Washington State Health Care Authority

Angioplasty and Stenting for Peripheral Artery Disease (PAD)

Final Appendix

August 18, 2025

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Angioplasty and Stenting for Peripheral Artery Disease (PAD)

Aggregate Analytics, Inc.

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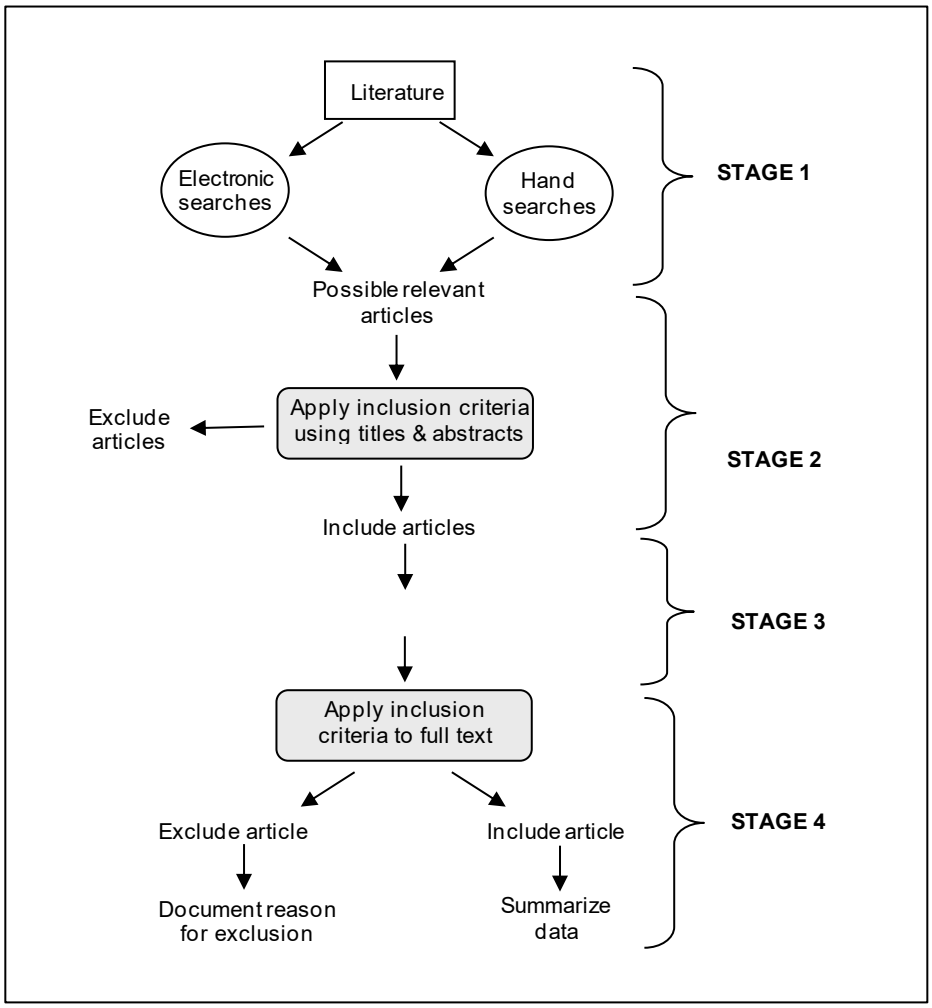
APPENDIX A. Algorithm for Article Selection



APPENDIX B. Search Strategies

Below is the search strategy for PubMed. Parallel strategies were used to search other electronic databases listed below. Keyword searches were conducted in the other listed resources. In addition, hand-searching of included studies was performed.

Appendix Table B1: PubMed Search Strategy for Lit Search

Search period: inception to February 10, 2025

1.	Arteriosclerosis[MeSH] OR "peripheral arterial disease"[MeSH] OR “peripheral artery disease”[TIAB] OR “peripheral arterial occlusive disease”[TIAB] OR “PAD”[TIAB] OR “PAOD”[TIAB] OR “PVD”[TIAB]
2.	claudication[TIAB] OR “intermittent claudication”[MeSH] OR “chronic limb threatening ischemia”[TIAB] OR “critical limb ischemia"[TIAB]
3.	aortoiliac[TIAB] OR infrainguinal[TIAB] OR femoropopliteal[TIAB] OR femoral artery[MeSH] OR iliac artery[MeSH] OR occlus*[TIAB] OR steno*[TIAB] OR obstruct*[TIAB] OR block*[TIAB] OR harden*[TIAB] OR stiffen*[TIAB] OR lesio*[TIAB] OR block*[TIAB] OR harden*[TIAB] OR stiffen*[TIAB] OR obliter*[TIAB]
4.	stents[MeSH] OR stent*[TIAB] OR “Lifestent” OR “Esprit” OR “Zilver” OR “Eluvia” OR “VIABAHN” OR “Luminexx” OR “nitinol”
5.	Endovascular Procedures[MeSH] OR angioplasty[TIAB] OR balloon[TIAB] OR percutaneous[TIAB] OR endovascular[TIAB] OR endoluminal[TIAB] OR endoprosthe*[TIAB] OR endograft*[TIAB] OR “Chocolate Touch” OR “Angiosculpt” OR “Wolverine” OR “VascuTrak” OR “Ranger” OR “Lutonix” OR “IN.PACT” OR “Stellarex”
6.	#1 OR #2 OR #3
7.	#4 OR #5
8.	#6 AND #7
9.	#8 NOT (infrapopliteal[TIAB] OR atherectomy[MeSH] OR atherectom*[TIAB] OR cadaver*[tw] OR case reports[Publication Type] OR Infant[mh] OR rat[tw] OR rats[tw] OR mouse[tw] OR mice[tw] OR dog[tw] OR dogs[tw])

*2 meta-analyses

Electronic Database Searches

The following databases have been searched for relevant information:

Cochrane Database of Systematic Reviews

Cochrane Registry of Clinical Trials (CENTRAL)

Database of Reviews of Effectiveness (Cochrane Library)

PubMed

ClinicalTrials.gov

Additional Economics, Clinical Guideline and Gray Literature Databases

AHRQ - Healthcare Cost and Utilization Project

Canadian Agency for Drugs and Technologies in Health

Centers for Medicare and Medicaid Services (CMS)

Food and Drug Administration (FDA)

Google

APPENDIX C. Excluded Articles

Articles excluded as primary studies after full text review, with reason for exclusion.

Appendix Table C1. List of Excluded Articles

Citation	Reason for exclusion after full-text review
1. Adams GL, Mustapha J, Gray W, Hargus NJ, Martinsen BJ, Ansel G, Jaff MR. The LIBERTY study: Design of a prospective, observational, multicenter trial to evaluate the acute and long-term clinical and economic outcomes of real-world endovascular device interventions in treating peripheral artery disease. Am Heart J. 2016 Apr;174:14-21. doi: 10.1016/j.ahj.2015.12.013. Epub 2015 Dec 30. PMID: 26995365.	Ineligible publication type
2. Ahn SS, Tahara RW, Jones LE, Carr JG, Blebea J. Preliminary Results of the Outpatient Endovascular and Interventional Society National Registry. Journal of endovascular therapy : an official journal of the International Society of Endovascular Specialists 2020;27:956-63.	Ineligible study design
3. Albrecht T, Waliszewski M, Roca C, et al. Two-Year Clinical Outcomes of the CONSEQUENT Trial: Can Femoropopliteal Lesions be Treated with Sustainable Clinical Results that are Economically Sound? Cardiovasc Intervent Radiol. 2018 Jul;41(7):1008-14. doi: 10.1007/s00270-018-1940-1. PMID: 29589098.	Ineligible comparator
4. Angraal S, Hejjaji V, Tang Y, et al. One-Year Health Status Outcomes Following Early Invasive and Noninvasive Treatment in Symptomatic Peripheral Artery Disease. Circulation Cardiovascular interventions 2022;15:e011506.	Ineligible intervention
5. Azuma N, Iida O, Takahara M, Soga Y, Kodama A. Surgical reconstruction versus peripheral intervention in patients with critical limb ischemia - a prospective multicenter registry in Japan: the SPINACH study design and rationale. Vascular 2014;22:411-20.	Ineligible study design
6. Banerjee S, Jeon-Slaughter H, Armstrong EJ, et al. Clinical Outcomes and Cost Comparisons of Stent and Non-Stent Interventions in Infrainguinal Peripheral Artery Disease: Insights From the Excellence in Peripheral Artery Disease (XLPAD) Registry. The Journal of invasive cardiology 2019;31:1-9.	Ineligible comparator
7. Baumgartner I, Norgren L, Fowkes FGR, et al. Cardiovascular Outcomes After Lower Extremity Endovascular or Surgical Revascularization: The EUCLID Trial. J Am Coll Cardiol. 2018 Oct 2;72(14):1563-72. doi: 10.1016/j.jacc.2018.07.046. PMID: 30261955.	Ineligible intervention
8. Bisdas T, Borowski M, Stavroulakis K, Torsello G. Endovascular Therapy Versus Bypass Surgery as First-Line Treatment Strategies for Critical Limb Ischemia: Results of the Interim Analysis of the CRITISCH Registry. JACC Cardiovascular interventions 2016;9:2557-65.	Ineligible population
9. Bosiers M, G DED, Torsello G, et al. ZILVERPASS Study: ZILVER PTX Stent vs. Bypass Surgery in Femoropopliteal Lesions, 3 year results and economic analysis. J Cardiovasc Surg (Torino). 2023 Aug;64(4):413-21. doi: 10.23736/s0021-9509.23.12607-3. PMID: 37162238.	Could not obtain publication
10 Bradbury AW, Adam DJ, Bell J, et al. Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial: A survival prediction model to facilitate clinical decision making. J Vasc Surg. 2010 May;51(5 Suppl):52S-68S. doi: 10.1016/j.jvs.2010.01.077. PMID: 20435262.	Ineligible outcome

