conducted a prospective study to investigate the reliability and diagnostic accuracy of individual tests and a combination of multiple tests for subacromial impingement syndrome (SAIS). A total of 55 patients were included who presented with shoulder pain (for at least one week) to an orthopedic surgeon's office. A total of 47 were men and 8 were women, and the mean age was 40.6 years (SD 15.1). The prevalence of shoulder impingement syndrome (SAIS) was 29%; 16 out of 55 patients were confirmed with surgical findings (gold standard) to have SAIS in isolation or in combination with another glenohumeral joint diagnosis. The intraoperative reference standard criteria for SAIS were the presence of any of the following: visually enlarged bursa, fibrotic appearing bursa, or degeneration of the supraspinatus tendon at the superficial aspect. Patients with additional shoulder pathologies such as partial or full-thickness rotator cuff tears, labral tears, or fraying and instability were not excluded. The 39 patients without a confirmed diagnosis of SAIS were diagnosed with glenohumeral instability, glenoid labral tear, rotator cuff tear, acromion-clavicular joint arthritis, and adhesive capsulitis. Patients were examined with five physical examination tests: the Neer, Hawkins-Kennedy, Painful arc, empty can (Jobe), and the external rotation resistance test. Surgical reference was the reference standard. Sensitivity and specificity were reported.

Somerville (2014) conducted a cohort study to determine the diagnostic validity of physical examination manoeuvres for rotator cuff lesions (defined as full-thickness tears, partial-thickness tears, and tendinosis of any of the three rotator cuff tendons: supraspinatus, infraspinatus, and subscapularis). Patients were recruited between May 2007 and November 2008 from two tertiary care orthopaedic centres. All participants were seen in the clinic for complaints about their shoulder (for the first time). Patients referred for shoulder replacement surgery were excluded. A total of 139 patients were included in the study, of which 101 were male and 38 were women, with a mean age of 46.0 years (SD 16.0). Physical examination tests were identified through a systematic review and consisted of the two supraspinatus tests (Jobe/empty can and full can), lift-off test, belly press test, internal

rotation lag sign, lateral rotation lag sign, painful arc, Hawkins-Kennedy, and Neer test. The main reference standards were arthroscopy and magnetic resonance imaging with arthrogram (MRIa). The sensitivity, specificity, and likelihood ratios were calculated to investigate whether combinations of the top tests provided stronger predictions of the presence or absence of disease.

Results

Two studies were included that reported on the combination of multiple physical examination tests for diagnosing SAPS.

Diagnostic outcome measures - sensitivity and specificity (crucial)

Michener (2009) reported the sensitivity and specificity for subacromial impingement syndrome (SAIS). The prevalence of SAIS was 29%: 16 out of 55 patients were confirmed via the golden standard of surgical findings with SAIS in isolation or in combination with another glenohumeral joint diagnosis. The 39 subjects who did not have a confirmed diagnosis of SAIS were diagnosed via surgical findings with (in order of frequency) glenohumeral instability, glenoid labral tear, rotator cuff tear, acromion-clavicular joint arthritis, and adhesive capsulitis. Table 1 depicts the diagnostic test accuracy results for individual tests as well as any test combination with a cut point of at least 3 out of 5 tests positive. The false-positive, false-negative, true-positive, and true-negative values with 95% CI and the NPV and PPV were manually calculated, using the sensitivity and specificity values and incidence numbers reported in the study, and added to the table.

Table 1. Diagnostic accuracy measures for impingement shoulder tests and any test combination.

Test	Sensitivity (95% CI)	Specificity (95% CI)	TP (95% CI)	FP (95% CI)	FN (95% CI)	TN (95% CI)	PPV	NPV
Hawkins-Kennedy	0.63 (0.39 to 0.86)	0.62 (0.46 to 0.77)	10.1 (6.2 to 13.7)	14.8 (21.1 to 9.0)	5.9 (9.7 to 2.2(	24.2 (18.0 to 30.1)	0.41	0.80
Neer	0.81 (0.62 to 1.0)	0.54 (0.38 to 0.69)	12.9 (9.9 to 16.0)	18.0 (24.2 to 12.1)	3.0 (6.1 to 0)	21.1 (14.8 to 27.0)	0.42	0.86
Painful arc	0.75 (0.54 to 0.96)	0.67 (0.52 to 0.81)	12.0 (8.6 to 15.3)	12.9 (18.7 to 7.4)	4.0 (7.4 to 0.6)	26.2 (20.3 to 31.6)	0.48	0.87
Empty can (Jobe)	0.50 (0.26 to 0.75)	0.87 (0.77 to 0.98)	8.0 (4.2 to 12.0)	5.1 (9.0 to 0.8)	8.0 (11.8 to 4.0)	34.0 (30.1 to 38.3)	0.61	0.81
External rotation resistance	0.56 (0.32 to 0.81)	0.87 (0.77 to 0.98)	8.9 (5.1 to 12.9)	5.1 (9.0 to 0.8)	7.0 (10.9 to 3.0)	34.0 (30.1 to 38.3)	0.64	0.83
Any test combination (cut point: 3+ of 5 tests)	0.75 (0.54 to 0.96)	0.74 (0.61 to 0.88)	12.0 (8.6 to 15.3)	10.2 (15.2 to 4.7)	4.0 (7.3 to 0.6)	28.9 (23.8 to 34.4)	0.54	0.88

N=55 subjects. Note: 3+ of 5 tests is the cut point for the discrimination of the presence or absence of SAIS using the 5 impingement tests. Abbreviations: CI, confidence interval; TP, true-positives; FP, false-positives; FN, false-negatives; TN, true-negatives; PPV, positive predictive value; NPV, negative predictive value.

Somerville (2014) reported the sensitivity and specificity for individual physical examination tests and a combination of tests for rotator cuff tears and tendinosis. However, to make a comparison between individual tests and a combination of multiple tests, these values must be reported. This was only the case for tests for the supraspinatus tendon, specifically for a full-thickness (FT) tear and FT and partial-thickness (PT) tear. Hence, only these results were subtracted from Somerville (2014).

Table 2 and 3 depict the diagnostic test accuracy results for the three individual tests as well as a combination of tests for the supraspinatus tendon. The study reported 53 patients with a FT tear, 14 patients with a PT tear, 16 patients with tendinosis and 56 patients without a RC lesion of the supraspinatus tear. The false-positive, false-negative, true-positive, and true-negative values with 95% CI and the NPV and PPV were manually calculated, using the sensitivity and specificity values and incidence numbers reported in the study, and added to the tables.
Note that for calculating the TP, FP, FN, TN, PPV and NPV values for the full-thickness and partial-thickness tears taken together, we assumed that the incidence numbers of the number of patients with a FT and PT tear could be added up (n=53 plus n=14)(Table 3).

Table 2. Sensitivity and specificity for three physical examination tests and a combination of these tests for the diagnosis of a full-thickness tear in the supraspinatus tendon

	Sensitivity (95% CI)	Specificity (95% CI)	TP (95% CI)	FP (95% CI)	FN (95% CI)	TN (95% CI)	PPV	NPV
Supraspinatus test	71.7 (58.4 to 82.0)	64.6 (53.6 to 74.2)	38.0 (31.0 to 43.5)	30.4 (39.9 to 22.2)	15.0 (22.1 to 9.5)	55.6 (46.1 to 63.8)	0.56	0.79
Full can test	64.2 (50.7 to 75.7)	67.1 (56.2 to 76.5)	34.0 (26.9 to 40.1)	28.3 (37.7 to 20.2)	19.0 (26.1 to 12.9)	57.7 (48.3 to 65.8)	0.55	0.75
Lateral rotation lag sign	19.6 (11.0 to 32.5)	97.5 (91.3 to 99.3)	10.4 (5.8 to 17.2)	2.2 (7.5 to 0.6)	42.6 (47.2 to 35.8)	83.9 (78.5 to 85.4)	0.83	0.66
Combination of tests								
At least 1 positive	73.6 (60.4 to 83.6)	57.5 (46.6 to 67.7)	39.0 (32.0 to 44.3)	36.6 (45.9 to 27.8)	14.0 (21.0 to 8.7)	49.5 (40.1 to 58.2)	0.52	0.78
At least 2 positive	62.3 (48.8 to 74.1)	73.8 (63.2 to 82.1)	33.0 (25.9 to 39.3)	22.5 (31.7 to 15.4)	20.0 (27.1 to 13.7)	63.5 (54.4 to 70.6)	0.60	0.76
All 3 positive	18.9 (10.6 to 31.4)	98.8 (93.3 to 99.8)	10.0 (5.6 to 16.6)	1.0 (5.8 to 0.2)	43.0 (47.4 to 36.4)	85.0 (80.2 to 85.8)	0.91	0.66

Abbreviations: CI, confidence interval; TP, true-positives; FP, false-positives; FN, false-negatives; TN, true-negatives; PPV, positive predictive value; NPV, negative predictive value.

Table 3. Sensitivity and specificity for three physical examination tests and a combination of these tests for the diagnosis of full-thickness and partial-thickness tears taken together in the supraspinatus tendon

	Sensitivity (95% CI)	Specificity (95% CI)	TP (95% CI)	FP (95% CI)	FN (95% CI)	TN (95% CI)	PPV	NPV
Supraspinatus test	65.6 (52.2 to 74.6)	64.6 (52.5 to 75.1)	44.0 (35.0 to 50.0)	25.5 (34.2 to 17.9)	23.1 (32.0 to 17.0)	46.5 (37.8 to 54.1)	0.63	0.67
Full can test	58.2 (46.3	67.7 (55.6	39.0 (31.0	23.2 (32.0	28.0 (36.0	48.7 (40.0	0.63	0.64

	to 69.3)	to 77.8)	to 46.4)	to 16.0)	to 20.6)	to 56.0)		
Lateral rotation lag sign	15.4 (8.6 to 26.1)	97.0 (89.6 to 99.2)	10.3 (5.8 to 17.5)	2.2 (7.5 to 0.6)	56.7 (61.2 to 49.5)	69.8 (64.5 to 71.4)	0.82	0.55
Combination of tests								
At least 1 positive	67.2 (55.3 to 77.2)	57.6 (45.6 to 68.8)	45.0 (37.1 to 51.7)	30.5 (39.2 to 22.5)	22.0 (30.0 to 15.3)	41.5 (32.8 to 49.5)	0.60	0.65
At least 2 positive	55.2 (43.4 to 66.5)	74.2 (62.6 to 83.3)	37.0 (29.1 to 44.6)	18.6 (26.9 to 12.0)	30.0 (37.9 to 22.5)	53.4 (45.1 to 60.0)	0.67	0.64
All 3 positive	14.9 (8.3 to 25.3)	98.5 (91.9 to 99.7)	10.0 (5.6 to 17.0)	1.1 (5.8 to 0.2)	57.0 (61.4 to 50.1)	70.9 (66.2 to 71.8)	0.90	0.55

Abbreviations: CI, confidence interval; TP, true-positives; FP, false-positives; FN, false-negatives; TN, true-negatives; PPV, positive predictive value; NPV, negative predictive value.

Pain (important)
No study reported pain.

Functionality (important)
No study reported functionality.

Return to work or leisure (important)
No study reported return to work or leisure.

Level of evidence of the literature

Diagnostic accuracy – sensitivity and specificity (crucial)
The level of evidence regarding the outcome measures **sensitivity and specificity** was downgraded by two levels to **low** because of wide confidence intervals around the point estimate (-2, imprecision).

Pain (important)
The level of evidence for pain could not be established, since none of the included studies reported this outcome.

Functionality (important)
The level of evidence for functionality could not be established, since none of the included studies reported this outcome.

Return to work or leisure (important)
The level of evidence for return to work or leisure could not be established, since none of the included studies reported this outcome.

Conclusions

Diagnostic accuracy measures – sensitivity and specificity (crucial)

Low GRADE	There is little confidence in the reported sensitivity and specificity values for a combination of tests compared to solitary tests for the diagnosis of subacromial pain syndrome and for the diagnosis of a supraspinatus tendon tear (full-thickness and full-thickness plus partial-thickness). *Source: Michener, 2009; Somerville, 2014.*

Pain, functionality, and return to work or leisure (important)

No GRADE	No evidence was found regarding the effect of a combination of tests on pain, functionality, and return to work or leisure when compared with a solitary test for the diagnosis of subacromial pain syndrome and for the diagnosis of a supraspinatus tendon tear (full-thickness and full-thickness plus partial-thickness).

Overwegingen – van bewijs naar aanbeveling

Voor- en nadelen van de interventie en de kwaliteit van het bewijs

Er is literatuuronderzoek verricht naar de diagnostische accuratesse van het gebruik van een enkele fysiek diagnostische test vergeleken met een combinatie van meerdere fysiek diagnostische testen voor het diagnosticeren van SAPS (met uitzondering van pathologie aan de subscapularispees). Er zijn twee studies geïncludeerd die enkele testen vergeleken hebben met een combinatie van testen; echter wel in twee verschillende subcategorieën van SAPS.

Beide studies rapporteerden de sensitiviteit en specificiteit (cruciale uitkomstmaten). De bewijskracht voor beide uitkomstmaten was echter laag, waardoor er weinig vertrouwen is in deze gerapporteerde maten. De reden hiervoor zijn de brede betrouwbaarheidsintervallen rondom de gerapporteerde puntschatters. De overall bewijskracht voor de cruciale uitkomstmaten is laag. De vooraf gedefinieerde belangrijke uitkomstmaten pijn, functionaliteit en terugkeer naar werk en vrije tijdsbesteding werden niet gerapporteerd in beide studies en kunnen daarom ook geen verdere richting geven. Hier bestaat een kennisvraag. Derhalve is het hele diagnostische proces van belang, waarbij naast het lichamelijk onderzoek ook anamnese en aanvullend onderzoek worden verricht. Fysische testen gericht op andere pathologie in en om het schouder gewricht zijn nodig om verder richting te geven.

Diagnostisch traject van de patiënt

Patiënten met non-traumatische schouderpijn die zich presenteren bij een zorgverlener zullen na een uitvoerige anamnese onderzocht worden. Om al richting te geven aan de mogelijke diagnose is het belang van deze anamnese groot. Voor inspectie en beoordeling van de bewegelijkheid zijn er meerdere fysieke tests beschikbaar om SAPS meer of minder aannemelijk te maken. Hierbij is het belangrijk om eerst andere oorzaken van schouderpijn uit te sluiten, zoals intra-articulaire pathologie, AC artrose, en totaal rupturen, maar ook oncologische en neurologische aandoeningen. Hierbij kan een röntgenfoto of een echo meer duidelijkheid geven. Het onderzoek van de cervicale wervelkolom en psychosociale factoren vallen buiten de afbakening van deze module.

SAPS is een beschrijving van een typisch pijnpatroon van de schouder. De oorzaak is echter niet altijd duidelijk. De besproken testen compromitteren de subacromiale ruimte of er wordt getracht de rotator cuff aan te spannen. Compromittering van de subacromiale ruimte kan zowel intrinsiek als extrinsiek ontstaan. Intrinsieke compromittering kan ontstaan door degeneratieve veranderingen in de cuff al dan niet gepaard gaande met een subacromiale bursitis, en extrinsieke compromittering kan ontstaan door mechanische oorzaken op basis van houdingsproblematiek of anatomische veranderingen (Consigliere, 2018). Door toepassing van de besproken testen wordt hypothetisch gezien de pijn geprovoceerd en kan gedetecteerd worden of de rotator cuff intact is of samen met de bursa geprikkeld is.

Daarnaast kan uitvoeren van anamnese en lichamelijk onderzoek meerdere doelstellingen hebben. De keuze van in te zetten methodiek (testen) zal bepaald worden door deze doelstelling. De eerder beschreven literatuur in deze module heeft betrekking op het stellen van de diagnose SAPS. Lichamelijk onderzoek kan bijvoorbeeld echter ook als doel hebben om te bepalen of fysieke klachten positief te beïnvloeden zijn. In dit kader zouden ook *symptom modification* testen ingezet kunnen worden (Riley 2020, Lewis 2016).

Reflectie op de literatuur

Beide aangehaalde studies (Michener, 2009; Somerville, 2014) zijn meer dan tien jaar oud. Dit geeft impliciet aan dat dit niet een makkelijk onderwerp is. De moeilijkheid ligt in het juist diagnosticeren en vervolgens de verschillende testen uitvoeren.

De studie van Michener (2009) beschrijft SAPS patiënten met een intacte rotator cuff, terwijl Somerville (2014) juist de SAPS patiënt met (partiele) cuff rupturen heeft onderzocht. Daarnaast is er een verschil in gehanteerde fysische testen. In beide studies worden patiënten op basis van een arthroscopie en MRI gediagnosticeerd. Degeneratieve afwijkingen in de schouder hoeven echter niet altijd symptomatisch te zijn (Girish, 2011), zoals de opstroping van de subacromiale bursa (Daghir, 2011) of artrose van het AC gewricht (Veen, 2018).

De positief voorspellende waarde (*positive predictive value,* PPV*)* is het deel van de onderzochte personen met een positieve testuitslag die de eigenschappen ook daadwerkelijk heeft. Hierop scoren de empty can test (PPV 0,61) en de external rotation resistance test (PPV 0,64) het hoogst in de studie van Michener (2009). Desondanks is het goed om te beseffen dat een patiënt mogelijk fout positief gediagnosticeerd wordt, waarbij het uitvoeren van meerdere testen de kans hierop minimaal verlaagd (PPV 0,54). Terwijl in de studie van Somerville (2014) de PPV (0,91) sterk verhoogd werd bij drie positieve testen.

De negatief voorspellende waarde (*negative predictive value*, NPV) daarentegen is het deel van de onderzochte personen met een negatieve testuitslag die de eigenschappen inderdaad niet heeft. In de studie van Michener (2009) varieert de NPV tussen de 0,80 en 0,88 voor afzonderlijke of gezamenlijke testen. In de studie Somerville (2014) liggen de waarden tussen 0,66 en 0,79 voor full thickness cuff rupturen en tussen 0,55 en 0,67 voor partial tickness rupturen.

Mocht een patiënt een fout-negatieve diagnose krijgen, dan zou dit ook consequenties hebben. Bijvoorbeeld een goed te behandelen schouderpijn, zoals bij omartrose, krijgt dan de verkeerde therapie en daarmee aanhoudende klachten, hoewel de kans dat het gemist wordt klein is in het hele diagnostische proces in de tweede lijn waarbij ook een röntgenfoto wordt gemaakt.

Daarnaast bestaan er meer fysische testen rondom de rotator cuff die buiten de studie vallen maar van meerwaarde kunnen zijn, zoals de yocum test en countertest with elevation with lateral rotation (Ferenczi, 2018). Tevens is het lastig dat er in de literatuur geen eenduidige terminologie is voor beschreven testen. De suspraspinatus test wordt ook beschreven als empty can test en jobe's test (Gismervik, 2017).

<u>Toekomstig onderzoek</u>
Ondanks dat SAPS een zeer veel voorkomende aandoening is, blijft de betrouwbaarheid van het lichamelijk onderzoek c.q. diagnostische accuratesse van de beschreven testen beperkt. Een vervolgonderzoek naar de individuele onderzoeken zou wenselijk zijn, waarbij een flowchart opgesteld kan worden waarin de kansen toe- of afnemen per positieve of negatieve test. De controle zou kunnen plaatsvinden op basis van echografie, waarbij een controlegroep lastig is aangezien een pijnsyndroom niet te diagnosticeren is. Veel voorkomende echografische afwijkingen worden ook gevonden bij asymptomatische schouders. Andersom geredeneerd is het belangrijk om andere aandoeningen uit te sluiten. Vooral een cuff ruptuur waarbij de testen ook positief kunnen zijn, maar welke mogelijk in aanmerking komt voor een chirurgische behandeling. Het is de kunst om als zorgprofessional

de verschillende uitkomsten op waarde te schatten en af te wegen bij elke individuele patiënt.

Waarden en voorkeuren van patiënten (en evt. hun verzorgers)
De testen die beschreven worden in de studies zijn pijnprovocatie- en functietesten. Hierboven kan het uitvoeren van de testen in meer of mindere mate pijnklachten tijdelijk doen toenemen. De fysieke testen kunnen snel uitgevoerd worden. Het toepassen van nadere diagnostiek kost relatief meer tijd.

Voor de patiënt is het belangrijk om duidelijkheid te krijgen over de diagnose en het te volgen behandelbeleid. Is er inderdaad sprake van SAPS klachten en dient er conservatief beleid te volgen in eerste lijn middels oefen-/fysiotherapie, dienen andere disciplines betrokken te worden (bijv. ergotherapie) of is er een indicatie voor vervolgonderzoek omdat er klinisch vermoeden is dat er een mogelijke indicatie is voor operatieve behandeling van rotator cuff?

Zowel bij een conservatief als operatieve interventie zal met patiënt besproken moeten worden welke verwachtingen er zijn met betrekking tot pijn en functie en hoe het revalidatietraject er grofweg uit zal zien op het gebied van tijd en functionaliteit. Hierdoor kan de patiënt een weloverwogen keuze maken of en wanneer het gekozen beleid ingezet wordt. Dit kan ondersteund worden door pijnmedicatie en/of een subacromiale injectie met steroïden.

Kosten (middelenbeslag)
Het kost niet veel meer tijd om multipele testen uit te voeren en daarmee worden er geen aanvullende kosten verwacht.

Aanvaardbaarheid, haalbaarheid en implementatie
De verschillende testen zijn in geoefende handen in een kort tijdsbestek uit te voeren tijdens het lichamelijk onderzoek. Daarmee vormt het geen belemmering. Daarnaast heeft het systematisch beoordelen van een patiënt het voordeel dat er geen elementen worden overgeslagen en gedocumenteerd kunnen worden.

Aanbeveling
Rationale van de aanbeveling: weging van argumenten voor en tegen de diagnostische procedure
De werkgroep heeft onderzocht dat meerdere fysische diagnostische testen afnemen niet bijdraagt aan het stellen van de diagnose SAPS ten opzichte van een enkele test. De werkgroep benadrukt dat de bewijskracht laag is en dat de onderzoeken zijn uitgevoerd met gebruik van een ‘gouden standaard’. Dit was op basis van echografie, MRI of arthroscopische bevindingen. Dit blijft echter een lastig gegeven waarbij dergelijke afwijkingen ook bij asymptomatische schouders worden gevonden. Van alle onderzochte testen om SAPS en/of rotator cuff ruptuur vast te stellen, heeft de lateral rotation lag sign de hoogste positief voorspellende waarde. Het uitvoeren van lichamelijk onderzoek kan helpen rom ichting te geven voor verder aanvullend onderzoek.

Aanbeveling

Gebruik na anamnese het lichamelijk onderzoek om de diagnose SAPS of rotator cuff ruptuur te stellen, om te bepalen of en welk vervolgonderzoek nodig is en/of om te bepalen of fysieke klachten te beïnvloeden zijn.

Gebruik bij patiënten met schouderpijn een enkele test voor het aantonen dan wel uitsluiten van SAPS of een rotator cuff ruptuur.

- Een enkele test is voldoende bij verdenking op SAPS. Bijvoorbeeld de de empty can test (insluiten indien positief).
- Gebruik bij verdenking op een (posterieure) rotator cuff ruptuur bij voorkeur de lateral rotation lag sign (insluiten indien positief).

Kennisvragen

Op basis van de beschikbare literatuur zou toekomstig onderzoek zich moeten richten op de fysisch diagnostische testen bij schouderpijn. De verschillende tests kunnen worden vergeleken met elkaar. Daarnaast zou een vaste volgorde van testen geëvalueerd kunnen worden om te meten of per aanvullende test de kans op het wel/niet aanwezig zijn van SAPS of een cuff ruptuur groter wordt. Dit kan dan als een flowchart gehanteerd worden en kan daarmee behulpzaam zijn om hopelijk aanvullende diagnostiek te vermijden.

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Bijlagen bij module 2 Diagnostische testen voor SAPS

Implementatieplan

Aanbeveling	Tijdspad voor implementatie: <1 jaar, 1-3 jaar of >3 jaar	Verwacht effect op kosten	Randvoorwaarden voor implementatie (binnen aangegeven tijdspad)	Mogelijke barrières voor implementatie	Te ondernemen acties voor implementatie	Verantwoordelijken voor acties	Overige opmerkingen
Gebruik na anamnese het lichamelijk onderzoek om de diagnose SAPS of rotator cuff ruptuur te stellen, om te bepalen of en welk vervolgonderzoek nodig is en/of om te bepalen of fysieke klachten te beïnvloeden zijn.	nvt	nvt	nvt	Onvoldoende bewustzijn van het toepassen/gebruiken van de richtlijn bij zorgaanbieders	Kennisneming van de richtlijn bijvoorbeeld via richtlijnenkennisspel	Beroepsverenigingen	geen
Gebruik bij patiënten met schouderpijn een enkele test voor het aantonen dan wel uitsluiten van SAPS of een rotator cuff ruptuur. • Een enkele test is voldoende bij verdenking op SAPS.	nvt	nvt	nvt	Onvoldoende bewustzijn/gebruiken van de richtlijn bij zorgaanbieders	Kennisneming van de richtlijn bijvoorbeeld via richtlijnenkennisspel	Beroepsverenigingen	geen

Bijvoorbeeld de de empty can test (insluiten indien positief). • Gebruik bij verdenking op een (posterieure) rotator cuff ruptuur bij voorkeur de lateral rotation lag sign (insluiten indien positief).							

Evidence tabellen

Evidence table for diagnostic test accuracy studies

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
Michener, 2009	Type of study: Diagnostic test accuracy study (prospective, blinded study design) Setting and country: Orthopedic surgeon shoulder clinic Funding and conflicts of interest: No commercial party having a direct financial	Inclusion criteria: - Consecutive patients presenting with shoulder pain to an orthopedic surgeon's office - patients had to report shoulder pain for at least 1 week, and shoulder pain had to be their primary complaint. Exclusion criteria:	5 shoulder tests were compared to each other: Neer, Hawkins-Kennedy, painful arc, empty can (Jobe), and external rotation resistance test. Neer test: the Neer test was performed with the examiner stabilizing the scapula with a downward force while fully flexing the humerus overhead maximally while applying overpressure. A	The operative findings were used as the reference standard, and the patients were classified as positive or negative for SAIS based on the surgical findings. Description: The reference standard was determined via operative findings reported by an operative surgeon blinded to the clinical examination	After completion of the history and physical examination, the patients underwent an arthroscopic examination within an average of 2.6 months (+-2.7mo, range: 1d–8mo) after the clinical examination. There were no missing values.	Outcome measures and effect size ROC curve analysis: The cut point to discriminate between patients with and without SAIS was 3 positive tests out of 5 (AUC=0.79, 95% CI 0.66–0.92; P=0.001). Diagnostic accuracy for any test combination (≥ 3 out of 5 positive): Sens: 0.75 (95% CI 0.54-0.96)	Author's conclusion: The single tests of painful arc, external rotation resistance test, and empty can provide the best diagnostic utility and reliability. The Neer test has clinical utility to screen for SAIS but has only fair reliability. Also of diagnostic utility is the use of the cut point of 3+/5 tests, with 3 or more tests positive of 5 useful in

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
	interest in the results of the research supporting this article has or will confer a benefit on the authors or on any organization with which the authors are associated.	Not reported. <u>Characteristics</u> N=55 patients Age,mean ± SD (range): 40.6 ± 15.1 years (range 18–83y) Sex: 47 M/8 F Average symptom duration 33.8 ± 48.9 months (range 2-230 months)	positive test was reproduction of pain of the superior shoulder. Hawkins-Kennedy test: performed by the examiner flexing the humerus and elbow to 90° and then maximally internally rotating the shoulder and applying overpressure. A positive test was reproduction of pain of the superior shoulder. Painful arc: performed by asking the patient to actively abduct his/her shoulder	findings. The intraoperative reference standard criteria for SAIS were the presence of any of the following: visually enlarged bursa, fibrotic appearing bursa, or degeneration of the supraspinatus tendon at the superficial aspect. Patients with additional shoulder pathologies such as partial or full-thickness rotator cuff tears, labral tears, or fraying and instability were not excluded.		Spec: 0.74 (95% CI 0.61-0.88) LR+: 2.93 (95% CI 1.60-5.36) LR-: 0.34 (95% CI 0.14-0.80) <u>Posttest probabilities:</u> ≥ 3 out of 5 positive: LR+= 54.4% < 3 out of 5 positive: LR- = 12.1%	confirming SAIS, whereas less than 3 positive of the 5 tests is helpful in decreasing the likelihood of SAIS.

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
			and report any pain during abduction. If pain of the superior shoulder was noted between 60° and 120° of abduction, the test was considered positive. Empty can test (Jobe test): performed by the examiner elevating the shoulder to 90° in the scapular plane (30°– 40° anterior to the coronal plane) and then placing the shoulder in internal rotation by asking the patient to rotate the shoulder so that his/her thumb was				

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
			pointing toward the floor. The examiner then applied a downward directed forced at the wrist while the patient attempted to resist. A positive test was considered if weakness was detected of the involved shoulder as compared bilaterally. External rotation resistance test: performed by placing the arm at the patient's side and flexing their elbow to 90°. A medially directed force was exerted				

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
			on the distal forearm to resist shoulder external rotation. A positive test was considered if weakness was detected of the involved shoulder as compared bilaterally. <u>Cut-off point(s):</u> An ROC curve analysis for each physical examination test was used to calculate the AUC, which represents the probability that the test can discriminate between healthy and disease states.				

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
			The AUC values range from 0 to 1, with an AUC of 1 indicating 100% probability that a given test can discriminate between healthy and SAIS. The cut point for discrimination was 3 positive tests out of 5.				
Somerville, 2014	<u>Type of study:</u> Diagnostic test accuracy study <u>Setting and country:</u> Two tertiary orthopaedic clinics	<u>Inclusion criteria:</u> Participants who came to the clinic for their first consultation for complaints about their shoulder	We included the following physical examination tests: (1) supraspinatus test (Jobe test) and full can test (supraspinatus tears); (2) lift-off test, belly press	Although most patients went on to have surgery, some were not referred for surgery or opted out. These patients underwent a standardized MRIa	<u>Time between the index test en reference test:</u> Not specified. <u>Incomplete outcome data</u> Not reported.	<u>Outcome measures and effect size</u> Diagnostic validity of the combination of physical examination manaeuvers: **<u>Supraspinatus</u>**	<u>Authors' conclusion:</u> No test in isolation is sufficient to diagnose a patient with rotator cuff damage. A combination of tests improves the ability to diagnose

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
	<u>Funding and conflicts of interest:</u> One or more of the authors has declared the following potential conflict of interest or source of funding: This study received funding through an internal source that paid for research assistant time to collect data.	<u>Exclusion criteria:</u> Patients who were referred for shoulder replacement surgery. <u>Characteristics</u> N= 139 Mean age ± SD: 46.0 ± 16.0 years Sex: 101 M / 38 F The average supraspinatus tendon tear size was 2.4 ± 1.4 cm from anterior to	test, and internal rotation lag sign (subscapularis tears); (3) lateral rotation lag sign (infraspinatus tears); and (4) painful arc, Hawkins-Kennedy sign, and Neer impingement sign (tendinosis). Patients for whom the physician faced uncertainty in the diagnosis (ie, clinician rated as above the testing but below the treatment threshold) remained as part of the study group for	as the reference standard. All MRIs had an intra-articular injection of gadolinium done under fluoroscopy. The strength of the MRI magnet was 1.5 tesla, and the MRI sequences were all protocoled to provide optimal imaging of the lesions being investigated (axial T1-weighted and T1-weighted fat saturated [fat sat], coronal T1-weighted and T1-weighted fat sat, proton density fat sat, T2-weighted		**<u>tears (includes supraspinatus test, full can test, and lateral rotation lag sign)</u>** *Full thickness tears* At least one positive Sens: 73.6 (95% CI 60.4-83.6) Spec: 57.5 (95% CI 46.6-67.7) +LR: 1.73 -LR: 0.46 At least two positive Sens: 62.3 (95% CI 48.8-74.1) Spec: 73.8 (95% CI 63.2-82.1) +LR: 2.37 -LR: 0.51 All three positive Sens: 18.9 (95% CI	damage to the rotator cuff. It is recommended that the internal rotation and lateral rotation lag signs be removed from the gamut of physical examination tests for supraspinatus and subscapularis tears.

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
		posterior (range, 0.5-6 cm).	that diagnosis, and the physical examination maneuvers specific to that diagnosis were then performed. Cut-off point(s):	fat sat, and sagittal proton density fat sat sequences). All MRIs were done at a university center by radiologists with substantial expertise in musculoskeletal imaging. Images were interpreted by a fellowship-trained radiologist who was blinded to the physical examination results.		10.6-31.4) Spec: 98.8 (95% CI 93.3-99.8) +LR: 15.09 -LR: 0.82 *All tears* At least one positive Sens: 67.2 (95% CI 55.3-77.2) Spec: 57.6 (95% CI 45.6-68.8) +LR: 1.58 -LR: 0.57 At least two positive Sens: 55.2 (95% CI 43.4-66.5) Spec: 74.2 (95% CI 62.6-83.3) +LR: 2.14 -LR: 0.60 All three positive	

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
						Sens: 14.9 - 8.3-25.3) Spec: 98.5 (95% CI 91.9-99.7) +LR: 9.85 -LR: 0.86 **<u>Supraspinatus tears with the lateral rotation lag sign removed</u>** *Full thickness tears* At least one positive Sens: 73.6 (95% CI 60.4-83.6) Spec: 57.5 (95% CI 46.6-67.7) +LR: 1.73 -LR: 0.46 Two positive Sens: 62.3 (95% CI 48.8-74.1) Spec: 75.8 (95% CI 64.1-83.0)	

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
						+LR: 2.46 -LR: 0.51 *All tears* At least one positive Sens: 67.2 (95% CI 55.3-77.2) Spec: 57.6 (95% CI 45.6-68.8) +LR: 1.58 -LR: 0.57 Two positive Sens: 55.2 (95% CI 43.4-66.5) Spec: 75.8 (95% CI 64.2-84.5) +LR: 2.28 -LR: 0.59 **<u>Tendinosis (includes painful arc, Neer test, and Hawkins-Kennedy test)</u>**	

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
						Tendinosis At least one positive Sens: 75.0 (95% CI 50.5-89.8) Spec: 21.7 (95% CI 15.2-29.9) +LR: 0.96 -LR: 1.15 At least two positive Sens: 62.5 (95% CI38.6-81.5) Spec: 38.3 (95% CI 30.1-47.3) +LR: 1.01 -LR: 0.98 All three positive Sens: 31.3 (95% CI 14.2-55.6) Spec: 62.5 (95% CI 53.6-70.7) +LR: 0.83 -LR: 1.10	

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
						All disease At least one positive Sens: 80.5 (95% CI 70.6-87.6) Spec: 25.9 (95% CI 16.1-38.9) +LR: 1.09 -LR: 0.75 At least two positive Sens: 68.3 (95% CI 57.6-77.4) Spec: 48.2 (95% CI 35.4-61.2) +LR: 1.32 -LR: 0.66 All three positive Sens: 45.1 (95% CI 34.8-55.9) Spec: 75.9 (95% CI 63.1-85.4) +LR: 1.87	

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
						-LR: 0.72 *Full thickness tears* At least one positive Sens: 88.5 (95% CI 77.0-94.6) Spec: 28.6 (95% CI 20.0-39.0) +LR: 1.24 -LR: 0.40 At least two positive Sens: 73.1 (95% CI 59.8-83.2) Spec: 45.2 (95% CI 35.0-55.9) +LR: 1.33 -LR: 0.60 All three positive Sens: 51.9 (95% CI 38.7-64.9) Spec: 72.6 (95% CI 62.3-81.0)	

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
						+LR: 1.90 -LR: 0.66	

Risk of bias assessment for diagnostic accuracy studies (QUADAS II, 2011)

Study reference	Patient selection	Index test	Reference standard	Flow and timing	Comments with respect to applicability
Michener, 2009	Was a consecutive or random sample of patients enrolled? Yes, but 3 patients refused to participate, and 7 did not undergo the reference standard. Was a case-control design avoided? Yes Did the study avoid inappropriate exclusions? 7 patients refused to undergo the reference standard, these were excluded.	Were the index test results interpreted without knowledge of the results of the reference standard? Yes (Each clinician independently performed a standardized history and physical examination and was blinded to each other's findings and without knowledge of any imaging studies.) If a threshold was used, was it pre-specified? Yes	Is the reference standard likely to correctly classify the target condition? Yes Were the reference standard results interpreted without knowledge of the results of the index test? Yes (The reference standard was determined via operative findings reported by an operative surgeon blinded to the clinical examination findings.)	Was there an appropriate interval between index test(s) and reference standard? Yes Did all patients receive a reference standard? All patients who were included received the refence standard Did patients receive the same reference standard? Yes Were all patients included in the analysis? Yes	Are there concerns that the included patients do not match the review question? No Are there concerns that the index test, its conduct, or interpretation differ from the review question? No Are there concerns that the target condition as defined by the reference standard does not match the review question? No

Study reference	Patient selection	Index test	Reference standard	Flow and timing	Comments with respect to applicability
	CONCLUSION: Could the selection of patients have introduced bias? **RISK: LOW**	CONCLUSION: Could the conduct or interpretation of the index test have introduced bias? **RISK: LOW**	CONCLUSION: Could the reference standard, its conduct, or its interpretation have introduced bias? **RISK: LOW**	CONCLUSION Could the patient flow have introduced bias? **RISK: LOW**	
Somerville, 2014	Was a consecutive or random sample of patients enrolled? Yes, but 15 patients refused to undergo one of the reference standard tests or canceled their test. Was a case-control design avoided? Yes Did the study avoid inappropriate exclusions? 15 patients refused to undergo the reference standard, these were excluded.	Were the index test results interpreted without knowledge of the results of the reference standard? Yes (We ensured that the physician performing the physical examination tests did not review any available imaging studies or reports before evaluating the patient.) If a threshold was used, was it pre-specified? Yes	Is the reference standard likely to correctly classify the target condition? Yes (There is good evidence to suggest that MRIa is a comparable reference standard to arthroscopy, and MRIa has been shown to be highly sensitive and specific for detecting both rotator cuff and labral injuries) Were the reference standard results interpreted without knowledge of the results of the index test? Yes (The surgeon	Was there an appropriate interval between index test(s) and reference standard? Unclear Did all patients receive a reference standard? All patients who were included received the refence standard Did patients receive the same reference standard? No, but: “There is good evidence to suggest that MRIa is a comparable reference standard to arthroscopy, and MRIa	Are there concerns that the included patients do not match the review question? No Are there concerns that the index test, its conduct, or interpretation differ from the review question? No Are there concerns that the target condition as defined by the reference standard does not match the review question? No

Study reference	Patient selection	Index test	Reference standard	Flow and timing	Comments with respect to applicability
			performed a systematic diagnostic arthroscopy, taking care to visualize and evaluate the integrity of all pertinent anatomy, and was required to complete a standardized checklist documenting any findings for each structure (Appendix 2, available online). We developed this to minimize differences between surgeons due to variations in methods of examination and to minimize any detection bias should the clinician recall the physical examination or imaging at the time of interpreting the surgical examination. Images were interpreted by a fellowship-trained radiologist who was	has been shown to be highly sensitive and specific for detecting both rotator cuff and labral injuries." <u>Were all patients included in the analysis?</u> Unclear	

Study reference	Patient selection	Index test	Reference standard	Flow and timing	Comments with respect to applicability
			blinded tow the physical examination results.)		
	CONCLUSION: Could the selection of patients have introduced bias? **RISK: LOW**	CONCLUSION: Could the conduct or interpretation of the index test have introduced bias? **RISK: LOW**	CONCLUSION: Could the reference standard, its conduct, or its interpretation have introduced bias? **RISK: LOW**	CONCLUSION Could the patient flow have introduced bias? **RISK: LOW**	

Table of excluded studies

Reference	Reason for exclusion
Cotter, E. J. and Hannon, C. P. and Christian, D. and Frank, R. M. and Bach, B. R. Comprehensive Examination of the Athlete's Shoulder. Sports health. 2018; 10 (4) :366-375	Wrong comparison (not multiple tests, just single tests)
Beaudreuil, J. and Nizard, R. and Thomas, T. and Peyre, M. and Liotard, J. P. and Boileau, P. and Marc, T. and Dromard, C. and Steyer, E. and Bardin, T. and Orcel, P. and Walch, G. Contribution of clinical tests to the diagnosis of rotator cuff disease: A systematic literature review. Joint Bone Spine. 2009; 76 (1) :15-19	Wrong comparison (not multiple tests, just single tests)
Alqunaee, M. and Galvin, R. and Fahey, T. Diagnostic accuracy of clinical tests for subacromial impingement syndrome: A systematic review and meta-analysis. Archives of Physical Medicine and Rehabilitation. 2012; 93 (2) :229-236	Wrong comparison (not multiple tests, just single tests)
Dakkak, A. and Krill, M. K. and Krill, M. L. and Nwachukwu, B. and McCormick, F. Evidence-Based Physical Examination for the Diagnosis of Subscapularis Tears: A Systematic Review. Sports health. 2021; 13 (1) :78-84	Wrong P (subscapularis tears)
Hanchard NC, Lenza M, Handoll HH, Takwoingi Y. Physical tests for shoulder impingements and local lesions of bursa, tendon or labrum that may accompany impingement. Cochrane Database Syst Rev. 2013 Apr 30;2013(4):CD007427. doi: 10.1002/14651858.CD007427.pub2. PMID: 23633343; PMCID: PMC6464770.	Wrong study design (study protocol)
Rigsby, Ruel and Sitler, Michael and Kelly, John D. Subscapularis tendon integrity: an examination of shoulder index tests. Journal of athletic training. 2010; 45 (4) :404-6	Wrong study design (commentary)
Jain, N. B. and Luz, J. and Higgins, L. D. and Dong, Y. and Warner, J. J. and Matzkin, E. and Katz, J. N. The Diagnostic Accuracy of Special Tests for Rotator Cuff Tear: The ROW Cohort Study. American journal of physical medicine & rehabilitation. 2017; 96 (3) :176-183	Wrong comparison (not multiple tests, just single tests)
Kappe, T. and Sgroi, M. and Reichel, H. and Daexle, M. Diagnostic performance of clinical tests for subscapularis tendon tears. Knee surgery, sports traumatology, arthroscopy : official journal of the ESSKA. 2018; 26 (1) :176-181	Wrong comparison (not multiple tests, just single tests)
Verry, Christian and Fernando, Sheran Rotator Cuff Disease: Diagnostic Tests. American family physician. 2016; 94 (11) :925-926	Wrong study design (question and answer)

Yazigi Junior, J. A. and Anauate Nicolao, F. and Matsunaga, F. T. and Archetti Netto, N. and Belloti, J. C. and Sugawara Tamaoki, M. J. Supraspinatus tears: predictability of magnetic resonance imaging findings based on clinical examination. Journal of Shoulder and Elbow Surgery. 2021; 30 (8) :1834-1843	Wrong comparison (not multiple tests, just single tests)
Phillips, Nick Tests for diagnosing subacromial impingement syndrome and rotator cuff disease. Shoulder & elbow. 2014; 6 (3) :215-21	Wrong study design (narrative review)
Lädermann, A. and Meynard, T. and Denard, P. J. and Ibrahim, M. and Saffarini, M. and Collin, P. Reliable diagnosis of posterosuperior rotator cuff tears requires a combination of clinical tests. Knee surgery, sports traumatology, arthroscopy : official journal of the ESSKA. 2021; 29 (7) :2118-2133	Wrong comparison (not multiple tests, just single tests)
Hegedus, E. J. and Goode, A. P. and Cook, C. E. and Michener, L. and Myer, C. A. and Myer, D. M. and Wright, A. A. Which physical examination tests provide clinicians with the most value when examining the shoulder? Update of a systematic review with meta-analysis of individual tests. British journal of sports medicine. 2012; 46 (14) :964-978	Review comparing multiple combinations of factors and tests from individual studies (see table 4). However, these were all not the right tests/factors/pathologies or the individual study was already included.

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Subacromiaal Pijnsyndroom van de Schouder (SAPS)	
Uitgangsvraag/modules: Welke fysisch diagnostische tests zijn het meest geschikt voor het diagnosticeren van SAPS?	
Database(s): Ovid/Medline, Embase.com	Datum: 21 februari 2023
Periode: 2008 - heden	Talen: Engels, Nederlands
Literatuurspecialist: Miriam van der Maten	
BMI-zoekblokken: voor verschillende opdrachten wordt (deels) gebruik gemaakt van de zoekblokken van BMI-Online https://blocks.bmi-online.nl/ Bij gebruikmaking van een volledig zoekblok zal naar de betreffende link op de website worden verwezen.	
Toelichting: Voor deze vraag is gezocht op de elementen: • SAPS • Fysieke diagnostische testen, inclusief genoemde soorten testen • Diagnostisch filter, uitgebreid met logistische regressie en AUC De twee sleutelartikelen worden gevonden met de zoekopdracht.	
Te gebruiken voor richtlijnen tekst: *Nederlands* In de databases Embase.com en Ovid/Medline is op 21 februari 2023 systematisch gezocht naar systematische reviews, RCTs en overige studies over de diagnostische accuratesse voor het combineren van verschillende testen vergeleken met één test voor het diagnosticeren van SAPS. De literatuurzoekactie leverde 629 unieke treffers op. *Engels* On the 21st of February 2023, we performed a systematic search in the databases Embase.com and Ovid/Medline to find systematic reviews, RCTs and observational studies about the diagnostic accuracy for combining different tests compared to one test when diagnosing SAPS. The search resulted in 629 unique hits.	

Zoekopbrengst

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SRs	38	40	50
RCT	35	48	69
Overige studies	293	359	510
Totaal	366	447	**629**

Zoekstrategie

Embase.com

No.	**Query**	**Results**
#13	#10 OR #11 OR #12	366
#12	#7 NOT (#10 OR #11) **= overige studies**	293
#11	#7 AND #9 NOT #10 **= RCT**	35
#10	#7 AND #8 **= SR**	38
#9	'randomized controlled trial'/exp OR random*:ti,ab OR (((pragmatic OR	2018091

	practical) NEAR/1 'clinical trial*'):ti,ab) OR ((('non inferiority' OR noninferiority OR superiority OR equivalence) NEAR/3 trial*):ti,ab) OR rct:ti,ab,kw	
#8	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	733409
#7	#4 AND #5 AND #6 AND ([english]/lim OR [dutch]/lim) AND [2008-2023]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	366
#6	'diagnostic procedure'/exp OR diagnos*:ti,ab OR 'sensitivity and specificity'/de OR sensitiv*:ab,ti OR specific*:ab,ti OR predict*:ti,kw OR 'roc curve':ab,ti OR 'receiver operator':ab,ti OR 'receiver operators':ab,ti OR likelihood:ab,ti OR 'diagnostic error'/exp OR 'diagnostic accuracy'/exp OR 'diagnostic test accuracy study'/exp OR 'inter observer':ab,ti OR 'intra observer':ab,ti OR interobserver:ab,ti OR intraobserver:ab,ti OR validity:ab,ti OR kappa:ab,ti OR reliability:ab,ti OR reproducibility:ab,ti OR ((test NEAR/2 're-test'):ab,ti) OR ((test NEAR/2 'retest'):ab,ti) OR 'reproducibility'/exp OR accuracy:ab,ti OR 'differential diagnosis'/exp OR 'validation study'/de OR 'measurement precision'/exp OR 'diagnostic value'/exp OR 'reliability'/exp OR 'predictive value'/exp OR ppv:ti,ab,kw OR npv:ti,ab,kw OR 'logistic regression analysis'/exp OR 'area under the curve'/exp OR 'logistic regression*':ti,ab,kw OR auc:ti,ab,kw OR 'area under the curve':ti,ab,kw	24732558
#5	'physical examination'/exp/mj OR 'functional assessment'/exp/mj OR 'physical examination test*':ti,ab,kw OR 'physical test*':ti,ab,kw OR 'index test*':ti,ab,kw OR test*:ti OR (((empty OR full) NEAR/3 can):ti,ab,kw) OR neer:ti,ab,kw OR 'painful arc':ti,ab,kw OR yocum*:ti,ab,kw OR hawkins*:ti,ab,kw OR (((exorotation OR rotation) NEAR/5 (resistance OR resisted)):ti,ab,kw) OR jobe*:ti,ab,kw OR kennedy*:ti,ab,kw	617431
#4	'shoulder impingement syndrome'/exp/mj OR 'shoulder impingement syndrome':ti,ab,kw OR 'subacromial impingement syndrome':ti,ab,kw OR (('bursitis'/exp/mj OR bursitis:ti,ab,kw OR 'tendinitis'/exp/mj OR tendinitis:ti,ab,kw OR 'impingement':ti,ab,kw) AND ('shoulder'/exp/mj OR 'rotator cuff':ti,ab,kw OR acromion:ti,ab,kw OR acromial:ti,ab,kw OR subacromial:ti,ab,kw OR shoulder*:ti,ab,kw)) OR 'rotator cuff injury'/exp/mj OR 'rotator cuff rupture'/exp/mj OR ((('rotator cuff' OR	17682

	'shoulder cuff' OR infraspinatus OR supraspinatus OR subscapularis) NEAR/3 (tear* OR lesion* OR rupture* OR tendinopath* OR laceration*)):ti,ab,kw) OR (('full-thickness':ti,ab,kw OR partial:ti,ab,kw) AND 'rotator cuff':ti,ab,kw) OR ('rotator cuff'/exp/mj AND ('rupture'/exp/mj OR 'injury'/mj OR 'laceration'/exp/mj))	

Ovid/Medline

#	Searches	Results
11	8 or 9 or 10	447
10	5 not (8 or 9) **= overage studies**	359
9	(5 and 7) not 8 **= RCT**	48
8	5 and 6 **= SR**	40
7	exp randomized controlled trial/ or randomized controlled trials as topic/ or random*.ti,ab. or rct?.ti,ab. or ((pragmatic or practical) adj "clinical trial*").ti,ab,kf. or ((non-inferiority or noninferiority or superiority or equivalence) adj3 trial*).ti,ab,kf.	1588225
6	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	649856
5	limit 4 to ((english language or dutch) and yr="2008 -Current")	447
4	1 and 2 and 3	626
3	exp "Sensitivity and Specificity"/ or (Sensitiv* or Specific*).ti,ab. or predict*.ti,kf. or (ROC-curve or receiver-operator*).ti,ab. or (likelihood or LR*).ti,ab. or exp Diagnostic Errors/ or (inter-observer or intra-observer or interobserver or intraobserver or validity or kappa or reliability).ti,ab. or reproducibility.ti,ab. or (test adj2 (re-test or retest)).ti,ab. or "Reproducibility of Results"/ or accuracy.ti,ab. or Diagnosis, Differential/ or Validation Study/ or exp "Predictive Value of Tests"/ or ppv.ti,ab. or npv.ti,ab. or diagnos*.ti,ab. or predict*.ab,ti. or exp Logistic Models/ or exp Regression Analysis/ or 'logistic regression*'*.ti,ab,kf. or AUC*.ti,ab,kf. or 'area under the curve'*.ti,ab,kf.	9902765
2	exp *Physical Examination/ or 'physical examination test*'.ti,ab,kf. or 'physical test*'.ti,ab,kf. or 'index test*'.ti,ab,kf. or test*.ti. or (empty adj3 can).ti,ab,kf. or neer.ti,ab,kf. or 'painful arc'.ti,ab,kf. or yocum*.ti,ab,kf. or Hawkins*.ti,ab,kf. or ((exorotation or rotation) adj5 (resistance or resisted)).ti,ab,kf. or Jobe*.ti,ab,kf. or Kennedy*.ti,ab,kf.	891795
1	*Shoulder Impingement Syndrome/ or 'shoulder impingement syndrome'.ti,ab,kf. or 'subacromial impingement syndrome'.ti,ab,kf. or ((exp *bursitis/ or exp *Tendinopathy/ or bursitis.ti,ab,kf. or tendinitis.ti,ab,kf. or 'impingement'.ti,ab,kf.) and (exp *Shoulder/ or 'rotator cuff'.ti,ab,kf. or	17825

	acromion.ti,ab,kf. or acromial.ti,ab,kf. or subacromial.ti,ab,kf. or shoulder*.ti,ab,kf.)) or *Rotator Cuff/ or exp *Rotator Cuff Injuries/ or (('rotator cuff' or 'shoulder cuff' or infraspinatus or supraspinatus or subscapularis) adj3 (tear* or lesion* or rupture* or tendinopath* or laceration*)).ti,ab,kf. or (('full-thickness' or partial) and 'rotator cuff').ti,ab,kf.	

Module 3 Beeldvormende diagnostiek

Leeswijzer:
Onderstaande conceptrichtlijntekst wordt na het doorlopen van de commentaar- en autorisatiefase opgenomen in de Richtlijnendatabase (www.richtlijnendatabase.nl). Verwijzingen naar 'tabbladen' zijn in de huidige versie van de richtlijntekst terug te vinden in de 'bijlagen' aan het einde van de hoofdtekst. In verband met de modulaire opbouw van richtlijnen in de database wordt verwezen naar modules (i.p.v. hoofdstukken) en aanverwante producten (bijlagen).

Uitgangsvraag
Welke aanvullende beeldvormende diagnostiek heeft een meerwaarde voor het behandeltraject van SAPS?

Introduction (English)
The diagnosis of subacromial pain syndrome (SAPS) is made using clinical tests. An ultrasound or Magnetic Resonance Imaging (MRI) can be performed to assess whether there is underlying cuff pathology. The advantage of ultrasound examination over MRI is that it is readily available and inexpensive, and has a high specificity and sensitivity in the diagnosis of SAPS. When assessing the indication for rotator cuff repair surgery, it is important to also assess tendon and muscle retraction and degree of fatty infiltration of the rotator cuff. This can be assessed well with the MRI, but this is a burdensome and expensive examination.

Search and select
A systematic review of the literature was performed to answer the following question: What is the value of ultrasonography versus MRI in patients who are suspected to have a partial thickness tear in the supraspinatus tendon?

Patients	Patients who are suspected to have a partial thickness tear in the supraspinatus tendon
Index test	Utrasound
Comparator test	MRI
Reference standard	Arthroscopy
Outcomes	Diagnostic accuracy: false negatives (FN), sensitivity, negative predictive value (NPV), false positives (FP), true positives (TP), true negatives (TN), specificity, positive predictive value (PPV), Fatty-infiltration, Percentage tear rupture, return to work or leisure
Timing and setting	Arthroscopy within 6 months preoperative US/MRI

<u>Relevant outcome measures</u>
The guideline development group considered FP, specificity and PPV as critical outcome measures for decision making; and FN, sensitivity, NPV, TP, and TN, fatty-infiltration, percentage tear rupture, and return to work or leisure as important outcome measures for decision making.

The guideline development group defined a difference of 10% in specificity and PPV and a difference of 100 per 1000 patients in FP and 200 per 1000 FN as a minimal clinically (patient) important difference.

For the clinical outcomes fatty-infiltration, percentage tear rupture, and return to work or leisure, a difference of 25% was considered clinically relevant (RR≤0.8 or RR≥1.25).

Table 1 Consequences of diagnostic test characteristics

Outcome	Consequences	Relevance
Positive prediction value (PPV)	Proportion of patients who are justifiably not diagnosed with partial thickness tear in the supraspinatus or subscapulair tendon	Crucial
False positives (FP), low specificity	Patients are unjustifiably diagnosed with partial thickness tear in the supraspinatus or subscapulair tendon; giving treatment is unjustified	Crucial
True positives (TP), high sensitivity	Patients are justifiably diagnosed partial thickness tear in the supraspinatus or subscapulair tendon; giving treatment is justified	Important
True negatives (TN), high specificity	Patients are justifiably not diagnosed with partial thickness tear in the supraspinatus or subscapulair tendon; not giving treatment is justified	Important
False negatives (FN), low sensitivity	Patients are unjustifiably not diagnosed with partial thickness tear in the supraspinatus or subscapulair tendon; not giving treatment is unjustified	Important
Negative prediction value (NPV)	Proportion of patients who are unjustifiably not diagnosed with partial thickness tear in the supraspinatus or subscapulair tendon	Important

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until 06-06-2023. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 639 hits. Studies were selected based on the following criteria:

- Systematic reviews, RCTs or observational studies
- Publication date ≥ 2010 (due to advancement in techniques)
- Patients with suspected partial thickness rupture tear in the supraspinatus tendon
- Ultrasound, MRI in the same population
- Using current standard of care (non-handheld) ultrasound devices
- Arthroscopy as reference standard
- Reporting one or more of the following diagnostic accuracy measures: false negatives (FN), sensitivity, negative prediction value (NPV), false positives (FP), true positives (TP), true negatives (TN), specificity, positive prediction value (PPV) Diagnostic values as outcome measures

Twenty-nine studies were initially selected based on title and abstract screening. After reading the full text, 26 studies were excluded (see the table with reasons for exclusion under the tab Methods), and three studies were included.

Results

Three studies (one systematic reviews and two additional observational studies) were included in the analysis of the literature. Important study characteristics and results are summarized in the evidence tables. The assessment of the risk of bias is summarized in the risk of bias tables.

Summary of literature

Description of studies

All three studies examined the diagnostic accuracy of US and MRI in the preoperative diagnosis of partial thickness rupture with arthroscopy as the reference standard. Relevant study characteristics are shown in table 2.

Farooqi (2021) performed a SR and meta-analysis in which they evaluated the diagnostic accuracy of US for partial- and full-thickness rotator cuff tears and biceps tendon tears, and compared diagnostic values with those of MRI using arthroscopy as the reference standard. The literature search was performed up to January 1, 2010, and April 1, 2020. Five studies of the 23 included studies in de SR compared the diagnostic capability of US and MRI for partial supraspinatus tears using arthroscopy as the reference standard and were included in the current literature review (Abd-ElGawad, 2013; Day, 2016; Rutten, 2010; Sabharwal, 2019). The overall risk of bias among the included studies was low or unclear, with one study (Abd-ElGawad, 2013) exhibiting a high risk of bias in patient selection, and two studies (Abd-ElGawad, 2013; Elmorsy 2017) exhibiting >6 months of mean time between US and surgery.

Li (2023) performed a retrospective patient record study to explore the feasibility and diagnostic value of percutaneous US-guided subacromial bursography (PUSB) in evaluating rotator cuff tears. In total 78 patients with shoulder arthroscopic surgery and images of conventional US, MRI and PUSB were examined between July 2019 to October 2021. The risk of bias was unclear for blinding of the radiologists and surgeon.

McGuire (2023) performed a retrospective patient record study to compare the diagnostic sensitivity of ultrasound and MRI in the pre-operative diagnosis of partial thickness tears (PTT) and full thickness tears (FTT) of supraspinatus tendons compared to shoulder arthroscopy to assess if differences in detection rates exist. In total 103 patients that had a shoulder arthroscopic repair performed within 3 months of a positive supraspinatus tear diagnosed by both MRI and ultrasound were included (collected over a period from August 2020 to August 2021). The risk of bias was unclear for blinding of the radiologists and surgeon.

Table 2 Study characteristics

First author, year	design	N, mean age (years)	Selected cases	Prevalence PTT	Index and comparator	Reference standard
Farooqi, 2021						
Abd-ElGawad, 2013	Retrospective study	40, 55	partial supraspinatus tears	13 (32.5%)	US (GE Logiq 5, 12 MHz)[operator: general radiologist] 1T MRI	arthroscopy
Day, 2016	Prospective study	19, 55	partial supraspinatus tears	7 (36.8%)	US [operator: surgeon] MRI (not further specified)	arthroscopy
Elmorsy, 2017	Retrospective study	125, 52	partial supraspinatus tears	13 (10.4%)	US [operator: MSK radiologist] 1.5/ 3 T MRI	arthroscopy
Rutten, 2010	Retrospective study	48, 68	partial supraspinatus tears	9 (18.4%)	US [operator: MSK radiologist] 1.5 T MRI	arthroscopy
Sabharwal, 2019	Prospective study	60, 45	partial supraspinatus tears	20 (33.3%)	US (GE Voluson P8, 7-12 MHz) [operator: general radiologist] MRI (not further specified)	arthroscopy
Additional studies						
Li, 2023	Retrospective study	78, 53.9	partial-thickness rotator cuf tears (supraspinatus tendon)	42 (48%)	US with a 6-18 MHz linear array probe (18L6). 1.5T MRI with a special coil for the	shoulder arthroscopy performed by an associate chief physician with more

					shoulder joint.	than 10 years of shoulder arthroscopy experience
McGuire, 2023	Retrospective study	103, 64	partial thickness tears (PTT) of supraspinatus tendons	40 (38.8%)	US (10–15 MHz)[operator: general sonographers] 1.5-T/ 3 T MRI	shoulder arthroscopic repair

Results

The analyses were based on direct comparisons. The diagnostic accuracy measure outcomes for the tests are shown in Tables 3 and 4. The prevalence of partial thickness tears ranged from 18.4% to 38% (see Table 1).

FP, TN, specificity and PPV (Crucial outcomes)

Seven studies investigated the specificity of US and MRI (Li, 2023; Zhu, 2022; Abd-ElGawad, 2013; Day, 2016; Elmorsy, 2017; Rutten, 2010; Sabharwal, 2019). The specificity for the use of US varied from 0.68 (95%CI 0.56 to 0.79) to 0.93 (95%CI 0.80 to 0.98). In the same study population, specificity for the use of MRI varied from 0.72 (95%CI 0.63 to 0.80) to 0.93 (95%CI 0.76 to 0.99). The PPV for the use of US varied from 0.21 to 0.92; compared to PPV for the use of MRI ranging from 0.18 to 0.89. The test with better values for specificity, number of FP, number of TN and PVV varied between the studies – but overall, the differences were small.

FN, TP, sensitivity and NPV (Important outcomes)

All studies investigated the sensitivity of US and MRI. The sensitivity for the use of US varied from 0.23 (95%CI 0.05 to 0.54) to 0.95 (95%CI 0.75 to 1.00). In the same study population, sensitivity for the use of MRI varied from 0.38 (95%CI 0.30 to 0.47) to 0.86 (95%CI 0.42 to 1.00). The NPV for the use of US varied from 0.68 to 0.98; compared to NPV for the use of MRI ranging from 0.76 to 0.94. The test with better values for sensitivity, number of FN, number of TP and NPV varied between the studies – but overall, the differences were small.

Table 3. Diagnostic accuracy ultrasound

First author, year	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Li, 2023 US	27	4	15	32	0.64 [0.48, 0.78]	0.89 [0.74, 0.97]	0.87 (0.75, 1.00)	0.68 (0.54, 0.82)
McGuire, 2023 PTT<5mm	15	0	3	0	0.83 [0.59, 0.96]	Not estimable	Not estimable	Not estimable
McGuire, 2023 PTT>5mm	16	0	6	0	0.73 [0.50, 0.89]	Not estimable	Not estimable	Not estimable
Zhu, 2022	94	35	33	275	0.74 [0.65, 0.81]	0.89 [0.85, 0.92]	0.73	0.89
Abd-ElGawad, 2013	12	3	1	24	0.92 [0.64, 1.00]	0.89 [0.71, 0.98]	0.80	0.96
Day, 2016	5	2	2	25	0.71 [0.29, 0.96]	0.93 [0.76, 0.99]	0.71	0.93
Elmorsy, 2017	3	11	10	101	0.23 [0.05, 0.54]	0.90 [0.83, 0.95]	0.21	0.91
Rutten, 2010	8	22	1	47	0.89 [0.52, 1.00]	0.68 [0.56, 0.79]	0.27	0.98
Sabharwal, 2019	19	3	1	37	0.95 [0.75, 1.00]	0.93 [0.80, 0.98]	0.86	0.97

CI = confidence interval; FN = false negatives; FP = false positives; NPV = negative prediction value; NR = not reported; TN = true negatives; TP = true positives; PPV = positive prediction value

Table 4. Diagnostic accuracy MRI

First author, year	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)	PPV (95% CI)	NPV (95% CI)
Li, 2023	32	4	10	32	0.76 [0.61, 0.88]	0.89 [0.74, 0.97]	0.89 (0.78, 1.00)	0.76 (0.63, 0.90)
McGuire, 2023 PTT<5mm	14	0	4	0	0.78 [0.52, 0.94]	Not estimable	Not estimable	Not estimable
McGuire, 2023 PTT>5mm	19	0	3	0	0.86 [0.65, 0.97]	Not estimable	Not estimable	Not estimable
Zhu, 2022	48	42	78	268	0.38 [0.30, 0.47]	0.86 [0.82, 0.90]	0.53	0.77
Abd-ElGawad, 2013	11	2	2	25	0.85 [0.55, 0.98]	0.93 [0.76, 0.99]	0.85	0.93
Day, 2016	6	2	1	11	0.86 [0.42, 1.00]	0.85 [0.55, 0.98]	0.75	0.92
Elmorsy, 2017	7	31	6	81	0.54 [0.25, 0.81]	0.72 [0.63, 0.80]	0.18	0.93
Rutten, 2010	6	8	3	51	0.67 [0.30, 0.93]	0.86 [0.75, 0.94]	0.43	0.94
Sabharwal, 2019	17	3	3	37	0.85 [0.62, 0.97]	0.93 [0.80, 0.98]	0.85	0.93

CI = confidence interval; FN = false negatives; FP = false positives; NPV = negative prediction value; NR = not reported; TN = true negatives; TP = true positives; PPV = positive prediction value

Fatty-infiltration (important outcome)
Not reported

Percentage tear rupture (important outcome)
Not reported

Return to work or leisure (important outcome)
Not reported

Level of evidence of the literature

FP, TN, specificity and PPV (crucial outcomes)
The level of evidence regarding the outcome measures FP, TN, specificity and PPV was downgraded by two levels because of study limitations (risk of bias, -1) and limited number of included patients (imprecision, -1).

FN, TP, sensitivity and NPV (important outcomes)
The level of evidence regarding the outcome measures FN, TP, sensitivity and NPV was downgraded by two levels because of study limitations (risk of bias, -1) and limited number of included patients (imprecision, -1).

Clinical outcomes: fatty-infiltration and percentage tear rupture, return to work or leisure (important outcomes)

The level of evidence regarding fatty-infiltration,percentage tear rupture, and return to work or leisure could not be determined due to a lack of data.

Table 5. Overview of study results

	UTRASOUND								MRI							
First author, year	**TP**	**FP**	**FN**	**TN**	**Sensitivity (95% CI)**	**Specificity (95% CI)**	**PPV (95% CI)**	**NPV (95% CI)**	**TP**	**FP**	**FN**	**TN**	**Sensitivity (95% CI)**	**Specificity (95% CI)**	**PPV (95% CI)**	**NPV (95% CI)**
Li, 2023 US	27	4	15	32	0.64 [0.48, 0.78]	0.89 [0.74, 0.97]	0.87 (0.75, 1.00)	0.68 (0.54, 0.82)	32	4	10	32	0.76 [0.61, 0.88]	0.89 [0.74, 0.97]	0.89 (0.78, 1.00)	0.76 (0.63, 0.90)
Li, 2023 PUBS	*40*	*1*	*2*	*35*	*0.95 [0.84, 0.99]*	*0.97 [0.85, 1.00]*	*0.98*	*0.95 (0.87, 1.02)*								
McGuire, 2023 PTT<5mm	15	0	3	0	0.83 [0.59, 0.96]	Not estimable	Not estimable	Not estimable	14	0	4	0	0.78 [0.52, 0.94]	Not estimable	Not estimable	Not estimable
McGuire, 2023 PTT>5mm	16	0	6	0	0.73 [0.50, 0.89]	Not estimable	Not estimable	Not estimable	19	0	3	0	0.86 [0.65, 0.97]	Not estimable	Not estimable	Not estimable
Zhu, 2022	94	35	33	275	0.74 [0.65, 0.81]	0.89 [0.85, 0.92]	0.73	0.89	48	42	78	268	0.38 [0.30, 0.47]	0.86 [0.82, 0.90]	0.53	0.77
Abd-ElGawad, 2013	12	3	1	24	0.92 [0.64, 1.00]	0.89 [0.71, 0.98]	0.80	0.96	11	2	2	25	0.85 [0.55, 0.98]	0.93 [0.76, 0.99]	0.85	0.93
Day, 2016	5	2	2	25	0.71 [0.29, 0.96]	0.93 [0.76, 0.99]	0.71	0.93	6	2	1	11	0.86 [0.42, 1.00]	0.85 [0.55, 0.98]	0.75	0.92
Elmorsy, 2017	3	11	10	101	0.23 [0.05, 0.54]	0.90 [0.83, 0.95]	0.21	0.91	7	31	6	81	0.54 [0.25, 0.81]	0.72 [0.63, 0.80]	0.18	0.93
Rutten, 2010	8	22	1	47	0.89 [0.52, 1.00]	0.68 [0.56, 0.79]	0.27	0.98	6	8	3	51	0.67 [0.30, 0.93]	0.86 [0.75, 0.94]	0.43	0.94

Conclusions

Diagnostic accuracy outcomes

FP, TN, specificity and PPV (crucial outcomes)

Low GRADE	The use of US may not differ in FP, TN, specificity and PPV compared to MRI in patients who are suspected to have a partial thickness tear in the supraspinatus tendon. *Source: Li, 2023; Zhu, 2022; Abd-ElGawad, 2013; Day, 2016; Elmorsy, 2017; Rutten, 2010; Sabharwal, 2019*

FN, TP, sensitivity and NPV (important outcomes)

Low GRADE	The use of US may not differ in FN, TP, sensitivity and NPV compared to MRI in patients who are suspected to have a partial thickness tear in the supraspinatus tendon. *Source: Li, 2023; McGuire, 2023; Zhu, 2022; Abd-ElGawad, 2013; Day, 2016; Elmorsy, 2017; Rutten, 2010; Sabharwal, 2019*

Clinical outcomes (important outcomes)

No GRADE	No evidence was found regarding whether the use of US results in differences in ***fatty infiltration, percentage tear rupture, and return to work or leisure*** when compared to MRI in patients who are suspected to have a partial thickness tear in the supraspinatus tendon. *Sources: -*

Overwegingen – van bewijs naar aanbeveling

<u>Voor- en nadelen van de interventie en de kwaliteit van het bewijs</u>

De werkgroep heeft systematisch literatuuronderzoek verricht naar de diagnostische accuratesse van echografie in vergelijking met MRI om een partiële ruptuur van de supraspinatuspees te detecteren in patiënten met schouderpijn verdacht op het hebben van deze ruptuur, waarvoor zij een operatie (artroscopie) ondergingen. De operatie was hierbij de referentiestandaard. Het doel van dit literatuuronderzoek was onderzoeken of de diagnostische accuratesse van echografie voldoende is om te helpen sturen in de keuze voor conservatieve of operatieve therapie.

Alleen studies die echografie en MRI (en artroscopie als referentie standaard) in dezelfde populatie beoordeelden werden geïncludeerd in de literatuursamenvatting.
Voor de cruciale uitkomstmaten specificiteit, positief voorspellende waarde, foutpositieven en echt negatieven lijkt er geen verschil te zijn tussen echografie en MRI voor het detecteren van een partiële ruptuur van de supraspinatuspees. Ook voor de belangrijke uitkomstmaten sensitiviteit, negatief voorspellende waarde, foutnegatieven en echt positieven lijkt er geen verschil te zijn. Klinische uitkomsten werden niet gerapporteerd.

Er is voldoende wetenschappelijk onderzoek beschikbaar over het gebruik van echografie of MRI voor het aantonen van rotator cuff letsels, maar ook voldoende studies die MRI vergelijken met echografie voor het aantonen of uitsluiten van rotator cuff letsels.

Op basis van de literatuur kan voldoende zeker worden gesteld dat echografie, mits uitgevoerd door een professional met voldoende ervaring in de uitvoering hiervan en gebruikmakend van apparatuur die past in de huidige standaard van zorg (high-end echografie), gelijkwaardig is aan non-contrast MRI voor het aantonen en uitsluiten van supraspinatuspeesletsels.

Een vergelijking tussen echografie en MRI-arthrografie (MRA) valt buiten de zoekopdrachten van deze richtlijn. Een meta-analyse van DeJesus (2009) laat zien dat MRA superieur is aan echografie en non-contrast MRI met een sensitiviteit van 95% voor volledige dikte scheuren en 86% voor partiele dikte scheuren versus respectievelijk 92% en 64% voor non-contrast MRI en 92% en 67% voor echografie. De specificiteit van MRA is 99% voor volledige scheuren en 96% voor partiele scheuren versus 93% en 92% voor MRI en 94% en 94% voor echografie. Nadelen van MRA zijn het invasieve karakter waarbij er via een punctie contrast in het gewricht gebracht wordt, en de kans op een allergische reactie op het contrastmiddel. Daarnaast is MRA duurder en minder goed toegankelijk dan non-contrast MRI en belastender voor de patiënt. Wanneer een grote mate van zekerheid wordt vereist van de beeldvorming, bijvoorbeeld bij jonge, actieve patiënten die voor (top)sport of werk afhankelijk zijn van een goede schouderfunctie, moet MRA sterk worden overwogen.

Voor de beoordeling van vetinfiltratie in de spierbuiken van de rotatorcuff (voornamelijk de m. supraspinatus) is geen geschikte literatuur gevonden die echografie en MRI vergelijkt. Voor het beschrijven van de mate van vetinfiltratie is de Goutallier classificatie waarschijnlijk de bekendste (Goutallier, 1994). Deze is oorspronkelijk ontwikkeld voor CT onderzoeken, maar kan ook met de aanpassingen volgens Fuchs (1999) op MRI worden toegepast. De correlatie tussen CT en MRI voor de mate van vervetting is beperkt, door het vermogen van MRI om spierweefsel beter te onderscheiden van fibreus weefsel.

Deze vetinfiltratie kan ook met echografie worden beoordeeld, bijvoorbeeld met de techniek van Strobel (2005), waarbij de echogeniciteit en architectuur van de rotator-cuffspierbuiken worden vergeleken met de overliggende spieren. De correlatie tussen echografie en MRI is redelijk tot goed (Peeters, 2023). Dit levert echter beperkingen op wanneer de overliggende spieren ook afwijkend zijn, of wanneer de rotatorcuff spieren te diep liggen om goed te kunnen visualiseren. Dit is vooral een probleem bij de m. supraspinatus (Park, 2020), welke het vaakst betrokken is bij rotator cuff letsel.
Het gebruik van shear-wave elastografie is inferieur aan MRI gebleken in recente onderzoeken (Peeters, 2023).

<u>Waarden en voorkeuren van patiënten (en evt. hun verzorgers)</u>
Voor patiënten is het belangrijkste dat de beeldvorming een goed oordeel geeft. Aangezien de echografie ook een goede beoordeling geeft, er een lagere belasting is voor de patiënt, het onderzoek sneller is, minder contra-indicaties kent en claustrofobie geen probleem is, zullen patiënten een voorkeur voor echografie hebben. Daarnaast is echografie veel breder beschikbaar dan MRI.

Voor patiënten is het in ieder geval belangrijk dat meteen juist worden geïndiceerd en het juiste middel wordt ingezet, zodat patiënten niet met pijn nog een beeldvormend onderzoek moeten ondergaan.

<u>Kosten (middelenbeslag)</u>

Over het algemeen is MRI een duurder onderzoek dan echografie. Daarnaast kost MRI meer tijd, kent meer contra-indicaties, vereist duurdere apparatuur en in het geval van een MRA is de procedure ook meer invasief.

Aanvaardbaarheid, haalbaarheid en implementatie
Er zijn verschillende oorzaken voor het ontstaan van een subacromiaal pijn syndroom. Om aan te tonen of er een (partiele) ruptuur van de rotator cuff bestaat, is echografie zeer geschikt. Voorop bij het stellen van de diagnose staat echter het lichamelijk onderzoek. Indien er sprake is van instabiliteit van de schouder met secundaire subacromiaal pijn syndroom dan heeft een MRA de voorkeur boven echografie.

Echografie is breed beschikbaar en kan laagdrempelig uitgevoerd worden. Wel is het van belang dat de apparatuur van goede kwaliteit is en de professional ervaring heeft met het uitvoeren van dit onderzoek. Aan deze beide criteria zal in Nederland vrijwel overal kunnen worden voldaan. De werkgroep voorziet dan ook geen problemen met het implementeren van de aanbeveling.

Aanbeveling
Rationale van de aanbeveling: weging van argumenten voor en tegen de diagnostische procedure
Echografie heeft een diagnostische accuratesse die gelijk is aan MRI voor het aantonen en uitsluiten van supraspinatuspeesletsels. Gezien de goede beschikbaarheid van echografie, lagere kosten, lage belasting voor de patiënt en afwezigheid van significante contraindicaties, heeft dit de voorkeur als eerste modaliteit voor het aantonen of uitsluiten van supraspinatuspeesrupturen.

Bij een slechte beschikbaarheid van echografie, een inconclusief echografieonderzoek, discrepantie tussen kliniek en beeldvorming, of andere redenen waarom echografie niet mogelijk of wenselijk is, kan MRI worden ingezet.

Voor het beoordelen van vetinfiltratie verdient MRI de voorkeur, gezien de ruime ervaring op dit gebied. Bij contra-indicaties kan voor CT of echografie worden gekozen.

