Bijlagen bij de conceptrichtlijn Perifeer arterieel vaatlijden

Inhoudsopgave

Module 1: Antitrombotisch behandeling in het kader van secundaire preventie

Evidence tabel

Study	Participants (number, age, other important characteristics)	Comparison	Follow-up	Outcome measures	Comments	Risk of bias
Included in systematic review of Beiswenger (2018)						
CAPRIE (1996)	N at baseline Intervention: N = 3229 Control: N = 3223 Age Intervention: 64.4 (9.7) years Control: 64.2 (9.6) years Sex Intervention: 72% male Control: 73% male	Intervention: Aspirin (325 mg once daily) Control: Clopidogrel (75 mg once daily	Three years.	Stroke (fatal) I: 8/3229 (0.2%) C: 11/3223 (0.3%) Stroke (non-fatal) I: 74/3229 (2.3%) C: 70/3223 (2.2%) Myocardial infarction (fatal) I: 27/3229 (0.8%) C: 18/3223 (0.6%) Myocardial infarction (non-fatal) I: 81/3229 (2.5%) C: 50/3223 (1.6%)	The study was funded by Sanofi and Bristol-Myers Squibb.	Low

				Other vascular death I: 87/3229 (2.7%) C: 66/3223 (2.0%)		
EUCLID (2016)	N at baseline Intervention: N = 6930 Control: N = 6955 Age Intervention: 66 (60-72) years Control: 66 (60-72) years Sex Intervention: 1908 (27.5) females Control: 1980 (28.5) females	Intervention: Ticagrelor (90 mg twice daily) Control: Clopidogrel (75 mg once daily	The median follow-up was approximately 30 months.	Cardiovascular death, myocardial infarction, or ischemic stroke I: 751/6930 (10.8%) C: 740/6955 (10.6%) Cardiovascular death I: 363/6930 (5.2%) C: 343/6955 (4.9%) Myocardial infarction I: 349/6930 (5.0%) C: 334/6955 (4.8%) Ischemic stroke	Supported by AstraZeneca. Dr. Fowkes reports receiving consulting fees from Bayer and Merck; Dr. Berger, receiving fees for serving on advisory boards from Janssen, Merck, and Takeda; Dr. Baumgartner, receiving fees for serving on a steering committee from AstraZeneca, fees for serving on advisory boards from Bayer and Sanofi, and grant support from Abbott Vascular, Cook Medical, Optimed, Terumo Medical, Promedics, Amgen, and Boston Scientific; Drs. Held, Katona, and Blomster and Mr. Millegård, being employees of Astra-Zeneca, and Dr. Held,	Low

				I: 131/6930 (1.9%) C: 169/6955 (2.4%) <u>Hospitalization for acute limb ischemia</u> I: 117/6930 (1.7%) C: 115/6955 (1.7%) <u>Lower-limb revascularization</u> I: 846/6930 (12.2%) C: 892/6955 (12.8%) <u>Bleeding (any bleeding leading to discontinuation):</u> I: 168/6910 (2.4%) C: 112/6932 (1.6%)	having an equity interest in AstraZeneca; Dr. Mahaffey, receiving consulting fees from BAROnova, Bayer, Bio2 Medical, Boehringer Ingelheim, Bristol-Myers Squibb, Cub- ist, Eli Lilly, Epson, Forest Laboratories, GlaxoSmithKline, John- son & Johnson, Medtronic, Merck, MyoKardia, Omthera Pharma- ceuticals, Portola Pharmaceuticals, Purdue Pharma, the Medicines Company, Theravance, Vindico, and WebMD, grant support to his institution from Amgen, Daiichi Sankyo, Johnson & Johnson, Medtronic, Merck, St. Jude Medical, and TenaxTherapeutics, and having an equity interest in BioPrint Fitness; Dr. Norgren, receiv- ing fees for serving on steering	

					committees from Bayer, AnGes MG, and Pluristem Therapeutics, receiving fees for serving on an advisory board from Cesca Therapeutics, receiving consulting fees from Mitsubishi Tanabe Pharma, and receiving grant support from AnGes MG and Mitsubishi Tanabe Pharma; and Dr. Patel, receiving consulting fees from Bayer, Cardiovascular Systems, Genzyme, Janssen Research and Development, Medtronic, and Merck and receiving grant support to his institution from Cardio-vascular Systems, HeartFlow, Janssen Research and Development, Johnson & Johnson, Maquet, and Medtronic. No other potential conflict of interest relevant to this article was reported.	

Risk of bias tabel

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

	Probably no Definitely no	Definitely no		Probably yes Probably no Definitely no	Probably no Definitely no	Probably yes Probably no Definitely no	
CAPRIE (1996)	Definitely yes. Reason: The Independent Statistical Centre provided computer-generated balanced blocks of four treatments with random allocation to clopidogrel or aspirin, stratified by clinical centre and the three disease subgroups.	Definitely yes. Reason: The Independent Statistical Centre provided computer-generated balanced blocks of four treatments with random allocation to clopidogrel or aspirin, stratified by clinical centre and the three disease subgroups.	Definitely yes. Reason: Patients were allocated study drugs sequentially from supplies at the clinical centre packaged in a predetermined order in a carton that contained supplies for four patients. These supplies were in the form of blister packs containing either 75 mg tablets of clopidogrel plus aspirin placebo tablets or 325 mg aspirin tablets plus clopidogrel placebo tablets, such blister packs being indistinguishable from one another.	Probably yes. Reason: Loss to follow-up almost equally distributed between both groups.	Definitely yes. Reason: Alle predefined outcomes were reported.	Definitely yes. Reason: Not other bias reported.	Low
EUCLID (2016)	Definitely yes. Reason: Patients were randomized	No information. Reason: -	Definitely yes. Reason: Given in a double-blind fashion	Definitely yes. Reason: Not significant.	Definitely yes. Reason: Alle predefined outcomes	Definitely yes. Reason: Not other bias reported.	Low

	1:1 to either ticagrelor 90 mg twice daily or clopidogrel 75 mg daily				were reported.		

Exclusie tabel

Reference	Reason for exclusion
Wong PF, Chong LY, Mikhailidis DP, Robless P, Stansby G. Antiplatelet agents for intermittent claudication. Cochrane Database Syst Rev. 2011 Nov 9;(11):CD001272. doi: 10.1002/14651858.CD001272.pub2. PMID: 22071801.	The included randomized controlled trials in this systematic review were already included in the more recent systematic review of Beiswenger (2018).
Hiatt WR, Fowkes FG, Heizer G, Berger JS, Baumgartner I, Held P, Katona BG, Mahaffey KW, Norgren L, Jones WS, Blomster J, Millegård M, Reist C, Patel MR; EUCLID Trial Steering Committee and Investigators. Ticagrelor versus Clopidogrel in Symptomatic Peripheral Artery Disease. N Engl J Med. 2017 Jan 5;376(1):32-40. doi: 10.1056/NEJMoa1611688. Epub 2016 Nov 13. PMID: 27959717.	Already included in the included systematic review of Beiswenger (2018).

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Herziening richtlijn Perifeer Arterieel Vaatlijden – UV1 Antitrombotische behandeling in het kader van secundaire preventie	
Uitgangsvraag/modules: Wat is de optimale antitrombotische behandeling in het kader van secundaire preventie bij patiënten met PAV?	
Database(s): Embase.com, Ovid/Medline	Datum: 24 juni 2024
Periode: vanaf 2000	Talen: geen restrictie
Literatuurspecialist: Esther van der Bijl	Rayyan review: https://rayyan.ai/reviews/1068262
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 perifeer arterieel vaatlijden EN antitrombotische medicatie EN clopidogrelsecundaire EN preventie. De volgende sleutelartikelen worden gevonden met deze search: • Reduction in Acute Limb Ischemia With Rivaroxaban Versus Placebo in Peripheral Artery Disease After Lower Extremity Revascularization: Insights From VOYAGER PAD. Hess CN, Debus ES, Nehler MR, Anand SS, Patel MR, Szarek M, Capell WH, Hsia J, Beckman JA, Brodmann M, Diaz R, Habertheuer P, Leeper NJ, Powell RJ, Sillesen H, Muehlhofer E, Berkowitz SD, Haskell LP, Bauersachs RM, Bonaca MP. Circulation. 2021 Dec 7;144(23):1831-1841. • Prevalence of VOYAGER PAD trial exclusion criteria in unselected patients undergoing lower limb revascularisation.Moll MA, Zwerger D, Grassl KJ, Westreicher W, Neururer SB, Moll CW, Wipper SH, Klocker J. Int Angiol. 2021 Dec 16. • Revascularisation for Symptomatic Peripheral Artery Disease: External Applicability of the VOYAGER PAD Trial. Søgaard M, Nielsen PB, Skjøth F, Larsen TB, Eldrup N. Eur J Vasc Endovasc Surg. 2021 Dec 16:S1078-5884(21)00810-8.	

De volgende sleutelartikelen vallen uit op:

- CAPRIE Steering Committee. A randomised, blinded, trial of clopidogrel versus aspirin in patients at risk of ischaemic events (CAPRIE). CAPRIE Steering Committee. Lancet. 1996 Nov 16;348(9038):1329-39. doi: 10.1016/s0140-6736(96)09457-3. PMID: 8918275.

→ valt uit op datum

- The Voyager PAD Trial in a Surgical Perspective: A Debate. Vahl A, Leijdekkers V, Koelemay M, de Borst GJ, Bakker O. Eur J Vasc Endovasc Surg. 2021 May;61(5):721-722.

→ editorial

- Anand SS, Eikelboom JW, Dyal L, Bosch J, Neumann C, Widimsky P, Avezum AA, Probstfield J, Cook Bruns N, Fox KAA, Bhatt DL, Connolly SJ, Yusuf S; COMPASS Trial Investigators. Rivaroxaban Plus Aspirin Versus Aspirin in Relation to Vascular Risk in the COMPASS Trial. J Am Coll Cardiol. 2019 Jul 2;73(25):3271-3280. doi: 10.1016/j.jacc.2019.02.079. PMID: 31248548. → valt uit op de C
- Rivaroxaban in Peripheral Artery Disease after Revascularization.Bonaca MP, Bauersachs RM, Anand SS, Debus ES, Nehler MR, Patel MR, Fanelli F, Capell WH, Diao L, Jaeger N, Hess CN, Pap AF, Kittelson JM, Gudz I, Mátyás L, Krievins DK, Diaz R, Brodmann M, Muehlhofer E, Haskell LP, Berkowitz SD, Hiatt WR. N Engl J Med. 2020 May 21;382(21):1994-2004. → valt uit op de C
- Editor's Choice - External Applicability of the COMPASS and VOYAGER-PAD Trials on Patients with Symptomatic Lower Extremity Artery Disease in France: The COPART Registry. Lapébie FX, Aboyans V, Lacroix P, Constans J, Boulon C, Messas E, Ferrières J, Bongard V, Bura-Rivière A. Eur J Vasc Endovasc Surg. 2021 Sep;62(3):439-449. Editor's Choice - External Applicability of the COMPASS and VOYAGER-PAD Trials on Patients with Symptomatic Lower Extremity Artery Disease in France: The COPART Registry. Lapébie FX, Aboyans V, Lacroix P, Constans J, Boulon C, Messas E, Ferrières J, Bongard V, Bura-Rivière A. Eur J Vasc Endovasc Surg. 2021 Sep;62(3):439-449. → valt uit op studiedesign

Te gebruiken voor richtlijntekst:
In de databases Embase.com en Ovid/Medline is op 24 juni 2024 systematisch gezocht naar systematische reviews en RCT's over antitrombotische behandeling in het kader van secundaire preventie bij patiënten met PAV. De literatuurzoekactie leverde 570 unieke treffers op.

Zoekopbrengst 24 juni 2024

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	231	37	232
RCT	329	72	338
Totaal	560	109	**570***

****in Rayyan***

5 ***Zoekstrategie Embase.com 24 juni 2024***

No.	Query	Results
#1	'peripheral arterial occlusion'/exp OR 'peripheral arterial disease'/exp OR 'arteriosclerosis obliterans'/exp OR 'claudication'/exp OR 'critical limb ischemia'/exp OR 'intermittent claudication'/exp OR (((('arter* peripheral' OR 'peripheral arter*') NEAR/3 (disease* OR disorder* OR obstruct* OR occlus* OR stenos* OR calcifi* OR thrombos*)):ti,ab,kw) OR (((leg* OR	173003

	limb* OR extremit*) NEAR/3 (arteriosclero* OR atherosclero*) NEAR/3 (oblitera* OR occlus* OR insufficienc*)):ti,ab,kw) OR (((angiosclerotica OR claudicatio* OR dysbasia) NEAR/3 intermitten*):ti,ab,kw) OR (((leg* OR limb* OR extremit*) NEAR/3 (ischaemia OR ischemia)):ti,ab,kw) OR claudication*:ti,ab,kw OR 'angina cruris':ti,ab,kw	
#2	'rivaroxaban'/exp OR 'rivaroxaban':ti,ab,kw OR 'apixaban'/exp OR 'apixaban':ti,ab,kw OR 'edoxaban'/exp OR 'edoxaban':ti,ab,kw OR 'anti factor xa assay'/exp OR 'anti xa':ti,ab,kw OR 'dabigatran'/exp OR 'dabigatran':ti,ab,kw OR 'dual antiplatelet therapy'/exp OR ((('antiplatelet combination' OR 'combination antiplatelet' OR 'dual anti-platelet' OR 'dual antiplatelet') NEAR/3 therap*):ti,ab,kw) OR 'acetylsalicylic acid'/exp OR 'aspirin':ti,ab,kw OR 'ticagrelor'/exp OR 'ticagrelor':ti,ab,kw OR 'prasugrel'/exp OR 'prasugrel':ti,ab,kw	329117
#3	'clopidogrel'/exp OR 'agrelan':ti,ab,kw OR 'clopidogrel':ti,ab,kw OR 'clopilet':ti,ab,kw OR 'grepid':ti,ab,kw OR 'inhiplat':ti,ab,kw OR 'iscover':ti,ab,kw OR 'myogrel':ti,ab,kw OR 'osvix':ti,ab,kw OR 'pregrel':ti,ab,kw OR 'zopya':ti,ab,kw OR 'zylagren':ti,ab,kw OR 'zyllt':ti,ab,kw	80503
#4	'secondary prevention'/exp OR 'cardiovascular prevention'/exp OR 'recurrent disease'/exp OR 'revascularization'/exp/mj OR ((risk NEAR/3 ('ischaemi*' OR ischemi*)):ti,ab,kw) OR ((recurren* NEAR/3 (disease* OR event*)):ti,ab,kw) OR 'cardiovascular prevention*':ti,ab,kw OR 'secondary prevention*':ti,ab,kw OR caprie:ti,ab,kw OR revascularisation:ti,ab,kw OR revascularization:ti,ab,kw	486722
#5	#1 AND #2 AND #3 AND #4	2527
#6	#5 AND [2000-2024]/py 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)	2229
#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	1039560
#8	'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	2213926
#9	#6 AND #7 **– SR's**	231
#10	#6 AND #8 NOT #9 **– RCT's**	329

#11	#9 OR #10	560

Zoekstrategie Ovid/Medline 24 juni 2024

#	Searches	Results
1	exp Peripheral Arterial Disease/ or exp Chronic Limb-Threatening Ischemia/ or exp Intermittent Claudication/ or exp Arteriosclerosis Obliterans/ or ((arter* peripheral or peripheral arter*) adj3 (disease* or disorder* or obstruct* or occlus* or stenos* or calcifi* or thrombos*)).ti,ab,kf. or ((leg* or limb* or extremit*) adj3 (arteriosclero* or atherosclero*) adj3 (oblitera* or occlus* or insufficienc*)).ti,ab,kf. or ((angiosclerotica or claudicatio* or dysbasia) adj3 intermitten*).ti,ab,kf. or ((leg* or limb* or extremit*) adj3 (ischaemia or ischemia)).ti,ab,kf. or claudication*.ti,ab,kf. or angina cruris.ti,ab,kf.	54370
2	exp Rivaroxaban/ or exp Dabigatran/ or exp Aspirin/ or exp Ticagrelor/ or exp Prasugrel Hydrochloride/ or rivaroxaban.ti,ab,kf. or apixaban.ti,ab,kf. or edoxaban.ti,ab,kf. or anti xa.ti,ab,kf. or dabigatran.ti,ab,kf. or ((antiplatelet combination or combination antiplatelet or dual anti-platelet or dual antiplatelet) adj3 therap*).ti,ab,kf. or aspirin.ti,ab,kf. or ticagrelor.ti,ab,kf. or prasugrel.ti,ab,kf.	97376
3	exp Clopidogrel/ or agrelan.ti,ab,kf. or clopidogrel.ti,ab,kf. or clopilet.ti,ab,kf. or grepid.ti,ab,kf. or inhiplat.ti,ab,kf. or iscover.ti,ab,kf. or myogrel.ti,ab,kf. or osvix.ti,ab,kf. or pregrel.ti,ab,kf. or zopya.ti,ab,kf. or zylagren.ti,ab,kf. or zyllt.ti,ab,kf.	17179
4	exp Secondary Prevention/ or (risk adj3 (ischaemi* or ischemi*)).ti,ab,kf. or (recurren* adj3 (disease* or event*)).ti,ab,kf. or cardiovascular prevention*.ti,ab,kf. or secondary prevention*.ti,ab,kf. or caprie.ti,ab,kf. or revascularisation.ti,ab,kf. or revascularization.ti,ab,kf.	187167
5	1 and 2 and 3 and 4	267
6	limit 5 to yr="2000 -Current"	250
7	6 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	243
8	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.	754524
9	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.	1726199
10	7 and 8 **– SR's**	37

11	(7 and 9) not 10 **– RCT's**	72
12	10 or 11	109

Module 2: Antitrombotische therapie na chirurgische en/of endovasculaire interventie

Evidence tabel

Study	Participants (number, age, other important characteristics)	Comparison	Follow-up	Outcome measures	Risk of bias (adopted from the network meta-analysis of Willems (2022))*
Included in the systematic review of Willems (2022)					
Becquimin (1997)	N total: N = 243 Age 67.0 years Sex % (male) 77% male Population PVI	Intervention: TP2 Control: P	24 months	MACE	Low risk
BOA (2000)	N total: N = 2690 Age 69.0 years Sex % (male) 64% male Population PVI	Intervention: A Control: VKA2	21 months	MACE MALE	Low risk
CABBAGE (2017)	N total: N = 50 Age 73.0 years Sex % (male) 74% male Population PVI	Intervention: A Control: A+CI	3 months	MACE MALE MB	Low risk
CAPRIE (1996)	N total: N = 6452 Age 64.0 years	Intervention: A Control: C	23 months	MACE	Low risk

	Sex % (male) 72% male Population PAD				
CASPAR (2010)	N total: N = 851 Age 66.0 years Sex % (male) 76% male Population PVI	Intervention: A Control: A + C	12 months	MALE MB	Low risk
CHARISMA (2009)	N total: N = 3096 Age 60.0 years Sex % (male) 70% male Population PAD	Intervention: A Control: A + C	26 months	MACE MB	Low risk
CLIPS (2007)	N total: N = 366 Age 66.0 Sex % (male) 77% male Population PAD	Intervention: A Control: P	21 months	MACE	
COMPASS (2018)	N total: N = 7470 Age 68.0 Sex % (male) 72% male Population PAD	Intervention: A Control: A + R1 Control: R2	21 months	MACE MALE MB ALI	Some concerns

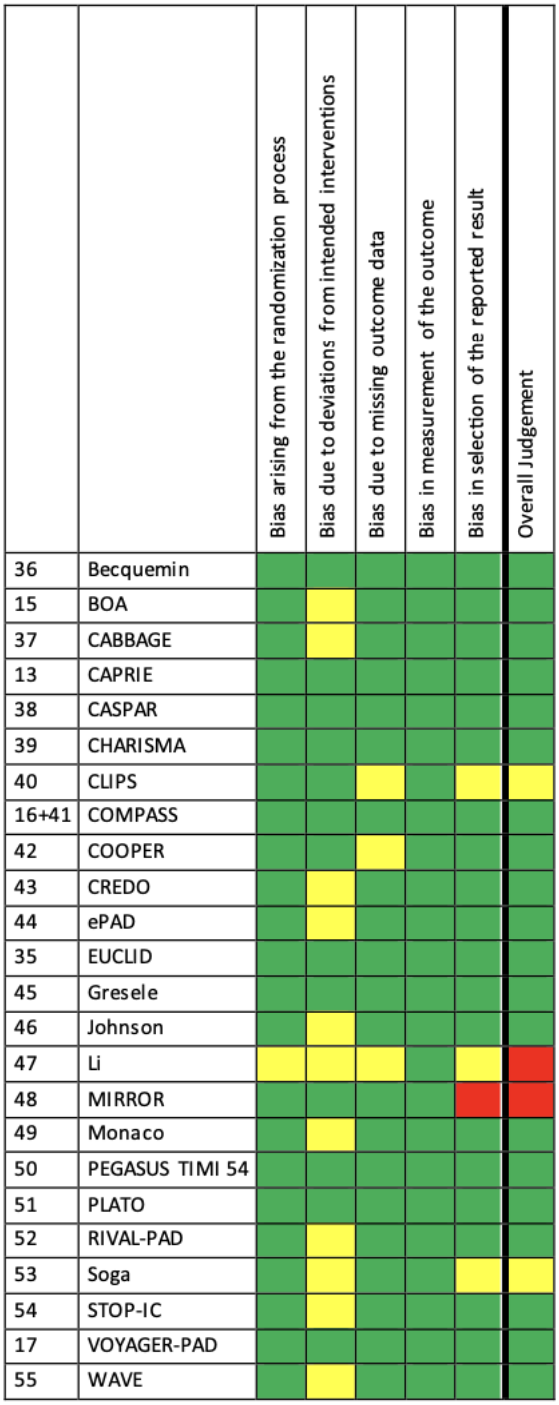
COOPER (2012)	N total: N = 431 Age 71.0 Sex % (male) 88% male Population PAD	Intervention: C Control: TPI	3 months	MACE	Low risk
CREDO (2006)	N total: N = 272 Age 67.0 Sex % (male) 66% male Population CAD	Intervention: A Control: A + C	12 months	MACE	Low risk
ePAD (2018)	N total: N = 203 Age 67.0 Sex % (male) 29% male Population PVI	Intervention: A + C Control: A + E	2.7 months	MACE MB	Low risk
EUCLID (2017)	N total: N = 13,885 Age 66.0 Sex % (male) 72% male Population PAD	Intervention: C Control: TG2	30 months	MACE MB ALI	Low risk
Gresele (2000)	N total: N = 159 Age 66.0 Sex % (male)	Intervention: A Control: A + CC	6 months	MACE	Low risk

	86% male Population PAD				
Johnson (2002)	N total: N = 831 Age 64.0 Sex % (male) Not reported. Population PVI	Intervention: A Control: A + VKA1	38 months	MB	Low risk
Li (2013)	N total: N = 50 Age 74.0 Sex % (male) Population PVI	Intervention: C Control: C + VKA1	12 months	MACE MB	High risk
MIRROR (2011)	N total: N = 80 Age 70.0 Sex % (male) 66% male Population PVI	Intervention: A Control: A + C	6 months	MACE	High risk
Monaco (2012)	N total: N = 318 Age 67.0 Sex % (male) 53% male Population PVI	Intervention: A + C Control: C + VKA1	77 months	MACE MB	Low risk
PEGASUS TIMI 54 (2016)	N total: N = 1143 Age	Intervention: A Control:	36 months	MACE MALE MB ALI	Low risk

	66.0 Sex % (male) 70% male Population CAD	A + TGI Control: A + TG2			
PLATO (2015)	N total: N = 1144 Age 66.0 Sex % (male) 78% male Population CAD	Intervention: A + C Control: A + TG2	9 months	MACE MB	Low risk
RIVAL-PAD (2020)	N total: N = 20 Age 67.0 Sex % (male) 60% male Population PVI	Intervention: A + C Control: A + R1	3 months	MB	Low risk
Soga (2009)	N total: N = 80 Age 71.0 Sex % (male) 83% male Population PVI	Intervention: A + TP1 Control: A + TP1 + CI	24 months	MACE MB	Some concerns
STOP-IC (2013)	N total: N = 200 Age 73.0 Sex % (male) 59% male Population PVI	Intervention: A Control: A + CI	12 months	MACE MALE	Low risk

VOYAGER-PAD (2020)	N total: N = 6564 Age 67.0 Sex % (male) 74% male Population PVI	Intervention: A Control: A + R1	28 months	MACE MALE MB ALI	Low risk
WAVE (2007)	N total: N = 2161 Age 64.0 Sex % (male) 74% male Population PAD	Intervention: A Control: A + VKA1	35 months	MACE MB ALI	Low risk

Risk of bias tabel



		Bias arising from the randomization process	Bias due to deviations from intended interventions	Bias due to missing outcome data	Bias in measurement of the outcome	Bias in selection of the reported result	Overall Judgement
36	Becquemin						
15	BOA						
37	CABBAGE						
13	CAPRIE						
38	CASPAR						
39	CHARISMA						
40	CLIPS						
16+41	COMPASS						
42	COOPER						
43	CREDO						
44	ePAD						
35	EUCLID						
45	Gresele						
46	Johnson						
47	Li						
48	MIRROR						
49	Monaco						
50	PEGASUS TIMI 54						
51	PLATO						
52	RIVAL-PAD						
53	Soga						
54	STOP-IC						
17	VOYAGER-PAD						
55	WAVE						

Exclusie tabel

Reference	Reason for exclusion
De Carlo M, Di Minno G, Sayre T, Fazeli MS, Siliman G, Cimminiello C. Efficacy and Safety of Antiplatelet Therapies in Symptomatic Peripheral Artery Disease: A Systematic Review and Network Meta-Analysis. Curr Vasc Pharmacol. 2021;19(5):542-555. doi:	A more recent published NMA was included.

10.2174/1570161118666200820141131. PMID: 32819249; PMCID: PMC8573731.	
Katsanos K, Spiliopoulos S, Saha P, Diamantopoulos A, Karunanithy N, Krokidis M, Modarai B, Karnabatidis D. Comparative Efficacy and Safety of Different Antiplatelet Agents for Prevention of Major Cardiovascular Events and Leg Amputations in Patients with Peripheral Arterial Disease: A Systematic Review and Network Meta-Analysis. PLoS One. 2015 Aug 14;10(8):e0135692. doi: 10.1371/journal.pone.0135692. PMID: 26274912; PMCID: PMC4537264.	A more recent published NMA was included.
Liang X, Wang Y, Zhao C, Cao Y. Systematic review the efficacy and safety of cilostazol, pentoxifylline, beraprost in the treatment of intermittent claudication: A network meta-analysis. PLoS One. 2022 Nov 1;17(11):e0275392. doi: 10.1371/journal.pone.0275392. PMID: 36318524; PMCID: PMC9624404.	A more recent published NMA was included.

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Perifeer arterieel vaatlijden – UV2 Antitrombotische therapie na chirurgische en/of endovasculaire interventie	
Uitgangsvraag/modules: Wat zijn de (on)gunstige effecten van verschillende antitrombotica bij patiënten met perifeer arterieel vaatlijden die een endovasculaire of chirurgische interventie ondergingen?	
Database(s): Embase.com, Ovid/Medline	Datum: 22 april 2024
Periode: vanaf 2000	Talen: geen restrictie
Literatuurspecialist: Esther van der Bijl	Rayyan review: https://rayyan.ai/reviews/1007290
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 perifeer arterieel vaatlijden EN antitrombotica. Deze zoekstrategie is opgebouwd naar het artikel van Willems et al (2022). Zoals afgesproken worden alleen de Netwerk meta-analyses aangeboden in Rayyan. → De volgende sleutelartikelen worden vanwege het studiedesign niet gevonden met deze search: • Capell WH, Bonaca MP, Nehler MR, Chen E, Kittelson JM, Anand SS, Berkowitz SD, Debus ES, Fanelli F, Haskell L, Patel MR, Bauersachs R, Hiatt WR. Rationale and design for the Vascular Outcomes study of ASA along with rivaroxaban in endovascular or surgical limb revascularization for peripheral artery disease (VOYAGER PAD). Am Heart J. 2018 May;199:83-91. doi:	

10.1016/j.ahj.2018.01.011. Epub 2018 Feb 3. PMID: 29754671. Let op: dit betreft de rationale en design van de trial.

- Belch JJ, Dormandy J; CASPAR Writing Committee, Biasi GM, Cairols M, Diehm C, Eikelboom B, Golledge J, Jawien A, Lepäntalo M, Norgren L, Hiatt WR, Becquemin JP, Bergqvist D, Clement D, Baumgartner I, Minar E, Stonebridge P, Vermassen F, Matyas L, Leizorovicz A. Results of the randomized, placebo-controlled clopidogrel and acetylsalicylic acid in bypass surgery for peripheral arterial disease (CASPAR) trial. J Vasc Surg. 2010 Oct;52(4):825-33, 833.e1-2. doi: 10.1016/j.jvs.2010.04.027. Epub 2010 Aug 1. Erratum in: J Vasc Surg. 2011 Feb;53(2):564. Biasi, B M [corrected to Biasi, G M]. PMID: 20678878.
- Bauersachs RM, Szarek M, Brodmann M, Gudz I, Debus ES, Nehler MR, Anand SS, Patel MR, Hess CN, Capell WH, Rogers K, Muehlhofer E, Haskell LP, Berkowitz SD, Hiatt WR, Bonaca MP; VOYAGER PAD Committees and Investigators. Total Ischemic Event Reduction With Rivaroxaban After Peripheral Arterial Revascularization in the VOYAGER PAD Trial. J Am Coll Cardiol. 2021 Jul 27;78(4):317-326. doi: 10.1016/j.jacc.2021.05.003. Epub 2021 May 16. PMID: 34010631.
- Bonaca MP, Bauersachs RM, Anand SS, Debus ES, Nehler MR, Patel MR, Fanelli F, Capell WH, Diao L, Jaeger N, Hess CN, Pap AF, Kittelson JM, Gudz I, Mátyás L, Krievins DK, Diaz R, Brodmann M, Muehlhofer E, Haskell LP, Berkowitz SD, Hiatt WR. Rivaroxaban in Peripheral Artery Disease after Revascularization. N Engl J Med. 2020 May 21;382(21):1994-2004. doi: 10.1056/NEJMoa2000052. Epub 2020 Mar 28. PMID: 32222135.
- Belch JJ, Dormandy J; CASPAR Writing Committee; Biasi GM, Cairols M, Diehm C, Eikelboom B, Golledge J, Jawien A, Lepäntalo M, Norgren L, Hiatt WR, Becquemin JP, Bergqvist D, Clement D, Baumgartner I, Minar E, Stonebridge P, Vermassen F, Matyas L, Leizorovicz A. Results of the randomized, placebo-controlled clopidogrel and acetylsalicylic acid in bypass surgery for peripheral arterial disease (CASPAR) trial. J Vasc Surg. 2010 Oct;52(4):825-33, 833.e1-2. doi: 10.1016/j.jvs.2010.04.027. Epub 2010 Aug 1. Erratum in: J Vasc Surg. 2011 Feb;53(2):564. Biasi, B M [corrected to Biasi, G M]. PMID: 20678878.
- Efficacy of oral anticoagulants compared with aspirin after infrainguinal bypass surgery (The Dutch Bypass Oral Anticoagulants or Aspirin Study): a randomised trial. Lancet. 2000 Jan 29;355(9201):346-51. Erratum in: Lancet 2000 Mar 25;355(9209):1104. PMID: 10665553.
- Moll F, Baumgartner I, Jaff M, Nwachuku C, Tangelder M, Ansel G, Adams G, Zeller T, Rundback J, Grosso M, Lin M, Mercur MF, Minar E; ePAD Investigators. Edoxaban Plus Aspirin vs Dual Antiplatelet Therapy in Endovascular Treatment of Patients With Peripheral Artery Disease: Results of the ePAD Trial. J Endovasc Ther. 2018 Apr;25(2):158-168. doi: 10.1177/1526602818760488. PMID: 29552984; PMCID: PMC5862321.

Het volgende sleutelartikel valt uit op de P, er wordt in titel, abstract of keywords niet over arterie gesproken:

- Efficacy of oral anticoagulants compared with aspirin after infrainguinal bypass surgery (The Dutch Bypass Oral Anticoagulants or Aspirin Study): a randomised trial. Lancet. 2000 Jan 29;355(9201):346-51. Erratum in: Lancet 2000 Mar 25;355(9209):1104. PMID: 10665553.

Te gebruiken voor richtlijntekst:
In de databases Embase.com en Ovid/Medline is op 22 april 2024 systematisch gezocht naar netwerk meta-analyses over de effecten van verschillende antitrombotica bij

patiënten met perifeer arterieel vaatlijden. De literatuurzoekactie leverde 29 unieke treffers op.