	Citation	Reason for exclusion after full-text review
11	Bronas UG, Hirsch AT, Murphy T, et al. Design of the multicenter standardized supervised exercise training intervention for the claudication: exercise vs endoluminal revascularization (CLEVER) study. Vasc Med. 2009 Nov;14(4):313-21. doi: 10.1177/1358863x09102295. PMID: 19808716.	Ineligible publication type
12	Cerrud-Rodriguez RC, Romain G, Hussain Y, et al. Impact of early intervention on health status outcomes in peripheral artery disease patients with chronic total occlusion lesions using the PORTRAIT registry. Journal of vascular surgery 2024;80:780-90 e10.	Ineligible outcome
13	Conte MS, Azene E, Doros G, et al. Secondary interventions following open vs endovascular revascularization for chronic limb threatening ischemia in the BEST-CLI trial. J Vasc Surg. 2024 Jun;79(6):1428-37 e4. doi: 10.1016/j.jvs.2024.02.005. PMID: 38368997.	Ineligible comparator
14	Damara FA, Alameddine D, Slade M, et al. Arterial dissection during peripheral vascular interventions. Journal of vascular surgery 2024;79:339-47 e6.	Ineligible population
15	Dick P, Sabeti S, Mlekusch W, et al. Conventional balloon angioplasty versus peripheral cutting balloon angioplasty for treatment of femoropopliteal artery in-stent restenosis: initial experience. Radiology 2008;248:297-302.	Ineligible comparator
16	Enzmann FK, Nierlich P, Aspalter M, et al. Nitinol Stent Versus Bypass in Long Femoropopliteal Lesions: 2-Year Results of a Randomized Controlled Trial. JACC Cardiovasc Interv. 2019 Dec 23;12(24):2541-9. doi: 10.1016/j.jcin.2019.09.006. PMID: 31786218.	Ineligible population
17	Enzmann FK, Nierlich P, Hölzenbein T, et al. Vein Bypass Versus Nitinol Stent in Long Femoropopliteal Lesions: 4-Year Results of a Randomized Controlled Trial. Ann Surg. 2023 Jun 1;277(6):e1208-e14. doi: 10.1097/sla.0000000000005413. PMID: 35185122.	Ineligible population
18	Fanari Z, Weintraub WS. Cost-effectiveness of medical, endovascular and surgical management of peripheral vascular disease. Cardiovascular revascularization medicine : including molecular interventions 2015;16:421-5.	Ineligible study design
19	Farber A, Menard MT, Conte MS, et al. Surgery or Endovascular Therapy for Chronic Limb-Threatening Ischemia. N Engl J Med. 2022 Dec 22;387(25):2305-16. doi: 10.1056/NEJMoa2207899. PMID: 36342173.	Ineligible intervention
20	Farber A, Rosenfield K, Menard M. The BEST-CLI trial: a multidisciplinary effort to assess which therapy is best for patients with critical limb ischemia. Tech Vasc Interv Radiol. 2014 Sep;17(3):221-4. doi: 10.1053/j.tvir.2014.08.012. PMID: 25241324.	Ineligible publication type
21	Forbes JF, Adam DJ, Bell J, et al. Bypass versus Angioplasty in Severe Ischaemia of the Leg (BASIL) trial: Health-related quality of life outcomes, resource utilization, and cost-effectiveness analysis. Journal of vascular surgery 2010;51:43S-51S.	Ineligible outcome
22	Frans FA, Bipat S, Reekers JA, et al. SUPERvised exercise therapy or immediate PTA for intermittent claudication in patients with an iliac artery obstruction--a multicentre randomised controlled trial; SUPER study design and rationale. Eur J Vasc Endovasc Surg. 2012 Apr;43(4):466-71. doi: 10.1016/j.ejvs.2012.01.014. PMID: 22326696.	Ineligible publication type
23	Gelin J, Jivegård L, Taft C, et al. Treatment efficacy of intermittent claudication by surgical intervention, supervised physical exercise training compared to no	Ineligible intervention

	Citation	Reason for exclusion after full-text review
	treatment in unselected randomised patients I: one year results of functional and physiological improvements. Eur J Vasc Endovasc Surg. 2001 Aug;22(2):107-13. doi: 10.1053/ejvs.2001.1413. PMID: 11472042.	
24	Gouëffic Y, Della Schiava N, Thaveau F, et al. Stenting or Surgery for De Novo Common Femoral Artery Stenosis. JACC Cardiovasc Interv. 2017 Jul 10;10(13):1344-54. doi: 10.1016/j.jcin.2017.03.046. PMID: 28683941.	Ineligible intervention
25	Hess CN, Patel MR, Bauersachs RM, et al. Safety and Effectiveness of Paclitaxel Drug-Coated Devices in Peripheral Artery Revascularization: Insights From VOYAGER PAD. J Am Coll Cardiol. 2021 Nov 2;78(18):1768-78. doi: 10.1016/j.jacc.2021.08.052. PMID: 34711335.	Ineligible comparator
26	Hicks CW, Najafian A, Farber A, et al. Below-knee endovascular interventions have better outcomes compared to open bypass for patients with critical limb ischemia. Vascular medicine (London, England) 2017;22:28-34.	Ineligible population
27	Higashitani M, Uemura Y, Mizuno A, et al. Cardiovascular Outcome and Mortality in Patients Undergoing Endovascular Treatment for Symptomatic Peripheral Artery Disease - Short-Term Results of the Toma-Code Registry. Circulation journal : official journal of the Japanese Circulation Society 2018;82:1917-25.	Ineligible comparator
28	Hobbs SD, Marshall T, Fegan C, et al. The constitutive procoagulant and hypofibrinolytic state in patients with intermittent claudication due to infrainguinal disease significantly improves with percutaneous transluminal balloon angioplasty. J Vasc Surg. 2006 Jan;43(1):40-6. doi: 10.1016/j.jvs.2005.09.013. PMID: 16414385.	Ineligible study design
29	Hobbs SD, Marshall T, Fegan C, et al. The effect of supervised exercise and cilostazol on coagulation and fibrinolysis in intermittent claudication: a randomized controlled trial. J Vasc Surg. 2007 Jan;45(1):65-70; discussion doi: 10.1016/j.jvs.2006.08.084. PMID: 17210383.	Ineligible intervention
30	Holler D, Claes C, von der Schulenburg JM. Treatment costs and quality of life of patients with peripheral arterial occlusive disease--the German perspective. VASA Zeitschrift fur Gefasskrankheiten 2004;33:145-53.	Ineligible intervention
31	Holm J, Arfvidsson B, Jivegård L, et al. Chronic lower limb ischaemia. A prospective randomised controlled study comparing the 1-year results of vascular surgery and percutaneous transluminal angioplasty (PTA). Eur J Vasc Surg. 1991 Oct;5(5):517-22. doi: 10.1016/s0950-821x(05)80338-x. PMID: 1835704.	Ineligible comparator
32	Hunink MG, Wong JB, Donaldson MC, Meyerovitz MF, de Vries J, Harrington DP. Revascularization for femoropopliteal disease. A decision and cost-effectiveness analysis. Jama 1995;274:165-71.	Ineligible study design
33	Hobbs SD, Marshall T, Fegan C, et al. The constitutive procoagulant and hypofibrinolytic state in patients with intermittent claudication due to infrainguinal disease significantly improves with percutaneous transluminal balloon angioplasty. J Vasc Surg. 2006 Jan;43(1):40-6. doi: 10.1016/j.jvs.2005.09.013. PMID: 16414385.	Ineligible study design
34	Iida O, Takahara M, Soga Y, Kodama A, Terashi H, Azuma N. Three-Year Outcomes of Surgical Versus Endovascular Revascularization for Critical Limb Ischemia: The SPINACH Study (Surgical Reconstruction Versus Peripheral Intervention in Patients With Critical Limb Ischemia). Circulation Cardiovascular interventions 2017;10:e005531.	Ineligible population

	Citation	Reason for exclusion after full-text review
35	Jansen RM, de Vries SO, Cullen KA, Donaldson MC, Hunink MG. Cost-identification analysis of revascularization procedures on patients with peripheral arterial occlusive disease. Journal of vascular surgery 1998;28:617-23.	Ineligible study design
36	Kabir R, Vuppala S, Liu Y, et al. Clinical outcomes of patients with and without chronic kidney disease undergoing endovascular revascularization of infrainguinal peripheral artery disease: Insights from the XLPAD registry. Catheterization and cardiovascular interventions : official journal of the Society for Cardiac Angiography & Interventions 2021;98:310-6.	Ineligible comparator
37	Kashyap VS, Pavkov ML, Bena JF, et al. The management of severe aortoiliac occlusive disease: endovascular therapy rivals open reconstruction. J Vasc Surg. 2008 Dec;48(6):1451-7, 7 e1-3. doi: 10.1016/j.jvs.2008.07.004. PMID: 18804943.	Ineligible study design
38	Kim TI, Zhang Y, Cardella JA, Guzman RJ, Ochoa Chaar CI. Outcomes of bypass and endovascular interventions for advanced femoropopliteal disease in patients with premature peripheral artery disease. Journal of vascular surgery 2021;74:1968-77.e3.	Ineligible population
39	Iida O, Takahara M, Soga Y, Kodama A, Terashi H, Azuma N. Three-Year Outcomes of Surgical Versus Endovascular Revascularization for Critical Limb Ischemia: The SPINACH Study (Surgical Reconstruction Versus Peripheral Intervention in Patients With Critical Limb Ischemia). Circulation Cardiovascular interventions 2017;10:e005531.	Ineligible population
40	Kluckner M, Nierlich P, Hitzl W, et al. Long-Term Results of Endovascular Treatment with Nitinol Stents for Femoropopliteal TASC II C and D Lesions. Medicina (Kaunas). 2022 Sep 5;58(9)doi: 10.3390/medicina58091225. PMID: 36143902.	Ineligible study design
41	Kodama A, Meecham L, Popplewell M, et al. Editor's Choice - Relationship Between Global Limb Anatomic Staging System (GLASS) and Clinical Outcomes Following Revascularisation for Chronic Limb Threatening Ischaemia in the Bypass Versus Angioplasty in Severe Ischaemia of the Leg (BASIL)-1 Trial. Eur J Vasc Endovasc Surg. 2020 Nov;60(5):687-95. doi: 10.1016/j.ejvs.2020.06.042. PMID: 32778491.	Ineligible study design
42	Konijn LCD, Wakkie T, Spreen MI, et al. 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):1881-8. doi: 10.1007/s00270-020-02602-6. PMID: 32725411.	Ineligible study design
43	Kruidenier LM, Nicolaï SP, Rouwet EV, et al. Additional supervised exercise therapy after a percutaneous vascular intervention for peripheral arterial disease: a randomized clinical trial. J Vasc Interv Radiol. 2011 Jul;22(7):961-8. doi: 10.1016/j.jvir.2011.02.017. PMID: 21571547.	Ineligible comparator
44	Lamberti N, Malagoni AM, Ficarra V, et al. Structured Home-Based Exercise Versus Invasive Treatment: A Mission Impossible? A Pilot Randomized Study in Elderly Patients With Intermittent Claudication. Angiology. 2016 Sep;67(8):772-80. doi: 10.1177/0003319715618481. PMID: 26635335.	Ineligible intervention
45	Kluckner M, Nierlich P, Hitzl W, et al. Long-Term Results of Endovascular Treatment with Nitinol Stents for Femoropopliteal TASC II C and D Lesions. Medicina (Kaunas). 2022 Sep 5;58(9)doi: 10.3390/medicina58091225. PMID: 36143902.	Ineligible study design
46	Laurila J, Brommels M, Standertskjold-Nordenstam CG, et al. Cost-effectiveness of Percutaneous Transluminal Angioplasty (PTA) Versus Vascular Surgery in Limb-threatening Ischaemia. Int J Angiol 2000;9:214-9.	Ineligible outcome