Verricht echografie indien aanvullende beeldvorming is geïndiceerd bij patiënten met klinische verdenking op een (partiële dikte) ruptuur van de supraspinatuspees.

Overweeg MRI bij patiënten met klinische verdenking op een (partiële dikte) ruptuur van de supraspinatuspees als echografie niet beschikbaar of inconclusief is.

Kennisvragen
Wat is de waarde van MR artrografie vergeleken met MRI voor de diagnostiek van rotatorcuffletsels?

Literatuur
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Bijlagen bij module 3 Beeldvormende diagnostiek

Implementatieplan

Aanbeveling	Tijdspad voor implementatie: <1 jaar, 1-3 jaar of >3 jaar	Verwacht effect op kosten	Randvoorwaarden voor implementatie (binnen aangegeven tijdspad)	Mogelijke barrières voor implementatie	Te ondernemen acties voor implementatie	Verantwoordelijken voor acties	Overige opmerkingen
Verricht echografie indien aanvullende beeldvorming is geïndiceerd bij patiënten met klinische verdenking op een (partiële dikte) ruptuur van de supraspinatuspees.	<1 jaar	Huidige standaard van zorg. Geen significant effect op kosten verwacht	geen	Veranderen van zorgpad / verwijsgewoonten. Mogelijk toegenomen druk op beschikbaarheid echografie.	Richtlijnpublicatie	NOV	
Overweeg MRI bij patiënten met klinische verdenking op een (partiële dikte) ruptuur van de supraspinatuspees als echografie niet beschikbaar of inconclusief is.	<1 jaar	Huidige standaard van zorg. Geen significant effect op kosten verwacht	geen	Veranderen van zorgpad / verwijsgewoonten. Mogelijk toegenomen druk op beschikbaarheid MRI.	Richtlijnpublicatie	NOV	

Evidence tabellen

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
Farooqi, 2021 PS., study characteristics and results are extracted from the SR (unless stated otherwise: * indicates data was extracted from individual studies)	SR and meta-analysis *Literature search up to January 1, 2010, and April 1, 2020* Five studies of the 23 included studies in de SR compared the diagnostic capability of US and MRI for partial supraspinatus tears using arthroscopy as the reference standard and were included:	Inclusion criteria SR: studies that evaluated the diagnostic accuracy of US in rotator cuff tears utilizing arthroscopy as the reference standard Exclusion criteria SR: review articles, meta-analyses, systematic reviews, case reports, cadaveric studies, non-	Index (1) and comparator tests (2)* and cut-off point(s): **A-1**: US (GE Logiq 5, 12 MHz); cut-off NA [operator: general radiologist] **A-2**: MRI, cut-off NA *MRI examinations were performed with a 1TMR Imagingunit(Intera, Philips Medical Systems, NeberlandB.V) and one surface coil was used* **B-1**: US; cut-off NA	Reference test and cut-off point(s): **A**: arthroscopy; cut-off NR **B**: arthroscopy; cut-off NR **C**: arthroscopy; cut-off NR **D**: arthroscopy; cut-off NR **E**: arthroscopy; cut-off NR Prevalence partial	Endpoint of follow-up: **A:** NR **B**: NR **C**: NR **D**: NR **E**: NR	TP/FP/FN/TN*: **A:** PTT+ / PTT- US+: TP: *12* / FP: 3 / *15* US-: FN: 1 / TN: 24 / 25 *13* / 27 / *40* PTT+ / PTT- MRI+: TP: *11* / FP: 2 / 13 MRI-: FN: 2 / TN: 25 / 27 *13* / 27 / *40* B: PTT+ / PTT- US: TP: / FP: / *7*	Study aim: To evaluate the diagnostic accuracy of US for partial- and full-thickness rotator cuff tears and biceps tendon tears, compare diagnostic values with those of magnetic resonance imaging (MRI) using arthroscopy as the reference standard, assess longitudinal improvements in accuracy, and

	A: Abd-ElGawad (2013)2 **B**: Day (2016)10 **C**: Elmorsy (2017)15 **D**: Rutten (2010)48 **E**: Sabharwal (2019)50 <u>Study design</u>: cohort, case-control [prospective / retrospective] **A**: Abd-ElGawad (2013)2 **B**: Day (2016)10 **C**: Elmorsy (2017)15 **D**: Rutten (2010)48 **E**: Sabharwal (2019)50 <u>Setting and Country</u>: USA	English text, studies with <10 patients, studies including massive tears without reporting diagnostic data for specific tendons, and studies lacking diagnostic outcome data. <u>Important patient characteristics</u>: <u>N, mean age</u> **A**: 40, 55 yrs **B**: 19, 55 yrs **C**: 125, 52 yrs **D**: 48, 68 yrs **E**: 60, 45 yrs	[operator: surgeon] **B-1**: MRI, cut-off NA *(MRI details/transducer not reported)* **C-1**: US; cut-off NA [operator: MSK radiologist] **C-2**: MRI, cut-off NA *MRI scans were performed using 1.5 or 3 Tesla MRI scanners* **D-1**: US; cut-off NA [operator: MSK radiologist] **D-2**: MRI, cut-off NA *All MRI examinations were performed with an 1.5-T MR system (Signa Horizon, GE, 's-Hertogenbosch, The Netherlands).*	thickness cuff tear (PPT) (%)* [based on refence test at specified cut-off point] **A:** 13 (32.5%) **B**: 7 (36.8%) **C**: 13 (10.4%) **D**: 9 (18.4%) **E**: 20 (33.3%) For how many participants were no complete outcome data available? N (%) **A:** NR **B**: NR **C**: NR **D**: NR			compare diagnostic values from operators with different training backgrounds. <u>Study quality (ROB):</u> The quality and risk of bias for each included study was assessed by 2 authors (A.S.F. and A.L.) using the Quality Assessment of Diagnostic Accuracy Studies–2 (QUADAS-2) Tool across 4 domains (For each domain, studies were assigned a score of low (low risk of bias or low concern regarding

+	*5*	2	
US -	FN: 2	TN: 10	12
	7	12	*19*

	PTT +	PTT -	
MRI +	TP: *6*	FP: 2	*7*
MRI -	FN: 1	TN: 11	12
	7	12	*19*

C:

	PTT +	PTT -	
US +	TP: NR	FP: NR	
US -	FN: NR	TN: NR	
			125

	PTT +	PTT -	
MRI +	TP: NR	FP: NR	
MRI -	FN: NR	TN: NR	
			125

	<u>Source of funding and conflicts of interest:</u> One or more of the authors has declared the following potential conflict of interest or source of funding: X.L. has received consulting fees and royalties from FH Ortho. J.D.K. has received consulting fees from Flexion and royalties from SLACK and Springer. R.L.P. has received grant/educational support from Arthrex. AOSSM checks author disclosures against the Open		**E-1**: US (GE Voluson P8, 7-12 MHz); cut-off NA [operator: general radiologist] **E-2**: MRI, cut-off NA *(MRI details/transducer not reported)*	**E**: NR Reasons for incomplete outcome data described? **A:** NR **B**: NR **C**: NR **D**: NR **E**: NR		**D:** <table><tr><td></td><td>PTT +</td><td>PTT -</td><td></td></tr><tr><td>US +</td><td>TP: *8*</td><td>FP: 22</td><td>*20*</td></tr><tr><td>US -</td><td>FN: 1</td><td>TN: 47</td><td>48</td></tr><tr><td></td><td>*9*</td><td>69</td><td>*68*</td></tr></table> <table><tr><td></td><td>PTT +</td><td>PTT -</td><td></td></tr><tr><td>MRI +</td><td>TP: *6*</td><td>FP: 8</td><td>*14*</td></tr><tr><td>MRI -</td><td>FN: 3</td><td>TN: 51</td><td>54</td></tr><tr><td></td><td>*9*</td><td>59</td><td>*68*</td></tr></table> **E:** <table><tr><td></td><td>PTT +</td><td>PTT -</td><td></td></tr><tr><td>US +</td><td>TP: *19*</td><td>FP: *3*</td><td>22</td></tr><tr><td>US -</td><td>FN: *1*</td><td>TN: *37*</td><td>38</td></tr><tr><td></td><td>20</td><td>40</td><td>60</td></tr></table> <table><tr><td></td><td>PTT +</td><td>PTT -</td><td></td></tr><tr><td>MRI</td><td>TP:</td><td>FP:</td><td>20</td></tr></table>	applicability), unclear, or high (high risk of bias or high concern regarding applicability).): Patient selection **A:** high **B**: low **C**: low **D**: low **E**: low Index test – US **A:** unclear **B**: low **C**: unclear **D**: low **E**: low Index test – MRI **A:** unclear **B**: low **C**: unclear **D**: NA **E**: low Reference

	Payments Database (OPD). AOSSM has not conducted an independent investigation on the OPD and disclaims any liability or responsibility relating thereto.					<table><tr><td>+</td><td>17</td><td>3</td><td></td></tr><tr><td>MRI -</td><td>FN: 3</td><td>TN: 37</td><td>40</td></tr><tr><td></td><td>20</td><td>40</td><td>60</td></tr></table> <u>Sensitivity/ specificity/ diagnostic accuracy-1/2*</u> **A-1**: 92.3%/ 92.6%/ 92.5% **A-2**: 84.6%/ 92.6%/ 90% **B-1**: 0.71/1.00/ 74% **B-2**: 1.00/ 1.00/ 100% ***But for all tears, no distinction in partial/ full tears → own calculations*** **C-1**: 23%/ 90.1% **C-2**: 54.1% (P=0.333) / 72.6% (P=0.0008) **D-1**: 89% [52%-100%]/ 80% [67%-89%]/ 81% [70%-89%] **D-2**: 67% [30%-93%]/ 86% [75%-94%]/ 84% [73%-92%] **E-1**: 95.0%/ 92.5%/	standard **A:** unclear **B**: low **C**: unclear **D**: low **E**: low Flow and Timing **A:** high **B**: unclear **C**: high **D**: unclear **E**: unclear <u>Place of the index test in the clinical pathway</u>: add-on (MRI after US) <u>Choice of cut-off point</u>: visual via operation <u>Brief description of author's discussion/ conclusion:</u> "This study demonstrated

						93.3% **E-2**: 85.0%/ 92.5%/ 90.0% US median sensitivity 0.89 US median specificity 0.89 MRI median sensitivity 0.85 MRI median specificity 0.87 Pooled characteristics: sensitivity = –2.36 [95% CI, –21.51 to 16.79], P = .81 specificity = 4.30 [95% CI, –7.06 to 15.66], P = .46 diagnostic accuracy = 5.25 [95% CI, –1.60 to 12.10], P = .13 Heterogeneity (reasons): No significant heterogeneity was observed among the studies in US and MRI diagnostic	that US is highly sensitive and specific in the diagnosis of supraspinatus tears and is more accurate in the diagnosis of full-thickness tears as compared to partial-thickness tears." "[..] US demonstrated a lower median sensitivity and specificity for partial thickness tears, at 0.65 and 0.86, respectively. In support of these findings, 1 study reported that diagnostic accuracy increased with tear size for full-

						outcomes when evaluating partial-thickness tears (I^2 = 0%-41%; P = 0.15-0.50) <u>PPV/NPV-1/2*</u> **A-1**: NR (own calculations) **A-2**: NR (own calculations) **B-1**: 1.00/ 0.29 **B-2**: 1.00/ 1.00 **C-1**: 21.4%/ 90.9% **C-2**: 30.9% (p=0.73) / 87.5% (p=0.48) **D-1**: 40% [19%-64%]/ 98% [89%-100%] **D-2**: 43% [18%-71%]/ 94% [85%-99%] **E-1**: 86.4%/ 97.4% **E-2**: 85.0%/ 92.5%	thickness supraspinatus tears.9 One proposed contributing factor to the lower US sensitivity realized for partial-thickness tears may be the variable echogenicity of synovial proliferation, granulation, and scar tissue formation surrounding a partial tear, thus impeding clear tissue differentiaiton.40 Because of the lower US sensitivity for partial-thickness tears, it has been recommended to follow a negative

							US examination with an MRI in patients who do not experience symptomatic relief following conservative treatment.53 We propose a similar diagnostic US screening algorithm shown in Figure 5.”

*comparator test equals the C of the PICO; two or more index/ comparator tests may be compared; note that a comparator test is not the same as a reference test (golden standard)

<table>
<tr><th>Study reference</th><th>Study characteristics</th><th>Patient characteristics</th><th>Index test (test of interest)</th><th>Reference test</th><th>Follow-up</th><th>Outcome measures and effect size</th><th>Comments</th></tr>
<tr>
<td>Li, 2023</td>
<td>Type of study[1]: retrospective study; to explore the feasibility and diagnostic value of percutaneous US-guided subacromial bursography (PUSB) in evaluating rotator cuff tears

Setting and country: single-centre, China

Funding and</td>
<td>Inclusion criteria: : 1) having complete clinical, US, MRI and PUSB data; 2) underwent shoulder arthroscopy surgery.

Exclusion criteria: 1) having incomplete imaging data; 2) patients unsuitable for</td>
<td>Index test 1: US
US and PUSB examinations were performed using SIEMENS ACUSON Sequoia (Siemens Medical Solu_tions, USA). US examination was performed with a 6-18 MHz linear array probe (18L6). The patient was seated and facing the operator, who performs the procedure</td>
<td>Reference test[3]: shoulder arthroscopy performed by an associate chief physician with more than 10 years of shoulder arthroscopy experience

Cut-off point(s): diagnostic criteria

the types of rotator cuff tears were classified</td>
<td>Time between the index test and reference test: NR

For how many participants were no complete outcome data available?
N (%): NR, it was an exclusion criterium

Reasons for incomplete outcome data described? NR, it was an exclusion criterium</td>
<td><u>TP/FP/FN/TN*:</u>
<table><tr><td></td><td>PTT +</td><td>PTT -</td><td></td></tr><tr><td>US +</td><td>TP: 27</td><td>FP: 4</td><td>31</td></tr><tr><td>US -</td><td>FN: 15</td><td>TN: 32</td><td>47</td></tr><tr><td></td><td>42</td><td>36</td><td>78</td></tr></table><table><tr><td></td><td>PTT +</td><td>PTT -</td><td></td></tr><tr><td>PUSB +</td><td>TP: 40</td><td>FP:1</td><td>41</td></tr><tr><td>PUSB -</td><td>FN:2</td><td>TN: 35</td><td>37</td></tr><tr><td></td><td>42</td><td>36</td><td>78</td></tr></table><table><tr><td></td><td>PTT +</td><td>PTT -</td><td></td></tr></table></td>
<td><u>Author conclusion:</u> In conclusion, PUSB is highly accurate, sensitive, and specific for the diagnosis of rotator cuff tears. At the same time, PUSB can be used to dynamically observe the rotator cuff tears in a timely manner. When patients have MRI contraindications</td>
</tr>
</table>

[1] In geval van een case-control design moeten de patiëntkarakteristieken per groep (cases en controls) worden uitgewerkt. NB; case control studies zullen de accuratesse overschatten (Lijmer et al., 1999)

[3] De referentiestandaard is de test waarmee definitief wordt aangetoond of iemand al dan niet ziek is. Idealiter is de referentiestandaard de Gouden standaard (100% sensitief en 100% specifiek). Let op! dit is niet de “comparison test/index 2”.

[4] Beschrijf de statistische parameters voor de vergelijking van de indextest(en) met de referentietest, en voor de vergelijking tussen de indextesten onderling (als er twee of meer indextesten worden vergeleken).

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
	conflicts of interest: Funding: NR; Conflict of interest: none	PUSB examination; 3) patients who have already undergone previous surgery on the shoulder area N=Seventy-eight patients with shoulder arthroscopic surgery and images of conventional US, MRI and PUSB examined in our department between July 2019 to October 2021.	according to the shoulder US technical guidelines recommended by the European Society of Musculoskeletal Radiology [15]. The biceps long-head tendon, subscapularis tendon, supraspinatus tendon, infraspinatus and teres minor tendons were examined successively. Transverse and longitudinal images were performed, and the dynamic and static images	as full-thickness tears, partial-thickness tears and no tears according to whether there were any rotator cuff defects and the location and size of defects.		<table><tr><td>MRI +</td><td>TP: 32</td><td>FP: 4</td><td>36</td></tr><tr><td>MRI -</td><td>FN: 10</td><td>TN: 32</td><td>42</td></tr><tr><td></td><td>42</td><td>36</td><td>78</td></tr></table> Sensitivity: US: 64.3 (49.17,79.40) PUBS: 95.2 (88.52,101.95) MRI: 76.2 (62.76,89.62) Specificity: US: 88.9 (78.10,99.67) PUBS: 97.2 (91.58,102.86) MRI: 88.9 (78.10,99.67) PPV: US: 87.1 (74.60,99.60) PUBS: 97.6 (92.63,102.49) MRI: 88.9 (78.10,99.67) NPV: US: 68.1 (54.25,81.92) PUBS: 94.6 (86,95,102.24) MRI: 76.2 (62.76,89.62)	or MRI cannot accurately deter_mine the types of rotator cuff tears, PUSB can be used for auxiliary diagnosis with decreased cost and increased efficiency, making this method a good choice for patients in urgent need of surgery.

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
		Prevalence: 42 cases of PTTs (48%) Mean age (range): mean age 53.9±9.1 years; age range, 31-70 years Sex: 32 males, 46 females	were retained. Index test 2: a 4-10 MHz linear array probe (10L4) was used to perform PUSB. The tip of the needle was directed into the subacromial bursa and the contrast agent was slowly injected. At the same time, the probe was rotated to observe the distribution of contrast agent in the bursa and tendon. Typical images were captured and				

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
			stored during the inspection for recording and analysis. After the examination, the puncture site was disinfected and covered with a sterile dressing. Comparator test[2]: MRI MRI was performed with 1.5 T superconducting MRI equipment from the German Siemens Magnetom Avanto, equipped				

[2] Comparator test is vergelijkbaar met de C uit de PICO van een interventievraag. Er kunnen ook meerdere tests worden vergeleken. Voeg die toe als comparator test 2 etc. Let op: de comparator test kan nooit de referentiestandaard zijn.

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
			with a special coil for the shoulder joint. For coronal section scanning, the scanning plane was perpendicular to the glenoid cavity and ranged from the acromion to subscapular humerus with a fast-spin echo T2-weighted sequence (TR/TE=2200 ms/84 ms) and a spin echo T1 weighted sequence (TR/TE=450 ms/16 ms). For oblique coronal scanning,				

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
			the scanning plane was parallel to the long axis of the supraspinatus muscle and ranged from the outer end of the clavicle to the ac_romion with rapid spin echo T2-weighted imaging (TR/ TE= 2370 ms/39 ms). The scanning parameters were as follows: a FOV = 20 cm×20 cm; a matrix =257×192; a layer thickness =4 mm; and a layer spacing = 4.8 mm.				

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
			Cut-off point(s): Diagnostic criteria MRI: (1) Full-thickness tear: the supraspinatus tendon was thickened and twisted, with a high signal involving the whole layer. (2) Partial-thickness tear: the supraspinatus tendon was irregular in shape, with a focal high signal, and the whole layer is not involved [16,17]. US: (1) Full-				

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
			thickness tear: (i) a hypoechoic defect extends from the bursal to the articular sides; (ii) local defects involving both the bursal and articular sides in the short-axis and long-axis views; and (iii) the rotatorcuff not visible due to extensive full-thickness tears and retraction below the acromion. (2) Partial-thickness tear: (i) an obvious hypoechoic defect area or a discontinuous area on the				

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
			bursal or articular sides of the tendon is pre_sent; (ii) focal hypoechoic defects within the tendon are seen in the longitudinal and transverse planes [18]. (3) No tear (NTs): a normal subacromial-subdeltoid bursa (SASD) appeared as a hypoechoic line between two hy_perechoic planes, with total thickness of less than 2 mm [12]. PUSB: (1) Full-thickness tear: the contrast agent leaks from				

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
			the defect area of the bursal side through the supraspinatus into the articular side. (2) Partial-thickness tear: for the part of bursal-side tears, PUSB shows that the contrast agent filled the bursal-side tear part and the contrast agent flows from the subacromial bursa to the bursal-side tears area in the PUSB dynamic imaging. For the intratendinous or articular side partial-thickness tears, the				

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
			contrast agent can be observed in tendons or from tendons to the articular side by injecting it into the area of the suspected tendon lesion directly. (3) No tear: the contrast agent is scattered only in the subacromial bursa, outlines the regular surface of the rotator cuff, and does not leak into the rotator cuff.				
McGuire, 2023	Type of study[4]: retrospective,	Inclusion criteria:	Index test: US Ultrasounds were	Reference test[6]: shoulder	Time between the index test and	TP/FP/FN/TN*:	Author conclusion:

[4] In geval van een case-control design moeten de patiëntkarakteristieken per groep (cases en controls) worden uitgewerkt. NB; case control studies zullen de accuratesse overschatten (Lijmer et al., 1999)

<table>
<tr><th>Study reference</th><th>Study characteristics</th><th>Patient characteristics</th><th>Index test (test of interest)</th><th>Reference test</th><th>Follow-up</th><th>Outcome measures and effect size</th><th>Comments</th></tr>
<tr>
<td></td>
<td>quantitative study with data collected from participants' medical records; to compare the diagnostic sensitivity of USS and MRI in the pre-operative diagnosis of partial thickness tears (PTT) and full thickness tears (FTT) of supraspinatus tendons compared to</td>
<td>NR

Exclusion criteria: those who had a longer than 3-month period between diagnosis and arthroscope, and whose pathology was unrelated to the supraspinatus tendon and participants aged less than 18 years.

N= One hundred and</td>
<td>performed by general sonographers. Ultrasound machines involved in the study included Philips Epiq5, Canon Aplio 500, and General Electric Logiq E9. These machines are equipped with high frequency linear probes in the range of 10–15 MHz appropriate for musculoskeletal scanning.</td>
<td>arthroscopic repair
Cut-off point(s): NR</td>
<td>reference test: NR
For how many participants were no complete outcome data available?
N (%): NR

Reasons for incomplete outcome data described? NR

Specificity could not be calculated as people with negative results did not present for surgery.</td>
<td>Partial thickness tear <5 mm
<table>
<tr><td></td><td>PTT +</td><td>PTT -</td><td></td></tr>
<tr><td>US +</td><td>TP: 15</td><td>FP:</td><td></td></tr>
<tr><td>US -</td><td>FN:</td><td>TN:</td><td></td></tr>
<tr><td></td><td>1815</td><td></td><td>103</td></tr>
</table>
<table>
<tr><td></td><td>PTT +</td><td>PTT -</td><td></td></tr>
<tr><td>MRI +</td><td>TP: 14</td><td>FP:</td><td></td></tr>
<tr><td>MRI -</td><td>FN:</td><td>TN:</td><td></td></tr>
<tr><td></td><td>18</td><td></td><td>103</td></tr>
</table>
<u>Sensitivity</u>:
US: 83.3%
MRI: 77.7%</td>
<td>Advances in USS shoulder imaging due to increased spatial resolution has revolutionised shoulder imaging over the last 20 years. This study indicates substantial agreement for supraspinatus tear diagnosis when comparing MRI to USS performed in general imaging departments. Given USS is less expensive and</td>
</tr>
</table>

[6] De referentiestandaard is de test waarmee definitief wordt aangetoond of iemand al dan niet ziek is. Idealiter is de referentiestandaard de Gouden standaard (100% sensitief en 100% specifiek). Let op! dit is niet de “comparison test/index 2”.

[4] Beschrijf de statistische parameters voor de vergelijking van de indextest(en) met de referentietest, en voor de vergelijking tussen de indextesten onderling (als er twee of meer indextesten worden vergeleken).

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
	gold-standard shoulder arthroscopy to assess if differences in detection rates exist. Setting and country: single-centre, Australia Funding and conflicts of interest: Funding: NR; Conflict of interest: Ann Quinton is an editorial board member for Sonography and a coauthor	three participants who had arthroscopic shoulder repair had their data reviewed comparing the diagnostic accuracy of pre-operative USS and MRI with arthroscopy used as gold standard. Overall, there were 63 FTT and 40 PTT diagnosed by arthroscopy. Prevalence	Comparator test[5]: MRI The MRI machines in this study included a Philips Ingenia 1.5 T, Philips Ingenia 3.T and a Siemens Magnetom 1.5 T. One orthopaedic practice was used to collate the data where there are two orthopaedic surgeons. Cut-off point(s): Data were analysed reporting on			**Partial thickness tear >5 mm** PTT + / PTT - US +: TP: 16 / FP: US -: FN: / TN: *22* / *103* MRI +: TP: 19 / FP: MRI -: FN: / TN: *22* / *103* Sensitivity: US: 73.3% MRI: 86.4%	more available, it could be considered as a first line screening tool when the main question is one of tendon integrity. However, where the patient has significant underlying osteoarthritis, MRI should be included in the imaging workup prior to surgery. As technology continues to improve with ultra-high

[5] Comparator test is vergelijkbaar met de C uit de PICO van een interventievraag. Er kunnen ook meerdere tests worden vergeleken. Voeg die toe als comparator test 2 etc. Let op: de comparator test kan nooit de referentiestandaard zijn.

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
	on this article. Other declare no conflict of interest.	PTT: 40 (38.8%) Mean age (SD): 64 (10.8) years. Sex: 63 males, 40 females	number of supraspinatus tears reported as sensitivity (true positive case) for USS and MRI and categorised into 1. number and sensitivity of partial thickness tears <than 5 mm 2. number and sensitivity of partial thickness tears >than 5 mm 3. number and sensitivity of full thickness tears				frequency ultrasound probes, further studies to assess accuracy of supraspinatus tear detection should be evaluated, the assumption is that in future, USS will have the capacity to serve as a stand-alone diagnostic tool in accurately assessing supraspinatus tears prior to arthroscopy.
Zhu, 2022	Type of study[7]: prospective	Inclusion criteria:	Index test: real-time US scanner	Reference test[9]: Diagnostic	Time between the index test en	Sensitivity: US: 73.8% [65.5%-80.7%]	Author conclusion: The

[7] In geval van een case-control design moeten de patiëntkarakteristieken per groep (cases en controls) worden uitgewerkt. NB; case control studies zullen de accuratesse overschatten (Lijmer et al., 1999)

[9] De referentiestandaard is de test waarmee definitief wordt aangetoond of iemand al dan niet ziek is. Idealiter is de referentiestandaard de Gouden standaard (100% sensitief en 100% specifiek). Let op! dit is niet de “comparison test/index 2”.

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
	diagnostic accuracy study; to evaluate the diagnostic reliability of ultrasonography (US) and magnetic resonance imaging (MRI) for subscapularis (SSC) tears with shoulder arthroscopy as the gold standard and to investigate the diagnostic value of 2 MRI signs (lesser tuberosity cysts	(1) patients who were diagnosed with RCTs by physical examination, US, and MRI; and (2) preoperative MRI scans and US were performed within 3 months of the arthroscopic shoulder procedures. Exclusion criteria: (1) patients with previous	(HI Vision Ascendus, Hitachi Medical, Japan) and linear-array transducer with a frequency of 12 to 18 MHz by a single experienced sonographer who specialized in musculoskeletal US. Cut-off point(s): NR Comparator test[8]: MRI was performed using 1.5-T MRI equipment	Shoulder Arthroscopy Cut-off point(s): NR	reference test: < 3 months For how many participants were no complete outcome data available? N (%): NR Reasons for incomplete outcome data described? NR	(93/126) MRI: 38.1% [29.7%-47.2%] (48/126) <u>Specificity:</u> US: 88.7% [84.8%-91.8%] (276/311) MRI: 86.5% [82.3%-89.9%] (269/311) <u>Accuracy:</u> US: 84.4% [80.7%-87.5%] (369/437) MRI: 72.5% [68.2%-76.5%] (317/437) <u>PPV:</u> US: 72.7% [65.5%-80.7%] (93/128) MRI: 53.3% [43.1%-63.3%] (48/90)	most important finding of the present study was that the diagnostic accuracy of US was significantly better than that of MRI for SSC tears. The data suggested that 1.5-T MRI was not quite reliable for diagnosing partial-thickness SSC tears, the sensitivity of which was only 38.1%, whereas a standardized and

[4] Beschrijf de statistische parameters voor de vergelijking van de indextest(en) met de referentietest, en voor de vergelijking tussen de indextesten onderling (als er twee of meer indextesten worden vergeleken).

[8] Comparator test is vergelijkbaar met de C uit de PICO van een interventievraag. Er kunnen ook meerdere tests worden vergeleken. Voeg die toe als comparator test 2 etc. Let op: de comparator test kan <u>nooit</u> de referentiestandaard zijn.

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
	and subcoracoid cysts) for SSC tears. Setting and country: single-centre, China Funding and conflicts of interest: The authors report the following potential conflicts of interest or sources of funding: this work was supported by grant from Chongqing medical scientific research project (No.	shoulder surgery or shoulder fracture; (2) recurrent shoulder instability; and (3) systemic inflammatory disease. N=437 (consecutive patient selection jan 2019- dec 2020) Prevalence articular-side partial-thickness SSC tears: 126 (29%)	(Magnetom Essenza; Siemens Healthcare, Erlangen, Germany) with a dedicated shoulder coil. Cut-off point(s): NR			<u>NPV:</u> US: 89.3% [85.4%-92.3%] (276/309) MRI: 77.5% [72.8%-81.6%] (269/347)	systematic US evaluation could provide much superior reliability, with 73.8% sensitivity and 88.7% specificity.

Study reference	Study characteristics	Patient characteristics	Index test (test of interest)	Reference test	Follow-up	Outcome measures and effect size	Comments
	2021MSXM032). Full ICMJE author disclosure forms are available for this article online, as supplementary material.	Mean age ± SD: Sex: % M / % F Other important characteristics:					

Risk of bias tabellen

Table of quality assessment for systematic reviews of diagnostic studies
Based on AMSTAR checklist (Shea et al.; 2007, BMC Methodol 7: 10; doi:10.1186/1471-2288-7-10) and PRISMA checklist (Moher et al 2009, PLoS Med 6: e1000097; doi:10.1371/journal.pmed1000097)

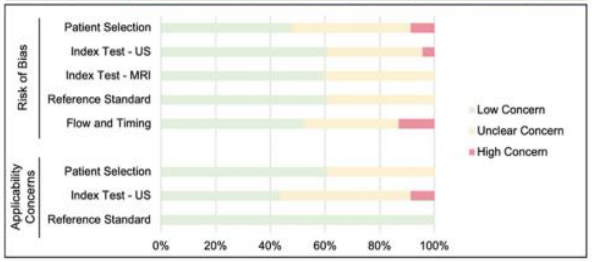
Study **First author, year**	**Appropriate and clearly focused question?[1]** **Yes/no/unclear**	**Comprehensive and systematic literature search?[2]** **Yes/no/unclear**	**Description of included and excluded studies?[3]** **Yes/no/unclear**	**Description of relevant characteristics of included studies?[4]** **Yes/no/unclear**	**Assessment of scientific quality of included studies?[5]** **Yes/no/unclear**	**Enough similarities between studies to make combining them reasonable?[6]** **Yes/no/unclear**	**Potential risk of publication bias taken into account?[7]** **Yes/no/unclear**	**Potential conflicts of interest reported?[8]** **Yes/no/unclear**
Farooqi, 2021	Yes, Purpose: To evaluate the diagnostic accuracy of US for partial- and full-thickness rotator cuff tears and biceps tendon tears, compare diagnostic	Yes, This systematic review was done in accordance with PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses)	Yes, A total of 804 articles were identified from the initial PubMed and Cochrane Library database search (Figure 1). An additional 367 studies were	Yes, table 1	Yes, Use of the g the Quality Assessment of Diagnostic Accuracy Studies–2 (QUADAS-2) Tool and funnel plots for assessment of publication bias in RevMan.	Yes, in accordance with predefined inclusion criteria	Yes (see column 6)	Yes, One or more of the authors has declared the following potential conflict of interest or source of funding: X.L. has received consulting fees and royalties from FH Ortho.

Study First author, year	Appropriate and clearly focused question?[1] Yes/no/unclear	Comprehensive and systematic literature search?[2] Yes/no/unclear	Description of included and excluded studies?[3] Yes/no/unclear	Description of relevant characteristics of included studies?[4] Yes/no/unclear	Assessment of scientific quality of included studies?[5] Yes/no/unclear	Enough similarities between studies to make combining them reasonable?[6] Yes/no/unclear	Potential risk of publication bias taken into account?[7] Yes/no/unclear	Potential conflicts of interest reported?[8] Yes/no/unclear
	values with those of magnetic resonance imaging (MRI) using arthroscopy as the reference standard	guidelines. The PubMed and Cochrane Library databases were systematically searched for full-text journal articles in English published in the past 10 years, between January 1, 2010, and April 1, 2020. The search strings are shown in Appendix Table	considered because of inclusion in relevant systematic reviews identified during the database search. Of the 1171 total studies reviewed, 1113 were excluded based on title and abstract, while 58 were further assessed for		Results of the Quality Assessment of Diagnostic Accuracy Studies–2 quality and bias assessment presented in figure 2 (see copied figure below this table).			J.D.K. has received consulting fees from Flexion and royalties from SLACK and Springer. R.L.P. has received grant/educational support from Arthrex. AOSSM checks author disclosures against the Open Payments Database (OPD). AOSSM has not conducted an independent investigation on

Study First author, year	Appropriate and clearly focused question?[1] Yes/no/unclear	Comprehensive and systematic literature search?[2] Yes/no/unclear	Description of included and excluded studies?[3] Yes/no/unclear	Description of relevant characteristics of included studies?[4] Yes/no/unclear	Assessment of scientific quality of included studies?[5] Yes/no/unclear	Enough similarities between studies to make combining them reasonable?[6] Yes/no/unclear	Potential risk of publication bias taken into account?[7] Yes/no/unclear	Potential conflicts of interest reported?[8] Yes/no/unclear
		A1. Previous systematic reviews identified via the PubMed and Cochrane Library search were also assessed for relevant studies. These studies were also considered for inclusion in this systematic review.	eligibility. Of these studies, 15 did not use arthroscopy as the reference standard, 4 were not in English, 2 included massive tears, and 4 lacked sufficient outcome data. After the removal of duplicates, 23 eligible studies involving 2054					the OPD and disclaims any liability or responsibility relating thereto.

Study First author, year	Appropriate and clearly focused question?[1] Yes/no/unclear	Comprehensive and systematic literature search?[2] Yes/no/unclear	Description of included and excluded studies?[3] Yes/no/unclear	Description of relevant characteristics of included studies?[4] Yes/no/unclear	Assessment of scientific quality of included studies?[5] Yes/no/unclear	Enough similarities between studies to make combining them reasonable?[6] Yes/no/unclear	Potential risk of publication bias taken into account?[7] Yes/no/unclear	Potential conflicts of interest reported?[8] Yes/no/unclear
			shoulders were included in this systematic review. And figure with study screening and selection process.					

	Risk of Bias					Applicability Concerns		
Author (Year)	Patient Selection	Index Test - US	Index Test - MRI	Reference Standard	Flow and Timing	Patient Selection	Index Test	Reference Standard
Sabharwal (2019)	Low	Low	Low	Low	Unclear	Low	Low	Low
Apostolopoulos (2019)	Low	Low	NA	Low	Low	Low	Unclear	Low
Gilat (2018)	Unclear	Low	NA	Low	Unclear	Unclear	High	Low
Ward (2018)	Unclear	Unclear	NA	Low	Unclear	Unclear	Unclear	Low
Elmorsy (2017)	Low	Unclear	Unclear	Unclear	High	Low	Unclear	Low
Cole (2016)	Unclear	Low	NA	Low	Low	Unclear	Low	Low
Kurz (2016)	Unclear	Low	NA	Low	Unclear	Low	Low	Low
Narasimhan (2016)	Unclear	Unclear	NA	Low	Low	Unclear	Low	Low
Guo (2016)	Low	Low	NA	Low	Low	Low	Low	Low
Day (2016)	Low	Low	Low	Low	Unclear	Low	Unclear	Low
Iossifidis (2014)	Low	Low	NA	Low	Low	Low	Low	Low
Gormeli (2014)	Unclear	Low	NA	Low	Low	Low	Low	Low
Punwar (2014)	Low	Unclear	NA	Unclear	High	Unclear	Unclear	Low
Murphy (2013)	Low	Low	NA	Low	Low	Unclear	Low	Low
Ok (2013)	Low	Low	NA	Low	Unclear	Unclear	Unclear	Low
Abd-ElGawad (2013)	High	Unclear	Unclear	Unclear	High	Low	Low	Low
McCulloch (2012)	Unclear	Low	NA	Unclear	Unclear	Unclear	Unclear	Low
Cowling (2011)	Low	High	NA	Unclear	Low	Low	High	Low
Skendzel (2011)	Unclear	Unclear	NA	Unclear	Low	Low	Low	Low
Singisetti (2011)	Unclear	Unclear	NA	Unclear	Low	Low	Unclear	Low
Rutten (2010)	Low	Low	NA	Low	Unclear	Unclear	Unclear	Low
El-Kouba (2010)	Unclear	Unclear	NA	Unclear	Low	Low	Unclear	Low
Rutten (2010)	High	Low	Low	Unclear	Low	Low	Unclear	Low



igure 2. Results of Quality Assessment of Diagnostic Accuracy Studies–2 quality and bias assessment. MRI, magnetic resonan naging; NA, not applicable; US, ultrasound.

Risk of bias assessment diagnostic accuracy studies (QUADAS II, 2011)

Study reference	Patient selection	Index test	Reference standard	Flow and timing	Comments with respect to applicability
McGuire, 2023	Was a consecutive or random sample of patients enrolled? Consecutive sample, retrospective study between August 2020 – August 2021 Was a case-control design avoided? Yes Did the study avoid inappropriate exclusions? Yes	Were the index test results interpreted without knowledge of the results of the reference standard? Unclear, not stated in the text If a threshold was used, was it pre-specified? n.a.	Is the reference standard likely to correctly classify the target condition? Yes, shoulder arthroscopy Were the reference standard results interpreted without knowledge of the results of the index test? Unclear, not stated in the text	Was there an appropriate interval between index test(s) and reference standard? Yes Did all patients receive a reference standard? Yes (retrospective study, inclusion criterium) Did patients receive the same reference standard? Yes (retrospective study, inclusion criterium) Were all patients included in the analysis? Yes	Are there concerns that the included patients do not match the review question? No Are there concerns that the index test, its conduct, or interpretation differ from the review question? No Are there concerns that the target condition as defined by the reference standard does not match the review question? No
	CONCLUSION: Could the selection of patients have introduced bias?	CONCLUSION: Could the conduct or interpretation of the index test have introduced bias?	CONCLUSION: Could the reference standard, its conduct, or its interpretation have	CONCLUSION Could the patient flow have introduced bias?	

Study reference	Patient selection	Index test	Reference standard	Flow and timing	Comments with respect to applicability
	RISK: LOW	**RISK: UNCLEAR**, blinding radiologists	introduced bias? **RISK: UNCLEAR**, blinding of surgeon	**RISK: LOW**	
Li, 2023	Was a consecutive or random sample of patients enrolled? Consecutive sample, retrospective study between July 2019 – October 2021 Was a case-control design avoided? Yes Did the study avoid inappropriate exclusions? Yes	Were the index test results interpreted without knowledge of the results of the reference standard? No/Unclear, this is not explicitly stated in the text *"The imaging results of US and PUSB were independently interpreted by 2 sonographers with 10 and 8 years of experience in musculoskeletal US. Similarly, 2 radiologists with 9 and 8 years of experience in musculoskeletal MRI, evaluated all images independently. When the*	Is the reference standard likely to correctly classify the target condition? Yes, shoulder arthroscopy Were the reference standard results interpreted without knowledge of the results of the index test? Unclear, this is not explicitly stated in the text	Was there an appropriate interval between index test(s) and reference standard? Yes Did all patients receive a reference standard? Yes (retrospective study, inclusion criterium) Did patients receive the same reference standard? Yes (retrospective study, inclusion criterium) Were all patients included in the analysis? Yes	Are there concerns that the included patients do not match the review question? No Are there concerns that the index test, its conduct, or interpretation differ from the review question? No Are there concerns that the target condition as defined by the reference standard does not match the review question? No

Study reference	Patient selection	Index test	Reference standard	Flow and timing	Comments with respect to applicability
		results were inconsistent, multidisciplinary consultation was conducted, and a consensus was reached. Finally, the results of MRI, US and PUSB were compared with those of arthroscopy." <u>If a threshold was used, was it pre-specified?</u> n.a.			
	CONCLUSION: Could the selection of patients have introduced bias? No **RISK: LOW**	CONCLUSION: Could the conduct or interpretation of the index test have introduced bias? **RISK: UNCLEAR**, blinding radiologists	CONCLUSION: Could the reference standard, its conduct, or its interpretation have introduced bias? **RISK: UNCLEAR**, blinding of surgeon	CONCLUSION Could the patient flow have introduced bias? **RISK: LOW**	

Table of excluded studies

Reference	Reason for exclusion
Agarwal, A., Vani, K., Batta, A. et al. Can ultrasound suffice for triaging patients requiring surgical correction of rotator cuff tears—a comparative evaluation of ultrasound and magnetic resonance imaging. Egypt J Radiol Nucl Med 52, 119 (2021). https://doi.org/10.1186/s43055-021-00477-2	No reference standard
Barad HV, Patel V, Patel S, Patel M. To determine the role of ultrasonography as a primary imaging modality as compared to MRI in patients with shoulder pain. J Family Med Prim Care. 2022 May;11(5):2119-2122. doi: 10.4103/jfmpc.jfmpc_2509_20. Epub 2022 May 14. PMID: 35800509; PMCID: PMC9254755.	Wrong reference (USG vs MRI)
Chauhan, N. S. and Ahluwalia, A. and Sharma, Y. P. and Thakur, L. A prospective comparative study of high resolution ultrasound and MRI in the diagnosis of rotator cuff tears in a tertiary hospital of North India. Polish Journal of Radiology. 2016; 81 :491-497	Wrong reference (MRI)
Day, M. and McCormack, R. A. and Nayyar, S. and Jazrawi, L. Physician training: Ultrasound and accuracy of diagnosis in rotator cuff tears. Bulletin of the Hospital for Joint Diseases. 2016; 74 (3) :207-211	Wrong outcome (learning curve of orthopaedic surgeon)
Fischer, C. A. and Weber, M. A. and Neubecker, C. and Bruckner, T. and Tanner, M. and Zeifang, F. Ultrasound vs. MRI in the assessment of rotator cuff structure prior to shoulder arthroplasty. Journal of Orthopaedics. 2015; 12 (1) :23-30	Wrong reference (MRI)
Fujiwara Y, Yamamoto S, Kato Y, Kurata S, Fujii S, Inoue K, Inoue T, Mondori T, Nakagawa Y, Tanaka Y. Usefulness of ultrasound in diagnosing long head of the biceps tendon malposition in patients with rotator cuff tears. J Med Ultrason (2001). 2022 Apr;49(2):289-295. doi: 10.1007/s10396-022-01200-y. Epub 2022 Mar 23. Erratum in: J Med Ultrason (2001). 2022 Apr 15;: PMID: 35320435.	Wrong P, no partial tears
Gallagher V, Buchanan J, Harris J, McCrum C. Audit: sonographic report correlation against surgical findings during elective shoulder surgery. Ultrasound. 2022 May;30(2):141-148. doi: 10.1177/1742271X211033314. Epub 2021 Aug 4. PMID: 35509294; PMCID: PMC9058382.	Wrong P: suspected full thickness tear of rotator cuff and imaging reports
Henderson RE, Walker BF, Young KJ. The accuracy of diagnostic ultrasound imaging for musculoskeletal soft tissue pathology of the extremities: a comprehensive review of the literature. Chiropr Man Therap. 2015 Nov 5;23:31. doi: 10.1186/s12998-015-0076-5. PMID: 26543553; PMCID: PMC4634582.	Wrong comparison (MSK-DUSI vs appropriate reference standard)
Lenza M, Buchbinder R, Takwoingi Y, Johnston RV, Hanchard NC, Faloppa F. Magnetic resonance imaging,	Included studies in this review are published before 2010

magnetic resonance arthrography and ultrasonography for assessing rotator cuff tears in people with shoulder pain for whom surgery is being considered. Cochrane Database Syst Rev. 2013 Sep 24;2013(9):CD009020. doi: 10.1002/14651858.CD009020.pub2. PMID: 24065456; PMCID: PMC6464715.	
Liu F, Dong J, Shen WJ, Kang Q, Zhou D, Xiong F. Detecting Rotator Cuff Tears: A Network Meta-analysis of 144 Diagnostic Studies. Orthop J Sports Med. 2020 Feb 5;8(2):2325967119900356. doi: 10.1177/2325967119900356. PMID: 32076627; PMCID: PMC7003181.	Better research designs are available for inclusion
Nabetani, Y. and Watanabe, T. and Terabayashi, N. and Hirose, A. and Nohisa, Y. and Shinoda, K. and Furuta, N. and Ito, H. and Matsuoka, T. and Seishima, M. [Diagnostic ability of ultrasonography for the rotator cuff tear: comparison with ultrasonography and MRI findings]. Rinsho byori. The Japanese journal of clinical pathology. 2014; 62 (1) :31-37	Reference not available
Ok, J. H. and Kim, Y. S. and Kim, J. M. and Yoo, T. W. Learning curve of office-based ultrasonography for rotator cuff tendons tears. Knee Surgery, Sports Traumatology, Arthroscopy. 2013; 21 (7) :1593-1597	MRA used instead of MRI
Okoroha, K. R. and Mehran, N. and Duncan, J. and Washington, T. and Spiering, T. and Bey, M. J. and Van Holsbeeck, M. and Moutzouros, V. Characterization of rotator cuff tears: Ultrasound versus magnetic resonance imaging. Orthopedics. 2017; 40 (1) :e124-e130	Wrong patient group (only full-thickness tears)
Ottenheijm, R. P. and Jansen, M. J. and Staal, J. B. and Van Den Bruel, A. and Weijers, R. E. and De Bie, R. A. and Dinant, G. J. Accuracy of diagnostic ultrasound in patients with suspected subacromial disorders: A systematic review and meta-analysis. Archives of Physical Medicine and Rehabilitation. 2010; 91 (10) :1616-1625	No comparison between US and MRI
Reddy KVK, Babu MML, Suresh A, Gupta S, Chalavadi DVKH. Clinico-radiological correlation of shoulder pain. European Journal of Molecular and Clinical Medicine 2022 Summer;9(4):60-69	Reference not available
Roy, Jean-Sebastien and Braen, Caroline and Leblond, Jean and Desmeules, Francois and Dionne, Clermont E. and MacDermid, Joy C. and Bureau, Nathalie J. and Fremont, Pierre Diagnostic accuracy of ultrasonography, MRI and MR arthrography in the characterisation of rotator cuff disorders: a systematic review and meta-analysis. British journal of sports medicine. 2015; 49 (20) :1316-28	Included studies that do not compare US with MRI, but report on US or MRI solely.
Saraya, S. and El Bakry, R. Ultrasound: Can it replace MRI in the evaluation of the rotator cuff tears?. Egyptian Journal of Radiology and Nuclear Medicine.	No reference standard

2016; 47 (1) :193-201	
Saremi, Hossein and Seifrabiei, Mohamadali Subscapularis tendon tear classification and diagnosis: A systemic review and meta-analysis. Frontiers in surgery. 2023; 10 :916694	"Search date: from the first date available to March 2022 Only subscapularis tears"
Sipola, P. and Niemitukia, L. and Kröger, H. and Höfling, I. and Väätäinen, U. Detection and quantification of rotator cuff tears with ultrasonography and magnetic resonance imaging - A prospective study in 77 consecutive patients with a surgical reference. Ultrasound in Medicine and Biology. 2010; 36 (12) :1981-1989	MRA used instead of MRI
Tenbrunsel TN, Whaley JD, Golchian D, Malone DL, Lima DJL, Sabesan VJ. Efficacy of Imaging Modalities Assessing Fatty Infiltration in Rotator Cuff Tears. JBJS Rev. 2019 Apr;7(4):e3. doi: 10.2106/JBJS.RVW.18.00042. PMID: 30969180.	No comparison between US and MRI.
Wall, L. B. and Teefey, S. A. and Middleton, W. D. and Dahiya, N. and Steger-May, K. and Kim, H. M. and Wessell, D. and Yamaguchi, K. Diagnostic performance and reliability of ultrasonography for fatty degeneration of the rotator cuff muscles. Journal of Bone and Joint Surgery. 2012; 94 (12) :e83(1)	Wrong reference (MRI)
And Alternative Medicine EC. Retracted: Comparative Analysis of Real-Time Dynamic Ultrasound and Magnetic Resonance Imaging in the Diagnosis of Rotator Cuff Tear Injury. Evid Based Complement Alternat Med. 2023 Jun 21;2023:9876180. doi: 10.1155/2023/9876180. PMID: 37388047; PMCID: PMC10307386.	Retracted article

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: NOV Subacromiaal Pijnsyndroom van de Schouder (SAPS)	
Uitgangsvraag/modules: Welke aanvullende beeldvormende diagnostiek heeft een meerwaarde voor het behandeltraject van SAPS?	
Database(s): Embase.com, Ovid/Medline	Datum: 6 juni 2023
Periode: vanaf 2010	Talen: geen restrictie
Literatuurspecialist: Alies van der Wal	Rayyan review: https://rayyan.ai/reviews/693195
BMI-zoekblokken: voor verschillende opdrachten wordt (deels) gebruik gemaakt van de zoekblokken van BMI-Online https://blocks.bmi-online.nl/ Bij gebruikmaking van een volledig zoekblok zal naar de betreffende link op de website worden verwezen.	
Toelichting: Voor deze vraag is gezocht op de elementen: - cuff ruptuur - echografie - MRI - diagnostisch filter De sleutelartikelen worden gevonden met deze search, m.u.v. PMID 18160242 (voldoet niet aan de opgegeven tijdslimiet). →Er is na het screenen van de SRs en RCTs voor gekozen om de observationele en overige referenties te screenen die gepubliceerd zijn vanaf 2020.	
Te gebruiken voor richtlijnen tekst: *Nederlands* In de databases Embase.com en Ovid/Medline is op 9 juni 2023 systematisch gezocht naar systematische reviews, RCTs en observationele studies over de diagnostische waarde van echografie/ MRI bij verdenking van een cuff ruptuur. De literatuurzoekactie leverde 639 unieke treffers op. *Engels* On the 9th of June 2023, a systematic search was performed in the databases Embase.com and Ovid/Medline for systematic reviews, RCTs and observational studies on the diagnostic value of ultrasound/ MRI in suspected cuff rupture. The search resulted in 639 unique hits.	

Zoekopbrengst

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	66	48	75
RCT	241	61	253
Observationele studies	509	554	616 (248 vanaf 2020)
Overig	182	183	252 (63 vanaf 2020)

Totaal	998	846	**639***

in Rayyan

Zoekstrategie

Embase.com

No.	Query	Results
#17	#9 NOT (#14 OR #15 OR #16) = overig	182
#16	#9 AND (#12 OR #13) NOT (#14 OR #15) = observationeel	509
#15	#9 AND #11 NOT #14 = RCT	241
#14	#9 AND #10 = SR	66
#13	'case control study'/de OR 'comparative study'/exp OR 'control group'/de OR 'controlled study'/de OR 'controlled clinical trial'/de OR 'crossover procedure'/de OR 'double blind procedure'/de OR 'phase 2 clinical trial'/de OR 'phase 3 clinical trial'/de OR 'phase 4 clinical trial'/de OR 'pretest posttest design'/de OR 'pretest posttest control group design'/de OR 'quasi experimental study'/de OR 'single blind procedure'/de OR 'triple blind procedure'/de OR (((control OR controlled) NEAR/6 trial):ti,ab,kw) OR (((control OR controlled) NEAR/6 (study OR studies)):ti,ab,kw) OR (((control OR controlled) NEAR/1 active):ti,ab,kw) OR 'open label*':ti,ab,kw OR (((double OR two OR three OR multi OR trial) NEAR/1 (arm OR arms)):ti,ab,kw) OR ((allocat* NEAR/10 (arm OR arms)):ti,ab,kw) OR placebo*:ti,ab,kw OR 'sham-control*':ti,ab,kw OR (((single OR double OR triple OR assessor) NEAR/1 (blind* OR masked)):ti,ab,kw) OR nonrandom*:ti,ab,kw OR 'non-random*':ti,ab,kw OR 'quasi-experiment*':ti,ab,kw OR crossover:ti,ab,kw OR 'cross over':ti,ab,kw OR 'parallel group*':ti,ab,kw OR 'factorial trial':ti,ab,kw OR ((phase NEAR/5 (study OR trial)):ti,ab,kw) OR ((case* NEAR/6 (matched OR control*)):ti,ab,kw) OR ((match* NEAR/6 (pair OR pairs OR cohort* OR control* OR group* OR healthy OR age OR sex OR gender OR patient* OR subject* OR participant*)):ti,ab,kw) OR ((propensity NEAR/6 (scor* OR match*)):ti,ab,kw) OR versus:ti OR vs:ti OR compar*:ti OR ((compar* NEAR/1 study):ti,ab,kw) OR (('major clinical study'/de OR 'clinical study'/de OR 'cohort analysis'/de OR 'observational study'/de OR 'cross-sectional study'/de OR 'multicenter study'/de OR 'correlational study'/de OR 'follow up'/de OR cohort*:ti,ab,kw OR 'follow up':ti,ab,kw OR followup:ti,ab,kw OR longitudinal*:ti,ab,kw OR prospective*:ti,ab,kw OR retrospective*:ti,ab,kw OR observational*:ti,ab,kw OR 'cross sectional*':ti,ab,kw OR cross?ectional*:ti,ab,kw OR multicent*:ti,ab,kw OR 'multi-cent*':ti,ab,kw OR consecutive*:ti,ab,kw) AND (group:ti,ab,kw OR groups:ti,ab,kw OR subgroup*:ti,ab,kw OR versus:ti,ab,kw OR vs:ti,ab,kw OR compar*:ti,ab,kw OR 'odds ratio*':ab OR 'relative odds':ab OR 'risk ratio*':ab OR 'relative risk*':ab OR 'rate ratio':ab OR aor:ab OR arr:ab OR rrr:ab OR ((('or' OR 'rr') NEAR/6 ci):ab)))	14157688
#12	'major clinical study'/de OR 'clinical study'/de OR 'case control study'/de OR 'family study'/de OR 'longitudinal study'/de OR 'retrospective study'/de OR 'prospective study'/de OR 'comparative study'/de OR 'cohort analysis'/de OR ((cohort NEAR/1 (study OR studies)):ab,ti) OR (('case control' NEAR/1 (study OR studies)):ab,ti) OR (('follow up' NEAR/1 (study OR studies)):ab,ti) OR (observational NEAR/1 (study OR studies)) OR ((epidemiologic NEAR/1 (study OR studies)):ab,ti) OR (('cross sectional' NEAR/1 (study OR studies)):ab,ti)	7679776
#11	'clinical trial'/exp OR 'randomization'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR 'placebo'/exp OR 'prospective study'/exp OR rct:ab,ti OR random*:ab,ti OR 'single blind':ab,ti OR 'randomised controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	3806445

#10	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	933865
#9	#8 AND [2010-2023]/py	99
#8	#7 NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp) NOT (('adolescent'/exp OR 'child'/exp OR adolescent*:ti,ab,kw OR child*:ti,ab,kw OR schoolchild*:ti,ab,kw OR infant*:ti,ab,kw OR girl*:ti,ab,kw OR boy*:ti,ab,kw OR teen:ti,ab,kw OR teens:ti,ab,kw OR teenager*:ti,ab,kw OR youth*:ti,ab,kw OR pediatr*:ti,ab,kw OR paediatr*:ti,ab,kw OR puber*:ti,ab,kw) NOT ('adult'/exp OR 'aged'/exp OR 'middle aged'/exp OR adult*:ti,ab,kw OR man:ti,ab,kw OR men:ti,ab,kw OR woman:ti,ab,kw OR women:ti,ab,kw))	1548
#7	#5 AND #6	1827
#6	'sensitivity and specificity'/de OR sensitivity:ab,ti OR sensitive:ab,ti OR specificity:ab,ti OR predict*:ab,ti OR 'roc curve':ab,ti OR 'receiver operator':ab,ti OR 'receiver operators':ab,ti OR likelihood:ab,ti OR 'diagnostic error'/exp OR 'diagnostic accuracy'/exp OR 'diagnostic test accuracy study'/exp OR 'inter observer':ab,ti OR 'intra observer':ab,ti OR interobserver:ab,ti OR intraobserver:ab,ti OR validity:ab,ti OR kappa:ab,ti OR reliability:ab,ti OR reproducibility:ab,ti OR ((test NEAR/2 're-test'):ab,ti) OR ((test NEAR/2 'retest'):ab,ti) OR 'reproducibility'/exp OR accuracy:ab,ti OR 'differential diagnosis'/exp OR 'validation study'/de OR 'measurement precision'/exp OR 'diagnostic value'/exp OR 'reliability'/exp OR 'predictive value'/exp OR ppv:ti,ab,kw OR npv:ti,ab,kw OR (((false OR true) NEAR/3 (negative OR positive)):ti,ab)	6682052
#5	#1 AND #4	5782
#4	#2 OR #3	2745662
#3	'nuclear magnetic resonance imaging'/exp OR 'mri scanner'/exp OR ('magnetic resonance':ti,ab,kw AND (image:ti,ab,kw OR images:ti,ab,kw OR imaging:ti,ab,kw)) OR mri:ti,ab,kw OR mris:ti,ab,kw OR nmr:ti,ab,kw OR mra:ti,ab,kw OR mras:ti,ab,kw OR zeugmatograph*:ti,ab,kw OR 'mr tomography':ti,ab,kw OR 'mr tomographies':ti,ab,kw OR 'mr tomographic':ti,ab,kw OR 'mr imag*':ti,ab,kw OR 'proton spin':ti,ab,kw OR ((magneti*:ti,ab,kw OR 'chemical shift':ti,ab,kw) AND imaging:ti,ab,kw) OR fmri:ti,ab,kw OR fmris:ti,ab,kw	1547891
#2	'ultrasound'/exp OR 'ultrasound scanner'/exp OR 'echography'/exp OR ultraso*:ti,ab,kw OR sonograph*:ti,ab,kw OR echograph*:ti,ab,kw OR sonogram*:ti,ab,kw	1405182
#1	'rotator cuff rupture'/exp OR ((('rotator cuff' OR supraspinatus OR subscapularis OR 'teres minor' OR 'glenoid labral' OR 'shoulder tendon*') NEAR/4 (ruptur* OR tear* OR tendinit* OR tendinos* OR tendinopath*)):ti,ab,kw)	14434

Ovid/Medline

#	Searches	Results
17	9 not (14 or 15 or 16) = overig	183
16	(9 and (12 or 13)) not (14 or 15) = observationeel	554
15	(9 and 11) not 14 = RCT	61
14	9 and 10 = SR	48
13	Case-control Studies/ or clinical trial, phase ii/ or clinical trial, phase iii/ or clinical trial, phase iv/ or comparative study/ or control groups/ or controlled before-after studies/ or controlled clinical trial/ or double-blind method/ or historically controlled study/ or matched-pair analysis/ or single-blind method/ or (((control or controlled) adj6 (study or studies or trial)) or (compar* adj (study or studies)) or ((control or controlled) adj1 active) or "open label*" or ((double or two or three or multi or trial) adj (arm or arms)) or (allocat* adj10 (arm or arms)) or placebo* or "sham-control*" or ((single or double or triple or assessor) adj1 (blind* or masked)) or nonrandom* or "non-random*" or "quasi-experiment*" or "parallel group*" or "factorial trial" or "pretest posttest" or (phase adj5 (study or trial)) or (case* adj6 (matched or control*)) or (match* adj6 (pair or pairs or cohort* or control* or group* or healthy or age or sex or gender or patient* or subject* or participant*)) or (propensity adj6 (scor* or match*))).ti,ab,kf. or (confounding adj6 adjust*).ti,ab. or (versus or vs or compar*).ti. or ((exp cohort studies/ or epidemiologic studies/ or multicenter study/ or observational study/ or seroepidemiologic studies/ or (cohort* or 'follow up' or followup or longitudinal* or prospective* or retrospective* or observational* or multicent* or 'multi-cent*' or consecutive*).ti,ab,kf.) and ((group or groups or subgroup* or versus or vs or compar*).ti,ab,kf. or ('odds ratio*' or 'relative odds' or 'risk ratio*' or 'relative risk*' or aor or arr or rrr).ab. or (("OR" or "RR") adj6 CI).ab.))	5439931
12	Epidemiologic studies/ or case control studies/ or exp cohort studies/ or Controlled Before-After Studies/ or Case control.tw. or cohort.tw. or Cohort analy$.tw. or (Follow up adj (study or studies)).tw. or (observational adj (study or studies)).tw. or Longitudinal.tw. or Retrospective*.tw. or prospective*.tw. or consecutive*.tw. or Cross sectional.tw. or Cross-sectional studies/ or historically controlled study/ or interrupted time series analysis/ [Onder exp cohort studies vallen ook longitudinale, prospectieve en retrospectieve studies]	4455625
11	exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti,ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind$3 or mask$3)).tw. or Placebos/ or placebo*.tw.	2596278
10	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	672666

9	limit 8 to yr="2010 -Current"	846
8	7 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/) not ((Adolescent/ or Child/ or Infant/ or adolescen*.ti,ab,kf. or child*.ti,ab,kf. or schoolchild*.ti,ab,kf. or infant*.ti,ab,kf. or girl*.ti,ab,kf. or boy*.ti,ab,kf. or teen.ti,ab,kf. or teens.ti,ab,kf. or teenager*.ti,ab,kf. or youth*.ti,ab,kf. or pediatr*.ti,ab,kf. or paediatr*.ti,ab,kf. or puber*.ti,ab,kf.) not (Adult/ or adult*.ti,ab,kf. or man.ti,ab,kf. or men.ti,ab,kf. or woman.ti,ab,kf. or women.ti,ab,kf.))	1314
7	5 and 6	1348
6	exp "Sensitivity and Specificity"/ or (sensitivity or sensitive or specificity).ti,ab. or (predict* or ROC-curve or receiver-operator*).ti,ab. or (likelihood or LR*).ti,ab. or exp Diagnostic Errors/ or (inter-observer or intra-observer or interobserver or intraobserver or validity or kappa or reliability).ti,ab. or reproducibility.ti,ab. or (test adj2 (re-test or retest)).ti,ab. or "Reproducibility of Results"/ or accuracy.ti,ab. or Diagnosis, Differential/ or Validation Study/ or ((false or true) adj3 (negative or positive)).ti,ab.	5335333
5	1 and 4	4294
4	2 or 3	1620282
3	exp magnetic resonance imaging/ or ("magnetic resonance" and (image or images or imaging)).ti,ab,kf. or mri.ti,ab,kf. or mris.ti,ab,kf. or nmr.ti,ab,kf. or mra.ti,ab,kf. or mras.ti,ab,kf. or zeugmatograph*.ti,ab,kf. or "mr tomography".ti,ab,kf. or "mr tomographies".ti,ab,kf. or "mr tomographic".ti,ab,kf. or 'mr imag*'.ti,ab,kf. or "proton spin".ti,ab,kf. or ((magneti* or "chemical shift") and imaging).ti,ab,kf. or fmri.ti,ab,kf. or fmris.ti,ab,kf.	948288
2	exp Ultrasonography/ or exp Ultrasonics/ or ultraso*.ti,ab,kf. or sonograph*.ti,ab,kf. or echograph*.ti,ab,kf. or sonogram*.ti,ab,kf.	745809
1	exp Rotator Cuff Injuries/ or (exp Rotator Cuff/ and (exp Rupture/ or exp Tears/)) or (('rotator cuff' or supraspinatus or subscapularis or 'teres minor' or 'glenoid labral' or 'shoulder tendon*') adj4 (ruptur* or tear* or tendinit* or tendinos* or tendinopath*)).ti,ab,kf.	12436

Module 4.1 Barbotage versus shockwave

Uitgangsvraag
Welke niet-chirurgische behandeling (barbotage versus shockwave) wordt aanbevolen bij patiënten met tendinosis calcarea?

Introduction (English)
In patients with SAPS calcification can occur in the tendons of the rotator cuff, usually in the tendon of the supraspinatus muscle, as a result of chronic inflammatory activity. This is often accompanied by thickening of the tendon (tendinosis), which can lead to chronic compression of the tendon impingement in the subacromial space when lifting the arm. This creates a vicious cycle. Thickening of the tendon due to calcification can also lead to chronic entrapment and/or persistent inflammation. Temoving the calcification is an effective method to solve this. This can be achieved by surgical evacuation of the calcification, but non-surgical methods are also successful.

Common non-surgical techniques are barbotage and shockwave. Barbotage involves puncturing and perforating calcifications under local anesthesia. Treatment with shockwave consists of shock waves generated by a probe against the outside of the skin at the site of calcification (Extracorporeal Shockwave Therapy, ESWT). Shockwave has several modalities. ESWT distinguishes between radial and focused ESWT.

Radial ESWT (also abbreviated as RSWT; radial shockwave therapy) is a treatment with low to moderate intensity shock waves and is generated mechanically where pressure waves are sent into the body via a treatment gun via a diverging beam. The peak of the shock wave is considerably lower in intensity than in focused ESWT and also builds up over a longer period of time (low energy ESWT). In the focused form (high energy) ESWT, there is a converging beam and, possibly with the help of ultrasound, a greater depth in the tissue can be reached.

Search and select
A systematic review of the literature was performed to answer the following question:
What is the effectiveness of barbotage compared to shockwave in patients with tendinosis alcarean on patient-reported outcome measures?

Patients	patients with tendinosis alcarean of the supraspinatus or infraspinatus
Intervention	barbotage
Control	shockwave
Outcomes	Pain, PROMs for function (CMS, CASH, WORC, ASES, OSS, DSST), patient satisfaction, complications/adverse events, return to work or leisure

Relevant outcome measures
The guideline development group considered **pain and function** (PROMs for function: CMS, DASH, WORC, ASES, OSS, DSST) as critical outcome measures for decision making; and **patient satisfaction, return to work or leisure and complications/adverse events** as an important outcome measure for decision making.

The guideline development group defined the outcome measures as follows:

- Pain: VAS-scale (0-10 points or 0-100mm scale)

- Patient reported outcomes measures for function: CMS, DASH, WORC, ASES, DSST, OSS
- Complications/adverse events: re-rupture, frozen shoulder and infection
- Patient satisfaction: self-reported satisfaction with treatment and/or function
- Return to work or leisure: definitions used in the studies

The guideline development group defined the minimal clinically (patient) important differences as follows:

- Pain
    - 1/10 points or 10/100 points on a VAS scale
- Patient reported outcome measures:
    - CMS: 15 points on a 100-point scale (Holmgren, 2014)
    - DASH: 13 on a 100 point scale (Koorevaar, 2018)
    - WORC : -282.6 on a 2100 point scale (Gagnier, 2018)
    - ASES : 9 on a 100 point scale (Gagnier, 2018)
    - DSST: 2.8 on a 12 point scale (Van Kampen, 2013)
    - OSS: 5 points on a 48-point scale (Nyring, 2021)
- Complications/adverse events:
    - Re-rupture: 5 mm difference in rupture size
    - Frozen shoulder: 25% (RR ≤ 0.80 and ≥ 1.25)
    - Infection: 25% (RR ≤ 0.80 and ≥ 1.25)
- Patient satisfaction: difference of 25% (RR ≤ 0.80 and ≥ 1.25) or 1/10 points or 10/100 points on a VAS scale.
- Return to work or leisure: difference of 25% (RR ≤ 0.80 and ≥ 1.25)

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until the 23th of October 2023. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 51 hits. Studies were selected based on the following criteria:

- Study design: randomized controlled trial or systematic review.
- Patients with tendinosis alcarean of the supraspinatus or infraspinatus, in adulthood.
- Comparing barbotage vs. schockwave.
- Describing at least one of the relevant outcomes specified in the PICO.
- Published from november 2017.
- Follow-up duration: 6 and 12 months

A total of 13 studies were initially selected based on title and abstract screening. After reading the full text, 6 studies were excluded, resulting in 7 studies for this literature analysis. Additionally, we included 2 RCTs (Del Castillo Del Castillo-Gonzalez, 2016; and De Boer (2017)) due to often being mentioned in the literature, resulting in a total of 9 studies. During the literature analysis, we additionally excluded 4 other studies: Zhang (2019), Verstraelen (2022), Lafrance (2019) and Simpson (2020), since these (systematic reviews/meta-analysis) discussed RCTs which were already included in our literature analysis (see the table with reasons for exclusion under the tab Methods). A total of five studies were included in the literature analysis).

Results

Five studies were included in the analysis of the literature. Important study characteristics and results are summarized in the evidence tables. The assessment of the risk of bias is summarized in the risk of bias tables.

Summary of literature

Description of studies

Table 1: Description of included studies

Author (year) Type of study	Patient characteristics (number, age, gender)	Intervention	Comparison	Follow-up	All reported outcome measures in the study	Comments
Castillo-Gonzalez (2016) Prospective, randomized, controlled trial.	Patients with rotator cuff calcific tendinopathy (RCCT). Total number of patients randomized: 243. I (UGPL): n=121 C (ESWT): n=80 <u>Patient characteristics:</u> Total population (analyzed, without loss to follow-up): *Gender (N,%)* F: 137 (68.16%) M: 64 (31.84%) *Age (Mean age)* 49±7	Ultrasound-guided percutaneous lavage (UGPL) Ultrasound diagnoses and the measurement of calcification size were performed using a TOSHIBA Xario SSA-660A equipped with a multifrequency probe (8 12 MHz). A portable I-Scan 4400 (FM.Control®) fluoroscope was used for radiological monitoring. uGpl was performed using 18-G and 20-G 10-ml syringes.	Extracorporeal shockwave treatment (ESWT) EsWt was provided using the swiss dolorclast device. Two sessions per week for four weeks was chosen.	3 months, 6 months, and 12 months after treatment.	Visual analogue scale to measure pain, and ultrasound to determine the extent of calcification.	
De Boer (2017) A prospective, Randomized trial	Patients with shoulder calcific tendinitis. Total number of patients: 25. Intervention: 11 Control: 14	Ultrasound needling (UN) UN: consisted of a single treatment procedure: The calcification was localized with ultrasound and pierced several times with 2 hollow 18 guage	Radial shockwave (RSWT) Consisted of 4 sessions of RSWT therapy one week apart, performed by a	6 weeks, and 1 year.	Functional ability (oxford shoulder score and constant murley score), pain, and calcification deposits.	During the trial, the Data Safety Monitoring Board decided to stop the inclusion prematurely

	Further baseline characteristics not specified.	needles. The procedure was done by the senior author who is a shoulder surgeon experienced in ultrasonography.	specialist physical therapist. Procedure: 500 pulses of 1.5 bar (150 kPa) with a frequency of 4.5 Hz, followed by 2000 pulses of 2.5 bar (250 kPa) with a frequency of 10 Hz; EFD 0.10 mJ/mm. Duration of pulses was 2 ms.			due to the extremely high NRS score of the patients in the RSWT group. Originally, 40 patients were needed for inclusion (power calculation), however when the study terminated 25 patients were included.
Kim (2014) A prospective, randomized comparison	Patients with calcific tendinitis of the shoulder. Total number of patients: 54. Intervention: 25 Control: 29 <u>Patient characteristics:</u> Per intervention and control group (not mentioned for total population): *Gender* Ratio male:female	US-PICT – local anaesthesia (2% lidocaine), single 18G needle without lavage, multiple percutaneous punctures. Then subacromial steroid injection (1 ml methylprednisolone acetate). Oral NSAIDs for 7 days. All US-guided needling procedures were performed by 1 orthopaedic surgeon (Y.S.K.) with a single needle without lavage. The procedure was performed by	ESWT – 3 sessions, 1 wk apart, 1,000 impulses at 0.36 mJ/mm2 (high energy), localized by maximum tenderness. Oral NSAIDs for 7 days. This procedure was also performed in the sitting position by 1 experienced technician. The	6 weeks, 12 weeks, 6 months, 12 months, and the last follow-up visit.	Clinical and radiologic evaluations. American Shoulder and Elbow Surgeons (ASES), Simple Shoulder Test (SST), and visual analog scale (VAS) for pain scores were recorded at each visit.	

	I: 2:23 C: 3:26 *Age (mean)* I: 53.9 years C: 57.4 years	sterile technique and surgical gloves. The patients in this group underwent multiple percutaneous punctures for each deposit with an 18-gauge needle under real-time monitoring with US. The final step in the procedure was an injection of 1 mL (40 mg) of Depo-Medrol into the subacromial space under US guidance.	procedure involved aiming at the maximum sore spot according to anatomic targeting. ESWT was administered for 3 sessions, 1 week apart (1000 impulses, 0.36 mJ/mm2). The ESWT group received ESWT 3 times a week.			
Kuo (2022) Single blind, randomized controlled trial	Patients with calcific tendinitis of the shoulder Total number of patients: 61 Intervention: 21 Control: 20 <u>Patient characteristics:</u> *Gender* Ratio Male/Female I: 8/13 C: 8/12 <u>*Age (Mean ± SD).*</u> I: 58.2 ± 7.9 C: 57.6 ± 9.4	ultrasound-guided fine-needle puncture (USNP). All needle punctures were guided by US and performed once. A 3.8 cm-long 22-gauge needle attached to a 5-mL syringe was used for puncturing.	Radial shockwave therapy: Radial shock wave therapy (RSWT), was delivered at 2 Hz (2000 shock waves; 0.26 mJ/mm2) once a week for 3 weeks.	At baseline, 1.5 and 3 months after completion of the treatment.	Pain using the VAS scale, Constant scores, 36-Item Short-Form Health Survey (quality of life), and range of motion.	Study also compares the combination of both treatments (USNP + RSWT)
Louwerens (2020)	Patients with calcific tendinitis of the rotator cuff.	Ultrasound-guided needling combined with a subacromial	High-energy extracorporeal	6 weeks and 3 months, 6	Clinical and radiographic	In total, 26 patients

A single-center, randomized controlled trial with parallel groups	Total number of patients: 82 Intervention: 41 Control: 41 <u>Patient characteristics:</u> *Gender* Ratio Male/Female 26/56 <u>Age (Mean ± SD)</u> 52.1 ± 9 years	corticosteroid injection. UGN was combined with a corticosteroid ultrasound-guided subacromial bursa injection.	shockwave therapy. The ESWT group received ESWT (2000 pulses, energy flux density 0.35 mJ/mm2) in 4 sessions with 1 week intervals.	months, and 12 months	evaluations. Regarding the clinical evaluations: CMS and DASH for clinical assessment, VAS for pain.	received an additional treatment due to persistent pain and symptoms: 9 patients (22%) in the UGN group and 17 (41%) in the ESWT group.

Results

1. Pain

6 months

Three studies reported pain at the 6 month follow-up using the VAS score. This scale ranges from 0 to 10 and a higher score indicates more pain.

Louwerens (2020) presented the VAS baseline scores, and the change from baseline scores at various timepoints. At six months, we calculated the VAS scores, which were respectively 3.1 in the ultrasound-guided needling combined with a subacromial corticosteroid injection (intervention) group and 3.5 in the high-energy extracorporeal shockwave therapy (ESWT) group (Mean Difference (MD): -0.4).
In Castillo-Gonzalez (2016), the mean VAS pain score at baseline was 7.43 ± 0.99 for both groups. At 6 months follow-up, the mean VAS pain score was solely presented in a visual graph and was respectively 2.2 (SD not reported) in the ultrasound-guided percutaneous lavage (UGPL) group and 4 (SD not reported) in the ESWT group 4 (MD: -1.8; 95% CI not reported and estimable).
In Kim (2014), the mean VAS score at baseline was respectively 6.8 and 6.3 in the US-guided needling group with an additional subacromial corticosteroid injection group and ESWT group. At six months follow-up, the mean VAS score in the US-guided needling group with an additional subacromial corticosteroid injection was 1.8 (SD not reported) and in the ESWT group 2.5 (SD not reported) (MD: -0.7; 95% CI not reported and estimable).

12 months

Four studies reported on pain at 12 months follow-up. Three studies reported pain at the 12 month follow-up using the VAS score. The scale ranges from 0 to 10 and a higher score indicates more pain. One study reported pain at the 12 month follow-up using the Numerical Rating Scale (NRS). The scale ranges from 0 to 10 in which a score of 0 equals no pain.