Zoekopbrengst 22 april 2024

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
Netwerk meta-analyse	28	16	29
Totaal			**29***

****in Rayyan***

5 ***Zoekstrategie Embase.com 22 april 2024***

No.	Query	Results
#1	'peripheral arterial disease'/exp OR 'intermittent claudication'/exp OR 'critical limb ischemia'/exp OR 'peripheral arterial occlusion'/exp OR 'iliac artery occlusion'/exp OR 'femoral artery disease'/exp OR 'popliteal artery occlusion'/exp OR 'femoropopliteal occlusive disease'/exp OR 'femoropopliteal occlusion'/exp OR ((('arter* peripheral' OR 'peripheral arter*' OR 'peripheral vascular') NEAR/3 disease*):ti,ab,kw) OR ((claudicatio* NEAR/3 intermitten*):ti,ab,kw) OR (((limb* OR leg*) NEAR/3 (ischaemia OR ischemia)):ti,ab,kw) OR (((aortic* OR iliac* OR femoral OR popliteal OR femoropopliteal) NEAR/3 'occlus*'):ti,ab,kw) OR ((('aortic arter*' OR 'iliac* arter*' OR 'femor* arter*' OR 'popliteal arter*' OR 'femoropopliteal arter*') NEAR/3 disease*):ti,ab,kw)	188686
#2	'anticoagulant agent'/exp OR 'antithrombocytic agent'/exp OR 'thienopyridine derivative'/exp OR 'acetylsalicylic acid'/exp OR 'acetylsalicylic acid 3 (nitroxymethyl)phenyl ester'/exp OR 'clopidogrel'/exp OR 'prasugrel'/exp OR 'satigrel'/exp OR 'elinogrel'/exp OR 'ticagrelor'/exp OR 'cangrelor'/exp OR 'carbasalate calcium'/exp OR 'dipyridamole'/exp OR 'ticlopidine'/exp OR 'picotamide'/exp OR 'triflusal'/exp OR 'cilostazol'/exp OR 'vorapaxar'/exp OR 'indobufen'/exp OR 'blood clotting factor 10a'/exp OR 'rivaroxaban'/exp OR 'apixaban'/exp OR 'edoxaban'/exp OR 'otamixaban'/exp OR 'betrixaban'/exp OR 'darexaban'/exp OR 'argatroban'/exp OR 'melagatran'/exp OR 'inogatran'/exp OR 'terutroban'/exp OR 'dabigatran'/exp OR 'ximelagatran'/exp OR 'lepirudin'/exp OR 'desulfatohirudin'/exp OR 'bivalirudin'/exp OR 'idraparinux'/exp OR 'idrabiotaparinux'/exp OR 'fondaparinux'/exp OR 'antivitamin k'/exp OR 'coumarin'/exp OR 'warfarin'/exp OR 'acenocoumarol'/exp OR 'phenprocoumon'/exp OR 'phenindione'/exp OR 'fluindione'/exp OR 'difenacoum'/exp OR 'dicoumarol'/exp OR 'heparin'/exp OR 'heparinoid'/exp OR 'tinzaparin'/exp OR 'reviparin'/exp OR 'parnaparin'/exp OR 'nadroparin'/exp OR 'enoxaparin'/exp OR 'danaparoid'/exp OR 'dalteparin'/exp OR 'certoparin'/exp OR 'ardeparin'/exp OR 'bemiparin'/exp OR anticoagula*:ti,ab,kw OR 'anti coagula*':ti,ab,kw OR antithrombo*:ti,ab,kw OR 'anti thrombo*':ti,ab,kw OR 'platelet aggregation inhibitor*':ti,ab,kw OR 'platelet inhibitor*':ti,ab,kw OR antiplatelet*:ti,ab,kw OR 'anti platelet*':ti,ab,kw OR p2y12:ti,ab,kw OR thienopyridine*:ti,ab,kw OR aspirin:ti,ab,kw OR 'acetylsalicylic acid*':ti,ab,kw OR nitroaspirin:ti,ab,kw OR asa:ti,ab,kw OR	1022673

	clopidogrel:ti,ab,kw OR prasugrel:ti,ab,kw OR satigrel:ti,ab,kw OR pyragrel:ti,ab,kw OR elinogrel:ti,ab,kw OR ticagrelor:ti,ab,kw OR cangrelor:ti,ab,kw OR 'carbasalate calcium':ti,ab,kw OR dipyridamole:ti,ab,kw OR ticlopidine:ti,ab,kw OR picotamide:ti,ab,kw OR triflusal:ti,ab,kw OR cilostazol:ti,ab,kw OR vorapaxar:ti,ab,kw OR indobufen:ti,ab,kw OR (('factor xa' NEAR/1 (antagon* OR inhibit*)):ti,ab,kw) OR rivaroxaban:ti,ab,kw OR apixaban:ti,ab,kw OR edoxaban:ti,ab,kw OR otamixaban:ti,ab,kw OR betrixaban:ti,ab,kw OR darexaban:ti,ab,kw OR argatroban:ti,ab,kw OR melagatran:ti,ab,kw OR inogatran:ti,ab,kw OR terutroban:ti,ab,kw OR dabigatran:ti,ab,kw OR ximelagatran:ti,ab,kw OR lepirudin:ti,ab,kw OR desirudin:ti,ab,kw OR bivalirudin:ti,ab,kw OR idraparinux:ti,ab,kw OR idrabiotaparinux:ti,ab,kw OR fondaparinux:ti,ab,kw OR (('vitamin k' NEAR/1 (antagon* OR inhibit*)):ti,ab,kw) OR coumarin:ti,ab,kw OR warfarin:ti,ab,kw OR acenocoumarol:ti,ab,kw OR phenprocoumon:ti,ab,kw OR phenindione:ti,ab,kw OR fluindione:ti,ab,kw OR difenacoum:ti,ab,kw OR dicumarol:ti,ab,kw OR heparin:ti,ab,kw OR lmwh:ti,ab,kw OR lmh:ti,ab,kw OR heparinoids:ti,ab,kw OR tinzaparin:ti,ab,kw OR reviparin:ti,ab,kw OR parnaparin:ti,ab,kw OR nadroparin:ti,ab,kw OR enoxaparin:ti,ab,kw OR danaparoid:ti,ab,kw OR dalteparin:ti,ab,kw OR certoparin:ti,ab,kw OR bemiparin:ti,ab,kw OR ardeparin:ti,ab,kw	
#3	#1 AND #2	32572
#4	#3 AND [2000-2024]/py 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)	21017
#5	'network meta-analysis'/exp OR ((network NEAR/3 ('meta analys*' OR metaanalys*)):ti,ab,kw) **– Netwerk meta-analyses**	15256
#6	#4 AND #5	28

Zoekstrategie Ovid/Medline 22 april 2024

#	Searches	Results
1	exp Peripheral Arterial Disease/ or exp Intermittent Claudication/ or exp Chronic Limb-Threatening Ischemia/ or ((arter* peripheral or peripheral arter* or peripheral vascular) adj3 disease*).ti,ab,kf. or (claudicatio* adj3 intermitten*).ti,ab,kf. or ((limb* or leg*) adj3 (ischaemia or ischemia)).ti,ab,kf. or ((aortic* or iliac* or femoral or popliteal or femoropopliteal) adj3 occlus*).ti,ab,kf. or ((aortic arter* or iliac* arter* or femor* arter* or popliteal arter* or femoropopliteal arter*) adj3 disease*).ti,ab,kf.	60861
2	exp Anticoagulants/ or exp Thienopyridines/ or exp Clopidogrel/ or exp Prasugrel Hydrochloride/ or exp Ticagrelor/ or exp Dipyridamole/ or exp Ticlopidine/ or exp Cilostazol/ or exp Rivaroxaban/ or exp Dabigatran/ or exp Fondaparinux/ or exp Coumarins/ or exp Warfarin/ or exp Acenocoumarol/ or exp Phenprocoumon/ or exp Phenindione/ or exp Dicumarol/ or exp Heparin/ or exp Heparinoids/ or exp Tinzaparin/ or exp Nadroparin/ or exp Enoxaparin/ or exp Dalteparin/ or anticoagula*.ti,ab,kf. or anti coagula*.ti,ab,kf. or antithrombo*.ti,ab,kf. or anti thrombo*.ti,ab,kf. or platelet aggregation inhibitor*.ti,ab,kf. or platelet inhibitor*.ti,ab,kf. or antiplatelet*.ti,ab,kf. or anti platelet*.ti,ab,kf. or p2y12.ti,ab,kf. or thienopyridine*.ti,ab,kf. or aspirin.ti,ab,kf. or acetylsalicylic acid*.ti,ab,kf. or nitroaspirin.ti,ab,kf. or asa.ti,ab,kf. or clopidogrel.ti,ab,kf. or prasugrel.ti,ab,kf. or satigrel.ti,ab,kf. or	499722

	pyragrel.ti,ab,kf. or elinogrel.ti,ab,kf. or ticagrelor.ti,ab,kf. or cangrelor.ti,ab,kf. or carbasalate calcium.ti,ab,kf. or dipyridamole.ti,ab,kf. or ticlopidine.ti,ab,kf. or picotamide.ti,ab,kf. or triflusal.ti,ab,kf. or cilostazol.ti,ab,kf. or vorapaxar.ti,ab,kf. or indobufen.ti,ab,kf. or (factor xa adj1 (antagon* or inhibit*)).ti,ab,kf. or rivaroxaban.ti,ab,kf. or apixaban.ti,ab,kf. or edoxaban.ti,ab,kf. or otamixaban.ti,ab,kf. or betrixaban.ti,ab,kf. or darexaban.ti,ab,kf. or argatroban.ti,ab,kf. or melagatran.ti,ab,kf. or inogatran.ti,ab,kf. or terutroban.ti,ab,kf. or dabigatran.ti,ab,kf. or ximelagatran.ti,ab,kf. or lepirudin.ti,ab,kf. or desirudin.ti,ab,kf. or bivalirudin.ti,ab,kf. or idraparinux.ti,ab,kf. or idrabiotaparinux.ti,ab,kf. or fondaparinux.ti,ab,kf. or (vitamin k adj1 (antagon* or inhibit*)).ti,ab,kf. or coumarin.ti,ab,kf. or warfarin.ti,ab,kf. or acenocoumarol.ti,ab,kf. or phenprocoumon.ti,ab,kf. or phenindione.ti,ab,kf. or fluindione.ti,ab,kf. or difenacoum.ti,ab,kf. or dicumarol.ti,ab,kf. or heparin.ti,ab,kf. or lmwh.ti,ab,kf. or lmh.ti,ab,kf. or heparinoids.ti,ab,kf. or tinzaparin.ti,ab,kf. or reviparin.ti,ab,kf. or parnaparin.ti,ab,kf. or nadroparin.ti,ab,kf. or enoxaparin.ti,ab,kf. or danaparoid.ti,ab,kf. or dalteparin.ti,ab,kf. or certoparin.ti,ab,kf. or bemiparin.ti,ab,kf. or ardeparin.ti,ab,kf.	
3	1 and 2	5659
4	limit 3 to yr="2000 -Current"	4646
5	4 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	4350
6	exp Network Meta-Analysis/ or (network adj3 ('meta analys*' or metaanalys*)).ti,ab,kf. **– Netwerk meta-analyses**	11107
7	5 and 6	16

Module 3: Iliacaal: Primaire stentplaatsing versus stentplaatsing op indicatie

Evidence tabel

Study reference	Study characteristics	Patient characteristics	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Jongsma (2020)	A: Klein (1997 - Dutch Iliac Stent Trial) B: Goode (20130 – STAG-trial). Study design: A: RCT B: RCT Setting and Country: A: 6 large Dutch hospitals B: 6 major hospitals in the UK Source of funding and conflicts of interest:	Inclusion criteria SR: • We included participants with symptomatic iliac artery occlusive disease. There were no restrictions based on either gender or age. Exclusion criteria SR: • No information.	Describe intervention: A: PS: a long 7-F introducer sheath was placed across the targeted segment. The stent (Palmaz, Johnson & Johnson, Warren, NY, USA) was mounted by hand on a folded angioplasty balloon catheter. The stent-balloon assembly was positioned at the site of the	Describe control: A: PTA: "PTA was performed according to standard techniques". Secondary stenting was performed in cases in which the residual mean pressure gradient after PTA was greater than 10 mmHg. In 38% of le-sions, stenting was required.	End-point of follow-up: A: 8 years. B: 2 years.	**Technical success *** A (Dutch Iliac Stent Trial) I: 119/143 (84%) C: 120/136 (88%) B (STAG trial) I: 56/57 (98%) C: 55/55 (84%) *In the Dutch Iliac Stent Trial, the treatment was considered a technical success when the pressure gradient across the treated segment was equal to or less than 10 mmHg after the procedure	-

	A: Flanders Medical Research Program. The long-term follow-up was funded by Cordis. No conflicts declared. It is stated that the investigators were in full control of the data for the long term follow up. B: NHS R&D Regional Programme Register - Department of Health (UK) No conflicts of interest.	<u>Important patient characteristics at baseline</u>: <u>N</u> A: N = 279 B: N = 118 <u>Mean age</u> A: PS: 59 (11) PTA: 60 (10) B: PS: 60.2 (8.9) PTA: 60.6 (10.5) <u>*Sex*</u>*:* A: PS: 102/143 (73%) male PTA: 37/136 (27%) male B: PS: 41/57 (73%) male PTA: 35/55 (64%) male Groups comparable at baseline? Yes.	intended intervention, the sheath withdrawn and the stent deployed by inflation of the balloon. The stent diameter was determined by the width of the uninvolved portion of the vessel. All patients received anticoagulant medication in accordance with local guidelines or the individual preference of the physician who initially referred the patient for treatment. B: PS: no details are given on the	All patients received anticoagulant medication in accordance with local guidelines or the individual preference of the physician who initially referred the patient for treatment. B: PTA: no details are given on the technique used for primary PTA. Secondary stenting was performed in case of no forward flow, or complications that could be resolved by the use of a stent. If		and during pharmacologically-induced vasodilatation. *The STAG trial defined technical success as the presence of antegrade flow through the treated segment. Therefore, patients in the PTA group who required a stent were categorised as having a technical failure. **<u>Reinterventions, two years</u>** A (Dutch Iliac Stent Trial) I: 10/143 (7.0%) C: 6/136 (4.4%) **<u>Reinterventions, five years</u>** A (Dutch Iliac Stent Trial) I: 33/187 segments (17.6%)	

			technique used for PS. Before intervention aspirin was started, or dipyridamole if patients were aspirin-intolerant. The trial was conducted before the introduction of statins and thienopyridines. After arterial access had been achieved, 5000 units of UFH were given.	any flow, re-gardless of residual stenosis or pressure gradient, no stent was placed. In 38% of lesions, stenting was required. Before intervention aspirin was started, or dipyridamole if patients were aspirin-intolerant. The trial was conducted before the introduction of statins and thienopyridines. After arterial access had been achieved, 5000 units of UFH were given.		C: 33/169 segments (19.5%) **<u>Reinterventions, five years</u>** A (Dutch Iliac Stent Trial) I: 25/143 (17.5%) C: 28/136 (20.6%) **<u>Complications</u>** ***Immediate complications (<72 hours)*** **A (Dutch Iliac Stent Trial) **** I: 6/143 (4%) C: 10/136 (10%) **In the Dutch Iliac Stent Trial, authors did not state in their publications' methods sections how complications were defined. They made no distinction between major or minor complications. They	

						stated that complications included haematoma at the puncture site, arterial-wall perforation, acute occlusion of the treated arterial segment, embolism and vasovagal collapse. They did not report how these complications were distributed over both treatment groups. ***Immediate complications (<72 hours) (major complications)*** B (STAG trial)*** I: 3/57 (5%) C: 11/55 (20%) ***Immediate complications (<72 hours) (other complications)*** B (STAG trial)*** I: 1/57 (1.8%) C: 2/55 (3.6%)	

						In the STAG trial, investigators defined major complications as those resulting in death, permanent disability, unplanned amputation due to the intervention, an unexpected or unplanned secondary procedure (excluding secondary stent placement), delayed hospital discharge or blood transfusion. The other complications were two acute thromboses in the PTA group, and one arterial wall rupture in the PS group. ***Delayed complications (>72 hours)*** None of the studies reported this outcome.	

						<u>Symptomatic improvement, three months</u> A (Dutch Iliac Stent Trial) I: 103/135 (76.3%) C: 101/123 (82.1%) **<u>Symptomatic improvement, one year</u>** A (Dutch Iliac Stent Trial) I: 64/80 (80.0%) C: 62/77 (80.5%) **<u>Symptomatic improvement, two years</u>** B (STAG Trial) I: 29/37 (78.4%) C: 26/34 (76.5%) **<u>Primary patency, one year</u>** B (STAG Trial) I: 39/41 (95.1%) C: 40/42 (95.2%)	

						<u>Primary patency, two years</u> B (STAG Trial) I: 25/30 (83.3%) C: 24/27 (88.9%) **<u>Secondary patency, eight years</u>** A (Dutch Iliac Stent Trial) I: 90/109 (82.6%) C: 67/90 (74.4%) **<u>Resolution of symptoms and signs, three months</u>** A (Dutch Iliac Stent Trial) I: 88/138 (63.8%) C: 85/125(68.0%) **<u>Resolution of symptoms and signs, one year</u>** A (Dutch Iliac Stent Trial) I: 72/112 (64.3%) C: 72/107 (67.3%)	

						<u>Resolution of symptoms and signs, two years</u> A (Dutch Iliac Stent Trial) I: 59/92 (64.1%) C: 56/91 (61.5%) **<u>Resolution of symptoms and signs, eight years</u>** A (Dutch Iliac Stent Trial) I: 31/90 (34.4%) C: 38/78 (48.7%)	

Risk of bias tabel

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?**	**Was the allocation adequately concealed?**	**Blinding: Was knowledge of the allocated interventions adequately prevented?** **Were patients/healthcare providers/data collectors/assessors/data analysts blinded?** Definitely yes	**Was loss to follow-up (missing outcome data) infrequent?**	**Are reports of the study free of selective outcome reporting?**	**Was the study apparently free of other problems that could put it at a risk of bias?**	**Overall risk of bias** **If applicable/necessary, per outcome measure** **LOW**

	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	**Some concerns** **HIGH**
Klein (1997 – DIST-trial)	Definitely yes. Reason: "For each hospital, a separate computer-generated randomisation table was produced to limit imbalance between treatment assignments to four."	Definitely yes. Reason: "This table was kept at the trial office and was not available to the treating physicians. The trial assignment was revealed .... by a trial co-worker."	Definitely no. Reason: "We decided that to conceal the assigned treatment from patients or physicians was not feasible." It is unclear if personnel performing ABI measurements, duplex and clinical ex- amination were blinded. Complications and technical success are probably scored by the operating personnel so these were probably not blinded.	Probably yes. Reason: Even for long-term results there was a relatively low number of patients lost to follow-up.	Probably no. Reason: Results from most outcomes that are described in the methods section of the study are actually reported. Only results on walking distance are not reported, and this is an outcome measure that is rarely reported in comparable studies. However, in their final publication	Probably yes. Reason: The original trial was supported by a PIONIER award from the Netherlands Or- ganization for Scientific Research and a grant from the Commission of Inves- tigative Medicine of the Dutch National Health Insurance Council. One article on long-term results	Some concerns.

					(Klein 1997), the study authors report on the proportion of patients that are symptom-free as defined by the Fontaine classification, which is an outcome measure that is not mentioned in any of their previous publications or in the methods section, and which is the one outcome in this publication that the authors report to be statistically signifi- cant.	was funded by Cordis, the company that manufactures Palmaz stents. However, it is stated that the investigators were in full control of the data.	

Goode (2013 – STAG-trial)	Definitely yes. Reason: Patients were assigned using randomly allocated, independently constructed envelopes	Definitely yes. Reason: Patients were assigned using randomly allocated, independently constructed envelopes	Definitely no. Reason: "It was not possible to blind the operator from the assigned treatment group." It is unclear whether patients were blinded	Probably no. Reason: Only 83 patients underwent a 1-year angiography, and only 47 patients under- went a 2-year angiography. It is unclear why these patients were lost to fol-low-up (i.e. death, migration, withdrawal)	Unclear risk Reason: Outcome measures were used according to the most recent internationally recognised reporting standards at the time of the study	Probably yes. Reason: This study was funded by Trent Regional Health Authority. The study authors declare no conflict of interest	Some concerns.

Exclusie tabel

Author and year	Reason for exclusion
Bosch (1999)	The included study of Klein (1997) was an update of this trial and used data from the same study population.
Jongsma (2020)	We included both RCTs from this systematic review individually.
Klein (2004)	The included study of Klein (1997) was an update of this trial and used data from the same study population.
Tetteroo (1996)	The included study of Klein (1997) was an update of this trial and used data from the same study population.
Tetteroo (1998)	The included study of Klein (1997) was an update of this trial and used data from the same study population.
Tetteroo (2000)	The included study of Klein (1997) was an update of this trial and used data from the same study population.

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: PAV 2022	
Uitgangsvraag/modules: Iliacaal: Primaire stentplaatsing versus stentplaatsing op indicatie	
Database(s): Ovid/Medline, Embase.com	Datum: 5 juli 2022
Periode: geen restrictie	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: • Ilicaal traject • Primaire stent De opgegeven sleutelartikelen worden gevonden met de zoekopdracht	
Te gebruiken voor richtlijnen tekst: *Nederlands* In de databases Embase.com en Ovid/Medline is op 5 juli 2022 met relevante zoektermen gezocht naar systematische reviews, RCT en observationele studies over behandeling van het iliacaal traject met een primaire stent. De literatuurzoekactie leverde 592 unieke treffers op. *Engels* On the 5th of July 2022, relevant search terms were used to search for systematic reviews, RCT and observational studies about treatment of iliac artery disease with a primary stent in the databases Embase.com and Ovid/Medline. The search resulted in 592 unique hits.	

Zoekopbrengst

	EMBASE	OVID/MEDLINE	Ontdubbeld
SRs	32	20	40
RCT	108	34	113

Observationele studies	347	201	439
Totaal	487	255	**592**

Zoekstrategie

Embase.com

No.	Query	Results
#10	#7 OR #8 OR #9	487
#9	#3 AND #6 NOT (#7 OR #8) **= observationeel**	347
#8	#3 AND #5 NOT #7 **= RCT**	108
#7	#3 AND #4 **= SR**	32
#6	'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)))	13242898
#5	'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

#4	'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
#3	#1 AND #2 AND ([english]/lim OR [dutch]/lim) 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)	1411
#2	'stent'/exp/mj AND (primary:ti,ab,kw OR primarily:ti,ab,kw) OR ((stent* NEAR/3 (primary OR primarily)):ti,ab,kw)	15335
#1	'iliac artery'/exp OR 'iliac artery obstruction'/exp OR (((ileac* OR aortoiliac*) NEAR/3 (obstruct* OR occlusi* OR stenos* OR ather?oscler* OR lesion* OR oblitera*)):ti,ab,kw) OR 'aortoiliac artery':ti,ab,kw OR 'arteria iliaca':ti,ab,kw OR 'ileal artery':ti,ab,kw OR 'iliac artery':ti,ab,kw OR 'ilial artery':ti,ab,kw	83508

Ovid/Medline

#	Searches	Results
12	9 or 10 or 11	255
11	(5 and 8) not (9 or 10) **= observationeel**	201
10	(5 and 7) not 9 **= RCT**	34
9	5 and 6 **= SR**	20
8	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	5190819

	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.))	
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.	1524920
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.	602175
5	4 not (comment/ or editorial/ or letter/ or ((exp animals/ or exp models, animal/) not humans/))	522
4	limit 3 to (english language or dutch)	529
3	1 and 2	579
2	(exp Stents/ and (primary or primarily).ti,ab,kf.) or (stent* adj3 (primary or primarily)).ti,ab,kf.	13174
1	(exp iliac artery/ and exp Arterial Occlusive Diseases/) or ((ileac* or aortoiliac*) adj3 (obstruct* or occlusi* or stenos* or ather?oscler* or lesion* or oblitera*)).ti,ab,kf. or aortoiliac artery.ti,ab,kf. or arteria iliaca.ti,ab,kf. or ileal artery.ti,ab,kf. or iliac artery.ti,ab,kf. or ilial artery.ti,ab,kf.	14898

Module 4: Iliacaal: Bare metal stent versus gecoverde stent

Evidence tabel

Study reference	Study characteristics	Patient characteristics [2]	Intervention (I)	Comparison / control (C) [3]	Follow-up	Outcome measures and effect size [4]	Comments
Mwipatayi, 2011	Type of study: Randomised controlled trial Setting and country: Hospital, Australia Funding and conflicts of interest: Atrium Medical Corporatio	Inclusion criteria: ● Men and women aged at least 18 years ● Informed consent obtained ● Evidence of TASC B, C, or D lesions ● Hemodynamically significant dissections and recurrent stenosis after angioplasty Exclusion criteria: ● Life expectancy less than 12 months (patients had to be followed up for at least 18 months in the first trial) ● Uncontrolled hypertension ● TASC A lesion ● Pregnant women or women of childbearing potential who were not using an effective method of contraception	Describe intervention (treatment/procedure/test): The Advanta V12 is encapsulated with expanded polytetrafluoroethylene (ePTFE), premounted on an Anertianoncompliant balloon (Atrium	Describe control (treatment/procedure/test): The bare-metal balloon-expandable stents used included Palmaz Genesis (Cordis Corp, East Bridgewater, NJ) in 32.5%, Express LD iliac stent (Boston Scientific, Natick, Mass) in 28%, Assurant Cobalt iliac stent (Medtronic, Minneapolis, Minn) in 18.6%, Peiron (Biotronik, Berlin, Germany) in 12.8%, and AVE-Bridge (Medtronic) in 2.3%. The two self-expandable BMSs used	Length of follow-up: 18 months Loss-to-follow-up: Intervention: 1 (1.2%) Reasons not described Control: 8 (9.4%) Reasons not described	Primary patency HR: 0.35 (95% CI; 0.15 to 0.82) Freedom from target lesion revascularization OR: 0.21 (95%CI; 0.07 - 0.64) Number of amputations I: 2	There is increasing evidence from single-center clinical investigations that patients with complex aortoiliac lesions, including chronic iliac artery occlusions and occlusion of

	n initially funded the study. However, the longterm follow-up of the patients was clinician driven, with no company or corporation funding involvement. The corresponding author had full access to all the data in the study, and the authors had final	● Prior enrollment in this trial, or a patient who had had any procedure performed at the aortoiliac level ● Extensive common femoral artery disease or multiple groin procedures ● Contraindication to aspirin or clopidogrel usage ● Occluded superficial and profunda femoral arteries ● Mental condition rendering the individual unable to understand the nature, scope and possible consequences of the study, or a language barrier preventing the individual from providing informed consent ● Uncooperative attitude or potential for noncompliance with the protocol requirements, making study participation impractical <u>N total at baseline</u>: Intervention: 83 arteries Control: 85 arteries <u>Important prognostic factors</u>[2]: age ± SD: I: 65.34 ± 1.43 C: 67.21 ± 1.29	Medical Corp), and compatible with a 6F to 7F sheath.	were the Smart (Cordis Corp) in 3.5% and Edwards Life Stent (Bard Peripheral Vascular Inc, Tempe, Ariz) in 2.3%. No drug-eluting stents were used.	Incomplete outcome data: NA	C: 2	the aortoiliac bifurcation, can be treated safely and effectively with a covered stent. The COBEST results demonstrate that for patients with severe aortoiliac arterial occlusive disease, there is an increased freedom from restenosis and occlusion with covered stents

	responsibility for the decision to submit for publication.	Sex: I: 67.7% M C: 57.1% M Groups comparable at baseline? Yes					compared with BMSs at 12 and 18 months. However, long-term durability data (5-year follow-up) is desirable.
Bekken, 2022	Type of study: Randomised controlled trial Setting and country: Hospital, The Netherlands Funding and conflicts of interest:	<u>Inclusion criteria</u>: - Age over 18 - Symptomatic, atherosclerotic lesion of the common iliac artery, either a hemodynamically significant stenosis with a length of more than 3 cm, or an occlusion. This will be measured on the pre-dilation DSA-images, where a diameter reduction of >50% is considered significant. A hemodynamically significant stenosis is confirmed with an intra-arterial translesional systolic blood pressure gradient measurement, where >10 mmHg pressure gradient is considered significant. Serial lesions less than 2 cm apart will be regarded as one long stenosis - Signed informed consent form.	The Advanta V12 stent (Atrium Medical Inc., Hudson, NH, USA) is a balloon-expandable stainless steel stent that is fully encapsulated in two layers of PTFE. The PTFE has a porosity of 100 to 120 µm. The Advanta V12	Omnilink Elite stent (Abbott Laboratories, North Chicago, IL, USA). The Omnilink Elite is a balloon-expandable CoCr (cobalt chromium alloy) stent. It is available in diameters of 4 to 10 mm. Available lengths are 12, 16, 19, 29, 39 and 59 mm. All Omnilink Elite stents are 0.035-inch guidewire compatible and are pre-mounted on a 6F dual layer compliant balloon catheter. Available catheter lengths are 80 and 135 cm.	<u>Length of follow-up</u>: 24 months <u>Loss-to-follow-up</u>: Intervention: 7 (8.05) 2 died 3 declined further participation 2 no show Control: 11 (12.6%) 5 died	<u>Primary patency</u> I: 89.1% (95% CI 82.4 - 95.8%) C: 84.7% (95% CI 76.7 - 92.7%) <u>Freedom from target lesion revascularization</u>	After two years of follow up, bare metal stents and covered balloon expandable stents both showed excellent results for treating advanced atherosclerotic lesions of the CIA. No difference was

	This study was funded by an Unrestricted Educational Grant from Getinge Maquet. The funder was not involved in the execution of the trial, data management, acquisition and analysis, writing of the article or in any other way.	<u>Exclusion criteria:</u> - Stenosis with a length of less than 3 cm; - Presence of a metastatic malignancy, or other disease that limits life expectancy to less than 2 years - Previous endovascular or surgical treatment of the common iliac artery on the affected side - Inability or unwillingness to comply with the follow-up schedule - Mental disability or language barrier that hinders the ability to understand and comply with the informed consent - Pregnancy or breast-feeding - Severe renal failure (e-GFR <30 mL/min/1.73m^2) - Known allergy to iodinated contrast agents or to PTFE - Contra-indication for anti-coagulation - Acute limb ischemia - Occlusion of the abdominal aorta - Aneurysm of the abdominal aorta that is not amenable to endograft placement	covered stent is available in diameters of 5 to 10 mm. Available stent lengths are 16, 22, 38, and 59 mm. All V12 stents are 0.035-inch guidewire compatible and are pre-mounted on a 7F non-compliant balloon catheter with gold markers embedded at the ends of the balloon. Available catheter lengths are 80 and 120 cm. It is the	Dynamic stent (Biotronik, Berlin, Germany). The Dynamic stent is a balloon-expandable stainless steel stent, with the stent struts coated with an amorphous silicon carbide coating. It is available in diameters of 5 to 10 mm. Available lengths are 15, 25, 38 and 56 mm. All Dynamic stents are 0.035-inch guidewire compatible and are pre-mounted on a 6 or 7F compliant balloon catheter. Available catheter lengths are 80 and 130 cm. Express LD Iliac stent (Boston Scientific, Natick, MA,USA). The Express LD Iliac is a balloon-expandable stainless steel stent. It is available in diameters of 6 to 10 mm. Available lengths are 20, 30, 40 and 60 mm. All Express LD Iliac stents are 0.035-inch guidewire compatible and are pre-	4 declined further participation 2 no show Incomplete outcome data: NA	I: 95.2% (95CI; 90.7 – 99.7) C: 91.1% (95%CI 84.8 – 97.3) <u>Number of amputations</u> I: 0 C: 0	identified between either stent type regarding freedom from restenosis or any of the secondary outcomes. Based on these results, the routine use of covered stents to treat CIA occlusive disease cannot be advocated.

		N total at baseline: Intervention: 87 Control: 87 Important prognostic factors[2]: Age ± SD: I: 60 ±10 C: 62 ± *9* Sex: I: 56.3% M C: 56.3% M Groups comparable at baseline? Yes	only balloon-expandable PTFE-covered stent that is registered for use in the iliac artery in Europe.	mounted on a 6 or 7F compliant balloon catheter. Available catheter lengths are 75 and 135 cm Palmaz Genesis stent (Cordis Corporation, Bridgewater, NJ, USA). The Palmaz Genesis is a balloon-expandable stainless steel stent. It is available in diameters of 4 to 10 mm. Available lengths are 12, 15, 18, 19, 24, 25, 29, 39 and 59 and 79 mm. In the participating centers, we only use 24, 39, 59 and 79 in the common iliac artery. All Palmaz Genesis Iliac stents are 0.035-inch guidewire compatible and are pre-mounted on a 6 or 7F compliant balloon catheter. Available catheter lengths are 80 and 135 cm. Scuba stent (INVATEC S.p.A, Roncadelle, Italy). The Scuba stent is a			

				balloon-expandable CoCr (cobalt chromium alloy) stent. It is available in diameters of 5 to 10 mm. Available lengths are 18, 30, 37, 55 and 75 mm. All Scuba stents are 0.035-inch guidewire compatible and are pre-mounted on a 5F compliant balloon catheter. Available catheter lengths are 80 and 130 cm.			

Risk of bias tabel

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?**	**Was the allocation adequately concealed?**	**Blinding: Was knowledge of the allocated interventions adequately prevented?** **Were patients blinded?**	**Was loss to follow-up (missing outcome data) infrequent?**	**Are reports of the study free of selective outcome reporting?**	**Was the study apparently free of other problems that could put it at a risk of bias?**	**Overall risk of bias** **If applicable/necessary, per outcome measure**

	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	**Were healthcare providers blinded?** **Were data collectors blinded?** **Were outcome assessors blinded?** **Were data analysts blinded?** Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	**LOW** **Some concerns** **HIGH**
Mwipatayi, 2011	Definitely yes Eligible patients were randomized to receive a covered stent or a BMS by an online computerized randomization program.	Definitely yes Reason: Unstratified randomization was used to randomize patients in a 1:1 ratio with a	Definitely no Reason: No mention	Probably no Reason: 1.2% loss to follow-up in intervention group vs 9.4% in control group.	Definitely yes Reason: All relevant outcomes mentioned	Definitely yes Reason: Study was founded by the manufacturer of the intervention but they were not involved in	Some concerns Reason: No mention of blinding and loss-to-follow-up reasoning is not given.

		minimization algorithm to allow balanced allocation of participants across intervention groups.		Reasons were not mentioned		writing the article	
Bekken, 2022	Definitely yes Patients were randomised 1:1 to the CS or BMS group. The online randomisation program Trans European Network for Clinical Trial Services (http://tenalea.net) was used. Rather than stratification, a minimisation algorithm was used to ensure comparable groups.	Definitely yes Patients were blinded for the allocated treatment.	Definitely yes The treating physicians could not be blinded due to the nature of the study. Patients were blinded for the allocated treatment, as were the vascular technicians performing the post-procedural ankle brachial index and duplex ultrasonography, and the research nurses	Definitely yes Looks random	Definitely yes All relevant outcomes mentioned	Probably yes Changes in Dutch guidelines with regards to prescribing clopidogrel instead of acetylsalicylic acid could affect the results	Low

			who performed post-procedural follow up and scoring of events.				