	Citation	Reason for exclusion after full-text review
47	Lawaetz M, Fisker L, Lönn L, Sillesen H, Eiberg J. In Situ Vein Bypass Is Superior to Endovascular Treatment of Femoropopliteal Lesions in Chronic Limb-Threatening Ischemia. Annals of vascular surgery 2020;67:437-47.	Ineligible publication type
48	Lensvelt MM, Holewijn S, Fritschy WM, et al. SUrgical versus PERcutaneous Bypass: SUPERB-trial; Heparin-bonded endoluminal versus surgical femoro-popliteal bypass: study protocol for a randomized controlled trial. Trials. 2011 Jul 18;12:178. doi: 10.1186/1745-6215-12-178. PMID: 21767371.	Ineligible publication type
49	Liang P, Soden PA, Zettervall SL, et al. Treatment outcomes in diabetic patients with chronic limb-threatening ischemia. Journal of vascular surgery 2018;68:487-94.	Ineligible population
50	Malas MB, Enwerem N, Qazi U, et al. Comparison of surgical bypass with angioplasty and stenting of superficial femoral artery disease. Journal of vascular surgery 2014;59:129-35.	Ineligible study design
51	Laurila J, Brommels M, Standertskjold-Nordenstam CG, et al. Cost-effectiveness of Percutaneous Transluminal Angioplasty (PTA) Versus Vascular Surgery in Limb-threatening Ischaemia. Int J Angiol 2000;9:214-9.	Ineligible outcome
52	Malas MB, Qazi U, Glebova N, et al. Design of the Revascularization With Open Bypass vs Angioplasty and Stenting of the Lower Extremity Trial (ROBUST): a randomized clinical trial. JAMA Surg. 2014 Dec;149(12):1289-95. doi: 10.1001/jamasurg.2014.369. PMID: 25353642.	Ineligible publication type
53	Mayor J, Branco BC, Chung J, et al. Outcome Comparison between Open and Endovascular Management of TASC II D Aortoiliac Occlusive Disease. Annals of vascular surgery 2019;61:65-71 e3.	Ineligible study design
54	McGinigle KL, Doros G, Alabi O, et al. Female patients have fewer limb amputations compared to male patients in the BEST-CLI trial. J Vasc Surg. 2025 Feb;81(2):366-73 e1. doi: 10.1016/j.jvs.2024.09.031. PMID: 39368637.	Ineligible intervention
55	Menard MT, Farber A, Assmann SF, Choudhry NK, Conte MS, Creager MA, Dake MD, Jaff MR, Kaufman JA, Powell RJ, Reid DM, Siami FS, Sopko G, White CJ, Rosenfield K. Design and Rationale of the Best Endovascular Versus Best Surgical Therapy for Patients With Critical Limb Ischemia (BEST-CLI) Trial. J Am Heart Assoc. 2016 Jul 8;5(7):e003219. doi: 10.1161/JAHA.116.003219. PMID: 27402237; PMCID: PMC5015366.	Ineligible publication type
56	Menard MT, Farber A, Powell RJ, et al. Quality of Life in Patients With Chronic Limb-Threatening Ischemia Treated With Revascularization. Circulation. 2024 Apr 16;149(16):1241-53. doi: 10.1161/circulationaha.123.065277. PMID: 38597097.	Ineligible intervention
57	Malas MB, Qazi U, Glebova N, et al. Design of the Revascularization With Open Bypass vs Angioplasty and Stenting of the Lower Extremity Trial (ROBUST): a randomized clinical trial. JAMA Surg. 2014 Dec;149(12):1289-95. doi: 10.1001/jamasurg.2014.369. PMID: 25353642.	Ineligible publication type
58	Menard MT, Farber A. The BEST-CLI trial: a multidisciplinary effort to assess whether surgical or endovascular therapy is better for patients with critical limb ischemia. Semin Vasc Surg. 2014 Mar;27(1):82-4. doi: 10.1053/j.semvascsurg.2015.01.003. Epub 2015 Jan 22. PMID: 25812762.	Ineligible publication type
59	Murphy TP, Hirsch AT, Cutlip DE, et al. Claudication: exercise vs endoluminal revascularization (CLEVER) study update. J Vasc Surg. 2009 Oct;50(4):942-5 e2. doi: 10.1016/j.jvs.2009.04.076. PMID: 19660897.	Ineligible publication type

	Citation	Reason for exclusion after full-text review
60	Nordanstig J, Gelin J, Hensäter M, et al. Walking performance and health-related quality of life after surgical or endovascular invasive versus non-invasive treatment for intermittent claudication--a prospective randomised trial. Eur J Vasc Endovasc Surg. 2011 Aug;42(2):220-7. doi: 10.1016/j.ejvs.2011.02.019. PMID: 21397530.	Ineligible intervention
61	Nordanstig J, Smidfelt K, Langenskiöld M, Kragsterman B. Nationwide experience of cardio- and cerebrovascular complications during infrainguinal endovascular intervention for peripheral arterial disease and acute limb ischaemia. European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery 2013;45:270-4.	Ineligible comparator
62	Plaisance BR, Munir K, Share DA, et al. Safety of contemporary percutaneous peripheral arterial interventions in the elderly insights from the BMC2 PVI (Blue Cross Blue Shield of Michigan Cardiovascular Consortium Peripheral Vascular Intervention) registry. JACC Cardiovascular interventions 2011;4:694-701.	Ineligible comparator
63	Menard MT, Farber A. The BEST-CLI trial: a multidisciplinary effort to assess whether surgical or endovascular therapy is better for patients with critical limb ischemia. Semin Vasc Surg. 2014 Mar;27(1):82-4. doi: 10.1053/j.semvascsurg.2015.01.003. Epub 2015 Jan 22. PMID: 25812762.	Ineligible publication type
64	Powell RJ, Choudhry N, Conte M, et al. Factors associated with lower preoperative quality of life in patients with chronic limb-threatening ischemia in the BEST-CLI trial. J Vasc Surg. 2022 Dec;76(6):1642-50. doi: 10.1016/j.jvs.2022.06.004. PMID: 35714891.	Ineligible intervention
65	Scheidhauer H, Moebius-Winkler S, Aftanski P, Schulze PC, Kretzschmar D. Analysis of interventional treatment options of the common femoral artery - a retrospective single center experience. VASA Zeitschrift fur Gefasskrankheiten 2024;53:227-36.	Ineligible study design
66	Schroë H, Sachar R, Keirse K, et al. The RANGER II superficial femoral artery trial: 1-year results of the long lesion cohort. Vasc Med. 2022 Oct;27(5):457-65. doi: 10.1177/1358863x221097164. PMID: 35943120.	Ineligible study design
67	Scierka LE, Jelani QU, Smolderen KG, et al. Patient representativeness of a peripheral artery disease cohort in a randomized control trial versus a real-world cohort: The CLEVER trial versus the PORTRAIT registry. Contemporary clinical trials 2022;112:106624.	Ineligible comparator
68	Shiraki T, Iida O, Takahara M, et al. Comparison of Clinical Outcomes after Surgical and Endovascular Revascularization in Hemodialysis Patients with Critical Limb Ischemia. Journal of atherosclerosis and thrombosis 2017;24:621-9.	Ineligible population
69	Powell RJ, Choudhry N, Conte M, et al. Factors associated with lower preoperative quality of life in patients with chronic limb-threatening ischemia in the BEST-CLI trial. J Vasc Surg. 2022 Dec;76(6):1642-50. doi: 10.1016/j.jvs.2022.06.004. PMID: 35714891.	Ineligible intervention
70	Shiraki T, Iida O, Takahara M, et al. Predictors of 2-Year Mortality and Risk Stratification After Surgical or Endovascular Revascularization of Infrainguinal Artery Disease in Hemodialysis Patients With Critical Limb Ischemia. Journal of endovascular therapy : an official journal of the International Society of Endovascular Specialists 2015;22:719-24.	Ineligible population
71	Simons JP, Schanzer A, Flahive JM, et al. Survival prediction in patients with chronic limb-threatening ischemia who undergo infrainguinal revascularization. Journal of vascular surgery 2019;69:137S-51S e3.	Ineligible comparator

	Citation	Reason for exclusion after full-text review
72	Siracuse JJ, Farber A, Menard MT, et al. Perioperative complications following open or endovascular revascularization for chronic limb-threatening ischemia in the BEST-CLI Trial. J Vasc Surg. 2023 Oct;78(4):1012-20 e2. doi: 10.1016/j.jvs.2023.05.040. PMID: 37318428.	Ineligible intervention
73	Siracuse JJ, Menard MT, Rosenfield K, et al. Characterization of cardiovascular serious adverse events after bypass or endovascular revascularization for limb-threatening ischemia in the BEST-CLI trial. J Vasc Surg. 2024 Sep;80(3):774-9. doi: 10.1016/j.jvs.2024.04.025. PMID: 38626847.	Ineligible intervention
74	Siracuse JJ, Rowe VL, Menard MT, et al. Relationship between WIfI stage and quality of life at revascularization in the BEST-CLI trial. J Vasc Surg. 2023 Apr;77(4):1099-106 e4. doi: 10.1016/j.jvs.2022.11.050. PMID: 36435274.	Ineligible intervention
75	Shiraki T, Iida O, Takahara M, et al. Predictors of 2-Year Mortality and Risk Stratification After Surgical or Endovascular Revascularization of Infrainguinal Artery Disease in Hemodialysis Patients With Critical Limb Ischemia. Journal of endovascular therapy : an official journal of the International Society of Endovascular Specialists 2015;22:719-24.	Ineligible population
76	Smolderen KG, Gosch K, Patel M, et al. PORTRAIT (Patient-Centered Outcomes Related to Treatment Practices in Peripheral Arterial Disease: Investigating Trajectories): Overview of Design and Rationale of an International Prospective Peripheral Arterial Disease Study. Circulation Cardiovascular quality and outcomes 2018;11:e003860.	Ineligible study design
77	Soga Y, Mii S, Iida O, et al. Propensity score analysis of clinical outcome after bypass surgery vs. endovascular therapy for infrainguinal artery disease in patients with critical limb ischemia. Journal of endovascular therapy : an official journal of the International Society of Endovascular Specialists 2014;21:243-53.	Ineligible population
78	Stavroulakis K, Borowski M, Torsello G, Bisdas T. One-Year Results of First-Line Treatment Strategies in Patients With Critical Limb Ischemia (CRITISCH Registry). Journal of endovascular therapy : an official journal of the International Society of Endovascular Specialists 2018;25:320-9.	Ineligible population
79	Stavroulakis K, Gkremoutis A, Borowski M, et al. Bypass Grafting vs Endovascular Therapy in Patients With Non-Dialysis-Dependent Chronic Kidney Disease and Chronic Limb-Threatening Ischemia (CRITISCH Registry). Journal of endovascular therapy : an official journal of the International Society of Endovascular Specialists 2020;27:599-607.	Ineligible population
80	Tepe, 2015 Angioplasty of femoral-popliteal arteries with drug-coated balloons: 5-year follow-up of the THUNDER trial	Ineligible comparator
81	Smolderen KG, Gosch K, Patel M, et al. PORTRAIT (Patient-Centered Outcomes Related to Treatment Practices in Peripheral Arterial Disease: Investigating Trajectories): Overview of Design and Rationale of an International Prospective Peripheral Arterial Disease Study. Circulation Cardiovascular quality and outcomes 2018;11:e003860.	Ineligible study design
82	Totić D, Đurović Sarajlić V, Vranić H, et al. Endovascular or open surgical treatment of high-risk patients with infrainguinal peripheral arterial disease and critical limb ischemia. Med Glas (Zenica). 2020 Aug 1;17(2):477-84. doi: 10.17392/1143-20. PMID: 32602301.	Ineligible population