In De Boer (2017), the Numeric Rating Scale (NRS) was used to measure pain. The mean NRS score (95% CI) at baseline was respectively 7.5 (95% CI, 6.5 to 8.6) in the ultrasound needling group and 7.9 (95% CI, 6.9 to 8.8) in the Radial Shockwave (RSWT) group. At 12 months follow-up, the NRS was 1.9 (95% CI, 0.6 to 3.2) in the intervention group and 2.1 (95% CI, 0.3 to 3.9) in the control group (MD: -0.20; 95% CI, -2.2 to 1.8).
In Louwerens (2020), at twelve months, we calculated the VAS scores, which were respectively 2.1 in the ultrasound-guided needling combined with a subacromial corticosteroid injection (intervention) group and 3.2 in the ESWT (control) group (MD: -1.1).
In Castillo-Gonzalez (2016), the mean VAS pain score at baseline was 7.43 ± 0.99 for both groups. At 12 months follow-up, the mean was score was in the ultrasound-guided percutaneous lavage (UGPL) group was 1.3 (SD not reported) and in the ESWT group 3.3 (SD not reported) (MD: -2; 95% CI not reported and estimable). Additionally, textually the complete relief of pain was indicated: 89% of the patients in the UPGL group compared to 65% of the patients in the ESWT group reported complete relief of pain at twelve months follow-up.
In Kim (2014), the mean VAS score in the US-guided needling group with an additional subacromial corticosteroid injection was 1.4 (SD not reported) and 3.3 (SD not reported) in the ESWT group (control group) (MD: -1.9, 95% CI not reported and estimable) at twelve months follow-up.

2. PROMS for function

6 months

Constant Murley Score (CMS)
Louwerens (2020) reported the Constant Murley Score (CMS) (ranging from 0 to 100 in which a higher score indicated better functioning) as a change in CMS from baseline. The change in CMS from baseline in the ultrasound-guided needling combined with a subacromial corticosteroid injection group (intervention group) was 12.4 (95% CI; 7.1 to 17.6) and in the high-energy extracorporeal shockwave therapy group this was 13.3 (95% CI; 7.8 to 18.8). The MD was -0.9 (95% CI; -8.3 to 6.5) and was not considered clinically relevant.

Disabilities of the arm, Shoulder and Hand (DASH)
Louwerens (2020) reported the change from baseline in DASH score (ranging from 0 to 100 in which a higher score indicates better functioning). The change from baseline in DASH score was -13.6 (95% CI; -18.5 to -8.7) in the ultrasound-guided needling combined with a subacromial corticosteroid injection group; and -17.6 (95% CI; -24.1 to -11.1) in the high-energy extracorporeal shockwave therapy group. The MD in change from baseline score was 4 (95% CI; -3.9 to 11.89) and was not considered clinical relevant.

The Western Ontario Rotator Cuff (WORC)
No study reported the WORC.

American Society of Shoulder and Elbow Surgeons (ASES)
Kim (2014) reported the ASES score at six months follow-up. The mean ASES score was 85.2 (SD not reported) in the US-guided needling group and 76.2 (SD not reported) in the ESWT group. The MD is 9 (95% CI not reported and estimable).

Oxford Shoulder Score (OSS)
No study reported the OSS.

Dutch Simple Shoulder Test (DSST)
No study reported the DSST.

12 months

Constant Murley Score (CMS)
Louwerens (2020) reported the Constant Murley Score (CMS) (ranging from 0 to 100 in which a higher score indicated better functioning) as a change in CMS from baseline. The change in CMS from baseline in the ultrasound-guided needling combined with a subacromial corticosteroid injection group (intervention group) was 20.9 (95% CI; 16.9 to 24.8) and in the high-energy extracorporeal shockwave therapy group this was 15.7 (95% CI; 10.1 to 21.3). The MD was 5.2 (95% CI; -1.5 to 11.9) and was not considered clinical relevant.

Disabilities of the arm, Shoulder and Hand (DASH)
Louwerens (2020) reported the change from baseline in DASH score (ranging from 0 to 100 in which a higher score indicates better functioning). The change from baseline in DASH score was -20.1 (95% CI; -25.4 to -14.8) in the ultrasound-guided needling combined with a subacromial corticosteroid injection group; and -20.7 (95% CI; -27.2 to -14.2) in the high-

energy extracorporeal shockwave therapy group. The MD in change from baseline score was 0.6 (95% CI; -7.5 to 8.7) and was not considered clinically relevant.

The Western Ontario Rotator Cuff (WORC)
No study reported the WORC.

American Society of Shoulder and Elbow Surgeons (ASES)
Kim (2014) reported an ASES score at twelve months follow-up. The mean ASES score was 90.3 (SD not reported) in the US-guided needling group and 74.6 (SD not reported) in the ESWT group. The MD is 15.7 (95% CI not reported and estimable).

Oxford Shoulder Score (OSS)
No study reported the OSS.

Dutch Simple Shoulder Test (DSST)
No study reported the DSST.

3. Patient satisfaction

6 months

No study reported patient satisfaction at six month follow-up.

12 months

Louwerens (2020) reported VAS for satisfaction at twelve month follow-up. However, solely textually the following results were presented: mean satisfaction scores were respectively 7.0 ± 2.8 in the ultrasound-guided needling combined with a subacromial corticosteroid injection (intervention), and 7.6 ± 2.2 in the ESWT (control group). However, no information about scale ranging etc. was provided. This difference was not considered clinically relevant.

4. Complications/adverse events

6 months

No study reported complications/adverse events at 6 month follow-up

12 months

No study reported complications/adverse events.

5. Return to work or leisure
Not reported.

Level of evidence of the literature
The level of evidence for all outcome measures started as high, since the included studies were RCTs.

1. Pain

The evidence regarding the outcome measure **pain at six months follow-up***,* was downgraded by two levels to **VERY LOW** because of study limitations (-1; risk of bias; concealment of allocation), conflicting results (-1; inconsistency) and limited population size (-1; imprecision).

The evidence regarding the outcome measure **pain at twelve months follow-up***,* was downgraded by two levels to **VERY LOW** because of study limitations (-1; risk of bias; concealment of allocation), conflicting results (-1; inconsistency) and limited population size (-1; imprecision).

2. PROMS for function

Constant Murley Score (CMS)

The evidence regarding the outcome measure **function at six months follow-up, measured with the CMS**, was downgraded by two levels to **LOW Grade** because of study limitations (-1; risk of bias; concealment of allocation unknown), and limited population size (-1; imprecision).

The evidence regarding the outcome measure **function at twelve months follow-up, measured with the CMS**, was downgraded by two levels to **LOW Grade** because of study limitations (-1; risk of bias; concealment of allocation unknown), and limited population size (-1; imprecision).

Disabilities of the arm, Shoulder and Hand (DASH)

The evidence regarding the outcome measure **function at six months follow-up, measured with the DASH**, was downgraded by two levels to **LOW Grade** because of study limitations (-1; risk of bias; concealment of allocation unknown), and limited population size (-1; imprecision).

The evidence regarding the outcome measure **function at twelve months follow-up, measured with the DASH**, was downgraded by two levels to **LOW Grade** because of study limitations (-1; risk of bias; concealment of allocation unknown), and limited population size (-1; imprecision).

The Western Ontario Rotator Cuff (WORC)

No studies were found that reported **function at six months follow-up using the WORC**. Therefore, the level of evidence for this outcome measure could not be assessed.

No studies were found that reported **function at twelve months follow-up using the WORC**. Therefore, the level of evidence for this outcome measure could not be assessed.

American Society of Shoulder and Elbow Surgeons (ASES)

No studies were found that reported **function at six months follow-up using the ASES.** Therefore, the level of evidence for this outcome measure could not be assessed.

No studies were found that reported **function at twelve months follow-up using the ASES.** Therefore, the level of evidence for this outcome measure could not be assessed.

Oxford Shoulder Score (OSS)

No studies were found that reported **function at six months follow-up using the OSS.** Therefore, the level of evidence for this outcome measure could not be assessed.

No studies were found that reported **function at twelve months follow-up using the OSS.** Therefore, the level of evidence for this outcome measure could not be assessed.

Dutch Simple Shoulder Test (DSST)
No studies were found that reported **function at six months follow-up using the DSST.** Therefore, the level of evidence for this outcome measure could not be assessed.

No studies were found that reported **function at twelve months follow-up using the DSST.** Therefore, the level of evidence for this outcome measure could not be assessed.

3. Patient satisfaction
No studies were found that reported on **patient satisfaction at six months follow-up**. Therefore, the level of evidence for this outcome measure could not be assessed.

No studies were found that reported on **patient satisfaction at twelve months follow-up**. Therefore, the level of evidence for this outcome measure could not be assessed.

4. Adverse events/complications
No studies were found that reported on **adverse events/complications at six months follow-up**. Therefore, the level of evidence for this outcome measure could not be assessed.

No studies were found that reported on **adverse events/complications at twelve months follow-up**. Therefore, the level of evidence for this outcome measure could not be assessed.

5. Return to work or leisure
No studies were found that reported on **return to work or leisure**. Therefore, the level of evidence for this outcome measure could not be assessed.

Conclusions

Pain

VERY LOW GRADE	The evidence is very uncertain about impact of barbotage on **pain score at 6 months follow-up** when compared with extracorporeal shockwave therapy in adult patients with shoulder calcific tendinitis. *Source: Louwerens (2020); Castillo-Gonzalez (2015); and Kim (2014).*

VERY LOW GRADE	The evidence is very uncertain about the impact of barbotage on **pain as measured with the VAS at 12 months follow-up** when compared with extracorporeal shockwave therapy in adult patients with shoulder calcific tendinitis. *Source: De Boer (2017); Louwerens (2020); Castillo-Gonzalez (2015); and Kim (2014).*

Function
Constant Murley Score

LOW GRADE	Barbotage may result in little to no difference in **function as measured with the constant murley score at 6 months follow-up** when compared with extracorporeal shockwave therapy in adult patients with shoulder calcific

	tendinitis. *Source: Louwerens, 2020*

LOW GRADE	Barbotage may result in little to no difference in **function as measured with the constant murley score at twelve months follow-up** when compared with extracorporeal shockwave therapy in adult patients with shoulder calcific tendinitis. *Source: Louwerens, 2020*

Disabilities of the arm, Shoulder and Hand (DASH)

LOW GRADE	Barbotage may result in little to no difference in **function as measured with the DASH at six months follow-up** when compared with extracorporeal shockwave therapy in adult patients with shoulder calcific tendinitis. *Source: Louwerens, 2020*

LOW GRADE	Barbotage may result in little to no difference in **function as measured with the DASH at twelve months follow-up** when compared with extracorporeal shockwave therapy in adult patients with shoulder calcific tendinitis. *Source: Louwerens, 2020*

The Western Ontario Rotator Cuff (WORC)

NO Grade	No evidence was found regarding the effect of barbotage on **function as measured with the WORC at six months follow-up** when compared with extracorporeal shock wave therapy in adult patients with shoulder calcific tendinitis.

NO Grade	No evidence was found regarding the effect of barbotage on **function as measured with the WORC at twelve months follow-up** when compared with extracorporeal shock wave therapy in adult patients with shoulder calcific tendinitis.

American Society of Shoulder and Elbow Surgeons (ASES)

NO Grade	No evidence was found regarding the effect of barbotage on **function as measured with the ASES at six months follow-up** when compared with extracorporeal shock wave therapy in adult patients with shoulder calcific tendinitis.

NO Grade	No evidence was found regarding the effect of barbotage on **function as measured with the ASES at twelve months follow-up** when compared with extracorporeal shock wave therapy in adult patients with shoulder calcific tendinitis.

Oxford Shoulder Score (OSS)

NO Grade	No evidence was found regarding the effect of barbotage on **function as measured with the OSS at six months follow-up** when compared with extracorporeal shock wave therapy in adult patients with shoulder calcific tendinitis.

NO Grade	No evidence was found regarding the effect of barbotage on **function as measured with the OSS at twelve months follow-up** when compared with extracorporeal shock wave therapy in adult patients with shoulder calcific tendinitis.

Dutch Simple Shoulder Test (DSST)

NO Grade	No evidence was found regarding the effect of barbotage on **function as measured with the DSST at six months follow-up** when compared with extracorporeal shock wave therapy in adult patients with shoulder calcific tendinitis.

NO Grade	No evidence was found regarding the effect of barbotage on **function as measured with the DSST at twelve months follow-up** when compared with extracorporeal shock wave therapy in adult patients with shoulder calcific tendinitis.

Patient satisfaction

NO Grade	No evidence was found regarding the effect of barbotage on **patient satisfaction at six months follow-up** when compared with extracorporeal shock wave therapy in adult patients with shoulder calcific tendinitis.

NO Grade	No evidence was found regarding the effect of barbotage on **patient satisfaction at twelve months follow-up** when compared with extracorporeal shock wave therapy in adult patients with shoulder calcific tendinitis.

Adverse events/complicaties

NO Grade	No evidence was found regarding the effect of barbotage on **adverse events/complications at six months follow-up** when compared with extracorporeal shock wave therapy in adult patients with shoulder calcific tendinitis.

NO Grade	No evidence was found regarding the effect of barbotage on **adverse events/complications at twelve months follow-up** when compared with extracorporeal shock wave therapy in adult patients with shoulder calcific tendinitis.

Return to work or leisure

NO Grade	No evidence was found regarding the effect of barbotage on **return to work or leisure** when compared with extracorporeal shock wave therapy in adult patients with shoulder calcific tendinitis.

Overwegingen – van bewijs naar aanbeveling

Voor- en nadelen van de interventie en de kwaliteit van het bewijs

Er is systematisch literatuuronderzoek verricht naar het effect van niet-chirurgische interventies (barbortage versus shockwave) bij volwassen patiënten met tendinosis calcarea van de schouder. Er zijn in totaal vijf gerandomiseerde studies geïncludeerd. De cruciale uitkomstmaten voor besluitvorming waren pijn en functioneren. De belangrijke uitkomstmaten waren patiënttevredenheid, complicaties, en terugkeer naar werk of vrijetijdsbezigheden.

Voor de uitkomstmaat pijn op zes maanden en twaalf maanden is de bewijskracht zeer laag. Deze zeer lage bewijskracht is onder andere te verklaren door het risico op vertekening, een beperkt aantal geïncludeerde patiënten, en inconsistentie in de gerapporteerde bevindingen.

De cruciale uitkomstmaat functioneren is gemeten op zes en twaalf maanden follow-up. Eén studie (Kim, 2014) liet op een verschil in functioneren zien – gemeten met de American Society of Shoulder and Elbow Surgeons (ASES) – in het voordeel van barbotage. Echter was de bewijskracht voor functioneren eveneens laag. Dit komt door imprecisie (weinig studies, inclusie van laag aantal patiënten per studie/onderzoeksarm).

Geen enkele studie heeft de belangrijke uitkomstmaten patiënttevredenheid, complicaties, en terugkeer naar werk of vrijetijdsbezigheden op respectievelijk zes en twaalf maanden gerapporteerd. De studie van Louwerens (2020) benoemt enkel het optreden van een frozen shoulder zonder vermelding van de tijdsperiode waarop deze gerapporteerd is, en de studie van Castillo-Gonzalez (2016) rapporteert enkel het optreden van een vagale reactie als complicatie – tijdens of direct na de procedure. De studie van De Boer (2017) heeft zelfs vroegtijdig moeten stoppen – en heeft daardoor het vooraf berekende aantal patiënten niet kunnen includeren – door de hoge pijnscore in de shockwave groep.

Overall is de bewijskracht voor de cruciale uitkomstmaten pijn en functioneren in volwassen patiënten met tendinosis calcarea van de schouder zeer laag. Daarom kan de huidige literatuur maar beperkt richting geven aan de besluitvorming.

Een systematic review van Gatt (2014) includeert dertien studies om de uitkomsten en complicaties van echogeleide barbotage (herhaalde injectie en aspiratie) voor tendinosis calcarea van de schouder te beoordelen. De studie van Gatt (2014) laat zien dat barbotage een veilige techniek is met een hoog slagingspercentage en laag complicatiepercentage. Daarnaast blijkt barbotage een succesvolle methode te zijn wat betreft afname van calcificatie, vermindering van pijn en verbetering van de schouderfunctie. In een meta-analyse van Verstraelen (2014) over het effect van shockwave wordt een significant beter effect gevonden ten voordele van high energy ten opzichte van low energy shockwave. In de studie van De Witte (2013) werd een significante verbetering gevonden in zowel de barbotage als de cortisoninjectie groep na één jaar follow-up. Echter de klinische en radiografische resultaten waren significant beter in de barbotage groep ten opzichte van cortisoninjectie groep.

Concluderend wordt in deze studies een gunstig effect gevonden van barbotage. Over high energy shockwave bestaat weinig literatuur, maar deze methode lijkt wel effectief. Onder andere de studie geïncludeerd in deze literatuur samenvatting (de Boer, 2017) laat zien dat barbotage een beter resultaat liet zien dan RSWT. Opvallend in deze studie was de uitval van

deelnemers in verband met de forse pijn ten gevolge van de behandeling met RSWT en het daardoor kleine aantal geïncludeerde patiënten.

Op grond van de literatuur over de beschikbare behandelmogelijkheden lijkt barbotage een succesvollere behandeling dan low energy shockwave. High energy shockwave is mogelijk ook effectief, maar nog niet uitgebreid voorhanden; misschien ten gevolge van de hoge prijs van de daarvoor benodigde apparatuur. Bovendien blijkt deze behandeling uit studies erg pijnlijk.

Barbotage kan poliklinisch onder lokale anesthesie worden toegepast. De kosten in Nederland voor barbotage bedragen ongeveer €1500, dit omhelst o.a. tweemaal een bezoek aan de orthopeed en eenmaal aan de radioloog.

Er bestaat weinig bewijs in de literatuur dat low energy shockwave effectief is (Verstraelen, 2014). Studies die een positief effect van low energy shockwave aantonen betreffen de vergelijking tussen shockwave met reguliere fysiotherapie.

Waarden en voorkeuren van patiënten (en evt. hun verzorgers)
Voor patiënten is het belangrijk om een goede uitleg te krijgen over welke behandelingen er zijn. Hier kan sprake zijn van een persoonlijke voorkeur en daarom is het belangrijk dat patiënten worden meegenomen in de voor- en nadelen van de behandelingen, maar dat er ook aandacht wordt besteed aan het verwachtingsmanagement. Patiënten kunnen hierdoor op basis van de principes van Samen Beslissen een keuze kunnen maken.
ssen een keuze kunnen maken.
Voor patiënten is barbotage een behandeling die goed te ondergaan is onder lokale anesthesie. Deze kan poliklinisch verricht worden zonder noodzaak voor algehele of regionale anesthesie. Het herhalen van alleen een corticosteroïdeninjectie bij recidief klachten wordt niet aangeraden, omdat de literatuur aantoont dat een injectie alleen niet voldoende effectief is zodat de patiënt eventueel later alsnog barbotage moet ondergaan. Dit leidt tot een onnodig lang pijn-/ziektetraject.

Het is belangrijk om het gunstige effect van de beschikbare interventies goed uit te leggen. Door uitstel van een adequate interventie kan een pijnperiode onnodig lang duren. Het doel van de interventie is het verwijderen/laten resorberen van calcificaties. Door het slanker worden van de supraspinatuspees zal de inklemming van de pees en slijmbeurs verminderen. Bij succesvolle resorptie kan door een fysiotherapeut na acht weken het bewegingspatroon van de schouder beoordeeld worden. Met een gericht fysiotherapietraject kan zo nodig het bewegingspatroon van de schouder geoptimaliseerd worden om recidief klachten te voorkomen.

Het potentiële nadeel van barbotage is pijn tijdens of na de behandeling. Met het achterlaten van corticosteroïd in de bursa kan de pijn goed onderdrukt worden. Ook kan een NSAID worden overwogen. Daarnaast brengt behandeling met barbotage in de tweede lijn kosten voor een orthopedisch en radiologisch consult met zich mee. Barbotage kan verder minder geschikt zijn voor mensen met allergie of contra-indicatie voor corticosteroïden of lokale analgetica. Bij gebruik van anticoagulantia dient rekening te worden gehouden met bloedingen.

Kosten (middelenbeslag)
De kosten voor barbotage zijn relatief laag. Door het gunstige effect wordt de ziekteduur bekort, wat ook een positief effect heeft op het maatschappelijk functioneren van patiënten

(uitval op werk e.d.). De kosten voor behandeling in de tweede lijn zijn relatief laag en wegen op tegen de winst wat betreft de herstelduur. De gemaakte kosten voor low energy shockwave zijn ook relatief laag. Echter gezien de lage effectiviteit leidt een traject met eerst shockwave en daarna alsnog barbotage tot dubbele kosten. Bij tendinosis calcarea is het qua kosten en herstelduur het meest effectief om direct barbotage te verrichten.

Aanvaardbaarheid, haalbaarheid en implementatie
Barbotage is een reguliere behandeling die op grote schaal in klinieken reeds wordt toegepast. Immobilisatie is niet nodig. Tegen napijn kan cortison in de bursa worden achtergelaten of reguliere pijnstilling worden gebruikt. Aan de patiënt worden geen specifieke eisen gesteld wat betreft nabehandeling (sling e.d.) anders dan het bewegen op geleide van pijn en eventueel medicamenteuze pijnbestrijding. Achterlaten van cortison in de bursa heeft een gunstig effect op de napijn. Low energy shockwave wordt in veel fysiotherapiepraktijken toegepast en is derhalve laagdrempelig bereikbaar.

Aanbevelingen
Rationale van de aanbeveling: weging van argumenten voor en tegen de interventies
Er is beperkt bewijs op grond van gerandomiseerde studies die tot behandelvoorkeur leiden wat betreft barbotage of shockwave. Verder is er enig bewijs voor effectiviteit van high energy shockwave, maar de behandeling kan erg pijnlijk zijn. Voor behandeling met low energy shockwave bestaat geen overtuigend bewijs.

Aangezien barbotage een succesvolle en relatief snelle methode is om tendinosis calcarea te behandelen, is dit voor patiënten de meest geschikte keuze. De nadelen zijn beperkt. Achterlaten van corticosteroïden in de bursa kan pijn en gebruik van pijnmedicatie reduceren. In sommige gevallen is een eenmalige barbotage onvoldoende en kan een tweede behandeling nodig zijn.

Overweeg barbotage bij symptomatische tendinosis calcarea, bij voorkeur met achterlaten van corticosteroïd in de bursa, wanneer eerder gegeven corticosteroïdeninjectie niet het gewenste effect heeft gehad.

Als barbotage niet tot het gewenste effect heeft geleid, overweeg dan eenmalig rebarbotage of een high energy shockwave behandeling bij patiënten met SAPS op basis van tendinosis calcarea.

Kennisvragen
Er is behoefte aan een RCT die barbotagebehandeling vergelijkt met high energy shock wave behandeling bij patiënten met SAPS klachten op basis van tendinosis calcarea.

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Bijlagen bij module 4.1 Niet-chirurgische behandeling

Implementatieplan

Aanbeveling	Tijdspad voor implementatie: < 1 jaar, 1 tot 3 jaar of > 3 jaar	Verwacht effect op kosten	Randvoorwaarden voor implementatie (binnen aangegeven tijdspad)	Mogelijke barrières voor implementatie	Te ondernemen acties voor implementatie	Verantwoordelijken voor acties	Overige opmerkingen
Overweeg barbotage bij symptomatische tendinosis calcarea, bij voorkeur met achterlaten van corticosteroïd in de bursa, wanneer eerder gegeven corticosteroïdeninjectie niet het gewenste effect heeft gehad.	<1 jaar	Beperkte kosten voor behandeling. Mogelijk lagere maatschappelijke kosten door verkorten ziektelast.	Barbotage is een reguliere behandeling die op grote schaal in klinieken reeds wordt toegepast.	Geen	Verspreiding van de richtlijn	Wetenschappelijke verenigingen	
Als barbotage niet tot het gewenste effect heeft geleid, overweeg dan eenmalig rebarbotage of een high energy shockwave behandeling bij patiënten met SAPS	<1 jaar	Toename van directe kosten, uiteindelijke effecten op kosten onduidelijk.	Aanwezigheid van apparatuur en ervaring met gebruik.	Shockwave is nog niet overal beschikbaar.	Aanschaf van materiaal en regionale afspraken voor verwijzing (naar instituut wat high energy shockwave ter beschikking heeft). Budget beschikbaar maken voor dit type shock	Wetenschappelijke verenigingen	

op basis van tendinosis calcarea.					wave behandeling.		

Evidence tabellen

Study reference	Study characteristics	Patient characteristics	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Castillo-Gonzalez (2016)	Type of study: Randomized, controlled trial Setting and country: Patients treated in our sports medicine and rehabilitation centre (Centro Médico Deyre, Madrid. Spain) between January 2007 and December 2013. Funding and conflicts of	Inclusion criteria: -patients whom attended our medical center between January 2007 and december 2013, -had a clinical, radiological and ultrasound diagnosis of rcct. -had a minimum calcification of 5 mm diameter, -had a minimum visual analogue scale	Describe intervention (treatment/procedure/test): Patients with rotator cuff calcific tendinopathy (RCCT) received ultrasound-guided percutaneous lavage (UGPL). Patients were provided an anxiolytic (bromazepam 1.5 mg) 30 minutes before the procedure to reduce the possibility of the appearance of vagal syndrome. A prior ultrasound examination was used to determine the position of the shoulder that would	Describe control (treatment/procedure/test): Patients with rotator cuff calcific tendinopathy (RCCT) receiving extracorporeal shockwave therapy. This was performed with the patient sat in a chair with armrests and facing the physician. a conducting gel was placed on the area where the waves were to be transmitted. The calcification was localized by fluoroscopy, and the point on the	Length of follow-up: 12 month Loss-to-follow-up: Intervention: N (%): 1 patient: Reasons (describe): did not attend appointments. Control (ESWT): N (%): 41 Reasons (describe): 38 patients did not	Outcome measures and effect size (include 95%CI and p-value if available): *6 months* **1. Pain** *Mean VAS-score (0-10) presented visually in a diagram* I: 2.2 C: 4 (p<0.01) with the UGPL treatment being more effective in reducing pain. **2. PROMS for function:** **2.1. CMS**	Conclusion: -Both techniques are valid for the treatment of RCCT, although UGPL is associated with a greater reduction of calcification and greater reduction in pain. -Clinical rehabilitation impact: the results obtained applying uGpl, the low cost and

	interest: Funding.—This work was partly funded by grant awarded by the Santander Group to the Foundation Alfonso X el Sabio University. Conflicts of interest.—The authors certify that there is no conflict of interest with any financial organization regarding the material discussed in the manuscript.	(VAS) pain score of 6 (where 0 represents no pain, and 10 maximum pain), -and have no allergies to the medications used. Exclusion criteria: - patients with any form of tendon rupture, total or partial, were excluded. N total at baseline: 201 Intervention: 121 Control: 80 Important prognostic factors[2]:	leave the calcification most accessible from the cutaneous plane. The procedure was performed with the patient sat in a chair with armrests, facing the physician, with the shoulder rotated internally and the forearm placed on the back. This position increases the pressure within the tendon and facilitates the movement of the calcium into the syringe. All patients were told to hold this position during the entire procedure, which lasts about 30 minutes. The needle insertion point was marked on the skin. asepsis was guaranteed by swabbing with iodated povidone. Under aseptic conditions, a 10-mL syringe filled with 2%	skin where the shockwaves would be delivered identified (Figure 3). A total of 2000 impacts (two series of 1000 each) at a frequency of 8-10 hz and an energy density of 0.20 J/mm2 was then delivered with the shockwave emitter in direct contact with the skin. this was performed twice per week for four weeks. After each session the patient was monitored in the waiting room for a few minutes to make sure no complications had arisen before discharge. the procedure can be painful, especially at the start of therapy, but never requires local anesthetic. Number of sessions: two sessions per week for four weeks was	complete treatment, and 3 patients did not attend appointments. Analysed: 80 patients Incomplete outcome data: Intervention: N (%) Reasons (describe) Control: N (%) Reasons (describe)	Not reported **2.2. CASH** Not reported **2.3. WORC** Not reported **2.4. ASES** Not reported **2.5. OSS** Not reported **2.6. DSST** Not reported **3. Patient satisfaction** Not reported **4. Complications/adverse events** Not reported *12 months* **1. Pain** *Mean VAS-score (0-10) presented visually in a diagram* I: 1.3 C: 3.3	the lack of complications should therefore make the treatment of choice in centres that are appropriately equipped and staffed. Pain measured using the visual analogue scale (VAS)

		<u>age ± SD:</u> *<u>I:</u> not reported* *<u>C:</u> not reported* *<u>Sex:</u>* *<u>I: % M</u> not reported* *<u>C: % M</u> not reported* *<u>VAS score at baseline:</u>* *mean VAS pain score: 7.43±0.99. Further solely textually mentioned that there was no significant difference between the groups. This was so high since solely people with VAS 6 or higher were included.*	mepivacaine, a 5-ml syringe containing triamcino lone, several syringes containing sterile physiological saline, and 18-G and 20-G needles were laid out on a sterile gauze. The procedure was begun by injecting the mepivacaine into the skin using a syringe with a 20G needle, and placing the ultrasound probe over the trajectory to cover (from the entry point to the calcification). The needle was gradually pushed towards the calcification, anesthetizing from the point of entry in the skin through to the subacromial bursa. the needle was then placed below the calcification, and the remaining anesthetic used to begin its fragmentation and	chosen.		(p<0.01) with the UGPL treatment being more effective in reducing pain. *Complete relive of pain **at 12 months*** I: 108 (89.26%) C: 52 (65.0%) **<u>2. PROMS for function:</u>** **<u>2.1. CMS</u>** Not reported **<u>2.2. CASH</u>** Not reported **<u>2.3. WORC</u>** Not reported **<u>2.4. ASES</u>** Not reported **<u>2.5. OSS</u>** Not reported **<u>2.6. DSST</u>** Not reported **<u>3. Patient satisfaction</u>** Not reported	

		<u>Groups comparable at baseline?</u> Not reported	lavage, working the plunger with a forward pumping movement only, i.e., without aspiration (Figure 2). These impulses were kept up until the calcified material began to leave the calcification and enter the syringe. When the syringe body was full it was replaced by one containing physiological saline, but without removing the needle from its position. the same lavage and pumping action was then performed again. the procedure was repeated until no more calcified material could be withdrawn, until the calcification had been completely fragmented, or until the patient showed signs of discomfort. at this point the syringe body was switched (without			**<u>4. Complications/adverse events</u>** Not reported	

			withdrawing the needle) for that containing 2 mL triamcinolone. The needle was then gradually extracted as far as the bursa where the syringe contents were emptied, before being completely removed. the insertion point in the skin was then covered with a sterile gauze. in patients with a hard calcification, or in which the needle became blocked due to the entry of dense material, the latter was switched for an 18-G one.				
De Boer (2017)	<u>Type of study:</u> A prospective, randomized trial <u>Setting and country:</u> All patients were seen on the outpatient	<u>Inclusion criteria:</u> -shoulder pain persisting more than 6 months, calcification in the rotator cuff region type I or II	<u>Describe intervention (treatment/procedure/test):</u> The UN protocol consisted of a single treatment procedure. Before the start , 1 ml (40 mg) of corticosteroid) was left	<u>Describe control (treatment/procedure/test):</u> Consisted of 4 sessions of RSWT therapy one week apart. Each session was similar: 500 pulses of 1.5 bar (150 kPa) with a	<u>Length of follow-up:</u> 1 year <u>Loss-to-follow-up:</u> <u>Intervention:</u> 1 <u>N (%)</u> <u>Reasons</u>	<u>Outcome measures and effect size (include 95%CI and p-value if available):</u> <u>*6 months*</u> **<u>1. Pain</u>** Not reported	Conclusion: Compared to RSWT, UN resulted in lower pain and faster resorption of calcifications after 6 weeks.

	clinic of the hospital (Hagaziekenhuis) between May 2010 and March 2011. <u>Funding and conflicts of interest:</u> Conflict of interest: none. Funding: not reported	according to Gartner on a standard shoulder radiograph. -Numeric Rating Scale (NRS) for pain had to be >= 4 at the time of inclusion, -previous conservative therapy (physio, NSAIDs, cortisone infiltration) should have failed. <u>Exclusion criteria:</u> -insufficient knowledge of Dutch language, -age under 18, -inability to receive	inside the subacromial bursa without ultrasound guidance. Then a local anaesthetic (lidocaine 1%) was administered to the skin, bursa and tendon. The calcification was localized with ultrasound and pierced several times with 2 hollow 18 guage needles. A saline solution was flushed through both needle portals in order to wash out the calcium. Procedure was done by the senior author who is a shoulder surgeon experienced in ultrasonography.	frequency of 4.5 Hz, followed by 2000 pulses of 2.5 bar (250 kPa) with a frequency of 10 Hz; EFD 0.10 mJ/mm. Duration of pulses was 2 ms. A Masterpuls MP 100 in combination with a standard ultrasound transfergel was used. RSWT was performed by a specialist physical therapist.	<u>(describe)</u> changed treatment due to consistent pain <u>Control:</u> <u>N (%) 5</u> <u>Reasons (describe)</u> changed treatment due to consistent pain <u>Incomplete outcome data:</u> <u>Intervention:</u> <u>N (%)</u> <u>Reasons (describe)</u> <u>Control:</u> <u>N (%)</u> <u>Reasons (describe)</u>	**<u>2. PROMS for function:</u>** **<u>2.1. CMS (95% CI)</u>** Not reported **<u>2.2. CASH</u>** Not reported **<u>2.3. WORC</u>** Not reported **<u>2.4. ASES</u>** Not reported **<u>2.5. OSS</u>** Not reported **<u>2.6. DSST</u>** Not reported **<u>3. Patient satisfaction</u>** Not reported **<u>4. Complications/adverse events</u>** *Subacromial debridement and decompression because of unacceptable persistent pain* I: 1 patient C: 0	No significant differences were found after 1 year. Since the study was terminated prematurely because of high NRS in the RSWT group, it could not be advised to use of RSWT over UN. Funding not reported. 5 patients in the RSWT group changed to the UN group due to pain in the period between 6 weeks and 1 years. However, During the trial, the Data Safety Monitoring Board decided

		informed consent, - participation in other study, - other pathology which could cause shoulder – or upper limb pain (eg. Rotator cuff tears, acromioclavicular arthropathy, frozen shoulder, cervical disc hernia), - patients suffering from inflammatory-, malignant, - or clotting disease, - pregnant woman. <u>N total at baseline:</u> 25				<u>*12 months*</u> **<u>1. Pain</u>** *Using the numerical rating scale (NRS)* I: 1.9 [0.6-3.2] C: 2.1 [0.3-3.9] **<u>2. PROMS for function:</u>** **<u>2.1. CMS (95% CI)</u>** Not reported **<u>2.2. CASH</u>** Not reported **<u>2.3. WORC</u>** Not reported **<u>2.4. ASES</u>** Not reported **<u>2.5. OSS</u>** (Mean, range) I: 53.2 [47.1-59.3] C: 49.1 [39.2-59.0] (p=0.32) **<u>2.6. DSST</u>** Not reported **<u>3. Patient satisfaction</u>** Not reported	to stop the inclusion prematurely due to the extremely high NRS score of the patients in the RSWT group. Originally, 40 patients were needed for inclusion (power calculation), however when the study terminated 25 patients were included. Pain was measured using the NRS (ranging from 0-10) in which only absolute numbers can be used. Score 0 equals no pain. When the

		Intervention: 11 Control: 14 Important prognostic factors[2]: *age ± SD:* *I:* not reported *C:* not reported *Sex:* *I: % M* not reported *C: % M* not reported *Mean VAS pain score at baseline* I: 7.5 (6.5 – 8.6) C: 7.9 [6.9 – 8.8] Groups comparable at baseline? Unknown				**4. Complications/adverse events** *Free of complaints [95 % CI]* I: 40% C: 44%	patient could not choose between two number (e.g. Between a score of 3 and 4), we used the higher (4) score). Oxford Shoulder Score, a 12-items questionnaire to assess the patients functional ability: for each question: 1 = worst, 5 = best). Score of 12 was the worst score which patients could receive, and a score of 60 the best score. The Constant Murley Score: is

							a combined score which measures the pain score, functional assessment, range of motion and strength. Maximum score is 100, minimum is 2.
Kim (2014)	Type of study: Prospective, randomized trial. Setting and country: From November 2005 to March 2011 in this study. patients diagnosed with unilateral calcium deposition at the supraspinatus	Inclusion criteria: -Patients diagnosed with unilateral calcium deposition at the supraspinatus tendon, -confirmed on radiologic examination, -and disease duration of more than 3 months were included in the study.	Describe intervention (treatment/procedure/test): The US needling group underwent US-guided needling and received a subacromial corticosteroid injection. The US needling group underwent US-guided needling and received a subacromial corticosteroid injection. All US-guided needling procedures were performed by 1	Describe control (treatment/procedure/test): This procedure was also performed in the sitting position by 1 experienced technician. The procedure involved aiming at the maximum sore spot according to anatomic targeting. ESWT was administered for 3 sessions, 1 week apart (1000 impulses, 0.36 mJ/mm2). The ESWT group received ESWT 3 times a week.	Length of follow-up: The average follow-up period was 23.0 months (range, 12.1-28.5 months) after treatment. Loss-to-follow-up: Intervention: N (%) 5 Reasons (describe) because of noncomplian	Outcome measures and effect size (include 95%CI and p-value if available): *6 months* **1. Pain** *Using the Visual analogue Scale (VAS)* I: 1.8 C: 2.5 **2. PROMS for function:** **2.1. CMS** Not reported **2.2. CASH**	Conclusion: Both methods showed improved outcomes without serious side effects. Both treatment modalities for calcific tendinitis improved clinical outcomes and eliminated calcium deposits. US-guided needling

	tendon, were included in the study. Department of orthopaedics, south Korea, Seoul. <u>Funding and conflicts of interest:</u> The authors, their immediate families, and any research foundation with which they are affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article.	<u>Exclusion criteria:</u> Patients with other shoulder disease, such as rotator cuff tear, adhesive capsulitis, arthritis, fracture, infection, and history of treatment for the affected shoulder, were excluded from this study with initial examination (physical examination, radiography, and US). <u>N total at baseline: 62</u> <u>Intervention:</u> 30 <u>Control:</u> 32	orthopaedic surgeon (Y.S.K.) with a single needle without lavage. The procedure was performed by sterile technique and surgical gloves. The skin was then cleaned with a 10% iodopovidone solution 3 times and antiseptically draped. After administration of local anesthesia (2% lidocaine), the patients in this group underwent multiple percutaneous punctures for each deposit with an 18-gauge needle under real-time monitoring with US. The final step in the procedure was an injection of 1 mL (40 mg) of Depo-Medrol into the subacromial space under US guidance.		ce with the follow-up protocol after the procedure. <u>Control:</u> <u>N (%) 3</u> <u>Reasons (describe)</u> because of noncompliance with the follow-up protocol after the procedure. <u>Incomplete outcome data:</u> <u>Intervention:</u> <u>N (%)</u> <u>Reasons (describe)</u> <u>Control:</u> <u>N (%)</u> <u>Reasons (describe)</u>	Not reported **<u>2.3. WORC</u>** Not reported **<u>2.4. ASES</u>** I: 85.2 C: 76.4 (p>0.5) **<u>2.5. OSS</u>** Not reported **<u>2.6. DSST</u>** *Simple Shoulder Test* I: 74.1 C: 70.8 **<u>3. Patient satisfaction</u>** Not reported **<u>4. Complications/adverse events</u>** Not reported *<u>12 months</u>* **<u>1. Pain</u>** *Using the Visual analogue Scale (VAS)*	treatment, however, was more effective in function restoration and pain relief in the short term. American Shoulder and Elbow Surgeons (ASES) Scale numbering/scoring of outcome measures not reported.

		Important prognostic factors[2]: *For example age ± SD:* *I: 53.9 years (range, 45-76 years)* *C: 57.4 years (47-78)* *Sex:* *I: 23 F, 2 M* *C: 26 F, 3 M* *VAS score at baseline:* *I: 6.8* *C: 6.3* Groups comparable at baseline? Yes				I: 1.4 C: 3.3 **2. PROMS for function:** **2.1. CMS** Not reported **2.2. CASH** Not reported **2.3. WORC** Not reported **2.4. ASES** I: 90.3 C: 74.6 (p<.05) **2.5. OSS** Not reported **2.6. DSST** Not reported **3. Patient satisfaction** Not reported **4. Complications/adverse events** Not reported	
Kuo	Type of study:	Inclusion	Describe intervention	Describe control	Length of	Outcome measures	Comments:

(2022)	A single-blind, randomized, controlled study. <u>Setting and country:</u> Between January 2013 and December 2014, 75 patients with calcific tendinitis of the shoulder were recruited from the outpatient clinic at the Department of Physical Medicine and Rehabilitation of the authors' Institution (Taiwan). <u>Funding and</u>	<u>criteria:</u> -between 20 and 75 years of age; 2), -at least a 3-month history of unilateral shoulder discomfort, - and radiological evidence of both type I and type II calcification– as defined by Gartner– or US-based evidence of arc-shaped calcification– as defined by Chiou. <u>Exclusion criteria:</u> -pregnancy, -clotting	<u>(treatment/procedure/test):</u> All needle punctures were guided by US and performed once. A 3.8 cm-long 22-gauge needle attached to a 5-mL syringe was used for puncturing. The puncture site was sterilized with iodine, and the transducer was covered with a sterilized plastic bag. After injecting 3 cc of lidocaine (1%) into the subcutaneous tissue, muscle layer, and subdeltoid bursa, multiple punctures (10–20, depending on plaque size) were performed without aspiration or barbotage. The needle tract was monitored with US to ensure that the needle penetrated through the calcific plaque but not the rotator cuff.	<u>(treatment/procedure/test):</u> RSWT was delivered at 2 Hz (2000 shock waves; energy level, 0.26 mJ/mm2) once a week for 3 weeks. Instead of nonsteroidal anti-inflammatory drugs (NSAIDs), acetaminophen was prescribed as a rescue medication to avoid negative effects on tissue healing.	<u>follow-up:</u> At baseline, 1.5 and 3 months after completion of the treatment. <u>Loss-to-follow-up:</u> <u>Intervention:</u> <u>N (%):</u> 0 patients <u>Reasons (describe)</u> <u>Control:</u> <u>N (%):</u> 1 patient <u>Reasons (describe):</u> not reported. <u>Incomplete outcome data:</u> <u>Intervention:</u> <u>N (%)</u> <u>Reasons</u>	<u>and effect size (include 95%CI and p-value if available):</u> <u>*6 months*</u> **<u>1. Pain</u>** Not reported **<u>2. PROMS for function:</u>** **<u>2.1. CMS</u>** Not reported **<u>2.2. CASH</u>** Not reported **<u>2.3. WORC</u>** Not reported **<u>2.4. ASES</u>** Not reported **<u>2.5. OSS</u>** Not reported **<u>2.6. DSST</u>** Not reported **<u>3. Patient satisfaction</u>** Not reported **<u>4. Complications/adv</u>**	Clinical registered trial: NCT02677103 Three groups were compared (USNP; RSWT; and the combination of USNP + RSWT). Although no significant differences were observed among the groups in the treatment of calcific tendinitis of the shoulder, more satisfactory outcomes were noted in the USNP group and the combination group (USNP + RSWT) than in

	conflicts of interest: This study was financially supported by Shin Kong WuHo-Su Memorial Hospital of Taiwan (SKH-8302 102-DR-33). Conflict of interest was reported: the authors declared no conflicts of interest.	disorders, anticoagulant or antiplatelet treatment, cardiac pacemaker, chronic inflammatory joint disease, infection or tumor of the shoulder, adhesive capsulitis, hyperalgesia of the shoulder due to resorption of a calcific deposit, Garner's type III calcification, or Chiou's nodular or cystic calcification. N total at baseline: 61 Intervention:			(describe) Control: N (%) Reasons (describe)	**erse events** Not reported *12 months* **1. Pain** Not reported **2. PROMS for function:** **2.1. CMS** Not reported **2.2. CASH** Not reported **2.3. WORC** Not reported **2.4. ASES** Not reported **2.5. OSS** Not reported **2.6. DSST** Not reported **3. Patient satisfaction** Not reported **4. Complications/adverse events**	the RSWT group. Pain was measured using the visual analogue scale (VAS). Pain was measured using three VASs (horizontal lines measuring 100 mm in length, with 0 on the left indicating no pain and 100 on the right indicating severe pain) pertaining to shoulder pain at rest, during movement, and during sleep. The Constant score is a 100 point scoring system

		21 Control: 20 Important prognostic factors[2]: *For example age ± SD:* I: 58.2 ± 7.9 C: 57.6 ± 9.4 *Sex: (M/F)* I: 8/13 C: 8/12 VAS pain score at T0 VAS Sleep I: 6.76 ± 3.40 C: 5.75 ± 2.77 VAS Rest I: 4.29 ± 3.95 C: 2.90 ± 2.95 VAS Activity I: 7.38 ± 2.44 C: 5.50 ± 2.33 Groups				Not reported	comprising 15 points for pain, 20 points for activities of daily living, 40 points for shoulder motion, and 25 points for muscle power of the affected arm. Active and passive ROMs were measured using a conventional goniometer; the measurements included abduction in the frontal plane, forward flexion, internal rotation, and external rotation with the arm at 0 degrees of

		comparable at baseline? Yes					abduction.
Louwerens (2020)	Type of study: A single-center, randomized controlled trial with parallel groups Setting and country: Patients were included between May 2014 and December 2017 at Spaarne Gasthuis (the Netherlands). Funding and conflicts of interest: The authors report the following	Inclusion criteria: -age >18 years, -clinical sign of subacromial pain syndrome, -standardized radiographs showing a calcific deposit with a diameter of at least 5 mm in size, -morphologic type I and type II deposits corresponding to the classification of Gärtner17 (type I, sharply out lined and densely structured;	Describe intervention (treatment/procedure/test): Patients with calcific tendinitis of the rotator cuff. UGN: In UGN, ultrasound is used to allow a radiation free, 3-dimensional localization and assessment of the calcific deposit. Assisted by real-time ultrasonic guidance the deposit is then punctured and irrigated with a needle to break it down. In this study a double-needle technique was used with repeated perforation of the deposit and subsequent aspiration and lavage. Patients were treated with a single UGN procedure. The patient was	Describe control (treatment/procedure/test): Patients with calcific tendinitis of the rotator cuff. ESWT: High-energy shockwave therapy is a technique in which monophasic pressure pulses with high peak pressure are distributed to the calcific deposit and the surrounding soft tissues through, in this study, a piezoelectric mechanism. The shockwave group was treated with 4 sessions of high-energy ESWT with a 1 week interval. Each session consisted of 2000 piezo electric pressure pulses, focused on the calcific deposit, at a frequency	Length of follow-up: Loss-to-follow-up: Intervention: 3 N (%) Reasons (describe) not reported Control: 2 N (%) Reasons (describe) not reported Incomplete outcome data: Intervention: N (%) Reasons (describe)	Outcome measures and effect size (include 95%CI and p-value if available): *6 months* **1. Pain** Baseline score VAS *(Mean, SD)* I: 6.0 (1.5) C: 5.8 (1.8) Vas pain (Change from Baseline) (Mean, 95% CI) I: -2.9 (-3.6; -2.2) C: -2.3 (-3.3; -1.3) (p=.28) VAS score at 6 months I: 3.1 C: 3.5 **2. PROMS for**	Comments: Conclusion: Both techniques are successful in improving function and pain, with high satisfaction rates after 1-year follow-up. However, UGN is more effective in eliminating the calcific deposit, and the amount of additional treatments was greater in the ESWT group. Clinical trial registered: NL4304/NTR4448.

	potential conflict of interest or source of funding: J.K.G.L. reports grants from Spaarne General Hospital and nonfinancial support from Richard Wolf GmbH, during the conduct of the study. D.E. reports personal fees from Zimmer Biomet, grants from Zimmer Biomet, and grants from Stryker, outside the conduct of the study. M.P.J.v.d.B. reports grants from Wright	type II, sharply outlined and inhomogeneous or homogenous with no defined border), - symptoms for more than 4 months, - a completed and unsuccessful nonsurgical treatment program including nonsteroidal anti-inflammatory drugs, physiotherapy (centric and eccentric rotator cuff strengthening exercises in	positioned in a supine position and the size and location of the calcific deposit was confirmed and marked by ultrasound imaging. After sterile preparation, patients received a local anesthetic injection of the skin and subcutaneous tissue with 5 cc of lidocaine HCL 10 mg/mL. The ultrasound transducer was kept focused on the calcific deposit and the deposit was punctured multiple times with a 40-mm 17-gauge needle. A second 40-mm 17 gauge needle was introduced from a different angle and lavage and aspiration of the deposit with a saline solution was performed. After the UGN procedure, one of the	of 4 Hz with a total energy flux density of 0.351 mJ/mm2 resulting in a total energy amount of 2808 mJ. The calcific deposit was localized by ultrasound with the patient positioned in a supine position. Patients initially received a small amount of low-energy pulse to get used to the sensation after which the actual therapeutic dose was administered. After treatment, when necessary the shoulder was cooled with ice packs. After treatment, both groups followed a standardized physical therapy program including active and passive exercise mobilization techniques. Oral analgesics were administered for a	Control: N (%) Reasons (describe)	**function:** **2.1. CMS** (change from baseline) I: 12.4 (7.1; 17.6) C: 13.3 (7.8; 18.8) (p=.80) **2.2. DASH** (change from baseline) I: -13.6 (-18.5; -8.7) C: -17.6 (-24.1; -11.1) (p=.32) **2.3. WORC** Not reported **2.4. ASES** Not reported **2.5. OSS** Not reported **2.6. DSST** Not reported **3. Patient satisfaction** Not reported **4. Complications/adverse events**	Pain: measured using VAS: VAS for average pain during the last week and VAS for satisfaction. At 6 months and 1 year, the patients' reported change in symptoms were screened using a 7-point Likert scale. CMS: 0-100 point scale. In total, 26 patients received an additional treatment due to persistent pain and symptoms: 9 patients (22%) in the UGN group and 17

	Medical Group and grants from Smith & Nephew, outside the submitted work. A.V.N. reports personal fees from DePuy Synthes and personal fees from Link Lima, outside the submitted work.	combination with scapular stabilization), -and at least 1 SAI with a corticosteroid. <u>Exclusion criteria:</u> -ultrasonic signs of a partial or full rotator cuff tendon,-clinical or radiographic signs of a resorption phase as defined as a recent period of increased pain in combination with a morphologic type III deposit (cloudy and transparent in	needles was introduced in the subacromial bursa under ultrasonic guidance and a mixture of 4 cc of bupivacaine HCL 0.5% and 1 cc Depo-Medrol 40 mg/mL was injected. The sterile drapes were removed and the puncture site was sealed with an island dressing. After treatment, both groups followed a standardized physical therapy program including active and passive exercise mobilization techniques. Oral analgesics were administered for a maximum of 7 days postintervention when necessary. The medication was only prescribed once.	maximum of 7 days postintervention when necessary. The medication was only prescribed once.		Not reported <u>*12 months*</u> **<u>1. Pain</u>** *Vas pain (Change from Baseline) (Mean, 95% CI)* I: -3.9 (-4.6; -3.1) C: -2.6 (-3.7; -1.6) (p=.05) <u>VAS score at 12 months</u> I: 2.1 C: 3.2 **<u>2. PROMS for function:</u>** **<u>2.1. CMS</u>** <u>(change from baseline)</u> I: 20.9 (16.9; 24.8) C: 15.7 (10.1; 21.3) (p=.13) **<u>2.2. DASH</u>** <u>(change from baseline)</u> I: -20.1 (-25.4; -14.8) C: -20.7 (-27.2; -14.2) (p=.87)	(41%) in the ESWT group.

		structure) on radiographs, - calcific deposits in multiple tendons of the rotator cuff, - osteoarthritis of the glenohumeral or acromioclavicular joint, - adhesive capsulitis, - previous shoulder surgery, -ESWT or UGN to the affected shoulder, - instability of the shoulder, - rheumatoid arthritis, - neurologic disorders or dysfunction of the upper				**<u>2.3. WORC</u>** Not reported **<u>2.4. ASES</u>** Not reported **<u>2.5. OSS</u>** Not reported **<u>2.6. DSST</u>** Not reported **<u>3. Patient satisfaction</u>** *VAS for satisfaction (mean satisfaction scores)* I: 7.0 ± 2.8 C: 7.6 ± 2.2 **<u>4. Complications/adverse events</u>** Not reported	

		limb, - and the inability to give informed consent. <u>N total at baseline:</u> 82 <u>Intervention: 41</u> <u>Control: 41</u> <u>Important prognostic factors[2]:</u> <u>*age ± SD:*</u> <u>*I: 52.7 (8.7)*</u> <u>*C: 51.6 (9.4)*</u> <u>*Sex (Female)*</u> <u>*I: 26 (63%)*</u> <u>*C: 27 (66%)*</u> <u>*Mean VAS score at baseline (Mean, SD)*</u> *I: 6.0 (1.5)* *C: 5.8 (1.8)*					

		Groups comparable at baseline? Yes ,except for the Gartner types.					

Risk of bias table

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?** Definitely yes Probably yes Probably no	**Was the allocation adequately concealed?** Definitely yes Probably yes Probably no Definitely no	**Blinding: Was knowledge of the allocated interventions adequately prevented?** **Were patients blinded?** **Were healthcare providers blinded?** **Were data collectors blinded?** **Were outcome assessors blinded?** **Were data analysts blinded?** Definitely yes	**Was loss to follow-up (missing outcome data) infrequent?** Definitely yes Probably yes Probably no	**Are reports of the study free of selective outcome reporting?** Definitely yes Probably yes Probably no	**Was the study apparently free of other problems that could put it at a risk of bias?** Definitely yes Probably yes Probably no Definitely no	**Overall risk of bias** **If applicable/necessary, per outcome measure** **LOW** **Some concerns** **HIGH**

	Definitely no		Probably yes Probably no Definitely no	Definitely no	Definitely no		
Castillo-Gonzalez (2016)	Probably yes Reason: Using tables of randomized numbers (www.random ized.org), a collaborator who took no further part in the study randomly assigned patients to undergo either ESWT or UGPL. The medical staff involved did not know to which arm the patients had been assigned before treatment	Probably no Reason: Not reported	Probably no Reason: Not reported. Solely stated that: all interventions in both groups were performed by specialist medical staff, and that the extent of calcification was determined by a specialist in radiodiagnosis (FCG) and it was always measured by ultrasound imaging.	Definitely no Reason: It was frequent. In the UPGL group, 1 patient was loss to follow-up. In the ESWT group, 41 patients were loss to follow-up (did not complete treatment, or did not attend appointments).	Definitely yes Reason: All relevant outcomes measures were reported.	Probably yes Reason:	**Pain** Some concerns of bias **PROMs for function** Some concerns of bias **Patient satisfaction** Some concerns of bias **Complications/adverse events** Some concerns of bias

	began.						
De Boer (2017)	Probably yes Reason: Randomization was done by allowing the patient to choose an unmarked envelope containing the treatment protocol for either UN or RSWT from a box. The envelopes were randomized in blocks (6 envelopes, 3 of each treatment). When a block was finished the next block was started.	Probably no Reason: Concealment of allocation not reported (also not stated whether envelopes were transparent etc.)	Probably no Reason: Not reported. It was stated that data was collected e.g. through self-reports (patients completed the oxford shoulder score and NRS at home before the start of the intervention and during the subsequent follow-up measurements), and e.g. NRS scoring was done by a nurse practitioner. However not stated whether this was blinded or not.	Probably no Reason: 5 patients in the RSWT group were loss to follow-up, however due to change to UN group due to pain during the follow-up measurements. In the UN group, one patients was loss to follow-up due to consistent pain.	Definitely yes Reason: All relevant outcomes measures were reported.	Probably no Reason: Baseline characteristics intervention and control group not reported: groups comparable at baseline? Unknown . During the trial, the Data Safety Monitoring Board decided to stop the inclusion prematurely due to the extremely high NRS score of the patients in the RSWT group. Originally, 40 patients were needed for	**Pain** High concerns of bias **PROMs for function** High concerns of bias **Patient satisfaction** High concerns of bias **Complications/adverse events** High concerns of bias

						inclusion (power calculation), however when the study terminated 25 patients were included.	
Kim (2014)	Probably yes Reason: The randomization was conducted by an independent statistician who provided us with a computer-generated randomization list.	Probably no Reason: Not reported	Probably no Reason: Solely reported that of the radiological outcomes, the resorption of the calcific deposit was graded by another physician who was blinded to the treatment status and grouping. However, this was not reported for the clinical outcome measures.	Probably yes Reason: Loss to follow-up during procedure and follow-up occurred, however the number and reasons for people lost to follow-up were comparable in both groups.	Definitely yes Reason: All relevant outcomes measures were reported.	Probably yes Reason: None	**Pain** Some concerns of bias **PROMs for function** Some concerns of bias **Patient satisfaction** Some concerns of bias **Complications/adverse events** Some concerns of bias
Kuo (2022)	Probably yes	Definitely no	Probably no	Definitely yes	Definitely yes	Probably yes	**Pain** Some concerns of bias

	Reason: an assignment scheme was generated from a table of random numbers. Written informed consent was obtained from all patients, who were subsequently randomly divided into three treatment groups: USNP, RSWT, and RSWT plus USNP (COMB).	Reason: Not reported	Reason: The article reported that all assessments were performed by a masked assessor who was a trained study assistant. The patients were instructed not to reveal any treatment details to the assessor.	Reason: Solely one patient was loss to follow-up during postop.	Reason: All relevant outcomes measures were reported.	Reason: None	**PROMs for function** Some concerns of bias **Patient satisfaction** Some concerns of bias **Complications/adverse events** Some concerns of bias
Louwerens (2020)	Probably yes Reason: A research nurse allocated the patients to 1 of 2 treatment groups using the computer-	Definitely no Reason: Not reported	Probably no Reason: for the assessment of the radiological outcomes: the independent physician was blinded for the	Probably yes Reason: Respectively 2 and 3 patients were lost to follow-up. Solely one patient was loss to follow-up	Definitely yes Reason: All relevant outcomes measures were reported.	Probably yes Reason: In total, 26 patients received an additional treatment due to persistent	**Pain** Some concerns of bias **PROMs for function** Some concerns of bias **Patient satisfaction** Some concerns of bias

	generated block randomization function (10 patients per block) in Research Manager.		allocated treatment. Patient and healthcare provider not blinded.	during postop. Study performed a per protocol analysis and an intention to treat analysis.		pain and symptoms: 9 patients (22%) in the UGN group and 17 (41%) in the ESWT group (additional treatment could be: subacromial infiltration, and when being in the ESWT group: US-guided needling or arthroscopic surgery).	**Complications/adverse events** Some concerns of bias

Table of excluded studies

Reference	Reason for exclusion
Zhang T, Duan Y, Chen J, Chen X. Efficacy of ultrasound-guided percutaneous lavage for rotator cuff calcific tendinopathy: A systematic review and meta-analysis. Medicine (Baltimore). 2019 May;98(21):e15552. doi: 10.1097/MD.0000000000015552. PMID: 31124934; PMCID: PMC6571387.	Those comparing UPG with ESWT were Kim (2014), Federico (2016), and De Boer (2017) and Federico (2016). De Boer (2017) and Kim (2014) > already included. After searching for the article of Federico (2016), it appeared that this was the study of Del Castillo-Gonzalez (2016). Other studies did not compare the I and C of our PICO or originated from <2010 thus not according to our search data; or compared e.g. UGPL + ESWT vs. ESWT (wrong comparison according to our PICO).
Verstraelen F, Verhagen S, Giesberts A, Bonneux I, Koot H, Boer WD, van der Steen M. Needle aspiration of calcific deposits versus shock wave therapy for conservative therapy resistant calcifying tendinitis of the shoulder: protocol of a randomized, controlled trial. BMC Musculoskelet Disord. 2022 Mar 31;23(1):308. doi: 10.1186/s12891-022-05259-z. PMID: 35361169; PMCID: PMC8968770.	The interventions compared in this article: Needle aspiration of the calcific deposits vs. extracorporeal shock wave therapy, among patients with conservative therapy resistant calcifying tendinitis of the shoulder met the requirements of the PICO. However, the article stated that the first patient was included in May 2018; the aim is to fulfill the inclusion in 2022 after which the study will be finalized in 2023. No data was presented since the data is collected but not yet analyzed/presented.
Lafrance S, Doiron-Cadrin P, Saulnier M, Lamontagne M, Bureau NJ, Dyer JO, Roy JS, Desmeules F. Is ultrasound-guided lavage an effective intervention for rotator cuff calcific tendinopathy? A systematic review with a meta-analysis of randomised controlled trials. BMJ Open Sport Exerc Med. 2019 Mar 9;5(1):e000506. doi: 10.1136/bmjsem-2018-000506. PMID: 31191964; PMCID: PMC6539165.	SR and meta-analysis comprising 3 RCTs: of wich 2 were already included in this literature summary: De Boer (2017); and Del Castillo-Gonzalez (2016). The other was: de Witte et al. 2013/2017. In this trial however, the I and C differs, since the authors compare the efficacy of: US-guided lavage with aspiration and a corticosteroid injection (5 mL of bupivacaine 5 mg/mL, 1 mL of Depo-Medrol 40 mg/mL and lidocaine 1%) compared to a corticosteroid injection. *(de Witte PB, Selten JW, Navas A, et al. Calcific tendinitis of the rotator cuff: a randomized controlled trial of ultrasound-guided needling and lavage versus subacromial corticosteroids. Am J Sports Med 2013;41:1665–73*.
Simpson M, Pizzari T, Cook T, Wildman S, Lewis J. Effectiveness of non-surgical interventions for rotator cuff calcific	SR comprised 18 RCTS. The SR assessed the efficacy and effectiveness of different non-surgical (e.g. medication, physiotherapy,

tendinopathy: A systematic review. J Rehabil Med. 2020 Oct 31;52(10):jrm00119. doi: 10.2340/16501977-2725. PMID: 32830280.	shockwave therapy, ultrasound-guided irrigation, acupuncture, taping) interventions. However, these interventions were compared to e.g. placebo treatment, or different application techniques or doses of the same non-surgical modality). Solely two RCTs compared the I and C in our PICO. These RCTs are already included in this literature review: Gonzales-Del Castillo (2016) and Kim et al. (2014).
Angileri HS, Gohal C, Comeau-Gauthier M, Owen MM, Shanmugaraj A, Terry MA, Tjong VK, Khan M. Chronic calcific tendonitis of the rotator cuff: a systematic review and meta-analysis of randomized controlled trials comparing operative and nonoperative interventions. J Shoulder Elbow Surg. 2023 Aug;32(8):1746-1760. doi: 10.1016/j.jse.2023.03.017. Epub 2023 Apr 18. PMID: 37080421.	SR included 27 studies: comparison I and C of PICO [ESWT and UGN] is made in: Louwerens (2020); Del Castillo-Gonzalez (2016); Kim (2014); > Louwerens (2020) and Kim (2014) already included seperately in excel file
Zhang T, Duan Y, Chen J, Chen X. Efficacy of ultrasound-guided percutaneous lavage for rotator cuff calcific tendinopathy: A systematic review and meta-analysis. Medicine (Baltimore). 2019 May;98(21):e15552. doi: 10.1097/MD.0000000000015552. PMID: 31124934; PMCID: PMC6571387.	does not meet I and C of PICO: SR solely assesses the efficacy of ultra-sound-guided percutaneous lavage (UGPL) for calcifying tendinitis of rotator cuff
Verstraelen FU, In den Kleef NJ, Jansen L, Morrenhof JW. High-energy versus low-energy extracorporeal shock wave therapy for calcifying tendinitis of the shoulder: which is superior? A meta-analysis. Clin Orthop Relat Res. 2014 Sep;472(9):2816-25. doi: 10.1007/s11999-014-3680-0. Epub 2014 May 29. PMID: 24872197; PMCID: PMC4117900.	compares different doses of ESWT and its effects (assesses treatment intensity of ESWT)
Surace SJ, Deitch J, Johnston RV, Buchbinder R. Shock wave therapy for rotator cuff disease with or without calcification. Cochrane Database Syst Rev. 2020 Mar 4;3(3):CD008962. doi: 10.1002/14651858.CD008962.pub2. PMID: 32128761; PMCID: PMC7059880.	Main comparison was shock wave therapy versus placebo; Single trials compared shock wave therapy to ultrasound-guided glucocorticoid needling. DeBoer (2017) compares RSWT vs US-guided needling; Del Castillo-Gonzales 2016 compared ESWT vs US-guided percutaneous lavage ; Kim (2014) ESWT vs US-guided needling
Gatt DL, Charalambous CP. Ultrasound-guided barbotage for calcific tendonitis of the shoulder: a systematic review including 908 patients. Arthroscopy. 2014 Sep;30(9):1166-72. doi: 10.1016/j.arthro.2014.03.013. Epub 2014	No comparision; study solely assesses barbotage and its complications/outcomes: also stated that ''no comparative studies being available''.

May 10. PMID: 24813322.	
Darrieutort-Laffite C, Varin S, Coiffier G, Albert JD, Planche L, Maugars Y, Cormier G, Le Goff B. Are corticosteroid injections needed after needling and lavage of calcific tendinitis? Randomised, double-blind, non-inferiority trial. Ann Rheum Dis. 2019 Jun;78(6):837-843. doi: 10.1136/annrheumdis-2018-214971. Epub 2019 Apr 11. PMID: 30975645.	no comparision; study assesses if saline solution or steroids after UGPL (ultrasound-guided puncture and lavage (UGPL)) was non inferior in prevention of pain reactions
Lee HW, Kim JY, Park CW, Haotian B, Lee GW, Noh KC. Comparison of Extracorporeal Shock Wave Therapy and Ultrasound-Guided Shoulder Injection Therapy in Patients with Supraspinatus Tendinitis. Clin Orthop Surg. 2022 Dec;14(4):585-592. doi: 10.4055/cios21191. Epub 2022 Aug 16. PMID: 36518938; PMCID: PMC9715920.	wrong comparison; ultrasound (US)-guided shoulder steroid injection not the same as barbotage

Literature search strategy

Zoekopbrengst

	EMBASE	OVID/MEDLINE	Ontdubbeld
SR	15	12	16
RCT	34	17	35
Totaal	49	29	**51***

in Rayyan

Zoekstrategie

Embase.com

No.	Query	Results
#1	('shoulder impingement syndrome'/exp OR 'shoulder impingement syndrome*':ti,ab,kw OR 'subacromial impingement syndrome*':ti,ab,kw OR (('bursitis'/exp OR bursitis:ti,ab,kw OR 'tendinitis'/exp OR tendinitis:ti,ab,kw OR tendinosis:ti,ab,kw OR tendinopath*:ti,ab,kw OR 'impingement':ti,ab,kw) AND ('shoulder'/exp OR 'shoulder pain'/exp OR 'rotator cuff':ti,ab,kw OR acromion:ti,ab,kw OR acromial:ti,ab,kw OR subacromial:ti,ab,kw OR shoulder*:ti,ab,kw)) OR 'rotator cuff injury'/exp OR 'rotator cuff rupture'/exp OR ((('rotator cuff' OR 'shoulder cuff' OR infraspinatus OR supraspinatus OR subscapularis) NEAR/3 (tear* OR lesion* OR rupture* OR tendinopath* OR laceration*)):ti,ab,kw) OR (('full-thickness':ti,ab,kw OR partial:ti,ab,kw) AND 'rotator cuff':ti,ab,kw) OR ('rotator cuff'/exp AND ('rupture'/exp OR 'injury' OR 'laceration'/exp))) AND ('calcification'/de OR 'calcinosis'/exp OR calcifying:ti,ab,kw OR calcification:ti,ab,kw OR calcarea*:ti,ab,kw OR calcific:ti,ab,kw OR calcinosis:ti,ab,kw OR calcified:ti,ab,kw OR calcinotic:ti,ab,kw)	1352
#2	'barbotage'/exp OR 'lavage'/de OR 'guided needle'/exp OR barbotage*:ti,ab,kw OR (((needle* OR needling OR 'ultrasound guided' OR 'ultrasonography guided' OR 'us guided' OR 'image guided') NEAR/3 (aspiration OR lavage OR fragmentation OR irrigation OR punctur* OR treatment* OR therap* OR procedure*)):ti,ab,kw) OR ((('ultrasound guided' OR 'ultrasonography guided' OR 'us guided') NEAR/3 needl*):ti,ab,kw) OR ((percutaneous NEAR/3 (therap* OR treatment* OR intervention*)):ti,ab,kw)	196517
#3	'shock wave therapy'/exp OR shockwave*:ti,ab,kw OR 'shock wave*':ti,ab,kw OR 'pulsed ultrasound*':ti,ab,kw OR 'ultrasonic vibration*':ti,ab,kw OR 'ultrasonic wave*':ti,ab,kw OR 'radiation ultrasound':ti,ab,kw OR 'ultrasound wave*':ti,ab,kw OR eswt:ti,ab,kw OR 'high energy':ti,ab,kw OR 'high intensity':ti,ab,kw OR 'low energy':ti,ab,kw OR 'low intensity':ti,ab,kw	160869
#4	#1 AND (#2 OR #3)	396
#5	#4 NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	298
#6	#5 AND [01-11-2017]/sd	96
#7	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3	970896

	search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	
#8	'clinical trial'/exp OR 'randomization'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR 'placebo'/exp OR 'prospective study'/exp OR rct:ab,ti OR random*:ab,ti OR 'single blind':ab,ti OR 'randomised controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	3896362
#9	#6 AND #7 = SR	15
#10	#6 AND #8 NOT #9 = RCT	34
#11	#9 OR #10	49

Ovid/Medline

#	Searches	Results
1	(Shoulder Impingement Syndrome/ or 'shoulder impingement syndrome*'.ti,ab,kf. or 'subacromial impingement syndrome*'.ti,ab,kf. or ((exp bursitis/ or exp Tendinopathy/ or bursitis.ti,ab,kf. or tendinitis.ti,ab,kf. or tendinosis.ti,ab,kf. or tendinopath*.ti,ab,kf. or 'impingement'.ti,ab,kf.) and (exp Shoulder/ or 'rotator cuff'.ti,ab,kf. or acromion.ti,ab,kf. or acromial.ti,ab,kf. or subacromial.ti,ab,kf. or shoulder*.ti,ab,kf.)) or Rotator Cuff/ or exp Rotator Cuff Injuries/ or (('rotator cuff' or 'shoulder cuff' or infraspinatus or supraspinatus or subscapularis) adj3 (tear* or lesion* or rupture* or tendinopath* or laceration*)).ti,ab,kf. or (('full-thickness' or partial) and 'rotator cuff').ti,ab,kf.) and (exp Calcinosis/ or calcifying.ti,ab,kf. or calcification.ti,ab,kf. or calcarea*.ti,ab,kf. or calcific.ti,ab,kf. or calcinosis.ti,ab,kf. or calcified.ti,ab,kf. or calcinotic.ti,ab,kf.)	1025
2	exp Ultrasonography, Interventional/ or Therapeutic Irrigation/ or barbotage*.ti,ab,kf. or ((needle* or needling or 'ultrasound guided' or 'ultrasonography guided' or 'us guided' or 'image guided') adj3 (aspiration or lavage or fragmentation or irrigation or punctur* or treatment* or therap* or procedure*)).ti,ab,kf. or (('ultrasound guided' or 'ultrasonography guided' or 'us guided') adj3 needl*).ti,ab,kf. or (percutaneous adj3 (therap* or treatment* or intervention*)).ti,ab,kf.	156933
3	exp Extracorporeal Shockwave Therapy/ or exp Ultrasonic Waves/ or (shockwave* or 'shock wave*' or 'pulsed ultrasound*' or 'ultrasonic vibration*' or 'ultrasonic wave*' or 'radiation ultrasound' or 'ultrasound wave*' or eswt or 'high energy' or 'high intensity' or 'low energy' or 'low intensity').ti,ab,kf.	146200
4	1 and (2 or 3)	298
5	4 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	280
6	5 and 20171101:20231023.(dt).	78
7	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or	700911

	pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	
8	exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti,ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind$3 or mask$3)).tw. or Placebos/ or placebo*.tw.	2645320
9	6 and 7 = SR	12
10	(6 and 8) not 9 = RCT	17
11	9 or 10	29

Module 4.2 Oefentherapie versus oefentherapie en corticosteroïdinjectie

Uitgangsvraag
Wat is de waarde van een subacromiale corticosteroidinjectie als aanvulling op oefentherapie bij patiënten met subacromiale schouderklachten?

Introduction (English)
Exercise therapy (with training of scapular rhythm and cuff loading and coordination) is the therapy of choice in SAPS, without (impending) cuff ruptures. In practice, a subacromial injection of corticosteroids is often given during or prior to therapy. Sometimes this injection serves to enable exercise; sometimes it is done routinely. It is unclear whether injection combined with exercise therapy provides demonstrable gains over exercise therapy alone in terms of pain, function, complications, recurrence, patient satisfaction and return to work and sport.

Search and select
A systematic review of the literature was performed to answer the following question: What are the benefits and harms of subacromial corticosteroid injection in addition to exercise in patients with subacromial shoulder complaints?

Patients	patients with SAPS
Intervention	exercise therapy
Control	corticosteroid injection + exercise therapy
Outcomes	pain, function, complications, recurrence, patient satisfaction, return to work

Relevant outcome measures
The guideline development group considered pain, function, complications, and recurrence as a critical outcome measure for decision making; and patient satisfaction and return to work as an important outcome measure for decision making.

The guideline development group defined the outcome measures as follows:
- Patient reported outcomes measures for function: CMS, DASH, WORC, ASES, DSST, OSS
- Pain: VAS-scale (0-10 points or 0-100mm scale)
- Complications/adverse events: re-rupture, frozen shoulder and infection
- Patient satisfaction: self-reported satisfaction with treatment and/or function

The guideline development group defined the minimal clinically (patient) important differences as follows:
- Patient reported outcome measures:
    - CMS: 15 points on a 100-point scale (Holmgren, 2014)
    - DASH: 13 on a 100 point scale (Koorevaar, 2018)
    - WORC: -282.6 on a 2100 point scale (Gagnier, 2018)
    - ASES: 9 on a 100 point scale (Gagnier, 2018)
    - DSST: 2.8 on a 12 point scale (Van Kampen, 2013)
    - OSS: 5 points on a 48-point scale (Nyring, 2021)
    - SPADI: 14 on a 100 point scale (Dabija, 2019)

- Pain
    - 1/10 points or 10/100 points on a VAS scale
- Complications/adverse events:
    - Recurrence: : 25% (RR ≤ 0.80 and ≥ 1.25)
    - Frozen shoulder: 25% (RR ≤ 0.80 and ≥ 1.25)
    - Infection: 25% (RR ≤ 0.80 and ≥ 1.25)
- Patient satisfaction: difference of 25% (RR ≤ 0.80 and ≥ 1.25) or 1/10 points or 10/100 points on a VAS scale.
- Return to work: difference of 25% (RR ≤ 0.80 and ≥ 1.25)

Search and select (Methods)
The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms from 2017 until 08-03-2024. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 264 hits. Studies were selected based on the following criteria:

- Study design: randomized controlled trial or systematic review
- Patients with SAPS in adulthood
- Comparing exercise therapy versus exercise therapy and subacromial corticosteroid injection.
- Describing at least one of the relevant outcomes specified in the PICO.
- Published from 2017 onwards (search date NHG standard) (see: Schouderklachten - totstandkoming versie 4.1.pdf (nhg.org) Uitgangsvraag 6.4 blz. 28 en search p. 56).
- Follow-up duration: ½ year / 6 months

22 studies were initially selected based on title and abstract screening. After reading the full text, 17 studies were excluded (see the table with reasons for exclusion under the tab Methods), and 5 studies were included.

Results
A total of 5 studies were included in the analysis of the literature. Important study characteristics and results are summarized in the evidence tables. The assessment of the risk of bias is summarized in the risk of bias tables.