Exclusie tabel

Reference	Reason for exclusion
Bekken JA, Geensen R, Kok R, Kuijper M, de Vries JPM, Fioole B. Covered Stents vs. Angioplasty for Common Iliac Artery In Stent Restenosis: A Retrospective Comparison. Eur J Vasc Endovasc Surg. 2022 Feb;63(2):315-322. doi: 10.1016/j.ejvs.2021.10.032. Epub 2021 Nov 22. PMID: 34824011.	Wrong design: retrospective
Bekken JA, Jongsma H, Fioole B. The use of covered stents in aortoiliac obstructions: a systematic review and meta-analysis. J Cardiovasc Surg (Torino). 2018 Feb;59(1):14-25. doi: 10.23736/S0021-9509.17.10213-2. Epub 2017 Sep 20. PMID: 28933521.	Wrong design: no comparison
Grimme FA, Goverde PA, Van Oostayen JA, Zeebregts CJ, Reijnen MM. Covered stents for aortoiliac reconstruction of chronic occlusive lesions. J Cardiovasc Surg (Torino). 2012 Jun;53(3):279-89. PMID: 22695260.	Wrong design: no comparison
Hajibandeh S, Hajibandeh S, Antoniou SA, Torella F, Antoniou GA. Covered vs Uncovered Stents for Aortoiliac and Femoropopliteal Arterial Disease: A Systematic Review and Meta-analysis. J Endovasc Ther. 2016 Jun;23(3):442-52. doi: 10.1177/1526602816643834. Epub 2016 Apr 20. PMID: 27099281.	Only 1 included RCT was relevant
Humphries MD, Armstrong E, Laird J, Paz J, Pevec W. Outcomes of covered versus bare-metal balloon-expandable stents for aortoiliac occlusive disease. J Vasc Surg. 2014 Aug;60(2):337-43. doi: 10.1016/j.jvs.2014.02.055. Epub 2014 Apr 13. PMID: 24725909; PMCID: PMC9891866.	Wrong comparison: no bare metal stent
Jia X, Guo W, Liu XP, Xiong J, Ma XH, Zhang HP, Xu YL. [The mid-term and long-term results of endovascular treatment of C/D aorto-iliac artery occlusive disease]. Zhonghua Yi Xue Za Zhi. 2020 Aug 4;100(29):2273-2277. Chinese. doi: 10.3760/cma.j.cn112137-20200211-00251. PMID: 32746597.	Wrong language: Chinese
Krajcer Z, Sioco G, Reynolds T. Comparison of Wallgraft and Wallstent for treatment of complex iliac artery stenosis and occlusion. Preliminary results of a prospective randomized study. Tex Heart Inst J. 1997;24(3):193-9. PMID: 9339507; PMCID: PMC325442.	Wrong outcome: no relevant outcome measures reported
Mallory A, Giannopoulos S, Lee P, Kokkinidis DG, Armstrong EJ. Covered Stents for Endovascular Treatment of Aortoiliac Occlusive Disease: A Systematic Review and Meta-Analysis. Vasc Endovascular Surg. 2021 Aug;55(6):560-570. doi:	Wrong design: no comparison

10.1177/15385744211010381. Epub 2021 Apr 27. PMID: 33902342.	
Mwipatayi BP, Ouriel K, Anwari T, Wong J, Ducasse E, Panneton JM, de Vries JPM, Dave R. A systematic review of covered balloon-expandable stents for treating aortoiliac occlusive disease. J Vasc Surg. 2020 Oct;72(4):1473-1486.e2. doi: 10.1016/j.jvs.2020.01.084. Epub 2020 Apr 28. PMID: 32360678.	Wrong design: no comparison
Mwipatayi BP, Sharma S, Daneshmand A, Thomas SD, Vijayan V, Altaf N, Garbowski M, Jackson M; COBEST co-investigators. Durability of the balloon-expandable covered versus bare-metal stents in the Covered versus Balloon Expandable Stent Trial (COBEST) for the treatment of aortoiliac occlusive disease. J Vasc Surg. 2016 Jul;64(1):83-94.e1. doi: 10.1016/j.jvs.2016.02.064. Epub 2016 Apr 28. PMID: 27131926.	Wrong design: post-hoc follow up
Piazza M, Squizzato F, Dall'Antonia A, Lepidi S, Menegolo M, Grego F, Antonello M. Editor's Choice - Outcomes of Self Expanding PTFE Covered Stent Versus Bare Metal Stent for Chronic Iliac Artery Occlusion in Matched Cohorts Using Propensity Score Modelling. Eur J Vasc Endovasc Surg. 2017 Aug;54(2):177-185. doi: 10.1016/j.ejvs.2017.03.019. Epub 2017 May 6. PMID: 28487112.	Wrong design: retrospective
Piazza M, Squizzato F, Spolverato G, Milan L, Bonvini S, Menegolo M, Grego F, Antonello M. Outcomes of polytetrafluoroethylene-covered stent versus bare-metal stent in the primary treatment of severe iliac artery obstructive lesions. J Vasc Surg. 2015 Nov;62(5):1210-8.e1. doi: 10.1016/j.jvs.2015.05.028. Epub 2015 Aug 6. PMID: 26254822.	Wrong design: retrospective
Piffaretti G, Fargion AT, Dorigo W, Pulli R, Gattuso A, Bush RL, Pratesi C; ILIACS Registry Group. Outcomes From the Multicenter Italian Registry on Primary Endovascular Treatment of Aortoiliac Occlusive Disease. J Endovasc Ther. 2019 Oct;26(5):623-632. doi: 10.1177/1526602819863081. Epub 2019 Jul 22. PMID: 31331235.	Wrong design: retrospective
Salem M, Hosny MS, Francia F, Sallam M, Saratzis A, Saha P, Patel S, Abisi S, Zayed H. Management of Extensive Aorto-Iliac Disease: A Systematic Review and Meta-Analysis of 9319 Patients. Cardiovasc Intervent Radiol. 2021 Oct;44(10):1518-1535. doi: 10.1007/s00270-021-02785-6. Epub 2021 Mar 3. PMID: 34279686.	Wrong design: only included retrospective studies
Saratzis A, Argyriou A, Davies R, Bisdas T, Chaudhuri A, Torsello G, Stavroulakis K, Zayed H; COBRA collaborative. Editor's Choice - Covered vs. Bare Metal Stents in the Reconstruction of the Aortic Bifurcation:	Wrong design: retrospective

Early and Midterm Outcomes from the COBRA European Multicentre Registry. Eur J Vasc Endovasc Surg. 2022 May;63(5):688-695. doi: 10.1016/j.ejvs.2021.12.020. Epub 2022 Mar 22. PMID: 35337725.	
Serefli D, Saydam O, Engin AY, Atay M. Midterm results of kissing stent reconstruction of the aortoiliac bifurcation. Ann Surg Treat Res. 2021 Oct;101(4):247-255. doi: 10.4174/astr.2021.101.4.247. Epub 2021 Oct 1. PMID: 34692597; PMCID: PMC8506018.	Wrong design: retrospective
Squizzato F, Piazza M, Pulli R, Fargion A, Piffaretti G, Pratesi C, Grego F, Antonello M; ILIACS Registry Group. Covered versus bare metal kissing stents for reconstruction of the aortic bifurcation in the ILIACS registry. J Vasc Surg. 2021 Jun;73(6):1980-1990.e4. doi: 10.1016/j.jvs.2020.10.066. Epub 2020 Nov 28. PMID: 33253875.	Wrong design: retrospective

Zoekverantwoording

Algemene informatie

Richtlijn: Perifeer arterieel vaatlijden (PAV)	
Uitgangsvraag: Iliacaal: Bare metal stent versus gecoverde stent	
Database(s): Ovid/Medline, Embase.com	Datum: 20-04-2022, update op 15 februari 2023
Periode: geen restrictie	Talen: Engels, Nederlands
Literatuurspecialist: Ingeborg van Dusseldorp & 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 op 15 feb 2023 een update gedaan voor de SR en RCT.** **Hier kwamen 12 nieuwe resultaten uit.** → Voor deze vraag is gezocht op de elementen: • Iliac artery obstructie **AND** Covered stents • Iliofemoral artery stent grafts (dit leverde vrij weinig extra hits op en is dus meegenomen) → De drie sleutelartikelen worden gevonden met de search.	
Te gebruiken voor richtlijnen tekst: In de databases Embase.com en Ovid/Medline is op 20 april 2022 met relevante zoektermen gezocht naar systematische reviews, RCT en observationele studies. De literatuurzoekactie leverde 526 unieke treffers op. In de databases Embase.com en Ovid/Medline is op 20 april 2022 met relevante zoektermen gezocht naar systematische reviews, RCT en observationele studies. De initiële literatuurzoekactie leverde 526 unieke treffers op. Op 15 februari 2023 is de	

search geüpdatet voor systematische reviews en RCTs. Er werden 12 aanvullende hits gevonden.

Zoekopbrengst

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SRs	20	15	24
RCT	21	19	26
Observationele studies	303	361	476
Totaal	344	395	**526 + 12**

Zoekstrategie

Embase.com

No.	**Query**	**Results**
#12	#9 OR #10 OR #11	344
#11	#5 AND #8 NOT (#9 OR #10) **= Observationeel**	303
#10	#5 AND #7 NOT #9 **= RCT**	21
#9	#5 AND #6 **= SR**	20
#8	'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 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	14773047

	((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)))	
#7	'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
#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	(#3 OR #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)	774
#4	'iliofemoral artery stent graft'/exp OR 'lifestream (iliofemoral artery stent graft)':ti,ab,kw OR 'iliofemoral artery endovascular stent graft':ti,ab,kw OR 'iliofemoral artery endovascular stent-graft':ti,ab,kw OR 'iliofemoral artery stent graft':ti,ab,kw OR cobest:ti,ab,kw	36
#3	#1 AND #2	1257
#2	(((expand* OR cover*) NEAR/3 stent*):ti,ab,kw) OR cguard:ti,ab,kw	22550
#1	'iliac artery'/exp OR 'iliac artery obstruction'/exp OR (((ileac* OR aortoiliac*) NEAR/3 (obstruct* OR occlusi* OR stenos* OR ather?oscler* OR lesion* OR oblitera*)):ti,ab,kw) OR 'aortoiliac artery':ti,ab,kw OR 'arteria iliaca':ti,ab,kw OR 'ileal artery':ti,ab,kw OR 'iliac artery':ti,ab,kw OR 'ilial artery':ti,ab,kw	28500

Ovid/Medline

No.	Query	Results

15	12 or 13 or 14	395
14	(8 and 11) not (12 or 13) **= Observationeel**	361
13	(8 and 10) not 12 **= RCT**	19
12	8 and 9 **= SR**	15
11	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/ 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.))	6808962
10	(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.) not (animals/ not humans/)	1368304
9	(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	559720

	(search* or database* or data-base*)).ab. or (metasynthes* or meta-synthes*).ti,ab,kf.) not (comment/ or editorial/ or letter/ or ((exp animals/ or exp models, animal/) not humans/))	
8	(5 and 6) or 7	767
7	('iliofemoral artery endovascular stent graft' or 'iliofemoral artery endovascular stent-graft' or 'iliofemoral artery stent graft' or cobest).ti,ab,kf.	2
6	(Stents/ and (expand* or cover*).ti,ab,kf.) or ((expand* or cover*) adj3 stent*).ti,ab,kf. or cguard.ti,ab,kf.	16192
5	(exp iliac artery/ and exp Arterial Occlusive Diseases/) or ((ileac* or aortoiliac*) adj3 (obstruct* or occlusi* or stenos* or ather?oscler* or lesion* or oblitera*)).ti,ab,kf. or aortoiliac artery.ti,ab,kf. or arteria iliaca.ti,ab,kf. or ileal artery.ti,ab,kf. or iliac artery.ti,ab,kf. or ilial artery.ti,ab,kf.	14804

Module 5: Covered Endovascular Reconstruction of the Aortic Bifurcation (CERAB)

Evidence tabel

Niet van toepassing.

5

Risk of bias tabel

Niet van toepassing.

Exclusie tabel

Reference	Reason for exclusion
Indes JE, Mandawat A, Tuggle CT, Muhs B, Sosa JA. Endovascular procedures for aorto-iliac occlusive disease are associated with superior short-term clinical and economic outcomes compared with open surgery in the inpatient population. J Vasc Surg. 2010 Nov;52(5):1173-9, 1179.e1. doi: 10.1016/j.jvs.2010.05.100. Epub 2010 Aug 5. PMID: 20691560.	Wrong comparison
Piffaretti G, Fargion AT, Dorigo W, Pulli R, Gattuso A, Bush RL, Pratesi C; ILIACS Registry Group. Outcomes From the Multicenter Italian Registry on Primary Endovascular Treatment of Aortoiliac Occlusive Disease. J Endovasc Ther. 2019 Oct;26(5):623-632. doi: 10.1177/1526602819863081. Epub 2019 Jul 22. PMID: 31331235.	Wrong comparison
Rocha-Neves J, Ferreira A, Sousa J, Pereira-Neves A, Vidoedo J, Alves H, Teixeira J, Azevedo A. Endovascular Approach Versus Aortobifemoral Bypass Grafting: Outcomes in Extensive Aortoiliac Occlusive Disease. Vasc Endovascular Surg. 2020 Feb;54(2):102-110. doi: 10.1177/1538574419888815. Epub 2019 Nov 20. PMID: 31746273.	Wrong comparison
Mayor J, Branco BC, Chung J, Montero-Baker MF, Kougias P, Mills JL Sr, Gilani R. Outcome Comparison between Open and Endovascular Management of TASC II D Aortoiliac Occlusive Disease. Ann Vasc Surg. 2019 Nov;61:65-71.e3. doi: 10.1016/j.avsg.2019.06.005. Epub 2019 Aug 6. PMID: 31394230.	Wrong comparison
Squizzato F, D'Oria M, Bozza R, Porcellato L, Grego F, Lepidi S. Propensity-Matched Comparison of Endovascular versus Open Reconstruction for TASC-II C/D AortoIliac Occlusive Disease. A Ten-Year Single-Center Experience with Self-Expanding Covered Stents. Ann Vasc Surg. 2021 Feb;71:84-95. doi:	Wrong comparison

10.1016/j.avsg.2020.08.139. Epub 2020 Sep 11. PMID: 32927036.	
Fujimura N, Takahara M, Obara H, Ichihashi S, George RK, Igari K, Banno H, Hozawa K, Yamaoka T, Kian CJ, Tan JWH, Park K, Skyi PYC, Kato T, Kawarada O. Comparison of Aortobifemoral Bypass and Endovascular Treatment for Chronic Infrarenal Abdominal Aortic Occlusion From the CHAOS (CHronic Abdominal Aortic Occlusion, ASian Multicenter) Registry. J Endovasc Ther. 2023 Dec;30(6):828-837. doi: 10.1177/15266028221098710. Epub 2022 Jun 8. PMID: 35674459.	Wrong comparison
Smith AH, Beach JM, Dash S, Rowse J, Parodi FE, Kirksey L, Caputo FJ, Lyden SP, Smolock CJ. Comparison of Aortobifemoral Bypass to Aortoiliac Stenting with Bifurcation Reconstruction for TASC II D Aortoiliac Occlusive Disease. Ann Vasc Surg. 2022 May;82:120-130. doi: 10.1016/j.avsg.2021.10.040. Epub 2021 Nov 14. PMID: 34788703.	Wrong comparison
Colacchio EC, Squizzato F, Boemo DG, Grego F, Piazza M, Antonello M. Open Versus Endovascular Repair With Covered Stents for Complex Aortoiliac Occlusive Disease: Cost Analysis Results. Ann Vasc Surg. 2023 Nov;97:382-391. doi: 10.1016/j.avsg.2023.05.029. Epub 2023 Jun 1. PMID: 37268106.	Wrong comparison

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Perifeer arterieel vaatlijden - Covered Endovascular Reconstruction of the Aortic Bifurcation (CERAB)	
Uitgangsvraag/modules: Wat is de waarde van CERAB-behandeling bij patiënten met perifeer arterieel vaatlijden?	
Database(s): Embase.com, Ovid/Medline	Datum: 5-3-2024 en 7-2-2024
Periode: vanaf 2000	Talen: geen restrictie
Literatuurspecialist: Esther van der Bijl	Rayyan review: https://rayyan.ai/reviews/923258
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: Aorta/ iliacaal occlusie en Covered Endovascular Reconstruction of Aortic Bifurcation (CERAB) In overleg is in eerste instantie gezocht naar SR's en RCT's (7 februari 2024). Op 5 maart 2024 is de search uitgebreid. Er is gezocht met een sensitief RCT filter, wat 136 RCT's extra opleverde en een observationeel filter, wat 443 observationele studies opleverde. De studies zijn aan de search van 7 februari 2024 toegevoegd. → Het sleutelartikel PMID 34279686 wordt gevonden met deze search.	

Te gebruiken voor richtlijntekst: In de databases Embase.com en Ovid/Medline is op 7 februari 2024 systematisch gezocht naar systematische reviews en RCTs over de waarde van CERAB-behandeling bij patiënten met perifeer arterieel vaatlijden. Op 5 maart 2024 is deze search uitgebreid met observationele studies. Deze literatuurzoekactie leverde 579 nieuwe unieke treffers op. In toaal werden 663 unieke treffers gevonden.

Zoekopbrengst 5-3-2024

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	51	28	
RCT	137	70	**136**
Observationele studies	434	257	**443**
Rayyan (7-2-2024)			84
Totaal	622	355	663
Ontdubbeld t.o.v. Rayyan			663-84= **579***

****in Rayyan***

5 ***Zoekopbrengst 7-2-2024***

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	51	28	51
RCT	31	20	33
Totaal	82	48	**84***

****in Rayyan***

Zoekstrategie Embase.com 5-3-2024

No.	Query	Results
#1	'iliac artery occlusion'/exp OR 'leriche syndrome'/exp OR 'iliac artery stenosis'/exp OR (((iliac* OR bifurcat* OR aortoiliac) NEAR/3 (obstruct* OR occlus* OR embolism* OR 'obliterative disease*')):ti,ab,kw) OR 'leriche* syndrome':ti,ab,kw OR aiod:ti,ab,kw	7468
#2	'covered endovascular reconstruction of aortic bifurcation'/exp OR 'balloon expandable covered stent'/exp OR 'stent graft'/exp OR (((chimney OR endovascular) NEAR/3 (tevar OR repair OR sealing OR approach OR procedure* OR technique* OR method* OR surger*)):ti,ab,kw) OR ((endovascular NEAR/3 ('stent' OR 'graft*' OR stentgraft*)):ti,ab,kw) OR cerab:ti,ab,kw OR 'covered endovascular reconstruct*':ti,ab,kw OR chevar:ti,ab,kw OR chtevar:ti,ab,kw OR 'ch tevar':ti,ab,kw OR 'covered stent':ti,ab,kw	57182
#3	#1 AND #2	1474
#4	#3 AND [2000-2024]/py 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)	1047

#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	1006741
#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 controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	3983283
#7	'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)	8102467
#8	'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	14873230

	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)))	
#9	#4 AND #5 **– SR's**	51
#10	#4 AND #6 NOT #9 **– RCT's**	137
#11	#4 AND (#7 OR #8) NOT (#9 OR #10) **– Observationele studies**	434
#12	#9 OR #10 OR #11	622

Zoekstrategie Ovid/Medline 5-3-2024

#	Searches	Results
1	exp Leriche Syndrome/ or ((iliac* or bifurcat* or aortoiliac) adj3 (obstruct* or occlus* or embolism* or obliterative disease*)).ti,ab,kf. or leriche* syndrome.ti,ab,kf. or aiod.ti,ab,kf.	3937
2	(((chimney or endovascular) adj3 (tevar or repair or sealing or approach or procedure* or technique* or method* or surger*)) or (endovascular adj3 (stent or graft* or stentgraft*)) or cerab or covered endovascular reconstruct* or chevar or chtevar or ch tevar or covered stent).ti,ab,kf.	35689
3	1 and 2	613
4	limit 3 to yr="2000 -Current"	579
5	4 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	572
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.	729897
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	2697008

	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$3)).tw. or Placebos/ or placebo*.tw.	
8	Epidemiologic studies/ or case control studies/ or exp cohort studies/ or Controlled Before-After Studies/ or Case control.tw. or cohort.tw. or Cohort analy$.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]	4666418
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.))	5635417
10	5 and 6 **– SR's**	28
11	(5 and 7) not 10 **– RCT's**	70
12	(5 and (8 or 9)) not (10 or 11) **– Observationele studies**	257
13	10 or 11 or 12	355

Module 6: Femoro-popliteaal: Gecoate ballonnen en stents

Evidence tabel

Study reference	Study characteristics	Patient characteristics	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Koeckerling, 2023 Individual study characteristics and results are extracted from the individual studies.	SR and meta-analysis of RCTs *Literature search up to 10th of December 2020* Drug-coated balloon vs. balloon angioplasty **A**: ILLUMENATE Pivotal trial **B**: IN.PACT SFA trial	Inclusion criteria SR: -Randomized trials with active controls -comparing efficacy or safety endpoints between two or more of the following device-based interventions: BA, DCB, DES, BMS, covered stents with atherectomy	Intervention: **A-Q**: Drug-coated balloon **R-T**: Drug eluting stents	Control: **A-Q**: balloon angioplasty **R-T**: bare metal stents	End-point of follow-up: Maximum follow-up duration, n (%): -Short-term (<1y): 0 -Mid-term (1-2y): 20 (39%) -Long-term (>2y): 31 (61%) For how many participants were no complete outcome data available? Not reported.	Primary patency See Results. Target-lesion revascularization See Results. Major amputations See Results. All-cause mortality See Results.	Risk of bias (high, some concerns or low): Tool used by authors: revised Cochrane Risk-of-Bias 2 tool. **A**: Some concerns (randomization process, measurement of outcomes, overall bias) **B**: Low **C**: Low **D**: Low **E**: Some concerns (deviations from intended

	C: ILLUMENATE EU trial **D**: MDT-2113 **E**: RANGER SFA **F**: BIOPAC trial **G**: LEVANT-2 trial **H**: Ranger II trial **I**: Levant 1 **J**: FREEWAY trial **K**: THUNDER trial **L**: BIOLUX P-I **M**: FEMPAC trial **N**: PACIFIER trial **O**: Ye, 2021 **P**: Freeway-China trial **Q**: ISAR-STATH **R**: BATTLE trial	-Reporting exact porportions of participants with aortoiliac and femoropoplit eal disease -Primarily investigated de novo atherosclero tic lesions -Proportion of study participants with IC exceeded 70% or estimates for IC patients were provided separately <u>Exclusion criteria SR:</u>					interventions, overall bias) **F**: Some concerns (deviations from intended interventions, measurement of outcomes, overall bias) **G**: Low **H**: Some concerns (randomization process, overall bias) **I**: High (missing outcome data, overall bias), some concerns (measurement of outcomes) **J**: Some concerns (randomization process, deviations from intended interventions, missing outcome data, overall bias) **K**: High (missing outcome data, selection of reported results, overall bias),

	S: DEBATE in SFA trial **T**: Zilver PTX trial <u>Study design</u>: RCT <u>Setting and Country</u>: Single centre and multicentre studies in Asia, Europe, America and Australia. <u>Source of funding and conflicts of interest:</u> [commercial / non-commercial / industrial co-authorship]	Trials examining isolated infrapopliteal artery disease. *51 studies included in the SR* *20 studies included in this analysis* <u>Important patient characteristics at baseline</u>: <u>Age (median, IQR)</u> 68 (66-70) years *<u>Sex median % male (IQR)</u>:* 68% (63.5-72)					some concerns (measurement of outcomes) **L**: Some concerns (deviations from intended interventions, measurement of outcomes, overall bias) **M**: Some concerns (missing outcome data, measurement of outcomes, selection of reported results, overall bias) **N**: Some concerns (randomization process, overall bias) **O**: Low **P**: Some concerns (measurement of outcomes, overall bias) **Q**: High (missing outcome data, overall bias) **R**: Some concerns (deviations from intended

		<u>Diabetes median (IQR):</u> 37.5% (31.3-47.3) Groups comparable at baseline? Not reported.					interventions, missing outcome data, overall bias) **S**: Some concerns (missing outcome data, overall bias) **T**: High (deviations from intended interventions, missing outcome data, overall bias), some concerns (measurement of outcomes, selection of reported results) <u>Author's conclusion:</u> DCB angioplasty was associated with significantly higher primary patency and reduced TLR risk compared with BA in low-complexity, femoropopliteal lesions across all time points, primary BMS implantation was associated with statistically

							significant efficacy benefits over provisional stenting in non-complex femoropopliteal lesions at short- and mid-term follow-up, but not in long-term. No statistically significant differences in mid-term efficacy were observed for DES over BMS in femoropopliteal arteries, and there was no randomized evidence supporting stand-alone or adjunctive atherectomy over alternative endovascular strategies.

Study reference	**Study characteristics**	**Patient characteristics [2]**	**Intervention (I)**	**Comparison / control (C) [3]**	**Follow-up**	**Outcome measures and effect size [4]**	**Comments**

Liao, 2022 Orchid China ChiCTR 1900023619	Type of study: RCT Setting and country: Single center, China Funding and conflicts of interest: The author(s) received no financial support for the research, authorship, and/or publication of this article. The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or	<u>Inclusion criteria</u>: 18 to 85 years patients with de novo stenosis of at least 70% or occlusion lesions between 40 and 200mm long in the femoropopliteal artery, artery diameter at 4 to 8 mm, Rutherford category 2 to 5 in the target limb, and at least 1 non occluded vessel runoff to the foot. <u>Exclusion criteria</u>: (1) acute or subacute thrombus or aneurysm in the target vessel; (2) the guidewire failed to cross the target lesion; (3) severe flow-limiting dissections grade D) or residual stenosis	Orchid DCB (Acotec Scientific, Beijing, China) coated with paclitaxel at a dose of 3.0 lg/mm2 in a urea excipient	PTA (Admiral Xtreme uncoated balloon)	<u>Length of follow-up</u>: 12 months <u>Loss-to-follow-up</u>: I: 1/30 (missed visit) C:1/30 (missed visit) <u>Incomplete outcome data</u>: none	<u>Patency/restenosis</u> *Defined as primary patency at 12 months* I: 24/29 (82.8%) C: 15/29 (48.3%) <u>Re-intervention based on symptomatic restenosis</u> *Defined as clinically driven target lesion revascularization* I: 1/29, 3.5% C: 8/29, 27.6% <u>Quality of life</u> *Defined as change from baseline by EQ-5D Index* I: 0.092 ± 0.142 C: 0.085 ± 0.147 <u>Wound healing</u> Not reported <u>Amputation</u>	

	publication of this article.	>70% are generated after predilation; (4) serum creatinine >2.5 mg/dL; (5) allergy to aspirin, heparin, clopidogrel, paclitaxel, or contrast agent; (6) patients with bilateral lower limb lesions need to be treated at the same time; (7) prior bypass surgery or stent implantation of the target vessel; (8) planned amputation of the target limb; and (9) life expectancy <1 years. <u>N total at baseline</u>: Intervention: 30 Control: 30 <u>Important prognostic factors</u>[2]: *Age, mean ± SD:* *I: 69.2±9.0* *C: 68.3±8.6*				*Defined as target limb major amputation* I: 0/29 C: 0/29 <u>Mortality</u> *Defined as limb related death* I: 0/29 C: 0/29	

		Sex: *I: 60% M* *C: 67% M* *Diabetes* *I: 46.7%* *C: 53.3%* *Rutherford class 2* *I: 20.0%* *C: 26.7%* *Rutherford class 3* *I: 40.0%* *C: 33.3%* *Rutherford class 4* *I: 33.3%* *C: 36.7%* *Rutherford class 5* *I: 6.7%* *C: 3.3%* Groups were comparable at baseline					
Lyden, 2022 ILLUMENATE Pivotal	Type of study: RCT	Inclusion criteria: Specified in previous publication.	Stellarex (Spectranetics LLC, Colorado Springs, CO,	POBA	Length of follow-up: 4 years	Patency/restenosis *Defined as primary patency at 36 months*	

NCT 01858428	Setting and country: multicenter, US and EU Funding and conflicts of interest: The author(s) disclosed receipt of the following financial support for the research, authorship and/or publication of this article: This trial was originally funded by Covidien who divested of the product to Spectranetics when acquired by Medtronic. Spectranetics	<u>Exclusion criteria</u>: Specified in previous publication. <u>N total at baseline</u>: Intervention: 200 Control: 100 <u>Important prognostic factors</u>[2]: *Age, mean:* *I: 68.3* *C: 69.8* *Sex:* *I: 56.0% M* *C: 64.0% M* *Diabetes* *I: 49.5%* *C: 52.0%* Groups were comparable at baseline.	an affiliate of Philips North America LLC, ambridge, MA) drug-coated angioplasty balloon		<u>Loss-to-follow-up</u>: Not specified <u>Incomplete outcome data</u>: Not specified	I: 64.2% (Kaplan-Meier) C: 51.0% at 36 months, 24.5% of DCB subjects and 13.0% of PTA subjects had missing data. <u>Re-intervention based on symptomatic restenosis</u> *Defined as freedom from CD-TLR* I: 76.7%, 95% CI = 69.8%–82.3% C: 71.0%, 95% CI = 60.5%–79.2% <u>Quality of life</u> Not reported <u>Wound healing</u> Not reported <u>Amputation</u> *Defined as major amputation* I: 1/153	

	was then acquired by Covidien, then Philips. The company and the National Co-PIs were responsible for design and conduct of the study, in the collection, analysis, interpretation of the data, and in the preparation, review and approval of the manuscript. The author(s) declared numerous potential conflicts of interest with respect to the research, authorship,					C: 0/77 All-cause mortality 36 months I: 19/199, 9.5% C: 10/96, 10.4% 48 months I: 30/192, 15.6% C: 14/92, 15.2%	

	and/or publication of this article (list too long to include in table).						
Hausegger, 2024 Freeway Stent Study	Type of study: RCT Setting and country: Multicenter, Germany and Austria Funding and conflicts of interest: This study was funded by Eurocor GmbH. S. Stahnke and J. Dambach were employees of Eurocor Tech GmbH, the other authors declare that	<u>Inclusion criteria</u>: Specified in previous publication. <u>Exclusion criteria</u>: Specified in previous publication. <u>N total at baseline</u>: Original RCT Intervention: 105 Control: 99 Present study I: 76 C: 74 <u>Important prognostic factors</u>[2]: *Age, mean ± SD:* *I: 65.5±9.5* *C: 64.8±9.3* *Sex:* *I: 76.0% M*	Nitinolstent plus FREEWAY drug-eluting balloon postdilatation. Reopening of original study Reasons for loss to follow-up compared to original study unclear	Nitinolstent plus non-paclitaxel PTA postdilatation.	<u>Length of follow-up</u>: 5-year follow-up <u>Loss-to-follow-up</u>: Not applicable <u>Incomplete outcome data</u>: Intervention: N=1 (1.3%) Reasons: missing vital data Control: N=1 (1.4%) Reasons: missing vital data	<u>Patency/restenosis</u> *Defined as rate of combined stent stenosis and very late stent thrombosis at 5 years* I: 18.0% C: 22.9% <u>Re-intervention based on symptomatic restenosis</u> *Defined as freedom from clinically driven target lesion revascularization at 5 years* I: 85.3% C:72.7% HR 0.48 (95% CI 0.25 to 0.93)	Author's conclusion: The present study did not find a mortality signal as seen in the 2018 meta-analysis data. To date, no plausible biological mechanism ahs been identified to explain the mortality, and no cause of death was found to be associated with the use of paclitaxel at doses administered with drug eluting devices. The efficacy results clearly demonstrate the clinical benefit of drug-eluting balloon treatment over a 5 year period.

	they have no conflict of interest.	*C: 78.1% M* *Diabetes* *I: 26.7%* *C: 27.4%* *Rutherford class:* *Not reported.* Groups were comparable at baseline.				Quality of life *Not reported.* Wound healing *Not reported.* Amputation *Defined as freedom from major or minor amputation* I: 97.1% C: 100.0% Mortality *Defined as all-cause mortality at 5 years* I: 12.0% C: 15.0% RR 0.81 (95% CI 0.35 to 1.90)	
Ni, 2022 NCT 03844724	Type of study: RCT Setting and country: multicenter, China	Inclusion criteria: 18–85 years of age had severe intermittent claudication or ischemic rest pain or minor tissue loss (Rutherford Clinical Category 3–5); stenosis of 70–99% with lesion lengths ≤30 cm, or a complete occlusion with	ZENFlow paclitaxel-coated balloon (PCB) catheter (Zylox Medical Device Inc., Zhejiang, China), a carrier-free	uncoated balloon	Length of follow-up: 12 months Loss-to-follow-up: I: 3/93 C: 6/99	Patency/restenosis *Defined as primary patency at 12 months* I: 54.0 (34/63) C: 31.3 (21/67) Re-intervention based on	Authors' conclusions: In conclusion, in this prospective, multicenter, randomized trial, the novel ZENFlow PCB was superior to standard PTA and had a favorable safety profile in

	Funding and conflicts of interest: No funding specified. The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.	lengths of ≤10 cm involving the superficial femoral or popliteal arteries (or both). <u>Exclusion criteria</u>: (1) acute thrombus in the target vessels; (2) severe renal or hepatic dysfunction; (3) known contraindication or allergy to aspirin, clopidogrel, heparin, or paclitaxel; (4) life expectancy <1 year; (5) vessel stenosis or occlusion due to Buerger's disease or autoimmune arteritis; (6) pregnancy; and (7) immunosuppressive agent therapy. <u>N total at baseline</u>: Intervention: 93 Control: 99 <u>Important prognostic factors</u>[2]: *Age, mean ± SD:*	DCB coated with paclitaxel (3 µg/mm2 ± 1 µg/mm2)		<u>Incomplete outcome data</u>: Not specified	<u>symptomatic restenosis</u> *Defined as CD-TLR at 6 months* I: 5.4 (5/93) C: 19.2 (19/99) <u>Quality of life</u> Not reported <u>Wound healing</u> Not reported <u>Amputation</u> *Defined as target limb major amputation* I: 0 (0) C: 1 (1.0) <u>All-cause mortality at 12 months</u> I: 3 (3.2) C: 2 (2.0)	patients with symptomatic femoropopliteal artery disease.