	Citation	Reason for exclusion after full-text review
83	Uhl C, Steinbauer M, Torsello G, Bisdas T. Outcomes After Endovascular Revascularization in Octogenarians and Non-Octogenarians With Critical Limb Ischemia. Journal of endovascular therapy : an official journal of the International Society of Endovascular Specialists 2017;24:471-7.	Ineligible comparator
84	Venermo MA, Farber A, Schanzer A, et al. Editor's Choice - Reduction of Major Amputations after Surgery versus Endovascular Intervention: The BEST-CLI Randomised Trial. Eur J Vasc Endovasc Surg. 2024 Nov;68(5):590-7. doi: 10.1016/j.ejvs.2024.06.018. PMID: 38925339.	Ineligible intervention
85	Venher I, Kostiv S, Selskiy B, et al. INTRAOPERATIVE LEVELS OF COAGULATION FACTORS IN PATIENTS TREATED WITH OPEN AND ENDOVASCULAR REVASCULARIZATION OF OCCLUDED TIBIAL ARTERIES. Georgian Med News. 2022 Feb(323):11-7. PMID: 35271465.	Ineligible intervention
86	Villemoes MK, Lindholt JS, Houlind KC, et al. Cost-Effectiveness Evaluation of Heparin Coated Versus Standard Graft for Bypass Surgery in Peripheral Artery Disease Alongside a Randomised Controlled Trial. European journal of vascular and endovascular surgery : the official journal of the European Society for Vascular Surgery 2018;56:87-93.	Ineligible intervention
87	Totić D, Đurović Sarajlić V, Vranić H, et al. Endovascular or open surgical treatment of high-risk patients with infrainguinal peripheral arterial disease and critical limb ischemia. Med Glas (Zenica). 2020 Aug 1;17(2):477-84. doi: 10.17392/1143-20. PMID: 32602301.	Ineligible population
88	Vogel TR, Braet DJ, Kruse RL, et al. Level of disease and association with health status in patients presenting with claudication from the PORTRAIT registry. Journal of vascular surgery 2020;72:2017-26.	Ineligible study design
89	Vossen RJ, Philipszoon PC, Vahl AC, Montauban van Swijndregt AD, Leijdekkers VJ, Balm R. A Comparative Cost-Effectiveness Analysis of Percutaneous Transluminal Angioplasty With Optional Stenting and Femoropopliteal Bypass Surgery for Medium-Length TASC II B and C Femoropopliteal Lesions. Journal of endovascular therapy : an official journal of the International Society of Endovascular Specialists 2019;26:172-80.	Ineligible outcome
90	Ye K, Shi H, Qin J, et al. Outcomes of endovascular recanalization versus autogenous venous bypass for thromboangiitis obliterans patients with critical limb ischemia due to tibioperoneal arterial occlusion. Journal of vascular surgery 2017;66:1133-42 e1.	Ineligible population

APPENDIX D. Risk of Bias, Strength of Evidence, QHES, and AMSTAR-2

Each included comparative study is rated against pre-set criteria that resulted in a Risk of Bias (ROB) assessment and presented in a table. Assessment of RCTs followed appropriate criteria based on methods described in *the Cochrane Handbook for Systematic Reviews of Interventions*[4] and guidance from the Agency for Healthcare Research and Quality (AHRQ) *Methods Guide for Effectiveness and Comparative Effectiveness Reviews*.[1] In keeping with the AHRQ methods, each study was given a final rating of "good", "fair", or "poor" quality as described below in Table D1. Discrepancies in ratings between reviewers were resolved through discussion and consensus. Where blinding is not possible, studies will automatically be rated as "fair" given the potential for biased assessment of outcomes. The final quality assessments are provided in Appendix E.

Table D2 provides an example of the format used to assess ROB for comparative studies of testing/therapy. Additional criteria for non-randomized studies includes consideration of how patients are selected and appropriate control for confounding. Table D3 provides an example for non-randomized studies of interventions. Table D4 provides an example for evaluating administrative database studies. A "No" indicates that the criterion was not met; an "Unclear" indicates that the criterion could not be determined with the information provided or was not reported by the author. Risk of bias assessments were not conducted for case series; all were considered High risk of bias.

Appendix Table D1. Definition of the risk of bias categories for individual studies of testing

Rating	Description and Criteria
Good	• Least risk of bias; study results generally considered valid • Employ valid methods for selection, inclusion, and allocation of patients to testing; report similar baseline characteristics in different test groups; clearly describe attrition and have low attrition; use appropriate means for preventing bias (e.g., blinding of patients, care providers, and outcomes assessors); and use appropriate analytic methods (e.g., intention-to-treat analysis)
Fair	• Study is susceptible to some bias but not enough to necessarily invalidate results • May not meet all criteria for good quality, but no flaw is likely to cause major bias; the study may be missing information making it difficult to assess limitations and potential problems • This category is broad; studies with this rating will vary in strengths and weaknesses; some fair-quality studies are likely to be valid, while others may be only possibly valid
Poor	• Significant flaws that imply biases of various kinds that may invalidate results; the study contains "fatal flaws" in design, analysis, or reporting; large amounts of missing information; discrepancies in reporting or serious problems with intervention delivery • Study results are at least as likely to reflect flaws in the study design or execution as the true difference between the compared interventions • Considered to be less reliable than higher quality studies when synthesizing the evidence, particularly if discrepancies between studies are present

Appendix Table D2: Assessment of ROB for Individual Randomized Control Trials

Methodological Principle	Author 1, 2023	Author 2 2024	Author 3, 2021
Study design			
Randomized controlled trial	■	■	■
Random sequence generation			
Concealed allocation			
Groups comparable at baseline*			
Outcome assessors independent or blinded			
Care providers blinded			
Patients blinded			
Reporting of attrition			
Complete follow-up of ≥80%			
<10% difference in follow-up between groups			
Intention to treat			
Outcomes prespecified			
Risk of Bias			

Unclear indicates that the study had insufficient detail to determine whether criteria were met

*Groups must be comparable on a robust set of baseline characteristics or present evidence that controlling of confounding presented was performed.

Appendix Table D3: Assessment of ROB for Individual Non-Randomized Studies of Interventions

Methodological Principle	Author 1, 2024	Author 2, 2019	Author 3, 2020
Did the study attempt to enroll a random sample or consecutive patients meeting inclusion criteria (inception cohort) from same underlying population?			
Were the groups comparable at baseline on key prognostic factors?			
Did the article report attrition?			
Overall loss to follow up acceptable? (≤20%) Differential loss to follow up acceptable? (≤10%)			
Were the outcomes investigated prespecified and defined?			
Did the study clearly describe and use accurate methods for ascertaining outcomes, exposures, and potential confounders?			
Were outcome assessors and/or data analysts blinded to treatment?			
Did the study perform appropriate statistical analyses on potential confounders or otherwise control for confounding (e.g. restriction, stratification, matching)?			
Was the duration of follow-up reasonable for investigated events?			
Risk of Bias			

NA = not applicable (due to being a case series)

Unclear indicates that the study had insufficient detail to determine whether criteria were met

Assessment of Economic Studies

Full formal economic analyses evaluate both costs and clinical outcomes of two or more alternative interventions. The four primary types are cost minimization analysis (CMA), cost-utility analysis (CUA), cost-effectiveness analysis (CEA), and cost-benefit analyses (CBA). Each employs different methodologies, potentially complicating critical appraisal, but some common criteria can be assessed across studies.

No standard, universally accepted method of critical appraisal of economic analyses is currently in use. A number of checklists [Canadian, BMJ, AMA] are available to facilitate critique of such studies. The Quality of Health Economic Studies (QHES) instrument developed by Ofman, et al. embodies the primary components relevant for critical appraisal of economic studies.[5] It also incorporates a weighted scoring process which was used as one factor to assess included economic studies. This tool has not yet undergone extensive evaluation for broader use but provides a valuable starting point for critique. Table D4 below provides a template of the instrument.

In addition to assessment of criteria in the QHES, other factors are important in critical appraisal of studies from an epidemiologic perspective to assist in evaluation of generalizability and potential sources of study bias.

Such factors include:

- Are the interventions applied to similar populations (e.g., with respect to age, gender, medical conditions, etc.)? To what extent are the populations for each intervention comparable and are differences considered or accounted for? To what extent are population characteristics consistent with “real world” applications of the comparators?
- Are the sample sizes adequate so as to provide a reasonable representation of individuals to whom the technology would be applied?
- What types of studies form the basis for the data used in the analyses? Data (e.g., complication rates) from randomized controlled trials or well-conducted, methodologically rigorous cohort studies for data collection are generally of highest quality compared with case series or studies with historical cohorts.
- Were the interventions applied in a comparable manner (e.g., similar protocols, follow-up procedures, evaluation of outcomes, etc.)?
- How were the data and/or patients selected or sampled (e.g., a random selection of claims for the intervention from a given year/source or all claims)? What specific inclusion/exclusion criteria or processes were used?

Were the outcomes and consequences of the interventions being compared comparable for each? (e.g., were all of the relevant consequences/complications for each intervention considered or do they primarily reflect those for one intervention?

Appendix Table D4. Assessment of Quality of Health Economic Studies Criteria

Question	Possible Points*	Criteria For Credit*
1. Was the study **objective** presented in a clear, specific, and measurable manner?	7	Authors must fully describe the objective; is it measurable?
2. Were the **perspective** of the analysis (societal, third-party payer, etc.) and reasons for its selection stated?	4	Authors must state perspective, provide rationale AND have done the correct analysis corresponding to the perspective
3. Were **variable estimates** used in the analysis from the best available source (i.e., randomized controlled trial - best, expert opinion - worst)?	8	No credit if most of estimates are not from the best sources available
4. If estimates came from a **subgroup analysis**, were the groups prespecified at the beginning of the study?	1	-
5. Was **uncertainty** handled by (1) statistical analysis to address random events, (2) sensitivity analysis to cover a range of assumptions?	9	NO credit if they do not give details regarding type of sensitivity analysis, methods (e.g. what assumptions or factors were varied/why), AND the results (what factors are influential, what is the range of ICERs, etc.)
6. Was **incremental analysis** performed between alternatives for resources and costs?	6	-
7. Was the methodology for **data abstraction** (including the value of health states and other benefits) stated?	5	No credit if sources of model inputs and process of choosing model inputs not specified
8. Did the **analytic horizon allow time** for all relevant and important outcomes? Were benefits and costs that went beyond 1 year discounted (3% to 5%) and justification given for the discount rate?	7	No credit if time horizon is too short to allow for important outcomes
9. Was the **measurement of costs** appropriate and the methodology for the estimation of quantities and unit costs clearly described?	8	No credit if sources of cost data or methods of estimating costs not clearly described
10. Were the primary **outcome measure(s)** for the economic evaluation clearly stated and did they include the major short-term, long-term and negative outcomes included?	6	NO credit if major important outcomes are not included or if time horizon did not allow for important outcomes to be measured
11. Were the health outcomes **measures/scales valid** and reliable? If previously tested valid and reliable measures were not available, was justification given for the measures/scales used?	7	No credit if sources of outcome data or not clearly described or if outcome data is not appropriate for the study population/outcome of interest (i.e. using utility weights from QOL measures that aren't validated or apply to a different population)
12. Were the **economic model** (including structure), study methods and analysis, and the components of the numerator and denominator displayed in a clear, transparent manner?	8	Must provide explicit detail for methods and should be able to trace/identify specific components, how they were derived, etc.
13. Were the choice of economic model, main **assumptions, and limitations** of the study stated and justified?	7	NO credit if insufficient detail of model, assumptions AND limitations are provided (No credit if they do not provide justifications/rationale)
14. Did the author(s) explicitly discuss direction and magnitude of potential **biases?**	6	NO credit if no discussion of direction and magnitude of biases
15. Were the **conclusions/recommendations** of the study justified and based on the study results?	8	NO credit if conclusions/recommendations are stronger than warranted based on findings
16. Was there a statement disclosing the **source of funding** for the study?	3	-
Total	100	-

ICER = Incremental Cost-Effectiveness Ratio; QOL = quality of life.