Summary of literature

Description of studies

Search NHG up till 2017	Patients	Intervention	Control	Measured outcomes	Duration and frequency follow-up
Crawshaw 2010	Patients with subacromial impingement syndrome total study population: 232 Intervention: 117 Control: 115 Mean age (year) total study population: 56 (range 40-78 years). Over half were woman. All had shoulder pain for a median of 16 weeks (IQR 12-28 weeks)	The group (n = 117; average duration of complaints 17 weeks, range 12-28 weeks) only received the combination of exercise therapy and manual therapy. The physiotherapist determined the duration of the treatment treatment and chose which exercises or mobilization technique(s) were applied (from a list of 23 exercises/mobilization techniques).	The group (n = 115) received a corticosteroid injection (20 mg triamcinolone acetonide + 4.5 ml 1% lidocaine) and a combination of exercise therapy and manual therapy (n = 115; average duration of complaints 14 weeks, range 10-26 weeks). The injection could be repeated after 6 weeks for moderate or severe pain.	SPADI score	Total follow-up of 24 weeks, SPADI score was measured after week 12.
Updated version literature from 2017 onwards	**Patients**	**Intervention**	**Control**	**Measured outcomes**	**Duration and frequency follow-up**
Hajivandi, 2021	Patients with full-thickness rotator cuff tearing separately and simultaneously Per intervention and control	The group underwent 12 sessions of physiotherapy twice a week for 6 weeks	The group received 80 mg of methylprednisolone and 1 ml of lidocaine 2%, and after 2 days, 6 sessions of physiotherapy twice a week	DASH questionnaire and VAS criterion, and the range of motions of all groups was measured by a	Not reported

	group, 32 patients were included. The mean age in physiotherapy, and physiotherapy + steroid groups was 51.78 ± 7.37 and 50.87 ± 5.65, respectively. More than 80% of patients in each group were female.		for 3 weeks were prescribed.	goniometer	
Hsieh (2023)	Prospective, three-arm randomised controlled trial; patients were divided into corticosteroid injection (N=36), physiotherapy (N=40) and combined (N=35) groups. total: 96 patients in all three groups. Intervention: 28 Control: 32 Mean age (year): I: 56.9 years C: 54.2 years Gender, Female I: 25 (62%) C: 23 (66%)	physical therapy (physiotherapy group); received 8-week physical therapy program.	Corticosteroid injection and physiotherapy (combined group): received 8-week physical therapy program and received 8-week physical therapy program. I If symptoms completely subsided after the first injection, the second injection was held.	VAS (pain), SPADI, the Shoulder Disability Questionnaire (SDQ), the Western Ontario Rotator Cuff Index (WORC), symptom recurrence	Measured 8 weeks after finishing treatment. In addition, recurrence of symptom was assessed 24 weeks after the third evaluation.
Raeessi (2023)	Patients with Subacromial Pain Syndrome (SAPS).	Physiotherapy group with a program including an	Combined group with the same treatment program,	Visual Analog Scale (VAS), Shortened	Were measured at pre intervention,

	50 patients with SAPS were randomly assigned into I: 25 patients C: 25 patients	individually tailored exercise and manual therapy program prescribed and supervised by a physiotherapist, involving up to 12 face-to-face sessions over 4 weeks (n=25);	preceded by corticosteroid injection (n=25).	Disability of the Arm, Shoulder, and Hand (Quick-DASH), Shoulder Pain and Disability Index (SPADI) (primary outcome measure), Western Ontario Rotator Cuff (WORC), and Global Rating of Change (GRC) respectively.	post-intervention, and 3 and 6-month follow-up
El Gendy (2023)	Sixty patients with unilateral shoulder impingement syndrome >3 mos were allocated to 3 groups. One group assessed conventional physiotherapy plus extracorporeal shock wave therapy. I: 20 patients C: 20 patients Age (years), mean (SD) I: 32.72 ± 4.38 C: 30.47 ± 3.69	Conventional physiotherapy	a 4-wk program of CPT plus a single local corticosteroid injection of 40 mg triamcinolone acetonide mixed with 1% xylocaine	Subacromial space, shoulder pain and disability index, and shoulder range of motion were assessed	At baseline and 4 and 12 wks posttreatment.

Results

Pain

Crashaw (2010) reported on pain using the SPADI Pain subscale (ranging from 0-100; the higher a patient scores on the SPADI, the greater the pain/limitation in activities) at respectively 6 weeks and 12 weeks. At 6 weeks, the mean difference in SPADI Pain score was 7.7 (95% CI 4.5 to 11.0) in favor of the control group (exercise therapy + injection). This difference is not considered clinically relevant. At 12 weeks, the mean difference in SPADI Pain score was 3.8 (95% CI -0.65 to 8.3) in favor of the control group (exercise therapy + injection). This difference is not considered clinically relevant.

Hajivandi (2021) reported pain scores using the VAS after the intervention (follow-up period was not specified). In the intervention group (exercise therapy) the mean VAS score was 4.00) (SD 0.91) and in the control group (exercise therapy + injection) the mean VAS score was 3.56 (SD 0.66). The MD was 0.44 (95% CI 0.05 to 0.83) in favor of the control group. This difference was not considered clinically relevant.

Hsieh (2023) reported on pain using the SPADI 8 weeks post intervention. The mean SPADI scores in the intervention group (exercise therapy) and control group (exercise therapy + injection) were respectively 32.7 (22.4) and 37.5 (26.6) (MD: -4.80, 95% CI -17.20 to 7.60) in favour of the intervention group (exercise therapy only). This difference was not considered clinically relevant. Additionally, the VAS at rest (0-100) was measured 8 weeks post intervention and these scores were respectively 13.1 (18.4) and 14.1 (21.5) in the intervention and control group (MD: -1.00, 95% CI -11.10 to 9.10) in favor of the intervention group (exercise only). This difference was not considered clinically relevant.

Raeeshi (2022) reported on pain using the VAS scale (range 0-10) at three and six months follow-up. At three months follow-up, the mean VAS score in the intervention group was 3.05 (SD: 2.17) and in the control group 1.19 (SD: 1.36). The mean difference was 1.86 (95% CI 0.78 to 2.94) in favor of the control group (exercise therapy plus injection). This difference was considered clinically relevant. At six months follow-up, the mean VAS score in the intervention group was 2.23 (SD: 1.99) and in the control group 0.62 (SD 0.59). The mean difference was 1.61 (95% CI 0.74 to 2.48) in favor of the control group (exercise therapy plus injection). This difference was considered clinically relevant.

ElGendy (2023) reported on pain using the SPADI score at 4 weeks post intervention and at 12 weeks post intervention.
At 4 weeks, the mean SPADI score in respectively the intervention and control group were 30.09 ± 19.61 and 23.28 ± 11.86 (MD: 6.81, 95% CI -3.23 to 16.85 in favor of the control group (exercise therapy + injection). This difference was not considered clinically relevant.
At 12 weeks, the mean SPADI score in respectively the intervention and control group were 32.23 ± 19.88 and 22.39 ± 11.08 (MD: 9.84, 95% CI -0.13 to 19.81 in favor of the control group (exercise therapy + injection). This difference was not considered clinically relevant.

Function

Crawshaw (2010) reported on function using the SPADI subscale disability (ranging from 0-100; the higher a patient scores on the SPADI, the greater the pain/limitation in activities) at respectively 6 and 12 weeks. At 6 weeks, the mean difference in SPADI score was 7.1 (95% CI 4.0 to 10.1) in favor of the control group (exercise therapy + injection). This difference was

not considered clinically relevant. At 12 weeks, the mean difference in SPADI score was 2.9 (95% CI -1.1 to 6.9) in favor of the control group (exercise therapy + injection). This difference was not considered clinically relevant.

Hajivandi (2021) reported on function using the DASH after the intervention (follow-up period was not specified). In the intervention group (exercise therapy) the mean DASH score was 48.77 (SD 4.0) after the intervention, and in the control group (exercise therapy + injection) the mean DASH score was 45.91 (SD 4.12) after the intervention. The MD was 2.86 (95% CI 0.87 to 4.85). This difference was not considered clinically relevant.

Hsieh (2023) reported on function using the using SPADI 8 weeks post intervention. In the intervention group, the mean SPADI score was 24.8 (SD: 21.7) and in the control group, the mean SPADI score was 28 (SD: 23.8). The mean difference was -3.20 (95% CI -14.72 to 8.32) in favor of the intervention group (exercise therapy only). This difference was not considered clinically relevant. Additionally, **Hsieh (2023)** used the Western Ontario Rotator Cuff (WORC) in which a higher score indicates worse functioning. The WORC score was 592.3 (SD 485.7) in the intervention group and 647.4 (SD: 547.5) in the control group 8 weeks post intervention. The mean difference was -55.10 (95% CI -316.54 to 206.34) in favor of the intervention group (exercise therapy only). This difference was not considered clinically relevant.

Raeeshi (2022) reported on function at three and six months follow-up.
At three months follow-up, **Raeeshi** reported on function using the SPADI, the DASH score, and the WORC score.
With regards to the SPADI score, at three months follow up the mean SPADI score in the intervention and control groups was respectively 21.79 (13.11) and 10.04 (10.49). The mean difference was 11.75 (95% CI 4.67 to18.83) in favor of the control group (exercise therapy + injection). This difference was not considered clinically relevant.
With regards to the DASH score, at three months follow up the mean DASH score in the intervention and control groups was respectively 23.33 (16.42) and 8.70 (9.55). The mean difference was 14.52 (95% CI 6.53 to 22.51) in favor of the control group (exercise therapy + injection). This difference was not considered clinically relevant.
With regards to the WORC score, at three months follow up the mean WORC score in the intervention and control groups was respectively 19.24 (12.99) and 12.41 (12.01). The mean difference was 6.83 (95% CI -0.64 to 14.30) in favor of the control group (exercise therapy + injection). This difference was not considered clinically relevant.
At six months follow-up, **Raeeshi** reported on function using the SPADI, the DASH score, and the WORC score.
With regards to the SPADI score, at six months follow up the mean SPADI score in the intervention and control groups was respectively 18.18 (16.93) and 6.87 (6.97). The mean difference was 11.31 (95% CI 3.63 to 18.99) in favor of the control group (exercise therapy + injection). This difference was not considered clinically relevant.
With regards to the DASH score, at six months follow up the mean DASH score in the intervention and control groups was respectively 19.09 (18.90) and 4.26 (5.08). The mean difference was 14.83 (95% CI 6.64 to 23.02) in favor of the control group (exercise therapy + injection). This difference was considered clinically relevant.
With regards to the WORC score, at six months follow up the mean WORC score in the intervention and control groups was respectively 18.45 (15.70) and 6.57 (7.56). The mean difference was 11.88 (95% CI 4.57 to 19.19) in favor of the control group (exercise therapy + injection). This difference was not considered clinically relevant.

ElGendy (2023) did not report on function.

Complications

No study reported on complications

Recurrence
Hsieh (2023) reported the recurrence of symptoms until 24 weeks post interventions. Recurrence was defined as a new episode of moderate shoulder pain lasting more than 1 day following a period of at least 1 week pain free (pain intensity 0 or 1) or as an episode of care seeking for the same problem. In the intervention group, 3 patients (7%) indicated having recurrence of symptoms. In the control group, 6 patients (17%) indicated having recurrence of symptoms. The RR was 0.57 (95% CI 0.16 to 2.08) in favor of the intervention group. This difference was considered clinically relevant.

Crashaw (2010), Hajivandi (2021) , Raeeshi (2022), and **ElGendy (2023)** did not report recurrence.

Patient satisfaction
Hsieh (2023) evaluated patient's evaluation of the treatment effect which was assessed by the answer to one question: 'Is the treatment effective?' scored on a Likert scale (very effective =1, effective=2, no change=3, worse =4, much worse=5). In the intervention group, the mean score was 3.1 (SD 1.7) and in the control group the mean score was 3.7 (SD: 1.1). The MD was -0.60 (95% CI -1.34, 0.14) in favor of the intervention group (exercise only). This difference was not considered clinically relevant.

Crashaw (2010), Hajivandi (2021), Raeeshi (2022), and **ElGendy (2023)** did not report patient satisfaction.

Return to work
No study reported return to work.

Level of evidence of the literature
The level of evidence for all outcome measures was based on randomized trials and therefore started at high.

Pain
The level of evidence regarding the outcome measure pain was downgraded by **two** levels to **LOW** because of study limitations (risk of bias; -1); and small samples within the studied populations (imprecision; -1).

Function
The level of evidence regarding the outcome measure function was downgraded by **two** levels to **LOW** because of study limitations (risk of bias; -1); and small samples within the studied populations (imprecision; -1).

Complications
The level of evidence regarding the outcome measure complications could not be determined due to a lack of data.

Recurrence

The level of evidence regarding the outcome measure recurrence was downgraded by **two** levels to **LOW** because of number of studied and included patients (imprecision; -2).

Patient satisfaction
The level of evidence regarding the outcome measure patient satisfaction was downgraded by **two** levels to **LOW** because of number of studied and included patients (imprecision; -2).

Return to work
The level of evidence regarding the outcome measure return to work could not be determined due to a lack of data.

<u>Conclusions</u>

Pain

Low GRADE	Exercise therapy may result in little to no difference in **pain** when compared with corticosteroid injection + exercise therapy in patients with SAPS. *Source: Crashaw (2010), Hajivandi (2021), Hsieh (2023), Raeeshi (2022), ElGendy (2023)*

Function

Low GRADE	Exercise therapy may result in little to no difference in **function** when compared with corticosteroid injection + exercise therapy in patients with SAPS. *Source: Crashaw (2010), Hajivandi (2021), Hsieh (2023), Raeeshi (2022)*

Complications

No GRADE	No evidence was found regarding the effect of exercise therapy on complications when compared with corticosteroid injection + exercise therapy in patients with SAPS.

Recurrence

Low GRADE	Exercise therapy may reduce the risk of **recurrence** when compared with corticosteroid injection + exercise therapy in patients with SAPS. *Source: Hsieh (2023)*

Patient satisfaction

Low GRADE	Exercise therapy may result in little to no difference in **patient satisfaction** when compared with corticosteroid injection + exercise therapy in patients with SAPS. *Source: Hsieh (2023)*

Return to work

no GRADE	No evidence was found regarding the effect of exercise therapy on return to work when compared with corticosteroid injection + exercise therapy in patients with SAPS.

Overwegingen – van bewijs naar aanbeveling

Voor- en nadelen van de interventie en de kwaliteit van het bewijs

Er is systematisch literatuuronderzoek verricht naar het effect van oefentherapie versus oefentherapie in combinatie met een corticosteroïdeninjectie bij patiënten met SAPS. Deze literatuursamenvatting is aanvullend op de literatuursamenvatting van de NHG, die systematisch naar literatuur heeft gezocht tot en met 2017. In deze zoekstrategie is aanvullend gezocht van 2017 tot 2024. In de literatuursamenvatting van de NHG was één RCT geïncludeerd (Crawshaw, 2010). Deze studie is geïncludeerd in deze literatuursamenvatting. Aanvullend werden nog vier gerandomiseerde studies geïncludeerd. De cruciale uitkomstmaten voor besluitvorming waren pijn, functioneren, complicaties, en recidief. De belangrijke uitkomstmaten waren patiënttevredenheid en terugkeer naar werk.

Voor de uitkomstmaten pijn en functie zijn de resultaten niet gepoold vanwege de variatie in follow-up duur en meetmethode. In slechts één van de vijf onderzoeken werd een klinisch relevante verbetering gevonden in beide uitkomstmaten na oefentherapie ten opzichte van oefentherapie plus een corticosteroïdeninjectie. De overige studies vonden geen verschillen. De bewijskracht was laag door het risico op bias en het beperkte aantal geïncludeerde patiënten. Recidief werd slechts in een enkele studie (Hsieh, 2023) gerapporteerd. Na 24 weken leek recidief minder vaak voor te komen bij oefentherapie ten opzichte van oefentherapie plus corticosteroïdeninjectie (lage bewijskracht). Complicaties werden in geen enkele studie gerapporteerd en konden daarom geen richting geven voor de besluitvorming.

Slechts één publicatie rapporteerde patiënttevredenheid. Hsieh (2023) vond geen verschillen tussen de interventie- en controlegroep (lage bewijskracht). Terugkeer naar werk werd in geen studie gerapporteerd. De totale bewijskracht voor de cruciale en belangrijke uitkomsten is laag. Uit de literatuur blijkt geen overtuigend voordeel voor oefentherapie met of zonder corticosteroïdeninjectie. De aanbeveling is daarom gebaseerd op andere argumenten.

Waarden en voorkeuren van patiënten (en evt. hun verzorgers)

Voor patiënten is verlichting van pijn belangrijk. Een subacromiale injectie met corticosteroïden en lidocaïne is voor de patiënt een Quick-fix, met meestal snelle vermindering van pijn gedurende enkele weken. De injectie wordt gegeven in een erg gevoelig gebied, maar slechts zelden wordt de pijn door de patiënt als onaanvaardbaar gezien.

Bij pijn die ondraagbaar is werkt een injectie meestal afdoende. Bij draaglijke pijn moet een patiënt de keuze krijgen waarbij het belangrijkste bezwaar benoemd moet worden: schade door het onvoldoende alert zijn op overbelasting. Voor patiënten is het dan ook belangrijk dat met hen wordt besproken dat de prik dient ter vermindering van de pijn, maar dat de injectie geen verbetering op pathologisch niveau geeft. Daarvoor is herstel van de bewegingsketen en relatieve rust nodig. Daarom is het voor patiënten belangrijk dat met hen ook een oefenadvies besproken wordt met restricties voor langdurige schouderbelasting, zoals bij werk en sport, echter wel met zo mogelijk een opbouw daarin. De belangrijkste subgroep waarbij voorzichtigheid geboden is, zijn de mensen met diabetes mellitus. Bloedglucosespiegels kunnen na een corticosteroïdeninjectie 3-10 dagen verhoogd zijn.

Kosten (middelenbeslag)

De kosten van lidocaine en triamcinolon zijn vrij beperkt. Natuurlijk is de setting wel medebepalend voor de totale prijs. Gezien het beperkte bewijs in de literatuur zou een

injectie in ieder geval geen routinehandeling moeten zijn. Volgens expert opinie heeft de patiënt met bewegingsbeperkingen door pijn echter wel degelijk te winnen bij een injectie. Gezien het slechts tijdelijke effect van het corticosteroïd dient de injectie wel gepaard te gaan met oefentherapie en advies.

Aanvaardbaarheid, haalbaarheid en implementatie

Het lege artis injecteren mag gezien worden als een basisvaardigheid van elke arts of PA die zich met de schouder bezighoudt. Het consult aan de schouderexpert, de injectie en het bijbehorende advies is een interventie uit het basispakket. De subacromiale injectie is een vaardigheid die redelijk eenvoudig te leren is, maar zeker wel bijgehouden moet worden in combinatie met het doen van echografisch onderzoek. Scholing daarvoor is voor iedereen toegankelijk, en er zijn ook veel online vraagbaken. Voorzichtigheid dient getracht te worden bij mensen met een degeneratieve cuff (vanwege een groter risico op rupturen) en mensen met diabetes mellitus (vanwege het voorkomen van tijdelijke hyperglycaemie). Een beweegadvies, een gebruiksadvies, en bij speciale groepen (zoals mensen met diabetes mellitus) extra aandacht door de arts, PA, verpleegkundig specialist of een duidelijke folder instructie, moet een routine zijn bij elke injectie. Gezien het effect van steroïden op vermindering van weefselregeneratie wordt in het algemeen, op basis van expert opinion, een frequentie van maximaal 4-6 maal per jaar per zijde aangehouden.

Aanbeveling

Rationale van de aanbeveling: weging van argumenten voor en tegen de interventies

Het argument tegen een routinematige injectie gevolgd door oefentherapie is de gebrekkige bewijsvorming in de literatuur. Op basis van de literatuur weegt de geringe meerprijs van een injectie niet op tegen het voordeel in tijd en comfort. Expert opinion is echter sterk overtuigend richting een gerichte injectie bij mensen die anders niet zouden kunnen bewegen door de pijn.

Bij mensen die weliswaar pijn hebben, maar nog vrijwel ongestoord bewegen, kan de voorkeur van de patiënt bepalend zijn. Een injectie moet in dat geval gepaard gaan met een duidelijk beweeg- en handeladvies, waarbij overbelasting voorkomen moet worden.

Aanbeveling

Overweeg samen met de patient (met voorlichting over werking en bijwerking) een subacromiale injectie met corticosteroïden met een lokaal anestheticum om de oefentherapie te vergemakkelijken, als oefentherapie niet adequaat kan worden uitgevoerd in verband met pijnklachten. Na de injectie dient de (z.n. begeleide) oefentherapie (gegeven door een oefen- of fysiotherapeut) weer hervat te worden.

Kennisvragen

Een belangrijke uitkomstmaat in de gevonden literatuur was de snelheid van terugkeer naar werk en sport (hetgeen ook een belangrijke macro-economische uitkomstmaat is). Hier is geen overtuigende literatuur over gevonden.

Literatuur

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Bijlagen bij module 4.2 Oefentherapie vs. oefentherapie en corticosteroïdinjectie

Implementatieplan

Aanbeveling	Tijdspad voor implementatie: < 1 jaar, 1 tot 3 jaar of > 3 jaar	Verwacht effect op kosten	Randvoorwaarden voor implementatie (binnen aangegeven tijdspad)	Mogelijke barrières voor implementatie	Te ondernemen acties voor implementatie	Verantwoordelijken voor acties	Overige opmerkingen
Overweeg samen met de patient (met voorlichting over werking en bijwerking) een subacromiale injectie met corticosteroïden met een lokaal anestheticum om de oefentherapie te vergemakkelijken, als oefentherapie niet adequaat kan worden uitgevoerd in verband met pijnklachten. Na de injectie dient de (z.n. begeleide) oefentherapie (gegeven door een oefen- of fysiotherapeut) weer hervat te worden.	<1 jaar	Vermindering	Patient consent	Alleen mogelijk daar waar injecteren routine is	geen		

Evidence tables

Study reference	Study characteristics	Patient characteristics	Intervention	Control	Follow-up	Outcome measures and effect size	Comments
Crashaw (2010)	Study design: Pragmatic randomised clinical trial simple block randomisation was performed for seven sites based on a computer generated randomisation list. Setting and Country: Leeds, London, UK Source of funding and conflicts of interest: The study was funded by a project grant	Inclusion criteria Adults aged 40 or over with subacromial impingement syndrome who reported moderate or severe shoulder pain and were referred from primary care. Exclusion criteria: Not reported N total at baseline: 232 Intervention: 117 Control: 115 Important prognostic factors[2]:	Describe intervention (treatment/procedure/ test): The group (n = 117; average duration of complaints 17 weeks, range 12-28 weeks) only received the combination of exercise therapy and manual therapy. The physiotherapist determined the duration of the treatment treatment and chose which exercises or mobilization technique(s) were applied (from a list of 23 exercises/mobilization	Describe control (treatment/procedure/ test): The group (n = 115) received a corticosteroid injection (20 mg triamcinolone acetonide + 4.5 ml 1% lidocaine) and a combination of exercise therapy and manual therapy (n = 115; average duration of complaints 14 weeks, range 10-26 weeks). The injection could be repeated after 6 weeks for moderate or severe pain.	Length of follow-up: 24 weeks Loss-to-follow-up: not reported Intervention: N (%): 1 Reasons (describe) Control: N (%): 20 Reasons (describe) Incomplete outcome data: not reported	Outcome measures and effect size (include 95%CI and p-value if available): *6 weeks* **Pain** Using the SPADI Pain subscale (0-100) *Mean:* I: 44.7 C: mean shoulder pain was 7.7. points	**Comments:** A corticosteroid injection prior to exercise therapy probably has a small, but insignificant effect on shoulder pain and function after 6 weeks and no effect on pain and shoulder function after 12 weeks compared to exercise therapy without corticosteroid injection. Trial registration number ISRCTN 25817033;

	17236 from Arthritis Research UK. No competing interests declared by all authors.	Mean age (year) total study population: 56 (range 40-78 years). Over half were woman. All had shoulder pain for a median of 16 weeks (IQR 12-28 weeks) <u>Groups comparable at baseline?</u> Unknown	techniques).		<u>Intervention:</u> <u>N (%)</u> <u>Reasons (describe)</u> <u>Control:</u> <u>N (%)</u> <u>Reasons (describe)</u>	less **MD: 7.7, 95% CI 4.5 to 11.0** **<u>Function</u>** *Using the SPADI subscale disability (0-100) Mean* I: 36.1 points C: 7.1 points more compared to the intervention group **MD: 7.1, 95% CI 4.0 to 10.1** **<u>Complications</u>** No adverse events	

						were reported in either group. **Risk of recurrence** Not reported **patient satisfaction** not reported **Return to work / active participation** Not reported *12 weeks* **Pain** Using the SPADI Pain subscale (0-	

						100) *Mean:* I: 38.7 C: mean shoulder pain was 3.8 points less **MD: 3.8, 95% CI -0.65 to 8.3** **<u>Function</u>** *Using the SPADI subscale disability (0-100)* *Mean* I: 29.7 points C: 2.9 points more compared to the I **MD: 2.9 (95% CI -1.1 to 6.9)**	

						<u>Complications</u> No adverse events were reported in either group. **<u>Risk of recurrence</u>** Not reported **<u>patient satisfaction</u>** not reported **<u>Return to work / active participation</u>** Not reported	
Hajivandi	<u>Study design</u>: Randomized clinical trial study	<u>Inclusion criteria</u> patients with an age range of 30 to	<u>Describe intervention (treatment/procedure/test):</u>	<u>Describe control (treatment/procedure/test):</u>	<u>Length of follow-up:</u> Not	<u>Outcome measures and effect</u>	**Comments:** This trial is registered

(2021)	Setting and Country: patients who had complete rotator cuff rupture in the period of February 2017 to November 2016 were identified and enrolled in the study. Patients were referred to the orthopedic clinic and assessed after signing the informed consent. University of Iran Source of funding and conflicts of interest: Funding: Conflict:	70 years who were diagnosed with complete rotator cuff degenerative rupture with MRI and clinical examination and were consciously and cooperatively willing to participate in the study. Exclusion criteria: any concomitant shoulder disease such as infection, fracture, and tumor as well as trauma during treatment and therapeutic intervention by other people N total at baseline: 96 patients Intervention: 32 Control: 32	The first group underwent 12 sessions of physiotherapy in the form of massage, rotator cuff and scapular muscle stretching exercises, strengthening exercises and modalities including laser, transcutaneous electrical nerve stimulation (TENS), and ultrasound (US) twice a week for 6 weeks with a duration of 45 minutes per session including 30 minutes of electrotherapy and 15 minutes of manual therapy training.	The group was injected with 8 mg of methylprednisolone and 1 ml of lidocaine 2% and, two days later, underwent 6 sessions of physiotherapy by a rehabilitation specialist twice a week for 3 weeks. The duration of each session was 45 minutes, including 30 minutes of electrotherapy and 15 minutes of manual therapy training; after 6 sessions of physiotherapy at the end of the third week, the injection was performed, and the other 6 sessions of physiotherapy twice a week for 2 weeks were performed with a duration of 45 minutes per session. All groups were	reported Loss-to-follow-up: not reported Intervention: N (%): Reasons (describe) Control: N (%): Reasons (describe) Incomplete outcome data: Intervention: N (%) Reasons (describe) Control: N (%) Reasons (describe)	size (include 95%CI and p-value if available): **Pain** Using the VAS: Before intervention: I: 5.53 ± 0.62 C: 5.59 ± 0.66 After intervention: I: 4.00 ± 0.91 C: 3.56 ± 0.66 **Function** Using the DASH:	with IRCT20200102045987N1**.** **Conclusion:** In the present study, despite the significant decrease in VAS and DASH scores in all three groups, no significant differences were observed between the two physiotherapy treatment approaches and CSI in the VAS and DASH scores. Instead, people who received both treatments showed significantly lower VAS as well as DASH scores than the other two groups.

		Another group is not included in this summery, in this group patients were solely provided steroids. <u>Important prognostic factors</u>[2]: *For example* *Mean age (year):* *Gender* More than 80% of patients in each group were female. I: 84.4% female C: 81.3% female Mean age I: 51.78 ± 7.37 C: 50.87 ± 5.65 <u>Groups comparable at baseline?</u> Yes		instructed not to use NSAIDs or herbal and home remedies either orally or systemically or topically during the study.		Before intervention: I: 57.21 ± 4.15 C: 56.77 ± 3.65 After intervention: I: 48.77 ± 4.0 C: 45.91 ± 4.12 **<u>Complications</u>** Not reported **<u>Risk of recurrence</u>** Not reported **<u>Patient satisfaction</u>** not reported	

						Return to work / active participation Not reported	
Hsieh (2023)	Study design: Prospective, three-arm randomised controlled trial Setting and Country: Patients with chronic subacromial bursitis were recruited from the department of Physical Medicine and Rehabilitation of the Shin Kong Wu Ho-Su Memorial Hospital. Trial was conducted from 1 August 2018	Inclusion criteria Patients with chronic subacromial bursitis. (1) shoulder pain for more than 3 months, (2) age ≥20 years old, (3) pain on shoulder abduction or internal rotation with a pain visual analogue scale (VAS) score ≥4, (4) a painful arc of motion or pain on range of motion of shoulder (particularly abduction or internal rotation)	Describe intervention (treatment/procedure/ test): physical therapy (physiotherapy group); received 8-week physical therapy programme. The physiotherapy programme consisted of hot pack, interferential therapy, and exercise programme, which includes stretch exercise, mobilisation of the glenohumeral joint, manual pressure to the possible trigger	Describe control (treatment/procedure/ test): corticosteroid injection and physiotherapy (combined group): received 8-week physical therapy programme and received 8-week physical therapy programme. I If symptoms completely subsided after the first injection, the second injection was held. 2 mL triamcinolone (1 mL/10 mg) and 3 mL	Length of follow-up: 8 weeks Loss-to-follow-up: Intervention: N (%): 1 Reasons (describe) Control: N (%): 20 Reasons (describe) Incomplete outcome data: Intervention:	Outcome measures and effect size (include 95%CI and p-value if available): *8 weeks postop* **Pain** *using SPADI* I: 32.7 (22.4) C: 37.5 (26.6) VAS at rest I: 13.1 (18.4)	**Comments:** The study was registered on ClinicalTrials. gov (no. NCT03871465) Conclusion: Corticosteroid subdeltoid injection, or combined with physiotherapy, was superior to physiotherapy alone, but the recurrence rate was least in the physiotherapy group. The pain VAS score, one of the commonly used measures of pain intensity, was

	through 31 July 2020. <u>Source of funding and conflicts of interest:</u> The study was financially supported by the National Science and Technology Council of Taiwan (no. NSTC 107-2314-B-341-002 and NSTC 108-2314-B-341-002). <u>Conflict:</u> The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.	with an empty or soft end feel, (5) positive shoulder impingement test (Neer's test and/or Hawkin's test) and (6) pain reduction ≥40% on active shoulder abduction or internal rotation at the terminal range after a diagnostic block (ultrasound-guided injection of 3 mL of 1% lidocaine into the subacromial subdeltoid bursa). <u>Exclusion criteria:</u> (1) a history of Uncontrolled systemic diseases, for example, blood dyscrasia, malignant neoplasms, and serious infection; (2) previous	points, scapular stabilisation exercise, and strengthening exercise of the rotator cuff, trapezius, and serratus anterior muscles. Regarding scapular stabilisation exercise, the first step was guiding patients to find the scapular neutral position. It was the mid-position between their available range of scapular upward and down ward rotation, protraction and retraction, posterior and anterior tilt. Patients were instructed to maintain the neutral position by visual, auditory or kinaesthetic cues, and were consequently be taught to find the neutral position themselves. Patients were then asked to	1%xylocaine were injected into the affected subacromial-subdeltoid bursa under ultrasound guidance. The injection was administered with a 22-gauze, 1.5-inch needle via a lateral approach with the patient sitting up. Injections were repeated after 2 weeks. Two injections with this interinjection interval were selected due to the size of the bursa and possibility of adhesions, requiring multiple injections. If patients were symptom-free after the first injection, no more injections would be given. All of the injections were administered by a senior physician who was a board-qualified physiatrist and	<u>N (%)</u> <u>Reasons (describe)</u> <u>Control:</u> <u>N (%)</u> <u>Reasons (describe)</u>	C: 14.1 (21.5) **Function** using SPADI I: 24.8 (21.7) C: 28 (23.8) Using WORC I: 592.3 (485.7) C: 647.4 (547.5) **Complications** **Risk of recurrence** Recurrence of symptoms in 24 weeks, Yes I: 3 (7%) C: 6 (17%)	obtained using a 100-mm-long horizontal line, with 0 mm on the left indicating no pain and 100 mm on the right indicating most imaginable pain. The SPADI, a self-administered questionnaire used to assess the pain and disability associated with shoulder diseases, consists of 13 items that are divided into 2 subclasses, with 5 items for pain and 8 items for disabilities. The total SPADI score ranges between 0 and 100, with a higher score indicating a worse condition. The SDQ is a symptoms-related questionnaire containing 16 items

		fracture, dislocation or surgery of the affected shoulder; (3) evidence of a rotator cuff tear or tendinopathy, demonstrated by positive resistive tests and/or ultrasonographic findings; (4) calcification of the rotator cuff, demonstrated by X-ray or ultrasonographic findings; (5) the presence of arthritis (or >30% limitation of passive range of motion on shoulder abduction or external rotation) or instability of the affected shoulder; (6) the presence of cervical	maintain scapular neutral position when doing shoulder flexion, abduction, internal and external rotation to the full range. Once scapular control was improved, resistance exercises of the rotator cuff and muscles related to scapular control (serratus anterior, middle and lower trapezius muscles, etc.) were added to the programme. The physiotherapy programme was supervised by a senior physical therapist and was conducted 3 times/week, for 8 weeks.	ultrasonographer in musculoskeletal medicine.		**Patient satisfaction** Patients evaluation I: 3.1 (1.7) C: 3.7 (1.1) **Return to work / active participation** Not reported	describing common situations that may induce symptoms in patients with shoulder disorders. The final score ranges between 0 (no disability) and 100 (the worst situation). The minimal clinical important difference of SDQ is unknown. Patient's evaluation of the treatment effect included the answer to one question: 'Is the treatment effective?' scored on a Likert scale (very effective =1, effective=2, no change=3, worse =4, much worse=5). Recurrence was defined as a new episode of moderate shoulder pain lasting more than

		radiculopathy or myelopathy; and (7) having received a corticosteroid subacromial or shoulder joint injection in the past 3 months. <u>N total at baseline</u>: *Patients were divided into corticosteroid injection (N=36), physiotherapy (N=40) and combined (N=35) groups. Two corticosteroid subdeltoid injections in corticosteroid group, 8-week phys ical therapy emphasising on therapeutic exercise in*					1 day following a period of at least 1 week pain free (pain intensity 0 or 1) or as an episode of care seeking for the same problem.

		physiotherapy group, and combined both treatments in combined group total: 96 patients Intervention: 28 Control: 32 <u>Important prognostic factors</u>[2]: *For example* *Mean age (year):* I: 56.9 years C: 54.2 years *Gender, Female* I: 25 (62%) C: 23 (66%) <u>Groups comparable at baseline?</u> Yes					
Raeeshi (2022)	<u>Study design</u>: Double-blind, parallel Randomized	<u>Inclusion criteria</u> (1) were Persian native speakers; (2) were aged 18–	<u>Describe intervention (treatment/procedure/ test):</u>	<u>Describe control (treatment/procedure/ test):</u>	<u>Length of follow-up:</u> 6 months	<u>Outcome measures and effect size</u>	**Comments:** Trial registration number:

	Controlled Trial (RCT) <u>Setting and Country</u>: The trial was carried out in a primary care-based physiotherapy service run by specialist practitioners that treat patients with a range of musculoskeletal conditions – a physiotherapist specializing in shoulder conditions for more than five years. An orthopaedist undertook clinical assessments of recruited patients according to eligibility criteria. Patients with SAPS	70; (3) Confirmed to have SAPS using the clinical cluster testing (more than three positive tests out of five): painful-arc motion during flexion or abduction, Hawkins-Kennedy test (shoulder elevation to 90 degrees, elbow flexed to 90 degrees, then passively internally rotate the humerus) , pain or weakness on resisted lateral rotation or abduction, Neer impingement test, and Empty can (Jobe) test, (4) have shoulder pain for more than 4 weeks, with the severity of more than three points	Physiotherapy group with a program including an individually tailored exercise and manual therapy program prescribed and supervised by a physiotherapist, involving up to 12 face-to-face sessions over 4 weeks (n=25); patients in the physiotherapy group started their program immediately after randomization. Both groups received a handout pamphlet about managing their symptomatic shoulder and were discouraged, but not prohibited, from seeking additional care during the study period.	Combined group with the same treatment program, preceded by corticosteroid injection (n=25). The corticosteroid, composed of 1cc triamhexal mixed with 2cc lidocaine, was injected using an anterolateral approach with a 20mm needle (Sterican, B. Braun Melsungen AG) and a 5cc syringe. Patients in the combined group received one landmark-guided injection in the shoulder subacromial bursa by an orthopedic surgeon. Patients were advised to take care of their shoulders and avoid heavy lifting for 48 hours post-injection. Patients in	<u>Loss-to-follow-up:</u> <u>Intervention:</u> <u>N (%): 1</u> <u>Reasons (describe)</u> <u>Control:</u> <u>N (%): 20</u> <u>Reasons (describe)</u> <u>Incomplete outcome data:</u> <u>Intervention:</u> <u>N (%)</u> <u>Reasons (describe)</u> <u>Control:</u> <u>N (%)</u> <u>Reasons (describe)</u>	<u>(include 95%CI and p-value if available):</u> *3 months follow-up* **Pain** *Using the VAS (Mean, SD)* I: 3.05 (2.17) C: 1.19 (1.36) Cohen's d: 1.02, 99% CI 0.35 to 3.35 **Function** *Using the SPADI* I: 21.79 (13.11) C: 10.04 (10.49) Cohen's d:	IRCT20201010048980N1 Conclusion: In conclusion, evidence obtained from this study indicates that the effects of physiotherapy plus corticosteroid injection could be more clinically effective and long-lasting than physiotherapy alone in improving pain intensity, disability, quality of life, and treatment effectiveness in patients with SAPS in the medium-term. The pain intensity was assessed using a Visual Analog Scale (VAS). Patients were asked to determine their pain intensity on a 0–10 points scale in

	symptoms, recruited from various sources, were referred to an orthopaedic shoulder specialist to be identified whether they had the criteria to enter the study. <u>Source of funding and conflicts of interest:</u> <u>Funding:</u> Acknowledgement This study is part of MSc thesis of Mr. Javad Raeesi. Special thanks to Mashhad University of Medical Sciences (MUMS) for the support [Master thesis grant no: 981570]. Also, we acknowledge the staff of the Rehabilitation	(moderate or severe) based on the Visual Analog Scale (VAS). (corticosteroid injection is not routinely used for mild pain). <u>Exclusion criteria:</u> (1) Red flags as stated in the BESS guideline; (2) Previous shoulder surgery, dislocation, or fracture; (3) Bilateral shoulder pain, concomitant cervical radicular pain, or shoulder pain referred from the cervical spine that can be provoked by active neck movement; (4) Clinical signs of full-thickness rotator cuff tear; (5) Other shoulder		the combined group started their physiotherapy program between 4 and 7days after the injection. Both groups received a handout pamphlet about managing their symptomatic shoulder and were discouraged, but not prohibited, from seeking additional care during the study period.		0.98, 99% CI 1.92 to 21.55 *Using the DASH* I: 23.33 (16.42) C: 8.70 (9.55) Cohen's d: 1.08, 99% CI 3.48 to 25.76 *Using the WORC* I: 19.24 (12.99) C: 12.41 (12.01) Cohen's d: 0.54, 99% CI -3.48 to 17.15 *6 months follow-up* **Pain**	which 0 indicates no pain and 10 indicates the most severe pain experienced. Disability was assessed using two self-reported questionnaires: The Shortened Disability of the Arm, Shoulder, and Hand (Quick-DASH) questionnaire and the Shoulder Pain and Disability Index (SPADI). The Quick-DASH, which its Persian version has been validated to use in Iran (with a 0.89 ICC score), comprises 11 items that measure upper limb physical disabilities and symptoms. Final scores range from 0 to 100 ("no disability" to "completely disabled"). The SPADI is a 0 to 100-point, 13-

	section of the Ghem Hospital, MUMS, IR; especially Mr Zarandi, who provided valuable assistance in sample collection. This work was supported by a MSc thesis grant from Mashhad University of Medical Sciences (MUMS), Mashhad, Iran [Master thesis grant no: 981570]. <u>Conflict:</u> None of the authors has any financial or other interests relating to the manuscript to be submitted for publication in the Journal of Disability and Rehabilitation.	disorders (e.g., frozen shoulder and/or severe degenerative joint disease); (6) Systematic pathologies including arthritis or neurological disease affecting the shoulder; (7) History of receiving corticosteroid injections or any physiotherapy intervention for shoulder pain within the last 6 months; (8) Contraindications to corticosteroid injection including pregnancy. <u>N total at baseline</u>: Intervention: 22 Control: 21 <u>Important prognostic</u>				*Using the VAS (Mean, SD)* I: 2.23 (1.99) C: 0.62 (0.59) Cohen's d: 1.08, 99% CI 0.35 to 3.35. **Function** *Using the SPADI* I: 18.18 (16.93) C: 6.87 (6.97) Cohen's d: 0,86, 99% CI 0.54 to 22.07 *Using the DASH* I: 19.09 (18.90) C: 4.26 (5.08)	item, self-administered questionnaire (lesser scores express poor outcomes) divided into two subscales: a 5-item pain subscale and an 8-item disability subscale. The Persian version of SPADI has been validated to use in Iran and has adequate responsiveness to clinical changes in shoulder disorders [33]. Our primary outcome was SPADI due to prior sample sizing calculation on disability. **Cohen's d** of 0.2, 0.5, 0.8 are considered small, medium and large effect sizes respectively

		<u>factors</u>[2]: *For example* *Mean age (SD):* I: 45.27 (13.09) C: 50.62 (12.49) *Gender, Female (n, %)* I: 9 (41%) C: 13 (62%) <u>Groups comparable at baseline?</u> Yes				Cohen's d: 1.05, 99% CI 3.30 to 26.35 *Using the WORC* I: 18.45 (15.70) C: 6.57 (7.56) Cohen's d : 0.95, 99% CI 1.64 to 22.11. **Complications** Not reported **Risk of recurrence** Not reported **Patient satisfaction not reported**	

						Not reported **Return to work / active participation** **Not reported** Not reported	
ElGendy (2023)	Study design: This study was a three-arm parallel-group, assessor, and patient-blinded, randomized controlled trial. Setting and Country: This study was performed at the physical therapy outpatient clinic of El-Safa General Hospital,	Inclusion criteria To be eligible, the individual should present SIS for more than 3 mos without signs of chronic inflammation or shoulder degeneration. The included patients were diagnosed by an orthopedist with a stage II Neer classification of unilateral SIS. Two or more of the	Describe intervention (treatment/procedure/ test): Participants in group B received CPT programs only	Describe control (treatment/procedure/ test): Participants allocated to group A received a CPT program for SIS three times per week for 4 wks, plus a dose of LCI applied in the first week of the exercise program. A trained orthopedist applied 40 mg triamcinolone acetonide plus 1%	Length of follow-up: Up to 12 weeks Loss-to-follow-up: Not reported, solely that *''63 were randomized to receive the interventions and*	Outcome measures and effect size (include 95%CI and p-value if available): *4 weeks* **Pain** *SPADI (0-100), mean* ± SD I: 30.09 ± 19.61	**Comments:** The protocol of this study was prospectively registered at Pan African Clinical Trial Registry (PACTR201910650013453). Conclusion: The addition of extracorporeal shock wave therapy to CPT (conventional physiotherapy)

	Damietta, Egypt, between September 2019 and October 2021. <u>Source of funding and conflicts of interest:</u> <u>Funding:</u> <u>Conflict:</u> Financial disclosure statements have been obtained, and no conflicts of interest have been reported by the authors or by any individuals in control of the content of this article.	following provocative tests for SIS were positive in the patients: Neer test, painful arc test, Hawkins-Kennedy test, and external rotation test. <u>Exclusion criteria:</u> Patients were excluded from the study if they had a body mass index >30 kg/m2, frozen shoulders, rheumatoid arthritis, arthritis of the shoulder, shoulder instability, previous shoulder surgery or trauma, history of dislocation/subluxation of the shoulder, fracture of the shoulder girdle, congenital		xylocaine to the subacromial space using the posterior approach. The physiotherapy program included shoulder mobilizations, scapular muscle exercises, and rotator cuff strengthening exercises	*60 completed both follow-ups at 4 and 12 wks''* <u>Intervention:</u> <u>N (%): 1</u> <u>Reasons (describe)</u> <u>Control:</u> <u>N (%): 20</u> <u>Reasons (describe)</u> <u>Incomplete outcome data:</u> <u>Intervention:</u> <u>N (%)</u> <u>Reasons (describe)</u> <u>Control:</u> <u>N (%)</u> <u>Reasons (describe)</u>	C: 23.28 ± 11.86 **<u>Function</u>** Not reported **<u>Complications</u>** Not reported **<u>Risk of recurrence</u>** Not reported **<u>Patient satisfaction</u>** Not reported **<u>Return to work / active participation</u>** Not reported	induced more noticeable intermediate-term effects than CPT plus local corticosteroid injection or CPT alone. The SPADI is a self-reported, planned, reliable, and valid questionnaire, which contains 13 questions assigned to a five-item pain domain and an eight-item disability domain. Each item was scored on a visual analog scale from 0 (no problem) to 10 (worst difficulty or pain). The total sum score varies from 0 to 100 (with a higher score indicating greater glenohumeral joint pain and disability). The physiotherapist responsible for the

		anomalies or internal metallic fixation of the shoulder, gout, cervical radiculopathy, full-thickness tear of the rotator cuff, neurologic or systemic diseases (as diabetes mellitus), previous LCI or ESWT of the shoulder, systemic lupus erythematosus, radiotherapy to shoulder, tumor of the shoulder, pacemaker, and physiotherapeutic shoulder treatment within the last 3 mos. <u>N total at baseline</u>: 60 Intervention: 20 Control: 20				*12 weeks* **<u>Pain</u>** *SPADI (0-100), mean* ± SD I: 32.23 ± 19.88 C: 22.39 ± 11.08 **<u>Function</u>** Not reported **<u>Complications</u>** Not reported **<u>Risk of recurrence</u>** Not reported **<u>Patient satisfaction</u>** Not reported	CPT program asked the participants about the presence of undesired effects such as transient pain, swelling and bruising at the site of application, and surface skin redness.

		Important prognostic factors[2]: *For example* *Mean age (year):* I: 32.72 ± 4.38 C: 30.47 ± 3.69 Groups comparable at baseline? Yes				**Return to work / active participation** Not reported	

Risk of bias Tables

Crawshaw (2011); GRADE is already performed in the NHG search. Some concerns of bias (Bias, confounding, and other reasons for caution. There are certain limitations to this study. Because of the pragmatic design, participants were not blinded to their interventions and there might have been a placebo or non-specific effect caused by the injection. The total treatment response probably includes both the treatment and associated placebo effects, as is the case in routine clinical practice).

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?** Definitely yes Probably yes Probably no Definitely no	**Was the allocation adequately concealed?** Definitely yes Probably yes Probably no Definitely no	**Blinding: Was knowledge of the allocated interventions adequately prevented?** **Were patients blinded?** **Were healthcare providers blinded?** **Were data collectors blinded?** **Were outcome assessors blinded?** **Were data analysts blinded?** Definitely yes Probably yes Probably no Definitely no	**Was loss to follow-up (missing outcome data) infrequent?** Definitely yes Probably yes Probably no Definitely no	**Are reports of the study free of selective outcome reporting?** Definitely yes Probably yes Probably no Definitely no	**Was the study apparently free of other problems that could put it at a risk of bias?** Definitely yes Probably yes Probably no Definitely no	**Overall risk of bias** **If applicable/necessary, per outcome measure** **LOW** **Some concerns** **HIGH**

Hajivandi, 2021	Probably yes Reason: Reported in text: *''A total of 96 patients were randomly assigned to the study and divided into 3 groups of 32 patients''*	Probably no Reason: Concealment of allocation not reported.	Probably no Reason: Blinding not reported.	Probably yes Reason: Loss to follow-up not reported	Definitely yes Reason: All outcome measures reported	Probably yes Reason: No other problems noted	Some concerns of bias
Hsieh (2023)	Definitely yes Reason: Groups were composed after randomization; The assignment scheme was generated using a table of computer-generated random numbers, which was placed into opaque, sealed envelopes. Each patient was allocated to one of the treatment groups according to the randomisation sequence.	Definitely yes Reason: Groups were composed after randomization; The assignment scheme was generated using a table of computer-generated random numbers, which was placed into opaque, sealed envelopes. Each patient was allocated to one of the treatment groups according to the randomisation sequence.	Probably yes Reason: Solely reported that the outcome assessor was blind to the treatment assignment.	Probably yes; Reason: Loss to follow up was not reported overall, however numbers were presented regarding loss to follow up at 28 weeks post intervention when measuring recurrence. In text referred as ''T*hird, a high percentage of loss to follow up in the physiotherapy group might inter fere with data analysis*.''	Definitely yes Reason: All outcome measures reported	Probably yes Reason: No other problems noted	Low concerns of bias

Raeesi (2022)	Definitely yes <u>Reason:</u> patients' baseline assessment (pre-test outcome) was gathered, and then they were randomly allocated (1:1) to either the combined (physiotherapy plus corticosteroid injection) group or the physiotherapy group to start their intervention protocol. An independent practitioner randomized patients with a simple, balanced process into two intervention groups using	Definitely yes <u>Reason:</u> An independent practitioner randomized patients with a simple, balanced process into two intervention groups using sequentially numbered cards (a computer software program generated sequential numbers) sealed in opaque envelopes to ensure concealed allocation.	Probably yes <u>Reason:</u> Since both intervention programs are prescribed routinely in SAPS's treatment protocol, patients' blinding would not violate ethics. However, although each group received intervention on different days (a group on odd days and another on even days) to reduce the biased effect of being acknowledged about having corticosteroid injection or not, the study's patients were not assessed regarding their blinding, and we cannot completely support our patients' blinding. The physiotherapist delivering	Probably yes <u>Reason:</u> Loss to follow up not reported	Definitely yes <u>Reason:</u> All outcome measures reported	Probably yes <u>Reason:</u> No other problems noted	Some concerns of bias

	sequentially numbered cards (a computer software program generated sequential numbers) sealed in opaque envelopes to ensure concealed allocation.		the intervention was not blind to the treatment allocation due to the different treatment methods (Corticosteroid injection in the combined group), but the trial assessor and statistician were blinded to the treatment allocation throughout the study period. Therefore, this study can be considered a double-blind clinical trial with the trial assessor and statistician blinding.				
ElGendy (2023)	Definitely yes <u>Reason;</u> An independent physiotherapist (not involved in the trial application and not informed of the study protocol) built a computer list that was used for the randomly allocated sequence in a 1:1 ratio. The	Definitely yes <u>Reason;</u> An independent physiotherapist (not involved in the trial application and not informed of the study protocol) built a computer list that was used for the randomly allocated sequence in a 1:1 ratio. The physiotherapist placed	Probably yes <u>Reason:</u> Patients were blinded before assignment to their corresponding groups (i.e., the patients were not aware of the interventional procedures of all groups). The assessor responsible for evaluating the participants' outcomes was also unaware of the	Probably yes <u>Reason:</u> Loss to follow-up occurred minimally	Definitely yes <u>Reason:</u> All outcome measures reported	Probably yes <u>Reason:</u> No other problems noted	Low concerns of bias

	physiotherapist placed the names of the patients in closed envelopes to confirm allocation concealment. Each envelope was opened by a nurse before the first treatment session. Patients were randomly assigned to receive conventional physiotherapy plus LCI (group A, n = 20), conventional physiotherapy alone (group B, n = 20), or conventional physiotherapy plus ESWT (group C, n = 20).	the names of the patients in closed envelopes to confirm allocation concealment. Each envelope was opened by a nurse before the first treatment session. Patients were randomly assigned to receive conventional physiotherapy plus LCI (group A, n = 20), conventional physiotherapy alone (group B, n = 20), or conventional physiotherapy plus ESWT (group C, n = 20).	participants' group allocation.				

Table of excluded studies

Reference	Reason for exclusion
Daghiani M, Negahban H, Ebrahimzadeh MH, Moradi A, Kachooei AR, Raeesi J, Divandari A. The effectiveness of comprehensive physiotherapy compared with corticosteroid injection on pain, disability, treatment effectiveness, and quality of life in patients with subacromial pain syndrome: a parallel, single-blind, randomized controlled trial. Physiother Theory Pract. 2023 Aug 3;39(8):1591-1605. doi: 10.1080/09593985.2022.2044421. Epub 2022 Mar 5. PMID: 35253581.	Wrong comparison
Comparison of subacromial corticosteroid injection and physical therapy in patients with subacromial impingement syndrome: A prospective, randomized trial	Wrong comparison
Hopewell S, Keene DJ, Heine P, Marian IR, Dritsaki M, Cureton L, Dutton SJ, Dakin H, Carr A, Hamilton W, Hansen Z, Jaggi A, Littlewood C, Barker K, Gray A, Lamb SE. Progressive exercise compared with best-practice advice, with or without corticosteroid injection, for rotator cuff disorders: the GRASP factorial RCT. Health Technol Assess. 2021 Aug;25(48):1-158. doi: 10.3310/hta25480. Erratum in: Health Technol Assess. 2022 Aug;25(48):159-160. PMID: 34382931; PMCID: PMC9421560.	Findings for comparison in our PICO are not presented. The results here are incorrect. Overarching (see numbers per group in e.g. table 15) targets everyone with progressive exercise and not the subgroup (so 2 groups) Same when comparing injection vs non-injection Displays the SPADI scores for e.g. the injection group which includes the following two subgroups: -corticosteroid injection then progressive exercise (n = 182) (six or fewer physiotherapy sessions) or -corticosteroid injection then best-practice advice (n = 178) (one physiotherapy session).
Hopewell S, Keene DJ, Marian IR, Dritsaki M, Heine P, Cureton L, Dutton SJ, Dakin H, Carr A, Hamilton W, Hansen Z, Jaggi A, Littlewood C, Barker KL, Gray A, Lamb SE; GRASP Trial Group. Progressive exercise compared with best practice advice, with or without corticosteroid injection, for the treatment of patients with rotator cuff disorders (GRASP): a multicentre, pragmatic, 2 × 2 factorial, randomised controlled trial. Lancet. 2021 Jul 31;398(10298):416-428. doi: 10.1016/S0140-6736(21)00846-1. Epub 2021 Jul 12. PMID: 34265255; PMCID: PMC8343092.	The GRASP trial is a 2×2 factorial trial, which was used to test the following four physiotherapy-led interventions: 1. Progressive exercise programme (i.e. an individually tailored, progressive, home exercise programme prescribed and supervised by a physiotherapist, involving up to six face-to-face sessions over 16 weeks). 2. best-practice advice (i.e. one face-to-face session with a physiotherapist and a home exercise programme supported by high-quality self-management materials). 3. Progressive exercise programme (as

	described above) preceded by a subacromial corticosteroid injection. 4. best-practice advice session (as described above) preceded by a subacromial corticosteroid injection. A parallel within-trial health economic analysis was also conducted. The factorial design allowed two primary comparisons, based on the assumption that there was no interaction effect: (1) progressive exercise programme compared with best-practice advice session and (2) subacromial corticosteroid injection compared with no injection
Ramírez-Ortiz J, Mendoza-Eufracio JD, García-Viveros MR, Márquez-Celedonio FG. Costo-efectividad de esteroides locales combinados con ejercicio terapéutico en síndrome de pinzamiento subacromial [Cost-effectiveness of local steroid combined with therapeutic exercise in subacromial impingement syndrome]. Rev Med Inst Mex Seguro Soc. 2017 Sep-Oct;55(5):608-614. Spanish. PMID: 29193943.	not equal to exercise therapy by physiotherapist or exercise therapist: ''HOME REHABILITATION: GUIDE TO CLINICAL PRACTICE is the first clinical reference for therapists practicing in the home care setting''
Roddy E, Ogollah RO, Oppong R, Zwierska I, Datta P, Hall A, Hay E, Jackson S, Jowett S, Lewis M, Shufflebotham J, Stevenson K, van der Windt DA, Young J, Foster NE. Optimising outcomes of exercise and corticosteroid injection in patients with subacromial pain (impingement) syndrome: a factorial randomised trial. Br J Sports Med. 2021 Mar;55(5):262-271. doi: 10.1136/bjsports-2019-101268. Epub 2020 Aug 19. PMID: 32816787; PMCID: PMC7907566.	No group with solely exercise therapy
Babatunde OO, Ensor J, Littlewood C, Chesterton L, Jordan JL, Corp N, Wynne-Jones G, Roddy E, Foster NE, van der Windt DA. Comparative effectiveness of treatment options for subacromial shoulder conditions: a systematic review and network meta-analysis. Ther Adv Musculoskelet Dis. 2021 Sep 9;13:1759720X211037530. doi: 10.1177/1759720X211037530. PMID: 34527083; PMCID: PMC8435933.	wrong design: netwerk meta-analysis. A systematic search of databases, MEDLINE, Embase, PEDro, AMED, CINAHL, Web of Science and the Cochrane Central Register of Controlled Trials from their inceptions to November 2017, was conducted. This search was updated in April 2020 to include newly published, eligible studies. Total of: ''Summary estimates (based on 99 trials providing suitable data, 6764 patients, 20 treatment options''. study published in 2020: then, 4 of the included studies were > 10 years old.
Babatunde OO, Jordan JL, Van der Windt DA,	Different P: patients with one of the five

Hill JC, Foster NE, Protheroe J. Effective treatment options for musculoskeletal pain in primary care: A systematic overview of current evidence. PLoS One. 2017 Jun 22;12(6):e0178621. doi: 10.1371/journal.pone.0178621. PMID: 28640822; PMCID: PMC5480856.	most common musculoskeletal pain presentations (back, neck, shoulder, knee and multi-site pain)
Gelber JD. CORR Insights®: Corticosteroid Injections Give Small and Transient Pain Relief in Rotator Cuff Tendinosis: A Meta-analysis. Clin Orthop Relat Res. 2017 Jan;475(1):244-246. doi: 10.1007/s11999-016-5044-4. Epub 2016 Aug 29. PMID: 27572298; PMCID: PMC5174046.	Wrong comparison
Lavoie-Gagne O, Farah G, Lu Y, Mehta N, Parvaresh KC, Forsythe B. Physical Therapy Combined With Subacromial Cortisone Injection Is a First-Line Treatment Whereas Acromioplasty With Physical Therapy Is Best if Nonoperative Interventions Fail for the Management of Subacromial Impingement: A Systematic Review and Network Meta-Analysis. Arthroscopy. 2022 Aug;38(8):2511-2524. doi: 10.1016/j.arthro.2022.02.008. Epub 2022 Feb 19. PMID: 35189304.	CSI vs. CSI + PT vs. PT (zie afbeelding). Arthroscopic decompression with acromioplasty and PT demonstrated superior outcomes whereas CSI demonstrated poor outcomes in all 3 domains (pain, PROMs, and ROM). For patients with significant symptoms, the authors recommend PT with CSI as a first-line treatment, followed by acromioplasty and PT if conservative treatment fails.
Buyuksireci DE, Turk AC. Evaluation of the effectiveness of dexamethasone iontophoresis in patients with subacromial impingement syndrome. J Orthop Sci. 2021 Sep;26(5):786-791. doi: 10.1016/j.jos.2020.09.007. Epub 2020 Oct 27. PMID: 33127212.	wrong comparison: ''Forty-six patients with subacromial impingement syndrome were recruited to the study and divided randomly into two groups (21 patients in iontophoresis group and 25 patients in control group)''
Göksu H, Tuncay F, Borman P. The comparative efficacy of kinesio taping and local injection therapy in patients with subacromial impingement syndrome. Acta Orthop Traumatol Turc. 2016 Oct;50(5):483-488. doi: 10.1016/j.aott.2016.08.015. Epub 2016 Sep 23. PMID: 27670388; PMCID: PMC6197412.	Wrong comparison
Marian IR, Hopewell S, Keene DJ, Cureton L, Lamb SE, Dutton SJ. Progressive exercise compared with best practice advice, with or without corticosteroid injection, for the treatment of rotator cuff disorders: statistical analysis plan for the Getting it Right: Addressing Shoulder Pain (GRASP) 2 × 2 factorial multicentre randomised controlled trial. Trials. 2020 Sep 7;21(1):767. doi: 10.1186/s13063-020-04704-5. PMID: 32894159; PMCID: PMC7487843.	The main analysis will be conducted as for two separate comparisons: (i) participants who receive progressive ex ercise compared to those who receive best practice ad vice, to determine the effectiveness of progressive exercise and (ii) participants who receive subacromial corticosteroid injection compared to those who do not, to determine the effectiveness of subacromial cortico steroid injection.

Oppong R, Jowett S, Lewis M, Roddy E, Ogollah RO, Zwierska I, Datta P, Hall A, Hay E, Shufflebotham J, Stevenson K, van der Windt DA, Young J, Foster NE. The cost-effectiveness of different approaches to exercise and corticosteroid injection for subacromial pain (impingement) syndrome. Rheumatology (Oxford). 2021 Sep 1;60(9):4175-4184. doi: 10.1093/rheumatology/keaa903. PMID: 33410493.	cost-effectiveness study; no clinical outcomes assessed
Benjamin-Damons N, Hussein El Kout NAR, van Bever Donker R, Edwards T, Ferguson G. Corticosteroid therapy versus physiotherapy on pain, mobility and function in shoulder impingement: A short note. S Afr J Physiother. 2022 Dec 12;78(1):1794. doi: 10.4102/sajp.v78i1.1794. PMID: 36569457; PMCID: PMC9772720.	included rcts in this TiAb more recent (2017 onwards). The three studies included here are; This evidence statement is based on a systematic review and meta-analysis of three randomised controlled trials (RCTs), namely, Rhon et al. (2014) (n = 136), Hay et al. (2003) (n = 207) and Van der Windt et al. (1998) (n = 109), with a total of 452 participants (more dated studies).
Benjamin-Damons N, Hussein El Kout NAR, van Bever Donker R, Edwards T, Ferguson G. Corticosteroid therapy versus physiotherapy on pain, mobility and function in shoulder impingement: A short note. S Afr J Physiother. 2022 Dec 12;78(1):1794. doi: 10.4102/sajp.v78i1.1794. PMID: 36569457; PMCID: PMC9772720.	we incuded more recent RCTs in this tiAb compared to the article (respectively 1998, 2003 and 2014); in the article stated that ''Only randomised controlled trials (RCTs) published in English from inception of the databases until February 2016 were eligible for inclusion in this review''
Pasin T, Ataoğlu S, Pasin Ö, Ankarali H. Comparison of the Effectiveness of Platelet-Rich Plasma, Corticosteroid, and Physical Therapy in Subacromial Impingement Syndrome. Arch Rheumatol. 2019 Mar 28;34(3):308-316. doi: 10.5606/ArchRheumatol.2019.7225. PMID: 31598597; PMCID: PMC6768781.	group 1 = reference groep. Comparison is compared to subacrominal joint space: and PRP compared to. physical therapy

Literature search strategy

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: NOV Subacromiaal Pijnsyndroom van de Schouder (SAPS)	
Uitgangsvraag/modules: UV7.2 oefentherapie vs corticosteroïdinjectie	
Database(s): Embase.com, Ovid/Medline	Datum: 8 maart 2024
Periode: vanaf 2017 (searchdate NHG richtlijn)	Talen: geen restrictie
Literatuurspecialist: Alies Oost	Rayyan review: https://rayyan.ai/reviews/959635
BMI-zoekblokken: voor verschillende opdrachten wordt (deels) gebruik gemaakt van de zoekblokken van BMI-Online https://blocks.bmi-online.nl/ Deduplication: voor het ontdubbelen is gebruik gemaakt van http://dedupendnote.nl/	
Toelichting: Voor deze vraag is gezocht op de elementen: - Subacromiaal Pijnsyndroom van de Schouder (SAPS) - Corticosteroïdinjectie - Oefentherapie → In overleg met de adviseur is ervoor gekozen om te zoeken naar interventie en comparison.	
Te gebruiken voor richtlijntekst: In de databases Embase.com en Ovid/Medline is op 8 maart 2024 systematisch gezocht naar systematische reviews en RCTs over subacromiaal pijnsyndroom van de schouder (SAPS) en corticosteroidinjectie vs oefentherapie. De literatuurzoekactie leverde 264 unieke treffers op.	

Zoekopbrengst

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	86	55	101
RCT	133	86	163
Totaal	219	141	**264***

****in Rayyan***

Zoekstrategie

Embase.com

No.	**Query**	**Results**
#1	'shoulder impingement syndrome'/exp OR 'shoulder impingement syndrome':ti,ab,kw OR 'subacromial impingement syndrome':ti,ab,kw OR (((subacromial OR shoulder) NEAR/3 pain*):ti,ab,kw) OR (('bursitis'/exp OR bursitis:ti,ab,kw OR 'tendinitis'/exp OR tendinitis:ti,ab,kw OR 'impingement':ti,ab,kw)	37131

	AND ('shoulder'/exp OR 'rotator cuff':ti,ab,kw OR acromion:ti,ab,kw OR acromial:ti,ab,kw OR subacromial:ti,ab,kw OR shoulder*:ti,ab,kw)) OR 'rotator cuff injury'/exp OR 'rotator cuff rupture'/exp OR ((('rotator cuff' OR 'shoulder cuff' OR infraspinatus OR supraspinatus OR subscapularis) NEAR/3 (tear* OR lesion* OR rupture* OR tendinopath* OR laceration*)):ti,ab,kw) OR (('full-thickness':ti,ab,kw OR partial:ti,ab,kw) AND 'rotator cuff':ti,ab,kw) OR ('rotator cuff'/exp AND ('rupture'/exp OR 'injury'/de OR 'laceration'/exp))	
#2	'corticosteroid'/exp OR 'corticosteroid therapy'/exp OR corticosteroid*:ti,ab,kw OR glucocortico*:ti,ab,kw OR 'adrenal cortex hormone*':ti,ab,kw OR 'adrenal steroid*':ti,ab,kw OR corticoid*:ti,ab,kw OR corticotherap*:ti,ab,kw OR 'steroid'/exp OR 'steroid therapy'/exp OR 'cyclosteroid*':ti,ab,kw OR 'steroid*':ti,ab,kw OR 'triamcinolone'/exp OR 'triamcinolone derivative'/exp OR 'triamcinolon*':ti,ab,kw	2156208
#3	'physiotherapy'/exp OR 'kinesiotherapy'/exp OR 'occupational therapy'/exp OR kinesiotherap*:ti,ab,kw OR 'occupation* therap*':ti,ab,kw OR ergotherap*:ti,ab,kw OR exercis*:ti,ab,kw OR physiotherap*:ti,ab,kw OR 'physio therap*':ti,ab,kw OR 'physical therap*':ti,ab,kw OR (((functional OR muscular) NEAR/3 training):ti,ab,kw) OR 'manual therap*':ti,ab,kw OR 'manipulat* therap*':ti,ab,kw OR ((musculoskeletal NEAR/3 manipulation*):ti,ab,kw)	728720
#4	#1 AND #2 AND #3 NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp) AND [01-01-2017]/sd	468
#5	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	1008329
#6	'clinical trial'/exp OR 'randomization'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR 'placebo'/exp OR 'prospective study'/exp OR rct:ab,ti OR random*:ab,ti OR 'single blind':ab,ti OR 'randomised	3987109

	controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	
#7	#4 AND #5 - SR	86
#8	#4 AND #6 NOT #7 - RCT	133
#9	#7 OR #8	219

Ovid/Medline

#	Searches	Results
1	Shoulder Impingement Syndrome/ or 'shoulder impingement syndrome'.ti,ab,kf. or 'subacromial impingement syndrome'.ti,ab,kf. or ((subacromial or shoulder) adj3 pain*).ti,ab,kf. or ((exp bursitis/ or exp Tendinopathy/ or bursitis.ti,ab,kf. or tendinitis.ti,ab,kf. or 'impingement'.ti,ab,kf.) and (exp Shoulder/ or 'rotator cuff'.ti,ab,kf. or acromion.ti,ab,kf. or acromial.ti,ab,kf. or subacromial.ti,ab,kf. or shoulder*.ti,ab,kf.)) or Rotator Cuff/ or exp Rotator Cuff Injuries/ or (('rotator cuff' or 'shoulder cuff' or infraspinatus or supraspinatus or subscapularis) adj3 (tear* or lesion* or rupture* or tendinopath* or laceration*)).ti,ab,kf. or (('full-thickness' or partial) and 'rotator cuff').ti,ab,kf.	29934
2	exp Adrenal Cortex Hormones/ or corticosteroid*.ti,ab,kf. or glucocortico*.ti,ab,kf. or 'adrenal cortex hormone*'.ti,ab,kf. or 'adrenal steroid*'.ti,ab,kf. or corticoid*.ti,ab,kf. or corticotherap*.ti,ab,kf. or exp Steroids/ or 'cyclosteroid*'.ti,ab,kf. or 'steroid*'.ti,ab,kf. or exp Triamcinolone/ or 'triamcinolon*'.ti,ab,kf.	1247865
3	exp Physical Therapy Modalities/ or exp Occupational Therapy/ or kinesiotherap*.ti,ab,kf. or 'occupation* therap*'.ti,ab,kf. or ergotherap*.ti,ab,kf. or exercis*.ti,ab,kf. or physiotherap*.ti,ab,kf. or 'physio therap*'.ti,ab,kf. or 'physical therap*'.ti,ab,kf. or ((functional or muscular) adj3 training).ti,ab,kf. or 'manual therap*'.ti,ab,kf. or 'manipulat* therap*'.ti,ab,kf. or (musculoskeletal adj3 manipulation*).ti,ab,kf.	564636
4	(1 and 2 and 3) not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	639
5	limit 4 to dt="20170101-20240308"	258
6	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	730984
7	exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti,ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind$3 or mask$3)).tw. or Placebos/ or placebo*.tw.	2698926
8	5 and 6 - SR	55

9	(5 and 7) not 8 - RCT	86
10	8 or 9	141

Module 4.3 Nervus suprascapularis blokkade

Uitgangsvraag
Wat is de waarde van nervus suprascapularis blokkade bij patienten met SAPS?

Introduction (English)
Conservative therapy with physical therapy, oral medication and subacromial corticosteroid injections is the standard in the treatment of SAPS. The effectiveness of these therapies can be disappointing in terms of pain reduction and function improvement and therefore suprascapular nerve blocks are increasingly used. Suprascapular nerve blocks may be more effective in reducing symptoms in SAPS patients, also for a longer period of time.

Search and select
A systematic review of the literature was performed to answer the following question:
What is the effectiveness of suprascapularis blokkade vs. corticosteroid injection in SAPS patients on patient-reported outcome measures?

Patients	patients with SAPS
Intervention	suprascapular nerve block (SSNB)
Control	subacromial infiltration with corticosteroid
Outcomes	pain reduction, function (constant Murley score), quality of life, rehabilitation time, return to work or leisure

Relevant outcome measures
The guideline development group considered **pain and function** (Constant Murley Score) as a critical outcome measure for decision making; and **quality of life, rehabilitation time, and return to work or leisure** as important outcome measures for decision making.

The guideline development group defined the outcome measures as follows:
- Patient reported outcomes measures for function: Constant Murley Score (CMS)
- Pain: VAS-scale (0-10 points or 0-100mm scale)
- Quality of life: the working group did not define this outcome measure but used the definitions used in the studies.
- Rehabilitation time: the guideline development group did not define this outcome measure but used the definitions used in the studies.
- Return to work or leisure: definitions used in the studies

The guideline development group defined the minimal clinically (patient) important differences as follows:
- Patient reported outcome measures:
    - CMS: 15 points on a 100-point scale (Holmgren, 2014; Louwerens, 2020)
- Pain
    - 1/10 points or 10/100 points on a VAS scale
- Quality of life:
    - The guideline development group used the GRADE standard limit of 25% as a minimal clinically (patient) important difference for dichotomous outcomes and 10% for continuous variables.
- Rehabilitation time:

    - The guideline development group used the GRADE standard limit of 25% as a minimal clinically (patient) important difference for dichotomous outcomes and 10% for continuous variables.
- Return to work or leisure: difference of 25% (RR ≤ 0.80 and ≥ 1.25)

Search and select (Methods)
The databases Embase.com, Ovid/Medline were searched with relevant search terms until 16-10-2023. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 269 hits. Studies were selected based on the following criteria:

- Study design: randomized controlled trial or systematic review
- Patients with SAPS
- Comparing intervening with a suprascapular nerve block (SSNB) versus subacromial infiltration with corticosteroid in order to reduce symptoms and to rehabilitate/recover from SAPS
- Describing at least one of the relevant outcomes specified in the PICO
- Published from 2013
- Follow-up duration: at least 3 months

Two studies were initially selected based on title and abstract screening. After reading the full text, 1 study was included. Chang (2016) conducted a systematic review which included 11 RCTs. The I and C specified in our PICO was met in 4/11 of these RCTs. These 4 RCTs were included separately (Jones and Chattopadhyay (1999); Taskaynatan et al., 2005; Adbelshafi et al., 2011; Eyigor et al., 2010). However, after reading the full-text, these four RCTs were also excluded (see the table with reasons for exclusion under the tab Methods).

Results
No studies were included in the analysis of the literature.

Summary of literature
Description of studies
No studies reported on the impact of suprascapularis nerve block compared with corticosteroid injection in SAPS patients.

Results
Pain reduction
No results could be reported as no studies report the impact of suprascapularis nerve block compared to subacromial corticosteroid injection in SAPS patients.

Function (constant Murley score)
No results could be reported as no studies report the impact of suprascapularis nerve block compared to subacromial corticosteroid injection in SAPS patients.

Quality of life
No results could be reported as no studies report the impact of suprascapularis nerve block compared to subacromial corticosteroid injection in SAPS patients.

Rehabilitation time
No results could be reported as no studies report the impact of suprascapularis nerve block compared to subacromial corticosteroid injection in SAPS patients.

Return to work or leisure
No results could be reported as no studies report the impact of suprascapularis nerve block compared to subacromial corticosteroid injection in SAPS patients.

Level of evidence of the literature
The level of evidence regarding the outcome measure **pain reduction** could not be graded as no studies report the impact of suprascapularis nerve block compared to subacromial corticosteroid injection in SAPS patients.

The level of evidence regarding the outcome measure **function (constant murley score)** could not be graded as no studies report the impact of suprascapularis nerve block compared to subacromial corticosteroid injection in SAPS patients.

The level of evidence regarding the outcome measure **quality of life** could not be graded as no studies report the impact of suprascapularis nerve block compared to subacromial corticosteroid injection in SAPS patients.

The level of evidence regarding the outcome measure **rehabilitation time** could not be graded as no studies report the impact of suprascapularis nerve block compared to subacromial corticosteroid injection in SAPS patients.

The level of evidence regarding the outcome measure **return to work or leisure** could not be graded as no studies report the impact of suprascapularis nerve block compared to subacromial corticosteroid injection in SAPS patients.

Conclusions

No GRADE	No evidence was found regarding the effect of suprascapularis nerve block compared to subacromial corticosteroid injection on **pain reduction** in SAPS patients. *Source: -*

No GRADE	No evidence was found regarding the effect of suprascapularis nerve block compared to subacromial corticosteroid injection on **function (constant murley score)** in SAPS patients. *Source: -*

No GRADE	No evidence was found regarding the effect of suprascapularis nerve block compared to subacromial corticosteroid injection on **quality of life** in SAPS patients. *Source: -*

No GRADE	No evidence was found regarding the effect of suprascapularis nerve block compared to subacromial corticosteroid injection on **rehabilitation time** in SAPS patients. *Source: -*

No GRADE	No evidence was found regarding the effect of suprascapularis nerve block compared to subacromial corticosteroid injection on **return to work or leisure** in SAPS patients. *Source: -*

Overwegingen – van bewijs naar aanbeveling

Voor- en nadelen van de interventie en de kwaliteit van het bewijs

Er is een systematisch literatuuronderzoek verricht naar de impact van een nervus suprascapularis blokkade bij SAPS patiënten (met intacte rotator cuff) vergeleken met het effect van een subacromiale corticosteroïdinjectie. Er werd geen literatuur gevonden waarin het effect van een suprascapularis blokkade werd vergeleken met een injectie met corticosteroïden bij SAPS. Op basis van de literatuur kan er nog geen conclusie getrokken worden over de impact van een suprascapularis blokkade in vergelijking met de veel vaker gebruikte subacromiale corticosteroïd injectie bij SAPS-patiënten. Er bestaat hier een evidente kennisvraag. Aanbevelingen op basis van de literatuur kunnen dan ook niet worden gegeven.

In de literatuur is gekeken naar de effectiviteit van een nervus suprascapularis blokkade bij mensen met pijnklachten bij SAPS. Uit de volledige literatuur search kwam slechts één studie naar voren die iets zou kunnen zeggen over een supraclaviculaire blokkade in vergelijking met huidige conservatieve therapie. Chang (2016) publiceerde een systematische review waarin elf studies zijn vergeleken. Na individuele analyse van de RCTs voldeden vier van de elf betrokken RCTs aan de I(nterventie) van de tevoren bepaalde PICO voor dit onderdeel van deze richtlijn. De vier RCTs werden separaat geïncludeerd (Jones and Chattopadhyay, 1999); Taskaynatan, 2005; Adbelshafi, 2011; Eyigor, 2010). Na het lezen van de complete tekst bleek dat deze RCTs allen geëxcludeerd dienden te worden (zie hiervoor de tabel met redenen voor exclusie onder de tab methods). De bewijskracht voor de cruciale uitkomstmaten pijn, patiënttevredenheid en complicaties en de overall bewijskracht komt daarmee op *niet aanwezig*. Nieuwe studies zijn noodzakelijk om te komen tot nieuwe inzichten met betrekking tot de uitgangsvraag.

Met het vaststellen van geen bewijskracht is niet gezegd dat er geen effect is van een nervus suprascapularis blokkade behandeling bij therapieresistente SAPS. Hierbij neemt de werkgroep het volgende in overweging.