		I: 68.8 ± 8.3 *C: 68.1 ± 10.5* *Sex:* *I: 72.0% M* *C: 71.7% M* *Diabetes* *I: 49.5%* *C: 46.5%* *Rutherford class 3* *I: 67.7%* *C: 67.7%* *Rutherford class 4* *I: 18.3%* *C: 22.2%* *Rutherford class 5* *I: 14.0%* *C: 10.1%* Groups were comparable at baseline.					
Gouëffic, 2022 EMINENT study	Type of study: RCT Setting and country: 10	<u>Inclusion criteria</u>: All the following inclusion criteria were required to be met: presentation with	Eluvia DES, a self-expanding nitinol stent coated with a	BMS, self-expanding bare nitinol stents.	<u>Length of follow-up</u>: 12 months	<u>Patency/restenosis</u> *Defined as peak systolic velocity ratio ≤2.4 at the 12 month visit in the*	Authors' conclusion: Eluvia is the first DES to demonstrate superior 1-year primary patency

	European countries (Austria, Belgium, France, Germany, Ireland, Italy, Spain, Switzerland, The Netherlands, the United Kingdom) Funding and conflicts of interest: The study was funded and sponsored by Boston Scientific Corp, Marlborough MA. Dr. Gouëffic has received research funding as	Rutherford category 2, 3 or 4 symptomatology; lesions in the native SFA or proximal popliteal artery with stenosis ≥70% by visual angiographic assessment; vessel diameter of 4 to 6 mm; and total lesion length of 30 to 210 mm. <u>Exclusion criteria</u>: Presence of any of the following exclusion criteria justified exclusion: dialysis treatment; target lesion or vessel previously treated with a drug-coated balloon within the prior 12 months or previously stented; prior SFA or proximal popliteal artery surgery in target limb; heavy calcification; and intraprocedural use of atherectomy, laser, or other debulking devices.	fluorinated polymer and paclitaxel at a dose density of 0.167 µg/mm^2 stent surface area. (stent length 150mm until November 2017, from November 2017 stent length 120 mm).		<u>Loss-to-follow-up</u>: Intervention: N=32 (6.3%) Reasons: withdrew (n=20), died (n=12) Control: N=12 (4.5%) Reasons: withdrew (n=8), died (n=3) <u>Incomplete outcome data</u>: Intervention: N=23 (4.5%) Reasons: missed visit/no data/out of window Control: N=7 (2.6%)	*absence of clinically driven target lesion revascularization or bypass of the target lesion* I: 83.2% (337/405) C: 74.3% (165/222) Difference 8.9% (95% CI 2.1 to 15.7) <u>Re-intervention based on symptomatic restenosis</u> *Defined as target lesion revascularization* I: 8.9% (42/474) C: 10.6% (28/263) Difference -1.8% (-6.3 to 2.7) <u>Quality of life</u> *Defined as health related quality of life (EuroQol 5-dimension 5-level questionnaire). Percentages of*	compared with any globally marketed BMS in an adequately designed randomized trial. The trial supports the benefit of a polymer-based paclitaxel-eluting stent for treating SFA or proximal popliteal artery lesions of intermediate length.

	well as personal fees and grants. Dr. Torsello, Dr. Zeller, Dr. Vermassen, Dr. Tepe, Dr. Kahlberg, Dr. Schindewolf, Dr. Sapoval, Dr. Diaz-Cartelle, and Dr. Stavroulakis received grants, travel grants, honoraria, or funding too.	<u>N total at baseline</u>: Intervention: 508 Control: 267 <u>Important prognostic factors</u>[2]: *Age, mean ± SD:* *I: 68.9±8.7* *C: 68.9±9.1* *Sex:* *I: 71.5% M* *C:67.4 % M* *Diabetes (medically-treated)* *I: 31.9%* *C: 32.6%* *Rutherford class 2* *I: 29.6%* *C: 35.2%* *Rutherford class 3* *I: 66.3%* *C: 62.2%* *Rutherford class 4* *I: 3.6%*			Reasons: missed visit/no data/out of window	*patients with improved scores at 12 months.* **Mobility** I: 66.4% (295/444) C: 64.2% (158/246) **Self-care** I: 8.8% (39/445) C: 7.7% (19/246) **Usual activities** I: 38.0% (169/445) C: 37.0% (91/246) **Pain/discomfort** I: 53.6% (238/444) C: 58.1% (143/246) **Anxiety/depression** I: 22.5% (100/444) C: 20.0% (49/245) <u>Wound healing</u> Not reported. <u>Amputation</u> *Defined as target limb major amputation* I: 0.2% (1/474) C: 0.0% (0/263) Difference 0.2% (-0.2 to 0.6)	

		C: 2.6% *Rutherford class 5* *I: 0.4%* *C: 0.0%* Groups were comparable at baseline.				<u>All-cause mortality</u> I: 2.7% (13/474) C: 1.1% (3/263) Difference 1.6% (-0.3 to 3.6)	
Teichgräber, 2022 EffPac trial	Type of study: RCT Setting and country: 11 German sites. Funding and conflicts of interest: Open Access funding enabled and organized by Projekt DEAL. The study was supported by iVascular S.L.U., Barcelona, Spain and Endoscout,	<u>Inclusion criteria</u>: 1. Age ≥ 18 years 2. Subject must agree to undergo the 6-month angiographic and clinical follow-up (at 12- and 24 months post-procedure) 3. Peripheral vascular disease Rutherford class 2-4 4. De novo stenotic/ re-stenotic lesion or occlusive lesions in the superficial	Luminor 35 DCB catheter (iVascular). Coated with paclitaxel at a surface concentration of 3 µg/mm^2 and an organic ester excipient.	Uncoated balloon catheters.	<u>Length of follow-up</u>: 5 years <u>Loss-to-follow-up</u>: Until 6 months Intervention: N=9 (10.6%) Reasons: withdrawal Control: N=10 (11.6%) Reasons: withdrawal (n=8), death (n=2)	<u>Patency/restenosis</u> *Defined as absence of >50% diameter restenosis of the target lesion by angiography or a peak systolic velocity ratio at <2.4 by duplex ultrasonography without the need for TLR.* I: 61.4% C: 53.5% <u>Re-intervention based on symptomatic restenosis</u> *Defined as: freedom from clinically driven*	Authors' conclusion: Long-term follow-up of the EffPac trial showed superiority in terms of primary patency after femoropopliteal Luminor 35 DCB angioplasty compared to POBA over a period of 5 years. This finding was reflected by freedom from TLR, however, no longer with a significant difference. Femoropopliteal Luminor 35 DCB angioplasty is a sustainably

	Freiburg, Germany. UT is a consultant for iVascular. TZ is coprincipal investigator of the ILICO study, a study sponsored by iVascular. Other authors declare no conflict of interest.	femoral (SFA) and/or popliteal arteries (PA) 5. If the index lesion is re-stenotic, the prior PTA must have been >30 days prior to treatment in the current study 6. ≥70% diameter stenosis or occlusion 7. Target lesion length: ≤15 cm 8. Only one lesion per limb and per patient can be treated 9. ≥ one patent infrapopliteal run-off artery to the index limb foot 10. Successful endoluminal guidewire passage			6 months – 1 year Intervention: N=1 (1.2%) Reasons: death Control: N=0 (0%) 1 year – 2 years Intervention: N=15 (17.6%) Reasons: withdrawal Control: N=20 (23.3%) Reasons: missed visits (n=2), withdrawal (n=18) 2 years – 42 months Intervention:	*target lesion revascularization (CD-TLR) at five years* I: 82.1% C: 73.7% <u>Quality of life</u> Not reported. <u>Wound healing</u> Not reported. <u>Amputation</u> *Defined as major target limb amputation* I: 0/49 C: 2% (1/51) <u>All-cause death:</u> I: 11% (9/80) C: 16% (14/86)	efficacious and safe treatment approach.

		through the target lesion 11. Pre-dilatation prior to randomization 12. Life expectancy, in the investigators' opinion of at least one year 13. Subject can verbally acknowledge and understand the aim of this trial and is willing and able to provide informed consent. <u>Exclusion criteria</u>: 1. Previous surgery in the target vessel 2. Patients who require a PTA balloon catheter in diameter size 4 mm or in diameter size greater 7 mm.			N=8 (9.4%) Reasons: missed visit (n=1), withdrawal (n=5), death (n=2) Control: N=7 (8.1%) Reasons: missed visit (n=2), death (n=5) 42 months – 5 years Intervention: N=6 (7.1%) Reasons: death Control: N=7 (8.1%) Reasons: death <u>Incomplete outcome data</u>:		

		3. Major amputation in the same limb as the target lesion 4. Acute myocardial infarction within 30 days before intervention 5. Severely calcified target lesions in the SFA/PA resistant to PTA 6. Subjects requiring different treatment or raising serious safety concern regarding the procedure or the required medication 7. Women of childbearing potential except women with the following criteria: -post-menopausal (12 months natural amenorrhea or 6 months amenorrhea with serum FSH > 40mIU/ml)			Not reported.		

		-sterilization after bilateral ovariectomy with or without hysterectomy -using an effective method of birth control for the duration of the trial: implants, injectables, combined oral contraceptives, intrauterine device (in place for a period of at least 2 months prior to screening) and with negative serum pregnancy test -sexual abstinence -vasectomy partner 8. Pregnant and nursing women 9. Acute thrombus aneurysm in the index limb or vessel 10. In-stent restenosis in the target lesion 11. Renal insufficiency with a serum creatinine >2.0 mg/dL at baseline					

		12. Platelet count <50 G/l or >600 G/l at baseline 13. Known hypersensitivity or contraindication to contrast agent that cannot be adequately pre-medicated 14. Subjects with known allergies against paclitaxel 15. Subjects with intolerance to antiplatelet, anticoagulant, or thrombolytic medications that would be administered during the trial 16. Dialysis or long-term immunosuppressant therapy 17. Current participation (or within the last 3 months) in another					

		interventional study. <u>N total at baseline</u>: Intervention: 85 Control: 86 <u>Important prognostic factors</u>[2]: *Age, mean ± SD:* *I: 68 ± 8* *C: 68 ± 9* *Sex:* *I: 60% M* *C: 70% M* *Diabetes* *I: 36%* *C: 41%* *Rutherford class 2* *I: 15%* *C: 21%* *Rutherford class 3* *I: 81%* *C: 78%* *Rutherford class 4*					

		I: 2% *C: 1%* *Rutherford class 5* *I: 1%* *C: 0%* Groups were comparable at baseline					
Fransson, 2023	Type of study: RCT Setting and country: Sweden Funding and conflicts of interest: supported by the Cook Medical, with limited unrestricted support. The authors and corresponding institution are solely responsible	<u>Inclusion criteria</u>: CLTI and lesions in the SFA and first part of PA (P1-P2), target vessel diameter 4-8 mm and at least one crural artery patent to the foot. <u>Exclusion criteria</u>: Age <18 years, ongoing or planned pregnancy, and patient unwillingness to participate. <u>N total at baseline</u>: Intervention: 27 Control: 22 <u>Important prognostic factors</u>[2]:	Zilver Flex DES (Drug eluting stents)	Zilver Flex BMS (Bare metal stents)	<u>Length of follow-up</u>: 24 months (national mortality records were monitored up to 5 years) <u>Loss-to-follow-up</u>: Intervention: N=3 (11.1%) Reasons: death Control: N=4 (18.2%)	<u>Patency/restenosis</u> *Defined as primary patency 12 months* I: 44% (12/27) C: 41% (9/22) *Defined as primary patency 24 months* I: 33% (9/27) C: 41% (9/22) <u>Re-intervention based on symptomatic restenosis</u> *Defined as target lesion revascularization 12 months* I: 37% (10/27) C: 27% (6/22)	Authors' conclusion: This study could not demonstrate superiority of DES compared to BMS in the treatment of long FP lesions in patients with CLTI, but was limited by insufficient patient inclusion.

	for data collection and interpretation. The authors declared no potential conflicts of interest.	*Age, median (IQR):* *I: 74 (68-79)* *C: 76 (70-80)* *Sex:* *I: 56% M* *C: 50% M* *Diabetes* *I: 59%* *C: 41%* *Rutherford Class, median (IQR):* *I: 5 (4-5)* *C: 5 (4-5)* Groups were comparable at baseline.			Reasons: death <u>Incomplete outcome data</u>: Not reported.	*Defined as target lesion revascularization 24 months* I: 41% (11/27) C: 36% (8/22) <u>Quality of life</u> Not reported. <u>Wound healing</u> Not reported. <u>Amputation</u> *Defined as amputation rate 24 months* I: 15% (4/27) C: 0% <u>Mortality:</u> *Defined as mortality 2 years* I: 11% (3/27) C: 18% (4/22) *Defined as mortality 5 years* I: 22% (6/27)	

						C: 23% (5/22)	

Risk of bias tabel

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?** Definitely yes	**Was the allocation adequately concealed?** Definitely yes Probably yes	**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	**Are reports of the study free of selective outcome reporting?**	**Was the study apparently free of other problems that could put it at a risk of bias?** Definitely yes Probably yes	**Overall risk of bias** **If applicable/necessary, per outcome measure**

	Probably yes Probably no Definitely no	Probably no Definitely no		Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	Probably no Definitely no	**LOW** **Some concerns** **HIGH**
Liao, 2022	Definitely yes Reason: The randomization sequence was computer-generated.	Probably yes Reason: The randomization sequence was only opened after angiographic confirmation that the patient met all inclusion criteria and none of the exclusion criteria.	**Definitely no** Reason: The treating physicians were aware of the treatment choice because the DCBs looked different from uncoated balloons. Patients, follow-up investigators, laboratory personnel and evaluators were unaware of treatment choices.	Definitely yes Reason: Loss to follow-up was infrequent in intervention and control group.	Definitely yes Reason: All relevant outcomes were reported.	**Probably no** Reason: Limited number of patients enrolled, restricted to Chinese patients. Longer-term follow-up is needed.	LOW (all outcomes)
Lyden, 2022	No information	No information	**Definitely no** Reason: Imaging core laboratories and clinical events committee were blinded, the operator could not be blinded to	No information	Definitely yes Reason: All relevant outcome measures	**Probably no** Reason: The trial was underpowered to detect differences on	HIGH (all outcomes)

			the treatment of the patient.		were reported.	any individual endpoint, and hence exposed to type II error. The results from the study are not directly generalizable to other DCBs.	
Hausegger, 2024	No information	**Probably no** Reason: randomization with envelopes, but the study was open.	**Definitely no** Reason: Open, randomized study.	Definitely yes Reason: Loss-to-follow-up was infrequent (approximately 1%) in both the intervention and control group.	Definitely yes Reason: All relevant outcome measures were reported.	**Definitely no** Reason: The study was a reopening of a former RCT, recontacting patients by telephone or during a routine check-up. The original study was not powered for statistical analysis of 5-year mortality or TLR between the two treatment arms.	HGH (all outcomes)

Ni, 2022	Definitely yes Reason: Randomization was computer-generated.	Definitely yes Reason: The generated numbers were sealed in envelopes, which were only opened after the evaluation of the target lesions.	**Definitely no** Reason: Due to visual differences the treating physician and catheterization laboratory staff were not blinded to the treatment assignment. The patients and radiologist/sonographer were blinded.	Definitely yes Reason: Loss-to-follow-up was infrequent in intervention and control group.	Definitely yes Reason: All relevant outcome measures were reported.	**Probably no** Reason: number of patients who agreed to angiography and duplex ultrasound was less than optimal, higher prevalence of longer lesion length in the DCB group, short follow-up duration.	LOW (all outcomes)
Gouëffic, 2022	Probably yes Reason: Randomization was stratified by study site and lesion length. For each site, a computer-generated list of random treatment allocations	**Probably no** Reason: No information.	**Definitely no** Reason: study staff were not blinded. Site personnel conducting clinical follow-up assessments were blinded whenever possible, patients were blinded, and core laboratory personnel and the CEC were blinded.	**Definitely no** Reason: Loss-to-follow-up was 10.8% in the intervention group, and 7.1% in the control group.	Definitely yes Reason: All relevant outcome measures were reported.	**Probably no** Reason: poor presentation of women and populations that are not White. The study reflects common practice in a limited geographic region. A pooled comparator	HIGH (all outcomes)

	using random permuted blocks of various sizes within each stratum was used.					group design was used. Follow-up occurred during COVID-19, which affected clinical trial conduct.	
Teichgräber, 2022	No information	No information	**Probably no** Reason: participants and core laboratory staff members were blinded. No information about blinding of treating physicians.	**Definitely no** Reason: Loss-to-follow-up was above 10% in both the intervention and control group within 1 year.	Definitely yes Reason: All relevant outcome measures were reported.	**Probably no** Reason: The study was not powered to assess a difference in long-term all-cause mortality. The results cannot be transferred automatically to other DCB types.	HIGH (all outcomes)
Fransson, 2023	No information Reason: the staff performed randomization.	Definitely yes Reason: Randomization was performed with blinded envelopes.	**Definitely no** Reason: The treating physician and staff were not blinded, patients were blinded.	**Definitely no** Reason: Loss to follow-up was 11.1% in the intervention group and 18.2% in the control group.	Definitely yes Reason: All relevant outcome measures were reported.	**Definitely no** Reason: Limited number of patients (underpowered), relative high rate of technical failure, non-	Some concerns (all outcomes)

						consecutive randomization because patients were treated without being included in the study.	

Exclusie tabel

Reference	Reason for exclusion
Briody H, Kearns CA, Lee MJ. Mortality, Safety, and Effectiveness of Paclitaxel-Containing Balloons and Stents in the Femoropopliteal Artery: Systematic Review and Meta-Analysis of Randomized Controlled Trials since 2018. J Vasc Interv Radiol. 2024 Feb 28:S1051-0443(24)00198-2. doi: 10.1016/j.jvir.2023.12.574. Epub ahead of print. PMID: 38428483.	More complete SR used
Cao S, He T, Xie J, Feng H, Liu K, Qu B, Wu X. Drug-coated balloon angioplasty versus balloon angioplasty for treating patients with in-stent restenosis in the femoropopliteal artery: A meta-analysis. Medicine (Baltimore). 2021 Apr 23;100(16):e25599. doi: 10.1097/MD.0000000000025599. PMID: 33879723; PMCID: PMC8078449.	Wrong P: in-stent restenosis
Diehm N, Schneider H. Cost-effectiveness analysis of paclitaxel-coated balloons for endovascular therapy of femoropopliteal arterial obstructions. J Endovasc Ther. 2013 Dec;20(6):819-25. doi: 10.1583/13-4416R.1. PMID: 24325699.	More complete SR used
Dinh K, Limmer AM, Chen AZL, Thomas SD, Holden A, Schneider PA, Varcoe RL. Mortality Rates After Paclitaxel-Coated Device Use in Patients With Occlusive Femoropopliteal Disease: An Updated Systematic Review and Meta-Analysis of Randomized Controlled Trials. J Endovasc Ther. 2021 Oct;28(5):755-777. doi: 10.1177/15266028211023505. Epub 2021 Jun 9. PMID: 34106028.	More complete SR used
D'Oria M, Mastrorilli D, Secemsky E, Behrendt CA, Veraldi G, DeMartino R, Mani K, Budtz-Lilly J, Scali S, Saab F, Calvagna C, Mezzetto L, Ruaro B, Lepidi S. Robustness of Longitudinal Safety and Efficacy After Paclitaxel-Based Endovascular Therapy for Treatment of Femoro-Popliteal Artery Occlusive Disease: An Updated Systematic Review and Meta-Analysis of Randomized Controlled Trials. Ann Vasc Surg. 2024 Apr;101:164-178. doi: 10.1016/j.avsg.2023.11.024. Epub 2023 Dec 26. PMID: 38154491.	More complete SR used
Duda SH, Pusich B, Richter G, Landwehr P, Oliva VL, Tielbeek A, Wiesinger B, Hak JB, Tielemans H, Ziemer G, Cristea E, Lansky A, Bérégi JP. Sirolimus-eluting stents for the treatment of obstructive superficial femoral artery disease: six-month results. J Invasive Cardiol. 2004 Jan;16 Suppl A:15A-19A. PMID: 23573600.	Wrong intervention
He Z, Wang H, Lin F, Ding W, Chen K, Zhang Z. The safety and efficacy of different endovascular	Wrong P: in-stent restenosis

treatments for in-stent restenosis of the femoropopliteal artery: A network meta-analysis. Vasc Med. 2022 Jun;27(3):239-250. doi: 10.1177/1358863X211070327. Epub 2022 Feb 15. PMID: 35164613.	
Katsanos K, Spiliopoulos S, Teichgräber U, Kitrou P, Del Giudice C, Björkman P, Bisdas T, de Boer S, Krokidis M, Karnabatidis D. Editor's Choice - Risk of Major Amputation Following Application of Paclitaxel Coated Balloons in the Lower Limb Arteries: A Systematic Review and Meta-Analysis of Randomised Controlled Trials. Eur J Vasc Endovasc Surg. 2022 Jan;63(1):60-71. doi: 10.1016/j.ejvs.2021.05.027. Epub 2021 Jul 27. PMID: 34326002.	More complete SR used
Katsogridakis E, Ballance L, Cawley O, Antoniou GA. Drug-eluting stents for the treatment of complex femoro-popliteal disease: a systematic review and meta-analysis. J Cardiovasc Surg (Torino). 2022 Jun;63(3):299-307. doi: 10.23736/S0021-9509.18.10614-8. Epub 2018 Aug 29. PMID: 30168308.	More complete SR used
Li M, Tu H, Yan Y, Guo Z, Zhu H, Niu J, Yin M. Meta-analysis of outcomes from drug-eluting stent implantation in femoropopliteal arteries. PLoS One. 2023 Sep 21;18(9):e0291466. doi: 10.1371/journal.pone.0291466. PMID: 37733656; PMCID: PMC10513203.	More complete SR used
Mao J, Sedrakyan A, Goodney PP, Malone M, Cavanaugh KJ, Marinac-Dabic D, Eldrup-Jorgensen J, Bertges DJ; Society for Vascular Surgery Vascular Quality Initiative and the Vascular Implant Surveillance and Interventional Outcomes Network. Editor's Choice - Real World Study of Mortality After the Use of Paclitaxel Coated Devices in Peripheral Vascular Intervention. Eur J Vasc Endovasc Surg. 2023 Jan;65(1):131-140. doi: 10.1016/j.ejvs.2022.08.014. Epub 2022 Aug 23. PMID: 36007713; PMCID: PMC9839562.	More complete SR used
Nowakowski P, Uchto W, Hrycek E, Kachel M, Ludyga T, Polczyk F, Żurakowski A, Kaźmierczak P, Granada JF, Nowakowska I, Kiesz RS, Milewski KP, Buszman PE, Buszman PP. Microcrystalline paclitaxel-coated balloon for revascularization of femoropopliteal artery disease: Three-year outcomes of the randomized BIOPAC trial. Vasc Med. 2021 Aug;26(4):401-408. doi: 10.1177/1358863X20988360. Epub 2021 Mar 9. PMID: 33686879.	In SR
Park JI, Ko YG, Lee YJ, Lee SJ, Hong SJ, Ahn CM, Kim JS, Kim BK, Hong MK, Yu CW, Rha SW, Park JK, Min PK, Yoon CH, Lee SR, Park SH, Choi DH. Long coverage with drug-eluting stents is superior to spot coverage	Wrong comparison

for long femoropopliteal artery disease: PARADE II study. Front Cardiovasc Med. 2022 Oct 19;9:1022071. doi: 10.3389/fcvm.2022.1022071. PMID: 36337904; PMCID: PMC9626975.	
Pecoraro F, Dinoto E, Pakeliani D, Mirabella D, Ferlito F, Bajardi G. Efficacy and one-year outcomes of Luminor® paclitaxel-coated drug-eluting balloon in the treatment of popliteal artery atherosclerosis lesions. Ann Vasc Surg. 2021 Oct;76:370-377. doi: 10.1016/j.avsg.2021.04.015. Epub 2021 May 2. PMID: 33951533.	?
Sachar R, Soga Y, Ansari MM, Kozuki A, Lopez L, Brodmann M, Schroë H, Ramanath VS, Diaz-Cartelle J, Zeller T; RANGER II SFA Investigators. 1-Year Results From the RANGER II SFA Randomized Trial of the Ranger Drug-Coated Balloon. JACC Cardiovasc Interv. 2021 May 24;14(10):1123-1133. doi: 10.1016/j.jcin.2021.03.021. PMID: 34016410.	In SR
Shishehbor MH, Scheinert D, Jain A, Brodmann M, Tepe G, Ando K, Krishnan P, Iida O, Laird JR, Schneider PA, Rocha-Singh KJ, Zeller T. Comparison of Drug-Coated Balloons vs Bare-Metal Stents in Patients With Femoropopliteal Arterial Disease. J Am Coll Cardiol. 2023 Jan 24;81(3):237-249. doi: 10.1016/j.jacc.2022.10.016. Epub 2022 Nov 1. PMID: 36332764.	Wrong comparison
Sun G, Liu J, Jia S, Zhang J, Zhuang B, Jia X, Fu W, Wu D, Wang F, Zhao Y, Guo P, Bi W, Wang S, Guo W; AcoArt I Trial Investigators. Comparison of drug-coated balloon angioplasty versus uncoated balloon angioplasty in treatment of total occlusions with severe femoropopliteal lesions: An additional analysis from the AcoArt I study. Vascular. 2021 Jun;29(3):340-349. doi: 10.1177/1708538120953663. Epub 2020 Sep 9. PMID: 32903168.	Wrong study design
Taneva GT, Pitoulias GA, Abu Bakr N, Kazemtash M, Muñoz Castellanos J, Donas KP. Assessment of Sirolimus- vs. paCLitaxEl-coated balloon angioPlasty In atherosclerotic femoropopliteal lesiOnS (ASCLEPIOS Study): preliminary results. J Cardiovasc Surg (Torino). 2022 Feb;63(1):8-12. doi: 10.23736/S0021-9509.21.12169-X. PMID: 35179337.	Preliminary results
Tepe G, Schnorr B, Albrecht T, Brechtel K, Claussen CD, Scheller B, Speck U, Zeller T. Angioplasty of femoral-popliteal arteries with drug-coated balloons: 5-year follow-up of the THUNDER trial. JACC Cardiovasc Interv. 2015 Jan;8(1 Pt A):102-8. doi: 10.1016/j.jcin.2014.07.023. PMID: 25616822.	In SR
Ullah W, Zghouzi M, Sattar Z, Ahmad B, Zahid S, Suleiman AM, Sattar Y, Khan MZ, Paul T, Bagur R, Qureshi MI, Fischman DL, Banerjee S, Prasad A,	More complete SR used

Alraies MC. Safety and efficacy of drug-coated balloon for peripheral artery revascularization-A systematic review and meta-analysis. Catheter Cardiovasc Interv. 2022 Mar;99(4):1319-1326. doi: 10.1002/ccd.30074. Epub 2022 Jan 18. PMID: 35043555.	
Xu Y, Liu J, Zhang J, Zhuang B, Jia X, Fu W, Wu D, Wang F, Zhao Y, Guo P, Bi W, Wang S, Guo W. Long-term safety and efficacy of angioplasty of femoropopliteal artery disease with drug-coated balloons from the AcoArt I trial. J Vasc Surg. 2021 Sep;74(3):756-762.e3. doi: 10.1016/j.jvs.2021.01.041. Epub 2021 Feb 15. PMID: 33600928.	In SR
Ye W, Zhang X, Dai X, Huang X, Liu Z, Jiang M, Liu C. Reewarm™ PTX drug-coated balloon in the treatment of femoropopliteal artery disease: A multi-center, randomized controlled trial in China. Int J Cardiol. 2021 Mar 1;326:164-169. doi: 10.1016/j.ijcard.2020.10.060. Epub 2020 Oct 28. PMID: 33127414.	In SR
Zhang B, Yang M, He T, Li X, Gu J, Zhang X, Dai X, Li X, Lu X, Lang D, Hu H, Chen X, Yang B, Gu H, Zhang X, Zou Y. Twelve-Month Results From the First-in-China Prospective, Multi-Center, Randomized, Controlled Study of the FREEWAY Paclitaxel-Coated Balloon for Femoropopliteal Treatment. Front Cardiovasc Med. 2021 Sep 10;8:686267. doi: 10.3389/fcvm.2021.686267. PMID: 34568443; PMCID: PMC8460758.	In SR
Zhang C, Yin G. Safety of paclitaxel-coated devices in the femoropopliteal arteries: A systematic review and meta-analysis. PLoS One. 2022 Oct 13;17(10):e0275888. doi: 10.1371/journal.pone.0275888. PMID: 36227807; PMCID: PMC9560511.	More complete SR used
Zhao S, Li L, Cui K. Network Analysis of Endovascular Treatment Strategies for Femoropopliteal Arterial Occlusive Disease. J Endovasc Ther. 2023 Aug;30(4):487-498. doi: 10.1177/15266028221090434. Epub 2022 Apr 8. PMID: 35392691.	Wrong study design: NMA
Zhou Y, Wang J, He H, Li Q, Li M, Li X, Shu C. Comparative effectiveness of endovascular treatment modalities for de novo femoropopliteal lesions in intermittent claudication: A network meta-analysis of randomized controlled trials. Int J Cardiol. 2021 Nov 15;343:122-130. doi: 10.1016/j.ijcard.2021.08.038. Epub 2021 Aug 27. PMID: 34461162.	Wrong study design: NMA

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Perifeer Arterieel Vaatlijden (PAV) – Femoro-popliteaal: Gecoate ballonnen en stents	
Uitgangsvraag/modules: Wat is de optimale behandeling van het femoro-popliteale traject (drug-eluting balloon en stents)	
Database(s): Ovid/Medline, Embase.com	Datum: 10 april 2024 (update van 5 juni 2022)
Periode: geen restrictie	Talen: Engels, Nederlands
Literatuurspecialist: Esther van der Bijl	
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: • Femoro-popliteaal letsel • Drug-eluting balloon en stents Het sleutelartikel wordt gevonden met de zoekopdracht. De resultaten staan in Rayyan: https://rayyan.ai/reviews/465123	
Te gebruiken voor richtlijnen tekst: *Nederlands* In de databases Embase.com en Ovid/Medline is op 10 april 2024 een update gedaan van de search uit 2022. Er is met relevante zoektermen gezocht naar systematische reviews en RCT's over behandeling met drug-eluting balloons en stents bij femoro-popliteaal letsel. De literatuurzoekactie leverde 69 nieuwe unieke treffers op.	

Zoekopbrengst 10 april 2024

	EMBASE	**OVID/MEDLINE**	**Rayyan**	**Ontdubbeld ten opzichte van Rayyan**
SRs	122	158	144	16
RCT	196	268	237	53
Observationele studies	236	227	225	
Totaal	318	426		**69***

****in Rayyan***

5 ***Zoekopbrengst 5 juni 2022***

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SRs	108	130	144
RCT	159	222	237
Observationele studies	162	159	225
Totaal	429	511	**606**

Zoekstrategie Embase.com 10 april 2024

No.	Query	Results
#1	'leg ischemia'/exp/mj OR 'claudication'/exp/mj OR 'popliteal artery'/exp/mj OR (((popliteal* OR femoropopliteal* OR 'femoro popliteal') NEAR/3 arter*):ti,ab,kw) OR claudicatio*:ti,kw OR 'angina cruris':ti,kw OR 'dysbasia':ti,kw OR ((isch?em* NEAR/3 ('lower limb*' OR leg*)):ti,kw) OR 'chronic limb-threatening isch?em*':ti,ab,kw OR clti:ti,ab,kw OR 'critical limb isch?em*':ti,ab,kw	23908
#2	'drug eluting cardiovascular stent'/exp OR 'drug-eluting balloon catheter'/exp OR (((eluting OR coated OR paclitaxel OR sirolimus OR everolimus) NEAR/3 (stent* OR balloon*)):ti,ab,kw) OR 'paclitaxel'/exp/mj OR 'sirolimus'/exp/mj OR 'everolimus'/exp/mj	81487
#3	#1 AND #2 AND ([english]/lim OR [dutch]/lim) 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)	601
#4	'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	'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
#6	'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-	13242898

	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)))	
#7	#3 AND #4 **– SR's**	122
#8	#3 AND #5 NOT #7 **– RCT's**	196
#9	#3 AND #6 NOT (#7 OR #8) **– Observationele studies**	236
#10	#7 OR #8 OR #9	554

Zoekstrategie Ovid/Medline 10 april 2024

#	Searches	Results
1	(exp Ischemia/ and exp Leg/) or exp Intermittent Claudication/ or exp Popliteal Artery/ or ((popliteal* or femoropopliteal* or femoro popliteal) adj3 arter*).ti,ab,kf. or claudicatio*.ti,ab,kf. or angina cruris.ti,ab,kf. or dysbasia.ti,ab,kf. or (isch?em* adj3 (lower limb* or leg*)).ti,ab,kf.	35234
2	(*Angioplasty, Balloon/ and (eluting or coated or paclitaxel or sirolimus or everolimus).ti,ab,kf.) or exp *Drug-Eluting Stents/ or ((eluting or coated or paclitaxel or sirolimus or everolimus) adj3 (stent* or balloon*)).ti,ab,kf. or exp *Paclitaxel/ or exp *Sirolimus/ or exp *Everolimus/	44191
3	1 and 2	1127
4	limit 3 to (english language or dutch)	1085
5	4 not (comment/ or editorial/ or letter/ or ((exp animals/ or exp models, animal/) not humans/))	932
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	738657

	(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.	
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.	1704596
8	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.))	5663934
9	5 and 6 **– SR's**	158
10	(5 and 7) not 9 **– RCT's**	268
11	(5 and 8) not (9 or 10) **– Observationele studies**	227
12	9 or 10 or 11	653

Module 7: Femoro-popliteaal: Endovasculaire behandeling versus bypasschirurgie

Evidence tabel

Study reference	Study characteristics	Patient characteristics [2]	Intervention (I)	Comparison / control (C) [3]	Follow-up	Outcome measures and effect size [4]	Comments
Bradbury (2023) (BASIL-2)	Type of study: RCT. Setting and country: 41 vascular surgery units in the UK Funding and conflicts of interest: The funder had no role in study design, data collection, data analysis, data interpretation, writing of the report, or	Inclusion criteria: • Life expectancy of more than 6 months, and judged by a minimum of two consultants (at least one of whom could undertake infra-popliteal vein bypass and one of whom could undertake infra-	Describe intervention (treatment/procedure/test): Best endovascular treatment. Regarding best endovascular treatment, any device being used as part of standard of care in that country was permissible. Drug coated balloons, bare metal stents,	Describe control (treatment/procedure/test): Vein bypass. For vein bypass, any vein deemed suitable by the responsible vascular surgeons could be used. If at operation it was discovered that the vein could not be used, then composite or prosthetic grafts could be inserted	Length of follow-up: Maximum of 24 months. Loss-to-follow-up: 1 month I: n=4 C: n=9 6 months I: n=3 C: n=4 12 months I: n=2 C: n=3	**No amputation-free survival** I: 92/173 (53%) C: 108 (63%) **Death from any cause** I: 77/173 (45%) C: 91/172 (53%) **30-day mortality** I: 5/173 (3%) C: 10/172 (6%) **Major amputation** I: 32/173 (18%) C: 35/172 (20%)	Author's conclusion: In the BASIL-2 trial, a best endovascular treatment first revascularisation strategy was associated with a better amputation-free survival, which was largely driven by fewer deaths in the best endovascular treatment group. These data suggest

	decision to submit the results for publication. All other authors declare no competing interests.	popliteal endovascular interventions in their clinical practice) to require and be suitable for both infra-popliteal vein bypass and infra-popliteal endovascular intervention. <u>Exclusion criteria</u>: • Ischaemic pain or tissue loss considered not to be primarily due to atherosclerotic peripheral artery disease.	and drug eluting stents could be used at the operator's discretion. Atherectomy devices were permitted but not used. In this pragmatic trial, all additional management strategies, including additional procedures, were at the responsible clinicians' discretion in the patient's best interests.	at the surgeon's discretion in the patient's best interests.	All participants were analyzed in the intention-to-treat analysis.	**Major adverse limb event** I: 77/173 (45%) C: 71/172 (41%) **Major adverse cardiac event** I: 73/173 (42%) C: 68/172 (40%) **Reintervention** I: 33/173 (19%) C: 9/172 (5%) **Quality of life (EQ5D5L health state score) 24 months** I: 63.2 (21.6) (n=85) C: 58.5 (22.7) (n=76)	that more patients with chronic limb-threatening ischaemia who required an infra-popliteal, with or without an additional more proximal infra-inguinal, revascularisation procedure to restore limb perfusion should be considered for a best endovascular treatment first revascularisation strategy.

		N total at baseline: Intervention: N = 173 Control: N = 172 Important prognostic factors[2]: *age:* *I: 72.5 (62.7 to 79.7)* *C: 72.4 (64.3 to 78.7)* *Sex:* *I:141/173 (82%) M* *C: 139/172 (81%) M* Groups comparable at baseline? Yes.					
Farber (2022) (BEST-CLI)	Type of study: RCT.	Inclusion criteria: • Male or female, age	Describe intervention	Describe control (treatment/procedure/test):	Length of follow-up: 24 months.	**Death from any cause**	Author's conclusion:

	<u>Setting and country:</u> 150 sites in the United States, Canada, Finland, Italy, and New Zealand. <u>Funding and conflicts of interest:</u>	35 years or older. • Atherosclerotic, infrainguinal PAD (occlusive disease of the arteries below the inguinal ligament caused by atherosclerosis). • CLI, defined as arterial insufficiency with gangrene, non-healing ischemic ulcer, or rest pain consistent with Rutherford Categories 4-6.	<u>(treatment/procedure/test):</u> Endovascular treatment within 30 days	Surgical treatment within 30 days	<u>Loss-to-follow-up</u>: I: n=44 (14.3%) C: n=58 (14.0%)	I: 269/716 (37.6%) C: 237/718 (33.0%) **Myocardial infarction** I: 85/716 (11.9%) C: 75/718 (10.4%) **Above-ankle amputation** I: 106/716 (14.8%) C: 74/718 (10.3%) **Major reintervention** I: 167/716 (23.3%) C: 66/718 (9.2%) **Minor reintervention** I: 237/716 (33.1%) C: 205/718 (28.6%)	Among patients with CLTI who had an adequate great saphenous vein for surgical revascularization (cohort 1), the incidence of a major adverse limb event or death was significantly lower in the surgical group than in the endovascular group. Among the patients who lacked an adequate saphenous vein conduit (cohort 2), the outcomes in the two groups were similar.

		• Candidate for either open or endovascular infrainguinal revascularization as judged by the treating investigators (see MOO for guidelines on decision-making). • Adequate aortoiliac inflow.* • Adequate popliteal, tibial or pedal revascularization target defined as an infrainguinal arterial segment distal to the area of stenosis/occlusion which				**Length of hospitalization after index procedure** I: 5.9 (7.3) days. C: 7.5 (6.2) days. **Technical success** I: 596/704 (84.7%) C: 651/662 (98.3%)	

		can support a distal anastomosis of a surgical bypass. • Willingness to comply with protocol, attend follow-up appointments, complete all study assessments, and provide written informed consent. <u>Exclusion criteria</u>: • Disease limited to the Femoropoplitteal segment with TASC II A pattern. • Presence of a femoral, popliteal or tibial					

		aneurysm in the index limb. • Life expectancy of less than 2 years • Deemed excessive risk for surgical bypass (defined as excessive operative risk by preprocedural cardiac risk assessment according to established AHA/ACCF criteria). • Planned above ankle amputation on ipsilateral limb within 4 weeks of index procedure.					