* Study must fit criteria in order to receive full points. Partial credit is not given. If criteria is not met, then the question receives no points.

Application of AMSTAR 2 to systematic reviews

Table D6 shows our criteria for RoB assessment based on the AMSTAR-2 tool. AMSTAR-2 is the revised and updated version of AMSTAR published in 2007 used for critical appraisal of systematic reviews (Shea, 2017).[8] It is not intended to provide an overall score, as high scores may hide weaknesses in critical domains. In light of this, we used a modified AMSTAR tool as determined by Dettori et al (2020).[3] Table D7 (adapted from Dettori 2020) describes how overall scores were determined considering critical domains.[2] Bold items in table 1 were considered as critical items. The original AMSTAR-2 guidance suggests grading each item as no or yes, with items 2, 4, 7, 8, and 9 allowing for a 'partial yes'. We considered a 'yes' or 'partial yes' as yes.

Appendix Table D5. Criteria for assessing systematic reviews based on AMSTAR-2.

Item	Criteria
1: Did the research questions and inclusion criteria for the review include the components of PICO?	• **Yes** if all components of PICO are described somewhere in the report. • **No** if any components of PICO are missing.
2: Did the report of the review contain an explicit statement that the review methods were established prior to the conduct of the review and did the report justify any significant deviations from the protocol?	• **Yes** if the protocol or review methods were established prior to review. • **No** if no protocol or discussion/description of methods decided prior to review.
3: Did the review authors explain their selection of the study designs for inclusion in the review?	• **Yes** if study design inclusion is justified or discussed. No penalty for restricting study designs. • **No** if no discussion of justification for inclusion.
4: Did the review authors use a comprehensive literature search strategy?	• **Yes** if 2 or more electronic databases were searched and key words are available in report or appendices. No penalty for language restrictions. • **No** if less than 2 electronic databases were searched or key words are unavailable.
5: Did the review authors perform study selection in duplicate?	• **Yes** if selection at title/abstract and full text reviews were performed by 2 authors with consensus upon disagreement or single author selecting with a second checking agreement on sample and a kappa reported of ≥0.80. • **No** if no second author involved or no kappa reported.
6: Did the review authors perform data extraction in duplicate?	• **Yes** if abstraction was performed by 2 authors with consensus upon disagreement or single author abstracting with a second checking agreement on sample and a kappa of reported of ≥0.80. • **No** if no second author involved or no kappa reported.
7: Did the review authors provide a list of excluded studies and justify the exclusions?	• **Yes** if a list of potentially relevant studies is reported in appendix or discussed in text with citations with justification for exclusion. List of references must be provided. • **No** if no list of references provided or not potentially relevant but excluded studies are discussed.

Item	Criteria
8: Did the review authors describe the included studies in adequate detail?	• **Yes** if study characteristics are reported in sufficient detail to determine whether the studies met PICO criteria and provides framework to judge heterogeneity. • **No** if study characteristics are not reported or table 1 does not include age, sex, (and #'s).
9: Did the review authors use a satisfying technique for assessing the RoB in individual studies that were included in the review?	**RCTS** • **Yes** if important domains similar to Cochrane. **Cohort studies** • **Yes** if it addresses all of the following: confounding, selection bias, measurement bias, and selective reporting of outcomes (Newcastle okay if all 8 questions included). **Case series** (study of incidence, no direct comparison) • **Yes** if selection bias, measurement bias, and selective reporting of outcomes met (Newcastle okay IF questions #1, 2, 3, 4, 6, 7, and 8 addressed). **For all studies** • **No** if there is obvious evidence that the authors misapplied an acceptable technique.
10: Did the review authors report on the sources of funding for the studies included in the review?	• **Yes** if authors report funding of individual studies. • **No** if authors do not report funding.
11: If meta-analysis was performed did the review authors use appropriate methods for statistical combination of results?	• **Yes** if all the following are present ○ Meta-analysis justified (e.g., studies comparable, direct comparison). ○ Explanation of fixed or random effects (must do more than merely report without explanation). ○ Pooled results reported separately for RCTs and cohort studies. ○ Assessment of heterogeneity (must address I^2). • **No** if one or more of the above are not present. • If no meta-analysis was done mark as **NM (No meta-analysis)**
12: If meta-analysis was performed, did the review authors assess the potential impact of RoB in individual studies on the results of the meta-analysis or other evidence synthesis?	• **Yes** if results are stratified by RoB or if the review only included the lowest RoB studies in the analysis. • **No** if results are not stratified by RoB and review includes a range of RoB outcomes in the analysis. No credit if RoB method from item #9 is not acceptable. • If no meta-analysis was done mark as **NM (No meta-analysis**)
13: Did the review authors account for RoB in individual studies when interpreting or discussing the results of the review?	• **Yes** if there is a discussion of the impact of RoB in the interpretation of results and/or accounting for differences between studies. • **No** if there is no discussion of the impact of RoB in the interpretation of results and/or accounting for differences between studies. No credit if method from #9 is not acceptable.
14: Did the review authors provide a satisfactory explanation for, and discussion of, any heterogeneity observed in the results of the review?	• **Yes** if I^2 demonstrates no heterogeneity (<50%) or authors explored reasons for heterogeneity if I^2 is ≥50%. • **No** if I^2 demonstrates heterogeneity (>50%) and authors do not explore reasons for heterogeneity.

Item	Criteria
15: If they performed quantitative synthesis did the review authors carry out an adequate investigation of publication bias (small study bias) and discuss its likely impact on the results of the review?	• **Yes** if there is an attempt to identify publication bias. Must also show awareness of likely impact of publication bias on results. Credit given if they acknowledge publication bias could be a problem but not enough data given or if they have fewer than 10 studies and show no evidence of publication bias. • **No** if there is no attempt to identify or discuss publication bias. • If no meta-analysis was done mark **as NM (No meta-analysis)**
16: Did the review authors report any potential sources of conflict of interest, including any funding they received for conducting the review?	• **Yes** if authors report no competing interests or how they managed potential conflicts of interest. • **No** if there is no discussion or reporting of potential conflicts of interest.

PICO = population, intervention, comparison, outcome; RoB = risk of bias.

Appendix Table D6. Rating overall Confidence in the Results of the Review (Dettori 2020).

High: No or 1 noncritical weakness	The systematic review provides an accurate and comprehensive summary of the results of the available studies that address the question of interest.
Moderate: More than 1 noncritical weakness*	The systematic review has more than 1 weakness but no critical flaws. It may provide an accurate summary of the results of the available studies that were included in the review.
Low: One critical flaw with or without noncritical weaknesses	The review has a critical flaw and may not provide an accurate and comprehensive summary of the available studies that address the question of interest.
Critically low: More than 1 critical flaw with or without noncritical weaknesses	The review has more than 1 critical flaw and should not be relied on to provide an accurate and comprehensive summary of the available studies.

* Multiple noncritical weaknesses may diminish confidence in the review, and it may be appropriate to move the overall appraisal down from moderate to low confidence.

Determination of Overall Strength (Quality) of Evidence

Following the assessment of the quality of each individual study included in the report, an *overall* "strength of evidence"/"quality of evidence" for all critical and important *primary* health outcomes and harms based on methods used by GRADE (Grading of Recommendation Assessment, Development and Evaluation) and the Agency for Healthcare Research and Quality (AHRQ) will be reported.[1]

The overall strength of evidence is based on assessment of the following required domains: risk of bias, consistency, directness, and precision. The overall Strength of Evidence (SoE) ranges from high for a body of evidence if new studies are unlikely to change the effect estimates to low if estimates from the currently available body of evidence is very likely to change as new data become available or insufficient if evidence is unavailable or does not permit a conclusion. To evaluate differential efficacy and safety (heterogeneity of effect, interaction), we will focus on RCTs as they have the least potential for bias and confounding thus potentially allowing for causal inference. Further, only RCTs that formally test for interaction between subgroups will be reported. SOE for these studies is based on consideration of the overall study risk of bias (study quality) as well as whether subgroup variables and analyses were specified a priori, the hypothesized impact of a subgroup on the outcome/effect and sample size as evaluation of interaction requires greater sample size are based on recommendations from Oxman and Guyatt[6] and the Instrument to assess the Credibility of Effect Modification (ICEMAN) criteria.[7] The

overall strength of evidence reflects our confidence in the effects estimated in the included studies and how likely new studies are to change the estimates. If only poor-quality studies are available for an outcome, SOE will be graded as insufficient.

The strength of evidence for the overall body of evidence for all *critical health outcomes* was assessed by one researcher following the principles for adapting GRADE (Grades of Recommendation Assessment, Development and Evaluation) as outlined by the Agency for Healthcare Research and Quality (AHRQ). The strength of evidence was based on the highest quality evidence available for a given *primary* outcome. In determining the strength of body of evidence regarding a given *primary* outcome, the following domains were considered:

- **Risk of bias:** the extent to which the included studies have protection against bias.
- **Consistency:** the degree to which the included studies report results are similar in terms of range and variability.
- **Directness:** describes whether the evidence is directly related to patient health outcomes.
- **Precision:** describes the level of certainty surrounding the effect estimates.
- **Publication bias:** is considered when there is concern of selective publishing.

All AHRQ "required" and "additional" domains (risk of bias, consistency, directness, precision, and if possible, publication bias) were assessed. Bodies of evidence consisting of RCTs were initially considered as High strength of evidence (SoE), while those that comprised nonrandomized studies began as Low strength of evidence. The strength of evidence could be downgraded based on the limitations described above. There could also be situations where the *nonrandomized* studies could be upgraded, including the presence of plausible unmeasured confounding and bias that would decrease an observed effect or increase an effect if none was observed, presence of a dose-response relationship, and large magnitude of effect (strength of association) *if no downgrades for domains above*. Publication and reporting bias are difficult to assess. Publication bias is particularly difficult to assess with fewer than 10 RCTs (AHRQ methods guide). When publication bias was unknown in all studies and this domain is often eliminated from the strength of evidence tables for our reports. The final strength of evidence for each **primary** outcome was assigned an overall grade of high, moderate, low, or insufficient, which are defined as follows:

High— Very confident that effect size estimates lie close to the true effect for this outcome; there are few or no deficiencies in the body of evidence; we believe the findings are stable.

Moderate— Moderately confident that effect size estimates lie close to the true effect for this outcome; some deficiencies in the body of evidence; we believe the findings are probably stable but some doubt remains.

Low— Limited confidence that effect size estimates lie close to the true effect for this outcome; important or numerous deficiencies in the body of evidence; we believe that additional evidence is needed before concluding that findings are stable or that the estimate is close to the true effect.

Insufficient— We have no evidence, are unable to estimate an effect or have no confidence in the effect estimate for this outcome; OR no available evidence or the body of evidence has unacceptable deficiencies precluding judgment.