De positieve studieresultaten van nervus suprascapularis blokkade bij cuff rupturen in vergelijking met een subacromiale injectie (Hussain, 2017; Coory, 2019). In de randomized controlled trial van Coory (2019) werd het effect van de nervus suprascapularis blokkade vergeleken met subacromiale injectie voor pijn bij cuff rupturen. Bij een follow-up duur van twaalf weken werd een significant betere functie volgens de Constant-Murley score gezien en significant minder pijn bij de groep met een nervus suprascapularis blokkade. Op eerdere tijdspunten in de follow-up werd dit effect nog niet gevonden. In een systematische review en meta-analyse van Hussain (2017) werd het pijnstillende effect van een nervus suprascapularis blokkade vergeleken met een interscaleen blok voor schouder chirurgie. In vergelijking met het interscaleen blok is de nervus suprascapularis blokkade niet inferieur voor de pijnstilling en heeft het minder complicatie risico's.

De nervus suprascapularis blokkade behandeling wordt in Nederland steeds vaker toegepast bij therapieresistente patiënten waar geen andere behandelopties voor zijn. De kosten van de behandeling zijn laag en er zijn weinig complicaties.

Er is een grote behoefte aan gerichte studies die kunnen zorgen voor vergroten van de bewijslast van deze behandeling en advies is de behandeling vooral in studieverband aan te bieden. De aanbeveling is daarom om de onderzoeksvraag op te nemen als kennisvraag op de wetenschapsagenda van de wetenschappelijke beroepsvereniging.

De nervus suprascapularis blokkade kan relatief makkelijk middels een naald met lokaal analgeticum of pulsed radiofrequency worden verkregen. Aangeraden wordt de blokkade echogeleid te plaatsten waarbij een anesthesie succes van 99,8% wordt beschreven met lage complicatierisico's (Bergamaschi, 2024 ; Kalthoff, 2022).

De nervus suprascapularis blokkade kan tot 70% van de schoudersensibiliteit verminderen. Deze zenuw is namelijk de belangrijkste sensorische zenuw naar het bovenste deel van de schouder. Het bevat de sensorische takken naar het acromioclaviculaire gewricht, de subacromiale ruimte, de rotator cuff, de regio rondom het coracoïd en een deel van het superieure labrumcomplex (Coory, 2019).

In de literatuur worden tegenstrijdige uitkomsten beschreven over effectiviteit van de nervus suprascapularis blokkade. De pijn verbetert het meest in combinatie met andere blokkades op het gebied van VAS score en PROMS, maar de suprascapularis blokkade op zichzelf zorgt ook voor minder pijn en analgetica gebruik naast de blokkade (Kalthoff, 2022; Lee, 2017). De pulsed radiofrequency blokkade heeft mogelijk een beter pijnstillend effect tot twaalf weken na interventie in vergelijking met lokale anesthesie, wat acht tot twaalf weken een pijnstillend effect kan hebben (Bergamaschi, 2024; Kalthoff, 2022; Coory, 2019).

Risico's zijn zenuwtrauma of -beschadiging, infectie, hematoom, pijn door de interventie en eventuele toxiciteit van het anestheticum. De nervus suprascapularis blokkade heeft een verminderd risico op complicaties in vergelijking met andere blokkades (Kalthoff, 2022; white 2022; Hussain, 2017).

Waarden en voorkeuren van patiënten (en evt. hun verzorgers)
De meeste SAPS patiënten die voor een nervus suprascapularis blokkade in aanmerking komen, hebben al alle andere opties binnen het conservatieve behandeltraject doorlopen met onvoldoende tot geen resultaat. De werkgroep geeft de voorkeur aan een beslissing in samenspraak met de patiënt, waarbij de voor- en nadelen worden afgewogen.

Kosten (middelenbeslag)
De werkgroep verwacht dat een nervus suprascapularis blokkade behandeling als interventie bescheiden kosten met zich meebrengt. Echter vraagt de behandeling om aanvullende diagnostiek middels echografie en is andere expertise noodzakelijk voor een nervus suprascapularis blokkade wanneer je dit vergelijkt met een subacromiale injectie met corticosteroïd. Deze poliklinische behandeling zal naar verwachting rond de €250 aan anesthesiologische consultkosten en materiaalkosten in beslag nemen.

Aanvaardbaarheid, haalbaarheid en implementatie
Op het gebied van aanvaardbaarheid, haalbaarheid en implementatie voorziet de werkgroep geen grote uitdagingen. De behandeling wordt op diverse plekken in Nederland reeds uitgevoerd. De werkgroep voorziet geen grote haalbaarheid en implementatie barrières.

Aanbevelingen
Rationale van de aanbeveling: weging van argumenten voor en tegen de interventies
Hoewel de bewijskracht er niet is, acht de werkgroep op basis van praktijkervaring, expert opinion en overige literatuur dat een nervus suprascapularis blokkade te overwegen is bij patiënten met therapieresistente SAPS waarbij andere behandelopties geen keuze meer zijn, na samen beslissen met de patiënt. Daarnaast is de aanbeveling aan de wetenschappelijke

beroepsvereniging de kennisvraag toe te voegen aan de wetenschapsagenda voor verder onderzoek.

Overweeg samen met de patient (met voorlichting over werking en bijwerking) om nervus suprascapularis blokkade toe te passen bij patiënten met therapieresistente SAPS, met als doel om pijnverlichting te bewerkstelligen indien eerdere adequate conservatieve therapie onvoldoende effectief is gebleken.

Kennisvragen

De werkgroep geeft de aanbeveling om de onderzoeksvraag op te nemen als kennisvraag op de wetenschapsagenda van de wetenschappelijke beroepsvereniging: *''What is the effectiveness of suprascapularis blokade vs. corticosteroid injection in SAPS patients on patient-reported outcome measures?''*

Een RCT opzetten met deze PICO moet zeker goed aanvaardbaar en haalbaar zijn. Bij goede resultaten zal de verwachting zijn dat ook de implementatie in de dagelijkse kliniek snel doorgang zal kunnen vinden.

Literatuur

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Bijlagen bij module 4.3. Nervus suprascapularis blokkade

Implementatieplan

Aanbeveling	Tijdspad voor implementatie: < 1 jaar, 1 tot 3 jaar of > 3 jaar	Verwacht effect op kosten	Randvoorwaarden voor implementatie (binnen aangegeven tijdspad)	Mogelijke barrières voor implementatie	Te ondernemen acties voor implementatie	Verantwoordelijken voor acties	Overige opmerkingen
Overweeg samen met de patient (met voorlichting over werking en bijwerking) om nervus suprascapularis blokkade toe te passen bij patiënten met therapieresistente SAPS, met als doel om pijnverlichting te bewerkstelligen indien eerdere adequate conservatieve therapie onvoldoende effectief is gebleken.	< 1 jaar	Mogelijk extra kosten consult anesthesiologische interventie. Geraamd op €250,- per behandeling.	Goede multidisciplinaire samenwerking. Behandelaar aanwezig in zorginstelling die interventie kan uitvoeren. Lokale richtlijn waarin alle andere conservatieve therapie doorlopen dient te zijn.	Geen expertise in zorginstelling die de interventie kan uitvoeren.	Kosten en baten in kaart brengen en vergoeding interventie bij zorgverzekering nagaan. Goede multidisciplinaire samenwerking en verwachting/”lokale” richtlijn aanpassen.	NOV/Werkgroep schouder en elleboog.	-

Table of excluded studies

Reference	Reason for exclusion
Chang KV, Hung CY, Wu WT, Han DS, Yang RS, Lin CP. Comparison of the Effectiveness of Suprascapular Nerve Block With Physical Therapy, Placebo, and Intra-Articular Injection in Management of Chronic Shoulder Pain: A Meta-Analysis of Randomized Controlled Trials. Arch Phys Med Rehabil. 2016 Aug;97(8):1366-80. doi: 10.1016/j.apmr.2015.11.009. Epub 2015 Dec 14. PMID: 26701762.	Additionally checked the validity of this article/search method of this meta-analysis by the literature specialist. The literature specialist states that the search is not valid, due to various reasons, a.o.: the search strategy is not clearly formulated; do not report which medical subject heading and text words were used; do not specify separate search terms; do not use Embase despite Embase being the most extensive database in the field of medication.
Reference included from Chang (2016): Jones DS, Chattopadhyay C. Suprascapular nerve block for the treatment of frozen shoulder in primary care: a randomized trial. Br J Gen Pract. 1999 Jan;49(438):39-41. PMID: 10622015; PMCID: PMC1313316	Patients in this study had frozen shoulder. Frozen shoulder does not correspond with the definition in the SAPS guidelines and the P in our PICO.
Reference included from Chang (2016): Taskaynatan MA, Yilmaz B, Ozgul A, Yazicioglu K, Kalyon TA. Suprascapular nerve block versus steroid injection for non-specific shoulder pain. Tohoku J Exp Med. 2005 Jan;205(1):19-25. doi: 10.1620/tjem.205.19. PMID: 15635270.	Follow-up does not correspond with the duration defined in our PICO. In this article, the measurements occurred respectively 1 week and 1 month after the intervention(s).
Reference included from Chang (2016): Abdelshafi ME, Yosry M, Elmulla AF, Al-Shahawy EA, Adou Aly M, Eliewa EA. Relief of chronic shoulder pain: a comparative study of three approaches. Middle East J Anaesthesiol. 2011 Feb;21(1):83-92. PMID: 21991738	C differs from the C in our comparison
Reference included from Chang (2016): Eyigor C, Eyigor S, Korkmaz OK, Uyar M. Intra-articular corticosteroid injections versus pulsed radiofrequency in painful shoulder: a prospective, randomized, single-blinded study. Clin J Pain. 2010 Jun;26(5):386-92. doi: 10.1097/AJP.0b013e3181cf5981. PMID: 20473045.	Wrong comparison
Yilmaz, E. A prospective, comparative study of subacromial corticosteroid injection and subacromial corticosteroid injection plus suprascapular nerve block in patients with shoulder impingement syndrome. Archives of Orthopaedic and Trauma Surgery. 2021; 141 (5) :733-741	wrong comparison: studied the combination effect of the I and C in our PICO *[subacromial corticosteroid injection (SCI) vs. SCI plus suprascapular nerve block (SSNB)'']*

Literature search strategy

De volgende databases zijn onderzocht: Embase.com en Ovid/Medline. Zoekstrategie is uitgevoerd op 16 oktober 2023. Resulteerde in 269 hits.

Zoekopbrengst

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	55	39	55
RCT	186	145	214
Observationeel	88	73	108
Totaal	241	184	**269***

in Rayyan

Zoekstrategie Embase.com 16-10-2023

No.	Query	Results
#1	'shoulder impingement syndrome'/exp OR 'shoulder impingement syndrome':ti,ab,kw OR 'subacromial impingement syndrome':ti,ab,kw OR (((subacromial OR shoulder) NEAR/3 pain*):ti,ab,kw) OR (('bursitis'/exp OR bursitis:ti,ab,kw OR 'tendinitis'/exp OR tendinitis:ti,ab,kw OR 'impingement':ti,ab,kw) AND ('shoulder'/exp OR 'rotator cuff':ti,ab,kw OR acromion:ti,ab,kw OR acromial:ti,ab,kw OR subacromial:ti,ab,kw OR shoulder*:ti,ab,kw)) OR 'rotator cuff injury'/exp OR 'rotator cuff rupture'/exp OR ((('rotator cuff' OR 'shoulder cuff' OR infraspinatus OR supraspinatus OR subscapularis) NEAR/3 (tear* OR lesion* OR rupture* OR tendinopath* OR laceration*)):ti,ab,kw) OR (('full-thickness':ti,ab,kw OR partial:ti,ab,kw) AND 'rotator cuff':ti,ab,kw) OR ('rotator cuff'/exp AND ('rupture'/exp OR 'injury'/de OR 'laceration'/exp))	36149
#2	'suprascapular nerve block'/exp OR 'nerve block'/exp OR (((nerve* OR neuro* OR suprascapular OR supraclavicular OR brachial) NEAR/3 block*):ti,ab,kw) OR ssnb:ti,ab,kw	84041
#3	#1 AND #2	966
#4	#3 NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	678
#5	#4 AND [2013-2023]/py	445
#6	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab	969507

	OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	
#7	'clinical trial'/exp OR 'randomization'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR 'placebo'/exp OR 'prospective study'/exp OR rct:ab,ti OR random*:ab,ti OR 'single blind':ab,ti OR 'randomised controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	3892820
#8	'major clinical study'/de OR 'clinical study'/de OR 'case control study'/de OR 'family study'/de OR 'longitudinal study'/de OR 'retrospective study'/de OR 'prospective study'/de OR 'comparative study'/de OR 'cohort analysis'/de OR ((cohort NEAR/1 (study OR studies)):ab,ti) OR (('case control' NEAR/1 (study OR studies)):ab,ti) OR (('follow up' NEAR/1 (study OR studies)):ab,ti) OR (observational NEAR/1 (study OR studies)) OR ((epidemiologic NEAR/1 (study OR studies)):ab,ti) OR (('cross sectional' NEAR/1 (study OR studies)):ab,ti)	7881241
#9	'case control study'/de OR 'comparative study'/exp OR 'control group'/de OR 'controlled study'/de OR 'controlled clinical trial'/de OR 'crossover procedure'/de OR 'double blind procedure'/de OR 'phase 2 clinical trial'/de OR 'phase 3 clinical trial'/de OR 'phase 4 clinical trial'/de OR 'pretest posttest design'/de OR 'pretest posttest control group design'/de OR 'quasi experimental study'/de OR 'single blind procedure'/de OR 'triple blind procedure'/de OR (((control OR controlled) NEAR/6 trial):ti,ab,kw) OR (((control OR controlled) NEAR/6 (study OR studies)):ti,ab,kw) OR (((control OR controlled) NEAR/1 active):ti,ab,kw) OR 'open label*':ti,ab,kw OR (((double OR two OR three OR multi OR trial) NEAR/1 (arm OR arms)):ti,ab,kw) OR ((allocat* NEAR/10 (arm OR arms)):ti,ab,kw) OR placebo*:ti,ab,kw OR 'sham-control*':ti,ab,kw OR (((single OR double OR triple OR assessor) NEAR/1 (blind* OR masked)):ti,ab,kw) OR nonrandom*:ti,ab,kw OR 'non-random*':ti,ab,kw OR 'quasi-experiment*':ti,ab,kw OR crossover:ti,ab,kw OR 'cross over':ti,ab,kw OR 'parallel group*':ti,ab,kw OR 'factorial trial':ti,ab,kw OR ((phase NEAR/5 (study OR trial)):ti,ab,kw) OR ((case* NEAR/6 (matched OR control*)):ti,ab,kw) OR ((match* NEAR/6 (pair OR pairs OR cohort* OR control* OR group* OR healthy OR age OR sex OR gender OR patient* OR subject* OR participant*)):ti,ab,kw) OR ((propensity NEAR/6 (scor* OR match*)):ti,ab,kw) OR versus:ti OR vs:ti OR compar*:ti OR ((compar* NEAR/1 study):ti,ab,kw) OR (('major clinical study'/de OR 'clinical study'/de OR 'cohort analysis'/de OR 'observational study'/de OR 'cross-sectional study'/de OR 'multicenter study'/de OR 'correlational study'/de OR 'follow up'/de OR cohort*:ti,ab,kw OR 'follow up':ti,ab,kw OR followup:ti,ab,kw OR longitudinal*:ti,ab,kw OR prospective*:ti,ab,kw OR retrospective*:ti,ab,kw OR observational*:ti,ab,kw OR 'cross sectional*':ti,ab,kw OR cross?ectional*:ti,ab,kw OR multicent*:ti,ab,kw OR 'multi-cent*':ti,ab,kw OR consecutive*:ti,ab,kw) AND (group:ti,ab,kw OR groups:ti,ab,kw OR subgroup*:ti,ab,kw OR versus:ti,ab,kw OR vs:ti,ab,kw OR compar*:ti,ab,kw OR 'odds ratio*':ab OR 'relative odds':ab OR 'risk ratio*':ab OR 'relative risk*':ab OR 'rate ratio':ab OR aor:ab OR arr:ab OR rrr:ab OR ((('or' OR 'rr') NEAR/6 ci):ab)))	14494134

#10	#5 AND #6 **– SR's**	55
#11	#5 AND #7 NOT #10 **– RCT's**	186
#12	#5 AND (#8 OR #9) NOT (#10 OR #11) - **Observationeel**	88
#13	#10 OR #11 OR #12	329

Ovid/Medline 16-10-2023

#	Searches	Results
1	Shoulder Impingement Syndrome/ or 'shoulder impingement syndrome'.ti,ab,kf. or 'subacromial impingement syndrome'.ti,ab,kf. or ((subacromial or shoulder) adj3 pain*).ti,ab,kf. or ((exp bursitis/ or exp Tendinopathy/ or bursitis.ti,ab,kf. or tendinitis.ti,ab,kf. or 'impingement'.ti,ab,kf.) and (exp Shoulder/ or 'rotator cuff'.ti,ab,kf. or acromion.ti,ab,kf. or acromial.ti,ab,kf. or subacromial.ti,ab,kf. or shoulder*.ti,ab,kf.)) or Rotator Cuff/ or exp Rotator Cuff Injuries/ or (('rotator cuff' or 'shoulder cuff' or infraspinatus or supraspinatus or subscapularis) adj3 (tear* or lesion* or rupture* or tendinopath* or laceration*)).ti,ab,kf. or (('full-thickness' or partial) and 'rotator cuff').ti,ab,kf.	29052
2	exp Nerve Block/ or ((nerve* or neuro* or suprascapular or supraclavicular or brachial) adj3 block*).ti,ab,kf. or ssnb.ti,ab,kf.	55198
3	1 and 2	591
4	3 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	552
5	limit 4 to yr=2013-2023	356
6	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	699693

7	exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti,ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind$3 or mask$3)).tw. or Placebos/ or placebo*.tw.	2643324
8	Epidemiologic studies/ or case control studies/ or exp cohort studies/ or Controlled Before-After Studies/ or Case control.tw. or cohort.tw. or Cohort analy$.tw. or (Follow up adj (study or studies)).tw. or (observational adj (study or studies)).tw. or Longitudinal.tw. or Retrospective*.tw. or prospective*.tw. or consecutive*.tw. or Cross sectional.tw. or Cross-sectional studies/ or historically controlled study/ or interrupted time series analysis/ [Onder exp cohort studies vallen ook longitudinale, prospectieve en retrospectieve studies]	4553864
9	Case-control Studies/ or clinical trial, phase ii/ or clinical trial, phase iii/ or clinical trial, phase iv/ or comparative study/ or control groups/ or controlled before-after studies/ or controlled clinical trial/ or double-blind method/ or historically controlled study/ or matched-pair analysis/ or single-blind method/ or (((control or controlled) adj6 (study or studies or trial)) or (compar* adj (study or studies)) or ((control or controlled) adj1 active) or "open label*" or ((double or two or three or multi or trial) adj (arm or arms)) or (allocat* adj10 (arm or arms)) or placebo* or "sham-control*" or ((single or double or triple or assessor) adj1 (blind* or masked)) or nonrandom* or "non-random*" or "quasi-experiment*" or "parallel group*" or "factorial trial" or "pretest posttest" or (phase adj5 (study or trial)) or (case* adj6 (matched or control*)) or (match* adj6 (pair or pairs or cohort* or control* or group* or healthy or age or sex or gender or patient* or subject* or participant*)) or (propensity adj6 (scor* or match*))).ti,ab,kf. or (confounding adj6 adjust*).ti,ab. or (versus or vs or compar*).ti. or ((exp cohort studies/ or epidemiologic studies/ or multicenter study/ or observational study/ or seroepidemiologic studies/ or (cohort* or 'follow up' or followup or longitudinal* or prospective* or retrospective* or observational* or multicent* or 'multi-cent*' or consecutive*).ti,ab,kf.) and ((group or groups or subgroup* or versus or vs or compar*).ti,ab,kf. or ('odds ratio*' or 'relative odds' or 'risk ratio*' or 'relative risk*' or aor or arr or rrr).ab. or (("OR" or "RR") adj6 CI).ab.))	5531506
10	5 and 6 **– SR's**	39

11	(5 and 7) not 10 **– RCT's**	145
12	(5 and (8 or 9)) not (10 or 11) **- Observationeel**	73
13	10 or 11 or 12	257

Module 5.1 Operatieve behandeling

Uitgangsvraag
Wat is de plaats van rotator cuff repair in vergelijking met oefen-/fysiotherapie (met of zonder een corticosteroïdeninjectie) bij patiënten met een geïsoleerde degeneratieve supraspinatuspeesruptuur?

Introduction (English)
A rotator cuff tear is common but does not always require surgery. A distinction needs to be made between traumatic and non-traumatic changes. Additionally, there is a difference in location and extent of degenerative cuff ruptures. It is known that subscapularis tendon ruptures are important for shoulder stability and the functioning of the long biceps tendon. Subscapularis tendon ruptures generally occur due to trauma (Ghasemi, 2023). Other traumatic rotator cuff ruptures, for example, after an anterior shoulder dislocation with good tissue quality, may indicate a need for surgical repair. In case of multi tendon tear a partial rotator cuff repair or tendon transfer can be a good indication to restore range of motion. For these reasons, traumatic and multi tendon tears are excluded from this research question. The indication and success of the repair of a non-traumatic supraspinatus tendon rupture depends on many factors (Lambers Heerspink, 2014). Together, a decision must be made whether surgery is beneficial or not.

Search and select
A systematic review of the literature was performed to answer the following question:
What is the effectivity of cuff repair compared with physiotherapy with or without corticosteroid injection on patient-reported outcome measures in adult patients (<70 years) with an isolated symptomatic, nontraumatic, supraspinatus tear?

Patients	Adults (<70 years) with an isolated symptomatic, nontraumatic, supraspinatus tear
Intervention	rotator cuff repair (surgery)
Control	physiotherapy with or without injection of corticosteroids
Outcomes	Pain, complications/adverse events, patient reported outcomes measures for function (CMS, DASH, WORC, ASES, OSS, DSST), patient satisfaction, return to work or leisure

<u>Relevant outcome measures</u>
The guideline development group considered **pain** and **function** as critical outcome measures for decision making; and **patient satisfaction**, **complications/adverse events**, and **return to work or leisure** as important outcome measures for decision making.
Results with a follow-up of 1 year and longer were considered relevant and were included in the literature summary.

The guideline development group defined the outcome measures as follows:

- Patient reported outcomes measures for function: CMS, DASH, WORC, ASES, DSST, OSS
- Pain: VAS-scale (0-10 points or 0-100mm scale)
- Complications/adverse events: re-rupture, frozen shoulder and infection
- Patient satisfaction: self-reported satisfaction with treatment and/or function
- Return to work or leisure: definitions used in the studies.

The guideline development group defined the minimal clinically (patient) important differences as follows:

- Patient reported outcome measures:
    - CMS: 15 points on a 100-point scale (Holmgren, 2014)
    - DASH: 13 on a 100 point scale (Koorevaar, 2018)
    - WORC: -282.6 on a 2100 point scale (Gagnier, 2018)
    - ASES: 9 on a 100 point scale (Gagnier, 2018)
    - DSST: 2.8 on a 12 point scale (Van Kampen, 2013)
    - OSS: 5 points on a 48-point scale (Nyring, 2021)
- Pain
    - 1/10 points or 10/100 points on a VAS scale
- Complications/adverse events:
    - Re-rupture: 5 mm difference in rupture size
    - Frozen shoulder: 25% (RR ≤ 0.80 and ≥ 1.25)
    - Infection: 25% (RR ≤ 0.80 and ≥ 1.25)
- Patient satisfaction: difference of 25% (RR ≤ 0.80 and ≥ 1.25) or 1/10 points or 10/100 points on a VAS scale.
- Return to work or leisure: difference of 25% (RR ≤ 0.80 and ≥ 1.25)

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until February 15, 2023. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 431 hits. Studies were selected based on the following criteria: 1) systematic review, meta-analysis or RCT 2) comparing rotator cuff repair surgery with physiotherapy alone or combined with corticosteroid injection 3) in adult patients aged 70 or younger 4) with an isolated symptomatic, nontraumatic, supraspinatus tear 5) reporting outcomes for pain, complications, PROMS and patient satisfaction 6) with a follow-up of 1 year and longer. Forty studies were initially selected based on title and abstract screening. After reading the full text, 32 studies were excluded (see the table with reasons for exclusion under the tab Methods), and eight publications reporting about four primary studies were included.

Results

Eight publications describing four studies and their follow-up were included in the analysis of the literature. Important study characteristics and results are summarized in the evidence tables. The assessment of the risk of bias is summarized in the risk of bias tables.

Summary of literature

Description of studies

An overview of characteristics of the included studies is presented in Table 1.

Table 1. Study descriptives

Author, year, study register	Study design	Intervention	Control	Population (type of tears, N, age)	Relevant outcome measures	Relevant follow up	Notes
Cederqvist, 2021 *NCT00695981 and NCT00637013.*	RCT	All patients first underwent a 3-months non-surgical treatment and MRI arthrography before randomized into the surgical or non-surgical treatment group. The non-surgical treatment before randomization consisted of: Physiotherapy: cold pack + exercises (3 times per week, with increasing load and decreasing repetitions over time) + stretching (glenohumeral joint), hanging exercises, manual therapy/cross-fiction massages (supraspinatus, e infraspinatus, subscapularis, teres minor, teres major muscles, trapezius, deltoid, long head of the	All patients first underwent a 3-months non-surgical treatment and MRI arthrography before randomized into the surgical or non-surgical treatment group. The non-surgical treatment before randomization consisted of: Physiotherapy: cold pack + exercises (3 times per week, with increasing load and decreasing repetitions over time) + stretching (glenohumeral joint), hanging exercises, manual therapy/cross-fiction massages (supraspinatus, e infraspinatus, subscapularis, teres minor, teres major muscles, trapezius, deltoid, long head of the triceps, and the biceps sulcus areas). Patients randomised to non-surgical treatment continued the	• *Only full-thickness tears included in the current summary, of which 88% in the intervention group and 90% in the control group were solely in the supraspinatus tendon.* Exclusion of high-energy trauma patients Full-thickness tear by MRA • N = 98 (50 vs. 48) • Mean age: 56 yr	Function: CS Pain: VAS Adverse events	Function: 2y Pain: 2y Adverse events: 2y	Group allocation (full-thickness or non-full-Thickness tendon lesion) was based on written statement made by clinical radiologist. Of these, 95 shoulders were randomised to receive surgery (50 shoulders with full-thickness ruptures, of which 44 solely in the supraspinatus tendon) and 95 to non-surgical Treatments (48 with full-thickness ruptures, of which 44 were solely in the supraspinatus tendon). In the non-surgery group, 12

		triceps, and the biceps sulcus areas). The surgical treatment consisted of: Arthroscopic or mini-open single-row surgical treatment of cuff repair. All patients underwent the same early post-surgery rehabilitation protocol.	previously initiated rehabilitation programme. It was not reported how long patients followed this program. Unsuccessful non-surgical treatment was defined as severe pain or poor subjective function in the shoulder during follow-up. These patients were offered a surgical intervention. All patients underwent the same early post-surgery rehabilitation protocol.				(13%) shoulders experienced severe pain and surgery was performed during the 2-year follow-up. In the surgery group, 36 (38%) shoulders experienced pain relief before surgery and did not undergo surgery. Shoulders treated per protocol were 75%.
Kukkonen, 2014 Kukkonen, 2015 Kukkonen 2021 NCT01116518	RCT	Repair: surgical rotator cuff repair + acromioplasty + immobilization in a sling for 3 weeks postoperatively + physiotherapy	Physiotherapy: instructions + home exercises + 10 sessions of physiotherapy The first 6 weeks of the exercise protocol aimed at improving glenohumeral motion and active scapular retraction, after which static and dynamic exercises to improve scapular and glenohumeral muscle function were gradually increased until 12 weeks. Thereafter, the patient increased resistance and strength training up to 6 months. In addition to	• Atraumatic symptomatic supraspinatus tendon tear comprising <75% of the tendon insertion and documented with MRI • N = 120 (60 vs. 60) • Mean age: 65 yr	Function: CS Pain: VAS Patient satisfaction: dichotomous question	Function: 1y, 2y, 5y Pain: 1y, 2y, 5y Patient satisfaction: 1y, 2y, 5y	There were eight cross-over cases in the physiotherapy group, and two cross-over cases in the acromioplasty and physiotherapy group.

			receiving written instructions, the patient was referred to undergo 10 sessions of physiotherapy at an outpatient health care facility.				
Lambers Heerspink, 2015 Netherlands Trial Registry (NTR TC 2343)	RCT	Repair: Open surgical treatment / repair. 14/25 augmented with bone anchors	Conservative treatment: Subacromial steroid infiltration, physiotherapy, and analgesic medication; further options: analgesic medication with NSAIDs, paracetamol, or tramadol). In weeks 4 to 6, exercises were gradually increased, and deltoid training was started. In weeks 6 to 12, rehabilitation was aimed at further optimization of mobility and strength regeneration of the remaining cuff and deltoid. Physical therapy was continued until patients reached an optimum range of motion and an improvement in strength was achieved.	• Degenerative, nontraumatic full-thickness rotator cuff tears • N = 56 (25 vs. 31) • Mean age = 61 yr	Function: CS Pain: VAS	Function: 1y Pain: 1y	Three patients were dissatisfied with the result of conservative treatment. A decision was made to perform rotator cuff repair and the patients discontinued their primary intervention
Moosmayer, 2010 Moosmayer, 2014 Moosmayer, 2019	RCT	Repair: Surgical treatment of cuff repair (through a deltoid splitting approach, anteroinferior acromioplasty was performed).	Physiotherapy: physiotherapy and exercises. Treatment sessions of 40 minutes were given twice weekly for 12 weeks and with decreasing frequency during the following 6 to 12 weeks.	• Full-thickness tear by sonography and MRI (traumatic or atraumatic) • N = 103 (52 vs. 51)	Function: CS, ASES Pain: VAS Patient satisfaction: VAS	Function: 1y, 2y, 5y, 10y Pain: 1y, 2y, 5y, 10y Patient satisfaction:	Fourteen patients (27%) in the physiotherapy group reported an insufficient treatment result from physiotherapy and

NCT00852657		Patients who were unsatisfied with their results after a minimum of 15 physiotherapy sessions and who had persistent clinical findings were offered a secondary surgical treatment.	Patients who were unsatisfied with their results after a minimum of 15 physiotherapy sessions and who had persistent clinical findings were offered a secondary surgical treatment.	• Mean age = 60 yr		1y, 2y, 5y, 10y	crossed over to secondary surgery (9 patients during the first year, 3 patients between 1 and 2 years, and 2 patients between 5 and 10 years). Treatment was by secondary tendon repair in 12 cases and, because of patient preference, by acromioplasty in 2 cases.

Results

1. **PROMS – Function**

Constant Murley Score (CMS)
1-year follow-up
Three studies reported the 1-year follow-up using the Constant-Murley score (CMS)(Figure 1). This scale ranges from 0 to 100 and a higher score indicates a better function.

The mean difference (MD) for Kukkonen et al. was 3.90 (95% CI -1.05 to 8.85).
The MD for Lambers Heerspink (2015) was 8.20 (95% CI -1.74 to 18.14).
The MD for Moosmayer et al. was 7.40 (95% CI 1.00 to 13.80).

The pooled MD was 5.61 (95% CI 1.97 to 9.26), in favor of surgery. This difference is not considered to be clinically relevant.

2-year follow-up
Three studies reported the 2-year follow-up using the CMS (Figure 1). This scale ranges from 0 to 100 and a higher score indicates a better function.
Two studies reported the absolute values at time of follow-up.

The MD for Kukkonen et al. was 4.20 (95% CI -0.48 to 8.88).
The MD for Moosmayer et al. was 1.60 (95% CI -3.97 to 7.17).

The pooled MD was 3.12 (95% CI -0.46 to 6.71), in favor of surgery. This difference is not considered to be clinically relevant.

Cederqvist (2021) reported the change in CMS score from baseline to 2-year follow-up. The change was +20.0 (SD 16.18) in the intervention group and +13.0 (SD 16.18) in the control group. The MD was 7.00 (95% CI 1.99 to 12.01), in favor of surgery. This difference is not considered to be clinically relevant.

5-year follow-up
Two studies reported the 5-year follow-up using the CMS (Figure 1). This scale ranges from 0 to 100 and a higher score indicates a better function.

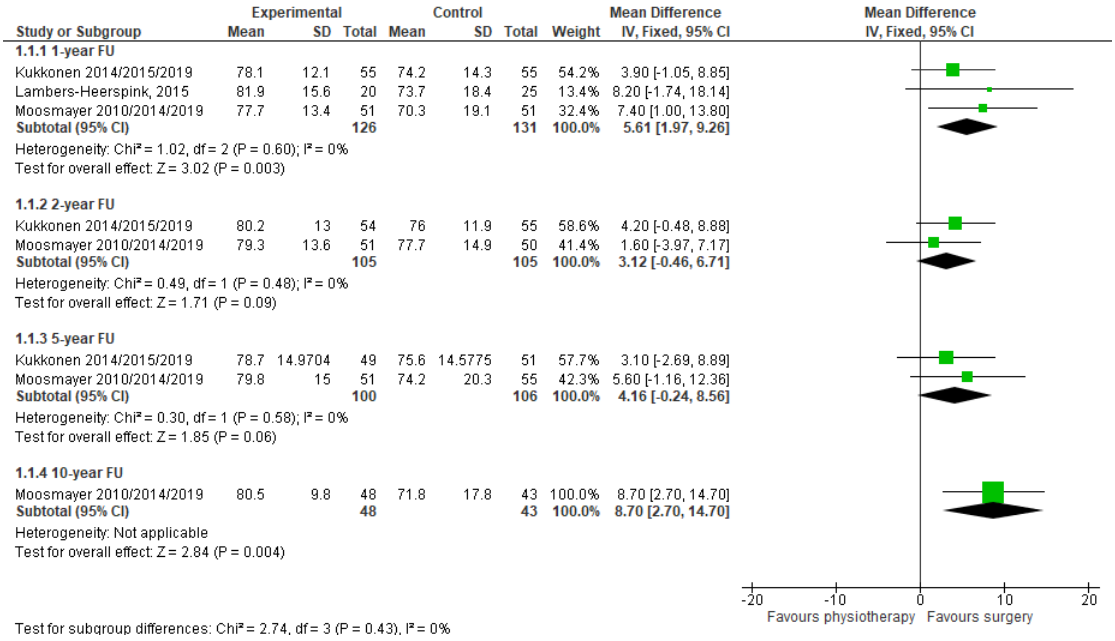
The MD for Kukkonen et al. was 3.10 (95% CI -2.69 to 8.89).
The MD for Moosmayer et al. was 5.60 (95% CI -1.16 to 12.36).

The pooled MD was 4.16 (95% CI -0.24 to 8.56), in favor of surgery. This difference is not considered to be clinically relevant.

10-year follow-up
One study reported the 10-year follow-up using the CMS (Figure 1) and ASES. These scales range from 0 to 100 and a higher score indicates a better function.

Moosmayer et al. reported that the CMS score after primary tendon repair was 80.5 (SD 9.8) in the intervention group and 71.8 (SD 17.8) in the control group. The MD was 8.70 (95% CI 2.70 to 14.70), in favor of surgery. This difference is not considered clinically relevant.
After secondary surgery, the mean Constant scores increased by 33.9 points (SD 19.7), which is less than that achieved in the primary surgery group (41.4 points). The MD was 7.5 (95% CI 0.9 to 19.2) in favor of surgery (Moosmayer, 2019). This difference is not considered clinically relevant.

Figure 1. The effect of rotator cuff repair surgery on function, measured with the Constant Murley Score



Abbreviations: FU, follow-up.

Disabilities of the Arm, Shoulder and Hand (DASH)

No study reported the DASH.

The Western Ontario Rotator Cuff (WORC)

No study reported the WORC.

American Society of Shoulder and Elbow Surgeons (ASES)

1-year follow-up

Moosmayer et al. also reported the American Society of Shoulder and Elbow Surgeons (ASES) score. This score ranges from 0 to 100 and a higher score indicates a better function. The ASES score was 93.6 (SD 12.5) in the intervention group and 83.6 (SD 18.3) in the control group. The MD was 10.00 (95% CI 3.92 to 16.08) in favor of surgery. This difference is considered to be clinically relevant.

2-year follow-up

Moosmayer et al. also reported the ASES score. The ASES score was 93.1 (SD 13.9) in the intervention group and 88.0 (SD 14.9) in the control group. The MD was 5.10 (95% CI -0.52 to 10.72), in favor of surgery. This difference is not considered to be clinically relevant.

5-year follow-up

Moosmayer et al. also reported the ASES score. The ASES score was 92.8 (SD 13.3) in the intervention group and 85.4 (SD 21.0) in the control group. The MD was 7.40 (95% CI 0.76 to 14.04), in favor of surgery. This difference is not considered to be clinically relevant.

10-year follow-up

Moosmayer et al. reported that the ASES score was 94.0 (SD 9.5) in the intervention group and 80.0 (SD 20.2) in the control group. The MD was 14.00 (95% CI 7.39 to 20.61), in favor of surgery. This difference is considered to be clinically relevant.

Dutch Simple Shoulder Test (DSST)

1-year follow-up
Lambers Heerspink (2015) reported the Dutch Simple Shoulder Test (DSST) scores. This score ranges from 0 to 100 and a higher score indicates a better function. The DSST score was 11.0 (SD 2.8) in the intervention group and 9.7 (SD 3.6) in the control group. The MD was 1.30 (95% CI -1.35 to 3.95), in favor of surgery. This difference is not considered to be clinically relevant.

2, 5 and 10-year follow-up
No studies reported the DSST at 2, 5 and 10 years follow-up.

Oxford Shoulder Score (OSS)
No study reported the OSS.

2. Pain

1- year follow-up
Three studies reported the 1-year follow-up using the VAS score. This scale ranges from 0 to 10 and a higher score indicates more pain.

The MD for Kukkonen et al. was -0.30 (95% CI -1.05 to 0.45).
The MD for Lambers Heerspink (2015) was -1.00 (95% CI -2.17, 0.17).
The MD for Moosmayer et al. was -1.10 (95% CI -1.65, -0.55).

The pooled MD was -0.81 (95% CI -1.35 to -0.28; figure 2), in favor of surgery. This difference is not considered clinically relevant.

2 years follow-up
Three studies reported the 2-year follow-up using the VAS score. This scale ranges from 0 to 10 and a higher score indicates more pain.
Two studies reported the absolute values at time of follow-up.

The MD for Kukkonen et al. was -0.80 (95% CI -1.50, -0.10).
The MD for Moosmayer et al. was -0.70 (95% CI -1.27, -0.13).

The pooled MD was -0.74 (95% CI -1.18 to -0.30; figure 2), in favor of surgery. This difference is not considered clinically relevant.

Cederqvist (2021) reported the change in pain score from baseline to 2-year follow-up on a 0-100 VAS scale. The change score was -37.0 (SD 26.96) in the intervention group and -24.0 (SD 26.96) in the control group. The MD was 13.00 (95% CI -4.64 to 21.36), in favor of surgery. This difference is considered clinically relevant.

5 years follow-up
Two studies reported the 5-year follow-up using the VAS score. This scale ranges from 0 to 10 and a higher score indicates more pain.

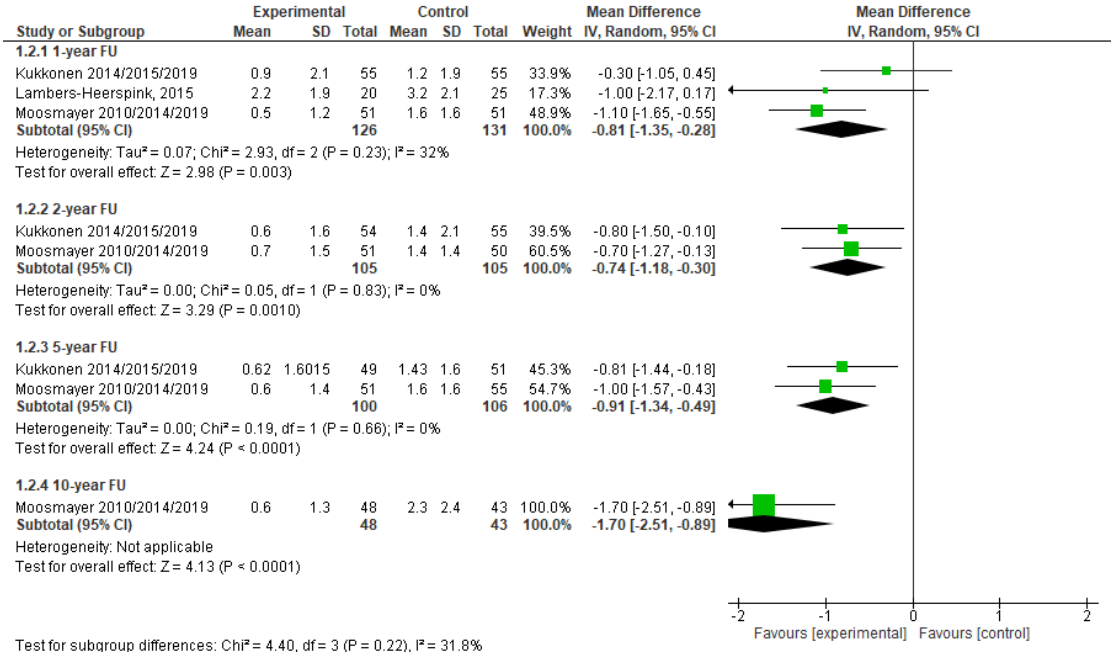
The MD for Kukkonen et al. was -0.81 (95% CI -1.44, -0.18).
The MD for Moosmayer et al. was -1.00 (95% CI -1.57, -0.43).

The pooled MD was -0.91 (95% CI -1.34, -0.49; figure 2), in favor of surgery. This difference is not considered clinically relevant.

10 years follow-up
One study reported the 10-year follow-up using the VAS score. This scale ranges from 0 to 10 and a higher score indicates more pain. Moosmayer et al. reported that the VAS score was 0.6 (SD 1.3) in the intervention group and 2.3 (SD 2.4) in the control group. The MD was

-1.70 (95% CI -2.51 to -0.89; figure 2), in favor of surgery. This difference is considered to be clinically relevant.

Figure 2. The effect of rotator cuff repair surgery on pain



3. Patient satisfaction

Three studies reported about patient satisfaction.

Kukkonen et al. reported the percentage of patients that were satisfied with the treatment outcome.

At 1-year follow-up, 95% of the intervention group and 87% of the control group were satisfied with the treatment outcome (difference of 7%).

At 2-year follow-up, 94% of the intervention group and 89% of the control group were satisfied with the treatment outcome (difference of 5%).

At 10-year follow-up, 92% of the intervention group and 88% of the control group were satisfied with the treatment outcome (difference of 4%).

These differences are in favor of surgery, but are not considered to be clinically relevant.

Moosmayer et al. reported patient satisfaction as measures on a VAS scale ranging from 0 to 10 with a higher score indicating more satisfaction.

At 1-year follow-up, the VAS score was 9.0 (SD 28.4) in the intervention group and 7.2 (SD 25.6) in the control group. The MD was 1.80 [-8.70, 12.30), in favor of surgery. This difference is considered to be clinically relevant.

At 5-year follow-up, the VAS score was 9.2 (SD or CI not reported) in the intervention group and 8.3 (SD or CI not reported) in the control group. The MD was 1.0 cm (95% CI 0.1 to 1.8), in favor of surgery. This difference is considered to be clinically relevant.

At 10-year follow-up, the VAS score was 9.2 (SD or CI not reported) in the intervention group and 8.2 (SD or CI not reported) in the control group. The MD was 0.97 cm (95% CI 0.13 to 1.82), in favor of surgery. This difference is not considered to be clinically relevant.

4. Complications/adverse events

Moosmayer (2019) reported tear size for 32 patients treated by physiotherapy only (assessed with sonographic tear size measurement at baseline and at 5- and 10-year follow-up), and for 47 patients who were treated by primary repair (assessed with MRI after one year and by sonography after 5 and 10 years). In the physiotherapy group (n=32), tear size increased from baseline to 10-year follow-up with 10.1 mm (95% CI 5.7 to 14.4) in the anterior-posterior plane and with 6.3 mm (95% CI 2.9 to 9.8) in the medial-lateral plane. A total of 19 patients (59%) had an increase of tear size greater than 5 mm, and 13 patients (41%) had an increase of tear size of ≥10 mm. Patients with tears with widening of >10 mm had a Constant score of 63.9 points, an outcome that was inferior by 14.0 points (95% CI, 4.1 to 24.0 points; p = 0.007) compared with the score of 78 points in patients with tears with widening of <10mm. These quantitative findings however do not represent a comparison between the physiotherapy and primary repair groups and therefore clinically relevance is not stated.

In the primary repair group (n=47), an increasing number of full or partial thickness retears was found: 10 (21%) after one year, 13 (28%) after 5 years, and 16 (34%) after 10 years.

Cederqvist (2021) reported that no patients required re-operation and no serious adverse events were noted. Kukkonen et al. reported that no treatment-related complications occurred in any group. Lambers Heerspink et al. did not report about the occurrence of complications.

5. Return to work or leisure

Not reported.

Level of evidence of the literature
The level of evidence started at high, as included studies were RCTs.

1. **PROMS – Function**

Constant Murley Score (CMS)
1-year follow-up
The level of evidence regarding the outcome measure *function*, measured with the CMS at 1 year follow-up, was downgraded by three levels to a **very low GRADE**, because of study limitations (-1; risk of bias), applicability of the results due to the inclusion of traumatic tears in Moosmayer et al. (-1, bias due to indirectness), and a small number of included patients (-1; imprecision).

1-year follow-up
The level of evidence regarding the outcome measure *function*, measured with the CMS at 2 years follow-up, was downgraded by three levels to a **very low GRADE** because of study limitations (-1; risk of bias), applicability of the results due to the inclusion of traumatic tears in Moosmayer et al. (-1, bias due to indirectness), and a small number of included patients (-1; imprecision).

5-year follow-up
The level of evidence regarding the outcome measure *function*, measured with the CMS at 5 years follow-up, was downgraded by three levels to a **very low GRADE** because of study limitations (-1; risk of bias), applicability of the results due to the inclusion of traumatic tears in Moosmayer et al. (-1, bias due to indirectness), and a small number of included patients (-1; imprecision).

10-year follow-up
The level of evidence regarding the outcome measure *function*, measured with the CMS at 10 years follow-up, was downgraded by three levels to a **very low GRADE** because of study limitations (-1; risk of bias), applicability of the results due to the inclusion of traumatic tears in Moosmayer et al. (-1, bias due to indirectness), and the confidence interval around the point estimate crossing the upper threshold for clinical relevance (-1; imprecision).

Disabilities of the Arm, Shoulder and Hand (DASH)
No studies were found that reported the DASH. Therefore, the level of evidence for this outcome measure could not be assessed.

The Western Ontario Rotator Cuff (WORC)
No studies were found that reported the WORC. Therefore, te level of evidence for this outcome measure could not be assessed.

American Society of Shoulder and Elbow Surgeons (ASES)
1-year follow-up
The level of evidence regarding the outcome measure *function*, measured with the ASES at 1 year follow-up, was downgraded by three levels to a **very low GRADE**, because of study limitations (-1; risk of bias), applicability of the results due to the inclusion of traumatic tears in Moosmayer et al. (-1, bias due to indirectness), and the confidence interval around the point estimate crossing the upper threshold for clinical relevance (-1; imprecision).

2-year follow-up

The level of evidence regarding the outcome measure *function*, measured with the ASES at 2 years follow-up, was downgraded by three levels to a **very low GRADE** because of study limitations (-1; risk of bias), applicability of the results due to the inclusion of traumatic tears in Moosmayer et al. (-1, bias due to indirectness), and the confidence interval around the point estimate crossing the upper threshold for clinical relevance (-1; imprecision).

5-year follow-up
The level of evidence regarding the outcome measure *function*, measured with the ASES at 5 years follow-up, was downgraded by three levels to a **very low GRADE** because of study limitations (-1; risk of bias), applicability of the results due to the inclusion of traumatic tears in Moosmayer et al. (-1, bias due to indirectness), and the confidence interval around the point estimate crossing the upper threshold for clinical relevance (-1; imprecision).

10-year follow-up
The level of evidence regarding the outcome measure *function*, measured with the ASES at 10 years follow-up, was downgraded by three levels to a **very low GRADE** because of study limitations (-1; risk of bias), applicability of the results due to the inclusion of traumatic tears in Moosmayer et al. (-1, bias due to indirectness), and the confidence interval around the point estimate crossing the upper threshold for clinical relevance (-1; imprecision).

Dutch Simple Shoulder Test (DSST)
1-year follow-up
The level of evidence regarding the outcome measure *function*, measured with the DSST at 1 year follow-up, was downgraded by two levels to a **low GRADE**, because of study limitations (-1; risk of bias) and a small number of included patients (-1; imprecision).

2, 5 and 10-year follow-up
No studies were found that reported the DSST at 2, 5 and 10 years follow-up. Therefore, te level of evidence for this outcome measure could not be assessed.

Oxford Shoulder Score (OSS)
No studies were found that reported the OSS. Therefore, te level of evidence for this outcome measure could not be assessed.

2. Pain

1-year follow-up
The level of evidence regarding the outcome measure *pain*, measured on a 0-10 VAS-scale at 1 year follow-up, was downgraded by three levels to a **very low GRADE** because of study limitations (-1; risk of bias), applicability of the results due to the inclusion of traumatic tears in Moosmayer et al. (-1, bias due to indirectness), and a small number of included patients (-1; imprecision).

2-year follow-up
The level of evidence regarding the outcome measure *pain*, measured on a 0-10 VAS-scale at 2 years follow-up, was downgraded by three levels to a **very low GRADE** because of study limitations (-1; risk of bias), applicability of the results due to the inclusion of traumatic tears in Moosmayer et al. (-1, bias due to indirectness), and a small number of included patients (-1; imprecision).

5-year follow-up

The level of evidence regarding the outcome measure *pain*, measured on a 0-10 VAS-scale at 5 years follow-up, was downgraded by three levels to a **very low GRADE** because of study limitations (-1; risk of bias), applicability of the results due to the inclusion of traumatic tears in Moosmayer et al. (-1, bias due to indirectness), and a small number of included patients (-1; imprecision).

10-year follow-up
The level of evidence regarding the outcome measure *pain*, measured on a 0-10 VAS-scale at 10 years follow-up, was downgraded by three levels to a **very low GRADE** because of study limitations (-1; risk of bias), applicability of the results due to the inclusion of traumatic tears in Moosmayer et al. (-1, bias due to indirectness), and a small number of included patients (-1; imprecision).

3. <u>Patient satisfaction</u>

The level of evidence regarding the outcome measure *patient satisfaction* was downgraded by three levels to a **very low GRADE** because of study limitations (-1; risk of bias), applicability of the results due to the inclusion of traumatic tears in Moosmayer et al. (-1, bias due to indirectness), conflicting results (-1; inconsistency), and a small number of included patients (-1; imprecision).

4. <u>Complications/adverse events</u>

The level of evidence regarding the outcome measure *re-rupture* was downgraded by three levels to a **very low GRADE** because of applicability of the results due to the inclusion of traumatic tears in Moosmayer et al. (-1, bias due to indirectness), and a very small number of included patients (-2, imprecision).

No study reported frozen shoulder or infection as adverse events. Therefore, the level of evidence for these outcome measures could not be assessed.

5. Return to work or leisure

No study reported return to work or leisure. Therefore, the level of evidence for these outcome measure could not be assessed.

Conclusions

Function

Constant Murley Score (CMS)

Very low GRADE	The evidence is very uncertain about the effect of rotator cuff repair on **function as measured with the Constant Murley Score** at 1, 2, 5 or 10 years follow-up when compared with physiotherapy (with or without injection of corticosteroids) in adult patients with an isolated non-traumatic, rupture of the supraspinatus tendon. *Source: Kukkonen, Lambers Heerspink, Moosmayer*

Disabilities of the Arm, Shoulder and Hand (DASH)

No GRADE	No evidence was found regarding the effect of rotator cuff repair on **function as measured with the DASH** when compared with physiotherapy (with or without injection of corticosteroids) in adult patients with an isolated rupture of the supraspinatus tendon.

The Western Ontario Rotator Cuff (WORC)

No GRADE	No evidence was found regarding the effect of rotator cuff repair on **function as measured with the WORC** when compared with physiotherapy (with or without injection of corticosteroids) in adult patients with an isolated rupture of the supraspinatus tendon.

American Society of Shoulder and Elbow Surgeons (ASES)

Very low GRADE	The evidence is very uncertain about the effect of rotator cuff repair **function as measured with the ASES** at 1, 2, 5 or 10 years follow-up when compared with physiotherapy (with or without injection of corticosteroids) in adult patients with an isolated non-traumatic rupture of the supraspinatus tendon. *Source: Moosmayer*

Dutch Simple Shoulder Test (DSST)

1-year follow-up

Low GRADE	Rotator cuff repair may result in little to no difference in **function as measured with the DSST** at 1 year follow-up when compared with physiotherapy (with or without injection of corticosteroids) in adult patients with an isolated rupture of the supraspinatus tendon. *Source: Lambers Heerspink*

2, 5 and 10-year follow-up

No GRADE	No evidence was found regarding the effect of rotator cuff repair on **function as measured with the DSST** at 2, 5 and 10 years follow-up when compared with physiotherapy (with or without injection of corticosteroids) in adult patients with an isolated rupture of the supraspinatus tendon.

Oxford Shoulder Score (OSS)

No GRADE	No evidence was found regarding the effect of rotator cuff repair on **function**

	as measured with the OSS when compared with physiotherapy (with or without injection of corticosteroids) in adult patients with an isolated rupture of the supraspinatus tendon.

Pain

Very low GRADE	The evidence is very uncertain about the effect of rotator cuff repair on **pain 1, 2, 5 or 10 years postoperatively** when compared with physiotherapy (with or without injection of corticosteroids) in adult patients with an isolated nontraumatic rupture of the supraspinatus tendon. *Source: Kukkonen, Lambers Heerspink, Moosmayer*

Patient satisfaction

Very low GRADE	The evidence is very uncertain about the effect of rotator cuff repair on patient satisfaction when compared with physiotherapy (with or without injection of corticosteroids) in adult patients with an isolated rupture of the supraspinatus tendon. *Source: Kukkonen, Moosmayer*

Complications

Re-rupture

Very low GRADE	The evidence is very uncertain about the effect of rotator cuff repair on patient re-rupture when compared with physiotherapy (with or without injection of corticosteroids) in adult patients with an isolated rupture of the supraspinatus tendon. *Source: Moosmayer*

Frozen shoulder and infection

No GRADE	No adverse events were reported in the included studies considering the outcome measures frozen shoulder and infection.

Return to work or leisure

No GRADE	No evidence was found regarding the effect of rotator cuff repair on **return to work or leisure** when compared with physiotherapy (with or without injection of corticosteroids) in adult patients with an isolated rupture of the supraspinatus tendon.

Overwegingen – van bewijs naar aanbeveling

Voor- en nadelen van de interventie en de kwaliteit van het bewijs

Er is literatuuronderzoek verricht naar het effect van een operatie waarbij de rotator cuff wordt gehecht in vergelijking met oefen-/fysiotherapeutische behandeling (met of zonder een corticosteroïdeninjectie) in volwassenen (<70 jaar) met een niet-traumatische geïsoleerde ruptuur van de supraspinatuspees. Er zijn vier studies geïncludeerd die zijn beschreven in acht publicaties.

Op basis van de literatuuranalyse konden geen conclusies worden getrokken over het effect van een operatie waarbij de rotator cuff wordt gehecht op de uitkomstmaten functie, pijn, kwaliteit van leven, terugkeer naar werk en vrijetijdsbestedingen, en complicaties, vergeleken met oefen-/fysiotherapeutische behandeling (met of zonder een corticosteroïdeninjectie) in volwassenen (<70 jaar) met een niet-traumatische geïsoleerde ruptuur van de supraspinatuspees. De bewijskracht voor de cruciale en belangrijke uitkomstmaten is zeer laag. Dit wordt met name veroorzaakt doordat in één studie (Moosmayer, 2019) de helft van de patiënten een traumatische scheur had (indirectheid van de patiëntenpopulatie), het risico op vertekening (bias) en het kleine aantal geïncludeerde patiënten. Hier ligt dan ook een kennisvraag. De keuze voor de ene dan wel de andere behandeling zal dan ook afhangen van andere factoren.

Eén studie rapporteerde re-rupturen na operatieve behandeling en toename van de grootte van de scheur bij conservatief behandelde patiënten en de invloed hiervan op de uitkomst. In de operatieve groep kwamen full thickness re-rupturen na tien jaar bij 23% van de patiënten voor. Dit beïnvloedde de functionele uitkomst niet. Bij 40% van de patiënten die conservatief behandeld werden, was de toename van de scheur meer dan 10 mm, wat tot significant slechtere functionele uitkomsten leidde. In de geïncludeerde studie met tien jaar follow-up worden geen gegevens gedeeld over het ontwikkelen van degeneratieve afwijkingen glenohumoraal in beide groepen. Er werden geen prognostische factoren voor toename van scheur grootte geïdentificeerd bij patiënten die conservatief behandeld werden. Dit bemoeilijkt de keuze voor conservatieve of operatieve behandeling bij de start van behandeling. Een andere geïncludeerde studie vergeleek de uitkomsten van de intacte repair met conservatief behandelde patiënten. In een kleine groep met intacte repair was de uitkomst beter dan de conservatief behandelde groep. De bewijskracht voor deze uitkomsten was echter zeer laag.

Waarden en voorkeuren van patiënten (en evt. hun verzorgers)

Voor patiënten is het belangrijk om de behandeling te krijgen die voor hen het meest passend is. Het is voor patiënten belangrijk dat zij worden meegenomen in het (mogelijke) behandeltraject zodat zij weten wat ze kunnen verwachten. Indien door de huisarts reeds een echografie is gemaakt en een cuff ruptuur met volledige dikte scheur is geconstateerd, wordt de patiënt (conform de NHG standaard) ter beoordeling naar de orthopedie verwezen. Bij mensen met langer bestaande SAPS-klachten en een niet-traumatische geïsoleerde supraspinatusruptuur bestaat bij patiënten vaak een overtuiging dat operatief herstel van de pees beter is. Dit komt mede doordat patiënten vaak al behandeld zijn door een oefen-/fysiotherapeut met onvoldoende succes. Daarnaast overzien patiënten het lange revalidatieproces na een cuff repair over het algemeen niet en hebben zij geen kennis van de uitkomst van conservatieve behandeling van geisoleerde supraspinatuspeesrupturen.

Fysiotherapie/oefentherapie eventueel in combinatie met een corticosteroïdeninjectie kan snel ingezet worden om de klachten te verlichten. Een operatie is niet alleen een veel meer

belastende behandeling met risico's, maar zal ten eerste niet direct uitgevoerd kunnen worden en kent ten tweede een lange revalidatietijd met ondersteuning van oefen-/fysiotherapie. Tijdens de genezingsfase van de pees na een operatieve ingreep moet een periode van meerdere weken een sling gedragen worden om de peeshechting te ontzien en mag patiënt de arm niet belasten. Mantelzorg of hulp thuis is de eerste weken nodig. Activiteiten zoals fietsen en autorijden zijn meerdere weken niet toegestaan en niet wenselijk.

Conservatieve behandeling van geïsoleerde supraspinatuspeesrupturen is bij driekwart van de patiënten effectief (Kuhn, 2013; Moosmayer, 2019). Ook zijn er aanwijzingen dat na conservatieve behandeling een operatie tot meer dan een jaar uitstellen tot minder goede uitkomsten leidt dan drie tot zes maanden uitstellen (Lu, 2023). Bij de overweging om conservatief te behandelen dan wel te opereren, dienen ook patiënt specifieke factoren overwogen te worden, zoals type werkzaamheden en sport. Een belangrijke factor die meegenomen moet worden in de beslissing tot een operatie of conservatief beleid is de leeftijd van patiënt. Bij toenemende leeftijd neemt de kans op een re-ruptuur na een operatie toe (Lambers Heerspink, 2014). De kans op progressie van een cuff ruptuur wordt door natuurlijk beloop bij oplopende leeftijd groter. Afhankelijk van de grootte, betrokkenheid van de rotator cable en de ontstaanswijze kan dit leiden tot een ruptuur waarvoor een eenvoudige reparatie niet meer mogelijk is (Keener, 2019). Daarom kan dit een reden zijn om op jongere leeftijd (bijvoorbeeld in de werkzame leeftijd) toch te besluiten tot een operatie.

Het is voor patiënten dus belangrijk dat zij bij de beslissing om conservatief te behandelen dan wel te opereren de voor- en nadelen van beide behandelingen, maar ook het revalidatieproces, verwachte revalidatietijd en verwachte uitkomst goed kunnen afwegen, zodat zij op basis van de principes van Samen Beslissen een keuze kunnen maken.

<u>Kosten (middelenbeslag)</u>
Conservatieve behandeling bestaat uit één of meerdere corticosteroïdeninjecties. De kosten hiervan zijn zeer beperkt in vergelijking met een operatie. Fysiotherapie/oefentherapie is gedurende de eerste twee maanden over het algemeen tweemaal per week nodig. Daarna neemt de intensiteit van de behandeling af en zal patiënt zelf moeten oefenen. In het hersteltraject is naar ervaring van de werkgroep over het algemeen zes tot negen maanden oefen-/fysiotherapie nodig.

Een operatieve behandeling brengt kosten met zich mee door de opname van de patiënt en materiaal gebruik peroperatief. Daarnaast kunnen patiënten door een periode immobilisatie niet werken en is over het algemeen postoperatief oefen-/fysiotherapie nodig gedurende zes maanden. Er zijn geen vergelijkende kosteneffectiviteitsstudies, maar het lijkt voor de hand te liggen dat de kosten van een operatieve behandeling hoger zijn dan van conservatieve behandeling.

<u>Aanvaardbaarheid, haalbaarheid en implementatie</u>
Fysiotherapie/oefentherapie voor schouderklachten is een gangbare behandeling. Afzien van een operatie is aan patiënten goed uit te leggen, gezien de grote succeskans van conservatieve behandeling en de nadelige effecten van operatieve behandeling (te weten langdurige revalidatie en tijdelijke sociale beperkingen). Doordat veel patiënten al bij een oefen-/fysiotherapeut zijn geweest, is de acceptatie van conservatieve behandeling mogelijk minder. Hier is mogelijk een plek voor een fysiotherapeut die gespecialiseerd is in behandeling van schouderaandoeningen. Ook zal er een groep blijven die ondanks

conservatieve behandeling klachten blijft houden. De werkgroep adviseert dan ook bij implementatie van conservatief beleid om patiënten drie maanden na start van conservatieve behandeling te controleren. Indien conservatieve behandeling onvoldoende effectief is, kan nadere diagnostiek (zie module Beeldvormende technieken) en operatieve behandeling overwogen worden. Het afwegen van belangrijke prognostische factoren is hierbij noodzakelijk (zie module Prognostische factoren).

Aanbeveling

Rationale van de aanbeveling: weging van argumenten voor en tegen de interventies

Overwegende het succespercentage van conservatieve behandeling, dat er op korte en middellange termijn geen verschil wordt gevonden tussen conservatieve en operatieve behandeling, dat de kosten van conservatieve behandeling lager zijn dan van operatieve behandeling, en dat na drie maanden conservatieve behandeling een operatieve behandeling nog goed mogelijk is, adviseert de werkgroep conservatieve therapie bij patiënten <70 jaar met een geïsoleerde, symptomatische en niet-traumatische supraspinatusruptuur. De conclusie met betrekking tot patiënten <70 jaar is gesteld op basis van de literatuuranalyse; voor patiënten >70 jaar is deze gesteld op basis van expert opinie.

Deze behandeling bestaat uit oefentherapie (gegeven door een oefen- of fysiotherapeut), eventueel in combinatie met een corticosteroïdeninjectie. Patiënten dienen geïnformeerd te worden over de kans op toename van de scheur in de toekomst bij conservatieve behandeling. De werkgroep adviseert om patiënten op te volgen na conservatieve behandeling. Als na adequate conservatieve behandeling na drie tot zes maanden geen verbetering optreedt, kan rotator cuff repair overwogen worden.

Aanbeveling

Schrijf bij patiënten met SAPS-klachten en een geïsoleerde, symptomatische en niet-traumatische supraspinatusruptuur als eerste een conservatieve behandeling (oefentherapie (gegeven door een oefen- of fysiotherapeut met affiniteit voor de behandeling van schouderklachten), eventueel in combinatie met een corticosteroïdeninjectie) voor.

Overweeg een operatie (rotator cuff repair) indien adequate conservatieve behandeling na 3-6 maanden niet succesvol is (oefentherapie (gegeven door een oefen- of fysiotherapeut met affiniteit voor de behandeling van schouderklachten), eventueel in combinatie met een corticosteroïdeninjectie).

Kennisvragen

Wat is de meest effectieve oefen-/fysiotherapeutische strategie bij een geïsoleerde, symptomatische, niet-traumatische supraspinatuspeesruptuur?

Wat is de kans op ontwikkeling van degeneratieve glenohumorale afwijkingen na conservatieve of operatieve behandeling van een geïsoleerde, symptomatische, niet-traumatische supraspinatusruptuur op lange termijn?

Het identificeren van prognostische factoren voor toename van scheur grootte bij patiënten die conservatief behandeld worden om progressie op latere leeftijd te voorkomen.

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Bijlagen bij module 5.1 Operatieve behandeling

Implementatieplan

Aanbeveling	Tijdspad voor implementatie: < 1 jaar, 1 tot 3 jaar of > 3 jaar	Verwacht effect op kosten	Randvoorwaarden voor implementatie (binnen aangegeven tijdspad)	Mogelijke barrières voor implementatie	Te ondernemen acties voor implementatie	Verantwoordelijken voor acties	Overige opmerkingen
Schrijf bij patiënten met SAPS-klachten en een geïsoleerde, symptomatische en niet-traumatische supraspinatusruptuur als eerste een conservatieve behandeling (oefentherapie (gegeven door een oefen- of fysiotherapeut met affiniteit voor de behandeling van schouderklachten), eventueel in combinatie met een corticosteroïdeninjectie) voor.	<1 jaar	Reductie door afname aantal operaties	Goed functionerend schoudernetwerk waarin patiënten adequate conservatieve therapie krijgen. Zo nodig corticosteroïden Injectie door huisarts of specialist.	Onvoldoende kennis en bewustzijn van deze module bij de zittende beroepsgroep.	Publicatie richtlijn in orthopedisch en fysiotherapeutisch tijdschrift en NTVG.	Orthopedisch chirurgen met lokale fysiotherapie netwerken Beroepsvereniging NOV	geen
Overweeg een operatie (rotator cuff repair)	<1 jaar	Reductie door	Goed functionerend	Onvoldoende kennis en	Publicatie richtlijn in orthopedisch en	Orthopedisch chirurgen met	Geen

indien adequate conservatieve behandeling na 3-6 maanden niet succesvol is (oefentherapie (gegeven door een oefen- of fysiotherapeut met affiniteit voor de behandeling van schouderklachten), eventueel in combinatie met een corticosteroïdeninjectie).		afname aantal operaties	schoudernetwerk waarin patiënten adequate postoperatieve behandeling krijgen	bewustzijn van deze module bij de zittende beroepsgroep.	fysiotherapeutisch tijdschrift en NTVG.	lokale fysiotherapie netwerken Beroepsvereniging NOV	

Evidence tables

Study reference	Study characteristics	Patient characteristics [2]	Intervention (I)	Comparison / control (C) [3]	Follow-up	Outcome measures and effect size [4]	Comments
Cederqvist, 2021 ClinicalTrials.gov, NCT00695981 and NCT00637013.	Type of study: RCT Setting and country: Finland Funding and conflicts of interest: "Funding This work was supported by grants from the Academy of Finland (grant 12321/13.9.2007) 265646/17.4.2013) and National Competitive Research Funding of the University of Eastern Finland.	*In this literature summary, the patients with full-thickness ruptures were included* *Surgical group: 50/95 were full-thickness ruptures, of which 44 (88%%) in the supraspinatus* *Non-surgical group: 48/95 were full-thickness ruptures, of which 44 (92%) in the supraspinatus* <u>Inclusion criteria</u>: • Pain in abduction of the shoulder • Age over 35 years • Duration of symptoms at least 3 months • Written informed consent by the	Repair: Arthroscopic or mini-open single-row surgical treatment of cuff repair In surgery, patients without full-thickness tendon tears underwent arthroscopic SAD. Patients with full-thickness tears received rotator cuff repair with single-row technique, with one or more bone anchors, via either an arthroscopic or	Physiotherapy: cold pack + exercises + stretching, manual therapy, cross-friction massages Patients randomised to non-surgical treatment continued the previously initiated rehabilitation programme. Unsuccessful non-surgical treatment was defined as severe pain or poor	<u>Length of follow-up</u>: 2 years <u>Loss-to-follow-up & incomplete outcome data</u>: Constant score 12 months I: 18 (19%) C: 18 (19%) 24 months: I: 15 (16%) C: 14 (15%) VAS pain score 12 months I: 18 (19%) C: 19 (20%) 24 months:	**Complications** "No patients required re-operation, and no serious adverse events were noted." **PROMS: function, strength, pain combined** Constant score FU 2 years, change from baseline I: +20.0 (16.4 to 23.7) C: +13.0 (9.4 to 16.7) MD 7.0 (95%CI 1.8 to 12.2; p=0.008). Calculated in RevMan I: +20.0 (SD 16.1769), n=80	

	None of the writers have any conflicts of interest relevant to this article. Competing interests None declared.”	participating subject • Additional inclusion criteria • Subacromial impingement without full-thickness tendon lesion • Pain in two of the three isometric tests (0 or 30 degrees of abduction or external rotation) • Subacromial injection of lidocaine significantly reduced pain • Full-thickness tendon rupture • Full-thickness rotator cuff rupture in one to three tendons documented with MRI arthrography <u>Exclusion criteria</u>: • Previous surgery of the same shoulder • High-energy trauma before symptoms • Inflammatory arthritis	mini-open approach. When necessary, patients underwent acromioplasty, acromioclavicular joint resection or tenotomy of the long head of the biceps. All patients followed a structured postoperative rehabilitation protocol (see online supplemental appendix).	subjective function in the shoulder during follow-up. These patients were offered a surgical intervention. All patients followed a structured postoperative rehabilitation protocol (see online supplemental appendix).	I: 15 (16%) C: 15 (16%)	C: +13.0 (SD 16.1769), n=80 MD 7.00 (95% CI 1.99 to 12.01) **Pain** **VAS 0-100** change score from baseline, mean (95% CI) FU 2 years I: -37 (95% CI 31 to 43) C: -24 (95% CI 18 to 30) MD -13 (95% CI 5 to 22; p=0.002). Calculated in RevMan: I: -37.0 (SD 26.9616), n=80 C: -24.0 (SD 26.9616), n=80 MD 13.00 (95% CI -4.64 to 21.36) Not included in plot, as change scores and difference scale (0-100) were used	

		• Adhesive capsulitis • Instability of the affected shoulder • Severe glenohumeral or acromioclavicular joint osteoarthritis • Cervical syndrome/radiculopathy • Progressive cancer • A too high risk for operation • Any disease, social problem or other reason reducing the ability to co-operate and jeopardising informed consent Irreparable rotator cuff tear on MRI arthrography <u>N total at baseline</u>: Intervention: 50 Control: 48 <u>Important prognostic factors</u>[2]: *in general intervention groups; not reported*				**Patient satisfaction** Not reported	

		for full-thickness only *age ± SD* *I: 56 y (SD 8)* *C: 56 y (SD 8)* *Sex:* *I: 50/95 (53%) M* *C: 52/95 (55%) M* Groups comparable at baseline.					
Kukkonen, 2014 / Kukkonen, 2015 a en b / Kukkonen 2019 NCT01116518	Type of study: RCT Setting and country: three hospitals in Finland (Turku University Hospital, Kuopio University Hospital and Hatanpää Hospital) between October 2007 and December 2012; Finland Funding and conflicts of interest:	Group 1 (surgery + physiotherapy) and group 3 (physiotherapy) were included in the current literature summary. <u>Inclusion criteria</u>: • Age > 55 years • Atraumatic symptomatic supraspinatus tendon tear comprising < 75% of the tendon insertion and documented with MRI • Full range of motion of the shoulder • Written informed consent	Repair: surgical rotator cuff repair + acromioplasty + immobilization in a sling for 3 weeks + physiotherapy (group 3 in article)	Physiotherapy: instructions + home exercises + 10 sessions of physiotherapy (group 1 in article)	<u>Length of follow-up</u>: 60 months / 5 years (mean follow-up period of 6.2 years) <u>Loss-to-follow-up & incomplete outcome data</u>: Intervention (group 3) Baseline data: n=59 shoulders Intervention:	**Complications** "No treatment-related complications occurred in any group." **PROMS: function, strength, pain combined** *Constant score (range from 0 to 100 points: worst and best shoulder function)* FU 1 year I: 78.1 (SD 12.1), n=55 C: 74.2 (SD 14.3), n=55	

	Not mentioned explicitly; "No benefits in any form have been received or will be received from a commercial party related directly or indirectly to the subject of this article."	<u>Exclusion criteria</u>: • Age < 55 years • History of trauma relating to the onset of symptoms • massive tendon tear involving whole supra-spinatus tendon and/or combined tear of two to three tendons, i.e., supra-spinatus with infraspinatus or subscapularis tendon tear • Stiffness of the glenohumeral joint (passive external rotation < 30° ± elevation < 120°) • Glenohumeral osteoarthritis with present osteophytes in radiographs • Systemic corticosteroid or antimetabolite medication • Significant malignant,			n=55 12m FU: 55 24m FU: 54 60m FU: 49 Control (group 1) Baseline data: n=58 shoulders Intervention: n=60 12m FU: 55 24m FU: 55 60m FU: 51	FU 2 years I: 80.2 (SD 13.0), n=54 C: 76 (SD 11.9), n=55 Calculated in RevMan: MD 4.20 (95% CI -0.48 to 8.88) *Mean change score baseline to 24 M (95% CI)* I: 22.6 points (18.4 to 26.8 points) C: 18.4 points (14.2 to 22.6 points) FU 5 years Mean (SD) score (95% CI) I: 78.7 (74.4- 83.0) C: 75.6 (71.5- 79.8) Calculated in RevMan: I: 78.7 (SD 14.9704), n=49 C: 75.6 (SD 14.5775), n=51 MD 3.10 (95% CI -2.69 to 8.89)	

		hematological, endocrine, metabolic, rheumatoid or gastrointestinal disease • History of alcoholism, drug abuse, psycho-logical or other emotional problems that are likely to invalidate informed consent • Previous surgery of same shoulder • Patient refusal <u>N total at baseline</u>: Intervention: 60 Control: 60 <u>Important prognostic factors</u>[2]: Female (n, %) I: 26/55 (47%) C: 31/55 (56%) Mean (SD) age (yrs) I: 65y (SD 6.0) C: 65y (SD 5.8)				Mean change (95% CI) I: 20.0 (15.0-24.9) C: 18.5 (13.6-23.4) **Pain** VAS pain scale 0-10; mean (SD) FU 1 year I: 0.9 (SD 2.1), N=55 C: 1.2 (SD 1.9), N=55 Calculated in RevMan: MD -0.30 (95% CI -1.05 to 0.45) FU 2 years I: 0.6 (SD 1.6), N=54 C: 1.4 (SD 2.1), N=55 Calculated in RevMan: MD -0.80 (95% CI -1.50 to -0.10) *VAS change score for pain* I: -2.0 C: -1.3 FU 5 years *VAS pain scale; mean (95% CI)* I: 0.62 (0.16-1.08)	

		Groups comparable at baseline.				C: 1.43 (0.98-1.88) Calculated in RevMan I: 0.62 (SD 1.6015), n=49 C: 1.43 (SD 1.6), n=51 MD -0.81 (95% CI -1.44 to -0.18) Mean change in VAS pain score (95% CI)* I: -1.85 (-2.66 to -1.04) C: -1.55 (-2.35 to -0.75) **Patient satisfaction** *At the control visits patients were asked if they were satisfied or dissatisfied with the treatment outcome* FU 1 year I: 95% C: 87% FU 2 years I: 94% C: 89% FU 5 years	