		• Renal dysfunction (defined as MDRD eGFR ≤ 30 mL/min/1.73 m2 at the time of screening). • Current dialysis • History of renal transplantation. • Presence of a documented hypercoagulable state (defined as a known blood disorder associated with venous or arterial thrombosis). • Non-atherosclerotic occlusive disease (e.g.					

		embolic disease, trauma, vasculitis, Buerger's disease) or acute limb-threatening ischemia (defined as tissue loss or ischemic rest pain of less than 14 days duration). • Any prior infrainguinal stenting or stent grafting (with or without atherectomy and/or balloon angioplasty) of the ipsilateral superficial femoral artery and/or					

		above knee popliteal artery. • Any prior percutaneous or surgical intervention involving arteries below the knee joint. • Any of the following procedures performed within 6 months prior to screening: ○ Percutaneous balloon angioplasty or atherectomy of the					

		superficial femoral artery and/or above knee popliteal artery; ○ Common, superficial, or deep femoral endarterectomy; ○ Femoral to above knee bypass with					

		either venous or prosthetic conduit; ○ Open surgical inflow procedure (aortofemoral, axillofemoral, iliofemoral, or femorofemoral bypass) involving					

		the index leg • Current immune-suppressive medication, chemotherapy or radiation therapy. • Absolute contraindication to iodinated contrast due to prior near-fatal anaphylactoid reaction (laryngospasm, bronchospasm, cardiorespiratory collapse, or equivalent) and which would preclude patient					

		participation in angiographic procedures. • Known allergy to stainless steel or nitinol. • Pregnancy or lactation. • Administration of an investigational drug for peripheral arterial disease within 30 days of randomization. • Participation in a clinical trial (except observational studies) within the previous 30 days.					

		N total at baseline: Intervention: N = 716 Control: N = 718 Important prognostic factors[2]: *age ± SD:* *I: 67.0 (10.0)* *C: 66.9 (9.8)* *Sex:* *I: 207/716 (28.9%) F* *C: 201/718 (28.0%) F* Groups comparable at baseline? Yes.					
Bosiers (2020)	Type of study: RCT Setting and country: 13	Inclusion criteria: Inclusion criteria: General • Patient presenting with lifestyle-	Describe intervention (treatment/procedure/test): Endovascular treatment with	Describe control (treatment/procedure/test): Bypass surgery.	Length of follow-up: 60 months maximum. Loss-to-follow-up:	**Technical success** I: 113/113 (100%) C: 107/107 (100%) **Length of hospital stay**	Author's conclusion: With noninferior patency results, a lower complication

	clinical sites in Belgium (n=5), Germany (n=4), Italy (n=2), and Brazil (n=2). <u>Funding and conflicts of interest:</u> The author(s) received no financial support for the research, authorship, and/or publication of this article. The author(s) declared the following potential conflicts of interest with respect to the research, authorship, and/or publication of this article: Pierre Galvagni Silveira	limiting claudication, rest pain or minor tissue loss (Rutherford category 2 to 5) • Patient is willing to comply with specified follow-up evaluations at the specified times • Patient is >18 years old • Patient understands the nature of the procedure and provides written informed consent prior to enrollment in the study	the ZILVER PTX stent.		None.	I: 2.5 (3.5) days C: 8.1 (6.0) days **Complications (30 days)** I: 5/113 (4.3% C: 12/107 (11.2%) **Primary patency (12 months)** I: (74.5%) C: (72.5%) **Secondary patency (12 months)** I: (95.1%) C: (95.9%) **Target lesion revascularization (12 months)** I: (80.9%) C: (76.2%) **Freedom of major amputation (12 months)** I: (98.0%)	rate, and shorter procedures and hospital stays, paclitaxel-eluting stenting might become a recommended treatment for long TASC C and D femoropopliteal lesions.

	received research, clinical trial, or drug study funds from Cook Medical. Giovanni Torsello received research grants from Cook Medical. Dr Koen Deloose is a clinical trial investigator, consultant, and lecturer for Cook Medical. Dierk Scheinert is a consultant for Cook Medical. Tulio Navarro received research grants from Cook Medical.	• Patient has a projected life expectancy of at least 24 months • Noninvasive lower extremity arterial studies (resting or exercise) demonstrate ankle-brachial index ≤0.8 • Patient is eligible for treatment with the ZILVER PTX paclitaxel-eluting stent (Cook) or with surgical above-the-knee • bypass placement • Male, infertile female, or				C: (98.1%) **Major amputations (12 months)** I: 2/113 (1.8%) C: 2/107 (1.9%) **Survival rate (12 months)** I: (94.5%) C: (96.1%)	

		female of childbearing potential practicing an acceptable method of birth control with a negative pregnancy test within 7 days prior to study procedure Inclusion criteria: Angiographic • Stenotic or occlusive de novo lesion located in the femoropoplit eal arteries, suitable for endovascular therapy and for bypass surgery • Total target lesion length					

		is at least 15 cm • Minimum of 1.0 cm of healthy vessel (non-stenotic) both proximal and distal to the treatment area • P2 and P3 are patent and there is angiographic evidence of at least 1 vessel runoff to the foot that does not require intervention (<50% stenotic) • Target vessel diameter visually estimated to be >4 mm and <9 mm at the proximal					

		and distal treatment segments within the SFA <u>Exclusion criteria</u>: • Untreated flow-limiting aortoiliac stenotic disease • Any previous surgery and endovascular procedure in the target vessel • Severe ipsilateral common/deep femoral disease requiring surgical reintervention • Perioperative unsuccessful ipsilateral					

		percutaneous vascular procedure to treat inflow disease just prior to enrollment • Femoral or popliteal aneurysm located at the target vessel • Nonatherosclerotic disease resulting in occlusion (eg, embolism, Buerger's disease, vasculitis) • No patent tibial arteries (>50% stenosis) • Prior ipsilateral femoral artery bypass • Severe medical					

		comorbidities (untreated CAD/CHF, severe COPD, metastatic malignancy, dementia, etc) or other medical condition that would preclude compliance with the study protocol or 2-year life expectancy • Serum creatinine >2.5 mg/dL within 45 days prior to study procedure unless the subject is currently on dialysis					

		• Major amputation (above the transmetatarsal) in the study or nonstudy limb • Any previously known coagulation disorder, including hypercoagulability • Contraindication to anticoagulation or antiplatelet therapy • Known allergies to stent components (nickel-titanium, paclitaxel, etc) or bypass					

		graft components (Dacron, ePTFE, etc) • Known allergy to contrast media that cannot be adequately premedicated prior to the study procedure • Currently participating in another clinical research trial • Angiographic evidence of intra-arterial thrombus or atheroembolism from inflow treatment • Any planned surgical intervention/ procedure					

		within 30 days of the study procedure • Target lesion access in the ZILVER PTX stent arm not performed by transfemoral approach <u>N total at baseline</u>: Intervention: N = 113 Control: N = 107 <u>Important prognostic factors</u>[2]: *age ± SD:* *I: 69.6 (10.8)* *C: 67.6 (10.1)* *Sex:* *I: 78/113 (69%) M* *C: 81/107 (72.3%) M*					

		Groups comparable at baseline? Yes.					
Eleissaway (2019)	Type of study: RCT. Setting and country: the Vascular Surgery Department of Tanta University and Leuven University Funding and conflicts of interest: There are no conflicts of interest related to this article.	Inclusion criteria: • patients having the angiographic criteria of flush SFA occlusion lesions, and an outflow artery (at least the below-knee popliteal artery). • lifestylelimiting IC or CLI (Fontaine stages IIb, III, and IV). Exclusion criteria: • Patients having a potential	Describe intervention (treatment/procedure/test): Endovascular treatment (Ipsilateral antegrade angioplasty)	Describe control (treatment/procedure/test): Bypass surgery.	Length of follow-up: 12 months. Loss-to-follow-up: N = 3 intervention group.	**Length of hospital stay** I: 1.84 (0.19) days. C: 6.24 (0.37) days. **Restenosis** I: 3/25 (12%) C: 2/25 (8%) **Complications** I: 4/25 (16%) C: 12/25 (48%) **Myocardial infarction** I: 1/25 (4%) C: 2/25 (8%) **Primary patency** I: (64.5%) C: (72.0%)	Author's conclusion: Technical success, patency, and limb salvage of endovascular approach were comparable to surgical bypass. The endovascular approach had the advantages of reduced local complications and hospitalization.

		etiology for lower limb ischemia of acute thromboembolism, trauma, or autoimmune disorders. • Patients having associated CFA lesions or having a CFA bifurcation level higher than the upper margin of the head of femur. • contraindication to endovascular intervention, such as allergy to contrast <u>N total at baseline</u>:				**Secondary patency** I: (74.2%) C: (81.6%)	

		Intervention: N = 25 Control: N = 25 <u>Important prognostic factors</u>[2]: *age ± SD:* *I: 72 (12.1)* *C: 72 (7.5)* *Sex:* *Not reported.* Groups comparable at baseline? Yes.					
Enzmann (2019)	<u>Type of study:</u> RCT. <u>Setting and country:</u> No information. <u>Funding and conflicts of interest:</u>	<u>Inclusion criteria</u>: • adult patient; • 30 years of age; • informed consent; • severe intermittent claudication (<200 m of	<u>Describe intervention (treatment/procedure/test):</u> Nitinol stents.	<u>Describe control (treatment/procedure/test):</u> Bypass surgery.	<u>Length of follow-up</u>: 12 months. <u>Loss-to-follow-up</u>: None.	**Technical success** I: 48/55 (87.3%) C: 55/55 (100%) **Primary patency** I: (60%) C: (56%) **Secondary patency**	<u>Author's conclusion:</u> There were no significant differences regarding patency rates, limb salvage, survival, or complications.

	No information.	walking distance) or critical limb threatening ischemia, including rest pain and ischemic lesions (Rutherford categories 3 to 6); • femoropoplit eal TASC II C or D lesions and no untreated inflow lesions in the ipsilateral iliac arteries; • at least 1 patent tibial artery; or symptoms for more than 2 months. <u>Exclusion criteria</u>:				I: (72%) C: (73%) **Target lesions revascularization** I: 14/55 (25.5%) C: 14/55 (25.5%) **Revascularization** I: 28/55 (50.9%) C: 35/55 (63.6%) **Survival (2 years)** I: (90%) C: (95%) **Overall complications** I: 21/55 (38.2%) C: 25/55 (45.5%) **Minor amputation** I: 4/55 (7.2%) C: 5/55 (9.1%)	after 2 years. Technical success and clinical improvement in the bypass group were significantly better, but the promising results of the stent group suggest that an endovascular-first strategy for femoropopliteal lesions up to 30 cm may be reasonable. Mid- as well as long-term results need to be awaited.

		• acute ischemia; • any form of vasculitis, or embolic or traumatic femoropoplit eal occlusions; previous ipsilateral bypass surgery; use of a prosthetic conduit; • chronic kidney disease without requiring dialysis • (glomerular filtration rate <45 ml/min/1.73 m2); • patients that are too frail for VBP					

		(American Society of Anesthesiologists [ASA] classification >3); • pregnancy. <u>N total at baseline</u>: Intervention: N = 50 (55 lesions) Control: N = 53 (55 lesions) <u>Important prognostic factors</u>[2]: *age ± SD:* *I: 69.5 (7.9)* *C: 68.3 (8.7)* *Sex:* *I: 35/50 (70%)* *C: 41/53 (77%)* Groups comparable at baseline? Yes.					

McQuade (2009)	Type of study: RCT Setting and country: a single institution. Funding and conflicts of interest: Competition of interest: Dr Gable received funding/grants for support of this study from W.L. Gore & Associates, Flagstaff, Ariz. Dr Gable received fees from W.L. Gore & Associates for speaking at organized educational events	Inclusion criteria: • patients that had atherosclerotic stenotic or occlusive lesions of the superficial femoral artery with no significant aorto-iliac disease. • The infrapopliteal segment had to be patent with at least single vessel run-off to the ankle. • Patients had to be acceptable surgical candidates in the event they were	Describe intervention (treatment/procedure/test): Stent graft.	Describe control (treatment/procedure/test): Surgical bypass.	Length of follow-up: 24 months maximum. Loss-to-follow-up: I: N = 4 C: N = 5	**Technical success** I: 40/40 (100%) C: 46/46 (100%) **Complications** I: 4/40 (10.0%)* C: 3/46 (6.5%)** *SFA dissection (n=1), transient mild leg edema (n=1), transient thigh pain in the treated limb (n=1), small groin hematoma (n=1). **groin lymphocele (n=2), small superficial groin wound dehiscence (n=1). **Length of hospital stay** I: 0.9 (0.8) days. C: 3.1 (1.8) days.	Author's conclusion: Management of superficial femoral artery occlusive disease with percutaneous stent-grafts exhibits similar primary patency at 24-month follow-up when compared with conventional femoral-popliteal artery bypass grafting with synthetic conduit. This treatment method may offer an alternative to treatment of the superficial femoral artery

		randomized to the surgical arm. <u>Exclusion criteria</u>: • No information. <u>N total at baseline</u>: Intervention: N = 40 Control: N = 46 <u>Important prognostic factors</u>[2]: *age ± SD:* *I: 72 (9.9)* *C: 67 (10.7)* *Sex:* *No information.* Groups comparable at baseline? Yes.				**Primary patency (24 months)** I: 63% C: 64% **Secondary patency (24 months)** I: 74% C: 76%	segment for revascularization when prosthetic bypass is being considered or when autologous conduit is unavailable.

Bradbury (2005)	Type of study: RCT Setting and country: 27 UK hospitals Funding and conflicts of interest: The sponsor of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for decision to submit for publication.	Inclusion criteria: • all patients who had presented to them with severe limb ischaemia, defined as rest pain or tissue loss (ulcer or gangrene) of presumed arterial aetiology for more than 2 weeks, and who on diagnostic imaging had a pattern of disease which, in their joint opinions, could equally well be treated by either infra-inguinal	Describe intervention (treatment/procedure/test): Balloon angioplasty.	Describe control (treatment/procedure/test): Bypass surgery	Length of follow-up: 2 years. Loss-to-follow-up: N = 7 after randomisation N = 3 during the first year of follow-up.	**Mortality during same hospital stay as first intervention** I: 7/237 C: 11/197 **Mortality following discharge from hospital after first intervention** I: 0/230 C: 0/186 **Myocardial infarction during same hospital stay as first intervention** I: 6/237 C: 13/197 **Myocardial infarction following discharge from hospital after first intervention** I: 1/230	Author's conclusion:

	The members of the writing committee declare that they have no conflict of interest.	bypass surgery or balloon angioplasty. <u>Exclusion criteria</u>: • No information. <u>N total at baseline</u>: Intervention: N = 224 Control: N = 228 <u>Important prognostic factors</u>[2]: *Age* *See original publication.* *Sex:* *No information.* Groups comparable at baseline? Yes				C: 2/186	

Risk of bias tabel

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/healthcare providers/data collectors/assessors/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**
Bradbury (2023) (BASIL-2)	Definitely yes Reason: Participants were randomly assigned (1:1) to receive	No information. Reason: -	Definitely no. Reason: BASIL-2 was an open-label study; participants, study	Probably no. Reason: Lost to follow-up almost equally distributed	Probably yes. Reason: All predefined outcomes	Probably no. Reason: No other bias reported.	Some concerns (no blinding and unclear allocation of concealment).

	either vein bypass (vein bypass group) or best endovascular treatment (best endovascular treatment group) as their first revascularisation procedure through a secure online randomisation system.		staff, and investigators were not masked to treatment allocation.	over both groups and all patients were included in the intention-to-treat analysis.	were reported.		
Farber (2022) (BEST-CLI)	Definitely yes. Reason: Patients were enrolled into one of two paralleltrial cohorts according to prerandomization duplex ultrasonography of the right and left great	No information. Reason: -	Definitely no. Reason: Open-label study.	Probably no. Reason: Lost to follow-up almost equally distributed over both groups and all patients were included in the	Probably yes. Reason: All predefined outcomes were reported.	Probably yes. Reason: Selection and operator bias as a consequence of its pragmatic design and implementation. Eligibility was determined locally and varied according	Some concerns (no blinding, unclear allocation of concealment and probability of selection bias).

	saphenous veins.			intention-to-treat analysis.		to the site and the individual investigator; patients who underwent randomization were those in whom the enrolling team believed there was equipoise between endovascular intervention and bypass surgery.	
Bosiers (2020)	Definitely yes. Reason: Using a computer-generated list for each site, permuted block randomization was applied with block sizes of 8 patients assigned in a 1:1 fashion to either endovascular	Definitely yes. Reason: Each site received closed envelopes that were opened only after the patient signed the informed consent. Once a treatment was assigned,	No information. Reason: -	Probably no. Reason: Lost to follow-up almost equally distributed over both groups.	Probably yes. Reason: All predefined outcomes were reported.	Probably no. Reason: No other bias reported.	Some concerns (unclear blinding).

	treatment with the ZILVER PTX stent or bypass surgery with a synthetic graft.	crossover was not permitted.					
Eleissaway (2019)	Definitely yes. Reason: patients were prospectively randomized to either endovascular therapy (n ¼ 28 patients) or surgical bypass.	Probably yes. Reason: Randomization was accomplished using the opaque closed envelopes system with a ratio of 1:1.	No information. Reason: -	Probably no. Reason: Lost to follow-up almost equally distributed over both groups.	Probably yes. Reason: All predefined outcomes were reported.	Probably no. Reason: No other bias reported.	Some concerns (no blinding and unclear allocation of concealment).
Enzmann (2019)	Definitely yes. Reason: The design of the study is a randomized, controlled, monocentric, sample size planned, group-sequential	Definitely yes. Reason: Patients were allocated to the stent or bypass group by using stratified randomization (TASC II	No information. Reason: -	Definitely no. Reason: No patient was lost to follow-up with a median follow-up	Probably yes. Reason: All predefined outcomes were reported.	Probably no. Reason: No other bias reported.	Some concerns (unclear blinding).

	clinical trial	category and Rutherford category were used as stratification variables).		of 23 (interquartile range: 14.1 to 27.6) months in the stent group and 21 (interquartile range: 15.7 to 26.0) months in the bypass group, respectively.			
McQuade (2009)	Definitely yes. Reason: the study is a prospective, randomized Trial. Enrolled patients were prospectively randomized by limb prior to intervention into one of two treatment	No information. Reason: -	No information. Reason: -	Probably no. Reason: Lost to follow-up almost equally distributed over both groups.	Probably yes. Reason: All predefined outcomes were reported.	Probably no. Reason: No other bias reported.	Some concerns (unclear allocation of concealment and unclear blinding).

	groups: percutaneous endovascular treatment with the stent-graft or open surgical femoral to above-knee popliteal artery bypass with synthetic graft.						
Bradbury (2005)	Definitely yes. Reason: The trial manager, independent of participating centres, randomly assigned patients to receive either surgery first or angioplasty first using a one-to-one ratio in randomly sized permutated blocks.	Probably yes. Reason: The randomisation sequences were generated by a computerised random-number generator in the University of Edinburgh Medical Statistics Unit (Edinburgh,	No information. Reason: -	Probably no. Reason: Lost to follow-up almost equally distributed over both groups.	Probably yes. Reason: All predefined outcomes were reported.	Probably no. Reason: No other bias reported.	Some concerns (unclear blinding).

		UK) and supplied to the coordinating centre in identical, sealed envelopes.					

Exclusie tabel

Author and year	Reason for exclusion
Bradbury (2010a)	Wrong outcomes.
Bradbury (2010b)	Wrong outcomes.
Bradbury (2010c)	Wrong study design.
Forbes (2010)	Wrong outcomes
Kedora (2007)	Duplicate.
Klaphake (2020)	Does not match the PICO of this guideline (wrong comparison of interventions).
Malas (2014)	Wrong study design.
McQuade (2010)	Wrong outcomes.
Siracuse (2023)	Duplicate.
Wolf (1993)	Does not match the PICO of this guideline (wrong comparison of interventions).

Zoekverantwoording

Algemene informatie

Richtlijn: NVVH Perifeer arterieel vaatlijden (PAV) Femoro-popliteaal: Endovasculaire behandeling versus bypasschirurgie	
Uitgangsvraag: Wat is de optimale behandeling van het femoro-popliteale traject	
Database(s): Ovid/Medline, Embase	Datum: 14-4-2022, 24-7-2023
Periode: nvt	Talen: nvt
Literatuurspecialist: Miriam van der Maten, Ingeborg van Dusseldorp	
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: 24-7-2023 Omdat de opbrengst van april niet volledig is, is de zoekstrategie sensitiever opgesteld en uitgebreid met terminologie die door de werkgroep is aangedragen. De concepten waarmee gezocht is zijn als volgt: (Leg ischemia OR claudicatio) EN endovasculaire behandeling, stent, PTA, EN chirurgische bypass 14-4-2023 (Leg ischemia OR claudicatio OR popliteal artery) EN endovasculaire behandeling EN chirurgische bypass Vanwege het groot aantal gevonden referenties is de zoekstrategie in Embase beperkt tot ti,kw en major terms en is de comparison meegenomen in de strategie. Alle sleutelartikelen worden gevonden binnen de SRs en RCTs.	
Te gebruiken voor richtlijnen tekst: In de databases Embase en Ovid/Medline is op 24-7-2023 met relevante zoektermen gezocht naar systematische reviews, en RCTs over de endovasculaire behandeling van het femoro-popliteale traject. De literatuurzoekactie leverde 791 unieke treffers op.	

Zoekopbrengst

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld t.o.v. Rayyan**
SRs	291	41	242
RCTs	415	74	302
Observationele studies			
Overig			
Totaal			
	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SRs	63	27	86
RCTs	131	48	161
Observationele studies			
Overig			
Totaal			791

5 ***Zoekstrategie***

Embase

24-7-2023

No.	Query	Results
#24	#14 AND #23 sleutelartikelen gevonden	9
#23	#15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22	9
#22	'randomized comparison of eptfe/nitinol self-expanding stent graft vs prosthetic femoral-popliteal bypass in the treatment of superficial femoral artery occlusive disease'	1
#21	'nitinol stent versus bypass in long femoropopliteal lesions: 2-year results of a randomized controlled trial.'	1
#20	'ipsilateral antegrade angioplasty for flush superficial femoral artery occlusion versus open bypass surgery'	1
#19	'bypass versus angioplasty in severe ischaemia of the leg (basil) trial: an intention-to-treat analysis of amputation-free and overall survival in patients randomized to a bypass surgery-first or a balloon angioplasty-first revascularization strategy' AND bradbury AND 2010 NOT erratum	1
#18	'randomized comparison of percutaneous viabahn stent grafts vs prosthetic femoral-popliteal bypass in the treatment of superficial femoral arterial occlusive disease' NOT letter	1
#17	'a vein bypass first versus a best endovascular treatment first revascularisation strategy for patients with chronic limb threatening ischaemia who required an infra-popliteal, with or without an additional more proximal infra-inguinal revascularisation procedure to restore limb perfusion (basil-2): an open-label, randomised, multicentre, phase 3 trial'	1

#16	'stent vs bypass surgery in femoropopliteal lesions' NOT corrigendum	2
#15	'surgery or endovascular therapy for chronic limb-threatening ischemia'	1
#14	#12 OR #13	706
#13	#2 AND #11 NOT #12 RCT	415
#12	#1 AND #11 SR	291
#11	#10 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)	3803
#10	#8 AND #9	6350
#9	'bypass surgery'/exp OR ((bypass NEAR/8 (surger* OR operati*)):ti,ab,kw) OR (((vascular OR vessel) NEAR/3 (anastomosis OR bypass OR shunt)):ti,ab,kw)	446646
#8	#3 AND #7	4397
#7	#4 OR #5 OR #6	52246
#6	'angioplasty'/exp OR 'stent'/exp OR 'angioplast*':ti,ab,kw OR stent*:ti,ab,kw	324472
#5	'percutaneous transluminal angioplasty'/exp OR pta:ti,kw OR (((balloon OR transluminal OR percutaneous OR dotter*) NEAR/3 (angioplast* OR 'artery dilati*')):ti,ab,kw)	52510
#4	'limb revascularization'/de OR ('revascularization'/exp AND 'limb'/exp) OR ((endovascular NEAR/3 (revascular* OR therapy OR surgery)):ti,ab,kw) OR ('leg revascularization'/exp AND endovasc*:ti,ab,kw) OR 'leg revascularizat*':ti,ab,kw	23085
#3	'critical limb ischemia'/exp OR 'leg ischemia'/exp OR 'claudication'/exp OR ('ischemia'/de AND ('limb'/exp OR 'popliteal artery'/exp)) OR (((popliteal* OR femoropopliteal* OR 'femoro popliteal') NEAR/3 (lesion* OR ischemi*)):ti,ab,kw) OR claudicatio*:ti,ab,kw OR 'angina cruris':ti,ab,kw OR 'dysbasia':ti,ab,kw OR ((isch?em* NEAR/3 ('lower limb*' OR leg*)):ti,ab,kw)	48219
#2	'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
#1	'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	813344

14-4-2023

No.	Query	Results
#31	#20 NOT #19 NOT #18 OBS	**352**
#30	#19 NOT #18 RCT	**131**
#29	#26 AND #28 Sleutelartikelen gevonden in SRs en RCTs	**5**
#28	#18 OR #19	**194**
#27	#21 AND #26	**5**
#26	#22 OR #23 OR #24 OR #25	**5**
#25	bypass AND versus AND angioplasty AND in AND severe AND ischaemia AND of AND the AND leg AND basil AND multicentre, AND randomised AND controlled AND trial AND bradbury AND lancet AND 2005 NOT salvage:ti	**1**
#24	endovascular AND revascularisation AND versus AND conservative AND management AND for AND intermittent AND claudication AND fakhry AND 2018	**2**
#23	'long term' AND 'follow up' AND of AND a AND randomized AND clinical AND trial AND comparing AND endovascular AND revascularization AND plus AND with AND supervised AND exercise AND only AND for AND intermittent AND claudication AND khaphake AND 2020	**1**
#22	(versus AND angioplasty AND severe AND ischaemia AND the AND leg AND basil AND trial AND an AND 'intention to treat' AND analysis AND of AND 'amputation free' AND overall AND survival AND in AND patients AND randomized AND to AND a AND bypass AND 'surgery first' OR a) AND balloon AND 'angioplasty first' AND revascularization AND strategy AND bradbury AND 20435258	**1**
#21	#18 OR #19 OR #20	**541**
#20	(#3 OR #4) AND #17	**533**
#19	#2 AND #17	**173**
#18	#1 AND #17 SR	**63**
#17	#16 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)	**682**
#16	#11 AND #15	**690**

No.	Query	Results
#15	'bypass surgery'/exp OR ((bypass NEAR/8 (surger* OR operati*)):ti,ab,kw)	**413876**
#14	(#3 OR #4) AND #11	**1153**
#13	#2 AND #11	**310**
#12	#1 AND #11	**116**
#11	#10 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)	**1759**
#10	#5 AND #9	**2080**
#9	#6 OR #7 OR #8	**52246**
#8	'angioplasty'/exp/mj OR 'angioplast*':ti,kw	**50511**
#7	'percutaneous transluminal angioplasty'/exp/mj OR pta:ti,kw OR (((balloon OR transluminal OR percutaneous OR dotter*) NEAR/3 (angioplast* OR 'artery dilati*')):ti,kw)	**19939**
#6	(((endovascular OR leg*) NEAR/3 revascular*):ti,kw) OR ('leg revascularization'/exp/mj AND endovasc*:ti,kw)	**992**
#5	'leg ischemia'/exp/mj OR 'claudication'/exp/mj OR 'popliteal artery'/exp/mj OR (((popliteal* OR femoropopliteal* OR 'femoro popliteal') NEAR/3 arter*):ti,ab,kw) OR claudicatio*:ti,kw OR 'angina cruris':ti,kw OR 'dysbasia':ti,kw OR ((isch?em* NEAR/3 ('lower limb*' OR leg*)):ti,kw)	**21621**
#4	'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	**13001828**

No.	Query	Results
	((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)))	
#3	'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**
#2	'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**
#1	'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	**813344**

Ovid/Medline
24-7-2023

#	Searches	Results

12	(9 and 10) not 11 RCT	74
11	8 and 10 SR	41
10	7 not ((exp animals/ or exp models, animal/) not humans/) not (letter/ or comment/ or editorial/)	706
9	(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.) not (animals/ not humans/)	1488822
8	(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.) not (comment/ or editorial/ or letter/ or ((exp animals/ or exp models, animal/) not humans/))	652231
7	5 and 6	713
6	Axillofemoral Bypass Grafting/ or ((bypass adj8 (surger* or operati*)) or artery bypass).ti,ab,kf. or ((vascular or vessel) adj3 (anastomosis or bypass or shunt)).ti,ab,kf.	81367
5	1 and 4	8491
4	2 or 3	259081
3	exp Angioplasty/ or exp Stents/ or pta.ti,kf. or ((balloon or transluminal or percutaneous or dotter*) adj3 (angioplast* or 'artery dilati*')).ti,ab,kf. or angioplast*.ti,ab,kf. or stent*.ti,ab,kf.	189034
2	exp Endovascular Procedures/ or (endovascular adj3 (revascular* or therapy or treatment)).ti,ab,kf. or ((leg or limb) adj3 revascularization).ti,ab,kf.	160800
1	(exp Extremities/ and (Chronic Limb-Threatening Ischemia/ or Ischemia/)) or exp Intermittent Claudication/ or exp Popliteal Artery/ or ((popliteal* or femoropopliteal* or femoro popliteal) adj3 (lesion* or isch?em*)).ti,ab,kf. or claudicatio*.ti,ab,kf. or angina cruris.ti,ab,kf. or dysbasia.ti,ab,kf. or (isch?em* adj3 (lower limb* or leg*)).ti,ab,kf.	38568

14-4-2023

#	Searches	Results
17	15 not 14 not 13 OBS	223
16	14 not 13 RCT	48
15	(10 or 11) and 12	285
14	9 and 12	69
13	8 and 12 SR	27

12	7 not ((exp animals/ or exp models, animal/) not humans/) not (letter/ or comment/ or editorial/)	429
11	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.))	5129770
10	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]	4119516
9	(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.) not (animals/ not humans/)	1366724
8	(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.) not (comment/ or editorial/ or letter/ or ((exp animals/ or exp models, animal/) not humans/))	558628

7	5 and 6	432
6	((bypass adj8 (surger* or operati*)) or artery bypass).ti,ab,kf.	74544
5	1 and 4	5064
4	2 or 3	83021
3	exp Angioplasty/ or pta.ti,kf. or ((balloon or transluminal or percutaneous or dotter*) adj3 (angioplast* or 'artery dilati*')).ti,ab,kf. or angioplast*.ti,ab,kf.	81897
2	((endovascular or leg*) adj3 revascular*).ti,ab,kf.	1640
1	(exp Ischemia/ and exp Leg/) or exp Intermittent Claudication/ or exp Popliteal Artery/ or ((popliteal* or femoropopliteal* or femoro popliteal) adj3 arter*).ti,ab,kf. or claudicatio*.ti,ab,kf. or angina cruris.ti,ab,kf. or dysbasia.ti,ab,kf. or (isch?em* adj3 (lower limb* or leg*)).ti,ab,kf.	33309

Module 8: Infragenuaal: Gecoate ballonnen en stents

Evidence tabel

Study reference	Study characteristics	Patient characteristics	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Ipema, 2020 PS., study characteristics and results are extracted from the SR (unless stated otherwise)	SR and meta-analysis of RCTs, comparative studies and case series. Only RCTs are included in current analysis. *Literature search up to November 2018* **A**: Liistro, 2013 **B**: Zeller, 2014	Inclusion criteria SR: Articles were eligible if they included DCB angioplasty or compared DCB angioplasty with standard PTA of infrapopliteal arteries in patients with peripheral	Describe intervention: **A**: DCB **B**: DCB **C**: DCB **D**: DCB	Describe control: **A**: PTA **B**: PTA **C**: PTA **D**: PTA	<u>End-point of follow-up</u>: For review: 12 months <u>For how many participants were no complete outcome data available?</u> Numbers specified under outcomes	<u>Restenosis</u> >50% recurrent stenosis on duplex ultrasound or angiography, or a peak systolic velocity rate ≥2.5 on duplex ultrasound, at 12 months **A**: I: 20/74; C: 55/74 **B**: I: 25/61; C: 11/31 **C**: - **D**: I: 14/40; C: 34/41 Target lesion revascularization A clinically driven repeat percutaneous intervention of the target lesion or	<u>Risk of bias (high, some concerns or low):</u> Tool used by authors: Cochrane tool for assessing risk of bias **A**: unclear for blinding outcome assessment, high for blinding participants and personnel **B**: unclear for incomplete outcome data and other bias, high for selective reporting and blinding participants and personnel

	C: Zeller, 2015 **D**: Haddad, 2017 <u>Study design</u>: RCT <u>Setting and Country</u>: The Netherlands <u>Source of funding and conflicts of interest:</u> CONFLICT OF INTEREST None. FUNDING None	arterial disease, were published in English, included human subjects, and had a full text available. Exclusion criteria SR: case reports, articles with fewer than 50 infrapopliteal angioplasties, the use of other types of balloons or stents, cutting balloon, cryoplasty, or laser technique,				bypass surgery of the target vessel, at 12 months **A**: - **B**: I: 27/226; C: 15/111 **C**: I: 12/40; C: 15/49 **D**: I: 9/54; C: 29/52 <u>Amputation</u> Limb salvage (avoidance of major amputation) at 12 months **A**: I: 65/65; C: 66/67 **B**: I: 207/227; C: 107/111 **C**: I: 29/30; C: 34/36 **D**: I: 47/48; C: 43/45 <u>Mortality</u> Overall survival at 12 months **A**: I: 60/65; C: 64/67 **B**: I: 204/227; C: 102/111 **C**: I: 33/36; C: 34/36 **D**: I: 38/48; C: 39/48 <u>Quality of life</u>	**C**: unclear for blinding participants and personnel and for blinding outcome assessment **D**: unclear for random sequence generation, allocation concealment, blinding participants and personnel and for blinding outcome assessment <u>Author's conclusion</u> In patients with peripheral arterial disease who underwent infrapopliteal angioplasty, no significant differences in limb salvage, survival, restenosis, TLR, and AFS rates were found when DCB angioplasty was

		reviews, commentaries, letters to the editor, or conference abstracts. *4 RCTs included* <u>Important patient characteristics at baseline</u>: <u>N, mean age</u> **A**: 132, 74/75y **B**: 358, 73/71y **C**: 72, 73/70y **D**: 93, NR <u>*Sex (% male)*</u> **A**: 80.3 **B**: 74.3 **C**: 79.1 **D**: NR				Not reported <u>Wound healing</u> Not reported	compared with standard PTA.