Similar methods for determining the overall quality (strength) of evidence related to economic studies have not been reported, thus the overall strength of evidence for outcomes reported in Key Question 4 was not assessed.

Appendix Table D7. Example methodology outline for determining overall strength of evidence (SoE):

All AHRQ "required" and "additional" domains* are assessed. Only those that influence the baseline grade are listed in table below.
Baseline strength: HIGH = RCTs. LOW = observational, cohort studies, administrative data studies.
DOWNGRADE: Risk of bias for the individual article evaluations (1 or 2); Inconsistency** of results (1 or 2); Indirectness of evidence (1 or 2); Imprecision of effect estimates (1 or 2); Sub-group analyses not stated *a priori* and no test for interaction (2)
UPGRADE (non-randomized studies): Large magnitude of effect (1 or 2); Dose response gradient (1) done for observational studies ***if no downgrade for domains above***

Outcome	Strength of Evidence	Conclusions & Comments	Baseline SOE	DOWNGRADE	UPGRADE
Outcome	**HIGH**	Summary of findings	**HIGH** RCTs	**NO** consistent, direct, and precise estimates	**NO**
Outcome	**MODERATE**	Summary of findings	**LOW** Cohort studies	**NO** consistent, direct, and precise estimates; high quality (moderately low ROB)	**YES** Large effect
Outcome	**LOW**	Summary of findings	**HIGH** RCTs	**YES (2)** Inconsistent Indirect	**NO**

RCT = randomized control trial; SOE = strength of evidence.
* Required domains: risk of bias, consistency, directness, precision. Plausible confounding that would decrease observed effect is accounted for in our baseline risk of bias assessment through individual article evaluation. Additional domains: dose-response, strength of association, publication bias.
** Single study = "consistency unknown", may or may not be downgraded

APPENDIX E. Study Quality: Risk of Bias, QHES, and AMSTAR-2 evaluation

See Appendix E. Study Quality Excel File

APPENDIX F. Demographic and Outcome Data Abstraction of Included Studies

See Appendix F. PAD DA Excel File

APPENDIX G. Information for Economic Studies

Appendix Table G1. Data Abstraction for Economic Studies Comparing Endovascular Treatments to Medical Therapy

Component	Reynolds 2014 USA	Djerf, 2021 Sweden	Treesak, 2004 USA
Population	N = 98 Patients with moderate to severe claudication due to aortoiliac disease	IC of femoropopliteal artery; N=84* Age 71, 51% male TASC II A-C lesions	N = 56† Patients with claudication, ilio-femoral PAD; Age, sex, severity NR
Intervention(s) vs. Comparator(s)	Stent vs. MT alone	Stent vs. MT	BA vs, no treatment
Time horizon, Discounting, Currency	5 years/Lifetime 3%/year 2011 USD	2 years 3%/year 2017 Euro	3, 6 months No discounting 2001 USD
Design **Perspective**	CUA Stated as societal Payer perspective (excludes patient time cost)	CEA Stated Payer Perspective	CEA Stated as Societal
Outcome (e.g. QALY), Source	QALY based on EQ-5D from CLEVER RCT data, literature	QALY from EQ-5D, Lindgren trial	Walking: Initial claudication distance, absolute claudication distance Trial by Creasy, Literature
Cost components **Source**	Treatment costs, facility costs, resource utilization, and hospital billing data-from CLEVER RCT; Patient treatment costs (for time spent)	Primary and secondary procedures, post-op care, medication, anesthetic/diagnostic procedures, clinical chemistry, bacteriology, staff; Costs for care outside of healthcare system imputed	Exercise sessions, patient time, BA cost, follow-up visits

Component	Reynolds 2014 USA	Djerf, 2021 Sweden	Treesak, 2004 USA
Primary Findings (e.g., base case ICER)	Base Case: $41 376/QALY	ICER: €23,785/QALY	Absolute cost-effectiveness ratio (ACER) for ICD: 3 months: $67/meter gained 6 months: $167/meter gained for ACD 3 months: $61/meter gained 6 months: $80/meter gained
Sensitivity Analysis (SA) results, range of cost-effectiveness measure	**One way:** durability of treatment effect over time horizon, impact on QOL; facility costs: SA Range: NR Probabilistic SA: **Probabilistic SA:** at WTP for ~$30,000 to $80,000/QALY	**One way SA:** ICER Range €24,000 to €34,000/QALY **Probabilistic SA:** 77% percent likely to be cost effective at €50,000 threshold; 90% likely to be cost effective at €75,000 threshold	NR
Author conclusion	SET and stent are economically attractive vs. MT.	Stent is more expensive but more cost effective than MT alone up to 2 years.	A program of supervised exercise provides clinical efficacy, cost-effectiveness, and probable cost-savings for improvement of claudication

Component	Reynolds 2014 USA	Djerf, 2021 Sweden	Treesak, 2004 USA
Limitations	• RCT data only 6 months; extrapolation to 5 years, lifetime (survival, QoL, costs assumed to be equal for all groups at 5 years) • Small sample size • Patients from CLEVER trial may differ vs. those seen in routine practice on comorbidities, symptoms etc. which may impact QOL • Unclear how modeling of harms for ST was done, impact on ICER	• Small sample size • Short follow-up does not capture long term harms or differences in benefits • Unclear modeling of harms • Generalizability to US system unclear	• Study was poorly reported • SA was limited, not well reported • Unclear modeling of AEs due to PTA with or without stent • Limited data from 1 RCT • Pre-PTA assessment, medications, PTA with stent placement not modeled • Only short-term outcomes addressed
Funding	NIH and industry	Government, non-industry; Some industry COI	None
QHES	75/100	73/100	39/100

ACD = absolute claudication distance; ACER = absolute cost-effectiveness ratio; AE = adverse event; BA = balloon angioplasty; CEA = cost-effectiveness analysis; CI = confidence interval; CrI = credibility interval; CUA = cost-utility analysis; EQ-5D = EuroQol 5-Dimensions; IC = intermittent claudication; ICD = initial claudication distance; ICER = incremental cost-effectiveness ratio; MD = mean difference; MT = medical therapy; NR = not reported; PAD = peripheral artery disease; PTA = percutaneous transluminal angioplasty; QALY = quality-adjusted life-year; QHES = Quality of Health Economic Studies instrument; QoL = quality of life; RCT = randomized controlled trial; SA = sensitivity analysis; SE = standard error; SET = supervised exercise therapy; TASC = TransAtlantic Inter-Society Consensus; USD = United States Dollar; WTP = willingness-to-pay.

* 100 randomized but only 84 able to be analyzed for CE, only 84 included in demographic table.

† N only includes patients from the RCT which represents BA vs. SET only; no treatment patients were modeled.

Appendix Table G2. Data Abstraction for Economic Studies Comparing Endovascular Treatments to Supervised Exercise Therapy

Component	Treesak 2004 USA	Mazari, 2013 UK	Reynolds 2014 USA	Van Reijin, 2022 Netherlands	Spronk, 2008 Netherlands	Van den Houten, 2016 Netherlands
Population	N = 56[*] Patients with claudication, ilio-femoral PAD; Age, sex, severity NR	IC of femoropopliteal artery; N=178 Age median 69, 58% male Tasc A: 45%, Tasc B: 37%, Tasc C: 13%, Tasc D: 3%	N = 98 Patients with moderate to severe claudication due to aortoiliac disease	IC of common/external iliac artery; N=240; Age 62, 61% male severity/classification NR	Patients with claudication, ilio-femoral PAD; N=121 66 years, 55% male, Rutherford classification 1 or 2: 76% 3: 24%	Patients with newly diagnosed claudication; N=309, 66 years, Fontaine II, Rutherford 1-3 (inclusion)
Intervention(s) vs. Comparator(s)	BA vs. supervised exercise (SET, 2x 30 min/week)	PTA vs. SET PTA + SET vs. SET	Stent vs. SET	PTA with selective stent (39%) vs. SET	PTA with selective stent (67%) vs. SET	PTA with selective stent (67%[†]) vs. SET
Time horizon, Discounting, Currency	3, 6 months No discounting 2001 USD	12 months No discounting Euro, year not reported	5 years/Lifetime 3%/year 2011 USD	12 months No discounting 2015 Euro	1 year 3% 2005 Euros	5 years 4% 2014 Euros
Design Perspective	CEA Stated as Societal	CUA Stated as Provider Perspective	CUA Stated as societal Payer perspective (excludes patient time cost)	CUA and CEA Stated as Restricted Societal Perspective	CUA Societal perspective	CUA Payer perspective

Component	Treesak 2004 USA	Mazari, 2013 UK	Reynolds 2014 USA	Van Reijin, 2022 Netherlands	Spronk, 2008 Netherlands	Van den Houten, 2016 Netherlands
Outcome (e.g. QALY), Source	Walking: Initial claudication distance, absolute claudication distance Trial by Creasy, Literature	QALY from SF-36, SF-6D per NICE guidelines, Author's trial	QALY based on EQ-5D from CLEVER RCT data, literature	QALY from EQ-5D, VascuQol; Cost per MCID on VascuQol SUPER Trial	QALY from EQ-5D CETAC Trial	QALY from EQ-5D EXITPAD and CETAC Trial‡ Additional information on rates of adverse events and utilities of outcomes obtained from literature
Cost components Source	Exercise sessions, patient time, BA cost, follow-up visits	Outpatient clinics, follow-up appointments, investigations performed, medical treatment, transport costs (patients), reintervention	Treatment costs, facility costs, resource utilization, and hospital billing data- from CLEVER RCT; Patient treatment costs (for time spent)	Allocated treatment, additional treatment during follow-up, patient travel and parking fees	Costs: Therapeutic procedures, personnel, materials, equipment, additional associated diagnostic or therapeutic procedures, associated hospital admissions Materials: summed cost prices Equipment: time spent on procures * hourly cost. Non-health costs: costs of supporting departments, housing, overhead, transportation costs, patient time costs.	Health state costs: asymptomatic PAD, mild claudication, moderate claudication, severe claudication, critical limb ischaemia (CLI), post major amputation and death Costs of interventions: Stent or SET

Component	Treesak 2004 USA	Mazari, 2013 UK	Reynolds 2014 USA	Van Reijin, 2022 Netherlands	Spronk, 2008 Netherlands	Van den Houten, 2016 Netherlands
Primary Findings (e.g., base case ICER)	3 months: BA more effective vs. SET; additional 38 meters walked, additional cost of $6,719 for ICER = $177/meter walked 6 months: Exercise more effective vs. PTA; additional 137 meters walked, cost savings with exercise $61 less cost per meter gained	**ICER**: for PTA versus SET, €-381,694.44/QALY and for PTA + SET vs. PTA alone, €152,529.50 **PTA Cost/QALY**: €11,777.00 (95% CI €11,198.99 to €12,417.92) **SET Cost/QALY:** €6,147.04 (95% CI €5,858.32 to €6,476.53) **PTA+ SET Cost/QALY:** €10,649.74 (95% CI €10,239·53 to €11,112.03)	Base Case: $122 600/QALY	**ICER:** €20,805/QALY (95% bcaCI 11,053 to 45,561)	After adjusting for baseline variables, cumulative costs of PTA with selective stent were higher than SET (MD €2,318; 99% CI €2,130 to €2,506) at 12 months **ICER**: €231,800/QALY. Combining QALYs and costs using WTP of €50,000/QALY resulted in higher mean net-benefit per patients from SET group (€6,891; 99% CI €5,128 to 8,656) compared to PTA with selective stent group (€3,639; 99% CI €2,214 to 5,064).	**5 years:** Mean total costs of stent were €16,631 vs. SET €10,219. Mean total QALYs were 2.85 vs. 2.78. Overall, MD €6,412, 95% CrI 1,939 to 11,874. ICER: Stent associated with additional €91600/QALY gained compared to SET. No difference between groups in the number of secondary interventions.