						I: 91.8% C: 88.2%	
Lambers Heerspink, 2015	Type of study: RCT Setting and country: January 2009 and December 2012 Funding and conflicts of interest: "This study received a grant from Anna Fonds. There was no involvement in data collection, data analysis, the preparation, or editing of the manuscript by Anna Fonds. The authors, their immediate families, and any research foundations with which they are	<u>Inclusion criteria</u>: • degenerative, nontraumatic full-thickness rotator cuff tears <u>Exclusion criteria</u>: • traumatic onset of complaints • previous surgical treatment of the shoulder, • frozen shoulder, • radiologic and symptomatic osteoarthritis of the glenohumeral (GH) or acromioclavicular joint, arthritis/rheumatoid arthritis, • diabetes mellitus, • cognitive disorders, • neurologic disease affecting function of the upper extremity, • language barriers impairing	Repair: Surgical treatment Surgery was scheduled within 6 weeks of inclusion and was done with the patient under general anaesthesia, supplemented with an interscalene brachial plexus block. The operation was performed in beach chair position using an anterolateral miniopen approach. The coraco-acromial ligament was detached from its insertion, and	Conservative treatment: Subacromial steroid infiltration, physiotherapy, and analgesic medication; further options: analgesic medication with NSAIDs, paracetamol, or tramadol) Treatment in the conservative group consisted of subacromial steroid infiltration, physiotherapy, and analgesic medication. After inclusion,	<u>Length of follow-up</u>: 12m <u>Loss-to-follow-up & incomplete outcome data</u>: Intervention: 20/25 analysed (1 moved, 4 excluded due to failed surgery) Control: 25/31 analysed (3 discontinued intervention, 1 death, 1 moved)	**Complications** Not reported **PROMS: function, strength, pain combined** CMS, mean (SD) FU 1 year I: 81.9 (15.6); n=20 C: 73.7 (18.4), n=25 Calculated in RevMan: MD: 8.20 (95% CI -1.74 to 18.14) DSST FU 1 year I: 11.0 (2.8); n=20 C: 9.7 (3.6), n=25 Calculated in RevMan: MD 1.30 (95% CI -1.35 to 3.95) **Pain** VAS pain score**, 0-10**; 0 represents no pain and restriction, and 10 the most likely	

	affiliated have not received any financial payments or other benefits from any commercial entity related to the subject of this article."	participation. <u>N total at baseline</u>: Intervention: 25 Control: 31 <u>Important prognostic factors</u>[2]: *Age, SD:* I: 60.8, 7.2 C: 60.5, 7.0 *Sex:* I: 60% M C: 64.5% M Groups comparable at baseline.	the subacromial bursa was excised. The anteroinferior part of the acromion was removed. The footprint of the rotator cuff on the greater tuberosity was debrided, and a bleeding bony bed was created. Side-to-side repair and repair augmented with bone anchors were performed depending on the shape of the rupture. A side-to-side repair was performed in 6 patients. The deltoid muscle was reattached to the acromion	patients were given an infiltration in the subacromial space by a posterior approach. If the first infiltration gave no pain relief, a second infiltration was performed under radiologic or ultrasound guidance. The number of subacromial infiltrations was limited to a maximum of 3. Further conservative treatment options consisted of analgesic medication		pain and disability FU 1 year I: 2.2 (1.9), n=20 C: 3.2 (2.1), n=25 Calculated in RevMan: MD -1.00 (95% CI -2.17 to 0.17) **Patient satisfaction** Not reported; "Three patients were dissatisfied with the result of conservative treatment and a decision was made to perform rotator cuff repair (discontinued intervention). In 2 of these patients, data were available until 3 months after treatment and in the other patient until 6 months after treatment."	

			by transosseous refixation. The repair in 14 patients was augmented using bone anchors. The tear in 2 patients could not be repaired, and no rotator cuff rupture was found in 2 patients despite an MRI-supported diagnosis. These 4 patients were excluded for primary per-protocol analysis but were included in the intention-to-treat analysis. After surgery, the patient wore a sling for 6 weeks. Patients were referred for	with nonsteroidal anti-inflammatory drugs (NSAIDs), paracetamol, or tramadol. Patients were referred to a physio-therapist. The Department of Physical Therapy of Martini Hospital, Groningen, The Netherlands, developed a standardized physical therapy protocol for the conservative treatment of rotator cuff tears.21 In addition to			

			physical therapy and treatment was commenced according to a standardized protocol.21 In the first 6 weeks, only passive movements were allowed. Passive GH movement was performed to prevent loss of mobility. The mobility of elbow and wrist was passively maintained. Circumduction exercises were allowed. After 6 weeks, active guided treatment was started and was expanded to active treatment. Strength development	explaining the cause of the symptoms and the rehabilitation protocol, the physiotherapist advised about activities of daily living (ADL). Passive GH and scapulothoracic movements were performed, and static and dynamic exercises were started. The aim of these exercises was to improve GH and scapulothoracic musculature. Poor posture was corrected. In weeks 4 to 6, exercises were			

			was started 3 months postoperatively.	gradually increased, and deltoid training was started. In weeks 6 to 12, rehabilitation was aimed at further optimization of mobility and strength regeneration of the remaining cuff and deltoid. Physical therapy was continued until patients reached an optimum range of motion and an improvement in strength was achieved. Three patients were dissatisfied with the result			

				of conservative treatment and a decision was made to perform rotator cuff repair (discontinued intervention). In 2 of these patients, data were available until 3 months after treatment and in the other patient until 6 months after treatment.			
Moosmayer, 2010 / Moosmayer, 2014 / Moosmayer, 2019	Type of study: RCT Setting and country: Single-centre; Norway Funding and conflicts of interest: “One or	Inclusion criteria: • lateral shoulder pain at rest or with exercise, • painful arc, • positive impingement signs • passive range of movement of at least 140° for abduction and flexion.	Repair: Surgical treatment of cuff repair (through a deltoid splitting approach, anteroinferior acromioplasty was performed)	Physiotherapy: physiotherapy and exercises	Length of follow-up: 10 years Loss-to-follow-up & incomplete outcome data: Intervention: 12m FU: 51	**Complications** Relevant complications according to guideline development group Index shoulder, need for additional physiotherapy I: 1 (within 2 years)	

	more of the authors received payments or services, either directly or indirectly (i.e., via his or her institution), from a third party in support of an aspect of this work. None of the authors, or their institution(s), have had any financial relation-ship, in the thirty-six months prior to submission of this work, with any entity in the biomedical arena that could be perceived to influence or have the potential to influence what is written in this work. Also, no author has had	• full thickness tear by sonography and MRI, • tear size of ≤ 3 cm on short and long axis ultrasound scans • muscle atrophy on MRI not exceeding stage 2, according to classification of Thomazeau et al. *Traumatic and atraumatic tears were included.* <u>Exclusion criteria</u>: • age < 18 years, • tears with absolute indication for surgery such as those involving substantial parts of the subscapularis tendon, • presence of other local or systemic diseases affecting shoulder function, • previous tendon surgery on the relevant shoulder, • medical comorbidities			24m FU: 51 5y FU: 51 10y: 48 Control: 12m FU: 51 24m FU: 50 5y FU: 55 10y: 43	C: 3 (after 5 years) Index shoulder, need for: I: reoperation with acromioplasty and biceps tenotomy (n = 1) C: Physiotherapy (n = 1) C: Glenohumeral arthrosis, conservatively treated (n = 1) **PROMS: function, strength, pain combined** <u>Constant score</u>, *mean ± SD* FU 1 year I: 77.7 ± 13.4, n=52 C: 70.3 ± 19.1, n=51 Calculated in RevMan: MD 7.40 [1.00, 13.80] FU 2 years I: 79.3 ± 13.6	

	any other relationships, or has engaged in any other activities, that could be perceived to influence or have the potential to influence what is written in this work. The complete Disclosures of Potential Conflicts of Interest submitted by authors are always provided with the online version of the article" Source of Funding "In support of the research for this manuscript, outside funding was given by the South-Eastern Norway Regional Health Authority.	• inability to comply with follow-up <u>N total at baseline</u>: Intervention: 52 Control: 51 <u>Important prognostic factors</u>[2]: *age (range):* *I: 59 (44 to 75)* *C: 61 (46 to 75)* *Sex:* *I: 37/52, 71% M* *C:36/51, 71 % M* Groups comparable at baseline				C: 77.7 ± 14.9 Calculated in RevMan: MD 1.60 [-3.97, 7.17] FU 5 years I: 79.8 ± 15.0 C: 74.2 ± 20.3 Calculated in RevMan: MD 5.60 [-1.16, 12.36] FU 10 years I: 80.5 ± 9.8 C: 71.8 ± 17.8 Calculated in RevMan: MD 8.70 [2.70, 14.70] <u>ASES score</u> - *self-report section of the ASES score; 0-100; higher score indicating better functioning; mean* ± SD FU 1 year I: 93.6 ± 12.5 C: 83.6 ± 18.3 Calculated in	

	Funds were used to pay for salaries. The source of funding did not play a role in the investigation.”					RevMan: MD 10.00 [3.92, 16.08] FU 2 years I: 93.1 ± 13.9 C: 88.0 ± 14.9 Calculated in RevMan: MD 5.10 [-0.52, 10.72] FU 5 years I: 92.8 ± 13.3 C: 85.4 ± 21.0 Calculated in RevMan: MD 7.40 [0.76, 14.04] FU 10 years I: 94.0 ± 9.5 C: 80.0 ± 20.2 Calculated in RevMan: MD 14.00 [7.39, 20.61] **Pain** VAS pain (cm); *mean ± SD* FU 1 year I: 0.5 ± 1.2	

						C: 1.6 ± 1.6 Calculated in RevMan: MD -1.10 [-1.65, -0.55] FU 2 years I: 0.7 ± 1.5 C: 1.4 ± 1.4 Calculated in RevMan: MD -0.70 [-1.27, -0.13] FU 5 years I: 0.6 ± 1.4 C: 1.6 ± 1.6 Calculated in RevMan: MD -1.00 [-1.57, -0.43] FU 10 years I: 0.6 ± 1.3 C: 2.3 ± 2.4 Calculated in RevMan: MD -1.70 [-2.51, -0.89] **Patient satisfaction** *VAS – scale: After 1, 5, and 10 years,*	

						patients had to answer the question "How satisfied are you with the treatment result of your shoulder?" on a visual analogue scale (VAS) ranging from 0 (very unsatisfied) to 10 (very satisfied). FU 1 year I: 9.0 (1.0 to 10.0) C: 7.2 (0.0 to 10.0) FU 2 years I: C: FU 5 years I: 9.2 cm C: 8.3 cm MD 1.0 cm [95% CI, 0.1 to 1.8 cm]; p = 0.03) FU 10 years I: 9.2 cm C: 8.2 cm MD 0.97 cm [95% CI, 0.13 to 1.82 cm]; p = 0.03)	

Risk of bias table

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?** Definitely yes Probably yes Probably no Definitely no	**Was the allocation adequately concealed?** Definitely yes Probably yes Probably no Definitely no	**Blinding: Was knowledge of the allocated interventions adequately prevented?** **Were patients blinded?** **Were healthcare providers blinded?** **Were data collectors blinded?** **Were outcome assessors blinded?** **Were data analysts blinded?** Definitely yes Probably yes Probably no Definitely no	**Was loss to follow-up (missing outcome data) infrequent?** Definitely yes Probably yes Probably no Definitely no	**Are reports of the study free of selective outcome reporting?** Definitely yes Probably yes Probably no Definitely no	**Was the study apparently free of other problems that could put it at a risk of bias?** Definitely yes Probably yes Probably no Definitely no	**Overall risk of bias** **If applicable/necessary, per outcome measure** **LOW** **Some concerns** **HIGH**

Cederqvist, 2021	Probably yes Reason: "A research assistant not involved in the study prepared a computer-generated, block randomisation list and sequentially numbered, sealed opaque envelopes for patient randomisation."	Probably yes Reason: Reason: no information about allocation concealment	Definitely no Reason: surgery vs. no surgery cannot be blinded; "The information regarding the treatment group was open to patients, the treating physicians and the study physiotherapists."	Definitely no Reason: missing outcome data comparable between groups but ranged from 16-20 % in 1-year and 2-year follow-up data.	Probably no Reason: Brindisino (2021): "RoB in measuring the outcomes showed high risk" and "selection of reported outcomes showed some concern"	… Reason: Trial registered	**High risk of bias**
Kukkonen, 2014 / Kukkonen, 2015 a en b / Kukkonen 2019 NCT01116518	Probably yes Reason: method for randomization not described	Probably yes Reason: no information about allocation concealment "… using sequentially	Probably no Reason: surgery vs. no surgery cannot be blinded; "After randomization, the patient and	Probably yes Reason: "One strength of our study is a good follow-up rate of 83%. The cases	Definitely yes Reason: outcomes defined and reported steadily over the years of FU.	Probably yes Reason: Trial registered, outcomes and population the same over the FU years	**Some concerns (all outcomes)**

		numbered, opaque, sealed envelopes. The randomization was stratified according to participating hospital into 3 blocks."	the treating physician were openly informed of the treatment group. The radiologists were blinded to clinical patient data."	of dropout partly comprised deceased patients, and some patients were not available because of migration to another district"			
Lambers Heerspink, 2015 Netherlands Trial Registry (NTR TC 2343)	Probably yes Reason: "Randomization was done by hand using 100 prefilled opaque sealed envelopes (50 for each treatment arm)."	Probably yes Reason: no information about allocation concealment	Probably no Reason: surgery vs. no surgery cannot be blinded; "Because we were dealing with a surgical vs conservative therapy setup, patients and outcome assessors could not be blinded for the type of treatment"	Probably yes Reason: 25/31 and 20/25 included in follow-up	Probably yes Reason: outcomes defined and reported steadily over the years of FU. Brindisino (2021): "RoB in measuring the outcomes showed high risk" and "selection of reported outcomes showed some	Probably yes Reason: Trial registered, outcomes and population the same over the FU years "As described in the discussion, the inclusion of patients for this trial was difficult. We eventually had to terminate the inclusion prematurely,	**Some concerns (all outcomes)**

					concern”	resulting in an unequal number of participants in the conservative and surgical groups.”	
Moosmayer, 2010 / Moosmayer, 2014 / Moosmayer, 2019 NCT00852657	Probably yes Reason: “A computer-generated randomisation list (block length 20, ratio 1:1) was drawn up by our statistician. Sequentially numbered, sealed envelopes were used to assign treatment according to the participants’ study number, given at baseline assessment. The randomisation	Definitely yes Reason: “Sequentially numbered, sealed envelopes were used to assign treatment according to the participants’ study number, given at baseline assessment. The randomisation sequence was concealed from the study’s collaborators until treatment was assigned.”	Probably no Reason: surgery vs. no surgery cannot be blinded “Only the outcome assessor (TH) remained blinded throughout the study.”	Probably yes Reason: 48/52 and 43/51 included in 10-year follow-up	Definitely yes Reason: outcomes defined and reported steadily over the years of FU.	Probably yes Reason: Trial registered, outcomes and population the same over the FU years	**Some concerns (all outcomes)**

	sequence was concealed from the study's collaborators until treatment was assigned. Only the outcome assessor (TH) remained blinded throughout the study."						

Table of excluded studies

Reference	Reason for exclusion
Abdul-Wahab TA, Betancourt JP, Hassan F, Thani SA, Choueiri H, Jain NB, Malanga GA, Murrell WD, Prasad A, Verborgt O. Initial treatment of complete rotator cuff tear and transition to surgical treatment: systematic review of the evidence. Muscles Ligaments Tendons J. 2016 May 19;6(1):35-47. doi: 10.11138/mltj/2016.6.1.035. PMID: 27331030; PMCID: PMC4915460.	Wrong outcome and more recent review available
Arce G, Bak K, Bain G, Calvo E, Ejnisman B, Di Giacomo G, Gutierrez V, Guttmann D, Itoi E, Ben Kibler W, Ludvigsen T, Mazzocca A, de Castro Pochini A, Savoie F 3rd, Sugaya H, Uribe J, Vergara F, Willems J, Yoo YS, McNeil JW 2nd, Provencher MT. Management of disorders of the rotator cuff: proceedings of the ISAKOS upper extremity committee consensus meeting. Arthroscopy. 2013 Nov;29(11):1840-50. doi: 10.1016/j.arthro.2013.07.265. Epub 2013 Sep 13. PMID: 24041864.	Wrong study design
Brindisino F, Salomon M, Giagio S, Pastore C, Innocenti T. Rotator cuff repair vs. nonoperative treatment: a systematic review with meta-analysis. J Shoulder Elbow Surg. 2021 Nov;30(11):2648-2659. doi: 10.1016/j.jse.2021.04.040. Epub 2021 May 19. PMID: 34020002.	Relevant studies included individually
Candela V, Longo UG, Di Naro C, Facchinetti G, Marchetti A, Sciotti G, Santamaria G, Piergentili I, De Marinis MG, Nazarian A, Denaro V. A Historical Analysis of Randomized Controlled Trials in Rotator Cuff Tears. Int J Environ Res Public Health. 2020 Sep 20;17(18):6863. doi: 10.3390/ijerph17186863. PMID: 32962199; PMCID: PMC7558823.	Wrong comparison
Cederqvist S, Flinkkilä T, Ylinen J, Kautiainen H, Tuominen A, Kiviranta I, Paloneva J; Surgery for rotator cuff disease Finland (SURFIN) Investigators. Response to: 'Correspondence on 'Non-surgical and surgical treatments for rotator cuff disease: a pragmatic randomised clinical trial with 2-year follow-up after initial rehabilitation'' by Randelli *et al*. Ann Rheum Dis. 2021 Feb 3:annrheumdis-2020-219782. doi: 10.1136/annrheumdis-2020-219782. Epub	wrong publication type

ahead of print. PMID: 33536163.	
Erratum regarding previously published articles (Journal of Clinical Orthopaedics and Trauma (2020) 11(S1) (S86–S92), (S0976566219303029), (10.1016/j.jcot.2019.09.014))	wrong population
Erratum regarding previously published articles (Journal of Clinical Orthopaedics and Trauma (2021) 20, (S0976566221003404), (10.1016/j.jcot.2021.06.003))	wrong publication type
Fahy K, Galvin R, Lewis J, Mc Creesh K. Exercise as effective as surgery in improving quality of life, disability, and pain for large to massive rotator cuff tears: A systematic review & meta-analysis. Musculoskelet Sci Pract. 2022 Oct;61:102597. doi: 10.1016/j.msksp.2022.102597. Epub 2022 Jun 10. PMID: 35724568.	wrong population
Franco ESB, Puga MEDS, Imoto AM, Almeida J, Mata VD, Peccin S. What do Cochrane Systematic Reviews say about conservative and surgical therapeutic interventions for treating rotator cuff disease? Synthesis of evidence. Sao Paulo Med J. 2019 Nov-Dec;137(6):543-549. doi: 10.1590/1516-3180.2019.0275160919. PMID: 32159641; PMCID: PMC9754280.	wrong publication type
Garibaldi R, Altomare D, Sconza C, Kon E, Castagna A, Marcacci M, Monina E, Di Matteo B. Conservative management vs. surgical repair in degenerative rotator cuff tears: a systematic review and meta-analysis. Eur Rev Med Pharmacol Sci. 2021 Jan;25(2):609-619. doi: 10.26355/eurrev_202101_24619. PMID: 33577014.	relevant studies included individually

Hopewell S, Keene DJ, Marian IR, Dritsaki M, Heine P, Cureton L, Dutton SJ, Dakin H, Carr A, Hamilton W, Hansen Z, Jaggi A, Littlewood C, Barker KL, Gray A, Lamb SE; GRASP Trial Group. Progressive exercise compared with best practice advice, with or without corticosteroid injection, for the treatment of patients with rotator cuff disorders (GRASP): a multicentre, pragmatic, 2 × 2 factorial, randomised controlled trial. Lancet. 2021 Jul 31;398(10298):416-428. doi: 10.1016/S0140-6736(21)00846-1. Epub 2021 Jul 12. PMID: 34265255; PMCID: PMC8343092.	wrong comparison
Huang DG, Wu YL, Chen PF, Xia CL, Lin ZJ, Song JQ. Surgical or nonsurgical treatment for nontraumatic rotator cuff tears: Study protocol clinical trial. Medicine (Baltimore). 2020 May;99(18):e20027. doi: 10.1097/MD.0000000000020027. PMID: 32358381; PMCID: PMC7440173.	wrong publication type
Jain NB, Ayers GD, Fan R, Kuhn JE, Warner JJP, Baumgarten KM, Matzkin E, Higgins LD. Comparative Effectiveness of Operative Versus Nonoperative Treatment for Rotator Cuff Tears: A Propensity Score Analysis From the ROW Cohort. Am J Sports Med. 2019 Nov;47(13):3065-3072. doi: 10.1177/0363546519873840. Epub 2019 Sep 13. PMID: 31518155; PMCID: PMC7325686.	wrong study design
Jain NB, Ayers GD, Koudelková H, Archer KR, Dickinson R, Richardson B, Derryberry M, Kuhn JE; ARC Trial Group. Operative vs Nonoperative Treatment for Atraumatic Rotator Cuff Tears: A Trial Protocol for the Arthroscopic Rotator Cuff Pragmatic Randomized Clinical Trial. JAMA Netw Open. 2019 Aug 2;2(8):e199050. doi: 10.1001/jamanetworkopen.2019.9050. PMID: 31397866; PMCID: PMC6692688.	wrong publication type
Kahlenberg CA, Dare DM, Dines JS. Further Research Is Needed to Define the Benefits of Non-operative Rotator Cuff Treatment. HSS J. 2016 Oct;12(3):291-294. doi: 10.1007/s11420-016-9495-7. Epub 2016 Feb 29. PMID: 27703426; PMCID: PMC5026654.	wrong publication type

Karjalainen TV, Jain NB, Heikkinen J, Johnston RV, Page CM, Buchbinder R. Surgery for rotator cuff tears. Cochrane Database Syst Rev. 2019 Dec 9;12(12):CD013502. doi: 10.1002/14651858.CD013502. PMID: 31813166; PMCID: PMC6900168.	wrong population
Kim S, Hwang J, Kim MJ, Lim JY, Lee WH, Choi JE. Systematic review with network meta-analyses of randomized controlled trials of rotator cuff tear treatment. Int J Technol Assess Health Care. 2018;34(1):78-86. doi: 10.1017/S0266462317004500. Epub 2018 Feb 22. PMID: 29467045.	relevant studies included individually
Lavoie-Gagne O, Farah G, Lu Y, Mehta N, Parvaresh KC, Forsythe B. Physical Therapy Combined With Subacromial Cortisone Injection Is a First-Line Treatment Whereas Acromioplasty With Physical Therapy Is Best if Nonoperative Interventions Fail for the Management of Subacromial Impingement: A Systematic Review and Network Meta-Analysis. Arthroscopy. 2022 Aug;38(8):2511-2524. doi: 10.1016/j.arthro.2022.02.008. Epub 2022 Feb 19. PMID: 35189304.	wrong population
Littlewood C, Wade J, Butler-Walley S, Lewis M, Beard D, Rangan A, Bhabra G, Kalogrianitis S, Kelly C, Mehta S, Singh HP, Smith M, Tambe A, Tyler J, Foster NE. Protocol for a multi-site pilot and feasibility randomised controlled trial: Surgery versus PhysiothErapist-leD exercise for traumatic tears of the rotator cuff (the SPeEDy study). Pilot Feasibility Stud. 2021 Jan 7;7(1):17. doi: 10.1186/s40814-020-00714-x. PMID: 33413664; PMCID: PMC7788278.	wrong publication type
Longo UG, Risi Ambrogioni L, Candela V, Berton A, Carnevale A, Schena E, Denaro V. Conservative versus surgical management for patients with rotator cuff tears: a systematic review and META-analysis. BMC Musculoskelet Disord. 2021 Jan 8;22(1):50. doi: 10.1186/s12891-020-03872-4. Erratum in: BMC Musculoskelet Disord. 2021 Sep 2;22(1):752. PMID: 33419401; PMCID: PMC7796609.	relevant studies included individually

Longo UG, Risi Ambrogioni L, Candela V, Berton A, Carnevale A, Schena E, Denaro V. Conservative versus surgical management for patients with rotator cuff tears: a systematic review and META-analysis. BMC Musculoskelet Disord. 2021 Jan 8;22(1):50. doi: 10.1186/s12891-020-03872-4. Erratum in: BMC Musculoskelet Disord. 2021 Sep 2;22(1):752. PMID: 33419401; PMCID: PMC7796609.	correction for review that was not included in this summary
Naimark M, Trinh T, Robbins C, Rodoni B, Carpenter J, Bedi A, Miller B. Effect of Muscle Quality on Operative and Nonoperative Treatment of Rotator Cuff Tears. Orthop J Sports Med. 2019 Aug 5;7(8):2325967119863010. doi: 10.1177/2325967119863010. PMID: 31428659; PMCID: PMC6683312.	wrong outcome
Narvani AA, Imam MA, Godenèche A, Calvo E, Corbett S, Wallace AL, Itoi E. Degenerative rotator cuff tear, repair or not repair? A review of current evidence. Ann R Coll Surg Engl. 2020 Apr;102(4):248-255. doi: 10.1308/rcsann.2019.0173. Epub 2020 Jan 3. PMID: 31896272; PMCID: PMC7099167.	wrong publication type
Nazari G, MacDermid JC, Bryant D, Athwal GS. The effectiveness of surgical vs conservative interventions on pain and function in patients with shoulder impingement syndrome. A systematic review and meta-analysis. PLoS One. 2019 May 29;14(5):e0216961. doi: 10.1371/journal.pone.0216961. PMID: 31141546; PMCID: PMC6541263.	wrong population
Piper CC, Hughes AJ, Ma Y, Wang H, Neviaser AS. Operative versus nonoperative treatment for the management of full-thickness rotator cuff tears: a systematic review and meta-analysis. J Shoulder Elbow Surg. 2018 Mar;27(3):572-576. doi: 10.1016/j.jse.2017.09.032. Epub 2017 Nov 21. PMID: 29169957.	relevant studies included individually
Randelli P, Coletto LA, Menon A, Caporali R. Correspondence on 'Non-surgical and surgical treatments for rotator cuff disease: a pragmatic randomised clinical trial with 2-year follow-up after initial rehabilitation'. Ann Rheum Dis. 2021 Feb 3:annrheumdis-2020-219751. doi: 10.1136/annrheumdis-2020-219751. Epub ahead of print. PMID:	wrong publication type

33536162.	
Ranebo MC, Björnsson Hallgren HC, Holmgren T, Adolfsson LE. Surgery and physiotherapy were both successful in the treatment of small, acute, traumatic rotator cuff tears: a prospective randomized trial. J Shoulder Elbow Surg. 2020 Mar;29(3):459-470. doi: 10.1016/j.jse.2019.10.013. Epub 2020 Jan 7. PMID: 31924516.	
Ryösä A, Kukkonen J, Björnsson Hallgren HC, Moosmayer S, Holmgren T, Ranebo M, Bøe B, Äärimaa V; ACCURATE study group. Acute Cuff Tear Repair Trial (ACCURATE): protocol for a multicentre, randomised, placebo-controlled trial on the efficacy of arthroscopic rotator cuff repair. BMJ Open. 2019 May 19;9(5):e025022. doi: 10.1136/bmjopen-2018-025022. PMID: 31110087; PMCID: PMC6530362.	wrong publication type
Ryösä A, Laimi K, Äärimaa V, Lehtimäki K, Kukkonen J, Saltychev M. Surgery or conservative treatment for rotator cuff tear: a meta-analysis. Disabil Rehabil. 2017 Jul;39(14):1357-1363. doi: 10.1080/09638288.2016.1198431. Epub 2016 Jul 6. PMID: 27385156.	relevant studies included individually
Schemitsch C, Chahal J, Vicente M, Nowak L, Flurin PH, Lambers Heerspink F, Henry P, Nauth A. Surgical repair *versus* conservative treatment and subacromial decompression for the treatment of rotator cuff tears: a meta-analysis of randomized trials. Bone Joint J. 2019 Sep;101-B(9):1100-1106. doi: 10.1302/0301-620X.101B9.BJJ-2018-1591.R1. PMID: 31474132.	relevant studies included individually
Schmucker C, Titscher V, Braun C, Nussbaumer-Streit B, Gartlehner G, Meerpohl J. Surgical and Non-Surgical Interventions in Complete Rotator Cuff Tears. Dtsch Arztebl Int. 2020 Sep 18;117(38):633-640. doi: 10.3238/arztebl.2020.0633. PMID:	relevant studies included individually

33263527; PMCID: PMC7817785.	
Tashjian RZ. Is there evidence in favor of surgical interventions for the subacromial impingement syndrome? Clin J Sport Med. 2013 Sep;23(5):406-7. doi: 10.1097/01.jsm.0000433152.74183.53. PMID: 23989383.	wrong population
Zadro JR, O'Keeffe M, Ferreira GE, Traeger AC, Gamble AR, Page R, Herbert RD, Harris IA, Maher CG. Diagnostic labels and advice for rotator cuff disease influence perceived need for shoulder surgery: an online randomised experiment. J Physiother. 2022 Oct;68(4):269-276. doi: 10.1016/j.jphys.2022.09.005. Epub 2022 Oct 17. PMID: 36257876.	wrong population, intervention, outcome

Literature search strategy

Zoekopbrengst

	EMBASE	OVID/MEDLINE	Ontdubbeld
SRs	136	120	177
RCT	201	178	254
Totaal	337	298	**431**

Zoekstrategie

Embase.com

No.	Query	Results
#17	#15 OR #16	337
#16	#12 AND #14 NOT #15 **= RCT**	201
#15	#12 AND #13 **= SR**	136
#14	'randomized controlled trial'/exp OR random*:ti,ab OR (((pragmatic OR practical) NEAR/1 'clinical trial*'):ti,ab) OR ((('non inferiority' OR noninferiority OR superiority OR equivalence) NEAR/3 trial*):ti,ab) OR rct:ti,ab,kw	2015900
#13	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	733409
#12	#9 AND #10 AND #11 AND ([english]/lim OR [dutch]/lim) AND [2013-2023]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	1129
#11	'conservative treatment'/exp OR 'physiotherapy'/exp OR physiotherap*:ti,ab,kw OR 'physio therap*':ti,ab,kw OR 'physical therap*':ti,ab,kw OR 'kinesiotherapy'/exp OR kinesiotherap*:ti,ab,kw OR kinesitherapeutic*:ti,ab,kw OR 'occupational therapy'/exp OR 'occupation* therap*':ti,ab,kw OR ergotherap*:ti,ab,kw OR 'conservative treatment*':ti,ab,kw OR nonsurg*:ti,ab,kw OR nonoperatic*:ti,ab,kw OR 'non-surg*':ti,ab,kw OR 'non-operati*':ti,ab,kw OR (((exercise* OR manual)	4349666

	NEAR/3 therap*):ti,ab,kw) OR 'exercise'/exp/mj OR 'rehabilitation'/exp OR 'rehabilitation medicine'/exp OR rehabilitat*:ti,ab,kw OR 'manipulative medicine'/exp OR 'manual therapist'/exp OR 'musculoskeletal manipulation'/exp OR manipulat*:ti,ab,kw OR 'mobilization'/exp OR mobilization:ti,ab,kw OR mobilisation:ti,ab,kw OR 'massage'/exp OR 'massage':ti,ab,kw OR 'stretching exercise'/exp OR 'muscle stretching'/exp OR 'stretching'/exp OR stretch*:ti,ab,kw OR 'resistance training'/exp OR (((resistance OR strength*) NEAR/3 (train* OR exercise*)):ti,ab,kw) OR 'injection'/exp OR inject*:ti,ab,kw OR 'nonsteroid antiinflammatory agent'/exp OR 'nonsteroid antiinflammatory agent*':ti,ab,kw OR nsaid*:ti,ab,kw	
#10	'shoulder surgery'/exp OR 'rotator cuff repair'/exp OR ((('rotator cuff' OR 'shoulder' OR tendon) NEAR/5 (repair* OR reconstruct* OR surger* OR surgic* OR operation* OR operative)):ti,ab,kw) OR surgic*:ti,kw OR surger*:ti,kw OR operation*:ti,kw OR operative:ti,kw OR 'single row':ti,ab,kw OR 'double row':ti,ab,kw	1241204
#9	'rotator cuff injury'/exp/mj OR 'rotator cuff rupture'/exp/mj OR ((('rotator cuff' OR 'shoulder cuff' OR infraspinatus OR supraspinatus OR subscapularis) NEAR/3 (tear* OR lesion* OR rupture* OR tendinopath* OR laceration*)):ti,ab,kw) OR (('full-thickness':ti,ab,kw OR partial:ti,ab,kw) AND 'rotator cuff':ti,ab,kw) OR ('rotator cuff'/exp/mj AND ('rupture'/exp/mj OR 'injury'/mj OR 'laceration'/exp/mj))	13918

Ovid/Medline

#	Searches	Results
11	9 or 10	298
10	(6 and 8) not 9 **= RCT**	178
9	6 and 7 **= SR**	120
8	exp randomized controlled trial/ or randomized controlled trials as topic/ or random*.ti,ab. or rct?.ti,ab. or ((pragmatic or practical) adj "clinical trial*").ti,ab,kf. or ((non-inferiority or noninferiority or superiority or equivalence) adj3 trial*).ti,ab,kf.	1587608
7	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	649325
6	limit 5 to ((english language or dutch) and yr="2013 -Current")	808
5	4 not (comment/ or editorial/ or letter/ or ((exp animals/ or exp models, animal/) not humans/))	1477
4	1 and 2 and 3	1634

3	exp Conservative Treatment/ or exp Physical Therapy Modalities/ or exp Exercise Therapy/ or exp Occupational Therapy/ or physiotherap*.ti,ab,kf. or 'physio therap*'.ti,ab,kf. or 'physical therap*'.ti,ab,kf. or kinesiotherap*.ti,ab,kf. or kinesitherapeutic*.ti,ab,kf. or 'occupation* therap*'.ti,ab,kf. or ergotherap*.ti,ab,kf. or 'conservative treatment'.ti,ab,kf. or nonsurg*.ti,ab,kf. or nonoperatic*.ti,ab,kf. or 'non-surg*'.ti,ab,kf. or 'non-operati*'.ti,ab,kf. or exp *Exercise/ or ((exercise or manual) adj3 therap*).ti,ab,kf. or exp Rehabilitation/ or exp "Physical and Rehabilitation Medicine"/ or rehabilitat*.ti,ab,kf. or exp Musculoskeletal Manipulations/ or manipulat*.ti,ab,kf. or mobilization.ti,ab,kf. or mobilisation.ti,ab,kf. or exp Massage/ or 'massage'.ti,ab,kf. or exp Muscle Stretching Exercises/ or stretch*.ti,ab,kf. or exp Resistance Training/ or ((resistance or strength*) adj3 (train* or exercise*)).ti,ab,kf. or exp Injections/ or inject*.ti,ab,kf. or exp Anti-Inflammatory Agents, Non-Steroidal/ or 'nonsteroid antiinflammatory agent*'.ti,ab,kf. or nsaid*.ti,ab,kf.	2267264
2	Rotator Cuff/su or Shoulder Joint/su or Acromion/su or Shoulder/su or (('rotator cuff' or 'shoulder' or tendon) adj5 (repair* or reconstruct* or surger* or surgic* or operation* or operative)).ti,ab,kf. or surgic*.ti,kf. or surger*.ti,kf. or operation*.ti,kf. or operative.ti,kf. or 'single row'.ti,ab,kf. or 'double row'.ti,ab,kf.	999872
1	*Rotator Cuff/ or exp Rotator Cuff Injuries/ or (('rotator cuff' or 'shoulder cuff' or infraspinatus or supraspinatus or subscapularis) adj3 (tear* or lesion* or rupture* or tendinopath* or laceration*)).ti,ab,kf. or (('full-thickness' or partial) and 'rotator cuff').ti,ab,kf.	13101

Module 5.2 Bicepspees tenotomie/tenodese

Uitgangsvraag
Wat is de toegevoegde waarde van een bicepspees tenotomie/dese versus geen bicepspees tenotomie/dese bij patiënten met een normale bicepspees waarbij de manchet (supraspinatus) gehecht is?

Introduction (English)
Patients with injuries to the supraspinatus tendon may also experience pain from the long biceps tendon. For this reason, biceps tenotomy or tenodesis can be performed in combination with suturing the supraspinatus tendon. This is a standard procedure for some shoulder surgeons, even when the long biceps tendon appears normal. The question is whether that is useful or whether it can have adverse effects.

Search and select
A systematic review of the literature was performed to answer the following question: What are the effects of tenotomy or tenodesis of the biceps tendon in patients with an isolated supraspinatus tendon tear and who have no pathology of the biceps tendon?

Patients	Patients with a repair of a supraspinatus tendon tear and without pathology of the intra-articular part of the biceps tendon
Intervention	Tenotomy or tenodesis of the biceps tendon
Control	No tenotomy or tenodesis
Outcomes	Complications, PROMS for pain and function, patient satisfaction, return to work or leisure

<u>Relevant outcome measures</u>
The guideline development group considered pain and function as critical outcome measures for decision making; and patient satisfaction, return to work or leisure, and complications as important outcome measures for decision making.

The guideline development group defined the outcome measures as follows:

- Patient reported outcomes measures: Constant Murley Score (CMS), Disability of the Arm, Shoulder and Hand Questionnaire (DASH), Western Ontario Rotator Cuff (WORC) Index, American Shoulder and Elbow Surgeons (ASES) Score, Oxford Shoulder Score (OSS)
- Pain: VAS-scale (0-10 points or 0-100mm scale)
- Complications: symptomatic Popeye sign, adhesion in the bicipital groove of the biceps tendon
- Patient satisfaction: self-reported satisfaction with treatment and/or function
- Return to work or leisure: definitions used in the studies.

The guideline development group defined the minimal clinically (patient) important differences as follows:

- Patient reported outcomes measures:
    - CMS: 10 points on this 100-point scale (Holmgren, 2014)
    - DASH: 13 on a 100 point scale (Koorevaar, 2018)
    - WORC: -282.6 on a 2100 point scale (Gagnier, 2018)
    - ASES: 9 on a 100 point scale (Gagnier, 2018)

    - DSST: 2.8 on a 12 point scale (Van Kampen, 2013)
    - OSS: 5 points on a 48-point scale (Nyring, 2021)
- Pain
    - 1/10 points or 10/100 points on a VAS scale
- Complications: 25% (RR ≤ 0.80 and ≥ 1.25)
- Patient satisfaction: difference of 25% (RR ≤ 0.80 and ≥ 1.25) or 1/10 points or 10/100 points on a VAS scale.
- Return to work or leisure: difference of 25% (RR ≤ 0.80 and ≥ 1.25)

Search and select (Methods)
The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until the 8th of March 2023. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 276 hits. Studies were selected based on the following criteria:

1) Systematic review, meta-analysis, RCT or other comparative research
2) Comparing bicep tenotomy or tenodesis with no tenotomy or tenodesis
3) In adult patients
4) With a surgery of the rotator cuff and who have no pathology of the tendon of the biceps
5) Reporting outcomes for complications, PROMS for pain and function, patient satisfaction
6) With a follow-up of 1 year and longer.

44 studies were initially selected based on title and abstract screening. After reading the full text, all studies were excluded (see the table with reasons for exclusion under the tab Methods) and no studies were included.

Results
No studies were included in the analysis of the literature, since the search results did not match the PICO.

Summary of literature
Description of studies
No studies were found that matched the PICO.

Conclusions

No GRADE	No evidence was found regarding the comparison between tenotomy or tenodesis of the biceps tendon and no tenotomy or tenodesis in adult patients with a repair of a supraspinatus tendon tear and without pathology of the intra-articular part of the biceps tendon.

Overwegingen – van bewijs naar aanbeveling

Voor- en nadelen van de interventie en de kwaliteit van het bewijs

Er is literatuuronderzoek verricht naar het effect van tenotomie (doorsnijden van de bicepspees) of tenodese (vastzetten van de bicepspees) van de lange bicepspees vergeleken met geen tenotomie of tenodese bij patiënten met een normaal uitziende bicepspees waarbij de cuff (supraspinatus) wordt gehecht. Er zijn geen systematische reviews, RCTs of vergelijkende observationele studies gevonden die aan deze PICO voldoen. Er zijn daarom geen studies geïncludeerd in de samenvatting van de literatuur als ook geen conclusies geformuleerd. Om deze reden zal de keuze voor de ene dan wel de andere behandeling dus afhangen van andere factoren.

Op grond van de bestaande literatuur is het dus niet duidelijk of er meerwaarde is voor operatieve additionele behandeling van een normale bicepspees.

Redenen waarom de meerwaarde mogelijk lastig te bewijzen is, kunnen zijn:

a. Een normale bicepspees veroorzaakt geen klachten.
b. Het is moeilijk om bij blijvende pijn na een cuff operatie te bewijzen dat de niet behandelde bicepspees de oorzaak daarvan is.

Nadelen van additionele behandeling kunnen zijn:

a) Tenodese: argumenten om geen tenodese te doen zijn de operatieduur, de additionele kosten, de onbelaste nabehandeling, en de complicatiekans zoals persisterende lokale pijn en falen van de fixatie (2,3%)(Ahmed, 2021).
b) Tenotomie: bij tenotomie bestaan de nadelen met name uit het verkorten van de spierbuik van de biceps leidend tot mogelijk (blijvende) pijn of spierkrampen (met name bij belasting), het kosmetische aspect (Popeye sign), of de kans op anterieure schouderpijn wanneer het uiteinde van de bicepspees in de bicepsgroeve verkleefd.

Voordelen van bicepspees bicepspeestenotomie of -dese is de mogelijkheid dat bicepspathologie bij scopie over het hoofd gezien wordt. Denk aan subluxatieproblemen of problemen in de (niet zichtbare) sulcus, waardoor klachten zouden kunnen blijven bestaan. Behandeling van de bicepspees sluit bij persisterende postoperatieve klachten een intra-articulair bicepsprobleem uit.

Uit de systematische review en meta-analyse van Ahmed (2021) blijkt dat zowel een bicepspeestenotomie als een -tenodese tot goede resultaten leidt zonder klinisch relevante verschillen.

Waarden en voorkeuren van patiënten (en evt. hun verzorgers)

Aangezien er aan beide keuzes voor- en nadelen verbonden zijn, zal het voor de patiënt net zo'n lastige keuze zijn als voor de operateur. De mogelijke behandeling van de bicepspees (tenotomie of tenodese) die de operateur peroperatief gaat verrichten, zal bij iedere cuff operatie sowieso van tevoren besproken moeten worden, aangezien bicepspathologie op voorhand niet altijd uit te sluiten is en een tenodese of tenotomie dus noodzakelijk kan zijn. Bij tenodese kan het maken van een extra wond nodig zijn (afhankelijk van de fixatiemethode, arthroscopisch of mini-open) met bijkomstige risico's zoals wondgenezingsstoornissen, diepe infectie en/of een afwijkend litteken. Voor patiënten is het belangrijk dat deze voor- en nadelen met hen besproken worden om zo volgens de principes van Samen Beslissen te bepalen welke behandeling passend is.

Kosten (middelenbeslag)

Tenotomie brengt geen extra kosten met zich mee, tenzij deze wordt uitgevoerd met een radiofrequentie ablatie-instrument. Tenodese is duurder omdat sprake is van een langere operatieduur en er meer kosten gemaakt worden in verband met het gebruik van eventuele implantaten (fixatieanker) en bijkomende materialen (denk aan een canule, boormateriaal, extra operatienetten e.d.).

Aanvaardbaarheid, haalbaarheid en implementatie
De interventie tenotomie of tenodese bestaat uit gangbare en goed bekende technieken.

Aanbeveling
Rationale van de aanbeveling: weging van argumenten voor en tegen de interventies
Op grond van de bestaande literatuur is het niet duidelijk of er meerwaarde is voor operatieve additionele bicepspeestenotomie of -dese van een (bij arthroscopie) normaal uitziende bicepspees. Op basis van operatie technische redenen kan door de operateur eventueel besloten worden tot tenotomie of tenodese, bijvoorbeeld wanneer de lange bicepspees bij een scheur ventraal in de supraspinatuspees belemmering kan geven om een adequate cuff repair uit te voeren.

Gezien de kans op mogelijke complicaties van een bicepspees behandeling en extra kosten van bicepspees tenodese, wordt terughoudendheid geadviseerd bij een normaal uitziende bicepspees.

Aanbeveling

Wees tijdens een supraspinatuspees repair terughoudend met het uitvoeren van bicepspeestenotomie of -dese bij een normaal uitziende lange bicepspees, tenzij er het risico bestaat op beschadiging van de bicepspees als gevolg van de supraspinatuspees repair.

Kennisvragen
Wat zijn de effecten van tenotomie of tenodese van de normale bicepspees bij patiënten met een geïsoleerde supraspinatuspeesscheuroperatie van de rotator cuff en die geen pathologie van de bicepspees hebben?

Literatuur

Ahmed AF, Toubasi A, Mahmoud S, Ahmed GO, Al Ateeq Al Dosari M, Zikria BA. Long head of biceps tenotomy versus tenodesis: a systematic review and meta-analysis of randomized controlled trials. Shoulder Elbow. 2021 Oct;13(6):583-591. doi: 10.1177/1758573220942923. Epub 2020 Jul 22. PMID: 34804206; PMCID: PMC8600672.

van Deurzen DFP, Garssen FL, Wessel RN, Kerkhoffs GMMJ, van den Bekerom MPJ, van Wier MF. The Popeye sign: a doctor's and not a patient's problem. J Shoulder Elbow Surg. 2021 May;30(5):969-976. doi: 10.1016/j.jse.2020.10.040. Epub 2020 Dec 5. PMID: 33290851.

Gagnier JJ, Robbins C, Bedi A, Carpenter JE, Miller BS. Establishing minimally important differences for the American Shoulder and Elbow Surgeons score and the Western Ontario Rotator Cuff Index in patients with full-thickness rotator cuff tears. J Shoulder Elbow Surg. 2018 May;27(5):e160-e166. doi: 10.1016/j.jse.2017.10.042. Epub 2018 Jan 4. PMID: 29307675.

Holmgren T, Oberg B, Adolfsson L, Björnsson Hallgren H, Johansson K. Minimal important changes in the Constant-Murley score in patients with subacromial pain. J Shoulder

Elbow Surg. 2014 Aug;23(8):1083-90. doi: 10.1016/j.jse.2014.01.014. Epub 2014 Apr 13. PMID: 24726486.

van Kampen DA, Willems WJ, van Beers LW, Castelein RM, Scholtes VA, Terwee CB. Determination and comparison of the smallest detectable change (SDC) and the minimal important change (MIC) of four-shoulder patient-reported outcome measures (PROMs). J Orthop Surg Res. 2013 Nov 14;8:40. doi: 10.1186/1749-799X-8-40. PMID: 24225254; PMCID: PMC3842665.

Koorevaar RCT, Kleinlugtenbelt YV, Landman EBM, van 't Riet E, Bulstra SK. Psychological symptoms and the MCID of the DASH score in shoulder surgery. J Orthop Surg Res. 2018 Oct 4;13(1):246. doi: 10.1186/s13018-018-0949-0. PMID: 30286775; PMCID: PMC6172756.

Nyring MRK, Olsen BS, Amundsen A, Rasmussen JV. Minimal Clinically Important Differences (MCID) for the Western Ontario Osteoarthritis of the Shoulder Index (WOOS) and the Oxford Shoulder Score (OSS). Patient Relat Outcome Meas. 2021 Sep 22;12:299-306. doi: 10.2147/PROM.S316920. PMID: 34588833; PMCID: PMC8473013.

Bijlagen bij module 5.2 Bicepspees tenotomie / tenodese

Implementatieplan

Aanbeveling	Tijdspad voor implementatie: < 1 jaar, 1 tot 3 jaar of > 3 jaar	Verwacht effect op kosten	Randvoorwaarden voor implementatie (binnen aangegeven tijdspad)	Mogelijke barrières voor implementatie	Te ondernemen acties voor implementatie	Verantwoordelijken voor acties	Overige opmerkingen
Wees tijdens een supraspinatuspees repair terughoudend met het uitvoeren van bicepspeestenotomie of -dese bij een normaal uitziende lange bicepspees, tenzij er het risico bestaat op beschadiging van de bicepspees als gevolg van de supraspinatuspees repair.	< 1 jaar	besparing kosten voor die patiënten waarbij anders een bicepspeestenode was verricht; voor de patiënten waarbij anders een tenotomie zou zijn verricht is het effect op de kosten nihil.	geen	Dit betreft een gedragsveranderin g van schouderchirurge n. Het kan moeilijk zijn een gewoonte te doorbreken.	Bewustwording schouderchirurge n Bijvoorbeeld door deelname aan kennisspel	Beroepsvverenigin g NOV/werkgroep schouder/elleboog NOV	geen

Table of excluded studies

Reference	Reason for exclusion
Aflatooni JO, Meeks BD, Froehle AW, Bonner KF. Biceps tenotomy versus tenodesis: patient-reported outcomes and satisfaction. J Orthop Surg Res. 2020 Feb 18;15(1):56. doi: 10.1186/s13018-020-1581-3. PMID: 32070381; PMCID: PMC7029563.	Wrong design, comparison tendodesis & tenotomy
Aydemir, A. N., Ergün, S., Berkem, L., Poyanlı, O. Ş., Esenkaya, İ., & Akan, H. K. Results of biceps tenotomy in the treatment of shoulder impingement and rotator cuff tears. Medical Journal of Bakirkoy. 2015; 11(2), 74-81.	Wrong I & C (subacromial decompression)
Baumgarten KM, Chang PS, Foley EK. Patient-determined outcomes after arthroscopic rotator cuff repair with and without biceps tenodesis utilizing the PITT technique. J Shoulder Elbow Surg. 2019 Jun;28(6):1049-1055. doi: 10.1016/j.jse.2019.01.024. Epub 2019 Apr 10. PMID: 30981549.	Wrong design, comparison tendodesis & tenotomy
Belay ES, Wittstein JR, Garrigues GE, Lassiter TE, Scribani M, Goldner RD, Bean CA. Biceps tenotomy has earlier pain relief compared to biceps tenodesis: a randomized prospective study. Knee Surg Sports Traumatol Arthrosc. 2019 Dec;27(12):4032-4037. doi: 10.1007/s00167-019-05682-1. Epub 2019 Sep 5. PMID: 31486915.	Tenotomy vs tenodesis
Belk JW, Kraeutler MJ, Houck DA, Chrisman AN, Scillia AJ, McCarty EC. Biceps tenodesis versus tenotomy: a systematic review and meta-analysis of level I randomized controlled trials. J Shoulder Elbow Surg. 2021 May;30(5):951-960. doi: 10.1016/j.jse.2020.11.012. Epub 2020 Dec 26. PMID: 33373685.	Tenotomy vs tenodesis
Çakar B, Güney A, Güney B, Uzun E, Sekban H. The effect of biceps tenotomy on humeral migration and clinical outcomes in arthroscopic rotator cuff repair. J Exp Orthop. 2022 Nov 30;9(1):113. doi: 10.1186/s40634-022-00550-3. PMID: 36447061; PMCID: PMC9708983.	Wrong P (bicep tendon pathology)
Can, F. İ., GULTAC, E., KILINÇ, C. Y., Şahin, İ. G., & AYDOĞAN, N. Comparison of the clinical outcomes of chronic rupture, arthroscopic tenotomy and tenodesis of proximal biceps tendon. Journal of Experimental and Clinical Medicine, 2022; 39(3).	Wrong P (biceps disorders), Wrong comparison

Carbone S, Castagna V, Passaretti D, Candela V, Cerciello S, Delli Sante E, Gumina S. Supraspinatus repair and biceps tenodesis in competitive CrossFit athletes allow for a 100% of return to sport. Knee Surg Sports Traumatol Arthrosc. 2021 Dec;29(12):3929-3935. doi: 10.1007/s00167-020-06345-2. Epub 2020 Nov 7. PMID: 33159531.	Wrong design, wrong P
Castricini R, Familiari F, De Gori M, Riccelli DA, De Benedetto M, Orlando N, Galasso O, Gasparini G. Tenodesis is not superior to tenotomy in the treatment of the long head of biceps tendon lesions. Knee Surg Sports Traumatol Arthrosc. 2018 Jan;26(1):169-175. doi: 10.1007/s00167-017-4609-4. Epub 2017 Jun 16. PMID: 28623414.	Tenotomy vs tenodesis
Cho NS, Cha SW, Rhee YG. Funnel tenotomy versus intracuff tenodesis for lesions of the long head of the biceps tendon associated with rotator cuff tears. Am J Sports Med. 2014 May;42(5):1161-8. doi: 10.1177/0363546514523719. Epub 2014 Feb 27. PMID: 24576743.	Wrong design
Clement X, Baldairon F, Clavert P, Kempf JF. Popeye sign: Tenodesis vs. self-locking "T" tenotomy of the long head of the biceps. Orthop Traumatol Surg Res. 2018 Feb;104(1):23-26. doi: 10.1016/j.otsr.2017.09.016. Epub 2017 Oct 18. Erratum in: Orthop Traumatol Surg Res. 2018 Mar 12;: PMID: 29055727.	Wrong design
Desai SS, Mata HK. Long Head of Biceps Tendon Pathology and Results of Tenotomy in Full-Thickness Reparable Rotator Cuff Tear. Arthroscopy. 2017 Nov;33(11):1971-1976. doi: 10.1016/j.arthro.2017.06.018. Epub 2017 Aug 26. PMID: 28847573.	Wrong design (retrospective), wrong I &C
Dwyer C, Kia C, Apostolakos JM, DiVenere J, Dyrna F, Cote M, Arciero RA, Mazzocca AD. Clinical Outcomes After Biceps Tenodesis or Tenotomy Using Subpectoral Pain to Guide Management in Patients With Rotator Cuff Tears. Arthroscopy. 2019 Jul;35(7):1992-2000. doi: 10.1016/j.arthro.2019.02.017. Epub 2019 Jun 10. PMID: 31196693.	Wrong design, comparison tendodesis & tenotomy
Fang JH, Dai XS, Yu XN, Luo JY, Liu XN, Zhang MF, Zhu SN. Lesions of the Long Head of the Biceps Tendon Concomitant with Rotator Cuff Tears: Tenotomy or Subpectoral Mini-open Tenodesis? A Comparative Short to Mid-term Follow-up Study. Orthop Surg. 2019	Wrong design, comparison tendodesis & tenotomy

Oct;11(5):857-863. doi: 10.1111/os.12536. Epub 2019 Sep 18. PMID: 31532924; PMCID: PMC6819190.	
Godenèche A, Kempf JF, Nové-Josserand L, Michelet A, Saffarini M, Hannink G, Collin P. Tenodesis renders better results than tenotomy in repairs of isolated supraspinatus tears with pathologic biceps. J Shoulder Elbow Surg. 2018 Nov;27(11):1939-1945. doi: 10.1016/j.jse.2018.03.030. Epub 2018 May 18. PMID: 29784596.	Wrong design, comparison tendodesis & tenotomy
Hartland AW, Islam R, Teoh KH, Rashid MS. Clinical effectiveness of tenotomy versus tenodesis for long head of biceps pathology: a systematic review and meta-analysis. BMJ Open. 2022 Oct 11;12(10):e061954. doi: 10.1136/bmjopen-2022-061954. PMID: 36220319; PMCID: PMC9557260.	Tenotomy vs tenodesis
Hughes JD, Gibbs CM, Drummond M, Vaswani R, Ayinon C, Fongod E, Godshaw BM, Popchak A, Lesniak BP, Lin A. Failure rates and clinical outcomes after treatment for long-head biceps brachii tendon pathology: a comparison of three treatment types. JSES Int. 2021 May 10;5(4):630-635. doi: 10.1016/j.jseint.2021.04.011. PMID: 34223407; PMCID: PMC8245991.	Wrong P (bicep tendon pathology)
Kawashima I, Sugaya H, Takahashi N, Matsuki K, Tokai M, Hiraiwa H, Imagama S. Assessment of the Preserved Biceps Tendon After Arthroscopic Rotator Cuff Repair in Patients ≤ 55 Years. Arthrosc Sports Med Rehabil. 2021 Jun 25;3(5):e1273-e1278. doi: 10.1016/j.asmr.2021.04.006. PMID: 34712963; PMCID: PMC8527261.	Wrong design, wrong comparison: compared postoperative pain between shoulders with or without vascularity in the bicipital groove
Kawashima I, Sugaya H, Takahashi N, Matsuki K, Tokai M, Ishizuka S, Hiraiwa H, Imagama S. Biceps tenotomy versus soft-tissue tenodesis in females aged 60 years and older with rotator cuff tears. J Orthop Sci. 2022 Jul;27(4):786-791. doi: 10.1016/j.jos.2021.04.012. Epub 2021 May 31. PMID: 34083089.	Wrong design, comparison tendodesis & tenotomy
Keong MW, Tjoen DLT. Does bicep pathology affect rotator cuff repair outcomes? J Orthop Surg (Hong Kong). 2018 Jan-Apr;26(1):2309499018762852. doi: 10.1177/2309499018762852. PMID: 29540098.	Wrong design (case-control)

Kim J, Nam JH, Kim Y, Kim JS, Kim SH. Long Head of the Biceps Tendon Tenotomy versus Subpectoral Tenodesis in Rotator Cuff Repair. Clin Orthop Surg. 2020 Sep;12(3):371-378. doi: 10.4055/cios19168. Epub 2020 Jun 24. PMID: 32904028; PMCID: PMC7449864.	Wrong design, comparison tendodesis & tenotomy
Kukkonen J, Rantakokko J, Virolainen P, Äärimaa V. The effect of biceps procedure on the outcome of rotator cuff reconstruction. ISRN Orthop. 2013 Feb 13;2013:840965. doi: 10.1155/2013/840965. PMID: 24967118; PMCID: PMC4045343.	Wrong P (irritated/frayed/unstable biceps tendon)
Lee HJ, Jeong JY, Kim CK, Kim YS. Surgical treatment of lesions of the long head of the biceps brachii tendon with rotator cuff tear: a prospective randomized clinical trial comparing the clinical results of tenotomy and tenodesis. J Shoulder Elbow Surg. 2016 Jul;25(7):1107-14. doi: 10.1016/j.jse.2016.02.006. PMID: 27283370.	Tenotomy vs tenodesis
Leroux T, Chahal J, Wasserstein D, Verma NN, Romeo AA. A Systematic Review and Meta-analysis Comparing Clinical Outcomes After Concurrent Rotator Cuff Repair and Long Head Biceps Tenodesis or Tenotomy. Sports Health. 2015 Jul;7(4):303-7. doi: 10.1177/1941738114539627. PMID: 26137174; PMCID: PMC4481674.	Tenotomy vs tenodesis
Malavolta EA, Sousa AC, Gracitelli MEC, Assunção JH, Andrade E Silva FB, Ferreira Neto AA. Biceps tenotomy or tenodesis in association with rotator cuff repair: is there an influence on functional results? A retrospective cohort study. Sao Paulo Med J. 2022 Mar 14;140(2):237-243. doi: 10.1590/1516-3180.2021.0219.R1.28062021. PMID: 35293936; PMCID: PMC9610255.	Wrong P (indication for LHBT procedures: subluxation, dislocation, lesions)
Mardani-Kivi M, Asadi K, Izadi A, Leili EK. Rotator cuff repair with or without proximal end detachment for long head of the biceps tendon tenodesis. Clin Shoulder Elb. 2022 Jun;25(2):101-105. doi: 10.5397/cise.2021.00493. Epub 2022 Mar 17. PMID: 35295070; PMCID: PMC9185117.	Wrong P (patients with a background of LHBT pathology)
Mardani-Kivi, M., Karimi Mobarakeh, M., Keyhani, S., Ebrahim-zadeh, M. H., & Haghparast Ghadim-Limudahi, Z. Treatment of long head of biceps tendon lesions together with rotator cuff tears: which method is preferred? Tenotomy or tenodesis. Techniques in Shoulder & Elbow	Tenotomy vs tenodesis

Surgery. 2018; 19(3), 101-105.	
Meraner D, Sternberg C, Vega J, Hahne J, Kleine M, Leuzinger J. Arthroscopic tenodesis versus tenotomy of the long head of biceps tendon in simultaneous rotator cuff repair. Arch Orthop Trauma Surg. 2016 Jan;136(1):101-6. doi: 10.1007/s00402-015-2343-2. Epub 2015 Oct 24. PMID: 26497981.	Wrong design, comparison tendodesis & tenotomy
Mijic D, Kurowicki J, Berglund D, Rosas S, McNeely E, Motisi M, Polisetty T, Levy JC. Effect of biceps tenodesis on speed of recovery after arthroscopic rotator cuff repair. JSES Int. 2020 Feb 24;4(2):341-346. doi: 10.1016/j.jseint.2019.12.010. PMID: 32490423; PMCID: PMC7256889.	Wrong P (patients with pathology of the long head of the biceps tendon)
Moorthy V, Tan AHC. Should long head of biceps tenodesis or tenotomy be routinely performed in arthroscopic rotator cuff repairs? J Orthop. 2020 Mar 25;21:161-165. doi: 10.1016/j.jor.2020.03.033. PMID: 32255998; PMCID: PMC7114602.	Wrong design: Narrative review
Na Y, Zhu Y, Shi Y, Ren Y, Zhang T, Liu W, Han C. A meta-analysis comparing tenotomy or tenodesis for lesions of the long head of the biceps tendon with concomitant reparable rotator cuff tears. J Orthop Surg Res. 2019 Nov 15;14(1):370. doi: 10.1186/s13018-019-1429-x. PMID: 31729995; PMCID: PMC6858715.	Tenotomy vs tenodesis
Nemirov DA, Herman Z, Paul RW, Beucherie M, Hadley CJ, Ciccotti MG, Freedman KB, Erickson BJ, Hammoud S, Bishop ME. Evaluation of Rotator Cuff Repair With and Without Concomitant Biceps Intervention: A Retrospective Review of Patient Outcomes. Am J Sports Med. 2022 May;50(6):1534-1540. doi: 10.1177/03635465221085661. Epub 2022 Apr 6. PMID: 35384741.	Wrong P (bicep tendon pathology)
O'Brien MJ. Editorial Commentary: Shoulder Biceps Tenotomy Versus Tenodesis Surgical Decision Making Must be Individualized for Each Patient. Arthroscopy. 2021 Jun;37(6):1777-1778. doi: 10.1016/j.arthro.2021.03.015. PMID: 34090564.	Wrong design: editorial commentary, tenotomy vs. Tenodesis

Patel KV, Bravman J, Vidal A, Chrisman A, McCarty E. Biceps Tenotomy Versus Tenodesis. Clin Sports Med. 2016 Jan;35(1):93-111. doi: 10.1016/j.csm.2015.08.008. Epub 2015 Sep 26. PMID: 26614471.	Tenotomy vs tenodesis
Pouliquen L, Berhouet J, Istvan M, Thomazeau H, Ropars M, Collin P. Popeye sign: Frequency and functional impact. Orthop Traumatol Surg Res. 2018 Oct;104(6):817-822. doi: 10.1016/j.otsr.2018.02.016. Epub 2018 May 24. PMID: 29803774.	Wrong design; wrong comparison (comparing patients with and without popeye sign)
Pozzetti Daou J, Nagaya DY, Matsunaga FT, Sugawara Tamaoki MJ. Does Biceps Tenotomy or Tenodesis Have Better Results After Surgery? A Systematic Review and Meta-analysis. Clin Orthop Relat Res. 2021 Jul 1;479(7):1561-1573. doi: 10.1097/CORR.0000000000001672. PMID: 33617158; PMCID: PMC8208384.	Tenotomy vs tenodesis
Shang X, Chen J, Chen S. A meta-analysis comparing tenotomy and tenodesis for treating rotator cuff tears combined with long head of the biceps tendon lesions. PLoS One. 2017 Oct 9;12(10):e0185788. doi: 10.1371/journal.pone.0185788. PMID: 29016616; PMCID: PMC5633150.	Tenotomy vs tenodesis
Srinivasan RC, Hao KA, Wright TW, Farmer KW, Wright JO, Roach RP, Moser MW, Freidl MC, Pazik M, King JJ. Outcomes of Biceps Tenotomy Versus Tenodesis During Arthroscopic Rotator Cuff Repair: An Analysis of Patients From a Large Multicenter Database. Orthop J Sports Med. 2022 Jul 15;10(7):23259671221110851. doi: 10.1177/23259671221110851. PMID: 35859647; PMCID: PMC9290127.	Tenotomy vs tenodesis
Vajda M, Szakó L, Hegyi P, Erőss B, Görbe A, Molnár Z, Kozma K, Józsa G, Bucsi L, Schandl K. Tenodesis yields better functional results than tenotomy in long head of the biceps tendon operations-a systematic review and meta-analysis. Int Orthop. 2022 May;46(5):1037-1051. doi: 10.1007/s00264-022-05338-9. Epub 2022 Mar 7. PMID: 35254476; PMCID: PMC9001564.	Tenotomy vs tenodesis

van Deurzen DFP, Auw Yang KG, Onstenk R, Raven EEJ, van den Borne MPJ, Hoelen MA, Wessel RN, Willigenburg NW, Klaassen AD, van den Bekerom MPJ; BITE Study Group. Long Head of Biceps Tenotomy Is Not Inferior to Suprapectoral Tenodesis in Arthroscopic Repair of Nontraumatic Rotator Cuff Tears: A Multicenter, Non-inferiority, Randomized, Controlled Clinical Trial. Arthroscopy. 2021 Jun;37(6):1767-1776.e1. doi: 10.1016/j.arthro.2021.01.036. Epub 2021 Feb 6. PMID: 33556551.	Tenotomy vs tenodesis
Watson ST, Robbins CB, Bedi A, Carpenter JE, Gagnier JJ, Miller BS. Comparison of Outcomes 1 Year After Rotator Cuff Repair With and Without Concomitant Biceps Surgery. Arthroscopy. 2017 Nov;33(11):1928-1936. doi: 10.1016/j.arthro.2017.05.009. Epub 2017 Aug 16. PMID: 28822640.	Wrong P (bicep tendon pathology)
Woodmass JM, McRae SMB, Lapner PL, Sasyniuk T, Old J, Stranges G, Dubberly J, Verhulst FV, MacDonald PB. Effect of age, gender, and body mass index on incidence and satisfaction of a Popeye deformity following biceps tenotomy or tenodesis: secondary analysis of a randomized clinical trial. J Shoulder Elbow Surg. 2021 Aug;30(8):1733-1740. doi: 10.1016/j.jse.2021.05.003. Epub 2021 May 19. PMID: 34022365.	Tenotomy vs tenodesis
Yoğun Y, Bezirgan U, Dursun M, Armangil M. Is biceps tenodesis necessary when performing arthroscopic rotator cuff repair in patients older than 55 years? Arch Orthop Trauma Surg. 2022 Nov 27. doi: 10.1007/s00402-022-04707-8. Epub ahead of print. PMID: 36436066.	Tenotomy vs tenodesis
Zhang Q, Zhou J, Ge H, Cheng B. Tenotomy or tenodesis for long head biceps lesions in shoulders with reparable rotator cuff tears: a prospective randomised trial. Knee Surg Sports Traumatol Arthrosc. 2015 Feb;23(2):464-9. doi: 10.1007/s00167-013-2587-8. Epub 2013 Jul 5. PMID: 23828089.	Tenotomy vs tenodesis

Literature search strategy

Zoekopbrengst

	EMBASE	OVID/MEDLINE	Ontdubbeld
SRs	22	27	33
RCT	32	40	40
Observationele studies	187	153	203
Totaal	241	220	**276**

Zoekstrategie

Embase.com

No.	Query	Results
#16	#13 OR #14 OR #15	241
#15	#9 AND #12 NOT (#13 OR #14) **= observationeel**	187
#14	#9 AND #11 NOT #13 **= RCT**	32
#13	#9 AND #10 **= SR**	22
#12	'clinical trial'/exp OR 'randomization'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR 'placebo'/exp OR 'prospective study'/exp OR rct:ab,ti OR random*:ab,ti OR 'single blind':ab,ti OR 'randomised controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti OR 'major clinical study'/de OR 'clinical study'/de OR 'family study'/de OR 'longitudinal study'/de OR 'retrospective study'/de OR 'prospective study'/de OR 'comparative study'/de OR 'cohort analysis'/de OR ((cohort NEAR/1 (study OR studies)):ab,ti) OR (('case control' NEAR/1 (study OR studies)):ab,ti) OR (('follow up' NEAR/1 (study OR studies)):ab,ti) OR (observational NEAR/1 (study OR studies)) OR ((epidemiologic NEAR/1 (study OR studies)):ab,ti) OR (('cross sectional' NEAR/1 (study OR studies)):ab,ti) OR 'case control study'/de OR 'comparative study'/exp OR 'control group'/de OR 'controlled study'/de OR 'controlled clinical trial'/de OR 'crossover procedure'/de OR 'double blind procedure'/de OR 'phase 2 clinical trial'/de OR 'phase 3 clinical trial'/de OR 'phase 4 clinical trial'/de OR 'pretest posttest design'/de OR 'pretest posttest control group design'/de OR 'quasi experimental study'/de OR 'single blind procedure'/de OR 'triple blind procedure'/de OR (((control OR controlled) NEAR/6 trial):ti,ab,kw) OR (((control OR controlled) NEAR/6 (study OR studies)):ti,ab,kw) OR (((control OR controlled) NEAR/1 active):ti,ab,kw) OR 'open label*':ti,ab,kw OR (((double OR two OR three OR multi OR trial) NEAR/1 (arm OR arms)):ti,ab,kw) OR ((allocat* NEAR/10 (arm OR arms)):ti,ab,kw) OR placebo*:ti,ab,kw OR 'sham-control*':ti,ab,kw OR (((single OR double OR triple OR assessor) NEAR/1 (blind* OR masked)):ti,ab,kw) OR nonrandom*:ti,ab,kw OR 'non-random*':ti,ab,kw OR 'quasi-experiment*':ti,ab,kw OR crossover:ti,ab,kw OR 'cross over':ti,ab,kw OR 'parallel group*':ti,ab,kw OR 'factorial trial':ti,ab,kw OR ((phase NEAR/5 (study OR trial)):ti,ab,kw) OR ((case* NEAR/6 (matched OR control*)):ti,ab,kw) OR ((match* NEAR/6 (pair OR pairs OR cohort* OR control* OR group* OR healthy OR	16441812

	age OR sex OR gender OR patient* OR subject* OR participant*)):ti,ab,kw) OR ((propensity NEAR/6 (scor* OR match*)):ti,ab,kw) OR versus:ti OR vs:ti OR compar*:ti OR ((compar* NEAR/1 study):ti,ab,kw) OR (('major clinical study'/de OR 'clinical study'/de OR 'cohort analysis'/de OR 'observational study'/de OR 'cross-sectional study'/de OR 'multicenter study'/de OR 'correlational study'/de OR 'follow up'/de OR cohort*:ti,ab,kw OR 'follow up':ti,ab,kw OR followup:ti,ab,kw OR longitudinal*:ti,ab,kw OR prospective*:ti,ab,kw OR retrospective*:ti,ab,kw OR observational*:ti,ab,kw OR 'cross sectional*':ti,ab,kw OR cross?ectional*:ti,ab,kw OR multicent*:ti,ab,kw OR 'multi-cent*':ti,ab,kw OR consecutive*:ti,ab,kw) AND (group:ti,ab,kw OR groups:ti,ab,kw OR subgroup*:ti,ab,kw OR versus:ti,ab,kw OR vs:ti,ab,kw OR compar*:ti,ab,kw OR 'odds ratio*':ab OR 'relative odds':ab OR 'risk ratio*':ab OR 'relative risk*':ab OR 'rate ratio':ab OR aor:ab OR arr:ab OR rrr:ab OR ((('or' OR 'rr') NEAR/6 ci):ab)))	
#11	'randomized controlled trial'/exp OR random*:ti,ab OR (((pragmatic OR practical) NEAR/1 'clinical trial*'):ti,ab) OR ((('non inferiority' OR noninferiority OR superiority OR equivalence) NEAR/3 trial*):ti,ab) OR rct:ti,ab,kw	1839814
#10	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	733409
#9	#6 AND (#7 OR #8) AND ([english]/lim OR [dutch]/lim) AND [2013-2023]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	349
#8	('biceps brachii muscle'/exp OR biceps:ti,ab,kw) AND ('tenodesis'/exp OR tenodesis:ti,ab,kw)	1286
#7	('biceps brachii muscle'/exp OR biceps:ti,ab,kw) AND ('tenotomy'/exp OR tenotom*:ti,ab,kw)	729
#6	'rotator cuff injury'/exp/mj OR 'rotator cuff rupture'/exp/mj OR 'rotator cuff repair'/exp/mj OR ((('rotator cuff' OR 'shoulder cuff' OR infraspinatus OR supraspinatus OR subscapularis OR cuff) NEAR/3 (tear* OR lesion* OR rupture* OR tendinopath* OR laceration* OR repair)):ti,ab,kw) OR ('rotator cuff'/exp/mj AND ('rupture'/exp/mj OR 'injury'/mj OR 'laceration'/exp/mj)) OR 'supraspinatus muscle'/exp	16992

Ovid/Medline

#	Searches	Results
11	8 or 9 or 10	220
10	(4 and 7) not (8 or 9) **= observationeel**	153
9	(4 and 6) not 8 **= RCT**	40
8	4 and 5 **= SR**	27
7	exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti,ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind$3 or mask$3)).tw. or Placebos/ or placebo*.tw. or pidemiologic studies/ or case control studies/ or exp cohort studies/ or Controlled Before-After Studies/ or Case control.tw. or cohort.tw. or Cohort analy$.tw. or (Follow up adj (study or studies)).tw. or (observational adj (study or studies)).tw. or Longitudinal.tw. or Retrospective*.tw. or prospective*.tw. or consecutive*.tw. or Cross sectional.tw. or Cross-sectional studies/ or historically controlled study/ or interrupted time series analysis/ or Case-control Studies/ or clinical trial, phase ii/ or clinical trial, phase iii/ or clinical trial, phase iv/ or comparative study/ or control groups/ or controlled before-after studies/ or controlled clinical trial/ or double-blind method/ or historically controlled study/ or matched-pair analysis/ or single-blind method/ or (((control or controlled) adj6 (study or studies or trial)) or (compar* adj (study or studies)) or ((control or controlled) adj1 active) or "open label*" or ((double or two or three or multi or trial) adj (arm or arms)) or (allocat* adj10 (arm or arms)) or placebo* or "sham-control*" or ((single or double or triple or assessor) adj1 (blind* or masked)) or nonrandom* or "non-random*" or "quasi-experiment*" or "parallel group*" or "factorial trial" or "pretest posttest" or (phase adj5 (study or trial)) or (case* adj6 (matched or control*)) or (match* adj6 (pair or pairs or cohort* or control* or group* or healthy or age or sex or gender or patient* or subject* or participant*)) or (propensity adj6 (scor* or match*))).ti,ab,kf. or (confounding adj6 adjust*).ti,ab. or (versus or vs or compar*).ti. or ((exp cohort studies/ or epidemiologic studies/ or multicenter study/ or observational study/ or seroepidemiologic studies/ or (cohort* or 'follow up' or followup or longitudinal* or prospective* or retrospective* or observational* or multicent* or 'multi-cent*' or consecutive*).ti,ab,kf.) and ((group or groups or subgroup* or versus or vs or compar*).ti,ab,kf. or ('odds ratio*' or 'relative odds' or 'risk ratio*' or 'relative risk*' or aor or arr or rrr).ab. or (("OR" or "RR") adj6 CI).ab.))	8150482
6	exp randomized controlled trial/ or randomized controlled trials as topic/ or random*.ti,ab. or rct?.ti,ab. or ((pragmatic or practical) adj "clinical trial*").ti,ab,kf. or ((non-inferiority or noninferiority or superiority or equivalence) adj3 trial*).ti,ab,kf.	1593790
5	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3	654023

	search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	
4	limit 3 to ((english language or dutch) and yr="2013 -Current")	335
3	1 and 2	492
2	(biceps.ti,ab,kf. and (exp Tenotomy/ or tenotom*.ti,ab,kf.)) or (biceps.ti,ab,kf. and (exp Tenodesis/ or tenodesis*.ti,ab,kf.))	1188
1	*Rotator Cuff/ or exp Rotator Cuff Injuries/ or (('rotator cuff' or 'shoulder cuff' or infraspinatus or supraspinatus or subscapularis or cuff) adj3 (tear* or lesion* or rupture* or tendinopath* or laceration* or repair)).ti,ab,kf.	14066

Module 5.3 Prognostische factoren voor rotator cuff rupturen

Uitgangsvraag
Wanneer is een operatieve behandeling voor een cuff ruptuur geïndiceerd?

Introduction (English)
Rotator cuff tears are frequently found with increasing age. They can be traumatic, degenerative, or a combination of both. Not all rotator cuff tears are symptomatic and they often respond well to conservative treatment. However, a rotator cuff tear may enlarge, become symptomatic or fail conservative treatment over time. Therefore, a predictive model can could help to identify which rotator cuff tear needs which treatment with the highest success rate.

Search and select
A systematic review of the literature was performed to answer the following question:
What are the prognostic factors for success or failure after a rotator cuff repair?

Patients	patients with a cuff tear
Intervention	prediction model that predicts success of operative treatment for patients with a cuff tear
Control	other prediction model or usual care
Outcomes	predictive value/model performance
Timing	before an operative treatment
Setting	during a consult with an orthopedic surgeon

Relevant outcome measures
The guideline development group considered predictive value/model performance as a critical outcome measure for decision making.

A priori, the guideline development group did not define the outcome measures listed above but used the definitions used in the studies.

The guideline development group defined the performance of the included models as follows:

- 0.7≤AUC<0.8: acceptable,
- 0.8≤AUC<0.9: excellent,
- AUC≥0.9: outstanding.

Search and select (Methods)
The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until April 26th, 2023. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 829 hits. Studies were selected based on the following criteria:

- Systematic review or cohort studies reporting a model predicting success or failure of operative treatment for patients with a cuff tear
- Predictors were measured before operative treatment
- Models need to be internally and/or externally validated
- At least one model performance measure was reported

One study was initially selected based on title and abstract screening. After reading the full text, one study was excluded (see the table with reasons for exclusion under the tab Methods), and no studies were included.