		Diabetes mellitus **A**: 100% **B**: 73.5% **C**: 66.7% **D**: 95.7% Range of Rutherford category **A**: 4-6 **B**: 3-6 **C**: 2-5 **D**: 4-6 **A**: Liistro **B**: Zeller **C**: Zeller **D**: Haddad Groups were comparable at baseline					

Study reference	Study characteristics	Patient characteristics [2]	Intervention (I)	Comparison / control (C) [3]	Follow-up	Outcome measures and effect size [4]	Comments

Jia, 2020 AcoArt II–BTK	Type of study: RCT Setting and country: multicenter, China Funding and conflicts of interest: The AcoArt II–BTK study was sponsored by Acotec Scientific. The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.	<u>Inclusion criteria</u>: single or sequential de novo or restenotic lesions with >70% diameter stenosis in the infrapopliteal arteries, at least 1 patent runoff vessel to the foot, **Rutherford category 4 to 6 ischemia**, and a maximum of 2 different arteries to be treated in the same limb. <u>Exclusion criteria</u>: Acute thrombosis in the target vessel, planned major amputation of the target limb, history of open surgery of the target vessel, the	Angioplasty with Litos or Tulip drug-coated balloons (DCBs) The balloons, which are coated in an inflated state, are covered with 3-µg/mm2 paclitaxel in a matrix containing magnesium stearate as a polymer-free natural excipient.	Angioplasty with uncoated balloons The study devices consisted of both the 0.014-inch wire–compatible Litos and the 0.018-inch–compatible Tulip series catheters, which are identical in terms of platform, drug material, and coating technology.	<u>Length of follow-up</u>: 12 months <u>Loss-to-follow-up</u>: Intervention: 2/61 (3.3%) Control: 3/59 (5.1%) <u>Incomplete outcome data</u>: N/A	<u>Freedom from binary restenosis</u> *Primary patency at 6 months* I: 36/48 patients (75.0) C: 13/46 patients (28.3) P<0.001 <u>Re-intervention based on symptomatic restenosis</u> *clinically-driven target lesion revascularization at 6 months* I: 3/65 patients (4.6%) C: 12/66 patients (18.2%) *clinically-driven target lesion revascularization at 12 months* I: 5/59 (8.5) C: 13/56 (23.2) P=0.03	<u>Authors' conclusion</u> This study demonstrated that the Litos/Tulip DCBs are safe and effective in treating infrapopliteal lesions, with improved angiographic and clinical outcomes vs plain balloon angioplasty. The DCBs demonstrated significantly higher primary patency with fewer CD-TLRs than conventional angioplasty. The safety of the DCBs was noninferior to that of the uncoated balloons after 1 year of follow-up.

		need for intervention in both limbs at the same time, an existing stenosis or occlusion >150 mm in the inflow vessels (including the iliac artery, superficial femoral artery, and popliteal artery), and in-stent restenosis. <u>N total at baseline</u>: Intervention: 61 Control: 59 <u>Important prognostic factors</u>[2]: *Age, mean ± SD:* *I: 70.7±7.4* *C: 70.8±9.0* *Sex:* *I: 59% M* *C: 61% M*				*Freedom from CD-TLR at 12-months* I: 91.8% (95% CI 81.9% to 97.3%) C: 78.0% (95% CI 65.3% to 87.7%) p=0.028 <u>Amputation</u> *Major amputation at 12 months* I: 1/59 patients (1.7%) C: 1/56 patients (1.8%) P=0.97 <u>Wound healing</u> *Complete healing at 12 months* I: 26/31 (83.9%) C: 24/32 (75.0%) P=0.39 <u>Quality of life</u> Not reported <u>Mortality</u>	

		Diabetes mellitus *I: 45/61 (74)* *C: 42/59 (71)* *ABI:* *I: 0.56±0.27* *C: 0.51±0.31* Groups were comparable at baseline.				One patient (1.7%) died of pneumonia in the DCB group, and 2 patients (3.6%) died of cardiac complications in the control group within 12 months	
Liistro, 2020 ACOART-BTK NCT 02563535	Type of study: RCT Setting and country: single center, Italy Funding and conflicts of interest: The study was partially supported by Acotec Scientific, which provided the DCBs and covered the	Inclusion criteria: CLTI (**Rutherford class ≥4**): stenosis ≥50% or occlusion of at least 40 mm by visual estimation, located in BTK arteries with distal runoff, defined as follows: reconstitution of the occluded or stenotic artery at the level of the malleolus or above with distal	Drug-coated balloon angioplasty Prior to randomization, single or sequential balloon dilatations were performed to reach an optimal angiographic result. Balloon diameter was chosen according to vessel diameter	Plain balloon angioplasty In case of randomization to POBA, the procedure ended with final angiography.	Length of follow-up: 12 months Loss-to-follow-up: I: 3/52 1 consent withdrawal, 2 refused re-angiography C: 1/53 refused re-angiography	Freedom from binary restenosis *Restenosis >50%* I: 22/58 (37.9%) lesions C: 54/62 (87.1%) lesions P <0.001 Re-intervention based on symptomatic restenosis *CDTLR at 12 months* I: 6/62 (10%) lesions	Authors' conclusion Litos DCB angioplasty of BTK arteries in patients with CLTI is associated with significant reductions in LLL, vessel reocclusion, and TVAL on 6-month angiography. The higher patency translated into a lower rate of target lesion

	costs of angiography core laboratory analysis. Dr. Liistro is principal investigator of the In.Pact BTK study for Medtronic; and is a consultant for Medtronic, Boston Scientific, and Biotronik. All other authors have reported that they have no relationships relevant to the contents of this paper to disclose.	direct filling through the dorsalis pedis or plantars of the digital arch (Kawarada classification types 1, 2A, and 2B). <u>Exclusion criteria</u>: Patients with absence of pedal arch (Kawarada classification type 3) or those who needed dilatation of the arch to re-establish its patency were excluded. <u>N total at baseline</u>: Intervention: 52 patients, 54 limbs, 63 lesions	measured by extravascular ultrasound (EVUS) with a balloon/artery ratio of 1. In case of DCB angioplasty, a Litos balloon of the same size as the last uncoated balloon was used as previously described. The Litos DCB is coated with paclitaxel.			C: 27/66 (41%) lesions P<0.001 <u>Amputation</u> Major amputation at 12 months I: 0 C: 0 <u>Wound healing</u> complete healing at 12 months I: 42/47 (89.4%) C: 35/47 (74.5%) P=0.05 <u>Quality of life</u> Not reported <u>Mortality</u> 12 months I: 4 (7.7%) C: 7 (13.2%) P=0.20	revascularization and a higher rate of complete foot healing, without, however, a difference in major amputation.

		Control: 53 patients, 55 limbs, 66 lesions <u>Important prognostic factors</u>[2]: *Age, mean ± SD:* *I: 75.4 ± 8.6* *C: 74.80 ± 8.8* *Sex:* *I: 75% M* *C: 77% M* *BMI* *I: 23.38 ± 3.46* *C: 23.31 ± 3.49* *Diabetes* *I: 52 (100)* *C: 49 (93)* *ABI:* *I: 0.38 ± 0.21* *C: 0.37 ± 0.23* Groups were comparable at baseline.					

Liistro, 2022 IN.PACT BTK NCT 02963649	Type of study: RCT Setting and country: multicentre, Belgium, France, Greece, Switzerland, Italy Funding and conflicts of interest: This study was supported by Medtronic. F. Liistro is an advisory board member for Biotronik, Boston Scientific, Medtronic, and Philips. I. Weinberg is a consultant for Magneto Thrombectomy Solutions, a	<u>Inclusion criteria</u>: Age ≥18 years. Subject has documented chronic Critical Limb Ischemia (CLI) in the target limb prior to the study procedure with Rutherford Clinical Category 4 or 5. Subjects with documented infection grade 0-2 and ischemia grade 2-3 according to WIfi classification. Reference Vessel Diameter (RVD) 2 - 4 mm, and confirmed by DUS assessment. Total occlusions with total lesion length ≥ 40 mm. Lesion must be located in the infrapopliteal	Drug coated balloon angioplasty IN.PACT 014 DCB	Plain balloon angioplasty	<u>Length of follow-up</u>: 9 months <u>Loss-to-follow-up</u>: Intervention: 0 Control: 0 <u>Incomplete outcome data</u>: Specified per outcome	<u>Freedom from binary restenosis</u> *Binary restenosis (≥50%), %* I: 70.0% (14/20 lesions) C: 83.3% (20/24 lesions) P=0.472 <u>Re-intervention based on symptomatic restenosis</u> *CD-TLR at 9 months* I: 8.7 (2/23 patients) C: 8.7 (2/23 patients) *CD-TVR at 9 months* I: 8.7 (2/23 patients) C: 13.0 (3/23 patients) <u>Amputation</u>	<u>Authors' conclusion</u> At nine months, participants in the DCB group experienced a large separation (53% lower) in subsegmental LLL compared to those in the PTA group. Similarly, using the classic method, participants in the DCB group showed a trend of lower LLL compared to those in the PTA group. Safety outcomes were similar between the two arms.

	National Principal Investigator for Penumbra, Inc., and Medical Director of VASCORE, the Vascular Imaging Core Laboratory. A. Almonacid Popma receives no personal fees; her spouse, J. Popma, joined Medtronic as an employee after completion of the analysis but prior to publication. M.H. Shishehbor reports consultant income from	arteries and above the ankle joint. Multiple lesions can be treated if located in separate vessels. … <u>Exclusion criteria</u>: Planned index limb amputation above the metatarsal level, or any other planned major surgery within 30 days pre or post-procedure. Lesion and/or occlusions located or extending in the popliteal artery or below the ankle joint space. Significant inflow lesion or occlusion in the ipsilateral iliac,				Major amputation at 9 months I: 0 C: 0 <u>Wound healing</u> Not reported <u>Quality of life</u> Not reported <u>Mortality</u> I: 4.3 (1/23) C: 8.0 (2/25)	

	Abbott Vascular, Boston Scientific, Medtronic, Philips, and Terumo. S. Deckers is a full-time employee of Medtronic. A. Micari is an advisory board member for Boston Scientific and Medtronic.	SFA and popliteal arteries left untreated. Failure to obtain ≤ 30% residual stenosis in pre-existing, hemodynamically significant inflow lesions in the ipsilateral iliac, SFA and popliteal artery. … <u>N total at baseline</u>: Intervention: 23 patients, 25 lesions Control: 27 patients, 30 lesions <u>Important prognostic factors</u>[2]: *Age, mean ± SD:* *I: 73.1±7.4* *C: 69.6±9.4*					

		Sex: *I: 82.6% M* *C: 74.1% M* *BMI ≥30 kg/m2* *I: 22.7%* *C: 26.9%* *Diabetes mellitus* *I: 73.9 (17/23)* *C: 96.3 (26/27)* *ABI* *Not reported* Groups were comparable at baseline.					
Liistro, 2022 DEBATE-BTK NCT 01556542	Type of study: RCT Setting and country: single-centre, Italy Funding and conflicts of interest:	<u>Inclusion criteria</u>: Presence of diabetes mellitus, CLI (Rutherford class 4 or greater), stenosis or occlusion ≥40 mm of at least 1 tibial vessel with distal runoff to	Drug coated balloon angioplasty IN.PACT balloon	Plain balloon angioplasty	<u>Length of follow-up</u>: 5 years <u>Loss-to-follow-up</u>: Not specified <u>Incomplete outcome data</u>: Not specified	<u>Freedom from binary restenosis</u> *Not specified for this time point* <u>Re-intervention based on symptomatic restenosis</u> *CD-TLR at 5 years, per lesion*	<u>Authors' conclusion</u> Overall survival at 5-year was similar in DCB treated patients compared to POBA. Moreover, survival was higher in patients that

	This study was not supported by any funding. Dr. Francesco Liistro has the following relation to disclose within the last 2 years: Consultant for Medtronic, Boston scientific and Biotronic. The authors declare that they have no conflict of interest.	the foot, and agreement to 12-month angiographic evaluation. <u>Exclusion criteria</u>: life expectancy <1 year, allergy to paclitaxel, contraindication to combined antiplatelet treatment, and planned major amputation before angiography <u>N total at baseline</u>: Intervention: 65 Control: 67 <u>Important prognostic factors</u>[2]: *Age, mean ± SD:* *I: 74 ± 9.4* *C: 75 ± 9.6*				I: 29 (37%) C: 36 (46%) <u>Amputation</u> Major amputation at 5 years I: 1/65 (2%) C: 2/67 (3%) <u>Wound healing</u> Not reported <u>Quality of life</u> Not reported <u>Mortality</u> I: 24/65 (36.9) C: 32/67 (46.3)	received DCB angioplasty at any time of the 5 years period.

		Sex: *I: 83% M* *C: 78% M* *Diabetes mellitus 100%* *ABI* *I: 0.31 ± 0.8* *C: 0.29 ± 1.0* Groups were comparable at baseline.					
Patel, 2021 SINGA-PACLI Trial NCT 02129634	Type of study: RCT Setting and country: two-center, Singapore. Funding and conflicts of interest: Supported by the National Medical Research	<u>Inclusion criteria</u>: 21 years or older; Rutherford category 4, 5, or 6; stenosis of 50% or more (at visual angiographic assessment) or occlusion of at least one native infrapopliteal artery; there had to be a	Drug-coated balloon angioplasty (Passeo-18 Lux; Biotronik)	Non-coated balloon angioplasty (Passeo-18; Biotronik)	<u>Length of follow-up</u>: 12 months <u>Loss-to-follow-up</u>: Intervention: 15/70 (21%) 1 withdrew consent 14 defaulted clinical follow-up Control: 7/68 (10%)	<u>Freedom from binary restenosis</u> *Primary patency of target lesion at 6 months:* I: 30/70 (43%) C: 26/68 (38%) <u>Re-intervention based on symptomatic restenosis</u> *CD-TLR at 12 months* I: 8/41 (20%)	<u>Authors' conclusion</u> Our randomized controlled trial demonstrated that drug-coated balloon angioplasty not only did not improve primary patency of the below-the-knee arteries in patients with critical limb ischemia

	Council (NMRC). One author disclosed payment for lectures from Boston Scientific. disclosed money to author's institution for grant from the National Medical Research Council Singapore; support for travel from Singapore Health Services. One author disclosed research grant from the National Medical Research	posttreatment expectation of at least one patent vessel to the ankle <u>Exclusion criteria</u>: The total lesion length was not to exceed 200 mm. <u>N total at baseline</u>: Intervention: 70 Control: 68 <u>Important prognostic factors</u>[2]: *Age, mean ± SD:* *I: 61 ± 10* *C: 64 ± 10* *Sex:* *I: 61% M* *C: 74% M* *Diabetes mellitus* *I: 94%*			2 withdrew consent 5 defaulted clinical follow-up <u>Incomplete outcome data</u>: Not specified	C: 10/53 (19%) <u>Amputation</u> Major amputation at 12 months I: 17/68 (25%) C: 10/65 (15%) <u>Wound healing</u> Complete healing of index wound I: 35/67 (52%) C: 39/67 (61%) <u>Quality of life</u> Not reported <u>Mortality</u> I: 15/70 (21%) C: 11/68 (16%)	compared with percutaneous transluminal angioplasty at 6 months, but also resulted in shorter amputation-free survival or in another term higher amputation rate after 12 months.

	Council Singapore.	*C: 94%* *ABI* *I: 0.80 ± 0.30* *C: 0.80 ± 0.28* Groups were comparable at baseline.					
Bosiers, 2012 DESTINY NTC 00510393	Type of study: RCT Setting and country: multicenter, Europe Funding and conflicts of interest: This trial was funded by Abbott Laboratories. Competition of interest: Drs Bosiers, Scheinert, and Zeller serve on the Advisory	<u>Inclusion criteria</u>: chronic symptomatic peripheral arterial disease (PAD) in **Rutherford-Becker clinical categories 4 to 5** (ischemic rest pain or ischemic ulceration) due to atherosclerotic de novo occlusive lesions of the tibial arteries. symptomatic PAD due to a maximum of two	Everolimus-eluting stent Xience V everolimus-eluting stent with Multi-Link Vision stent platform	Bare metal stent Multi-Link Vision stent.	<u>Length of follow-up</u>: 12 months <u>Loss-to-follow-up</u>: 12-month angiographic follow-up 46%. Reasons: death in 23, refusal in 21, excessive risk due to medical comorbidity in 14, poor image quality precluding reliable interpretation by the core laboratory in 14, loss to clinical follow-up in seven, and major	<u>Freedom for binary restenosis</u> *Restenosis ≥50% at 12 months* I: 17%, 13/75 C: 36%, 26/73 Freedom from restenosis I: 83%, 62/75 C: 64%, 47/73 <u>Primary patency</u> *At 12 months* I: 85.2% C: 54.4% Patency per lesion, but numbers not possible to deduce. Number of patients not specified.	<u>Authors' conclusion</u> The results showed that after 12 months, use of the Xience V DES significantly decreased late lumen loss, restenosis, and the need for repeat intervention. These data suggest that Xience V stenting is a useful therapeutic adjunct in patients with CLI that require prolonged patency following

	Board of Abbott Vascular. Dr Schwartz is a full-time employee of Abbott Laboratories.	focal de novo atherosclerotic target lesions in one or more infrapopliteal vessels. Lesions with ≥50% diameter stenosis were considered for the trial when their length was ≤40 mm and they arose in target vessels with diameters of 2.0 to 3.5 mm. <u>Exclusion criteria</u>: Not specified. <u>N total at baseline</u>: Intervention: 74 patients, 78 lesions, 86 stents Control: 66 patients, 76 lesions, 92 stents			extremity amputation in three. The frequency of angiographic follow-up was equal between the two groups (Vision 46% vs Xience V 49%; P = 0.73). <u>Incomplete outcome data</u>: Not specified	<u>Re-intervention based on symptomatic restenosis</u> *freedom from target lesion revascularization* I: 92% 78/85 C: 65% 76/117 <u>Amputation</u> Major amputation I: 1/74 C: 2/66 <u>Wound healing</u> Not reported <u>Quality of life</u> Not reported <u>Mortality</u> I: 18%, 13/74 C: 16% 11/66	endovascular recanalization.

		Important prognostic factors[2]: *Age, mean ± SD:* *I: 75 ± 8.0* *C: 76 ± 8.4* *Sex (%male):* *I: 61* *C: 67* *Diabetes mellitus* *I: 60%* *C: 50%* *ABI* *Not reported* Groups were comparable at baseline.					
Spreen, 2016 NCT 00471289 PADI trial	Type of study: RCT Setting and country: multi-center, the Netherlands	Inclusion criteria: Adult patients were eligible for enrollment if they have CLI (defined as Rutherford category ≥4) caused by	Drug-eluting stent In the DES arm, target lesions were treated with balloon expandable	Bare-metal stent Patients in the PTA±BMS arm received PTA according to the normal practice of the operator. A balloon with a	Length of follow-up: 12 months Loss-to-follow-up: Intervention: 7 patients incomplete follow-up for imaging	Freedom from binary restenosis *Less than 50% stenosis at 6 months* I: 48%, 47/98 lesions C: 35.1%, 27/77 lesions	Authors' conclusion In patients with critical limb ischemia caused by infrapopliteal lesions, DES provide better 6-month patency

	Funding and conflicts of interest: The PADI trial received an unrestricted grant during the conduct of the study from The Netherlands Society for Interventional Radiology, who had no role in study design, data collection, analysis, interpretation, or writing of the report. Dr Overhagen has received speaker's fees from Cordis Corporation, Fremont, CA; Cook Medical, Bloomington,	infrapopliteal lesions. Lesions were considered for inclusion if there was >50% luminal loss, lesion length of ≤90 mm, and reference vessel diameter 2 to 6 mm, estimated by pretreatment imaging.18 Inflow had to be unobstructed, possibly after revascularization in the femoropopliteal segment during the same session. Outflow distal to target lesions should consist of ≥1 crural vessel with expected unobstructed runoff until the	paclitaxel-eluting stainless steel coronary stents (TAXUS Liberté; Boston Scientific, Natick, MA). If necessary, according to the operator, mainly in cases of occlusion, lesions were predilated.	diameter matching the target vessel was advanced over the guidewire and inflated at the target lesion site.	Control: 6 patients incomplete follow-up for imaging <u>Incomplete outcome data</u>: Not specified	<u>Re-intervention based on symptomatic restenosis</u> *At 6 months* I: 3/73 patients, 4.1% C: 0/64 <u>Amputation</u> Major amputation at 12 months I: 8/74 limbs C: 13/66 limbs <u>Wound healing</u> Not reported <u>Quality of life</u> Not reported <u>Mortality</u> At 12 months I: 17/73 patients C: 16/64 patients	rates and less amputations after 6 and 12 months compared with PTA±BMS.

	IN; and AngioDynamics, Latham, NY. The above are unrelated to the submitted work. The other authors report no conflicts.	level of the ankle joint. Exclusion criteria: In data supplement N total at baseline: Intervention: 73 patients, 74 limbs Control: 64 patients, 66 limbs Important prognostic factors[2]: *For example age (SD):* *I: 74.2 (12.1)* *C: 72.9 (11.9)* *Sex:* *I: 67.1% M* *C: 73.4% M* *Diabetes:* *I: 60.3%*					

		C: 67.2% Groups were comparable at baseline.					
Spreen, 2017	Follow-up to Spreen, 2016				<u>Length of follow-up</u>: 5 years	<u>Freedom from binary restenosis</u> ≤50% stenotic at 2 years I: 15/48, 31.3% C: 11/45, 24.4% At 5 years I: 5/43, 11.6% C: 3/35, 8.6% <u>Re-intervention</u> Total number not reported <u>Amputation</u> Major amputation at 2 years I: 9/68, 13.2% C: 15/60, 24.8% At 5 years I: 11/57, 19.3% C: 17/50, 34%	<u>Authors' conclusion</u> this randomized controlled trial showed that long-term amputation- and event-free survival in patients with CLI due to infrapopliteal lesions is more favorable after treatment with DESs compared with the conventional endovascular strategy of PTA-BMS. The limited available morphological results also showed higher

						<u>Wound healing</u> Not reported <u>Quality of life</u> Not reported <u>Mortality</u> At 2 years I: 17/73, 23.3% C: 19/64, 29.7% At 5 years I: 32/73, 43.8% C: 31/64, 48.8%	preserved patency rates after DESs than after PTA-BMS. Given the feasibility of DESs for infrapopliteal lesions, proven not only at short and midterm but also long term, one should consider treatment with a DES in patients with CLI caused by lesions below the knee.

Risk of bias tabel

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?**	**Was the allocation adequately concealed?**	**Blinding: Was knowledge of the allocated interventions adequately prevented?** **Were patients blinded?**	**Was loss to follow-up (missing outcome data) infrequent?**	**Are reports of the study free of selective outcome reporting?**	**Was the study apparently free of other problems that could put it at a risk of bias?**	**Overall risk of bias** **If applicable/necessary, per outcome measure**

	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	**Were healthcare providers blinded?** **Were data collectors blinded?** **Were outcome assessors blinded?** **Were data analysts blinded?** Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	**LOW** **Some concerns** **HIGH**
Fanelli, 2014	Definitely yes; Reason: Patients were randomized (1:1) without stratification using computer-generated	Probably yes; Reason: not specified	**Probably no**; Reason: health care providers were not blinded, but patients and outcome	Definitely yes; Reason: No loss to follow-up reported.	Probably yes; Reason: All relevant outcomes were reported	Probably yes; Reason: No other problems noted	**Some concerns for CD-TLR**

	assignments when they entered the angiographic suite.		assessors were blinded.				
Jia, 2020	Definitely yes; Reason: All patients were randomly assigned to the DCB or control group (1:1 ratio) by a central randomization computer system.	Definitely yes; Reason: Opaque, sealed envelopes were used and opened by an independent researcher.	**Definitely no;** Reason: No specific measures were taken to blind the person who performed the repeat angiography or who made the decision about CD-TLR, whereas quantitative evaluation of the angiograms was performed by a core laboratory blinded to the type of treatment provided.	Definitely yes; Reason: Loss to follow-up was infrequent in intervention and control group.	Probably yes; Reason: All relevant outcomes were reported	Probably yes; Reason: No other problems noted	**Some concerns for CD-TLR**
Liistro, 2020	Definitely yes;	Probably yes;	**Definitely no**;	Definitely yes;	Probably yes;	Probably yes;	**Some concerns for CD-TLR**

	Reason: Target lesions were randomly assigned to 1 of the 2 study arms after optimal angioplasty. Randomization was performed in 2 parallel blocks of 10 with the use of computer-generated random digits.	Reason: Prior to randomization, single or sequential balloon dilatations were performed to reach an optimal angiographic result. In case of randomization to POBA, the procedure ended with final angiography.	Reason: patients were blinded, but health care providers were not. Outcomes of interest are not likely affected by lack of blinding, except CD-TLR	Reason: Loss to follow-up was infrequent in intervention and control group.	Reason: All relevant outcomes were reported	Reason: No other problems noted	
Liistro, 2022 IN.PACT BTK	Probably yes; Reason: mentioned but not specified.	Probably yes; Reason: mentioned but not specified.	**Definitely no**; Due to the nature of the procedure, it was not possible to blind the operator or study site staff. In addition, participants were not blinded due to	Definitely yes; Reason: Loss to follow-up was infrequent in intervention and control group.	Probably yes; Reason: All relevant outcomes were reported	Probably yes; Reason: No other problems noted	**Some concerns for CD-TLR**

			inherent differences in procedure between the DCB and PTA groups				
Liistro, 2022 DEBATE-BTK	Definitely yes; Lesions were randomly assigned to 1 of the 2 study arms after successful passage of the guidewire. Randomization was performed in blocks of 10 with the use of computer-generated random digits.	Definitely yes; Group assignments were placed in sealed envelopes.	**Definitely no**; The study was not blinded.	No information	Probably yes; Reason: All relevant outcomes were reported	Probably yes; Reason: No other problems noted	**Some concerns for CD-TLR**
Patel, 2021 SINGA-PACLI	Definitely yes; The randomization sequence was computer generated by our academic	Definitely yes; To conceal treatment allocation, we used tamper-proof serially numbered	**Definitely no;** Participants and study personnel who performed the follow-up imaging (duplex US and	**Probably no;** For later time points, loss to follow-up was considerable and different between	Probably yes; Reason: All relevant outcomes were reported	Probably yes; Reason: No other problems noted	**Some concerns for CD-TLR and outcomes at 12 months**

	collaborator (Singapore Clinical Research Institute), with permuted block lengths of four and six, and stratification by diabetes mellitus, end-stage renal failure status, and study site.	opaque envelopes accessible only to the operator performing the procedure.	angiography) assessments were blinded to the treatment assignment. Clinicians deciding revascularization were not blinded.	intervention and control group (20 vs 10%)			
Bosiers, 2020 DESTINY	Definitely yes; Block randomization and stratification per center were conducted using block sizes of eight, which resulted in slightly unequal study populations.	Definitely yes; After successful wire traversal, patients were randomized 1:1 using preprovided sealed envelopes.	**Definitely no**; Patients were blinded to their treatment assignment, and study site personnel were counseled on nondisclosure. The physician performing the procedure was not blinded to the assigned treatment.	**Probably no;** Loss to follow-up up to one year was limited for clinical outcomes, but high for outcomes based on imaging.	Probably yes; Reason: All relevant outcomes were reported	Probably yes; Reason: No other problems noted	**Some concerns for CD-TLR and patency at 12 months**

Falkowski, 2008	Definitely yes; Patients were randomly divided into two groups using statistica StatSoft	No information	**Definitely no**; Open-label study	Probably yes; Loss to follow-up up was infrequent	Probably yes; Reason: All relevant outcomes were reported	Probably yes; Reason: No other problems noted	**Some concerns for CD-TLR**
Rastan, 2011 Rastan, 2021	Definitely yes; We allocated patients to the two treatment groups using a computer-generated random sequence, set in blocks for each participating centre. Patients were randomly assigned to the groups in a 1:1 ratio.	Probably yes; Not specified, but likely.	Definitely yes; Physicians and patients were unaware of the treatment-group assignment. All clinical endpoints were adjudicated by an independent clinical-events committee. All physicians including the medical staffs, the research coordinators,	**Probably no;** Loss to follow-up up was limited for clinical outcomes, but high for outcomes based on imaging.	Probably yes; Reason: All relevant outcomes were reported	Probably yes; Reason: No other problems noted	**Some concerns for patency**

			and the clinical-events committee were blinded for the treatment-group assignments.				
Spreen, 2016 Spreen, 2017 PADI	Definitely yes; Computer-generated random sequence on a 1:1 basis. andomization was per limb and stratified in blocks per center.	Definitely yes; The attending radiological technician opened the sealed, opaque envelope. The block size (n=4) was known only to the statistician.	**Definitely no;** Patients, operators, and investigators were not blinded	Probably yes; Reason: Loss to follow-up up was infrequent	Probably yes; Reason: All relevant outcomes were reported	Probably yes; Reason: No other problems noted	**Some concerns for CD-TLR**

Exclusie tabel

Reference	Reason for exclusion
Falkowski A, Poncyljusz W, Wilk G, Szczerbo-Trojanowska M. The evaluation of primary stenting of sirolimus-eluting versus bare-metal stents in the treatment of atherosclerotic lesions of crural arteries. Eur Radiol. 2009 Apr;19(4):966-74. doi: 10.1007/s00330-008-1225-1. Epub 2008 Nov 26. PMID: 19034460.	Wrong population: majority patients with claudication
Haddad SE, Shishani JM, Qtaish I, Rawashdeh MA, Qtaishat BS. One Year Primary Patency of Infrapopliteal Angioplasty Using Drug- Eluting Balloons: Single Center Experience at King Hussein Medical Center. J Clin Imaging Sci. 2017 Aug 3;7:31. doi: 10.4103/jcis.JCIS_34_17. PMID: 28852581; PMCID: PMC5559924.	Data extracted from systematic review
Rastan A, Brechtel K, Krankenberg H, Zahorsky R, Tepe G, Noory E, Schwarzwälder U, Macharzina R, Schwarz T, Bürgelin K, Sixt S, Tübler T, Neumann FJ, Zeller T. Sirolimus-eluting stents for treatment of infrapopliteal arteries reduce clinical event rate compared to bare-metal stents: long-term results from a randomized trial. J Am Coll Cardiol. 2012 Aug 14;60(7):587-91. doi: 10.1016/j.jacc.2012.04.035. PMID: 22878166.	Wrong population: majority patients with claudication
Rastan A, Tepe G, Krankenberg H, Zahorsky R, Beschorner U, Noory E, Sixt S, Schwarz T, Brechtel K, Böhme C, Neumann FJ, Zeller T. Sirolimus-eluting stents vs. bare-metal stents for treatment of focal lesions in infrapopliteal arteries: a double-blind, multi-centre, randomized clinical trial. Eur Heart J. 2011 Sep;32(18):2274-81. doi: 10.1093/eurheartj/ehr144. Epub 2011 May 26. PMID: 21622669.	Wrong population: majority patients with claudication
Bosiers MJ, Deloose K, Peeters P, Torsello G, Zeller T, Scheinert D, Schmidt A, Maene L, Keirse K, Varcoe R, Bosiers M. Outcome of a drug-eluting stent in longer below-the-knee lesions in patients with critical limb ischemia. J Cardiovasc Surg (Torino). 2017 Feb;58(1):49-54. doi: 10.23736/S0021-9509.16.09546-X. Epub 2016 Jul 26. PMID: 27455888.	Wrong study design
Fanelli F, Cannavale A, Corona M, Lucatelli P, Wlderk A, Salvatori FM. The "DEBELLUM"--lower limb multilevel treatment with drug eluting balloon--randomized trial: 1-year results. J Cardiovasc Surg (Torino). 2014 Apr;55(2):207-16. PMID: 24670828.	Wrong population: femoro-popliteal region
Katsanos K, Spiliopoulos S, Diamantopoulos A, Siablis D, Karnabatidis D, Scheinert D. Wound Healing Outcomes and Health-Related Quality-of-Life Changes in the ACHILLES Trial: 1-Year Results From a	Wrong comparison

Prospective Randomized Controlled Trial of Infrapopliteal Balloon Angioplasty Versus Sirolimus-Eluting Stenting in Patients With Ischemic Peripheral Arterial Disease. JACC Cardiovasc Interv. 2016 Feb 8;9(3):259-267. doi: 10.1016/j.jcin.2015.10.038. Epub 2016 Jan 6. PMID: 26777329.	
Konijn LCD, Wakkie T, Spreen MI, de Jong PA, van Dijk LC, Wever JJ, Veger HTC, Statius van Eps RG, Mali WPTM, van Overhagen H. 10-Year Paclitaxel Dose-Related Outcomes of Drug-Eluting Stents Treated Below the Knee in Patients with Chronic Limb-Threatening Ischemia (The PADI Trial). Cardiovasc Intervent Radiol. 2020 Dec;43(12):1881-1888. doi: 10.1007/s00270-020-02602-6. Epub 2020 Jul 28. PMID: 32725411; PMCID: PMC7649154.	Wrong study design
Scheinert D, Katsanos K, Zeller T, Koppensteiner R, Commeau P, Bosiers M, Krankenberg H, Baumgartner I, Siablis D, Lammer J, Van Ransbeeck M, Qureshi AC, Stoll HP; ACHILLES Investigators. A prospective randomized multicenter comparison of balloon angioplasty and infrapopliteal stenting with the sirolimus-eluting stent in patients with ischemic peripheral arterial disease: 1-year results from the ACHILLES trial. J Am Coll Cardiol. 2012 Dec 4;60(22):2290-5. doi: 10.1016/j.jacc.2012.08.989. PMID: 23194941.	Wrong comparison
Sivapragasam N, Matchar DB, Zhuang KD, Patel A, Pua U, Win HH, Chandramohan S, Venkatanarasimha N, Chua JME, Tan GWL, Irani FG, Leong S, Tay KH, Chong TT, Tan BS. Cost-Effectiveness of Drug-Coated Balloon Angioplasty Versus Conventional Balloon Angioplasty for Treating Below-the-Knee Arteries in Chronic Limb-Threatening Ischemia: The SINGA-PACLI Trial. Cardiovasc Intervent Radiol. 2022 Nov;45(11):1663-1669. doi: 10.1007/s00270-022-03073-7. Epub 2022 Mar 2. PMID: 35237860.	Wrong study design
Zeller T, Micari A, Scheinert D, Baumgartner I, Bosiers M, Vermassen FEG, Banyai M, Shishehbor MH, Wang H, Brodmann M; IN.PACT DEEP Trial Investigators. The IN.PACT DEEP Clinical Drug-Coated Balloon Trial: 5-Year Outcomes. JACC Cardiovasc Interv. 2020 Feb 24;13(4):431-443. doi: 10.1016/j.jcin.2019.10.059. PMID: 32081236.	Wrong study design
Zeller T, Beschorner U, Pilger E, Bosiers M, Deloose K, Peeters P, Scheinert D, Schulte KL, Rastan A, Brodmann M. Paclitaxel-Coated Balloon in Infrapopliteal Arteries: 12-Month Results From the BIOLUX P-II Randomized Trial (BIOTRONIK'S-First in Man study of the Passeo-18 LUX drug releasing PTA Balloon Catheter vs. the uncoated Passeo-18 PTA balloon catheter in subjects requiring	Data extracted from systematic review

revascularization of infrapopliteal arteries). JACC Cardiovasc Interv. 2015 Oct;8(12):1614-22. doi: 10.1016/j.jcin.2015.07.011. PMID: 26493253.	
Zeller T, Baumgartner I, Scheinert D, Brodmann M, Bosiers M, Micari A, Peeters P, Vermassen F, Landini M, Snead DB, Kent KC, Rocha-Singh KJ; IN.PACT DEEP Trial Investigators. Drug-eluting balloon versus standard balloon angioplasty for infrapopliteal arterial revascularization in critical limb ischemia: 12-month results from the IN.PACT DEEP randomized trial. J Am Coll Cardiol. 2014 Oct 14;64(15):1568-76. doi: 10.1016/j.jacc.2014.06.1198. PMID: 25301459.	Data extracted from systematic review
Cassese S, Ndrepepa G, Liistro F, Fanelli F, Kufner S, Ott I, Laugwitz KL, Schunkert H, Kastrati A, Fusaro M. Drug-Coated Balloons for Revascularization of Infrapopliteal Arteries: A Meta-Analysis of Randomized Trials. JACC Cardiovasc Interv. 2016 May 23;9(10):1072-80. doi: 10.1016/j.jcin.2016.02.011. Epub 2016 Apr 27. PMID: 27131439.	More recent systematic review used
Chen X, Li J, Zheng C, He Y, Jia J, Wang X, Li D, Shang T, Li M. Drug-delivering endovascular treatment versus angioplasty in artery occlusion diseases: a systematic review and meta-analysis. Curr Med Res Opin. 2018 Jan;34(1):95-105. doi: 10.1080/03007995.2017.1372114. Epub 2017 Nov 6. PMID: 28837370.	More recent systematic review used
Matsuoka EK, Hasebe T, Ishii R, Miyazaki N, Soejima K, Iwasaki K. Comparative performance analysis of interventional devices for the treatment of ischemic disease in below-the-knee lesions: a systematic review and meta-analysis. Cardiovasc Interv Ther. 2022 Jan;37(1):145-157. doi: 10.1007/s12928-021-00758-7. Epub 2021 Feb 6. PMID: 33547627; PMCID: PMC8789697.	More complete systematic review used

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Perifeer arterieel vaatlijden - Infragenuaal: Gecoate ballonnen en stents	
Uitgangsvraag/modules: Wat is de optimale behandeling van het infragenuale traject?	
Database(s): Ovid/Medline, Embase.com	Datum: 10 augustus 2022
Periode: 2000 - 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: • Patiënten met PAV; infragenuaal letsel • Drug-eluting balloon and stents of vessel preparation gerelateerde termen De opgegeven sleutelartikelen worden gevonden met de search.
Te gebruiken voor richtlijnen tekst: *Nederlands* In de databases Embase.com en Ovid/Medline is op 10 augustus 2022 met relevante zoektermen gezocht naar systematische reviews, RCT en observationele studies over de optimale behandeling van het infragenuale traject. De literatuurzoekactie leverde 475 unieke treffers op. *Engels* On the 10th of August, relevant search terms were used to search for systematic reviews, RCT and observational studies about the optimal treatment for patients with infragenual/infrapopliteal arterial occlusive disease in the databases Embase.com and Ovid/Medline. The search resulted in 475 unique hits.