Component	Treesak 2004 USA	Mazari, 2013 UK	Reynolds 2014 USA	Van Reijin, 2022 Netherlands	Spronk, 2008 Netherlands	Van den Houten, 2016 Netherlands
Sensitivity Analysis (SA) results, range of cost-effectiveness measure	NR	**One way SA: Sensitivity analyses:** QALYs gained did not change, no change in ICER; Use of MRA vs. angiography reduced ICER for PTA+SET vs. SET to €67,977.50/QALY	**One way:** durability of treatment effect over time horizon, impact on QOL; facility costs: Base Case (payer – excluding patient time costs): $177,051/QALY SA Range: $94,315/QALY to $152,225/QALY **Notes:** Differences in durability of QoL over time for stent vs. SET could substantially impact cost-effectiveness; Uncertain whether stent increases QALYs by meaningful amount vs. SET relative to SET. **Probabilistic SA:** at WTP for ~$30,000 to $80,000/QALY, ~ 60% likelihood that SET is preferred option; at WTP>120,000 slightly greater proportion of iterations favored stent vs. SET	**One-way SA:** Cost of achieving MCID on VascuQol:§ VascuQoL sum score 1.19 €3,423 (95% CI 1,893 to 6,637) VascuQoL sum score 1.66 €4,775 (95% CI 2,640 to 9,258) **Probabilistic SA:** 40% percent likely to be cost effective at €20,000 threshold;	**One way:** Probabilistic SA looking at larger effectiveness following PTA with selective stent decreased ICER to €75,208/QALY.	**Monte Carlo, one way**: Probabilistic SA looked at changes health state utilities, costs, interventions costs, and secondary interventions; SET-first approach remained most cost-effective in all scenarios except in the situation where patients start in a severe claudication state (data NR)

Component	Treesak 2004 USA	Mazari, 2013 UK	Reynolds 2014 USA	Van Reijin, 2022 Netherlands	Spronk, 2008 Netherlands	Van den Houten, 2016 Netherlands
Author conclusion	A program of supervised exercise provides clinical efficacy, cost-effectiveness, and probable cost-savings for improvement of claudication	SET is the most cost-effective treatment for IC as a first line treatment and that PTA plus SET is more cost-effective than PTA alone.	Stent is more costly, provides marginal additional benefit over SET, SET may provide better value, at least in the short term. Longer term results are uncertain.	Endovascular revascularization provides slightly better improvement in QALYs and QoL than SET, but cost is higher and the difference is not clinically relevant. Authors state support for current guidelines describing SET as first line treatment	No difference in effectiveness between stent and SET during 12-month follow-up; any gains with stent were non-significant, and stent costs more than the generally accepted threshold WTP value, which favors SET.	SET is more cost-effective than stent for IC.

Component	Treesak 2004 USA	Mazari, 2013 UK	Reynolds 2014 USA	Van Reijin, 2022 Netherlands	Spronk, 2008 Netherlands	Van den Houten, 2016 Netherlands
Limitations	• Study was poorly reported • SA was limited, not well reported • Unclear modeling of AEs due to PTA with or without stent • Limited data from 1 RCT • Pre-PTA assessment, medications, PTA with stent placement not modeled • Only short-term outcomes addressed	• Limited SA • Possible limited applicability to a broader IC population • Shorter follow-up (12 months) may not capture long term harms or benefits • Generalizability to US system unclear	• RCT data only 6 months; extrapolation to 5 years, lifetime (survival, QOL, costs assumed to be equal for all groups at 5 years) • Small sample size • Patients from CLEVER trial may differ vs. those seen in routine practice on comorbidities, symptoms etc. which may impact QOL • Unclear how modeling of harms for stent was done, impact on ICER	• SET adherence was poor • Limited SA • Crossovers may negatively affect revascularization outcomes • Short follow-up does not capture long term harms • Study stopped early due to slow patient enrollment and funding termination • Generalizability to US system unclear	• PAD is a chronic condition; the impact of events beyond the 12 months is unclear • Study may be underpowered to detect clinically-relevant differences in effectiveness between groups • Difficult to confirm adherence to SET for anything not done in hospital • Unclear how specific AEs were evaluated • Generalizability to US system unclear	• Combined data from treatment arms of two RCTs with some differences in baseline prognostic factors • Most input parameters were based on data for 12 months • Model assumes that SET patients remain adherent. • Did not model comorbidities. • Evidence for cardiovascular venefit not included in base case model, but introduced in SA and contributed to large increase in relative cost-effectiveness of SET • Generalizability to US system unclear
Funding	None	Government (Not stated in econ publication)	NIH and industry	Government	None	NR
QHES	39/100	82/100	75/100	76/100	83/100	84/100

ACD = absolute claudication distance; AE = adverse event; BA = balloon angioplasty; bcaCI = bias-corrected and accelerated confidence interval; CEA = cost-effectiveness analysis; CETAC = Claudication: Exercise vs. Angioplasty Trial; CI = confidence interval; CrI = credibility interval; CUA = cost-utility analysis; EQ-5D = EuroQol 5-Dimensions; EXITPAD =

Exercise Intervention in Peripheral Arterial Disease trial; IC = intermittent claudication; ICER = incremental cost-effectiveness ratio; MCID = minimal clinically important difference; MD = mean difference; MRA = magnetic resonance angiography; NICE = National Institute for Health and Care Excellence; NR = not reported; PAD = peripheral artery disease; PTA = percutaneous transluminal angioplasty; QALY = quality-adjusted life-year; QHES = Quality of Health Economic Studies instrument; QoL = quality of life; RCT = randomized controlled trial; SA = sensitivity analysis; SD = standard deviation; SET = supervised exercise therapy; SF-36 = Short Form 36-item health survey; SF-6D = Short Form 6-Dimension health state utility; SUPER = Supervised Exercise Therapy vs. Percutaneous Transluminal Angioplasty trial; TASC = TransAtlantic Inter-Society Consensus; USD = United States Dollar; VascuQol = vascular-specific quality of life instrument; WTP = willingness to pay.

* N only includes patients from the RCT which represents BA vs. SET only; no treatment patients were modeled.

† Only relevant to the CETAC trial.

‡ The EXITPAD trial randomized patients to receive SET with and without feedback, and did not include a revascularization arm. The CETAC trial randomized patients to revascularization or SET.

§ The study provided two different values for minimum clinically important difference representing the upper and lower bounds of the minimum clinically important difference range found in the SUPER study group (N=118).

Appendix Table G3. Data Abstraction for Economic Studies Comparing Angioplasty to Bypass

Component	Bradbury (2010) UK	Forbes, 2010 UK
Population	N = 418 Severe Limb Ischemia from BASIL trial	N = 418 Severe Limb Ischemia from BASIL trial
Intervention(s) vs. Comparator(s)	Balloon Angioplasty vs. Bypass Surgery	Balloon Angioplasty vs. Bypass Surgery
Time horizon, Discounting, Currency	3 years, 7 years 3.5%/year 2006/2007 GBP	3 years 3.5%/year 2006/2007 GBP converted to 2006 USD
Design **Perspective**	CUA and CEA Payer, healthcare system	CUA Healthcare system
Outcome (e.g. QALY), Source	EQ-5D	EQ-5D
Cost components **Source**	Patient specific costs, subsequent procedures, hospital stays, clinic visits. Costs included all procedures (surgical, radiological, amputations), hospitalizations, equipment, consumables, and staff time.	Patient specific costs, subsequent procedures, hospital stays, clinic visits. Costs included all procedures (surgical, radiological, amputations), hospitalizations, equipment, consumables, and staff time.
Primary Findings (e.g., base case ICER)	**3 years:** £125,499/QALY to £134,257/QALY **7 years:** AFS: £26,032 per additional amputation-free survival year for Bypass vs. BA OS: £41,401 per additional year of life for bypass vs. BA	**ICER at 3-yrs** $184,492/QALY

Component	Bradbury (2010) UK	Forbes, 2010 UK
Sensitivity Analysis (SA) results, range of cost-effectiveness measure	**Probabilistic SA (CEAC):** **Cost per life-year over 3 years** 50% likelihood that surgery-first strategy being cost-effective at WTP~£135,000 **Cost per additional AFS year at 7 years** 50% likelihood that surgery-first strategy being cost-effective at WTP=£26,032 60% likelihood at WTP>=£50,000 **Cost per additional survival year at 7 years** ~55% likelihood that surgery-first strategy being cost-effective at WTP>=£42,000	**One-way SA sensitivity analyses (adjusted for outliers), 3 years:** Robust regression estimate $9,132/0.03 = $304,400/QALY Median regression estimate: $11,507/0.03 = $383,567/QALY **Probabilistic SA (CEAC):** 58% of estimates show bypass more costly, more effective vs. BA, 33% show bypass more costly and less effective vs. BA
Author conclusion	Costs over the first year were approximately a third higher with a surgery-first than with an angioplasty-first strategy.	A bypass first strategy results in modest increase in hospital costs with small but insignificant gain in QOL measures. The probability of bypass being more cost effective was relatively low given similar HRQOL, survival and hospital costs vs. BA.
Limitations	• Substantial loss to follow-up at 3years and imputation for missing data; unclear how differences between those lost to follow-up and those completing may impact results • Limited description of model assumptions and rationale for them. No one-way sensitivity analyses around assumptions. • Modeling to 7 years required substantial modeling with imputation of missing data. • Generalizability to the U.S. healthcare system is unclear.	• Substantial loss to follow-up at 3years and imputation for missing data; • Authors note substantial imprecision around estimates. • Limited description of model assumptions and rationale for them. No one-way sensitivity analyses around assumptions • Authors suggest that patients surviving < 2 years differ from those who do not but could not capture this in analyses. It is unclear how this may impact cost-effectiveness • Generalizability to the U.S. healthcare system is unclear
Funding	Government	Government
QHES	89/100	89/100