Results
No studies were included in the analysis of the literature.

Summary of literature
Description of studies
No studies reporting a model predicting success or failure of operative treatment for patients with a cuff tear were found.

Results
No results could be reported, as no studies reporting a model predicting success or failure of operative treatment for patients with a cuff tear were found.

Level of evidence of the literature
The level of evidence regarding the outcome measure 'predictive value/model performance' could not be graded, as no studies reporting a model predicting success or failure of operative treatment for patients with a cuff tear were found.

Conclusions

No GRADE	No evidence was found regarding the prediction of success or failure of operative treatment for patients with a rotator cuff tear.

Overwegingen – van bewijs naar aanbeveling
Voor- en nadelen van de interventie en de kwaliteit van het bewijs
Er is literatuuronderzoek verricht naar de prognostische factoren voor het succes of falen van een operatieve ingreep bij patiënten met een cuff ruptuur. Er werd geen literatuur gevonden die aan de PICO voldoet. Er kunnen daarom uit de literatuur geen conclusies worden getrokken over de prognostische factoren voor het succes of falen van een operatieve ingreep bij patiënten met een cuff ruptuur. Hier bestaat een kennisvraag.

Ondanks dat er geen gevalideerde predictiemodellen zijn voor het bepalen van een succes van een rotator cuff repair, zijn er wel vele factoren bekend die handvatten kunnen geven in het adviseren van patiënten met een rotator cuff scheur. Er zijn in de literatuur verschillende factoren beschreven die van belang zijn voor de integriteit van de cuff en de klinische uitkomsten na een operatieve behandeling. Deze factoren kunnen worden onderverdeeld in drie categorieën:

1. Cuffscheur gerelateerde factoren
2. Patiëntgebonden factoren
3. Chirurgische hersteltechniek en postoperatieve revalidatie

Al deze factoren dragen in meer of mindere mate bij aan het genezingspercentage van een pees na een cuff repair (Jensen, 2020). Het wetenschappelijk bewijs hiervan komt van zeer uiteenlopende studies: prospectieve studies, retrospectieve studies, multivariate analyses, studies bij dieren, underpowered studies, verschillende uitkomstmaten, et cetera. Hierdoor zijn de resultaten onderling moeilijk te vergelijken. De chirurgische hersteltechniek valt

buiten de scoop van deze richtlijn. Hieronder staat een onvolledig overzicht van punten van ad. 1 en 2, maar welke in wetenschappelijke studies veelal worden beschreven.

Ad. 1 Cuffscheur gerelateerde factoren
Grootte van de leasie
Spiervervetting
Neuropathie nervus suprascapularis
Spieratrofie
Pees delaminatie en weefsel kwaliteit
Pees retractie en lengte
Locatie van de scheur
Schouder stijfheid

Ad. 2 Patiëntgebonden factoren
Leeftijd
Roken
Body mass index
Diabetes mellitus
Dyslipidemie
Vitamine D
Osteoporose
NSAID gebruik

De nabehandeling wordt toegelicht in module Duur van immobilisatie als nabehandeling.

In verschillende studies komen “grootte van de cuffleasie, spiervervetting, spieratrofie en pees retractie” naar voren als onafhankelijke risicofactoren voor het niet genezen van de pees na een cuff repair (Heerspink, 2015; Jensen, 2020; Lee, 2017; Raman, 2017). Voor neuropathie nervus suprascapularis, pees delaminatie, diabetes mellitus, dyslipidemie, vitamine D tekort, oudere leeftijd, roken, BMI, osteoporose, NSAID gebruik, ondervoeding, alcoholisme, slechte compliantie, bot morfometrie (zoals glenoid inclinatie, critical shoulder angle, etc), hypermobiliteit syndromen, inflammatoire aandoeningen (zoals reumatoïde artritis), gebruik van plaatjes aggregatie remmers, et cetera, is er conflicterend of onvoldoende bewijs (als onafhankelijke risicofactor) voor hun relatie tot cuffintegriteit na een hersteloperatie. Roken is bijvoorbeeld een risicofactor voor het ontstaan van degeneratieve rotator cuff scheuren en is afhankelijk van de dosis en duur van het gebruik. De ernst van de cuffscheuren is groter bij rokers dan niet-rokers. Voor het verschil in genezingspercentage tussen rokers en niet-rokers is echter geen eenduidig bewijs.

Multipele database studies hebben de relatie tussen steroïde injecties voorafgaand aan een cuffrepair onderzocht en vonden een toegenomen risico op een revisie operatie vergeleken met een op elkaar afgestemde controle groep (dosis en tijd afhankelijk) (drie tot zes maanden vooraf, aangepaste Odds Ratio 1.822 (95% CI, 1.290-2.573); Traven, 2019 – en twee of meer injecties met Odds Ratio 2.53-3.26; Desai, 2019).

Verschillende voorspellingsmodellen zijn ontwikkeld op basis van onafhankelijke risicofactoren voor het niet-genezen na een cuff repair (Jeong, 2018; Kwon, 2019). Deze zijn echter nog niet prospectief gevalideerd. Toekomstige validatiestudies met grote patiënten cohorten zullen hopelijk de nauwkeurigheid van de modellen bewijzen.

<u>Waarden en voorkeuren van patiënten (en evt. hun verzorgers)</u>

Voor een patiënt zijn pijn reductie en verbeterde functie belangrijk. Hierbij moet worden afgewogen wat een patiënt in het dagelijks leven nodig heeft en bijvoorbeeld lichamelijke arbeid en/of intensieve sport verricht. De voor- en nadelen voor een rotator cuff repair, zoals in module 'Operatieve versus niet-operatieve behandeling' uiteengezet, dienen te worden besproken met de patiënt, om zo samen te beslissen welke behandeling het meest passend is.

Kosten (middelenbeslag)
De kosten van een operatie kunnen met name beïnvloed worden door procedure afhankelijke factoren, zoals aantal ankers, aanvullende procedures (zoals AC resectie, biceps behandeling) en chirurgische tijd (Morris, 2021). Dit is echter minder te beïnvloeden in het Nederlandse bekostigingssysteem. Een rotator cuff repair kan met name kosteneffectief zijn als daardoor een patiënt weer kan deelnemen aan het arbeidsproces.

Aanvaardbaarheid, haalbaarheid en implementatie
Er moet samen met de patiënt een afgewogen beslissing worden gemaakt over het wel of niet opereren. Hierbij dienen de verschillende cuff en patiënt gerelateerde factoren meegenomen te worden, evenals bijvoorbeeld fysieke werk gerelateerde behoeftes, psychosociale factoren, en/of wens/noodzaak om zelfredzaam te blijven. Daarnaast is de compliantie van de patiënt voor de revalidatie van belang. Is een immobilisatieduur van twee tot zes weken haalbaar voor de patiënt en heeft de patiënt de motivatie en financiële middelen om een gedegen oefen-/fysiotherapeutische nabehandeling te volgen (zie ook module Operatieve versus niet-operatieve behandeling).

Ook dient het risico op progressie van de grootte van een cuffruptuur in de tijd besproken te worden, de mogelijke gevolgen daarvan voor pijn en functieverlies, en het al dan niet nog operatief kunnen herstellen van deze grotere ruptuur. Een niet-reparabele cuffruptuur kan door alternatieve operaties (bijvoorbeeld spiertransposities, superior capsular reconstruction, prothesiologie) leiden tot hogere kosten, een uitgebreid revalidatietraject, of minder goede functionele uitkomsten.

Door de verschillende factoren af te wegen, kan een 'informed consent' worden verkregen indien besloten wordt tot operatie. Daarnaast zijn (commerciële) hulpmiddelen in Nederland beschikbaar om de patiënt te informeren, zoals de website www.zorgvoorbeweging.nl en module rotatorcuff ruptuur van www.keuzehulp.info (https://www.keuzehulp.info/pp/rotatorcuffruptuur/intro).

Aanbeveling
Rationale van de aanbeveling: weging van argumenten voor en tegen de interventies
Het succes van een rotator cuff repair is afhankelijk van vele factoren. Er is echter nog geen gevalideerd predictiemodel beschikbaar om het succes hiervan in te schatten. Derhalve adviseert de werkgroep om per patiënt zowel de patiënt- als de rotator cuff scheur gerelateerde factoren mee te wegen. Hiermee kan een afgewogen beslissing worden gemaakt met de patiënt. Als de slagingskans beperkt is, zijn er andere operatie opties te overwegen met elk hun voor- en nadelen.

Aanbeveling

Breng patiënt en cuff scheur gerelateerde prognostische factoren in kaart om een inschatting te maken van de succeskans van een rotator cuff repair. Bespreek de voor- en nadelen voor een rotator cuff repair met de patiënt, om zo samen te beslissen welke behandeling het meest passend is.

Maak laagdrempelig een MRI van de schouder voor een betere beoordeling van de cuff scheur gerelateerde factoren zoals de grootte, spiervervetting, -atrofie en retractie.

Kennisvragen

Wat zijn de prognostische factoren voor succes of falen na een operatieve behandeling bij patiënten met een cuffscheur? Er bestaat nog geen intern en extern gevalideerd predictiemodel met cuff scheur gerelateerde en patiëntgebonden factoren waarmee de slagingskans van een cuff repair kan worden voorspeld.

Literatuur

de Andrade ALL, Garcia TA, Brandão HS, Sardeli AV, Mouraria GG, Belangero WD. Benefits of Patch Augmentation on Rotator Cuff Repair: A Systematic Review and Meta-analysis. Orthop J Sports Med. 2022 Mar 24;10(3):23259671211071146. doi: 10.1177/23259671211071146. PMID: 35360882; PMCID: PMC8961381.

Desai VS, Camp CL, Boddapati V, Dines JS, Brockmeier SF, Werner BC. Increasing numbers of shoulder corticosteroid injections within a year preoperatively may be associated with a higher rate of subsequent revision rotator cuff surgery. Arthroscopy. 2019;35(1):45–50. https://doi.org/10.1016/j.arthro.2018.07.043.

Frangiamore S, Dornan GJ, Horan MP, Mannava S, Fritz EM, Hussain ZB, Moatshe G, Godin JA, Pogorzelski J, Millett PJ. Predictive Modeling to Determine Functional Outcomes After Arthroscopic Rotator Cuff Repair. Am J Sports Med. 2020 Jun;48(7):1559-1567. doi: 10.1177/0363546520914632. Epub 2020 May 14. PMID: 32406765.

Heerspink, F. O. L., van Raay, J. J., Koorevaar, R. C., van Eerden, P. J., Westerbeek, R. E., van't Riet, E. et al. (2015). Comparing surgical repair with conservative treatment for degenerative rotator cuff tears: a randomized controlled trial. *Journal of shoulder and elbow surgery*, *24*(8), 1274-1281.

Jensen, A. R., Taylor, A. J., & Sanchez-Sotelo, J. (2020). Factors influencing the reparability and healing rates of rotator cuff tears. *Current Reviews in Musculoskeletal Medicine*, *13*, 572-583.

Jeong HY, Kim HJ, Jeon YS, Rhee YG. Factors predictive of healing in large rotator cuff tears: is it possible to predict retear preoperatively? Am J Sports Med. 2018;46(7):1693–700. https:// doi.org/10.1177/0363546518762386

Lee YS, Jeong JY, Park CD, Kang SG, Yoo JC. Evaluation of the risk factors for a rotator cuff retear after repair surgery. Am J Sports Med. 2017;45(8):1755–61. doi.org/10.1177/0363546517695234

Kwon J, Kim SH, Lee YH, Kim TI, Oh JH. The rotator cuff healing index: a new scoring system to predict rotator cuff healing after surgical repair. Am J Sports Med. 2019;47(1):173–80. https://doi.org/10.1177/0363546518810763.

Morris JH, Malik AT, Hatef S, Neviaser AS, Bishop JY, Cvetanovich GL. Cost of Arthroscopic Rotator Cuff Repairs Is Primarily Driven by Procedure-Level Factors: A Single-Institution Analysis of an Ambulatory Surgery Center. Arthroscopy. 2021 Apr;37(4):1075-1083. doi: 10.1016/j.arthro.2020.11.033. Epub 2020 Nov 23. PMID: 33242633.

Raman, Jayaprakash, David Walton, Joy C. MacDermid, and George S. Athwal. "Predictors of outcomes after rotator cuff repair—a meta-analysis." Journal of Hand Therapy 30, no. 3 (2017): 276-292.

Traven SA, Brinton D, Simpson KN, Adkins Z, Althoff A, Palsis J, et al. Preoperative shoulder injections are associated with increased risk of revision rotator cuff repair. Arthroscopy. 2019;35(3):706–13. https://doi.org/10.1016/j.arthro.2018.10.107.

Implementatieplan

Aanbeveling	Tijdspad voor implementatie: < 1 jaar, 1 tot 3 jaar of > 3 jaar	Verwacht effect op kosten	Randvoorwaarden voor implementatie (binnen aangegeven tijdspad)	Mogelijke barrières voor implementatie	Te ondernemen acties voor implementatie	Verantwoordelijken voor acties	Overige opmerkingen
Breng patiënt en cuff scheur gerelateerde prognostische factoren in kaart om een inschatting te maken van de succeskans van een rotator cuff repair. Bespreek de voor- en nadelen voor een rotator cuff repair met de patiënt, om zo samen te beslissen welke behandeling het meest passend is.	< 1 jaar	Lagere kosten door onnodig falen van een cuffrepair.	Bekendmaking richtlijn.	Geen	Publicatie van deze richtlijn.		
Maak laagdrempelig een MRI van de schouder voor een betere beoordeling van de cuff scheur	< 1 jaar	Radiologie kosten.		Deze informatie ook verspreiden onder radiologen.			

gerelateerde factoren zoals de grootte, spiervervetting, -atrofie en retractie.							

Evidence tables

No evidence tables were created, as there was no literature included in the results section.

Table of excluded studies

Reference	Reason for exclusion
Frangiamore S, Dornan GJ, Horan MP, Mannava S, Fritz EM, Hussain ZB, Moatshe G, Godin JA, Pogorzelski J, Millett PJ. Predictive Modeling to Determine Functional Outcomes After Arthroscopic Rotator Cuff Repair. Am J Sports Med. 2020 Jun;48(7):1559-1567. doi: 10.1177/0363546520914632. Epub 2020 May 14. PMID: 32406765.	No predicting value, internal and external validation reported.

Literature search strategy

Zoekverantwoording

Cluster/richtlijn: SAPS	
Uitgangsvraag/modules: Wanneer is een operatieve behandeling voor een cuff ruptuur geïndiceerd?	
Database(s): Ovid/Medline, Embase.com	Datum: 26 april 2023
Periode:	Talen: Engels, Nederlands
Literatuurspecialist: Miriam van der Maten	
BMI-zoekblokken: voor verschillende opdrachten wordt (deels) gebruik gemaakt van de zoekblokken van BMI-Online https://blocks.bmi-online.nl/ Bij gebruikmaking van een volledig zoekblok zal naar de betreffende link op de website worden verwezen.	
Toelichting: Voor deze vraag is gezocht op de elementen: ○ Patiënten met SAPS/cuff ruptuur (termen gebaseerd op eerdere PICO's) ○ Operatie aan de rotator cuff ○ Prognostische filter (in Embase de aanvulling 'univariate' gedaan i.v.m. sleutelartikel dat deze term gebruikte, resulteerde in +/- 10 extra hits)	
Te gebruiken voor richtlijnen tekst: *Nederlands* In de databases Embase.com en Ovid/Medline is op 26 april 2023 systematisch gezocht naar studies over prognostische factoren voor succes of falen na een operatieve behandeling van de cuff ruptuur. De literatuurzoekactie leverde 829 unieke treffers op. *Engels* On the 26th of April 2023, we performed a systematic search in the databases Embase.com and Ovid/Medline to find studies about prognostic factors for success or failure of operative treatment of rotator cuff injuries. The search resulted in 829 unique hits.	

Zoekopbrengst

	EMBASE	OVID/MEDLINE	Ontdubbeld
SRs			

RCT			
Observationele studies			
Totaal	604	685	**829**

Zoekstrategie

Embase.com

No.	Query	Results
#10	#7 AND #8 AND #9 AND ([english]/lim OR [dutch]/lim) AND [2000-2023]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	604
#9	'area under the curve'/exp OR 'brier score'/exp OR 'computer prediction'/exp OR 'c statistic'/exp OR 'c statistics'/exp OR 'integrated discrimination improvement'/exp OR 'net reclassification improvement'/exp OR 'net reclassification index'/exp OR 'prediction'/exp OR 'predictive model'/exp OR 'predictive modeling'/exp OR 'predictive validity'/exp OR 'predictive value'/exp OR 'regression analysis'/exp OR 'statistical model'/exp OR 'area under the curve':ti,ab,kw OR 'brier score*':ti,ab,kw OR 'c statistic*' OR 'computer prediction':ti,ab,kw OR 'decision curve anal*':ti,ab,kw OR (('net reclassification' NEAR/2 (improvement OR index)):ti,ab,kw) OR (((predict* OR statistical*) NEAR/3 (model* OR validity OR value)):ti,ab,kw) OR 'proportional hazards model*':ti,ab,kw OR 'r square*':ti,ab,kw OR regression:ti,ab,kw OR predict*:ti OR multivariate:ti,ab,kw OR multivariab*:ti,ab,kw OR 'univariate analysis'/exp OR 'multivariate analysis'/exp OR univariate:ti,ab,kw	3395824
#8	'shoulder surgery'/exp/mj OR 'rotator cuff repair'/exp/mj OR ((('rotator cuff' OR 'shoulder' OR tendon) NEAR/5 (repair* OR reconstruct* OR reparability OR surger* OR surgic* OR operation* OR operative)):ti,ab,kw) OR surgic*:ti OR surger*:ti OR operation*:ti OR operative:ti OR 'single row':ti,ab,kw OR 'double row':ti,ab,kw OR 'surgery'/mj OR 'surgical patient'/mj OR 'surgical risk'/mj OR 'perioperative period'/mj	1150564
#7	'shoulder impingement syndrome'/exp/mj OR 'shoulder impingement syndrome':ti,ab,kw OR 'subacromial impingement syndrome':ti,ab,kw OR (('bursitis'/exp/mj OR bursitis:ti,ab,kw OR 'tendinitis'/exp/mj OR tendinitis:ti,ab,kw OR 'impingement':ti,ab,kw) AND ('shoulder'/exp/mj OR 'rotator cuff':ti,ab,kw OR acromion:ti,ab,kw OR acromial:ti,ab,kw OR subacromial:ti,ab,kw OR shoulder*:ti,ab,kw)) OR ((('rotator cuff' OR 'shoulder cuff' OR infraspinatus OR supraspinatus OR subscapularis) NEAR/3 (tear* OR lesion* OR rupture* OR tendinopath* OR laceration*)):ti,ab,kw) OR (('full-thickness':ti,ab,kw OR partial:ti,ab,kw) AND 'rotator cuff':ti,ab,kw) OR 'rotator cuff injury'/exp/mj OR 'rotator cuff rupture'/exp/mj OR ((('rotator cuff' OR 'shoulder cuff' OR infraspinatus OR supraspinatus OR subscapularis OR cuff) NEAR/3 (tear* OR lesion* OR rupture* OR tendinopath* OR laceration*)):ti,ab,kw) OR ('rotator cuff'/exp/mj AND ('rupture'/exp/mj OR 'injury'/mj OR 'laceration'/exp/mj)) OR 'supraspinatus muscle'/exp	19135

Ovid/Medline

#	Searches	Results

6	limit 5 to ((english language or dutch) and yr="2000 -Current")	685
5	4 not (comment/ or editorial/ or letter/ or ((exp animals/ or exp models, animal/) not humans/))	732
4	1 and 2 and 3	750
3	Area Under Curve/ or exp Forecasting/ or "Predictive Value of Tests"/ or exp Multivariate Analysis/ or exp Regression Analysis/ or exp Models, Statistical/ or area under the curve.ti,ab,kf. or brier score*.ti,ab,kf. or c statistic*.ti,ab,kf. or computer prediction.ti,ab,kf. or decision curve anal*.ti,ab,kf. or (net reclassification adj2 (improvement or index)).ti,ab,kf. or ((predict* or statistical*) adj3 (model* or validity or value)).ti,ab,kf. or proportional hazards model*.ti,ab,kf. or r square*.ti,ab,kf. or regression.ti,ab,kf. or predict*.ti. or multivaria*.ti,ab,kf.	2394116
2	Rotator Cuff/su or Shoulder Joint/su or Acromion/su or Shoulder/su or (('rotator cuff' or 'shoulder' or tendon) adj5 (repair* or reconstruct* or surger* or surgic* or operation* or operative)).ti,ab,kf. or surgic*.ti,kf. or surger*.ti,kf. or operation*.ti,kf. or operative.ti,kf. or 'single row'.ti,ab,kf. or 'double row'.ti,ab,kf.	1010948
1	*Rotator Cuff/ or exp Rotator Cuff Injuries/ or (('full-thickness' or partial) and 'rotator cuff').ti,ab,kf. or (('rotator cuff' or 'shoulder cuff' or infraspinatus or supraspinatus or subscapularis or cuff) adj3 (tear* or lesion* or rupture* or tendinopath* or laceration*)).ti,ab,kf. or *Shoulder Impingement Syndrome/ or 'shoulder impingement syndrome'.ti,ab,kf. or 'subacromial impingement syndrome'.ti,ab,kf. or ((exp *bursitis/ or exp *Tendinopathy/ or bursitis.ti,ab,kf. or tendinitis.ti,ab,kf. or 'impingement'.ti,ab,kf.) and (exp *Shoulder/ or 'rotator cuff'.ti,ab,kf. or acromion.ti,ab,kf. or acromial.ti,ab,kf. or subacromial.ti,ab,kf. or shoulder*.ti,ab,kf.))	18674

Module 5.4 Duur van immobilisatie als nabehandeling

Uitgangsvraag
Welke duur van immobilisatie heeft de voorkeur als nabehandeling na het hechten van de supraspinatuspees?

Introduction (English)
The goal of supraspinatus tendon repair is to allow the tendon to grow anatomically attached to the tuberculum majus. To allow the tendon to attach properly, expert opinion recommends immobilization for siz weeks (long-term) with an immobilizer. Early mobilization is also described in the literature. Potential advantages of early mobilization are less risk of stiffness and better return to function, but there may be a greater risk of tendon re-rupture. This could lead to poorer functional outcomes from earlier mobilization.

Search and select
A systematic review of the literature was performed to answer the following question:
What is the effectiveness of early mobilization (up to max. 3 weeks) in which possibly a sling can be used as follow-up treatment, versus long-term (6 weeks) immobilization in patients where the supraspinatus tendon is repaired?

Patients	patients in whom the supraspinatus tendon is repaired
Intervention	early mobilization whereby a sling can be used for the first few weeks (up to a maximum of 3) (short-term immobilization to achieve early mobilization. Immediate practice with pendulum exercises after surgery can be performed/is allowed).
Control	long-term immobilization: 6 weeks
Outcomes	function (including post-op stiffness), pain, frozen shoulder (postoperative stiffness), complications (re-ruptures), patient satisfaction, return to work/sport.

<u>Relevant outcome measures</u>
The guideline development group considered function as a critical outcome measure for decision making; and pain, frozen shoulder, complications/adverse events (re-ruptures, capsulitis), patient satisfaction and return to work/sport as important outcome measures for decision making.

The guideline development group defined the outcome measures as follows:
- Function: patient reported outcomes measures for function: CMS, DASH, WORC, ASES, DSST, OSS, postoperative stiffness
- Pain: VAS-scale (0-10 points or 0-100mm scale)
- Frozen shoulder: definitions used in the studies
- Complications/adverse events: re-ruptures and capsulitis
- Patient satisfaction: self-reported satisfaction with treatment and/or function
- Return to work/sport: definitions used in the studies

The guideline development group defined the minimal clinically (patient) important differences as follows:
- Patient reported outcome measures:
    - CMS: 15 points on a 100-point scale (Holmgren, 2014)
    - DASH: 13 on a 100 point scale (Koorevaar, 2018)

    - WORC: -282.6 on a 2100 point scale (Gagnier, 2018) or
    - ASES: 9 on a 100 point scale (Gagnier, 2018)
    - DSST: 2.8 on a 12 point scale (Van Kampen, 2013)
    - OSS: 5 points on a 48-point scale (Nyring, 2021)
    - A threshold of 10% for continuous outcomes and a relative risk (RR) for dichotomous outcomes of <0.80 and >1.25
- Pain
    - 1/10 points or 10/100 points on a VAS scale
- Frozen shoulder: 25% (RR ≤ 0.80 and ≥ 1.25).
- Complications/adverse events (re-ruptures: yes/no, capsulitis: yes/no).
- Patient satisfaction: difference of 25% (RR ≤ 0.80 and ≥ 1.25) or 1/10 points or 10/100 points on a VAS scale.
- Return to work/sport
    - A threshold of 10% for continuous outcomes and a relative risk (RR) for dichotomous outcomes of <0.80 and >1.25

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until 23-10-2023. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 180 hits. Studies were selected based on the following criteria:

1) systematic review, meta-analysis, or RCT,
2) comparing early mobilization whereby a sling can be used for the first few weeks (up to a maximum of 3) to long-term immobilization (6 weeks),
3) in an adult population of patients in whom the supraspinatus tendon is repaired,
4) reporting outcomes for function (including post-op stiffness), pain, frozen shoulder, complications/adverse events (re-ruptures), patient satisfaction, and return to work/sport),
5) including studies published since 2013 and including at least > 10 people per research arm.

A total of 38 studies were initially selected based on title and abstract screening. After reading the full text, 35 studies were excluded (see the table with reasons for exclusion under the tab Methods), and 3 studies were included.

Results

Three studies were included in the analysis of the literature. Important study characteristics and results are summarized in the evidence tables. The assessment of the risk of bias is summarized in the risk of bias tables.

Summary of literature

Description of studies

Author, year	Study design	Population	Intervention	Control	Reported outcome measures	Follow-up measurements and duration
Düzgün (2014)	Clinical research	Total of 40 patients with stage 2 or 3 rotator cuff tear as determined by MRI who underwent arthroscopic rotator cuff repair for a full-thickness tear. All the patients had non-traumatic degenerative tears. The patients were referred for rehabilitation by a single orthopedic surgeon to the Sports Physiotherapy Unit, and were enrolled in this study. ACCEL: n=19 patients SLOW: n=21 patients	Accelerated (ACCEL) protocol Patients enrolled in the ACCEL group were given 6 weeks of preoperative rehabilitation. The ACCEL protocol was initiated at the 2nd postoperative week and included soft tissue mobilization for the scapulothoracic and glenohumeral joint along with motion exercises. Active ROM exercises with scapular plane elevation, flexion and abduction was initiated at the 3rd week as long as the patient reported no pain at rest with their surgically repaired shoulder. Active exercises were delayed by 1 week in 1 patient due to pain upon removal of the support which later resolved. Light resistive elastic resistance (Thera-Band, red color-coded) exercises were initiated at the 4th postoperative week.	Slow (SLOW) protocol In the SLOW group, soft tissue mobilization for the scapulothoracic and glenohumeral joint along with passive ROM exercises were initiated at the 4th postoperative week. Active ROM in scapular plane elevation, flexion and abduction was initiated at the 6th week and light resistive elastic resistance exercises at the 8th week. The protocol was applied 3 days a week for 14 weeks.	Shoulder flexion, abduction, external and internal rotation. Active total elevation	Postoperative weeks 3, 5, 8, 12, and 24.

			The ACCEL protocol was applied 3 days a week for 6 weeks.			
Jenssen (2018)	Prospective, randomized, controlled non-inferiority trial	120 patients were included after arthroscopic rotator cuff repair surgery for a small – to medium-sized tear of supraspinatus and upper infraspinatus tendons. I: n=60 patients C: n=58 patients	Group of patients immobilized in a simple sling for 3 weeks. All patients started active range of motion when they removed the sling.	Group of patients with a brace with a small abduction pillow with the arm in neutral position for 6 weeks. All patients started active range of motion when they removed the brace.	MRI, WORC index, en CM (Constant Murley) score.	Follow-up measurement at 6 weeks, 3, 6, and 12 months.
Zhang (2017)		132 patients underwent arthroscopic repair of a large size rotator cuff tear, patients were recruited and divided into intervention (66 cases) and control (66 cases) group.	After surgery, the affected limbs were immobilized and suspended by using brackets in the two groups to keep the shoulder joint at 30 degrees abduction and 0 degrees external rotation. The patients in the observation group began exercise at 24 h postoperative and the motion range was gradually increased, active external rotation and back extensor exercise began at 72 h postoperative, strength training of the deltoid started 1		Pain (VAS), passive motion of the shoulder joint was evaluated including anteflexion, abduction, external and internal rotation (Constant shoulder score and UCLA score).	3, 6 and 12 months after surgery.

			w postoperatively and muscular counterforce training started 6 w after surgery. The affected limbs were immobilized in the control group until 6 w after surgery, and the motion range of the shoulder joint was gradually increased.			

Results

1. Function

1.1. Function 6 weeks post op

Düzgün (2014), Jenssen (2018), and **Zhang (2017)** did not report on function 6 weeks post op.

Data could not be pooled.

1.2. Function 3 months post op

Jenssen, 2018 reported the Constant Murley Score and the Western Ontario Rotator Cuff (WORC) index at three months post op.
The Constant Murley score in the intervention group (immobilized in a simple sling for 3 weeks) the CMS was 41 ± 23, and in the control group (patients with a brace for six weeks) the CMS was 38 ± 19 at three months post op. The MD was -3 (95% CI -5 to -10) at 3 months post op and this difference was not considered clinically relevant.
With regards to the WORC score, in the intervention group the WORC score was 58 ± 20, and in the control group, the WORC score was 59 ± 18 at 3 months post op. The MD was -1 (95% CI -8 to 6) and this difference was not considered clinically relevant.

Düzgün (2014) and **Zhang (2017)** did not report on function at 3 months post op.

1.3. Function 6 months post op

Jenssen, 2018 reported the Constant Murley Score and the WORC score at six months post op. The Constant Murley Score in the intervention group (immobilized in a simple sling for 3 weeks) was 68 ± 28, and in the control group (patients with a brace for six weeks) the CMS was 71 ± 25 (MD: -3, 95% CI -12 to -7) at six months. This difference is not considered clinically relevant. With regards to the WORC score, in the intervention group the WORC score was 75 ± 22, and in the control group, the WORC score was 77 ± 18 (MD: -2, 95% CI -9 to -5) at six months post op. This difference is not considered clinically relevant.

Düzgün (2014) and **Zhang (2017)** did not report on function at 6 months post op.

1.4. Function 12 months post op

Jenssen (2018) reported the Constant Murley Score and the WORC score at twelve months post op. The Constant Murley Score in the intervention group was 86 ± 27, and in the control group the CMS was 90 ± 23 (MD: -4, 95% CI 13 to 5) at twelve months. This difference is not considered clinically relevant. The WORC score in the intervention group was 83 (SD ± 19) and 87 (SD ± 14) in the control group (MD: -4, 95% CI -10 to -3). This difference is not considered clinically relevant.
Zhang (2017) reported the Constant Murley Score at twelve months post op. The CMS score was 91.25 ± 10.93 in the intervention group and 88.40 ± 11.37 in the control group (MD: 2.85, 95% CI -0.95 to 6.65). This difference is not considered clinically relevant.

Düzgün (2014) did not report on function at twelve months post op.

2. Pain

2.1. Pain at 6 weeks post op

No study reported on pain at 6 weeks post op.

2.2. Pain at 3 months post op

No study reported on pain at 3 months post op.

2.3. Pain at 6 months post op

No study reported on pain at 6 months post op.

2.4. Pain at 12 months post op.

Zhang (2017) reported on pain at 12 months post op using the VAS score. The VAS score was 3.27 ± 1.02 in the intervention group, and 3.51 ± 0.92 in the control group (MD: -0.24, 95% CI -0.57 to 0.09). This difference is not considered clinically relevant.

Düzgün (2014) and **Jenssen (2018)** did not report on pain at 12 months post op.

3. Frozen shoulder

3.1.: Frozen shoulder at 6 weeks post op

No study reported on frozen shoulder at 6 weeks post op.

3.2.: Frozen shoulder at 3 months post op

No study reported on frozen shoulder at 3 months post op.

3.3.: Frozen shoulder at 6 months post op

No study reported on frozen shoulder at 6 months post op.

3.4.: Frozen shoulder at 12 months post op

Zhang (2017) reported that the incidence of ankylosis (referring to pain, stiffness, inflammation and loss of range of motion of the shoulders) was amongst 10 out of 66 patients in the intervention group (15%) and 24 out of 66 patients in the control group (36%) (RR: 0.41, 95% CI 0.21 to 0.80). This difference was considered clinically relevant in favor of the intervention group. No follow-up period was specified when presenting these incidence ratings, however presumably these incidence ratings refer to the total follow-up period.

4. Complications/adverse events (re-ruptures, capsulitis)

4.1. Complications/adverse events at 6 weeks post op

No study reported on complications/adverse events at 6 weeks post op.

4.2. Complications/adverse events at 3 months post op

No study reported on complications/adverse events at 3 months post op.

4.3. Complications/adverse events at 6 months post op

No study reported on complications/adverse events at 6 months post op.

4.4. Complications/adverse events at 12 months post op

Düzgün (2014) reported that there were no surgical complications or adverse responses throughout the duration of the rehabilitation protocol.

Jenssen (2018) reported that due to postoperative capsulitis amongst 2 out of 60 patients in the intervention group (3%), and amongst 0 out of 58 patients in the control group (0%), corticosteroid injections were performed. The risk difference of 3% was not considered clinically relevant.

Zhang (2017) reported the incidence of re-tears. The incidence of retears was amongst 6 out of 66 patients in the intervention group (9%), and 4 out of 66 patients in the control group (6%). The risk difference of 3% was not considered clinically relevant.

5. Patient satisfaction

5.1. Patient satisfaction at 6 weeks post op

No study reported on patient satisfaction at 6 weeks post op.

5.2. Patient satisfaction at 3 months post op

No study reported on patient satisfaction at 3 months post op.

5.3. Patient satisfaction at 6 months post op

No study reported on patient satisfaction at 6 months post op.

5.4. Patient satisfaction at 12 months post op

Jenssen (2018) reported on patient satisfaction using the VAS ratings. The mean VAS score was 8.6 (SD ± 1.8) in the intervention group, and 8.7 (SD ± 1.9) in the control group (MD: -0.03, 95% CI -0.7 to 0.7). This difference was not considered clinically relevant.

Zhang (2017) and **Düzgün (2014)** did not report on patient satisfaction at 12 months post op.

6. Return to work/sport

No study reported on return to work/sports.

Level of evidence of the literature
The level of evidence for all outcome measures started out as high, as the included studies were RCTs.

1. Function

The level of evidence regarding the outcome measure **function at 6 weeks post op** could not be graded as none of the included studies reported these.

The level of evidence regarding the outcome measure **function at 3 months** post op was downgraded by **one level** to **moderate** because of OIS criteria not met (imprecision, -1).

The level of evidence regarding the outcome measure **function at 6 months** post op was downgraded by **one level** to **moderate** because of OIS criteria not met (imprecision, -1).

The level of evidence regarding the outcome measure **function at 12** months post op was downgraded by **two levels** to **low** because of study limitations (risk of bias due to not reporting about allocation of sequence, blinding, -1); and limited population size (imprecision, -1).

Conclusions

No GRADE	No evidence was found regarding the effect of early mobilization in **function at 6 weeks post op** when compared with long-term immobilization in patients in whom the supraspinatus tendon is repaired. *Source: none*

Moderate GRADE	Early mobilization likely results in little to no difference in **function at 3 months post op** when compared with long-term immobilization in patients in whom the supraspinatus tendon is repaired. *Source: Jensen (2018)*

Moderate GRADE	Early mobilization likely results in little to no difference in **function at 6 months post op** when compared with long-term immobilization in patients in whom the supraspinatus tendon is repaired. *Source: Jensen (2018)*

Low GRADE	Early mobilization may result in little to no difference in **function at 12 months post op** compared to long-term immobilization in patients in whom the supraspinatus tendon is repaired. *Source: Zhang (2017) and Jensen (2018)*

2. Pain

The level of evidence regarding the outcome measure **pain at 6 weeks, 3 months or 6 months post op** could not be graded as none of the included studies reported these.

The level of evidence regarding the outcome measure **pain at 12** months post op was downgraded by **two levels** to **low** because of study limitations (risk of bias due to not reporting about allocation of sequence, blinding, -1); and OIS criteria not met (imprecision, -1).

Conclusions

No GRADE	No evidence was found regarding the effect of early mobilization in **pain at 6 weeks, 3 months or 6 months post op** when compared with long-term immobilization in patients in whom the supraspinatus tendon is repaired.

Low GRADE	Early mobilization may result in little to no difference in **pain at 12 months post op** compared to long-term immobilization in patients in whom the supraspinatus tendon is repaired. *Source: Zhang (2017)*

3. Frozen shoulder

The level of evidence regarding the outcome measure **frozen shoulder** at 6 weeks, 3 months or 6 months post op could not be graded as none of the included studies reported these.

The level of evidence regarding the outcome measure **frozen shoulder** at 12 months post op was downgraded by **two levels** to **low** because of no blinding and reporting of sequence of allocation (high risk of bias; -1) and OIS criteria not met (imprecision, -1).

Conclusions

No GRADE	No evidence was found regarding the effect of early mobilization in **frozen shoulder at 6 weeks, 3 months or 6 months post op** when compared with long-term immobilization in patients in whom the supraspinatus tendon is repaired.

Low GRADE	Early mobilization may reduce **frozen shoulder at 12 months post op** when compared to long-term immobilization in patients in whom the supraspinatus tendon is repaired. *Source: Zhang (2017)*

4. Complications/adverse events

The level of evidence regarding the outcome measure **complications/adverse events at 6 weeks, 3 months or 6 months post op** could not be graded as none of the included studies reported these.

The level of evidence regarding the outcome measure **complications/adverse events at 12 months post op** was downgraded by **two levels** to **low** because of risk of bias (-1) and OIS criteria not met (imprecision, -1).

Conclusions

No GRADE	No evidence was found regarding the effect of early mobilization in **complications/adverse events at 6 weeks, 3 months or 6 months post op** when compared with long-term immobilization in patients in whom the

	supraspinatus tendon is repaired.

Low GRADE	Early mobilization likely results in little to no difference in **complications/adverse events at 12 months post op** when compared to long-term immobilization in patients in whom the supraspinatus tendon is repaired. *Source: Düzgün (2014), Jenssen (2018), and Zhang (2017)*

5. Patient satisfaction

The level of evidence regarding the outcome measure **patient satisfaction at 6 weeks, 3 months or 6 months post op** could not be graded as none of the included studies reported these.

The level of evidence regarding the outcome measure **patient satisfaction at 12 months post op** was downgraded by **one level** to **moderate** due to the limited population size (imprecision, -1).

Conclusions

No GRADE	No evidence was found regarding the effect of early mobilization in **patient satisfaction at 6 weeks, 3 months or 6 months post op** when compared with long-term immobilization in patients in whom the supraspinatus tendon is repaired.

Moderate GRADE	Early mobilization likely results in little to no difference in **patient satisfaction at 12 months post op** when compared with long-term immobilization in patients in whom the supraspinatus tendon is repaired. *Source: Jensen (2018)*

6. Return to work/sport

The level of evidence regarding the outcome measure **return to work/sport** could not be graded as none of the included studies reported these.

Conclusions

No GRADE	No evidence was found regarding the effect of early mobilization in **return to work/sport** when compared with long-term immobilization in patients in whom the supraspinatus tendon is repaired.

Overwegingen – van bewijs naar aanbeveling

Voor- en nadelen van de interventie en de kwaliteit van het bewijs

Er is literatuuronderzoek verricht naar de effectiviteit van vroege mobilisatie (tot maximaal drie weken) waarbij eventueel een sling gebruikt kan worden als nabehandeling versus langdurende (zes weken) immobilisatie bij patiënten waarbij de supraspinatuspees is gehecht. Er werden drie RCTs geïncludeerd die vroege mobilisatie (tot maximaal drie weken) vergeleken met langdurige immobilisatie (zes weken). Functie was gedefinieerd als cruciale uitkomstmaat. Pijn, frozen shoulder, complicaties, patiënttevredenheid, en terugkeer naar werk/sport werden gedefinieerd als belangrijke uitkomstmaten.

Functie is gemeten op verschillende tijdsmomenten. Vroege mobilisatie heeft mogelijk geen effect op functie, gemeten met de Constant Murley score en de WORC index op drie, zes en twaalf maanden (lage tot redelijke bewijskracht), vergeleken met lange immobilisatie. De overall bewijskracht is laag, door beperkingen in de onderzoeksopzet en beperkte patiëntaantallen. Pijn, complicaties en patiënttevredenheid op twaalf maanden lijken ook niet verschillend tussen vroege mobilisatie en langdurige immobilisatie (lage tot redelijke bewijskracht). Alleen *frozen shoulder* twaalf maanden na operatie lijkt minder vaak voor te komen bij vroege mobilisatie vergeleken met langdurige immobilisatie (één publicatie, lage bewijskracht). Terugkeer naar werk en sport werd niet beschreven in de geïncludeerde publicaties.

De literatuur kan onvoldoende richting geven aan de besluitvorming. De aanbeveling is daarom gebaseerd op aanvullende argumenten waaronder expert opinie, waar mogelijk aangevuld met (indirecte) literatuur.

Het doel van de operatie is om een heling van de gescheurde pees op het tuberculum majus te krijgen. Deze uitkomstmaat werd slechts in één studie meegenomen. De beschreven retear rate is laag t.o.v. andere studies. Deze studie is underpowered om een uitspraak te doen over de retear rate na beide interventies. In een vergelijkende gerandomiseerde studie met klein tot middelgrote supraspinatuspees rupturen werd tussen drie en zes weken nabehandeling met immobilizer vergeleken. Er werd geen verschil gevonden tussen beide groepen in het voorkomen van een reruptuur met MRI onderzoek (Jenssen, 2018). In een subgroepanalyse van een systematische review werd na repair van grotere cuff rupturen significant meer rerupturen gevonden na vroeg mobilisatie (Saltzman, 2017).

Waarden en voorkeuren van patiënten (en evt. hun verzorgers)

Het doel van een rotator cuff repair is om de gescheurde cuff te laten genezen op het tuberculum majus. Om dit te bereiken wordt er historisch op basis van expert opinie zes weken een immobilizer voorgeschreven. Voor patiënten is dit beperkend in het dagelijks leven. Het slapen met een immobilizer is hinderlijk en voor patiënten vaak niet goed mogelijk. Het dragen van een immobilizer geeft daarnaast ook een verhoogd val risico (Sridharan, 2020; Sonoda, 2018). Het korter geven van een immobilizer heeft voor het grootste deel van de patiënten een voordeel t.o.v. langer dragen van een immobilizer.

Kosten (middelenbeslag)

Voor beide behandelingen wordt geen verschil in kosten verwacht gedurende het herstel. Beide groepen zullen binnen zes weken niet aan het werk zijn. Beide groepen zullen evenveel oefen-/fysiotherapie nodig hebben na de operatieve behandeling. De kosten van een immobilizer zijn verwaarloosbaar laag.

Aanvaardbaarheid, haalbaarheid en implementatie

Voor beide interventies wordt een goede aanvaardbaarheid verwacht. Patiënten kunnen goed begrijpen dat afhankelijk van de grote van de cuff ruptuur de duur van de immobilisatie na de operatie wordt bepaald. In dit geval geldt geen *one size fits all*; de nabehandeling dient geïndividualiseerd te worden. Het is belangrijk dat de oefen-/fysiotherapeuten, eventueel verenigd in een schoudernetwerk, goed geïnformeerd worden over de duur van immobilisatie en nabehandeling, zodat deze optimaal kan verlopen.
Na drie weken immobilizeren kan worden gestart met oefentherapeutische nabehandeling. Deze zal bestaan uit advies en informeren aangaande pijneducatie, dagelijkse activiteiten, en het gedoseerd opbouwen van belasting. Aanvankelijk dienen patiënten te letten op het vermijden van activiteiten die klachten provoceren of overmatige belasting op cuff veroorzaken, zoals tillen (van lasten), sportactiviteiten of fysieke werkzaamheden. Daarnaast zal gestart worden met een laag gedoseerd geleid actief oefenschema, welke thuis uitgevoerd kan worden (drie tot acht weken na de operatie). In de daaropvolgende weken zal op geleide van pijn worden opgebouwd naar een actief oefenschema. Vanaf circa twaalf weken kan weerstand worden opgevoerd.

Aanbeveling

Rationale van de aanbeveling: weging van argumenten voor en tegen de interventies

Op basis van bovenstaande kan geconcludeerd worden dat er geen nadelen kleven aan kortdurige immobilisatie (drie weken) en direct functioneel starten ten opzichte van zes weken immobilisatie bij geïsoleerde supraspinatuspees rupturen. Patiënten ervaren gelijke pijnscores en hebben gelijke functie uitkomsten. Er is geen verhoogde kans op een reruptuur. Voor herstel van geïsoleerde supraspinatuspees rupturen kan dus een korte immobilisatieduur gekozen worden waarbij patiënten eerder functioneel behandeld kunnen worden. Voor grotere peesrupturen waarbij meerdere pezen aangedaan zijn, lijkt het verstandiger om voor zes weken immobilisatie te opteren, aangezien dit de kans op een reruptuur verlaagd.

Immobiliseer de schouder voor een periode van drie weken na operatief herstel van een geïsoleerde supraspinatuspeesruptuur.

Kennisvragen

Is immobilisatie nodig na het herstel van een geisoleerde supraspinatuspeesruptuur?

Er mist een evidence based behandelstrategie voor oefen-/fysiotherapeuten na een rotator cuff repair.

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Bijlagen bij module 5.4 Duur van immobilisatie als nabehandeling

Implementatieplan

Aanbeveling	Tijdspad voor implementatie: < 1 jaar, 1 tot 3 jaar of > 3 jaar	Verwacht effect op kosten	Randvoorwaarden voor implementatie (binnen aangegeven tijdspad)	Mogelijke barrières voor implementatie	Te ondernemen acties voor implementatie	Verantwoordelijken voor acties	Overige opmerkingen
Immobiliseer de schouder voor een periode van drie weken na operatief herstel van een geïsoleerde supraspinatuspeesruptuur.	<1 jaar	geen	Goed functionerend schoudernetwerk met voldoende kennis over nabehandeling aanbeveling.	Onvoldoende kennis en of bewustwording van de richtlijn bij zorgaanbieders.	Publicatie richtlijn Uitrollen van deze richtlijn bijv via richtlijnenkennisspeel en via KNGF.	Beroepsvereniging NOV evt ism kwaliteitsinstituut	geen

Evidence tables

Study reference	Study characteristics	Patient characteristics [2]	Intervention (I)	Comparison / control (C) [3]	Follow-up	Outcome measures and effect size [4]	Comments
Düzgün, 2014	Type of study: a prospective, clinical study (quasi-randomly assigned into accelerated groups) Setting and country: Sports Physiotherapy Unit, University, Turkey. Funding and conflicts of interest: Written informed consent (Hacettepe University Ethics Committee; FON 05/15-30) was obtained from all patients.	Inclusion criteria: Patients with stage 2 or 3 rotator cuff tear determined by MRI whom underwent arthroscopic rotator cuff repair for a full-thickness tear were included in the study. Exclusion criteria: Patients presenting with a central nervous system disorder or a peripheral nerve disorder, who were not willing to cooperate with the rehabilitation	Patients were quasi-randomly assigned to one of the two groups based on their year of enrolment in the study. The 19 patients presenting in the 1st year were placed in the accelerated (ACCEL) protocol group (17 females, 2 males). Surgery was performed according to the procedure described by Düzgün et al.	21 patients were enrolled in the 2nd year were placed in the slow (SLOW) protocol group (17 females, 4 males). Surgery was performed according to the procedure described by Düzgün et al. In the SLOW group, soft tissue mobilization for the scapulothoracic and glenohumeral joint along with passive ROM	Length of follow-up: at the 3rd, 5th, 8th, 12th, and 24th postoperative week Loss-to-follow-up: Intervention: 1 (loss to follow-up since 24 week follow-up). Control: 1 (loss to follow-up since 24 week follow-up). Incomplete outcome data:	**1. Function (including post-op stiffness)** **1.1. Function at 6 weeks post op** Not reported **1.2. Function at 3 months post op** Not reported **1.3. Function at 6 months post op** Not reported **1.4. Function at 12 months post op** Not reported **2. Pain** Not reported **2.1. Pain at 6 weeks post op**	Authors' conclusion: In conclusion, in both early and late initiation of the rehabilitation protocol, ROM eventually reaches normal values by 6 months. Patients in the current study received the same rehabilitation protocol with passive, active, and resistive exercises introduced at either the earlier (ACCEL) or later (SLOW) postoperative period. All patients demonstrated improvement in ROM through the course of rehabilitation.

	No conflict of interest.	duration, or who self-reported psychological disorder, were excluded. <u>N total at baseline</u>: 40 Intervention: 19 Control: 21 <u>Important prognostic factors</u>: *All patients had non-traumatic degenerative tears.* *Age (years):* *Mean ± SD* *I: 57.68 ± 7.8* *C: 57.2 ± 10.1* *Sex:* *I: 17 females, 2 males* *C: 17 females, 4 males* <u>Groups</u>	Patients enrolled in the ACCEL group were given 6 weeks of preoperative rehabilitation. The ACCEL protocol was initiated at the 2nd postoperative week and included soft tissue mobilization for the scapulothoracic and glenohumeral joint along with motion exercises. Active ROM exercises with scapular plane elevation, flexion and abduction was initiated at the 3rd week as long as the patient reported no pain at rest with their surgically repaired shoulder. Active exercises were	exercises were initiated at the 4th postoperative week. Active ROM in scapular plane elevation, flexion and abduction was initiated at the 6th week and light resistive elastic resistance exercises at the 8th week. The protocol was applied 3 days a week for 14 weeks.	Intervention: 0 Control: 0	Not reported **<u>2.2. Pain at 3 months post op</u>** Not reported **<u>2.3. Pain at 6 months post op</u>** Not reported **<u>2.4. Pain at 12 months post op</u>** Not reported **<u>3. Frozen shoulder</u>** **<u>3.1. Frozen shoulder at 6 weeks post op</u>** <u>Not reported</u> **<u>3.2. Frozen shoulder at 3 months post op</u>** <u>Not reported</u> **<u>3.3. Frozen shoulder at 6 months post op</u>** <u>Not reported</u> **<u>3.4. Froze shoulder at 12 months post op.</u>** **<u>4. Complications/adverse events</u>** Not reported **<u>4.1. Complications at 6 weeks post op</u>** Not reported	-No baseline assessment/measurement (makes it difficult to determine whether the protocol or the individual in the groups accounted for the differences observed).

		comparable at baseline? yes	delayed by 1 week in 1 patient due to pain upon removal of the support which later resolved. Light resistive elastic resistance (Thera-Band, red color-coded) exercises were initiated at the 4th postoperative week. The ACCEL protocol was applied 3 days a week for 6 weeks.			**4.2. Complications at 3 months post op** Not reported **4.3. Complications at 6 months post op** Not reported **4.4. Complications at 12 months post op** Surgical complications or adverse responses throughout the duration of the rehabilitation protocol, NO (N, %): I: 19 (100%) C: 21 (100%) **5. Patient satisfaction** Not reported **5.1. Patient satisfaction at 6 weeks post op** Not reported **5.2. Patient satisfaction at 3 months post op** Not reported **5.3. Patient satisfaction at 6 months post op** Not reported **5.4. Patient satisfaction at 12 months post op** Not reported	

						<u>6. Return to work/sport</u> Not reported **<u>6.1. Return to work/sport at 6 weeks post op</u>** Not reported **<u>6.2. Return to work/sport at 3 months post op</u>** Not reported **<u>6.3. Return to work/sport at 6 months post op</u>** Not reported **<u>6.4. Return to work/sport at 12 months post op</u>** Not reported	
Jenssen 2018	<u>Type of study:</u> a prospective, randomized, non-inferiority trial. <u>Setting and country:</u> Patients were recruited between 2013 to 2015. Patients from a single orthopaedic practice of 5 shoulder surgeons were enrolled in this trial. Further not specified:	<u>Inclusion criteria</u>: Eligible patients had repairable full-thickness RC tears =< 3 cm affecting the supraspinatus or upper infraspinatus tendon. The patients had dysfunctional and painful shoulders due to a chronic RC tear nonresponsive to exercise therapy	Surgical procedures to repair RC, were performed by specialized shoulder surgeons. Surgical procedures were the same in both groups. RC repair was performed with an arthroscopic, single-row, repair technique using 1	Surgical procedures to repair RC, were performed by specialized shoulder surgeons. Surgical procedures were the same in both groups. RC repair was performed with an arthroscopic, single-row, repair technique using 1	<u>Length of follow-up</u>: 1 year follow-up <u>Loss-to-follow-up</u>: 2 patients loss to follow-up after 1 year: one withdrew and one was terminally ill. Intervention: Control:	**<u>1. Function (including post-op stiffness)</u>** **<u>1.1. Function at 6 weeks post op</u>** Not reported **<u>1.2. Function at 3 months post op</u>** *Constant Murley Score* I: 41 ± 23 C: 38 ± 19 MD: -3, 95% CI -5 to -10. *WORC*	<u>Authors' conclusion:</u> Clinical trial registered RC repair resulted in improved postoperative shoulder function, regardless of whether the shoulder was immobilized for 3 or 6 weeks. Regarding WORC index: a difference between the 2 groups of 13 points (out of a total of 100) on the WORC index after 12

	first author was affiliated with Oslo University Hospital in Oslo, Norway. <u>Funding and conflicts of interest:</u> Not reported	for a minimum of 3 months or an acute on chronic RC tear. <u>Exclusion criteria</u>: -irreparable cuff tears, -tears >= 3 cm, -full-thickness subscapularis tendon tear, -adhesive capsulitis, -concomitant labral repair, -revision repair, -fatty muscle infiltration of the RC > 50%, -shoulder joint osteoarthritis, -diabetes mellitus, and -systemic inflammatory disorders. *In both groups, patients reported the duration of symptoms to be longer than 1 year on average.*	or 2 triple-loaded healicoil PK suture anchors after debridement and micro fracture of the tendon footprint. Had an early active range of motion starting at 3 weeks. Had a simple sling for 3 weeks. The patients were told to keep the sling on day and night and to take it off 3 times a day to perform pendulum exercises. All patients were allowed active ROM of elbow and hand and passive ROM of the shoulder joint from day 1. An in-house physiotherapist	or 2 triple-loaded healicoil PK suture anchors after debridement and micro fracture of the tendon footprint. Had a delayed active range of motion starting 6 weeks after surgery. Had a brace with a small abduction pillow with the arm in neutral position for 6 weeks after surgery. The patients were told to keep the brace on day and night and to take it off 3 times a day to perform pendulum exercises. Some asked to remove the brace when sitting because it was pain relieving	<u>Incomplete outcome data</u>: Intervention: Control:	I: 58 ± 20 C: 59 ± 18 MD: -1, 95% CI -8 to 6. **<u>1.3. Function at 6 months post op</u>** *CM* I: 68 ± 28 C: 71 ± 25 MD: -3, 95% CI -12 to -7. *WORC* I: 75 ± 22 C: 77 ± 18 MD: -2, 95% CI -9 to -5. **<u>1.4. Function at 12 months post op</u>** *Constant Murley score* I: 86 ± 27 C: 90 ± 23 MD: -4, 95% CI -13 to 5. *Western Ontario Rotator Cuff (WORC) index.* I: 83 (SD ± 19) C: 87 (SD ± 14) MD: -4, 95% CI -10 to -3. **<u>2. Pain</u>**	months was considered clinically relevant.

		N total at baseline: 120 Intervention: 60 Control: 58 Important prognostic factors: *Age, mean (min-max) years* I: 56 (34-69) C: 55 (34-73) *Gender (male/female)* I: 37/23 C: 32/26 RC tear associated with a previous trauma to the shoulder: I: 33 patients C: 26 patients Groups comparable at baseline? Yes	educated the patients before they were discharged, and they were advised to visit their own physiotherapist for 2 to 3 times a week. A report regarding advised rehabilitation after RC surgery was given to the patients' physiotherapist, and individual adjustments were made at the 6-weeks follow-up visit in the orthopaedic clinic. Both groups were not allowed active ROM with resisted loading (lifting anything greater than the weight of the arm) for the	– however not reported whether patients did so. All patients were allowed active ROM of elbow and hand and passive ROM of the shoulder joint from day 1. An in-house physiotherapist educated the patients before they were discharged, and they were advised to visit their own physiotherapist for 2 to 3 times a week. A report regarding advised rehabilitation after RC surgery was given to the patients' physiotherapist, and individual adjustments were		Not reported **2.1. Pain at 6 weeks post op** Not reported **2.2. Pain at 3 months post op** Not reported **2.3. Pain at 6 months post op** Not reported **2.4. Pain at 12 months post op** Not reported **3. Frozen shoulder** Not reported **3.1. Frozen shoulder 6 weeks post op** Not reported **3.2. Frozen shoulder 3 months post op** Not reported **3.3. Frozen shoulder 6 months post op** Not reported **3.4. Frozen shoulder 12 months post op** Not reported **4. Complications/adverse events**	

			first 3 months after surgery.	made at the 6-weeks follow-up visit in the orthopaedic clinic. Both groups were not allowed active ROM with resisted loading (lifting anything greater than the weight of the arm) for the first 3 months after surgery.		**<u>4.1. Complications/adverse events 6 weeks post op</u>** Not reported **<u>4.2. Complications/adverse events 3 months post op</u>** Not reported **<u>4.3. Complications/adverse events 6 months post op</u>** Not reported **<u>4.4. Complications at 12 months post op</u>** *Corticosteroid injections because of postoperative capsulitis* I: 2/60 C: 0/58 **<u>5. Patient satisfaction</u>** Not reported **<u>5.1. Patient satisfaction at 6 weeks post op</u>** Not reported **<u>5.2. Patient satisfaction at 3 months post op</u>** Not reported **<u>5.3. Patient satisfaction at 6 months post op</u>** Not reported **<u>5.4. Patient satisfaction at 12 months post op</u>**	

						Patient satisfaction VAS ratings at 12 months follow-up: I: 8.6 (SD ± 1.8) C: 8.7 (SD ± 1.9) MD: -0.03, 95% CI -0.7 to 0.7. **6. Return to work/sport** Not reported **6.1. Return to work/sport at 6 weeks post op** Not reported **6.2. Return to work/sport at 3 months post op** Not reported **6.3. Return to work/sport at 6 months post op** Not reported **6.4. Return to work/sport at 12 months post op** Not reported	
Zhang (2017)	Type of study: Clinical study Setting and country: 132 cases were recruited from January 2013 to July 2016. Further not	Inclusion criteria: -restricted mobility of shoulder joint was no less than in 30 degrees at least 2 directions out of a total of 3 directions	Early motion group. Patients included after undergoing an arthroscopic rotator cuff repair. After surgery, the	Control group received immobilization. Patients included after undergoing an arthroscopic rotator cuff repair.	Length of follow-up: 1 year follow-up Loss-to-follow-up: 0 Intervention: Control:	**1. Function (including post-op stiffness)** **1.1. Function at 6 weeks post op** Not reported **1.2. Function at 3 months post op** Not reported	Authors' conclusion: Compared with immobilization, early motion can obtain similar functional outcomes in the later stage and reduce incidence of stiffness,

	specified: however author was affiliated with the department of orthopedics, in Shanxi province, China. <u>Funding and conflicts of interest:</u> not reported	(anteflexion, abduction and external rotation); rotator cuff injury diagnosed by MRI; patients were willing to receive rehabilitation, and have good cooperation in evaluation. <u>Exclusion criteria</u>: Patients with acute phase of shoulder injury, and the age is older than 70 years (> 70 years); patients with neurological disorders of the cervical vertebra of upper limbs; patients with dislocation of shoulder joint and previous surgical history, patients combined with severe	affected limbs were immobilized and suspended by using brackets in the two groups to keep the shoulder joint at 30 degrees abduction and 0 degrees external rotation. The patients in the observation group began exercise at 24 h postoperative and the motion range was gradually increased, active external rotation and back extensor exercise began at 72 h postoperative, strength training of the deltoid started 1 w postoperatively and muscular counterforce training started 6 w after surgery.	Patients in the control group began exercise at 6 w after surgery. The affected limbs were immobilized in the control group until 6 w after surgery, and the motion range of the shoulder joint was gradually increased.	<u>Incomplete outcome data</u>: 0 Intervention: Control:	**<u>1.3. Function at 6 months post op</u>** Not reported **<u>1.4. Function at 12 months post op</u>** *Constant shoulder score at 12 months postop* I: 91.25 ± 10.93 C: 88.40 ± 11.37 MD: 2.85, 95% CI -0.95 to 6.65 **<u>2. Pain</u>** Not reported **<u>2.1. Pain at 6 weeks post op</u>** Not reported **<u>2.2. Pain at 3 months post op</u>** Not reported **<u>2.3. Pain at 6 months post op</u>** Not reported **<u>2.4. Pain at 12 months post op</u>** VAS score: I: 3.27 ± 1.02 C: 3.51 ± 0.92 MD: -0.24, 95% CI -0.57 to 0.09	which should be recommended in large size rotator cuff tear after arthroscopy repair.

		cardiovascular, cerebrovascular diseases, nervous system diseases and infection. <u>N total at baseline</u>: 132 Intervention: 66 Control: 66 <u>Important prognostic factors</u>: *Age (year)* I: 52.32 ± 12.71 C: 50.43 ± 10.92 *Gender (male/female)* I: 37/29 C: 32/34 *Tear length (mm)* I: 37.28 ± 2.28 C: 38.49 ± 3.38 <u>Groups comparable at</u>	.			**<u>3. Frozen shoulder</u>** Not reported **<u>3.1. Frozen shoulder 6 weeks post op</u>** Not reported **<u>3.2. Frozen shoulder 3 months post op</u>** Not reported **<u>3.3. Frozen shoulder 6 months post op</u>** Not reported **<u>3.4. Frozen shoulder 12 months post op</u>** *Ankylosis* I: 10 (15.15) C: 24 (36.36) RD: -0.21, 95% CI -0.35 to -0.06; and RR: 0.41, 95% CI 0.21 to 0.80 **<u>4. Complications/adverse events</u>** **<u>4.1. Complications at 6 weeks post op</u>** Not reported **<u>4.2. Complications at 3 months post op</u>** Not reported **<u>4.3. Complications at 6 months post op</u>**	

		baseline? Yes				Not reported **4.4. Complications at 12 months post op** *Incidence of complications: Re-tear* *(N, %) (time period not specified)* I: 6 (9.09) C: 4 (6.06) RD: 0.03, 95% CI -0.05 to 0.12; and RR: 1.5, 95% CI 0.44 to 5.07 **5. Patient satisfaction** Not reported **5.1. Patient satisfaction at 6 weeks post op** Not reported **5.2. Patient satisfaction at 3 months post op** Not reported **5.3. Patient satisfaction at 6 months post op** Not reported **5.4. Patient satisfaction at 12 months post op** Not reported **6. Return to work/sport** Not reported	

						<u>6.1. Return to work/sport at 6 weeks post op</u> Not reported **<u>6.2. Return to work/sport at 3 months post op</u>** Not reported **<u>6.3. Return to work/sport at 6 months post op</u>** Not reported **<u>6.4. Return to work/sport at 12 months post op</u>** Not reported	

Risk of bias table

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?** Definitely yes Probably yes Probably no Definitely no	**Was the allocation adequately concealed?** Definitely yes Probably yes Probably no Definitely no	**Blinding: Was knowledge of the allocated interventions adequately prevented?** **Were patients blinded?** **Were healthcare providers blinded?** **Were data collectors blinded?** **Were outcome assessors blinded?** **Were data analysts blinded?** Definitely yes Probably yes Probably no Definitely no	**Was loss to follow-up (missing outcome data) infrequent?** Definitely yes Probably yes Probably no Definitely no	**Are reports of the study free of selective outcome reporting?** Definitely yes Probably yes Probably no Definitely no	**Was the study apparently free of other problems that could put it at a risk of bias?** Definitely yes Probably yes Probably no Definitely no	**Overall risk of bias** **If applicable/necessary, per outcome measure** **LOW** **Some concerns**

							HIGH
Duzgun (2014)	Probably no <u>Reason:</u> Did not mention the sequence of allocation. Solely mentioned: ''Patients were quasi-randomly assigned to one of the two groups based on their year of enrolment in the study. ''	Probably no <u>Reason:</u> Solely mentioned: '' *Patients were quasi-randomly assigned to one of the two groups based on their year of enrollment in the study*.''	Definitely yes <u>Reason:</u> It was not possible to blind all stakeholders (patients etc.). however, the orthopaedic surgeon with 19 years of experience was blinded to the rehabilitation protocol until the end of the study; treatments were performed by a single physiotherapist with 10 years of experience and who was blinded to the patients' rotator cuff tear	Definitely yes <u>Reason:</u> Solely one patient in each research arm was loss to follow-up since measurement post op 24 weeks.	Probably yes <u>Reason:</u> All outcome measures reported	No baseline assessment/measurement (makes it difficult to determine whether the protocol or the individual in the groups accounted for the differences observed). <u>Reason:</u> However, a preoperative baseline is difficult to establish when performing clinical research on rehabilitation as in clinical practice patients are not often referred	Some concerns of bias

			size and surgical technique; and evaluations were performed by a single physiotherapist with 13 years of experience and who was blinded to group membership; and additionally all outcome measurements were performed at the 3rd, 5th, 8th, 12th, and 24th postoperative week by the same blinded physiotherapist			before surgery	
Jenssen (2018)	Probably yes, <u>Reason:</u> A computer calculated the block randomization,	Probably yes <u>Reason</u> The treatment allocation was organized by an independent	Probably yes <u>Reason</u> The treating surgeon was blinded to the randomization	Definitely yes <u>Reason:</u> 2 patients loss to follow-up after 1 year: one withdrew and one	Probably yes <u>Reason:</u> All outcome measures reported	Different shoulder surgeons performed the RC surgery so there were likely minor differences in the surgical	No concerns of bias

	and all patients were given a study number, which they kept throughout the trial. Randomization into groups took place in the operation theatre at the end of each surgical procedure.	nurse who distributed sealed and numbered opaque envelopes to the nurse manager in the operation theatre. The envelope was not opened until the surgical repair was complete, and thus the treating surgeon was blinded to the randomization assignment before and during surgery.	before and during surgery, and the radiologist was blinded throughout the analysis of the study. It was not possible to blind the patients. Not possible to blind the examining physiotherapist to the randomization because, whenever possible, the same physiotherapist examined the patients at each contact point to ensure the quality of shoulder scores.	was terminally ill.		techniques. Funding and conflict of interests not reported	

Zhang (2017)	Probably not Reason Did not report on allocation of sequence.	Probably not Reason Did not report on concealment of allocation.	Probably not Reason Did not report on blinding	Definitely yes Reason No loss to follow-up occured	Probably yes Reason: All outcome measures reported	Probably yes Reason Funding and conflict of interests not reported	High concerns of bias

Table of excluded studies

Reference	Reason for exclusion
Bouché PA, Gaujac N, Descamps J, Conso C; francophone arthroscopy society (SFA). Assessment of several postoperative protocols after rotator cuff repair: A network meta-analysis. Orthop Traumatol Surg Res. 2022 Dec;108(8S):103418. doi: 10.1016/j.otsr.2022.103418. Epub 2022 Sep 22. PMID: 36152940.	Wrong design; netwerk meta-analysis
Li S, Sun H, Luo X, Wang K, Wu G, Zhou J, Wang P, Sun X. The clinical effect of rehabilitation following arthroscopic rotator cuff repair: A meta-analysis of early versus delayed passive motion. Medicine (Baltimore). 2018 Jan;97(2):e9625. doi: 10.1097/MD.0000000000009625. PMID: 29480870; PMCID: PMC5943887.	Duration of interventions not >3 wks and >6 wks
Yi A, Villacis D, Yalamanchili R, Hatch GF 3rd. A Comparison of Rehabilitation Methods After Arthroscopic Rotator Cuff Repair: A Systematic Review. Sports Health. 2015 Jul;7(4):326-34. doi: 10.1177/1941738115576729. PMID: 26137178; PMCID: PMC4481677.	Included the same RCTs (Arndt; Cuff; Kim; Lee; Keener, Duzgun; Roo; Mazocca) > includes Keener en Arnd t> AROM starts >6 wks post op
Longo UG, Risi Ambrogioni L, Berton A, Candela V, Migliorini F, Carnevale A, Schena E, Nazarian A, DeAngelis J, Denaro V. Conservative versus accelerated rehabilitation after rotator cuff repair: a systematic review and meta-analysis. BMC Musculoskelet Disord. 2021 Jul 24;22(1):637. doi: 10.1186/s12891-021-04397-0. PMID: 34303366; PMCID: PMC8310609.	Duration of interventions not the same: only in Jenssen (2018) and Duzgun (2014), but these are already included
Chan K, MacDermid JC, Hoppe DJ, Ayeni OR, Bhandari M, Foote CJ, Athwal GS. Delayed versus early motion after arthroscopic rotator cuff repair: a meta-analysis. J Shoulder Elbow Surg. 2014 Nov;23(11):1631-9. doi: 10.1016/j.jse.2014.05.021. Epub 2014 Aug 13. PMID: 25127908.	Includes Keener > AROM starts >6 wks post op
Houck DA, Kraeutler MJ, Schuette HB, McCarty EC, Bravman JT. Early Versus Delayed Motion After Rotator Cuff Repair: A Systematic Review of Overlapping Meta-analyses. Am J Sports Med. 2017 Oct;45(12):2911-2915. doi: 10.1177/0363546517692543. Epub 2017 Mar 13. PMID: 28288280.	Other relevant studies included (Jenssen, 2018, Zhang, 2017 en Duzgun 2014). The meta-analyses of Chan (2014); chen (2015); Chang (2015): already included in TiAb > apart bekijken
Chang KV, Hung CY, Han DS, Chen WS, Wang TG, Chien KL. Early Versus Delayed Passive Range of Motion Exercise for Arthroscopic Rotator Cuff Repair: A Meta-analysis of Randomized Controlled Trials. Am J Sports Med. 2015 May;43(5):1265-73. doi: 10.1177/0363546514544698. Epub 2014 Aug 20. Erratum in: Am J Sports Med. 2015 Aug;43(8):NP26. PMID: 25143489.	Other relevant studies included RCTs geincludeerd; Cuff (2012); Arndt (2012); Kim (2012); Keener (2014) ; Duzgun (2011). Lee (2012) wrong comparison , Keener & Arndt > includes Keener & Arndt> AROM starts >6 wks post op
Gallagher BP, Bishop ME, Tjoumakaris FP, Freedman	Other relevant studies included

KB. Early versus delayed rehabilitation following arthroscopic rotator cuff repair: A systematic review. Phys Sportsmed. 2015 May;43(2):178-87. doi: 10.1080/00913847.2015.1025683. Epub 2015 Mar 22. PMID: 25797067.	
Mazuquin BF, Wright AC, Russell S, Monga P, Selfe J, Richards J. Effectiveness of early compared with conservative rehabilitation for patients having rotator cuff repair surgery: an overview of systematic reviews. Br J Sports Med. 2018 Jan;52(2):111-121. doi: 10.1136/bjsports-2016-095963. Epub 2016 Dec 30. PMID: 28039127.	Relevant RCTs (duzgun > already included). (Jenssen en Zhang) > included
Mazuquin B, Moffatt M, Gill P, Selfe J, Rees J, Drew S, Littlewood C. Effectiveness of early versus delayed rehabilitation following rotator cuff repair: Systematic review and meta-analyses. PLoS One. 2021 May 28;16(5):e0252137. doi: 10.1371/journal.pone.0252137. PMID: 34048450; PMCID: PMC8162656.	Cuff, Kim, Jenssen, Keener, Arndt, etc included in this meta-analyses, > K en I : active from 6 weken. Other RCTs in this meta analysis had other timing of rehabilitation procotols compared to I and C in our PICO
Chen L, Peng K, Zhang D, Peng J, Xing F, Xiang Z. Rehabilitation protocol after arthroscopic rotator cuff repair: early versus delayed motion. Int J Clin Exp Med. 2015 Jun 15;8(6):8329-38. PMID: 26309485; PMCID: PMC4538011.	4 RCTs included: Arndt (2012), Cuff (2012), Keener (2014) and Lee (2012) > Keener en Arndt: active from6 weken
Bandara U, An VVG, Imani S, Nandapalan H, Sivakumar BS. Rehabilitation protocols following rotator cuff repair: a meta-analysis of current evidence. ANZ J Surg. 2021 Dec;91(12):2773-2779. doi: 10.1111/ans.17213. Epub 2021 Sep 28. PMID: 34582083.	Relevant RCT separately included > Duzgun (2014)
Sheps DM, Silveira A, Beaupre L, Styles-Tripp F, Balyk R, Lalani A, Glasgow R, Bergman J, Bouliane M; Shoulder and Upper Extremity Research Group of Edmonton (SURGE). Early Active Motion Versus Sling Immobilization After Arthroscopic Rotator Cuff Repair: A Randomized Controlled Trial. Arthroscopy. 2019 Mar;35(3):749-760.e2. doi: 10.1016/j.arthro.2018.10.139. PMID: 30827428.	Exclusion: intervention duration up to 6 weeks instead of 3 weeks. Unclear when intervention started: early mobilization (EM) with standard rehabilitation (SR); waarbij EM (n = 103; self-weaned from sling and performed pain-free active ROM during the first 6 weeks) VS. Standard rehabilitation: SR (n = 103); wore a sling for 6 weeks with no active ROM
Mazzocca AD, Arciero RA, Shea KP, Apostolakos JM, Solovyova O, Gomlinski G, Wojcik KE, Tafuto V, Stock H, Cote MP. The Effect of Early Range of Motion on Quality of Life, Clinical Outcome, and Repair Integrity After Arthroscopic Rotator Cuff Repair. Arthroscopy. 2017 Jun;33(6):1138-1148. doi: 10.1016/j.arthro.2016.10.017. Epub 2017 Jan 19. PMID: 28111006.	Sling use was discontinued in both groups at the 6-week mark
Misir A, Oguzkaya S, Kizkapan TB, Eken G, Sayer G. The	Wrong duration intervention

effect of postoperative sling immobilization and early mobilization on clinical and functional outcomes after arthroscopic rotator cuff repair: A propensity score-matched analysis. J Back Musculoskelet Rehabil. 2022;35(6):1391-1398. doi: 10.3233/BMR-210358. PMID: 35723088.	
Keener JD, Galatz LM, Stobbs-Cucchi G, Patton R, Yamaguchi K. Rehabilitation following arthroscopic rotator cuff repair: a prospective randomized trial of immobilization compared with early motion. J Bone Joint Surg Am. 2014 Jan 1;96(1):11-9. doi: 10.2106/JBJS.M.00034. PMID: 24382719.	Intervention: only active from 6 weeks
Schulze C, Knaack F, Goosmann M, Mittelmeier W, Bader R. Kontinuierliche passive Bewegungstherapie (CPM-Therapie) in der orthopädischen Rehabilitation am Schultergelenk – eine Literaturübersicht [Continuous Passive Motion in Orthopaedic Rehabilitation of the Shoulder Girdle - A Literature Survey]. Rehabilitation (Stuttg). 2021 Dec;60(6):364-373. German. doi: 10.1055/a-1500-8567. Epub 2021 Jul 14. PMID: 34261143.	Different P : shoulder joint surgery
Saltzman BM, Zuke WA, Go B, Mascarenhas R, Verma NN, Cole BJ, Romeo AA, Forsythe B. Does early motion lead to a higher failure rate or better outcomes after arthroscopic rotator cuff repair? A systematic review of overlapping meta-analyses. J Shoulder Elbow Surg. 2017 Sep;26(9):1681-1691. doi: 10.1016/j.jse.2017.04.004. Epub 2017 Jun 12. PMID: 28619382.	Includes chen, chang, chan > excluded already
Shen C, Tang ZH, Hu JZ, Zou GY, Xiao RC, Yan DX. Does immobilization after arthroscopic rotator cuff repair increase tendon healing? A systematic review and meta-analysis. Arch Orthop Trauma Surg. 2014 Sep;134(9):1279-85. doi: 10.1007/s00402-014-2028-2. Epub 2014 Jun 11. PMID: 25027677.	Arndt: only active from 6 weeks
Shen C, Tang ZH, Hu JZ, Zou GY, Xiao RC, Yan DX. Does immobilization after arthroscopic rotator cuff repair increase tendon healing? A systematic review and meta-analysis. Arch Orthop Trauma Surg. 2014 Sep;134(9):1279-85. doi: 10.1007/s00402-014-2028-2. Epub 2014 Jun 11. PMID: 25027677.	Included 3 RCTs which not met duration
Riboh JC, Garrigues GE. Early passive motion versus immobilization after arthroscopic rotator cuff repair. Arthroscopy. 2014 Aug;30(8):997-1005. doi: 10.1016/j.arthro.2014.03.012. Epub 2014 May 10. PMID: 24813324.	Includes 5 RCTs: arndt (2012); Cuff (2012) Keener (2014) and Kim (2012) and Lee (2012) > did not meet duration
Silveira A, Luk J, Tan M, Kang SH, Sheps DM, Bouliane M, Beaupre L. Move It or Lose It? The Effect of Early Active Movement on Clinical Outcomes Following Rotator Cuff Repair: A Systematic Review With Meta-analysis. J Orthop Sports Phys Ther. 2021 Jul;51(7):331-	Relevant RCTs separately included

344. doi: 10.2519/jospt.2021.9634. Epub 2021 May 15. PMID: 33998264.	
Matlak S, Andrews A, Looney A, Tepper KB. Postoperative Rehabilitation of Rotator Cuff Repair: A Systematic Review. Sports Med Arthrosc Rev. 2021 Jun 1;29(2):119-129. doi: 10.1097/JSA.0000000000000310. PMID: 33972488.	Relevant RCTs separately included
Littlewood C, Bateman M, Cooke K, Hennnings S, Cookson T, Bromley K, Lewis M, Funk L, Denton J, Moffatt M, Winstanley R, Mehta S, Stephens G, Dikomitis L, Chesterton L, Foster NE. Protocol for a multi-centre pilot and feasibility randomised controlled trial with a nested qualitative study: rehabilitation following rotator cuff repair (the RaCeR study). Trials. 2019 Jun 6;20(1):328. doi: 10.1186/s13063-019-3407-3. PMID: 31171031; PMCID: PMC6554931.	Wrong design: protocol
Littlewood C, Bateman M, Clark D, Selfe J, Watkinson D, Walton M, Funk L. Rehabilitation following rotator cuff repair: a systematic review. Shoulder Elbow. 2015 Apr;7(2):115-24. doi: 10.1177/1758573214567702. Epub 2015 Jan 29. PMID: 27582966; PMCID: PMC4935113.	Included arndt, cuff, duzgun, keener, kim, lee etc. > Arndt en Keener > AROM from week 6 intervention group.
Raschhofer R, Poulios N, Schimetta W, Kisling R, Mittermaier C. Early active rehabilitation after arthroscopic rotator cuff repair: a prospective randomized pilot study. Clin Rehabil. 2017 Oct;31(10):1332-1339. doi: 10.1177/0269215517694931. Epub 2017 Feb 1. PMID: 28933605.	Wrong comparison: Rehabilitation protocols of both groups during the postoperative hospitalization (5-6 days) were identical. All patients had to wear sling in both groups
Sheps DM, Bouliane M, Styles-Tripp F, Beaupre LA, Saraswat MK, Luciak-Corea C, Silveira A, Glasgow R, Balyk R. Early mobilisation following mini-open rotator cuff repair: a randomised control trial. Bone Joint J. 2015 Sep;97-B(9):1257-63. doi: 10.1302/0301-620X.97B9.35250. PMID: 26330594.	Wrong duration intervention group
Kruse, Lisa M.; Falconer, Travis M.; Dimmick, Simon J.; Balestro, Jean C.; Cunningham, Greg; Cass, Ben; Young, Allan A. Early Sling Discontinuation Following Rotator Cuff Repair. Techniques in Shoulder & Elbow Surgery, Volume 19, Number 3	No comparison
Koh KH, Lim TK, Shon MS, Park YE, Lee SW, Yoo JC. Effect of immobilization without passive exercise after rotator cuff repair: randomized clinical trial comparing four and eight weeks of immobilization. J Bone Joint Surg Am. 2014 Mar 19;96(6):e44. doi: 10.2106/JBJS.L.01741. PMID: 24647511.	Immobilization for four or eight weeks. During the immobilization period, no passive or active range-of-motion exercise, including pendulum exercise, was allowed.
De Roo PJ, Muermans S, Maroy M, Linden P, Van den Daelen L. Passive mobilization after arthroscopic rotator cuff repair is not detrimental in the early postoperative period. Acta Orthop Belg. 2015 Sep;81(3):485-92. PMID: 26435245.	Duration does not match I and C; The mobilization group (79 patients) received immediate daily passive mobilization. The immobilization group (51

	patients) was immobilized for 4 weeks until physiotherapy was started.
Tirefort J, Schwitzguebel AJ, Collin P, Nowak A, Plomb-Holmes C, Lädermann A. Postoperative Mobilization After Superior Rotator Cuff Repair: Sling Versus No Sling: A Randomized Prospective Study. J Bone Joint Surg Am. 2019 Mar 20;101(6):494-503. doi: 10.2106/JBJS.18.00773. PMID: 30893230.	Wrong comaprison (first in both groups passive mobilization, then active mobilization): not compared to immobilization. Study does compare: Passive mobilization was performed in both groups during the first 4 postoperative weeks, and this was followed by progressive active mobilization
Hurley ET, Maye AB, Mullett H. Arthroscopic Rotator Cuff Repair: A Systematic Review of Overlapping Meta-Analyses. JBJS Rev. 2019 Apr;7(4):e1. doi: 10.2106/JBJS.RVW.18.00027. PMID: 30939497.	24 meta analyses included: 7 meta-analyses on early motion compared with late motion (Zhang (2013); Shen (2014); hurley (2018); Chen (2015); Chang (2015) > already excluded)
Kluczynski MA, Nayyar S, Marzo JM, Bisson LJ. Early Versus Delayed Passive Range of Motion After Rotator Cuff Repair: A Systematic Review and Meta-analysis. Am J Sports Med. 2015 Aug;43(8):2057-63. doi: 10.1177/0363546514552802. Epub 2014 Oct 8. PMID: 25296646.	4 RCTs compared Early vs delayed passive range of motion (Cuff, Keener, Kim, Lee) > wrong duration
Bakti N, Antonios T, Phadke A, Singh B. Early versus delayed mobilization following rotator cuff repair. J Clin Orthop Trauma. 2019 Mar-Apr;10(2):257-260. doi: 10.1016/j.jcot.2019.01.016. Epub 2019 Feb 1. Erratum in: J Clin Orthop Trauma. 2020 Nov-Dec;11(6):1176. Erratum in: J Clin Orthop Trauma. 2021 Aug 05;21:101556. PMID: 30828188; PMCID: PMC6382997.	Wrong design: protocol study. cuff re-tear main outcome --> wrong design: protocol study: compared EPM with DPM however no groups compared.
Littlewood C, Bateman M, Butler-Walley S, Bathers S, Bromley K, Lewis M, Funk L, Denton J, Moffatt M, Winstanley R, Mehta S, Stephens G, Dikomitis L, Foster NE. Rehabilitation following rotator cuff repair: A multi-centre pilot & feasibility randomised controlled trial (RaCeR). Clin Rehabil. 2021 Jun;35(6):829-839. doi: 10.1177/0269215520978859. Epub 2020 Dec 11. PMID: 33305619; PMCID: PMC8191146.	Wrong design

Literature search strategy

Algemene informatie

Cluster/richtlijn: NOV Subacromiaal Pijnsyndroom van de Schouder (SAPS)	
Uitgangsvraag/modules: Welke duur van immobilisatie heeft de voorkeur als nabehandeling na het hechten van de supraspinatuspees?	
Database(s): Embase.com, Ovid/Medline	Datum: 23 oktober 2023
Periode: vanaf 2013	Talen: geen restrictie
Literatuurspecialist: Alies van der Wal	Rayyan review: https://rayyan.ai/reviews/818474
BMI-zoekblokken: voor verschillende opdrachten wordt (deels) gebruik gemaakt van de zoekblokken van BMI-Online https://blocks.bmi-online.nl/ Bij gebruikmaking van een volledig zoekblok zal naar de betreffende link op de website worden verwezen.	
Toelichting: Voor deze vraag is gezocht op de elementen: - supraspinatus repair - mobilisatie/ immomobilisatie De sleutelartikelen worden gevonden met deze search, m.u.v. PMID 32386779; deze voldoet niet aan het gevraagde studytype (SR/ RCT).	
Te gebruiken voor richtlijntekst: In de databases Embase.com en Ovid/Medline is op 23 oktober 2023 systematisch gezocht naar systematische reviews en RCTs over de duur van immobilisatie na supraspinatus repair. De literatuurzoekactie leverde 180 unieke treffers op.	