Zoekopbrengst

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SRs	61	45	64
RCT	89	101	114
Observationele studies	151	233	297
Totaal	301	379	**475**

Zoekstrategie

Embase.com

No.	**Query**	**Results**
#21	#18 OR #19 OR #20	301
#20	#14 AND #17 NOT (#18 OR #19) = **Observationeel**	151
#19	#14 AND #16 NOT #18 = **RCT**	89
#18	#14 AND #15 = **SR**	61
#17	'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-	15094884

	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))) OR '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)	
#16	'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	1943343
#15	'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	847757
#14	#11 AND #12 AND #13 AND ([english]/lim OR [dutch]/lim) AND [2000-2022]/py NOT ('conference abstract'/it OR 'editorial'/it OR 'letter'/it OR	394

	'note'/it) NOT (('animal experiment'/exp OR 'animal model'/exp OR 'nonhuman'/exp) NOT 'human'/exp)	
#13	'drug eluting cardiovascular stent'/exp OR 'drug-eluting balloon catheter'/exp OR 'drug-coated balloon'/exp OR (((eluting OR drug OR coated OR paclitaxel OR sirolimus OR everolimus) NEAR/3 (stent* OR balloon*)):ti,ab,kw) OR 'paclitaxel'/exp OR 'sirolimus'/exp OR 'everolimus'/exp OR 'vessel preparation':ti,ab,kw OR 'lithotripsy'/exp OR 'intravascular lithotripsy'/exp OR 'intravascular lithotripsy':ti,ab,kw OR 'cutting balloon catheter'/exp OR ((balloon* NEAR/3 (cutting OR scoring)):ti,ab,kw) OR 'laser'/exp OR laser*:ti,ab,kw OR 'orbital atherectomy'/exp OR 'orbital atherectomy device'/exp OR 'orbital atherectomy*':ti,ab,kw OR csi:ti,ab,kw	601485
#12	((below NEAR/3 knee*):ti,ab,kw) OR btk:ti,ab,kw OR infrapopliteal:ti,ab,kw OR infragenual:ti,ab,kw OR genicular:ti,ab,kw	16771
#11	'peripheral vascular disease'/exp OR 'artery disease'/exp OR 'peripheral occlusive artery disease'/exp OR 'critical limb ischemia'/exp OR 'leg ischemia'/exp OR ((isch?em* NEAR/3 ('lower limb*' OR leg*)):ti,ab,kw) OR 'chronic limb-threatening isch?em*':ti,ab,kw OR clti:ti,ab,kw OR 'critical limb isch?em*':ti,ab,kw OR isch?em*:ti,ab,kw	221788

Ovid/Medline

#	Searches	Results
23	20 or 21 or 22	379
22	(16 and 19) not (20 or 21) = **Observationeel**	233
21	(15 and 19) not 20 = **RCT**	101
20	14 and 19 = **SR**	45
19	limit 18 to ((english language or dutch) and yr="2000 -Current")	481
18	17 not (comment/ or editorial/ or letter/ or ((exp animals/ or exp models, animal/) not humans/))	571
17	11 and 12 and 13	616
16	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/ 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.	6935662

	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.))	
15	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.	1536826
14	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.	611021
13	exp *Angioplasty, Balloon/ or exp Drug-Eluting Stents/ or ((eluting or drug or coated or paclitaxel or sirolimus or everolimus) adj3 (stent* or balloon*)).ti,ab,kf. or exp Paclitaxel/ or exp Sirolimus/ or exp Everolimus/ or 'vessel preparation'.ti,ab,kf. or exp Lithotripsy/ or exp Lithotripsy, Laser/ or exp Lasers/ or 'intravascular lithotripsy'.ti,ab,kf. or laser*.ti,ab,kf. or (balloon* adj3 (cutting or scoring)).ti,ab,kf. or 'orbital atherectomy*'.ti,ab,kf. or CSI.ti,ab,kf.	427852
12	((below adj3 knee*) or btk or infrapopliteal or infragenual or genicular).ti,ab,kf.	10209
11	exp Ischemia/ or isch?em*.ti,ab,kf. or clti.ti,ab,kf. or exp Arterial Occlusive Diseases/ or exp Peripheral Vascular Diseases/ or exp Peripheral Vascular Diseases/	878584

Module 9: Vessel preparation (femoro-popliteaal)

Evidence tabel

Study reference	Study characteristics	Patient characteristics [2]	Intervention (I)	Comparison / control (C) [3]	Follow-up	Outcome measures and effect size [4]	Comments
Böhme, 2021	Type of study: RCT Setting and country: three medical centers in Germany. Funding and conflicts of interest: funding not reported. Different authors have received honoraria, were members of advisory boards/consultant.	Inclusion criteria: Rutherford Clinical Category Score of 1-5, willing and capable of complying with all follow-up evaluations at the specified times, aged ≥18 years, and providing written informed consent prior to the study procedures. Exclusion criteria: Exclusion criteria were	Intervention: Photoablation (laser atherectomy) procedure followed by drug-coated balloon angioplasty.	Control: PTA followed by drug-coated balloon angioplasty.	Length of follow-up: 24 months Loss-to-follow-up: At 24 months: 16 patients did not complete the 24 month follow-up. Incomplete outcome data: Not reported.	Patency/restenosis: *Defined as primary patency at 12 months* I: 20/30 C: 24/30 *Defined as primary patency at 24 months* I: 10/18 (56.6%) C: 11/20 (53.8%) Amputation: Not reported. Re-intervention based on symptomatic restenosis (TLR):	Authors' conclusion: The study confirms the safety of instent photoablation with use of the excimer laser. Due to sample size, no significant difference between the two cohorts with respect to primary patency and restenosis rate could be shown.

		contraindications, hypersensitivity to contrast material/device material, uncontrollable hypercoagulable condition or refuses blood transfusion, life expectancy of less than 12 months, pregnant, not taking adequate contraceptives or nursing, surgical or endovascular procedure of the target vessel within 14 days prior to the index procedure, planned surgical intervention or endovascular procedure within 30 days after the index procedure, currently				*Defined as target lesion revascularization at 12 months* I: 4/30 C: 4/31 *Defined as target lesion revascularization at 24 months* I: 8/22 (36.4%) C: 7/25 (28.0%) <u>Quality of life:</u> *Defined as health related quality of life measured by EQ-5D at 12 months* I: mean 64.46 (SD ± 20.7) C: mean 68.71 (SD ± 22.5) *Defined as health related quality of life measured by EQ-5D at 24 months*	

		participating in a study which may interfere, co-morbid condition which precludes safe percutaneous intervention, previous peripheral bypass affecting the target vessel, chronic renal insufficiency with creatinine >2.5 mg/L, and unable or unwilling to receive dual anti-platelet therapy. <u>N total at baseline</u>: Intervention: 30 Control: 31 <u>Important prognostic factors</u>[2]: *Age ± SD:* *I: 66.00 ± 9.6*				I: mean 61.84 (SD ± 18.57) C: mean 68.36 (SD ± 23.06) <u>Mortality:</u> I: 2/30 C: 1/31 <u>Complications:</u> Not reported.	

		C: 69.48 ± 9.8 *Sex:* *I: 66.7% M* *C: 74.2% M* *Diabetes:* *I: 12 (40.0%)* *C: 12 (38.7%)* *Rutherford class 1:* *I: 2 (6.7%)* *C: 1 (3.2%)* *Rutherford class 2:* *I: 2 (6.7%)* *C: 7 (22.6%)* *Rutherford class 3:* *I: 22 (73.3%)* *C: 19 (61.3%)* *Rutherford class 4:* *I: 3 (10%)* *C: 1 (3.2%)*					

		Rutherford class 5: *I: 1 (3.3%)* *C: 3 (9.7%)* Groups were comparable at baseline, except for current smoking status.					
Cai, 2019	Type of study: RCT Setting and country: single-center, Beijing, China Funding and conflicts of interest: The study is supported by Beijing municipal administration of hospitals clinical technology innovation program, talent training program, outstanding	<u>Inclusion criteria</u>: All patients signed an informed consent form, digital subtraction angiography revealed femoropropliteal artery stenosis >70%, or occlusion with unobstructured vascular inflow, with at least a vessel runoff, good compliance and regular follow-up.	DA-DCB: Directional atherectomy + drug-coated balloon A plaque excision system was used firstly, after removal of the plaques the lesion site was pre-dilated with an uncoated balloon, and then was treated with	DCB: Drug-coated balloon Pre-dilation by uncoated balloon catheters and the dilation by Orchid paclitaxel-coated peripheral balloon catheters.	<u>Length of follow-up</u>: Patients were evaluated up to hospital discharge, at 30 days, and at 6, 12, 18, 24 months after endovascular interventions. <u>Loss-to-follow-up</u>: Not reported. <u>Incomplete outcome data</u>: Not reported.	<u>Patency/restenosis:</u> *Defined as primary patency at 12 months (no significant restenosis (<50%) or occlusion with no clinically drive reintervention)* I: 80.5% C: 75.7% *Defined as primary patency at 24 months (no significant restenosis (<50%) or occlusion with no clinically drive reintervention)*	Authors' conclusion: DA combined with DCBs in the treatment of femoropopliteal atherosclerotic occlusion has a satisfactory effect, and it can reduce the incidence of flow-limiting dissection. There was no significant difference between the two groups in terms of primary patency rate.

	talents project, incubating program, and innovation program. The authors declared no potential conflicts of interest.	Exclusion criteria: Patients with cerebrovascular diseases less than half a year, arterial thrombosis, abnormal liver function (serum creatinine >176 micromol/L), contraindications on paclitaxel, antiplatelet or anticoagulation, abnormal protein C, protein S, and antithrombin III, abnormal number of platelets and lower fibrinogen, unsatisfactory control of blood pressure, blood glucose and lipid, unable to quit smoking completely, poor compliance	DCBs angioplasty.			I: 67.1% C: 55.1% Amputation: *Defined as limb amputation* I: 0% C: 0% Re-intervention based on symptomatic restenosis (TLR): *Defined as clinically driven target lesion revascularization* I: 2/45 (4.4%) C: 2/49 (4.1%) Quality of life: Not reported. Mortality: *Defined as overall mortality* I: 0/45 (0%) C: 2/49 (4.1%) Complications:	

		makes regular follow-up impossible. <u>N total at baseline</u>: Intervention: 45 Control: 49 <u>Important prognostic factors</u>[2]: *Age ± SD:* *I: 67 ± 11* *C: 67 ± 9* *Sex:* *I: 82.2% M* *C: 71.4% M* *Diabetes:* *I: 53.3%* *C: 65.3%* *Rutherford class 2:* *Not reported.* *Rutherford class 3:*				*Defined as flow-limiting dissections (treated by bailout stenting)* I: 2/45 (4.4%) C: 12/49 (24.5%)	

		I: 37.5% *C: 58.3%* *Rutherford class 4:* *I: 20.0%* *C: 16.7%* *Rutherford class 5:* *I: 10.0%* *C: 8.3%* There was no significant difference between the study arms with regards to lesion location, TASC classification, lesion length, reference vessel diameter or vessel runoff.					
Dattilo, 2014	Type of study: RCT – pilot study	<u>Inclusion criteria</u>: Eligible patients were 18 years or older, had	OA + BA: vessel preparation utilizing orbital atherectomy +	BA: balloon angioplasty	<u>Length of follow-up</u>: 12 months	<u>Patency/Freedom from binary restenosis:</u>	Authors' conclusion: Compared to BA alone for the

	Setting and country: 9 centers in the United States. Funding and conflicts of interest: The COMPLIANCE 360° study was sponsored by Cardiovascular Systems, Inc. Dr. Dattilo reports research grants, consulting fees, and speaking/teaching honoraria from Cardiovascular Systems, Inc. Dr. Himmelstein reports consulting fees and speaking/teaching honoraria from Cardiovascular Systems, Inc. Dr. Cuff reports no disclosures.	peripheral arterial disease with Rutherford class 2-4 symptoms and de novo FP lesions of ≥70% stenosis with fluoroscopically visible calcium, and gave informed consent. All patients had to have at least 1 patent run-off vessel. Distal popliteal lesions were included, only one limb per patient. Exclusion criteria: An anticipated life span of less than 1 year, known allergy to heparin, aspirin, and clopidogrel, or sensitivity to	balloon angioplasty		Loss-to-follow-up: Not reported. Incomplete outcome data: Not reported.	*Defined as freedom from TLR or restenosis at 6 months* I: 77.1% (27/35) C: 11.5% (3/26) *Defined as freedom from TLR or restenosis at 12 months* I: 6/32 (81.2%) C: 5/23 (78.3%) Complications: *Defined as perforations* I: 0/38 (0%) C: 1/27 (3.7%) *Defined as dissections* I: 6/38 (15.8%) C: 13/27 (48.1%) Amputation: Not reported. Re-intervention based on	treatment of calcium-containing FP lesions, OA pretreatment likely improves lesion compliance and leads to better luminal gain with lower balloon pressures, resulting in a marked reduction of adjunctive stenting.

		contrast media, chronic renal failure, cardiac arrhytmias, congestive heart failure exacerbation, and myocardial infarction. <u>N total at baseline</u>: Intervention: 25 (38 lesions) Control: 25 (27 lesions) <u>Important prognostic factors</u>[2]: *Age ± SD:* *I: 68.0 ± 11.0* *C: 71.3 ± 10.5* *Sex:* *I: 28% M* *C: 36% M* *Diabetes:* *I: 18 (72%)*				<u>symptomatic restenosis:</u> Not reported. <u>Quality of life:</u> Not reported. <u>Mortality:</u> Not reported.	

		C: 10 (40%) *Rutherford classification (baseline):* *I: 2.80 (2-4)* *C: 2.92 (2-4)* Significantly more patients in the OA group were diabetic. For the other characteristics, the groups were comparable.					
Zeller, 2017	Type of study: RCT – pilot study Setting and country: 10 hospitals in Belgium, Germany, Poland, and Switzerland Funding and conflicts of interest: The study was an	Inclusion criteria: RCC of 2-4, 18 years or older, target lesion of ≥70% de novo stenosis or restenosis or occlusion in the SFA and/or popliteal artery, had a target lesion length of 7-15 cm, had a reference vessel	DA + DCB angioplasty: directional atherectomy (removal of plaque from the vessel wall) + drug-coated balloon angioplasty	DCB angioplasty: drug-coated balloon angioplasty	Length of follow-up: 1 year Loss-to-follow-up: Intervention: N=7 (14.6%) Reasons: -Withdrew (n=3) -Lost to follow-up (n=2) -Died (n=2) Control:	Patency/restenosis: *Defined as primary patency measured with ultrasonography at 1 year* I: 84.6% (33/39) C: 81.3% (39/48) Amputation: *Defined as amputation of the treated limb* I: 0	Author's conclusion: For the treatment of femoropopliteal lesions, vessel preparation with DA before DCB angioplasty seems to be safe in mid-term follow-up and might have benefits in more challenging lesion

	investigator-initiated study with industry funding from Covidien (now Medtronic PLC). Study cohort size was limited by funding. Dr. Zeller, Dr. Rocha-Singh, Dr. Jaff, Dr. Blessing, Dr. Cheinert, Dr. Langhoff, and Dr. Tepe report being member of advisory boards, being non-compensated and compensated members, receiving speakers honoraria, being a consultant.	diameter of 4-7 mm. <u>Exclusion criteria</u>: Surgical or endovascular procedure of the target vessel within 14d before the index procedure, planned intervention within 30d after the index procedure, had ≥2 lesions that required treatment in the target limb (not including the iliac arteries), had a target lesion with an occluded segment ≥5 cm in length, had in-stent restenosis of the target lesion or restenosis of the			N=4 (7.4%) Reasons: -Withdrew (n=3) -Died (n=1) <u>Incomplete outcome data</u>: Not reported.	C: 0 <u>Re-intervention based on symptomatic restenosis:</u> *Defined as CD-TLR* I: 3/41 C: 5/50 <u>Quality of life:</u> Not reported. <u>Mortality:</u> *Defined as death at 1 year* I: 2/41 C: 1/50 <u>Complications</u> *Defined as grade C/D dissections* I: 1/41 (2.1%) C: 10/50 (18.5%) *Defined as arterial perforation* I: 2/48 (4.2%) C: 0/54 (0%)	subsets that are at higher risk for acute and chronic technical treatment failure of PTA, such as severely calcified lesions.

		target lesion after previous treatment with a drug-coated balloon, had an acute intraluminal thrombus within the target lesion, had an aneurysmal target vessel. Randomization exclusion criterion: had severe calcification in the target lesion. <u>N total at baseline</u>: Intervention: 48 Control: 54 <u>Important prognostic factors</u>[2]: *Age ± SD:* *I: 70.1 ± 9.7* *C: 69.0 ± 8.2*					

		Sex: *I: 64.6% M* *C: 68.5% M* *Diabetes:* *I: 27.1% (13/48)* *C: 35.2% (19/54)* *Rutherford class 2:* *I: 27.1% (13/48)* *C: 24.1% (13/54)* *Rutherford class 3:* *I: 70.8% (34/48)* *C: 74.1% (40/54)* *Rutherford class 4:* *I: 2.1% (1/48)* *C: 1.9% (1/54)* *Rutherford class 5:* *Not reported.*					

		Groups were comparable at baseline.					
Tepe, 2021	Type of study: RCT Setting and country: 45 centers in Austria, Germany, New Zealand, and the United States Funding and conflicts of interest: Shockwave Medical provided financial support for this research. The authors were on advisory boards, have received honoraria, were consultant, and received funds.	Inclusion criteria: Eligible patients presented with symptomatic leg claudication or rest pain (Rutherford class 2 to 4) and angiographic evidence of $70% stenosis within the superficial femoral or popliteal artery, lesion length up to 180 mm (up to 100 mm for chronic total occlusion), reference vessel diameter 4 to 7 mm, and moderate or severe calcification. Exclusion criteria:	IVL + DCB: vessel preparation with a low pressure lithotripsy balloon.	PTA + DCB: treatment with a standard PTA balloon.	Length of follow-up: 30 days Loss-to-follow-up: Intervention: N=1 (0.7%) Reason: withdrawn Control: N=1 (0.7%) Reasons: withdrawn Incomplete outcome data: Intervention: N=7 (4.6%) Reasons: missing core lab-adjudicated angiographic data occurred at random. Control:	Patency/restenosis: Not reported. Amputation: Not reported. Re-intervention based on symptomatic restenosis: *Defined as CD-TLR within 30 days* I: 1/152 C: 1/152 Quality of life: Not reported. Mortality: *Defined as death within 30 days* I: 0 C: 0 Complications *Defined as perforation*	Authors' conclusions: IVL is a safe and effective vessel preparation strategy that facilitates a leave-nothing-behind approach to definitive endovascular treatment in patients with calcified femoropopliteal arteries.

		See supplemental table 1. <u>N total at baseline</u>: Intervention: 153 Control: 153 <u>Important prognostic factors</u>[2]: *Age ± SD:* *I: 72.2 ± 8.0* *C: 71.5 ± 7.7* *Sex:* *I: 69.3% M* *C: 78.4% M* *Diabetes:* *I: 41.1% (64/152)* *C: 46.7% (71/152)* *Rutherford class 2:* *I: 16.3% (25/153)* *C: 16.3% (25/153)* *Rutherford class 3:*			N=20 (13.1%) Reasons: missing core lab-adjudicated angiographic data occurred at random.	I: 0 C: 0 *Defined as any dissection (including flow-limiting dissection):* I: 18.5% C: 32.3% *Defined as flow-limiting dissections:* I: 1.4% C: 6.8%	

		I: 77.8% (119/153) *C: 75.2% (115/153)* *Rutherford class 4:* *I: 5.9% (9/153)* *C: 7.8% (12/153)* *Rutherford class 5:* *I: 0.0% (0/153)* *C: 0.7% (1/153)* Groups were comparable at baseline.					

Risk of bias tabel

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?**	**Was the allocation adequately concealed?**	**Blinding: Was knowledge of the allocated interventions adequately prevented?** **Were patients blinded?**	**Was loss to follow-up (missing outcome data) infrequent?**	**Are reports of the study free of selective outcome reporting?**	**Was the study apparently free of other problems that could put it at a risk of bias?**	**Overall risk of bias If applicable/necessary, per outcome measure**

	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	**Were healthcare providers blinded?** **Were data collectors blinded?** **Were outcome assessors blinded?** **Were data analysts blinded?** Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	**LOW** **Some concerns** **HIGH**
Böhme, 2021	No information	No information	No information	**Probably no** Reason: loss-to-follow-up was 26% in the total study cohort. Loss-to-follow-up was not	Probably yes Reason: It seems like all relevant outcome measures were reported.	**Definitely no** Reason: small number of patients in the treatment group due to slow enrolment and early termination,	**HIGH** (all outcomes except for mortality)

				described for intervention and control group separately.		majority of patients treated at two sites (potential bias in procedure outcome and results).	
Cai, 2019	No information	No information	No information	Probably yes Reason: Loss-to-follow-up was not described, but two patients died in the control group and no patients died in the intervention group.	Definitely yes Reason: All relevant outcome measures were reported.	**Definitely no** Reason: small sample size, and some patients' follow-up did not reach 24 months.	**Some concerns** (all outcomes except for mortality)
Dattilo, 2014	No information	Definitely yes Reason: Sealed randomization envelopes were provided to each site.	No information	No information	Definitely yes Reason: All relevant outcome measures were reported.	**Definitely no** Reason: small number of patients (differences in baseline characteristics), lack of independent angiographic and duplex ultrasound core lab adjudication,	**Some concerns** (all outcomes except for mortality)

						patients were lost to follow-up during the study, operator discretion to adjunctively stent lesions failing to achieve residual stenosis of <30%, rather than being protocol driven.	
Zeller, 2017	Definitely yes Reason: Block randomization by center was used to assign patients in a 1:1 fashion to the intervention and control group.	No information	**Definitely no** Reason: Investigators, patients, and the angiographic core laboratory were not blinded. The duplex ultrasound core laboratory staff and the clinical events committee were blinded to the treatment assignment.	**Definitely no** Reason: Loss-to-follow-up was 14.6% in the intervention group and 7.4% in the control group.	Definitely yes Reason: All relevant outcome measures were reported.	**Definitely yes** Reason: The study was not sufficiently powered to draw conclusions about the impact of DA for lesion preparation before DCB angioplasty in femoropopliteal interventions. There was a significant difference in balloon pre- and postdilatation between trial arms. The mean lesion length was longer in	**HIGH** (all outcomes except for mortality)

						the intervention group.	
Tepe, 2021	No information	Definitely yes Reason: Randomized group assignments were provided to investigators using an interactive voice response system or via a secure website.	**Definitely no** Reason: Single-blind study (the clinical events committee were blinded). Investigators and research staff were not blinded to treatment assignment.	**Probably no** Reason: Incomplete outcome data was 4.6% in the intervention group and 13.1% in the control group. Loss to follow-up was less than 1% in both groups.	Definitely yes Reason: All relevant outcome measures were reported.	**Definitely no** Reason: Interpretation of 30-day clinical outcomes is confounded by definitive treatment using DCB or stent placement in all patients. Longer - term follow-up will be needed to evaluate treatment durability after IVL.	**HIGH** (all outcomes except for mortality)

Exclusie tabel

Reference	Reason for exclusion
Amighi J, Schillinger M, Dick P, Schlager O, Sabeti S, Mlekusch W, Haumer M, Mathies R, Heinzle G, Schuster A, Loewe C, Koppensteiner R, Lammer J, Minar E, Cejna M. De novo superficial femoropopliteal artery lesions: peripheral cutting balloon angioplasty and restenosis rates--randomized controlled trial. Radiology. 2008 Apr;247(1):267-72. doi: 10.1148/radiol.2471070749. Epub 2008 Feb 12. PMID: 18270378.	Verkeerde vergelijking van interventies.
Diamantopoulos A, Katsanos K. Atherectomy of the femoropopliteal artery: a systematic review and meta-analysis of randomized controlled trials. J Cardiovasc Surg (Torino). 2014 Oct;55(5):655-65. Epub 2014 Jul 10. PMID: 25008063.	De drie geïncludeerde RCTs worden los meegenomen.
Gupta R, Siada S, Lai S, Al-Musawi M, Malgor EA, Jacobs DL, Malgor RD. Critical appraisal of the contemporary use of atherectomy to treat femoropopliteal atherosclerotic disease. J Vasc Surg. 2022 Feb;75(2):697-708.e9. doi: 10.1016/j.jvs.2021.07.106. Epub 2021 Jul 22. PMID: 34303802.	Geïncludeerde studies in de SR voldoen niet.
Lin F, Wang H, Ding W, Chen G, Zhang Z. Atherectomy plus drug-coated balloon versus drug-coated balloon only for treatment of femoropopliteal artery lesions: A systematic review and meta-analysis. Vascular. 2021 Dec;29(6):883-896. doi: 10.1177/1708538120985732. Epub 2021 Jan 21. PMID: 33478353.	De twee geïncludeerde RCTs worden los meegenomen.
Poncyljusz W, Falkowski A, Safranow K, Rać M, Zawierucha D. Cutting-balloon angioplasty versus balloon angioplasty as treatment for short atherosclerotic lesions in the superficial femoral artery: randomized controlled trial. Cardiovasc Intervent Radiol. 2013 Dec;36(6):1500-1507. doi: 10.1007/s00270-013-0603-5. Epub 2013 Apr 11. PMID: 23576210.	Verkeerde vergelijking van interventies.
Shammas NW, Coiner D, Shammas GA, Dippel EJ, Christensen L, Jerin M. Percutaneous lower-extremity arterial interventions with primary balloon angioplasty versus Silverhawk atherectomy and adjunctive balloon angioplasty: randomized trial. J Vasc Interv Radiol. 2011 Sep;22(9):1223-8. doi: 10.1016/j.jvir.2011.05.013. Epub 2011 Jul 14. PMID: 21757372.	Verkeerde populatie (verkeerd traject, tibiaal).
Wardle BG, Ambler GK, Radwan RW, Hinchliffe RJ, Twine CP. Atherectomy for peripheral arterial disease. Cochrane Database Syst Rev. 2020 Sep 29;9(9):CD006680. doi:	De drie geïncludeerde RCTs worden los meegenomen.

10.1002/14651858.CD006680.pub3. PMID: 32990327; PMCID: PMC8513671.	
Wu Z, Huang Q, Pu H, Qin J, Wang X, Ye K, Lu X. Atherectomy Combined with Balloon Angioplasty versus Balloon Angioplasty Alone for de Novo Femoropopliteal Arterial Diseases: A Systematic Review and Meta-analysis of Randomised Controlled Trials. Eur J Vasc Endovasc Surg. 2021 Jul;62(1):65-73. doi: 10.1016/j.ejvs.2021.02.012. Epub 2021 Jun 8. PMID: 34112574.	De vier geïncludeerde RCTs worden los meegenomen.
Zhen Y, Chang Z, Wang C, Liu Z, Zheng J. Directional Atherectomy with Antirestenotic Therapy for Femoropopliteal Artery Disease: A Systematic Review and Meta-Analysis. J Vasc Interv Radiol. 2019 Oct;30(10):1586-1592. doi: 10.1016/j.jvir.2019.06.012. Epub 2019 Aug 27. PMID: 31471198.	Geïncludeerde studies in de SR voldoen niet.
Zhou Y, Wang J, He H, Li Q, Li M, Li X, Shu C. Comparative effectiveness of endovascular treatment modalities for de novo femoropopliteal lesions in intermittent claudication: A network meta-analysis of randomized controlled trials. Int J Cardiol. 2021 Nov 15;343:122-130. doi: 10.1016/j.ijcard.2021.08.038. Epub 2021 Aug 27. PMID: 34461162.	Verkeerde studie design: netwerk meta analyse.

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: PAV – Vessel preparation (femoro-popliteaal)	
Uitgangsvraag/modules: Wat is de optimale behandeling van het femoro-popliteale traject (vessel preparation)	
Database(s): Ovid/Medline, Embase.com	Datum: 15 april 2024 (update van 6 juli 2022)
Periode: 2022 - heden	Talen: Engels, Nederlands
Literatuurspecialist: Esther van der Bijl	
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: • Femoro-popliteaal letsel • Vessel preparation Zoals afgesproken worden in eerste instantie allen de SR's aangeboden in Rayyan: https://rayyan.ai/reviews/998616 De sleutelartikelen worden gevonden met de zoekopdracht.	
Te gebruiken voor richtlijnen tekst: *Nederlands* Dit betreft een update van de search van 6 juli 2022. In de databases Embase.com en Ovid/Medline is op 15 april 2024 met relevante zoektermen gezocht naar systematische	

reviews en RCT's over behandeling van het femoro-popliteale traject. De literatuurzoekactie leverde 36 nieuwe unieke treffers op.

Engels
This is an update of the search from 6th of July 2022. On the 15th of April relevant search terms were used to search for systematic reviews and RCTs about treatment of the femoro-popliteal tract in the databases Embase.com and Ovid/Medline. The search resulted in 36 new unique hits.

Zoekopbrengst 15 april 2024

	EMBASE	**OVID/MEDLINE**	**Rayyan 6 juli 2022**	**Ontdubbeld**
SRs	50	35		18
RCT	69	68		18
Observationele studies	210	151		64
Totaal	329	254	321	**36*** (100-64)

Zoekopbrengst 6 juli 2022

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SRs	36	26	41
RCT	54	59	80
Observationele studies	153	124	200
Totaal	243	209	**321 (Rayyan 6 juli 2022)**

ZoekstrategieEmbase.com 15 april 2024

No.	Query	Results
#1	'leg ischemia'/exp/mj OR 'claudication'/exp/mj OR 'popliteal artery'/exp/mj OR (((popliteal* OR femoropopliteal* OR 'femoro popliteal') NEAR/3 arter*):ti,ab,kw) OR claudicatio*:ti,kw OR 'angina cruris':ti,kw OR 'dysbasia':ti,kw OR ((isch?em* NEAR/3 ('lower limb*' OR leg*)):ti,kw) OR 'chronic limb-threatening isch?em*':ti,ab,kw OR clti:ti,ab,kw OR 'critical limb isch?em*':ti,ab,kw	26078
#2	'atherectomy'/exp OR 'atherectomy device'/exp OR atherectom*:ti,ab,kw OR predilatation:ti,ab,kw OR 'pre dilatation':ti,ab,kw OR 'cutting balloon catheter'/exp OR (((cutting OR 'high pressure') NEAR/3 balloon*):ti,ab,kw) OR ((vessel NEAR/3 prepar*):ti,ab,kw) OR 'lithotripsy'/exp OR 'lithotripsy':ti,ab,kw	42293
#3	#1 AND #2 AND ([english]/lim OR [dutch]/lim) AND [2000-2024]/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)	544
#4	'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	1018893

	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	
#5	'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	2184718
#6	'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	14991452

	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)))	
#7	#3 AND #4 **– SR's**	50
#8	#3 AND #5 NOT #7 **– RCT's**	69
#9	#3 AND #6 NOT (#7 OR #8) **– observationele studies**	210
#10	#7 OR #8 OR #9	329

Ovid/Medline 15 april 2024

#	Searches	Results
1	(exp Ischemia/ and exp Leg/) or exp Intermittent Claudication/ or exp Popliteal Artery/ or ((popliteal* or femoropopliteal* or femoro popliteal) adj3 arter*).ti,ab,kf. or claudicatio*.ti,ab,kf. or angina cruris.ti,ab,kf. or dysbasia.ti,ab,kf. or (isch?em* adj3 (lower limb* or leg*)).ti,ab,kf.	35255
2	exp Atherectomy/ or atherectom*.ti,ab,kf. or predilatation.ti,ab,kf. or 'pre dilatation'.ti,ab,kf. or ((cutting or 'high pressure') adj3 balloon*).ti,ab,kf. or (vessel adj 3 prepar*).ti,ab,kf. or exp Lithotripsy/ or 'lithotripsy'.ti,ab,kf.	22523
3	1 and 2	663
4	limit 3 to ((english language or dutch) and yr="2000 -Current")	513
5	4 not (comment/ or editorial/ or letter/ or ((exp animals/ or exp models, animal/) not humans/))	472
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.	739031
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.	1705396
8	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	5665970

	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.))	
9	5 and 6 **– SR's**	35
10	(5 and 7) not 9 **– RCT's**	68
11	(5 and 8) not (9 or 10) **– observationele studies**	151
12	9 or 10 or 11	254

Module 10: Voorkomen van wondinfecties in de lies na arteriële chirurgie

Evidence tabel

Study reference	Study characteristics	Patient characteristics [2]	Intervention (I)	Comparison / control (C) [3]	Follow-up	Outcome measures and effect size [4]	Comments
Ploeg, 2009	Type of study: RCT Setting and country: Singel center, the Netherlands Funding and conflicts of interest: No statements of funding and conflict of interest.	Inclusion criteria: All patients who underwent an exploration of the femoral artery for either a central or a peripheral arterial reconstruction. Exclusion criteria: All patients in which the femoral artery was explored in	Medial approach with sparing of the lymphatics The medial approach included a straight-down approach of the femoral artery through the subcutis, holding the lymphatics until the artery was reached. A vertical skin incision in the groin was performed in the	Lateral approach in which the lymphatics were cut The lateral approach included a vertical skin incision after which the subcutis was cut approximately 5 cm lateral of the skin incision straight down until the fascia lata was reached; from there, the artery was explored	Length of follow-up: 6 weeks Loss-to-follow-up: Intervention: N (%) Reasons (describe) Control: N (%) Reasons (describe) Incomplete outcome data: Intervention: N (%) Reasons (describe) Control:	Wound infection *Per operation* Week 1 Szilagyi I Medial: 22/98 (22.4%) Lateral: 18/100 (18.0%) Szilagyi II Medial: 14/98 (14.3%) Lateral: 10/100 (10.0%) Szilagyi III none Week 2 Szilagyi I	Authors' conclusions: Using a lateral vertical incision for the approach of the common femoral artery did not decrease the incidence of postoperative wound complications.

		previous operations were excluded. <u>N total at baseline</u>: Medial: 90 patients, 98 operations Lateral: 81 patients, 100 operations <u>Important prognostic factors</u>[2]: *Age, median (range:* *medial: 70 (36–91)* *lateral: 69 (44–94)* *Sex:* *medial: 64.4% M* *lateral: 60.5% M*	same manner in both groups at the level of the common femoral artery.	medially, whereas the skin and subcutis holding the lymphatics were kept medial.	N (%) Reasons (describe)	Medial: 14/98 (14.3%) Lateral: 12/100 (12.0%) Szilagyi II Medial: 8/98 (8.2%) Lateral: 11/100 (11.0%) Szilagyi III none Week 6 Szilagyi I Medial: 4/98 (4.1%) Lateral: 5/100 (5.0%) Szilagyi II Medial: 2/98 (2.0%) Lateral: 1/100 (1.0%) Szilagyi III none	

		Diabetes mellitus *medial: 25.6%* *lateral: 19.8%* *Severe claudication* *medial: 42.9%* *lateral: 46.0%* *Ischemic rest pain* *medial: 26.5%* *lateral: 30.0%* Groups were comparable at baseline.				<u>Seroma</u> Lymphorrhea 1 week Medial: 28 (28.6%) Lateral: 25 (25.0%) 2 weeks Medial: 13 (13.3%) Lateral: 16 (16.0%) 6 weeks Medial: 3 (3.1%) Lateral: 5 (5.0%)	

Risk of bias tabel

Study reference (first author, publication year)	**Was the allocation sequence adequately generated?**	**Was the allocation adequately concealed?**	**Blinding: Was knowledge of the allocated interventions adequately prevented?** **Were patients blinded?**	**Was loss to follow-up (missing outcome data) infrequent?**	**Are reports of the study free of selective outcome reporting?**	**Was the study apparently free of other problems that could put it at a risk of bias?**	**Overall risk of bias** **If applicable/necessary, per outcome measure**

	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	**Were healthcare providers blinded?** **Were data collectors blinded?** **Were outcome assessors blinded?** **Were data analysts blinded?** Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	**LOW** **Some concerns** **HIGH**
Ploeg, 2009	Definitely yes; Randomization was performed before the study by computer randomization.	Definitely yes; The approach of the femoral artery (lateral or direct) to be used was	Definitely yes; Examination of the wound took place 1, 2, and 6 weeks after surgery by an independent	Definitely yes; No loss to follow-up for main outcomes.	Probably yes; All relevant outcomes were reported.	Probably yes; No problems noted.	**LOW**

		assigned with numbered sealed envelopes to be opened after skin incision.	observer at the ward or at the outpatient clinic. Because the skin incision in both groups was at the same location and the patient and the blinded observer were not aware of the randomization, this study was considered a double-blind trial.				

Exclusie tabel

Reference	Reason for exclusion
Antoniou GA, Onwuka CC, Antoniou SA, Russell D. Meta-analysis and trial sequential analysis of prophylactic negative pressure therapy for groin wounds in vascular surgery. J Vasc Surg. 2019 Nov;70(5):1700-1710.e6. doi: 10.1016/j.jvs.2019.01.083. Epub 2019 May 22. PMID: 31126768.	Wrong comparison
Bennett KM, Levinson H, Scarborough JE, Shortell CK. Validated prediction model for severe groin wound infection after lower extremity revascularization procedures. J Vasc Surg. 2016 Feb;63(2):414-9. doi: 10.1016/j.jvs.2015.08.094. Epub 2015 Oct 30. PMID: 26526055.	Wrong study design
Bloom JA, Tian T, Homsy C, Singhal D, Salehi P, Chatterjee A. A Cost-Utility Analysis of the Use of Closed-Incision Negative Pressure System in Vascular Surgery Groin Incisions. Am Surg. 2023 Jun;89(6):2237-2246. doi: 10.1177/00031348221087395. Epub 2022 Apr 7. PMID: 35392664.	Wrong comparison
Canteras M, Baptista-Silva JC, do Carmo Novaes F, Cacione DG. Transverse versus vertical groin incision for femoral artery approach. Cochrane Database Syst Rev. 2020 Apr 22;4(4):CD013153. doi: 10.1002/14651858.CD013153.pub2. PMID: 32319682; PMCID: PMC7175778.	Wrong comparison
Gwilym BL, Dovell G, Dattani N, Ambler GK, Shalhoub J, Forsythe RO, Benson RA, Nandhra S, Preece R, Onida S, Hitchman L, Coughlin P, Saratzis A, Bosanquet DC. Editor's Choice - Systematic Review and Meta-Analysis of Wound Adjuncts for the Prevention of Groin Wound Surgical Site Infection in Arterial Surgery. Eur J Vasc Endovasc Surg. 2021 Apr;61(4):636-646. doi: 10.1016/j.ejvs.2020.11.053. Epub 2021 Jan 7. PMID: 33423912.	Wrong comparison
Gwilym BL, Ambler GK, Saratzis A, Bosanquet DC; Groin wound Infection after Vascular Exposure (GIVE) Study Group. Groin Wound Infection after Vascular Exposure (GIVE) Risk Prediction Models: Development, Internal Validation, and Comparison with Existing Risk Prediction Models Identified in a Systematic Literature Review. Eur J Vasc Endovasc Surg. 2021 Aug;62(2):258-266. doi: 10.1016/j.ejvs.2021.05.009. Epub 2021 Jul 8. PMID: 34246547.	Wrong comparison
Gwilym BL, Locker DT, Matthews EK, Mazumdar E, Adamson G, Wall ML, Bosanquet DC. Systematic review of groin wound surgical site infection	Wrong comparison

incidence after arterial intervention. Int Wound J. 2023 Apr;20(4):1276-1291. doi: 10.1111/iwj.13959. Epub 2022 Oct 2. PMID: 36184849; PMCID: PMC10031242.	
Kirkham AM, Candeliere J, McIsaac DI, Stelfox HT, Dubois L, Gill HL, Brandys T, Nagpal SK, Roberts DJ. Efficacy of Strategies Intended to Prevent Surgical Site Infection After Lower Limb Revascularization Surgery: A Systematic Review and Meta-Analysis of Randomized Controlled Trials. Ann Surg. 2023 Sep 1;278(3):e447-e456. doi: 10.1097/SLA.0000000000005867. Epub 2023 Mar 30. PMID: 36994744.	Wrong comparison
Kuyumdzhiev S, Kuyumdzhieva G, Tiwari A. Comparison of transverse versus longitudinal skin incisions for femoral endarterectomy and patchplasty. Vascular. 2022 Dec;30(6):1168-1173. doi: 10.1177/17085381211051483. Epub 2021 Dec 4. PMID: 34866514.	Wrong comparison
Svensson-Björk R, Hasselmann J, Acosta S. Evaluation of inguinal vascular surgical scars treated with closed incisional negative pressure wound therapy using three-dimensional digital imaging-A randomized controlled trial on bilateral incisions. Wound Repair Regen. 2018 Jan;26(1):77-86. doi: 10.1111/wrr.12615. Epub 2018 Mar 7. PMID: 29381241.	Wrong comparison
Svensson-Björk R, Zarrouk M, Asciutto G, Hasselmann J, Acosta S. Meta-analysis of negative pressure wound therapy of closed groin incisions in arterial surgery. Br J Surg. 2019 Mar;106(4):310-318. doi: 10.1002/bjs.11100. Epub 2019 Feb 6. PMID: 30725478.	Wrong comparison

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Perifeer arterieel vaatlijden - Voorkomen van wondinfecties in de lies na arteriële chirurgie	
Uitgangsvraag/modules: Wat is de waarde van verschillende liesbenaderingen bij patiënten met perifeer arterieel vaatlijden?	
Database(s): Embase.com, Ovid/Medline	Datum: 17 april 2024
Periode: vanaf 2000	Talen: geen restrictie
Literatuurspecialist: Esther van der Bijl	Rayyan review: https://rayyan.ai/reviews/1001524
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 artery surgery EN groin incision. → Het sleutelartikel wordt gevonden met deze search.
Te gebruiken voor richtlijntekst: In de databases Embase.com en Ovid/Medline is op 17 april 2024 systematisch gezocht naar systematische reviews, RCTs en observationele studies over verschillende liesbenaderingen bij patiënten met perifeer arterieel vaatlijden. De literatuurzoekactie leverde 1013 unieke treffers op.

Zoekopbrengst 17 april 2024

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	63	46	66
RCT	275	147	321

Zoekstrategie Embase.com 17 april 2024

No.	Query	Results
#1	'artery surgery'/exp OR 'femoral artery stent'/exp OR 'common femoral endarterectomy'/exp OR 'endarterectomy'/exp OR (((endovascular OR arter*) NEAR/3 (intervention* OR 'surger*' OR repair*)):ti,ab,kw) OR ((arter* NEAR/3 (graft* OR stent* OR shunt* OR bypass*)):ti,ab,kw) OR 'end arteriectom*':ti,ab,kw OR 'endarterectom*':ti,ab,kw OR 'endarteriectom*':ti,ab,kw OR 'thrombendarterectom*':ti,ab,kw OR 'thromboendarterectom*':ti,ab,kw OR 'thromboendarteriectom*':ti,ab,kw OR pad:ti,ab,kw OR paod:ti,ab,kw	371965
#2	'incision'/exp AND 'inguinal region'/exp OR ((('groin*' OR inguinal* OR infrainguinal* OR fem?r*) NEAR/3 (incision* OR approach* OR access*)):ti,ab,kw)	14130
#3	#1 AND #2	2772
#4	#3 AND [2000-2024]/py 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)	1420
#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	1020060

	synthes*)):ab) AND (search*:ab OR database*:ab OR 'data base*':ab)) OR metasynthes*:ti,ab OR 'meta synthes*':ti,ab	
#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 controlled trial':ab,ti OR 'randomized controlled trial'/exp OR placebo*:ab,ti	4013301
#7	'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)	8177691
#8	'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)))	15001482

#9	#4 AND #5 **– SR's**	63
#10	#4 AND #6 NOT #9 **– RCT's**	275
#11	#4 AND (#7 OR #8) NOT (#9 OR #10) **– Observationele studies**	568
#12	#9 OR #10 OR #11	906

Zoekstrategie Ovid/Medline 17 april 2024

#	Searches	Results
1	exp Endarterectomy/ or (exp Femoral Artery/ and exp Stents/) or ((endovascular or arter*) adj3 (intervention* or surger* or repair*)).ti,ab,kf. or (arter* adj3 (graft* or stent* or shunt* or bypass*)).ti,ab,kf. or end arteriectom*.ti,ab,kf. or endarterectom*.ti,ab,kf. or endarteriectom*.ti,ab,kf. or thrombendarterectom*.ti,ab,kf. or thromboendarterectom*.ti,ab,kf. or thromboendarteriectom*.ti,ab,kf. or pad.ti,ab,kf. or paod.ti,ab,kf.	170340
2	(('groin*' or inguinal* or infrainguinal* or fem?r*) adj3 (incision* or approach* or access*)).ti,ab,kf.	6994
3	1 and 2	1175
4	limit 3 to yr="2000 -Current"	1087
5	4 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	1050
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.	739750
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$3)).tw. or Placebos/ or placebo*.tw.	2714120
8	Epidemiologic studies/ or case control studies/ or exp cohort studies/ or Controlled Before-After Studies/ or Case control.tw. or cohort.tw. or Cohort analy$.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]	4702541

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.))	5668381
10	5 and 6 **– SR's**	46
11	(5 and 7) not 10 **– RCT's**	147
12	(5 and (8 or 9)) not (10 or 11) **– Observationele studies**	466
13	10 or 11 or 12	659

Module 11: Beeldvorming bij follow-up na interventie

Evidence tabel

Study reference	Study characteristics	Patient characteristics	Intervention (I)	Comparison / control (C)	Follow-up	Outcome measures and effect size	Comments
Sarpe (2023)	SR and meta-analysis of randomized controlled trials *Literature search up to the 1st of February 2022.* A: Davies (2005) B: Lundell (1995) Study design: A: Randomized controlled trial B: Randomized controlled trial	Inclusion criteria SR: • all RCTs and quasi-RCTs with a parallel (e.g. cluster or individual) design that assessed DUS for postprocedure surveillance following lower limb revascularisation. Quasi-RCTs are studies in which participants	Describe intervention: A: Clinical examination with ABPI measurements plus duplex scan(duplex group). B: Intensive surveillance (combination of clinical examination, ABI, and duplex at 1, 3, 6, 9, 12, 15, 18, 24, and 36 months after surgery).	Describe control: A: Clinical examination with ABPI measurements. B: Intensive surveillance (combination of clinical examination, ABI at 1, 3, 6, 9, 12, 15, 18, 24, and 36 months after surgery).	End-point of follow-up: A: 18 months. B: 36 months. For how many participants were no complete outcome data available? (intervention/ control) A: 13% in the duplex group and 11% in the clinical group.	**Limb salvage rate** *A (Davies, 2005)* I: 283/304 C: 269/290 **All-cause mortality** *A (Davies, 2005)* I: 36/304 C: 31/290 **Quality of life (mean, SD)** SF-36 physical score *A (Davies, 2005)* I: 50 (28) (N=304)	Author's conclusion Based on low certainty evidence, we found no clear difference between DUS and standard surveillance in preventing limb amputation, morbidity, and mortality after lower limb revascularisation. We found no studies on DUS surveillance after angioplasty

	Setting and Country: A: B: Source of funding and conflicts of interest:	are allocated to intervention groups based on methods that are not truly random, such as hospital number or date of birth. We included studies reported as full text, those published as abstract only, and unpublished data. We did not apply any limitations on language of publication, sample size, date of publication, or minimal follow-up			B: N=2 in the duplex group and N=1 in the clinical group.	C: 48 (29) (N=290) SF-36 mental score *A (Davies, 2005)* I: 74 (21) (N=304 C: 71 (21) (N=290) EQ-5D utility score *A (Davies, 2005)* I: 0.64 (0.29) (N=304) C: 0.62 (0.29) (N=290) **Re-intervention** Any therapeutic intervention *A (Davies, 2005)* I: 66/304 C: 46/290) *B (Lundell, 1995)* I: 24/79 C: 19/77 Angiogram	or stenting (or both), only studies on bypass grafting. High-quality RCTs should be performed to better inform the best medical surveillance of lower limb revascularisation that may reduce the burden of peripheral arterial disease.

		period during study selection. Exclusion criteria • RCTs with a cross-over design, as these are not suitable to investigate DUS for the surveillance of lower limb revascularisation. *Two studies included* <u>Important patient characteristics at baseline</u>: <u>N, mean age</u> A: 70 years (range 63 to 76 for the duplex group and 61 to 77) for the clinical group).				*A (Davies, 2005)* I: 58/304) C: 43/290 *B (Lundell, 1995)* I: 27/79 C: 15/77	

		B: Duplex group mean (SD) 73.66 (11.32) years and clinical group 74.33 (11.83) years. <u>*Sex*</u>*:* A: N=218/304 male in duplex group and N=210/290 male in clinical group. B: 39/40 male in duplex group and 32/45 male in clinical group. Groups comparable at baseline? Yes.					

Risk of bias tabel

Study reference (first author,	**Was the allocation sequence adequately generated?**	**Was the allocation adequately concealed?**	**Blinding: Was knowledge of the allocated**	**Was loss to follow-up (missing outcome data) infrequent?**	**Are reports of the study free of selective**	**Was the study apparently free of other**	**Overall risk of bias If applicable/necessary, per outcome measure**

publication year)	Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	**interventions adequately prevented?** **Were patients/healthcare providers/data collectors/assessors/data analysts blinded?** Definitely yes Probably yes Probably no Definitely no	Definitely yes Probably yes Probably no Definitely no	**outcome reporting?** Definitely yes Probably yes Probably no Definitely no	**problems that could put it at a risk of bias?** Definitely yes Probably yes Probably no Definitely no	**LOW** **Some concerns** **HIGH**
Davies (2005)	Definitely yes. Reason: People from participating centres whose vein graft was patent at 30 days after surgery were randomised at 6 weeks (range 4 to 10 weeks)	Definitely yes Reason: Quote "The allocation of patients was performed by a central computer–based randomization service at the University of York."	No information. Reason: -	Probably yes. Reason: Quote "Apart from deaths, the withdrawal from follow-up was 12% overall (11% and 13% in the clinical and duplex groups, respectively). Of the withdrawals, 45% were due to amputation. Among	Definitely yes. Reason: All prespecified outcomes were reported.	Probably yes. Reason: No other bias reported or observed.	Some concerns Reason: no information regarding blinding of patients and/or outcome assessors.

	after surgery to either the clinical group or the duplex group. Quote "The allocation of patients was performed by a central computer–based randomization service at the University of York. This used randomly sized allocation blocks of sizes 4 and 6 (plus a small number of odd-sized blocks), stratified by center and presenting symptoms (claudication or critical ischemia)"			patients remaining in the tri- al, the proportion of follow-up appointments attended was 89% in the clinical group and 90% in the duplex group. At 18 months, 91% of all patients due for follow-up had a duplex scan. The response rate to the quality-of-life questionnaires was slightly lower at 80%." Quote "On the basis of anticipated 18-month amputation rates of 10%, the sample size of 600 patients yields a standard error for the difference in amputation rates between groups of 2.5%. The original plan was to recruit 1200 patients, but this proved impossible in the time available because of the in-			

				creased use of percutaneous endovascular treatments; the standard error based on 1200 patients would have been 1.7%" The study randomised only half the number of patients it required to be powered.			
Lundell (1995)	Probably no Reason: Quote "Randomization to an intensive surveillance group or to a routine sur-veillance group was done after the surgical procedure."	No information. Reason: -	No information. Reason: -	Probably yes. Reason: Quote "Three patients, two in the intensive surveillance group (one vein and one ePTFE graft) and one (ePTFE graft) in the routine surveillance group, were lost to follow-up examination after a median of 15 months"	Definitely yes. Reason: All prespecified outcomes were reported.	Probably yes. Reason: No other bias reported or observed.	High Reason: no information regarding selection bias or blinding of patients and/or outcome assessors.

Exclusie tabel

Author and year	Reason for exclusion
Draxler (2021)	Wrong study design.
Martinez-Rico (2022)	Wrong study design.
Martinez-RICO (2019)	Wrong study design.
McKenna (2023)	Wrong study design of the included studies in this systematic review.

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: NVvH Perifeer arterieel vaatlijden - Beeldvorming bij follow-up na interventie	
Uitgangsvraag/modules: UV 11 Wat is de waarde van aanvullende beeldvorming bij follow-up na interventies bij patiënten met perifeer arterieel vaatlijden?	
Database(s): Embase.com, Ovid/Medline	Datum: 30-1-2024
Periode: vanaf 2016	Talen: geen restrictie
Literatuurspecialist: Ingeborg van Dusseldorp	Rayyan review: https://rayyan.ai/reviews/915139
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 met de concepten: Vaatchirurgie, endovasculaire procedures EN duplex doppler ultrasonograpy/imaging surveillance EN lower extremities/iliac artery/femoral artery 16 van de 17 sleutelartikelen worden gevonden. Het artikel van Dalsing wordt niet gevonden omdat het niet over arteriën gaat. **1** Femorodistal vein grafts: The utility of graft surveillance criteria Dalsing M.C., Cikrit D.F., Lalka S.G., Sawchuk A.P., Schulz C. *Journal of Vascular Surgery* 1995 21:1 (127-134) Cited by: 21	
Te gebruiken voor richtlijntekst: In de databases Embase.com en Ovid/Medline is op 30-1-2024 systematisch gezocht naar systematische reviews, RCTs en observationele studies over de waarde van aanvullende beeldvorming bij follow-up na interventies bij patiënten die een vaatchirurgische of endovasculaire procedure hebben ondergaan. De literatuurzoekactie leverde 833 unieke treffers op.	

5

Zoekopbrengst

	EMBASE	OVID/MEDLINE	Ontdubbeld
SR	31	24	40
RCT	226	129	293
Observationele studies	368	328	500

Totaal	628	451	**833**

in Rayyan

Zoekstrategie

Embase.com

No.	Query	Results
#1	'color-flow duplex criteria for grading stenosis in infrainguinal vein grafts.':ti	1
#2	'femorodistal vein grafts: the utility of graft surveillance criteria.':ti	1
#3	'principal results of the vein graft surveillance randomised trial':ti	1
#4	'is early postoperative duplex scan surveillance of leg bypass grafts clinically important':ti	1
#5	'comparison of clinical follow-up and duplex surveillance of infrainguinal vein bypasses':ti	1
#6	'impact of a color-flow duplex surveillance program on infrainguinal vein graft patency':ti	1
#7	'does a completely accomplished duplex-based surveillance prevent vein-graft failure':ti	1
#8	'the utility of duplex scanning in infrainguinal vein graft surveillance':ti	1
#9	'a prospective comparison of ankle/brachial indices and color duplex imaging in surveillance of the in situ saphenous vein bypass':ti	1
#10	'the progression and correction of duplex detected velocity shifts in angiographically normal vein grafts':ti	1
#11	'femoropopliteal-crural graft patency is improved by an intensive surveillance program':ti	1
#12	'vein graft-surveillance improves patency in femoro-popliteal bypass':ti	1
#13	'early detection of saphenous vein arterial bypass graft stenosis by color-assisted duplex sonography':ti	1
#14	'the role of colour flow duplex screening in infra-inguinal vein grafts':ti	1
#15	'duplex scan surveillance during the first year after infrainguinal autologous vein bypass grafting surgery':ti	1
#16	#1 OR #2 OR #3 OR #4 OR #5 OR #6 OR #7 OR #8 OR #9 OR #10 OR #11 OR #12 OR #13 OR #14 OR #15 sleutelartikelen	15
#17	'systematic review and meta-analysis of duplex ultrasound surveillance for infrainguinal vein bypass grafts'	1
#18	'meta-analysis of duplex surveillance following lower limb endovascular intervention'	1
#19	#17 OR #18 sleutelartikelen	2
#20	'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	997753

	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	
#21	'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	3960697
#22	'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)	8047997
#23	'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-	14781768

	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)))	
#24	'vascular surgery'/exp OR 'graft dysfunction'/exp OR 'blood vessel graft'/exp OR 'blood vessel shunt'/exp OR 'revascularization'/exp OR 'endovascular surgery'/exp OR revascular*:ti,ab,kw OR ((endovascular NEAR/3 (intervention OR surgery)):ti,ab,kw) OR pad:ti,ab,kw OR paod:ti,ab,kw OR (((endovascular OR artery) NEAR/3 (intervention* OR repair*)):ti,ab,kw) OR ((arter* NEAR/3 (graft* OR stent* OR shunt* OR bypass*)):ti,ab,kw)	882586
#25	((imaging NEAR/2 (surveillanc* OR 'follow up' OR followup)):ti,ab,kw) OR 'duplex doppler ultrasonography'/exp OR 'duplex scanning'/exp OR 'duplex ultrasound'/exp OR (('duplex':ti,ab,kw OR doppler:ti,ab,kw OR dus:ti,ab,kw) AND ('disease surveillance'/de OR 'follow up'/exp OR 'aftercare'/exp OR 'evaluation and follow up'/de OR surveillanc*:ti,ab,kw OR 'follow up':ti,ab,kw OR followup:ti,ab,kw))	56427
#26	'lower limb'/exp OR 'leg artery'/exp OR leg:ti,ab,kw OR legs:ti,ab,kw OR ((lower NEAR/2 (limb* OR extremit*)):ti,ab,kw) OR femoral:ti,ab,kw OR infrainguinal:ti,ab,kw OR 'infra inguinal':ti,ab,kw OR femoropopliteal*:ti,ab,kw OR 'femoro popliteal':ti,ab,kw OR 'ileac arter*':ti,ab,kw	962272
#27	#24 AND #25 AND #26	3953
#28	#27 AND [01-11-2016]/sd 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)	977
#29	#20 AND #28 SR	31
#30	#21 AND #28 NOT #29 Clinical trials, RCT	226
#31	(#22 OR #23) AND #28 NOT #29 NOT #30 OBS	368
#32	#29 OR #30 OR #31	625
#33	#19 AND #32 sleutelartikelen gevonden	2
#34	#16 AND #27 1 sleutelartikel niet gevonden	14

Ovid/Medline

#	Searches	Results
1	exp Vascular Surgical Procedures/ or exp Primary Graft Dysfunction/ or exp Graft Rejection/ or Blood Vessel Prosthesis/ or Arteriovenous Shunt, Surgical/ or Axillofemoral Bypass Grafting/ or revascular*.ti,ab,kf. or (endovascular adj3 (intervention or surgery)).ti,ab,kf. or pad.ti,ab,kf. or paod.ti,ab,kf. or ((endovascular or artery) adj3 (intervention* or repair*)).ti,ab,kf. or (arter* adj3 (graft* or stent* or shunt* or bypass*)).ti,ab,kf.	479099
2	exp Ultrasonography, Doppler, Duplex/ or (imaging adj2 (surveillanc* or 'follow up' or followup or watchful waiting)).ti,ab,kf. or (('duplex' or doppler or dus).ti,ab,kf. and (Watchful Waiting/ or Aftercare/ or surveillanc*.ti,ab,kf. or 'follow up'.ti,ab,kf. or followup.ti,ab,kf.))	52748

3	exp Lower Extremity/ or Femoral Artery/ or Iliac Artery/ or Popliteal Artery/ or Tibial Arteries/ or Ulnar Artery/ or leg.ti,ab,kf. or legs.ti,ab,kf. or (lower adj2 (limb* or extremit*)).ti,ab,kf. or femoral.ti,ab,kf. or infrainguinal.ti,ab,kf. or infra inguinal.ti,ab,kf. or femoropopliteal*.ti,ab,kf. or femoro popliteal.ti,ab,kf. or ileac arter*.ti,ab,kf.	533704
4	1 and 2 and 3	2758
5	limit 4 to yr="2016 -Current"	647
6	5 not ((exp animals/ or exp models, animal/) not humans/) not (letter/ or comment/ or editorial/)	637
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.	722995
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$3)).tw. or Placebos/ or placebo*.tw.	2684882
9	Epidemiologic studies/ or case control studies/ or exp cohort studies/ or Controlled Before-After Studies/ or Case control.tw. or cohort.tw. or Cohort analy$.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]	4639685
10	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	5610648

	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.))	
11	6 and 7 SR	24
12	(6 and 8) not 11 Clinical trials, RCT	129
13	(6 and (9 or 10)) not 11 not 12 OBS	328
14	11 or 12 or 13	481

Module 12: Kwetsbare ouderen

Evidence tabel

Niet van toepassing.

Risk of bias tabel

Niet van toepassing.

Exclusie tabel

Reference	Reason for exclusion
Alamarie B, Paracha AW, Zil-E-Ali A, Krause K, Aziz F. Association of Preoperative Frailty with Inferior Outcomes for Patients Undergoing Lower Extremity Bypass for Chronic Limb Threatening Ischemia: A Systematic Review. Ann Vasc Surg. 2023 Nov;97:320-328. doi: 10.1016/j.avsg.2023.05.044. Epub 2023 Jun 24. PMID: 37356656.	Wrong comparison of interventions.
Pacha HM, Al-Khadra Y, Darmoch F, Soud M, Kwok CS, Mamas MA, Ashraf S, Sattar Y, Ullah W, Banerjee S, Arain SA, Feldman DN, Abu-Fadel M, Aronow HD, Shishehbor MH, Alraies MC. In-Hospital Outcomes and Trends of Endovascular Intervention vs Surgical Revascularization in Octogenarians With Peripheral Artery Disease. Am J Cardiol. 2021 Apr 15;145:143-150. doi: 10.1016/j.amjcard.2020.12.091. Epub 2021 Jan 15. PMID: 33460607.	Wrong comparison of interventions.
Sun Y, Zhou X, Zhang J. Bypass surgery versus endovascular intervention for lower extremity revascularization in patients with chronic renal disease or end-stage renal disease: a systematic review and meta-analysis. Int Urol Nephrol. 2022 Mar;54(3):589-600. doi: 10.1007/s11255-021-02940-5. Epub 2021 Jul 7. PMID: 34235596.	Wrong comparison of interventions.

Zoekverantwoording

Algemene informatie

Cluster/richtlijn: Richtlijn PAV – Kwetsbare ouderen	
Uitgangsvraag/modules: Wat is de waarde van behandelen van kwetsbare ouderen met perifeer arterieel vaatlijden?	
Database(s): Embase.com, Ovid/Medline	Datum: 4 maart 2024
Periode: geen restrictie	Talen: geen restrictie
Literatuurspecialist: Esther van der Bijl	Rayyan review: https://rayyan.ai/reviews/952068
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 kwetsbare ouderen met perifeer arterieel vaatlijden EN endovasculaire/chirurgische behandeling. Zoals besproken worden vanwege de grote opbrengst in eerste instantie alleen de SR's en de RCT's aangeboden. → De sleutelartikelen PMID28689942, PMID29772334 en PMID34913364 worden niet gevonden met deze search. Zij vallen uit op studiedesign.
Te gebruiken voor richtlijntekst: In de databases Embase.com en Ovid/Medline is op 4 maart 2024 systematisch gezocht naar systematische reviews en RCTs over endovasculair/chirurgisch behandelen van kwetsbare ouderen met perifeer arterieel vaatlijden. De literatuurzoekactie leverde 455 unieke treffers op.

Zoekopbrengst 4-3-2024

	EMBASE	**OVID/MEDLINE**	**Ontdubbeld**
SR	139	42	147
RCT	294	90	308
Observationeel			
Totaal	433	132	**455***

****in Rayyan***

5 ***Zoekstrategie Embase.com 4-3-2024***

No.	Query	Results
#1	'peripheral arterial occlusion'/exp OR 'peripheral arterial disease'/exp OR 'arteriosclerosis obliterans'/exp OR 'claudication'/exp OR 'critical limb ischemia'/exp OR 'intermittent claudication'/exp OR ((('arter* peripheral' OR 'peripheral arter*') NEAR/3 (disease* OR disorder* OR obstruct* OR occlus* OR stenos* OR calcifi* OR thrombos*)):ti,ab,kw) OR (((leg* OR limb* OR extremit*) NEAR/3 (arteriosclero* OR atherosclero*) NEAR/3 (oblitera* OR occlus* OR insufficienc*)):ti,ab,kw) OR (((angiosclerotica OR claudicatio* OR dysbasia) NEAR/3 intermitten*):ti,ab,kw) OR (((leg* OR limb* OR extremit*) NEAR/3 (ischaemia OR ischemia)):ti,ab,kw) OR claudication*:ti,ab,kw OR 'angina cruris':ti,ab,kw	169691
#2	'frailty'/exp OR 'frail elderly'/exp OR 'elderly care'/exp OR 'institutionalized elderly'/exp OR 'very elderly'/exp OR 'geriatrics'/exp OR 'geriatric assessment'/exp OR 'geriatric patient'/exp OR eldest:ti,ab,kw OR frail*:ti,ab,kw OR geriatri*:ti,ab,kw OR (((old OR older OR elder*) NEXT/1 (age* OR subject* OR patient* OR pts OR adult* OR population* OR person* OR people OR citizen*)):ti,ab,kw) OR ((oldest NEXT/1 old*):ti,ab,kw) OR ((very NEXT/1 old*):ti,ab,kw) OR senium:ti,ab,kw OR septuagenarian*:ti,ab,kw OR octagenarian*:ti,ab,kw OR octogenarian*:ti,ab,kw OR nonagenarian*:ti,ab,kw OR centarian*:ti,ab,kw OR centenarian*:ti,ab,kw OR supercentenarian*:ti,ab,kw	1093052

#3	'vascular surgery'/exp OR 'graft dysfunction'/exp OR 'blood vessel graft'/exp OR 'blood vessel shunt'/exp OR 'revascularization'/exp OR 'endovascular surgery'/exp OR revascular*:ti,ab,kw OR ((endovascular NEAR/3 (intervention OR surgery)):ti,ab,kw) OR pad:ti,ab,kw OR paod:ti,ab,kw OR (((endovascular OR artery) NEAR/3 (intervention* OR repair*)):ti,ab,kw) OR ((arter* NEAR/3 (graft* OR stent* OR shunt* OR bypass*)):ti,ab,kw)	886776
#4	#1 AND #2 AND #3	5185
#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)	4116
#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	1006491
#7	'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	2166528
#8	#5 AND #6 **– SR's**	139
#9	#5 AND #7 NOT #8 **– RCT's**	294
#10	#8 OR #9	433

Zoekstrategie Ovid/Medline 4-3-2024

#	Searches	Results
1	exp Peripheral Arterial Disease/ or exp Chronic Limb-Threatening Ischemia/ or exp Intermittent Claudication/ or exp Arteriosclerosis Obliterans/ or ((arter* peripheral or peripheral arter*) adj3 (disease* or disorder* or obstruct* or occlus* or stenos* or calcifi* or thrombos*)).ti,ab,kf. or ((leg* or limb* or extremit*) adj3 (arteriosclero* or atherosclero*) adj3 (oblitera* or occlus* or insufficienc*)).ti,ab,kf. or ((angiosclerotica or claudicatio* or dysbasia) adj3 intermitten*).ti,ab,kf. or ((leg* or limb* or extremit*) adj3 (ischaemia or ischemia)).ti,ab,kf. or claudication*.ti,ab,kf. or angina cruris.ti,ab,kf.	53213
2	exp Frail Elderly/ or *"Aged, 80 and over"/ or exp Centenarians/ or exp Nonagenarians/ or exp Octogenarians/ or exp "Health Services for the Aged"/ or exp Geriatrics/ or eldest.ti,ab,kf. or frail*.ti,ab,kf. or geriatri*.ti,ab,kf. or 'oldest old*'.ti,ab,kf. or 'very old*'.ti,ab,kf. or	579846

	senium.ti,ab,kf. or septuagenarian*.ti,ab,kf. or octagenarian*.ti,ab,kf. or octogenarian*.ti,ab,kf. or nonagenarian*.ti,ab,kf. or centarian*.ti,ab,kf. or centenarian*.ti,ab,kf. or supercentenarian*.ti,ab,kf. or ((old or older or elder*) adj (age* or subject* or patient* or pts or adult* or population* or person* or people or citizen*)).ti,ab,kf.	
3	exp Vascular Surgical Procedures/ or exp Primary Graft Dysfunction/ or exp Graft Rejection/ or Blood Vessel Prosthesis/ or Arteriovenous Shunt, Surgical/ or Axillofemoral Bypass Grafting/ or revascular*.ti,ab,kf. or (endovascular adj3 (intervention or surgery)).ti,ab,kf. or pad.ti,ab,kf. or paod.ti,ab,kf. or ((endovascular or artery) adj3 (intervention* or repair*)).ti,ab,kf. or (arter* adj3 (graft* or stent* or shunt* or bypass*)).ti,ab,kf.	479481
4	1 and 2 and 3	1140
5	4 not (comment/ or editorial/ or letter/) not ((exp animals/ or exp models, animal/) not humans/)	1120
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.	720601
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.	1680578
8	5 and 6 **– SR's**	42
9	(5 and 7) not 8 **– RCT's**	90
10	8 or 9	132

Module 13a: Patiëntvoorlichting en shared decision making

Evidence tabel

Niet van toepassing.

Risk of bias tabel

Niet van toepassing.

Exclusie tabel

Niet van toepassing.

Zoekverantwoording

Niet van toepassing.

Module 13b: Stepped care en bewustwording kosten

Evidence tabel

Niet van toepassing.

Risk of bias tabel

Niet van toepassing.

Exclusie tabel

Niet van toepassing.

Zoekverantwoording

Niet van toepassing.