Zoekopbrengst

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	55	40	61
RCT	106	49	119
Totaal	161	89	**180***

****in Rayyan***

Zoekstrategie

Embase.com

No.	**Query**	**Results**
#1	'rotator cuff repair'/exp OR (('rotator cuff' OR 'shoulder cuff' OR supraspinatus) NEAR/3 (repair* OR reconstruct* OR arthroscop* OR arthroendoscop* OR surg*)):ti,ab,kw) OR (('rotator cuff rupture'/exp OR 'rotator cuff injury'/de OR 'supraspinatus tendon tear'/exp OR 'supraspinatus tear'/exp OR 'supraspinatus tendon rupture'/exp OR (('rotator cuff'/exp OR 'supraspinatus muscle'/exp OR 'supraspinatus tendon'/exp OR 'supraspinatus muscle tendon'/exp OR 'supraspinatus'/exp) AND ('rupture'/exp OR 'injury'/de OR 'laceration'/exp)) OR ((('rotator cuff' OR 'shoulder cuff' OR supraspinatus) NEAR/3 (ruptur* OR tear* OR torn OR lesion* OR laceration*)):ti,ab,kw)) AND ('arthroscopy'/de OR 'shoulder arthroscopy'/exp OR 'surgery'/exp OR 'surgical patient'/exp OR 'perioperative period'/exp OR 'postoperative	14412

	period'/exp OR 'postoperative care'/exp OR 'surgery'/lnk OR surgic*:ti,ab,kw OR surger*:ti,ab,kw OR operation*:ti,ab,kw OR operative:ti,ab,kw OR arthroscop*:ti,ab,kw OR perisurg*:ti,ab,kw OR perioperati*:ti,ab,kw OR postsurg*:ti,ab,kw OR 'post surg*':ti,ab,kw OR postoperati*:ti,ab,kw OR 'post operati*':ti,ab,kw OR intraoperati*:ti,ab,kw))	
#2	'mobilization'/exp OR 'immobilization'/exp OR 'immobilization device'/de OR 'limb immobilizer'/exp OR 'shoulder sling'/exp OR 'arm sling'/exp OR 'shoulder brace'/exp OR 'brace'/de OR 'orthosis'/de OR mobiliz*:ti,ab,kw OR mobilis*:ti,ab,kw OR immobilis*:ti,ab,kw OR immobiliz*:ti,ab,kw OR sling*:ti,ab,kw OR polysling*:ti,ab,kw OR orthosis:ti,ab,kw OR orthoses:ti,ab,kw OR orthotic:ti,ab,kw OR orthesis:ti,ab,kw OR brace*:ti,ab,kw OR bracing:ti,ab,kw OR (((early OR accelerat* OR late OR delay* OR conservative) NEAR/3 (motion OR movement OR rehabilitat*)):ti,ab,kw)	391152
#3	#1 AND #2	949
#4	#3 NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp) NOT (('adolescent'/exp OR 'child'/exp OR adolescent*:ti,ab,kw OR child*:ti,ab,kw OR schoolchild*:ti,ab,kw OR infant*:ti,ab,kw OR girl*:ti,ab,kw OR boy*:ti,ab,kw OR teen:ti,ab,kw OR teens:ti,ab,kw OR teenager*:ti,ab,kw OR youth*:ti,ab,kw OR pediatr*:ti,ab,kw OR paediatr*:ti,ab,kw OR puber*:ti,ab,kw) NOT ('adult'/exp OR 'aged'/exp OR 'middle aged'/exp OR adult*:ti,ab,kw OR man:ti,ab,kw OR men:ti,ab,kw OR woman:ti,ab,kw OR women:ti,ab,kw))	748
#5	#4 AND [2013-2023]/py	496
#6	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	970896
#7	'clinical trial'/exp OR 'randomization'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR 'placebo'/exp OR 'prospective study'/exp OR rct:ab,ti OR random*:ab,ti OR 'single blind':ab,ti OR 'randomised controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	3896362
#8	#5 AND #6 = SR	55
#9	#5 AND #7 NOT #8 = RCT	106
#10	#8 OR #9	161

Ovid/Medline

#	Searches	Results
1	(('rotator cuff' or 'shoulder cuff' or supraspinatus) adj3 (repair* or reconstruct* or arthroscop* or arthroendoscop* or surg*)).ti,ab,kf. or ((exp Rotator Cuff Injuries/ or (exp Rotator Cuff/ and (Rupture/ or exp Lacerations/ or exp Tendon Injuries/)) or (('rotator cuff' or 'shoulder cuff' or supraspinatus) adj3 (ruptur* or tear* or torn or	10747

	lesion* or laceration*)).ti,ab,kf.) and (exp Arthroscopy/ or exp Surgical Procedures, Operative/ or exp Specialties, Surgical/ or exp Perioperative Care/ or exp Perioperative Period/ or Postoperative Care/ or exp Postoperative Period/ or su.fs. or surgic*.ti,ab,kf. or surger*.ti,ab,kf. or operation*.ti,ab,kf. or operative.ti,ab,kf. or arthroscop*.ti,ab,kf. or perisurg*.ti,ab,kf. or perioperati*.ti,ab,kf. or postsurg*.ti,ab,kf. or 'post surg*'.ti,ab,kf. or postoperati*.ti,ab,kf. or 'post operati*'.ti,ab,kf. or intraoperati*.ti,ab,kf.))	
2	exp Immobilization/ or exp Orthotic Devices/ or mobiliz*.ti,ab,kf. or mobilis*.ti,ab,kf. or immobilis*.ti,ab,kf. or immobiliz*.ti,ab,kf. or sling*.ti,ab,kf. or polysling*.ti,ab,kf. or orthosis.ti,ab,kf. or orthoses.ti,ab,kf. or orthotic.ti,ab,kf. or orthesis.ti,ab,kf. or brace*.ti,ab,kf. or bracing.ti,ab,kf. or ((early or accelerat* or late or delay* or conservative) adj3 (motion or movement or rehabilitat*)).ti,ab,kf.	290280
3	1 and 2	469
4	3 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/) not ((Adolescent/ or Child/ or Infant/ or adolescen*.ti,ab,kf. or child*.ti,ab,kf. or schoolchild*.ti,ab,kf. or infant*.ti,ab,kf. or girl*.ti,ab,kf. or boy*.ti,ab,kf. or teen.ti,ab,kf. or teens.ti,ab,kf. or teenager*.ti,ab,kf. or youth*.ti,ab,kf. or pediatr*.ti,ab,kf. or paediatr*.ti,ab,kf. or puber*.ti,ab,kf.) not (Adult/ or adult*.ti,ab,kf. or man.ti,ab,kf. or men.ti,ab,kf. or woman.ti,ab,kf. or women.ti,ab,kf.))	425
5	limit 4 to yr="2013 -Current"	261
6	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	700911
7	exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti,ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind$3 or mask$3)).tw. or Placebos/ or placebo*.tw.	2645320
8	5 and 6 = SR	40
9	(5 and 7) not 8 = RCT	49
10	8 or 9	89

Module 5.5 Operatieve behandeling versus barbotage

Uitgangsvraag
Wat is de plaats van een operatieve behandeling in vergelijking met een barbotage bij patiënten met tendinosis calcarea?

Introduction (English)
Calcific tendinitis of the rotator cuff is a common cause of subacromial pain syndrome. This is a self-limiting condition and is usually treated conservatively. Some calcifications remain present for a long time and continue to hinder functioning. If conservative treatment with subacromial infiltration, physical therapy or shockwave is unsuccessful (Module Barbotage versus shockwave), it may be desirable to remove the calcifications. This can be accomplished through arthroscopy, but it has drawbacks, including the need for surgery and an extended rehabilitation period for approximately six months. An alternative approach is barbotage (needle aspiration of the calcific depot, NACD), which involves puncturing the calcification deposits using two needles and attempting to flush the calcium from the tendon. This is often done by a radiologist under local anesthesia. Barbotage is an effective method. The rehabilitation can vary between 3 months and 1 year. This partly depends on the duration of recovery of the movement pattern.

Search and select
A systematic review of the literature was performed to answer the following question:
What is the effectiveness of surgical calcium removal compared to barbotage on patient-reported outcome measures in adult patients with supra- or infraspinatus calcarea tendinosis?

Patients	Patients with a calcareous tendinosis of the supra- or infraspinatus
Intervention	Surgical removal of limescale
Control	Barbotage
Outcomes	Pain, complications/adverse events, PROMs for function (CMS, DASH, WORC, ASES, OSS, DSST), patient satisfaction, return to work or leisure

Relevant outcome measures
The guideline development group considered pain and function (PROMs for function: CMS, DASH, WORC, ASES, OSS, DSST) as critical outcome measures for decision making; and patient satisfaction, return to work or leisure, and complications/adverse events as an important outcome measure for decision making.

The guideline development group defined the outcome measures as follows:

- Patient reported outcomes measures for function: CMS, DASH, WORC, ASES, DSST, OSS
- Pain: VAS-scale (0-10 points or 0-100mm scale)
- Complications/adverse events: re-rupture, frozen shoulder and infection
- Patient satisfaction: self-reported satisfaction with treatment and/or function
- Return to work or leisure: definitions used in the studies.

The guideline development group defined the minimal clinically (patient) important differences as follows:

- Patient reported outcome measures:
    - CMS: 15 points on a 100-point scale (Holmgren, 2014)
    - DASH: 13 on a 100 point scale (Koorevaar, 2018)
    - WORC: -282.6 on a 2100 point scale (Gagnier, 2018)
    - ASES: 9 on a 100 point scale (Gagnier, 2018)
    - DSST: 2.8 on a 12 point scale (Van Kampen, 2013)
    - OSS: 5 points on a 48-point scale (Nyring, 2021)
- Pain
    - 1/10 points or 10/100 points on a VAS scale
- Complications/adverse events:
    - Re-rupture: 5 mm difference in rupture size
    - Frozen shoulder: 25% (RR ≤ 0.80 and ≥ 1.25)
    - Infection: 25% (RR ≤ 0.80 and ≥ 1.25)
- Patient satisfaction: difference of 25% (RR ≤ 0.80 and ≥ 1.25) or 1/10 points or 10/100 points on a VAS scale.
- Return to work or leisure: difference of 25% (RR ≤ 0.80 and ≥ 1.25)

Search and select (Methods)

The databases Medline (via OVID) and Embase (via Embase.com) were searched with relevant search terms until the 16th of August 2023. The detailed search strategy is depicted under the tab Methods. The systematic literature search resulted in 103 hits. Studies were selected based on the following criteria:

- Study design: randomized controlled trial or systematic review.
- Patients with a calcareous tendinosis of the supra- or infraspinatus, in adulthood.
- Comparing surgery versus barbotage in order to remove limescale.
- Describing at least one of the relevant outcomes specified in the PICO.
- Published from 2008.
- Follow-up duration: 6 months

A total of 14 studies were initially selected based on title and abstract screening. After reading the full text, 13 studies were excluded (see the table with reasons for exclusion under the tab Methods), and 1 study was included.

Results

One study was included in the analysis of the literature. Important study characteristics and results are summarized in the evidence tables. The assessment of the risk of bias is summarized in the risk of bias tables.

Summary of literature

Description of studies

Maugars (2009) performed a randomized controlled study to validate bursoscopy (BS) and needling fragmentation irrigation (NFI) versus a control group (CT). A total of 102 shoulders (96 patients) with calcifications > 5mm whose medical treatment had failed (>4months) were first injected using a corticosteroid. Of those, 49 shoulders improved by more than 70 percent. The other 53 shoulders (52 patients) were randomized in 3 groups: NFI (n=16), BS (n=20) and CT (n=17). Follow-up was performed at 1, 4, 12, and 24 months. Patients with chronic painful shoulders related to one or more tendon calcifications of the cuff,

symptomatic for more than 4 months, permanent or intermittent but with a continuation, despite usual medical symptomatic treatments, including analgesics, NSAID and infiltration, were included. Patients were respectively 46.8; 48.1; and 43.5 years in the NFI, BS and CT group. The intervention - bursoscopy (BS) - was carried out under general anesthesia by two experienced surgeons. Both articular and sub-acromial stages were performed. The calcification was extracted either with a curette or with a high pressure water jet when it was softened. There was no acromioplasty neither tendon suture nor total bursectomy. The patients were hospitalized 12-24 h, and a rehabilitation began in the next 24-48 h, passive then active. The NFI was performed under local anesthesia (15-30 cc of lidocaine) and the first stage was a needling under fluoroscopy. A first needle (18 Gauge, 50 mm) was inserted directly in line with the X-Ray by anterior way until the center of the calcification. A second needle was interested by an external way in the axis of calcification. Several tens of intra-calcic drillings were carried out via the needles for this second phase of fragmentation (fragmentation is succeeded when no more resistance and/or calcic cores were met). The third stage is irrigation for which 100-200 cc of physiological salt solution was used (irrigation is succeeded when seringe brings back a clear liquid).

Results

1. Pain

Maugars (2009) reported pain in terms of ''pain VAS improvement''. Scale scoring and/or ranging was not reported. In the article, it was solely stated textually that '*the principal parameter of the follow-up was a global subjective evaluation of an improvement by the patient, which included painful and functional disability, on a visual scale graduated 10 by 10 from 0 to 100%. The principal objective of this study was to obtain an improvement of at least 70%'.* In line with other studies, we interpreted that a higher score indicates greater pain intensity. Patients were re-examined at 1, 4, 12 and 24 months intervals after the technique.

12 months follow-up

At twelve months follow-up, pain VAS improvement was respectively -26.7 and -56.1 in the bursoscopy and needling fragmentation irrigation group (MD 29.4; this difference was considered clinically relevant in favor of the NFI group. Maugars did not report on baseline pain scores or VAS scale scoring.

24 months follow-up

At twenty-four months follow-up, pain VAS improvement was respectively -54.7 and -64.7 in the bursoscopy and needling fragmentation irrigation group (MD 10; this difference was not considered clinically relevant). Maugars did not report on baseline pain scores or VAS scale scoring.

2. Complications/adverse events at 6 months follow-up

12 months follow-up

Maugars (2009) did not report on complications/adverse events at twelve months follow-up.

24 months follow-up

Maugars (2009) reports on various complications/adverse events after two-year follow-up. In the burscopy and needle irrigation fragmentation group, one and one person reported partial rupture of rotator cuff (all superficial and at the supra-spinateus level). None of the patients in the bursoscopy or needling fragmentation group reported complete rupture.

Capsulitis after removal of the calcification was reported by respectively one and one patient in the burscopy and needle irrigation fragmentation group. Additionally, a total of 8 patients reported bursitis and 15 patients reported tendinitis of supra and/or infra-spinatus, however Maugars did not report on the specific cases per group bursoscopy or needling fragmentation irrigation.

3. PROMs for function:

3.1. CMS (constant murley score)

12 months

The constant score improvement was +10.7 and +20.7 in the bursoscopy and needling fragmentation irrigation groups, respectively, which was not considered clinically relevant.

24 months

The constant score improvement was +46.5 and +25.9 in the bursoscopy and needling fragmentation irrigation groups, respectively, which was considered clinically relevant in favor of the group of patients receiving bursoscopy.

3.2. Disabilities of the Arm, Shoulder, and Hand (DASH)

Maugars (2009) did not report the DASH.

3.3. The Western Ontario Rotator Cuff (WORC)

Maugars (2009) did not report the WORC.

3.4. American Society of Shoulder and Elbow Surgeons (ASES)

Maugars (2009) did not report the ASES.

3.5. Oxford Shoulder Score (OSS)

Maugars (2009) did not report the OSS.

3.6. Dutch Simple Shoulder Test (DSST)

Maugars (2009) did not report the DSST.

4. Patient satisfaction

Maugars (2009) did not report on patient satisfaction at >6 months follow-up.

5. Return to work or leisure

Maugars (2009) did not report of return to work or leisure at >6 months follow-up.

Level of evidence of the literature

The level of evidence started as high, as the included study was a RCT.

1. Pain

VAS improvement

12 months follow-up

The level of evidence regarding the outcome measure **pain**, measured as percentage pain VAS improvement, was downgraded by **two** levels to **LOW** because of study limitations (randomization and concealment of allocation not reported) (risk of bias, -1) and limited population size (imprecision, -1).

24 months follow-up

The level of evidence regarding the outcome measure **pain**, measured as percentage pain VAS improvement, was downgraded by **two** levels to **LOW** because of study limitations (randomization and concealment of allocation not reported) (risk of bias, -1) and limited population size (imprecision, -1).

2. Complications/adverse events

12 months follow-up

As Maugars (2009) did not report on complications/adverse events at 12 months follow-up, it was not possible to assess the level of evidence.

24 months follow-up

The level of evidence regarding the outcome measure **complications/adverse events** was downgraded by **two** levels to **LOW** because of study limitations (randomization and concealment of allocation not reported) (risk of bias, -1) and limited population size (imprecision, -1).

3. PROMS for function

3.1. Constant Murley Score

12 months follow-up

The level of evidence regarding the outcome measure **function,** measured with the Constant Murley Score, was downgraded by **two** levels to **LOW** because of study limitations (randomization and concealment of allocation not reported) (risk of bias, -1) and limited population size (imprecision, -1).

24 months follow-up

The level of evidence regarding the outcome measure **function,** measured with the Constant Murley Score, was downgraded by **two** levels to **LOW** because of study limitations (randomization and concealment of allocation not reported) (risk of bias, -1) and limited population size (imprecision, -1).

3.2. DASH

As Maugars (2009) did not report on DASH, it was not possible to assess the level of evidence.

3.3. WORC

As Maugars (2009) did not report on WORC, it was not possible to assess the level of evidence.

3.4. ASES

As Maugars (2009) did not report on ASES, it was not possible to assess the level of evidence.

3.5. OSS

As Maugars (2009) did not report on OSS, it was not possible to assess the level of evidence.

3.6. DSST

As Maugars (2009) did not report on DSST, it was not possible to assess the level of evidence.

4. Patient satisfaction

As Maugars (2009) did not report on patient satisfaction >6 months follow-up, it was not possible to assess the level of evidence.

5. Return to work or leisure

As Maugars (2009) did not report on return to work or leisure >6 months follow-up, it was not possible to assess the level of evidence.

Conclusions

Pain

Low GRADE	Bursoscopy may result in little to no difference in **pain measured as VAS improvement** at 12 and 24 months of follow-up when compared with needling fragmentation irrigation in patients with shoulder calcifications. *Source: Maugars (2009)*

Complications/adverse events

Low GRADE	Bursoscopy may result in little to no **difference in complications/adverse events** at 24 months follow-up when compared with needling fragmentation irrigation in patients with shoulder calcifications. Source: Maugars (2009)

PROMS for function

Constant Murley Score (CMS)

Low GRADE	Bursoscopy may result in little to no difference in **function measured with the constant murley score** at 12 months, but may improve function at 24 months of follow-up, when compared with needling fragmentation irrigation in patients with shoulder calcifications. *Source: Maugars (2009)*

Disabilities of the Arm, Shoulder and Hand (DASH)

No GRADE	No evidence was found regarding the effect of bursoscopy on **function measured with the DASH** when compared with needling fragmentation irrigation in patients with shoulder calcifications

The Western Ontario Rotator Cuff (WORC)

No GRADE	No evidence was found regarding the effect of bursoscopy on **function measured with the WORC** when compared with needling fragmentation irrigation in patients with shoulder calcifications

American Society of Shoulder and Elbow Surgeons (ASES)

No GRADE	No evidence was found regarding the effect of bursoscopy on **function measured with the ASES** when compared with needling fragmentation irrigation in patients with shoulder calcifications

Oxford Shoulder Score (OSS)

No GRADE	No evidence was found regarding the effect of bursoscopy on **function measured with the OSS** when compared with needling fragmentation irrigation in patients with shoulder calcifications

Dutch Simple Shoulder Test (DSST)

No GRADE	No evidence was found regarding the effect of bursoscopy on **function measured with the DSST** when compared with needling fragmentation irrigation in patients with shoulder calcifications

Patient satisfaction

No GRADE	No evidence was found regarding the effect of bursoscopy on **patient satisfaction >6 months follow-up** when compared with needling fragmentation irrigation in patients with shoulder calcifications

Return to work or leisure

No GRADE	No evidence was found regarding the effect of bursoscopy on **return to work of leisure >6 months follow-up** when compared with needling fragmentation irrigation in patients with shoulder calcifications

Overwegingen – van bewijs naar aanbeveling

Voor- en nadelen van de interventie en de kwaliteit van het bewijs

Er is literatuuronderzoek verricht naar het effect van artroscopisch verwijderen van een calcificatie versus barbotage/NACD bij patiënten met tendinitis calcarea. Er is één studie geïncludeerd die deze vergelijking onderzocht heeft.

Op basis van de literatuuranalyse lijkt er geen verschil te zijn in pijn en complicaties tussen artroscopisch verwijderen van calcificaties en barbotage/NACD bij patiënten met tendinitis calcarea. Functie gemeten met de Constant Murley score leek niet verschillend na twaalf maanden, maar leek op 24 maanden beter na artroscopisch verwijderen van calcificaties ten opzichte van barbotage/NACD. De bewijskracht voor de deze uitkomstmaten is laag. Dit komt doordat er slechts één studie geïncludeerd is met een laag aantal patiënten per onderzoeksarm, waarbij patiënten tijdens de follow-up periode opnieuw zijn gerandomiseerd. De methode van randomiseren werd echter niet gespecificeerd. Daarnaast worden de schaalscores niet geduid in het artikel. Patiënttevredenheid en terugkeer naar werk en vrijetijdsbezigheden na zes maanden werden niet gerapporteerd.

Het voordeel van barbotage is behandeling in poliklinische setting met lokale anesthesie. Daardoor is het makkelijk inplanbaar, zijn de kosten laag en is deze behandeling in principe geschikt voor iedere patiënt. Nadelen zijn het invasieve karakter met gebruik van naalden (naaldenfobie), het gebruik van lokale anesthetica (allergie) en het eventueel tijdelijk moeten stoppen met bloed verdunnende medicatie. Daarnaast kunnen calcificaties dermate groot zijn dat deze niet met een behandeling te verwijderen zijn. Ook kan barbotage forse napijn kan geven. Met het achterlaten van cortison aan het eind van de behandeling kan deze pijnreactie onderdrukt worden.

Voor een operatie gelden ook de bij barbotage eerder beschreven nadelen (zie module Barvotage versus shockwave). Verder is een operatie veel duurder en vereist het algehele of plexus anesthesie. Daarnaast brengt het operatierisico's met zich mee. Hert voordeel is dat grotere calcificaties in één keer behandeld kunnen worden.

De revalidatie van beide behandelingen is lang: tussen de drie maanden en één jaar. Voor beide behandelingen is het dan ook goed om de patiënt hierover in te lichten.

Waarden en voorkeuren van patiënten (en evt. hun verzorgers)

Voor de patiënt heeft barbotage een sterke meerwaarde boven operatie. De behandeling kan gemakkelijk poliklinisch uitgevoerd worden onder lokale anesthesie met zeer lage risico's. Er zijn geen operatierisico's bij barbotage. Barbotage is dermate effectief en goedkoop dat het een goed alternatief is voor een operatie voor een reguliere tendinosis calcarea behandeling. Na de behandeling kan patiënt de arm belasten op geleide van de klachten, net als na een operatie. Pijn kan het gebruik van de arm belemmeren.
Voor beide behandelmethoden geldt dat de herstelduur lang is.

Voor patiënten is het daarom belangrijk dat de voor- en nadelen, onder andere het resultaat, napijn, bewijs, revalidatieduur, vervolgtraject en opties, van barbotage en een operatie worden besproken, zodat de patiënt volgens de principes van Samen Beslissen een keuze kan maken.

Kosten (middelenbeslag)

De kosten die gemaakt worden voor barbotage zijn in vergelijking met een operatie zeer laag. De calcificaties worden in principe in één sessie behandeld. De kosten bestaan uit het

honorarium van de radioloog, het gebruik van een echografie apparaat en kosten voor materiaal dat benodigd is voor lokale anesthesie. Soms is een re-barbotage nodig. Echter gelden ook daarvoor dezelfde lage kosten. De kosten voor een operatie (in dagbehandeling) zijn vele malen hoger. Barbotage is dus een zeer kosteneffectieve methode voor de behandeling van tendinosis calcarea in vergelijking tot een operatie.

Aanvaardbaarheid, haalbaarheid en implementatie
Barbotage wordt al op grote schaal in klinieken toegepast. Het is een reguliere behandeling die vergoed wordt door verzekeraars en voor iedereen bereikbaar is. Indien barbotage met eventuele re-barbotage niet succesvol is, kan operatieve behandeling overwogen worden. Ook dat is een reguliere behandeling die voor iedereen bereikbaar is.

Barbotage is een weinig risicovolle behandeling van tendinosis calcarea die voor iedereen toegankelijk is en reeds op grote schaal toegepast wordt.

Aanbeveling
Rationale van de aanbeveling: weging van argumenten voor en tegen de interventies
Op basis van de literatuuranalyse lijkt er geen positiever effect van arthroscopie op de uitkomstmaten pijn, functie en complicaties vergeleken met naaldfragmentatie bij patiënten met tendinosis calcarea. Er is slechts één goede vergelijkende studie. Het bewijs dat endoscopische behandeling geen meerwaarde biedt boven barbotage is mager. Klinische ervaring van experts ondersteunen de bevindingen in de literatuur. Voor de patiënt heeft barbotage een sterke meerwaarde boven operatie. De behandeling kan gemakkelijk poliklinisch uitgevoerd worden onder lokale anesthesie, er zijn geen operatierisico's, het is goedkoop en het is effectief. Barbotage voor subacromiale pijn met calcificaties heeft de voorkeur boven endoscopische behandeling.

Aanbeveling

Overweeg barbotage bij symptomatische tendinosis calcarea. Overweeg bij onvoldoende verbetering eventueel eenmalig re-barbotage. Reserveer endoscopische behandeling voor gevallen waarbij barbotages niet succesvol zijn gebleken en er een grote calcificatie blijft bestaan. Bespreek de voor- en nadelen van barbotage en de operatie met de patiënt om samen de meest passende behandeling te kiezen.

Kennisvragen

Wat is de effectiviteit van chirurgische kalkverwijdering vergeleken met barbotage op door de patiënt gerapporteerde uitkomstmaten bij volwassen patiënten met supra- of infraspinatus calcarea tendinose?

Wat is de effectiviteit van kalkverwijdering na eerder uitgevoerde barbotage behandeling bij volwassen patiënten met tendinitis calcarea in de supra en infraspinatuspees.

Literatuur

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Holmgren T, Oberg B, Adolfsson L, Björnsson Hallgren H, Johansson K. Minimal important changes in the Constant-Murley score in patients with subacromial pain. J Shoulder Elbow Surg. 2014 Aug;23(8):1083-90. doi: 10.1016/j.jse.2014.01.014. Epub 2014 Apr 13. PMID: 24726486.

van Kampen DA, Willems WJ, van Beers LW, Castelein RM, Scholtes VA, Terwee CB. Determination and comparison of the smallest detectable change (SDC) and the minimal important change (MIC) of four-shoulder patient-reported outcome measures (PROMs). J Orthop Surg Res. 2013 Nov 14;8:40. doi: 10.1186/1749-799X-8-40. PMID: 24225254; PMCID: PMC3842665.

Koorevaar RCT, Kleinlugtenbelt YV, Landman EBM, van 't Riet E, Bulstra SK. Psychological symptoms and the MCID of the DASH score in shoulder surgery. J Orthop Surg Res. 2018 Oct 4;13(1):246. doi: 10.1186/s13018-018-0949-0. PMID: 30286775; PMCID: PMC6172756.

Maugars Y, Varin S, Gouin F, Huguet D, Rodet D, Nizard J, N'Guyen JM, Guillot P, Glémarec J, Passutti N, Berthelot JM. Treatment of shoulder calcifications of the cuff: a controlled study. Joint Bone Spine. 2009 Jul;76(4):369-77. doi: 10.1016/j.jbspin.2008.10.016. Epub 2009 Jun 21. PMID: 19541525.

Nyring MRK, Olsen BS, Amundsen A, Rasmussen JV. Minimal Clinically Important Differences (MCID) for the Western Ontario Osteoarthritis of the Shoulder Index (WOOS) and the Oxford Shoulder Score (OSS). Patient Relat Outcome Meas. 2021 Sep 22;12:299-306. doi: 10.2147/PROM.S316920. PMID: 34588833; PMCID: PMC8473013.

Verstraelen, F., Schotanus, M., Klemann-Harings, S., Lambers Heerspink, O., & Jansen, E. (2022). Comparison of clinical and radiological outcomes after three different surgical treatments for resistant calcifying tendinitis of the shoulder: a short-term randomized controlled trial. Journal of Orthopaedic Surgery and Research, 17(1), 480.

Bijlagen bij module 5.5 Operatieve behandeling versus barbotage

Implementatieplan

Aanbeveling	Tijdspad voor implementatie: < 1 jaar, 1 tot 3 jaar of > 3 jaar	Verwacht effect op kosten	Randvoorwaarden voor implementatie (binnen aangegeven tijdspad)	Mogelijke barrières voor implementatie	Te ondernemen acties voor implementatie	Verantwoordelijken voor acties	Overige opmerkingen
Overweeg barbotage bij symptomatische tendinosis calcarea.	< 1 jaar	Lagere kosten	Direct toepasbaar	Geen, wordt al regulier toegepast	Geen, wordt al regulier toegepast	Verwijzing via artsen (orthopeden, sportartsen e.a.)	Indien radioloog duidelijk aangeeft bij Röntgenfoto of ECHO dat barbotage zinvol is, zou initiële aanvraag ook via huisarts kunnen gaan.
Overweeg bij onvoldoende verbetering eventueel eenmalig re-barbotage.	< 1 jaar	Lagere kosten	Direct toepasbaar	Geen, wordt al regulier toegepast	Geen, wordt al regulier toegepast	Verwijzing via artsen (orthopeden, sportartsen e.a.)	
Reserveer endoscopische behandeling voor gevallen waarbij barbotages niet succesvol zijn	< 1 jaar	Gelijkblijvend	Direct toepasbaar	Geen, wordt al regulier toegepast	Geen, wordt al regulier toegepast	Verwijzing via artsen (orthopeden, sportartsen e.a.)	

gebleken en er een grote calcificatie blijft bestaan. Bespreek de voor- en nadelen van barbotage en de operatie met de patiënt om samen de meest passende behandeling te kiezen.							

Evidence tables

Study reference	Study characteristics	Patient characteristics [2]	Intervention (I)	Comparison / control (C) [3]	Follow-up	Outcome measures and effect size [4]	Comments
Maugars (2009)	Type of study: A randomized controlled study Setting and country: Patients were recruited between 1996 and 2001 in the departments of Rheumatology and Orthopaedics of the Nantes University	Inclusion criteria: -chronic painful shoulders related to one or more tendon calcification of the cuff, symptomatic for more than 4 months, permanent or intermittent but with a continuation, despite usual medical symptomatic treatments, including analgesics, NSAID and infiltration. -The length of the calcifications	Describe intervention (treatment/procedure/test): Bursoscopy (occurs under anaesthesia) Almost all the patients without contraindication received a treatment with analgesics, NSAID and blinded corticosteroid infiltration before the protocol. To standardize a same medical approach of these patients, another corticosteroid infiltration (3.75 mg of cortivazol) was performed exactly at the proximity of the calcification under fluoroscopy.	Describe control (treatment/procedure/test): Needling fragmentation irrigation (NFI) Almost all the patients without contraindication received a treatment with analgesics, NSAID and blinded corticosteroid infiltration before the protocol. To standardize a same medical approach of these patients, another corticosteroid infiltration (3.75 mg of cortivazol) was performed exactly at the proximity of the calcification under fluoroscopy.	Length of follow-up: T 1-4-12-24 months FU Loss-to-follow-up: Intervention : Needling fragmentation irrigation N (%) 3 Reasons (describe) Lost of sight between T12 and T24 months (reason not described) Intervention : barbotage	**Outcome measures and effect size (include 95%CI and p-value if available):** **T 12 months** **1. Pain** *Pain VAS improvement (%):* I (BS): -26.7 ± 62.1 C (NFI): -56.1 ± 51.7 *Function VAS improvement (%):* I: -27.9 ± 65.9 C: -50.1 ± 57.0 **2.Complications/adverse events** Not reported **3. PROMs for function:** **3.1. CMS** *Constant score improvement (%)*	Conclusion: NFI and BS are validated techniques when other medical treatments have failed. Results were maintained after 24 months, and were similar between NFI and BS. However, NFI could e preferred because of its simplicity and costs (low).

	Hospital. <u>Funding and conflicts of interest:</u> Authors declare no conflict of interest. Funding not reported	in their larger axis was more than 5 mm; localization of the calcification was in the infra or supra-spinatus, -the calcification of type A or B was in accordance with the classification of the French Arthroscopic Society: type A: well-defined limits, dense and homogenous; type B: well-defined limits and fragmented. <u>Exclusion criteria</u>: -excluded heterogeneous calcification with poorly defined limits (type C), often secondary	They were re-examined thereafter 2 weeks later. In the absence of a subjective global improvement higher than 70% (scale 0-100%) evaluated by the patient, a randomization was carried out by drawing preestablished lots in 3 groups. The bursoscopy (BS) was carried out under general anaesthesia by two experienced surgeons. Both articular and sub-acromial stages were performed. The calcification was extracted either with a curette or with a high pressure water jet when it was softened. There was no acromioplasty neither tendon suture nor total bursectomy. The patients were hospitalized 12-24 h, and a rehabilitation began in	They were re-examined thereafter 2 weeks later. In the absence of a subjective global improvement higher than 70% (scale 0-100%) evaluated by the patient, a randomization was carried out by drawing preestablished lots in 3 groups. Needling fragmentation irrigation (NFI) were performed by the same practitioner. The patients was lengthened in dorsal decubitus, a cushion under the concerned shoulder and the arm in rotation to release calcification under the fluoroscopy. The conditions of asepsis included mask, casaque, sterile gloves and fields. The skin was disinfected with an iodized solution. A local anaesthesia of 15-30 cc of lidocaine 1%	<u>N (%)</u> 2 <u>Reasons (describe)</u> Lost of sight between T12 and T24 months (reason not described) <u>Control:</u> 1 <u>N (%)</u> <u>Reasons (describe):</u> Stopped attending consultation between T12 and T24 months <u>Incomplete outcome data:</u> not reported	I: +10.7 ± 29.2 C: + 20.7 ± 33.0 **3.2. DASH** **3.3. WORC** **3.4. ASES** **3.5. OSS** **3.6. DSST** **4. Patient satisfaction** not reported **<u>T 24 months</u>** **1. Pain** *Pain VAS improvement (%):* I: -54.7 ± 56.9 C: -64.2 ± 47.8 *Function VAS improvement (%):* I: -56.1 ± 48.0 C: -64.3 ± 55.5 **2.Complications/adverse events** *Partial rupture of rotator cuff (all superficial and at the supra-spinatus level)* I: 1 C: 1 *Complete rupture:* I: 0	N.B. the 49 other shoulders (54 patients) which had not been randomized and which had significantly improved by the initial infiltration under fluoroscopy also benefited from a follow-up over two years. Twelve patients were randomized a second time. At T4 months: 3 in the NFI

		to hyperalgic acute episodes with resorption of the calcification. - anticoagulant treatment, - haemorrhagiparous diseases, - recent acute hyperalgic flare (<1 month), - capsulitis, - known or clinically significant tear of the rotator cuff, - previous history of shoulder arthritis (infection or metabolic or chronic inflammatory rheumatism of the concerned shoulder), - previous history of fracture, luxation, surgery	the next 24-48 h, passive then active. A prescription of NSAID and analgesics were systematically prescribed, to use if necessary. They were each given a medical certificate for a 2 week recovery period.	was injected from the surface of the skin until the proximity of the calcification. The first stage was a needling under fluoroscopy. A first needle (18 Gauge, 50 mm) was inserted directly in line with the X-Ray by an anterior way until the center of the calcification. The depth was located rotating the arm of the fluoroscopy. A second needle was inserted by an external way, perpendicular to the X-ray, in the axis of calcification. Several tens of intra-calcic drillings were carried out via the needles for this second phase of fragmentation. When the needle no longer meets any more resistance and does not bring back any more calcic cores, this second stage of fragmentation is considered as finished.		C: 0 *Capsulitis after removal of the calcification* I: 1 C: 1 *Bursitis* n = 8 cases *Tendinitis of supra and/or infra-spinatus* n = 15 cases N.B.: without any significant difference between the three groups (NFI, CT, and BS) > exact numbers per group remains unknown. **3. PROMs for function:** **3.1. CMS** *Constant score improvement (%)* I: + 46.5 ± 37.4 C: + 25.9 ± 27.8 **3.2. DASH** **3.3. WORC** **3.4. ASES** **3.5. OSS** **3.6. DSST**	group and 4 in the BS group; at T12 months 2 in the NFI group and 1 in the BS group, and at T12 months, 1 in the NFI group and 1 in the BS group. In this study: three groups were distinguished: the third was a control group of patients whom could benefit from NSAID and analgesics on request. After

		or arthroscopy, extracorporeal shock wave therapy or needling of the concerned shoulder, -type 3 accromion (Aggressive) according to the classification of Bigliani, -pregnancy, -allergy to Lidocaine, -general anaesthesia contraindication. <u>N total at baseline</u>: 96 patients (102 shoulders), however eventually 53 shoulders were randomized (49 shoulders not randomized; since these were		The third stage is irrigation. One hundred to 200 cc of physiological salt solution is first injected through a needle and then recovered by the other, making it possible to bring back calcic material and tissue fragments, sometimes more or less moderately haemorrhagic. Irrigation is considered as finished when the seringe brings back a clear liquid. Corticoid infilitration is not carried out at the end of the technique, so as not to interfere with the results of the two other groups on the one hand, and so as not to prevent the expected calcic resorption on the other hand. A control X-ray is taken at the end of the technique, showing most often a persisting calcification, which		**4. Patient satisfaction** not reported	randomizati on of the 53 shoulders, patients were again randomized at amongst others T1 and T4 (due to condition which has not improved by more than 70 per cent at T4 for instance). In the long term, there were only six patients in the control group, the other 11 patients required a therapeutic removal technique of the

		improved by more than 70% by the simple infiltration near the calcification area). <u>Intervention</u> (BS): 20 <u>Control</u> (NFI): 16 <u>Important prognostic factors</u>[2]: *For example age ± SD:* *I (BS): 48.1* *C (NFI): 46.8* *Sex (F/M ratio):* *I (BS): 12/5* *C: 16/4* *NSAID use* *I: 94%* *C: 90%* <u>Groups comparable at baseline?</u> Yes		evolved heterogenous and hypodense. A gleno-humeral arthrography was performed to make sure that there was no rupture of the rotator cuff caused by the technique. The patient was informed of a possible recrudescence of the pain in the 24-72 h following the technique, and an analgesic and NSAID treatment was systematically prescribed. Each patient was given a minimum of two weeks time off work. Physiotherapy was not systematically recommended.			calcification during the 2 year follow-up. **Outcomes (secondary outcomes of this study)** Functional score of Constant out of 100; VAS of the pain; VAS of the functional repercussion ; mobility of the shoulder; testing for sub-acromial conflict (Hawkins and Neer); testing of the infra and supra-spinatus tendons;

							intake of NSAID and analgesics; duration of time off work; area of calcifications

Risk of Bias table

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?** Definitely yes Probably yes Probably no Definitely no	**Was the allocation adequately concealed?** Definitely yes Probably yes Probably no Definitely no	**Blinding: Was knowledge of the allocated interventions adequately prevented?** **Were patients blinded?** **Were healthcare providers blinded?** **Were data collectors blinded?** **Were outcome assessors blinded?** **Were data analysts blinded?** Definitely yes Probably yes Probably no Definitely no	**Was loss to follow-up (missing outcome data) infrequent?** Definitely yes Probably yes Probably no Definitely no	**Are reports of the study free of selective outcome reporting?** Definitely yes Probably yes Probably no Definitely no	**Was the study apparently free of other problems that could put it at a risk of bias?** Definitely yes Probably yes Probably no Definitely no	**Overall risk of bias If applicable/necessary, per outcome measure** **LOW** **Some concerns** **HIGH**

Maugars (2009)	Probably no <u>Reason:</u> Not reported. Solely stated that after four months, the patients who had been randomized in the control group and the infiltrated patients initially improved could be randomized BS versus NFI if the improvement proved to decrease lower than 70%. A considerable number of patients were rerandomized at T 4months (24.5 per cent) (they were 6 in each group), due to various reasons (wanting to receive the intervention, or stopped attending	Probably no <u>Reason:</u> Not reported. Solely stated that they performed ''a randomized study''.	Definitely not <u>Reason:</u> All the patients received analgesics, NSAID, and blinded corticosteroid infiltration before the protocol. To standardize the same medical approach of these patients, another corticosteroid infilitration was performed exactly at the proximity of the calcification under fluoroscopy. Not reported whether someone was blinded (probably not). All NFI was performed by the same practitioner. Follow-up was carried out by	<u>Probably no</u> <u>Reason:</u> Loss to follow-up between the in-between measurements occurred, however the number of people and reasons for loss to follow-up were reported.	Probably no <u>Reason:</u> All relevant outcome measures were reported.	Probably yes <u>Reason:</u> The number of patients in each group was considerably low. In the control group – at the end of the two-year follow-up period – solely 6 patients remained in the control group. Funding not reported Scale scoring not reported	**Pain** High concerns **Complications/adverse events at 24 months** High concerns **CMS** High concerns **DASH** not reported **WORC** not reported **ASES** not reported **OSS** not reported **DSST** not reported **Patient satisfaction** not reported

	consultation etc.).		practitioners who did not perform the operations.				

Table of excluded studies

Reference	Reason for exclusion
Angileri, H. S. and Gohal, C. and Comeau-Gauthier, M. and Owen, M. M. and Shanmugaraj, A. and Terry, M. A. and Tjong, V. K. and Khan, M. Chronic calcific tendonitis of the rotator cuff: a systematic review and meta-analysis of randomized controlled trials comparing operative and nonoperative interventions. Journal of Shoulder and Elbow Surgery. 2023; 32 (8) :1746-1760	Systematic review including a total of 27 studies. A total of 24 studies assessed nonoperative interventions: 24 nonoperative studies; the nonoperative group included combined interventions (such as UGN + ESWT), or post procedure rehabilitation programs (which included a combination of anti-inflammatory medications, ice, activity limitations, and formalized physical therapy). The other studies either compared - two surgical interventions (Rubenthaler), - had no control group, or – not the comparison defined in our PICO.
Louwerens, J. K. G. and Veltman, E. S. and Van Noort, A. and Van Den Bekerom, M. P. J. The effectiveness of high-energy extracorporeal shockwave therapy versus ultrasound-guided needling versus arthroscopic surgery in the management of chronic calcific rotator cuff tendinopathy: A systematic review. Arthroscopy - Journal of Arthroscopic and Related Surgery. 2016; 32 (1) :165-175	Systematic review of 22 RCTs. None of the included RCTs studied the comparison of the I and C of our PICO. Assessed all the included references: many RCTs solely assessed efficacy of ''needling'', ref. 25, 26, 27, 32, 39, 41; and other RCTs solely assessed the efficacy of ''arthroscopy'': ref. 11, 13, 14, 28, 35, 37, 38, 40.
Wu, Yi-Cheng and Tsai, Wen-Chung and Tu, Yu-Kung and Yu, Tung-Yang Comparative Effectiveness of Nonoperative Treatments for Chronic Calcific Tendinitis of the Shoulder: A Systematic Review and Network Meta-Analysis of Randomized Controlled Trials. Archives of physical medicine and rehabilitation. 2017; 98 (8) :1678-1692.e6	No comparison between non-operative interventions and operative interventions; this SR assesses the effectiveness of different non-operative treatments (Interventions included the following nonoperative treatments: UGN, H-FSW, RSW, L-FSW, ultrasound therapy, and TENS.). The search terms they used: the keywords *calcific tendinitis, ultrasound, shock wave, needling, shoulder, and rotator cuff.*
Simpson M, Pizzari T, Cook T, Wildman S, Lewis J. Effectiveness of non-surgical interventions for rotator cuff calcific tendinopathy: A systematic review. J Rehabil Med. 2020 Oct 31;52(10):jrm00119. doi: 10.2340/16501977-2725. PMID: 32830280.	Clinical trials solely assessing non-surgical interventions for adults with rotator cuff calcific tendinopathy were included in this SR (Five non-surgical interventions were identified (extracorporeal shockwave therapy, ultrasound-guided percutaneous intervention, pulsed ultrasound, acetic acid iontophoresis, and transcutaneous electrical nerve stimulation)). Thus comparison between non-operative and operative treatments not possible.
Louwerens, J. K. G. and Sierevelt, I. N. and	No comparison possible; minimally invasive

van Noort, A. and van den Bekerom, M. P. J. Evidence for minimally invasive therapies in the management of chronic calcific tendinopathy of the rotator cuff: A systematic review and meta-analysis. Journal of Shoulder and Elbow Surgery. 2014; 23 (8) :1240-1249	therapies not involving operation. These minimally invasive therapies involve a.o. high-energy extracorporeal shockwave therapy, Ultrasound-guided needling, corticosteroid injection.
González-Martín D, Garrido-Miguel M, de Cabo G, Lomo-Garrote JM, Leyes M, Hernández-Castillejo LE. Rotator cuff debridement compared with rotator cuff repair in arthroscopic treatment of calcifying tendinitis of the shoulder: A systematic review and meta-analysis. Rev Esp Cir Ortop Traumatol. 2023 Sep 12:S1888-4415(23)00187-X. English, Spanish. doi: 10.1016/j.recot.2023.08.015. Epub ahead of print. PMID: 37573942.	operative vs operative? Voldoet dus niet aan de I en C van de PICO (arthroscopic removal (operative) vs rotator cuff debridement repair (operative; Debridement may be done in arthroscopic surgery (through two or three tiny incisions) or in open surgery (usually one larger incision))
Verstraelen FU, Fievez E, Janssen L, Morrenhof W. Surgery for calcifying tendinitis of the shoulder: A systematic review. World J Orthop. 2017 May 18;8(5):424-430. doi: 10.5312/wjo.v8.i5.424. PMID: 28567346; PMCID: PMC5434349.	Study does not compare I and C: study aims to determine a preferable surgical procedure in patients with failed conservative treatment of calcifying tendinitis of the shoulder. The three three available treatment options were: acromioplasty with the removal of the calcific deposits, acromioplasty or solely the removal of the calcific deposits.
Gatt DL, Charalambous CP. Ultrasound-guided barbotage for calcific tendonitis of the shoulder: a systematic review including 908 patients. Arthroscopy. 2014 Sep;30(9):1166-72. doi: 10.1016/j.arthro.2014.03.013. Epub 2014 May 10. PMID: 24813322.	Gatt's 2014 article in Arthroscopy is about the results of barbotage. There is no comparison group receiving an arthroscopic procedure that is being compared. Solely 2 patients undergo surgery because the barbotage is unsuccessful.
Maier D, Jaeger M, Izadpanah K, Köstler W, Bischofberger AK, Südkamp NP, Ogon P. Arthroscopic Removal of Chronic Symptomatic Calcifications of the Supraspinatus Tendon Without Acromioplasty: Analysis of Postoperative Recovery and Outcome Factors. Orthop J Sports Med. 2014 May 12;2(5):2325967114533646. doi: 10.1177/2325967114533646. PMID: 26535331; PMCID: PMC4555535.	Wrong study design (case series)
Verstraelen F, Schotanus M, Klemann-Harings S, Lambers Heerspink O, Jansen E. Comparison of clinical and radiological outcomes after three different surgical treatments for resistant calcifying tendinitis of the shoulder: a short-term	Study aimed to evaluate and compare short-term clinical and radiological results of three surgical treatment options (no comparison)

randomized controlled trial. J Orthop Surg Res. 2022 Nov 5;17(1):480. doi: 10.1186/s13018-022-03373-1. PMID: 36335393; PMCID: PMC9636666.	
Huisstede BM, Gebremariam L, van der Sande R, Hay EM, Koes BW. Evidence for effectiveness of Extracorporal Shock-Wave Therapy (ESWT) to treat calcific and non-calcific rotator cuff tendinosis--a systematic review. Man Ther. 2011 Oct;16(5):419-33. doi: 10.1016/j.math.2011.02.005. Epub 2011 Mar 10. PMID: 21396877.	No comparison, study assessed the evidence for effectiveness of ESWT for respectively calcific and non-calcific rotator cuff tendinosis (RC-tendinosis)
Tashjian RZ. Is there evidence in favor of surgical interventions for the subacromial impingement syndrome? Clin J Sport Med. 2013 Sep;23(5):406-7. doi: 10.1097/01.jsm.0000433152.74183.53. PMID: 23989383.	No comparison: effectiveness of surgical and postsurgical interventions for the subacromial impingement syndrome (SIS).
Verstraelen F, Bemelmans Y, Lambers Heerspink O, van der Steen M, Jong B, Jansen E, Schotanus M. Comparing midterm clinical outcome of surgical versus ultrasound guided needle aspiration of the calcific deposits for therapy resistant calcifying tendinitis of the shoulder. A comparative cohort study. J Orthop Sci. 2023 Apr 18:S0949-2658(23)00091-X. doi: 10.1016/j.jos.2023.03.021. Epub ahead of print. PMID: 37080824.	Wrong study design > cohort study

Literature search strategy

On the 16th of August 2023, a systematic search was performed in the databases Embase.com and Ovid/Medline for systematic reviews and RCTs about surgery or barbotage for tendinosis calcarea. The search resulted in 103 unique hits.

Zoekopbrengst

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	26	26	31
RCT	62	46	72
Totaal	88	72	**103***

****in Rayyan***

Zoekstrategie

Embase.com

No.	**Query**	**Results**
#11	#9 OR #10	88
#10	#6 AND #8 NOT #9 = RCT	62
#9	#6 AND #7 = SR	26
#8	'clinical trial'/exp OR 'randomization'/exp OR 'single blind procedure'/exp OR 'double blind procedure'/exp OR 'crossover procedure'/exp OR 'placebo'/exp OR 'prospective study'/exp OR rct:ab,ti OR random*:ab,ti OR 'single blind':ab,ti OR 'randomised controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	3853133
#7	'meta analysis'/exp OR 'meta analysis (topic)'/exp OR metaanaly*:ti,ab OR 'meta analy*':ti,ab OR metanaly*:ti,ab OR 'systematic review'/de OR 'cochrane database of systematic reviews'/jt OR prisma:ti,ab OR prospero:ti,ab OR (((systemati* OR scoping OR umbrella OR 'structured literature') NEAR/3 (review* OR overview*)):ti,ab) OR ((systemic* NEAR/1 review*):ti,ab) OR (((systemati* OR literature OR database* OR 'data base*') NEAR/10 search*):ti,ab) OR (((structured OR comprehensive* OR systemic*) NEAR/3 search*):ti,ab) OR (((literature NEAR/3 review*):ti,ab) AND (search*:ti,ab OR database*:ti,ab OR 'data base*':ti,ab)) OR (('data extraction':ti,ab OR 'data source*':ti,ab) AND 'study selection':ti,ab) OR ('search strategy':ti,ab AND 'selection criteria':ti,ab) OR ('data source*':ti,ab AND 'data synthesis':ti,ab) OR medline:ab OR pubmed:ab OR embase:ab OR cochrane:ab OR (((critical OR rapid) NEAR/2 (review* OR overview* OR synthes*)):ti) OR ((((critical* OR rapid*) NEAR/3 (review* OR overview* OR synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	953361
#6	#5 AND [2008-2023]/py	298
#5	#4 NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR 'note'/it) NOT (('animal'/exp OR 'animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT ('human'/exp OR 'groups by age and sex'/exp))	500
#4	#1 AND (#2 OR #3)	616
#3	'barbotage'/exp OR 'lavage'/de OR 'guided needle'/exp OR	93451

	barbotage*:ti,ab,kw OR (((needle* OR needling OR 'ultrasound guided' OR 'us guided' OR 'image guided') NEAR/3 (aspiration OR lavage OR fragmentation OR irrigation OR punctur* OR treatment* OR therap* OR procedure*)):ti,ab,kw)	
#2	'arthroscopy'/de OR 'arthroscopic surgery'/exp OR 'shoulder arthroscopy'/exp OR 'arthroendoscop*':ti,ab,kw OR 'arthroscop*':ti,ab,kw OR 'debridement'/exp OR 'debridement':ti,ab,kw OR 'surgery'/exp OR 'surgical patient'/exp OR 'surgical risk'/exp OR 'perioperative period'/exp OR surgic*:ti,ab,kw OR surger*:ti,ab,kw OR operation*:ti,ab,kw OR operative:ti,ab,kw OR presurg*:ti,ab,kw OR preoperati*:ti,ab,kw OR perisurg*:ti,ab,kw OR perioperati*:ti,ab,kw OR postsurg*:ti,ab,kw OR postoperati*:ti,ab,kw OR laparoscop*:ti,ab,kw OR intraoperati*:ti,ab,kw	7420378
#1	('shoulder impingement syndrome'/exp/mj OR 'shoulder impingement syndrome*':ti,ab,kw OR 'subacromial impingement syndrome*':ti,ab,kw OR (('bursitis'/exp/mj OR bursitis:ti,ab,kw OR 'tendinitis'/exp/mj OR tendinitis:ti,ab,kw OR tendinosis:ti,ab,kw OR tendinopath*:ti,ab,kw OR 'impingement':ti,ab,kw) AND ('shoulder'/exp/mj OR 'rotator cuff':ti,ab,kw OR acromion:ti,ab,kw OR acromial:ti,ab,kw OR subacromial:ti,ab,kw OR shoulder*:ti,ab,kw)) OR 'rotator cuff injury'/exp/mj OR 'rotator cuff rupture'/exp/mj OR ((('rotator cuff' OR 'shoulder cuff' OR infraspinatus OR supraspinatus OR subscapularis) NEAR/3 (tear* OR lesion* OR rupture* OR tendinopath* OR laceration*)):ti,ab,kw) OR (('full-thickness':ti,ab,kw OR partial:ti,ab,kw) AND 'rotator cuff':ti,ab,kw) OR ('rotator cuff'/exp/mj AND ('rupture'/exp/mj OR 'injury'/mj OR 'laceration'/exp/mj))) AND ('calcification'/de OR 'calcinosis'/exp OR calcifying:ti,ab,kw OR calcification:ti,ab,kw OR calcarea*:ti,ab,kw OR calcific:ti,ab,kw OR calcinosis:ti,ab,kw OR calcified:ti,ab,kw OR calcinotic:ti,ab,kw)	1183

Ovid/Medline

#	Searches	Results
11	9 or 10	72
10	(6 and 8) not 9 = RCT	46
9	6 and 7 = SR	26
8	exp clinical trial/ or randomized controlled trial/ or exp clinical trials as topic/ or randomized controlled trials as topic/ or Random Allocation/ or Double-Blind Method/ or Single-Blind Method/ or (clinical trial, phase i or clinical trial, phase ii or clinical trial, phase iii or clinical trial, phase iv or controlled clinical trial or randomized controlled trial or multicenter study or clinical trial).pt. or random*.ti,ab. or (clinic* adj trial*).tw. or ((singl* or doubl* or treb* or tripl*) adj (blind$3 or mask$3)).tw. or Placebos/ or placebo*.tw.	2621313
7	meta-analysis/ or meta-analysis as topic/ or (metaanaly* or meta-analy* or metanaly*).ti,ab,kf. or systematic review/ or cochrane.jw. or (prisma or prospero).ti,ab,kf. or ((systemati* or scoping or umbrella or "structured literature") adj3 (review* or overview*)).ti,ab,kf. or (systemic* adj1 review*).ti,ab,kf. or ((systemati* or literature or database* or data-base*) adj10 search*).ti,ab,kf. or ((structured or comprehensive* or systemic*) adj3 search*).ti,ab,kf. or ((literature adj3 review*) and (search* or database* or data-base*)).ti,ab,kf. or (("data extraction" or "data source*") and "study selection").ti,ab,kf. or ("search strategy" and "selection criteria").ti,ab,kf. or ("data source*" and "data synthesis").ti,ab,kf. or (medline or pubmed or embase or cochrane).ab. or ((critical or rapid) adj2 (review* or overview* or	687043

	synthes*)).ti. or (((critical* or rapid*) adj3 (review* or overview* or synthes*)) and (search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.	
6	limit 5 to yr="2008 -Current"	291
5	4 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not (humans/ or exp Age Groups/))	509
4	1 and (2 or 3)	536
3	exp Ultrasonography, Interventional/ or Therapeutic Irrigation/ or barbotage*.ti,ab,kf. or ((needle* or needling or 'ultrasound guided' or 'us guided' or 'image guided') adj3 (aspiration or lavage or fragmentation or irrigation or punctur* or treatment* or therap* or procedure*)).ti,ab,kf.	96650
2	exp Arthroscopy/ or 'arthroendoscop*'.ti,ab,kf. or 'arthroscop*'.ti,ab,kf. or exp Debridement/ or 'debridement'.ti,ab,kf. or exp Surgical Procedures, Operative/ or exp Specialties, Surgical/ or exp Perioperative Period/ or surgic*.ti,ab,kf. or surger*.ti,ab,kf. or operation*.ti,ab,kf. or operative.ti,ab,kf. or presurg*.ti,ab,kf. or preoperati*.ti,ab,kf. or perisurg*.ti,ab,kf. or perioperati*.ti,ab,kf. or postsurg*.ti,ab,kf. or postoperati*.ti,ab,kf. or laparoscop*.ti,ab,kf. or intraoperati*.ti,ab,kf.	5280298
1	(Shoulder Impingement Syndrome/ or 'shoulder impingement syndrome*'.ti,ab,kf. or 'subacromial impingement syndrome*'.ti,ab,kf. or ((exp bursitis/ or exp Tendinopathy/ or bursitis.ti,ab,kf. or tendinitis.ti,ab,kf. or tendinosis.ti,ab,kf. or tendinopath*.ti,ab,kf. or 'impingement'.ti,ab,kf.) and (exp Shoulder/ or 'rotator cuff'.ti,ab,kf. or acromion.ti,ab,kf. or acromial.ti,ab,kf. or subacromial.ti,ab,kf. or shoulder*.ti,ab,kf.)) or Rotator Cuff/ or exp Rotator Cuff Injuries/ or (('rotator cuff' or 'shoulder cuff' or infraspinatus or supraspinatus or subscapularis) adj3 (tear* or lesion* or rupture* or tendinopath* or laceration*)).ti,ab,kf. or (('full-thickness' or partial) and 'rotator cuff').ti,ab,kf.) and (exp Calcinosis/ or calcifying.ti,ab,kf. or calcification.ti,ab,kf. or calcarea*.ti,ab,kf. or calcific.ti,ab,kf. or calcinosis.ti,ab,kf. or calcified.ti,ab,kf. or calcinotic.ti,ab,kf.)	1016

Addendum Pijnrevalidatie bij SAPS

Achtergrond
In de richtlijn chronische pijnrevalidatie wordt SAPS niet specifiek behandeld. Met de huidige tekst beoogt de richtlijnwerkgroep concrete handvatten te geven voor behandeling van SAPS binnen de gestelde kaders van de richtlijn Chronische pijnrevalidatie.

Rol van de revalidatiearts
Overweeg verwijzing naar een revalidatiearts (met affiniteit voor chronische pijn en bij voorkeur ook voor de schouder) als pijnklachten persisteren ondanks adequate zorg, en ook als de pijnklachten en de ervaren beperkingen niet in relatie lijken te staan tot de gevonden pathologie. Onder adequate eerstelijnszorg wordt verstaan: fysiotherapie of oefentherapie gegeven door een therapeut met gebleken affiniteit met de schouder, eventueel in combinatie met ergotherapie en of psycholoog/POH-GGZ. Daar waar dat beschikbaar is is een Multidisciplinair eerstelijns revalidatietraject (MER) zeker te overwegen.
Het is vervolgens aan de revalidatiearts om te evalueren waarom de pijn en beperkingen zo hevig blijven. Redenen daarvoor kunnen bijvoorbeeld zijn:

- Pathologische redenen zoals nevenpathologie (denk bijvoorbeeld aan Neuralgische Amyotrofie, beperkingen in ellenboog en polsfunctie etc)
- Gedragsmatige redenen: te lang volgehouden of te vaak gerepeteerde houdingen en bewegingen, te weinig herstelmomenten of juist beweegangst.
- Mentale cq softwarematige aspecten: In chronische pijn spelen vaak nevendiagnoses als PTSS, depressies, maar zeker niet vergeten moet worden de Centrale sensitisatie (zie o.a. Central Sensitization Inventory – Meetinstrumenten in de zorg (meetinstrumentenzorg.nl), https://www.ntvg.nl/artikelen/uitleg-aan-patienten-met-onverklaarde-klachten)
  Een heel nuttig en snel instrument voor Centrale sensitisatie is de Central Sensitisation Inventory, CSI: https://meetinstrumentenzorg.nl/wp-content/uploads/instrumenten/Central-Sensitization-Inventory.pdf

Essentieel in het consult van een revalidatiearts is dat de spreekuurtijd gebruikelijk lang genoeg is om een dergelijke multidimensionale screening te kunnen doen. Echter: niet elke revalidatiearts heeft affiniteit met schouders en met chronische pijn. Binnen samenwerkingsverbanden zijn die echter bijna altijd te vinden.

Behandelaanpak
Van de consulterend revalidatiearts moet verwacht worden dat die een meerdimensionale intake doet (met aandacht voor zowel de biologische, psychologische als sociale redenen en gevolgen van de klacht).
De uitkomst moet zijn dat op basis van een zorgvuldige afweging er een meerdimensionaal advies gegeven kan worden waarbij uiteraard het adagio geldt: makkelijk en dichtbij waar het kan, moeilijk en complex waar het moet. Het merendeel van de patiënten kan met een gericht advies terug naar de eerste lijn. Een IMSR traject is intensief en in de regel 4 maanden lang.

Een behandeladvies kan een stagnerend herstel vaak weer op gang helpen, maar gewaakt moet worden om standaard te kiezen voor de duurste therapievorm. Die is vaak niet nodig. Adviseer na een multimodale evaluatie bij voorkeur voor de minst ingrijpende therapievorm, te weten een net anders ingestoken eerstelijns oefentherapie.

Bio-Psycho-sociale aspecten

Bij elke patiënt met chronische pijn, dus ook bij SAPS, is er vaak een belangrijke onderhoudende reden.
Als anatomische/pathologische redenen uit te sluiten zijn (denk aan bijv. cervicale radiculopathieen, plexusletsels zoals Neuralgische Amyotrofie, maar ook longtoptumoren), overweeg ook een niet-pathologische/anatomische oorzaak. Er is vaak sprake van persisterend gedrag (te lang, te vaak, te zwaar, ergonomisch onhandig), een persisterende houding (mn hoogstand van de schouders, anteflexie in de schouder, hyperflexie van de nek, App-Houding), een gestoord pijnsysteem (volgens de literatuur al aantoonbaar vanaf 3 maanden pijn) en achterliggende psychopathologie.
Echter: Er is onvoldoende kennis van die aspecten van chronische pijn bij meer somatisch ingestelde behandelaren, en dus ook te weinig alertheid. De meeste curricula bieden daar onvoldoende ruimte aan. Maar ook is er anderzijds weinig bewustzijn van de complexiteit van het schoudergewricht bij pijntherapeuten en -revalidatieartsen.

Een nieuw curriculum binnen de opleidingen voor artsen en therapeuten kost tijd en volharding, echter een wat bredere scope met kennis van andere dan anatomische aspecten maakt een behandelaar zeker niet slechter. Geef in de opleidingen meer aandacht aan de Bio-Psycho-sociale aspecten van chronische pijn, vooral binnen de bestaande schoudernetwerken.

De werkgroep is van mening dat een patient met een SAPS verwezen dient te worden naar een pijnspecialist bij een (dreigend) chronisch pijnsyndroom en ter uitsluiting van overige pathologie. Zie ook de richtlijn Chronische pijnrevalidatie.

Kennisvragen

Volgens de Grade systematiek is de bewijskracht voor Interdisciplinaire Medisch Specialistische Revalidatie zeer beperkt. Redenen daarvoor zijn onder anderen dat de patiëntenpopulaties zeer divers zijn (er weinig homogeniteit is, en in essentie SAPS niet specifiek benoemd is maar gevangen in Musculoskeletale klachten), dat dubbelblind gerandomiseerd onderzoek (vrijwel) onmogelijk is, en dat ook de interventie internationaal zeer uiteenloopt. Voor toekomstige bewijsvorming wordt daarom gewerkt aan meer bij dergelijke interventie passende onderzoeksdesigns.

Kennisvragen

Algemene kennisvragen

Over het algemeen is er een gebrek aan informatie over de uitkomstmaat 'return to work or leisure' in alle kennisvragen. Het verdient de aanbeveling om deze uitkomstmaat in vervolgstudies te includeren.

Module 1 Secundaire preventie SAPS

Welke preventieve maatregelen kunnen in de beroepsbevolking worden ingezet om recidiverende SAPS te voorkomen?

Module 2 Diagnostische testen voor SAPS

Op basis van de beschikbare literatuur zou toekomstig onderzoek zich moeten richten op de fysisch diagnostische testen bij schouderpijn. De verschillende tests kunnen worden vergeleken met elkaar. Daarnaast zou een vaste volgorde van testen geëvalueerd kunnen worden om te meten of per aanvullende test de kans op het wel/niet aanwezig zijn van SAPS of een cuff ruptuur groter wordt. Dit kan dan als een flowchart gehanteerd worden en kan daarmee behulpzaam zijn en hopelijk aanvullende diagnostiek kunnen vermijden.

Module 3 Beeldvormende diagnostiek

Wat is de waarde van MR artrografie vergeleken met MRI voor de diagnostiek van rotatorcuffletsels?

Module 4.1 Barbotage versus shockwave

Er is behoefte aan een RCT die barbotagebehandeling vergelijkt met high energy shock wave behandeling bij patiënten met SAPS klachten op basis van tendinosis calcarea.

Module 4.2 Oefentherapie versus oefentherapie en corticosteroïdinjectie

Een belangrijke uitkomstmaat in de gevonden literatuur was de snelheid van terugkeer naar werk en sport (hetgeen ook een belangrijke macro-economische uitkomstmaat is). Hier is geen overtuigende literatuur over gevonden.

Module 4.3 Nervus suprascapularis blokkade

De werkgroep geeft de aanbeveling om de onderzoeksvraag op te nemen als kennisvraag op de wetenschapsagenda van de wetenschappelijke beroepsvereniging: *''What is the effectiveness of suprascapularis blokade vs. corticosteroid injection in SAPS patients on patient-reported outcome measures?''*

Een RCT opzetten met deze PICO moet zeker goed aanvaardbaar en haalbaar zijn. Bij goede resultaten zal de verwachting zijn dat ook de implementatie in de dagelijkse kliniek snel doorgang zal kunnen vinden.

Module 5.1 Operatieve behandeling

Wat is de meest effectieve oefen-/fysiotherapeutische strategie bij een geïsoleerde, symptomatische, niet-traumatische supraspinatuspeesruptuur?

Wat is de kans op ontwikkeling van degeneratieve glenohumorale afwijkingen na conservatieve of operatieve behandeling van een geïsoleerde, symptomatische, niet-traumatische supraspinatusruptuur op lange termijn?

Het identificeren van prognostische factoren voor toename van scheur grootte bij patiënten die conservatief behandeld worden om progressie op latere leeftijd te voorkomen.

Module 5.2 Bicepspees tenotomie/tenodese
Wat zijn de effecten van tenotomie of tenodese van de normale bicepspees bij patiënten met een geïsoleerde supraspinatuspeesscheuroperatie van de rotator cuff en die geen pathologie van de bicepspees hebben?

Module 5.3 Prognostische factoren voor cuff rupturen
Wat zijn de prognostische factoren voor succes of falen na een operatieve behandeling bij patiënten met een cuffscheur? Er bestaat nog geen intern en extern gevalideerd predictiemodel met cuff scheur gerelateerde en patiëntgebonden factoren waarmee de slagingskans van een cuff repair kan worden voorspeld.

Module 5.4 Duur van immobilisatie als nabehandeling
Is immobilisatie nodig na het herstel van een geisoleerde supraspinatuspeesruptuur?

Er mist een evidence based behandelstrategie voor oefen-/fysiotherapeuten na een rotator cuff repair.

Module 5.5 Operatieve behandeling versus barbotage
Wat is de effectiviteit van chirurgische kalkverwijdering vergeleken met barbotage op door de patiënt gerapporteerde uitkomstmaten bij volwassen patiënten met tendinosis calcarea van de supra- of infraspinatuspees?

Wat is de effectiviteit van kalkverwijdering na eerder uitgevoerde barbotage behandeling bij volwassen patiënten met tendinosis calcarea in de supra- en infraspinatuspees?