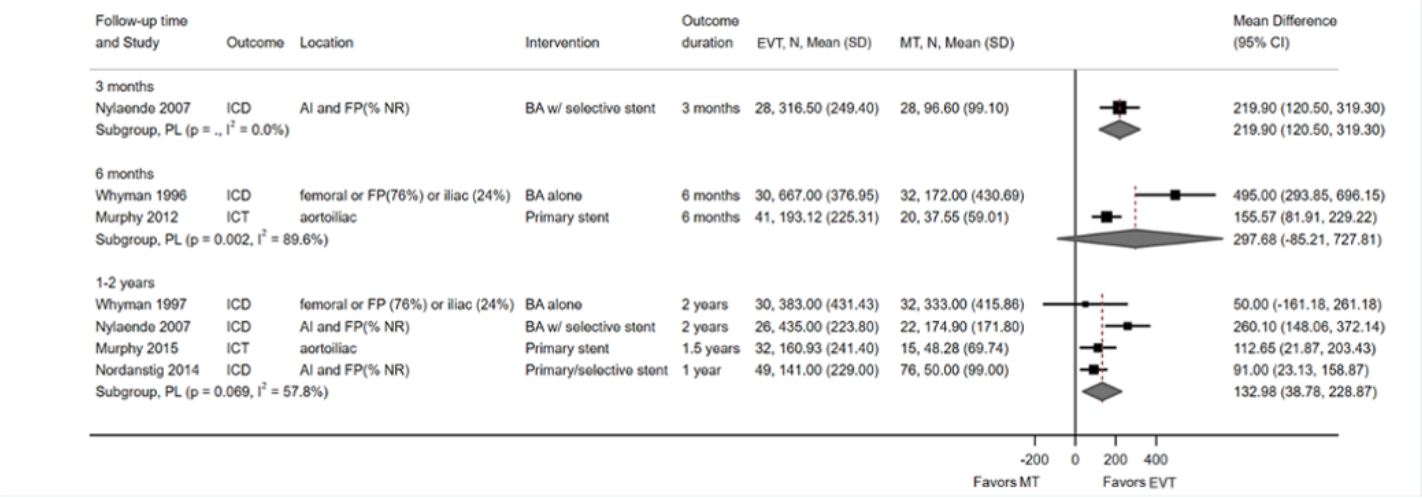
AFS = amputation-free survival; BA = balloon angioplasty; CEA = cost-effectiveness analysis; CEAC = cost-effectiveness acceptability curve; CUA = cost-utility analysis; EQ-5D = EuroQol 5-Dimensions; GBP = British Pound Sterling; HRQOL = health-related quality of life; ICER = incremental cost-effectiveness ratio; OS = overall survival; QALY = quality-adjusted life-year; QHES = Quality of Health Economic Studies instrument; QoL = quality of life; RCT = randomized control trial; SA = sensitivity analysis; USD = United States Dollar; WTP = willingness to pay.

APPENDIX H. Additional Forest Plots

Appendix Figure H1. Intermittent claudication distance (ICD) by longest follow-up (primary analysis): Endovascular intervention versus MT

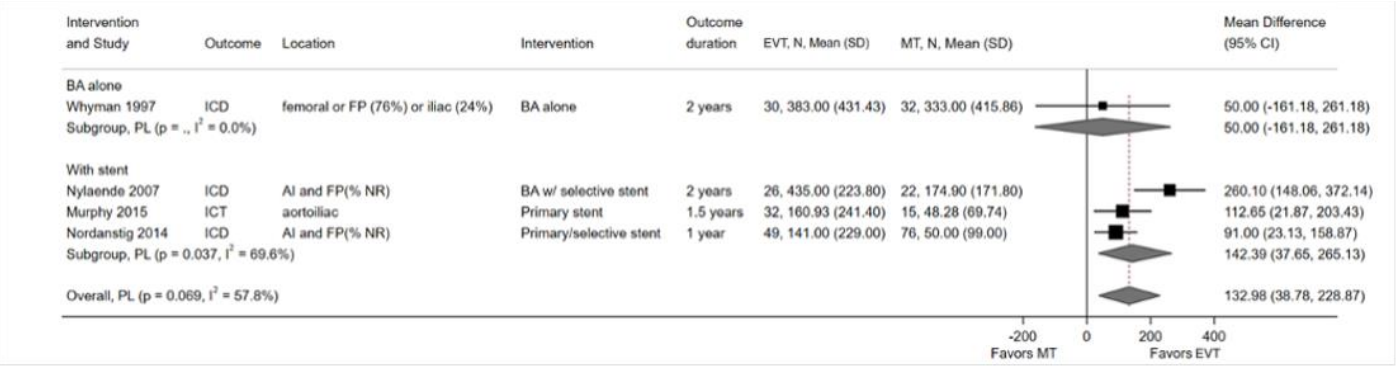
AI = aortoiliac; BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; ICD = initial claudication distance; ICT = intermittent claudication trial; MT = medical therapy; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SMD = standardized mean difference.

Appendix Figure H2. Intermittent claudication distance (ICD) by timepoint using mean difference*: Endovascular intervention versus MT



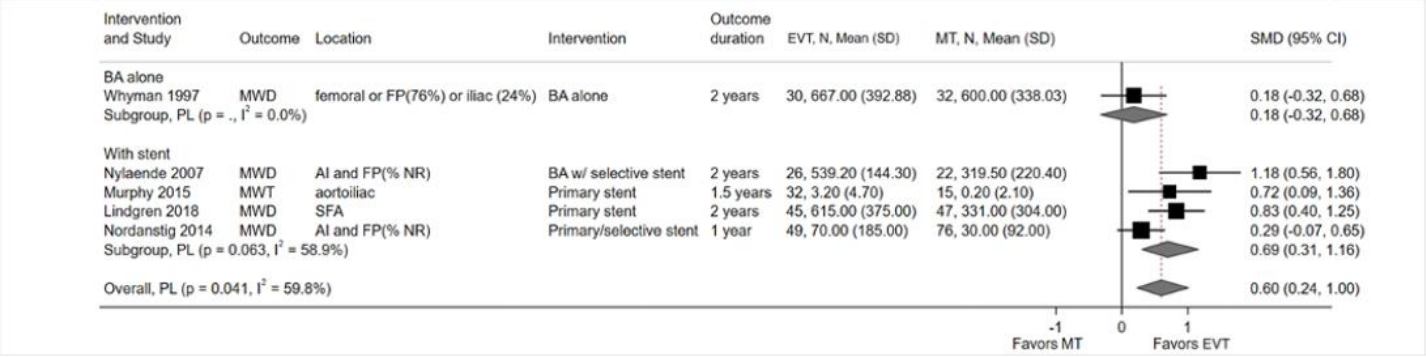
AI = aortoiliac; BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; ICD = initial claudication distance; ICT = intermittent claudication trial; MT = medical therapy; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation.
* Converted ICT to ICD using speed of 2 mph (3.2 km/hour); from Murphy et. al.

Appendix Figure H3. Intermittent claudication distance (ICD) by longest follow-up using mean difference*: Endovascular intervention versus MT



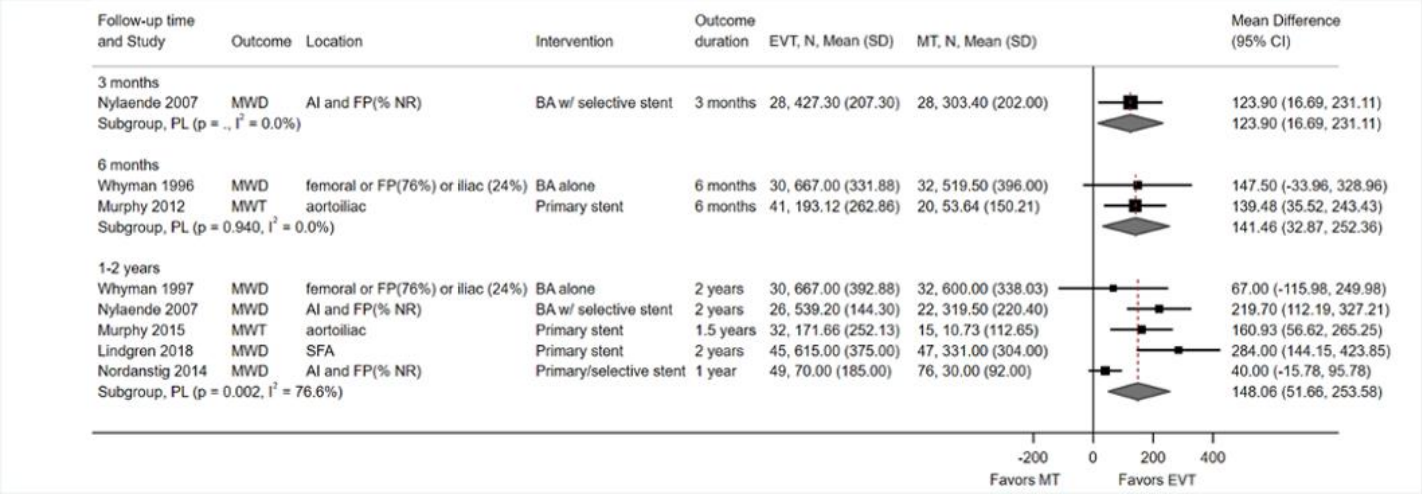
AI = aortoiliac; BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; ICD = initial claudication distance; ICT = intermittent claudication trial; MT = medical therapy; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation.
* Converted ICT to ICD using speed of 2 mph (3.2 km/hour); from Murphy et. al.

Appendix Figure H4. Maximum walking distance (MWD) by longest follow-up (primary analysis): Endovascular intervention versus MT



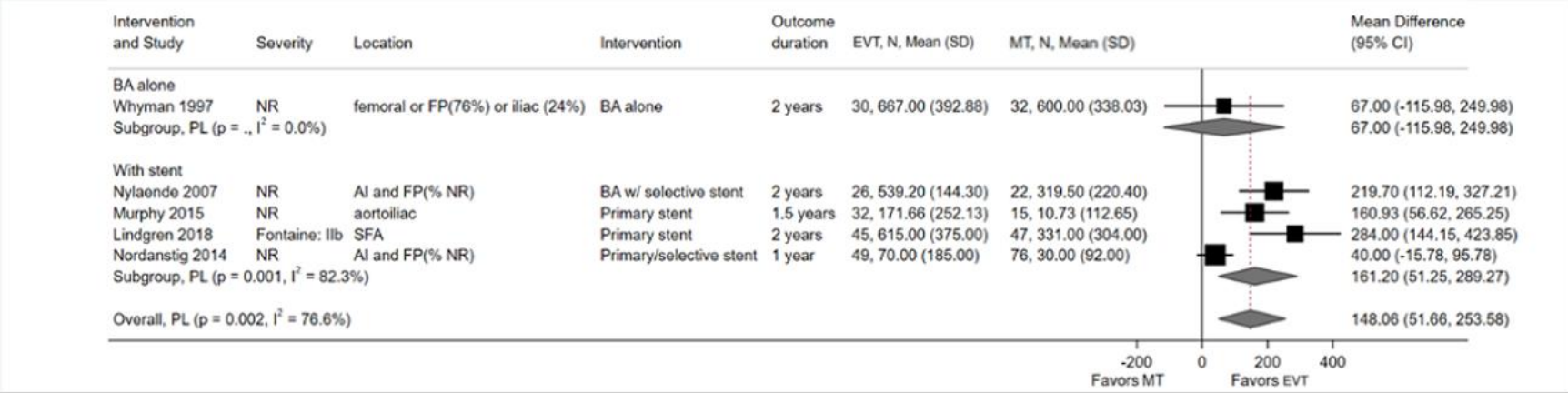
AI = aortoiliac; BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; MT = medical therapy; MWD = maximum walking distance; MWT = maximum walking time; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SFA = superficial femoral artery; SMD = standardized mean difference.

Appendix Figure H5. Maximum walking distance (MWD) by timepoint using mean difference*: Endovascular intervention versus MT



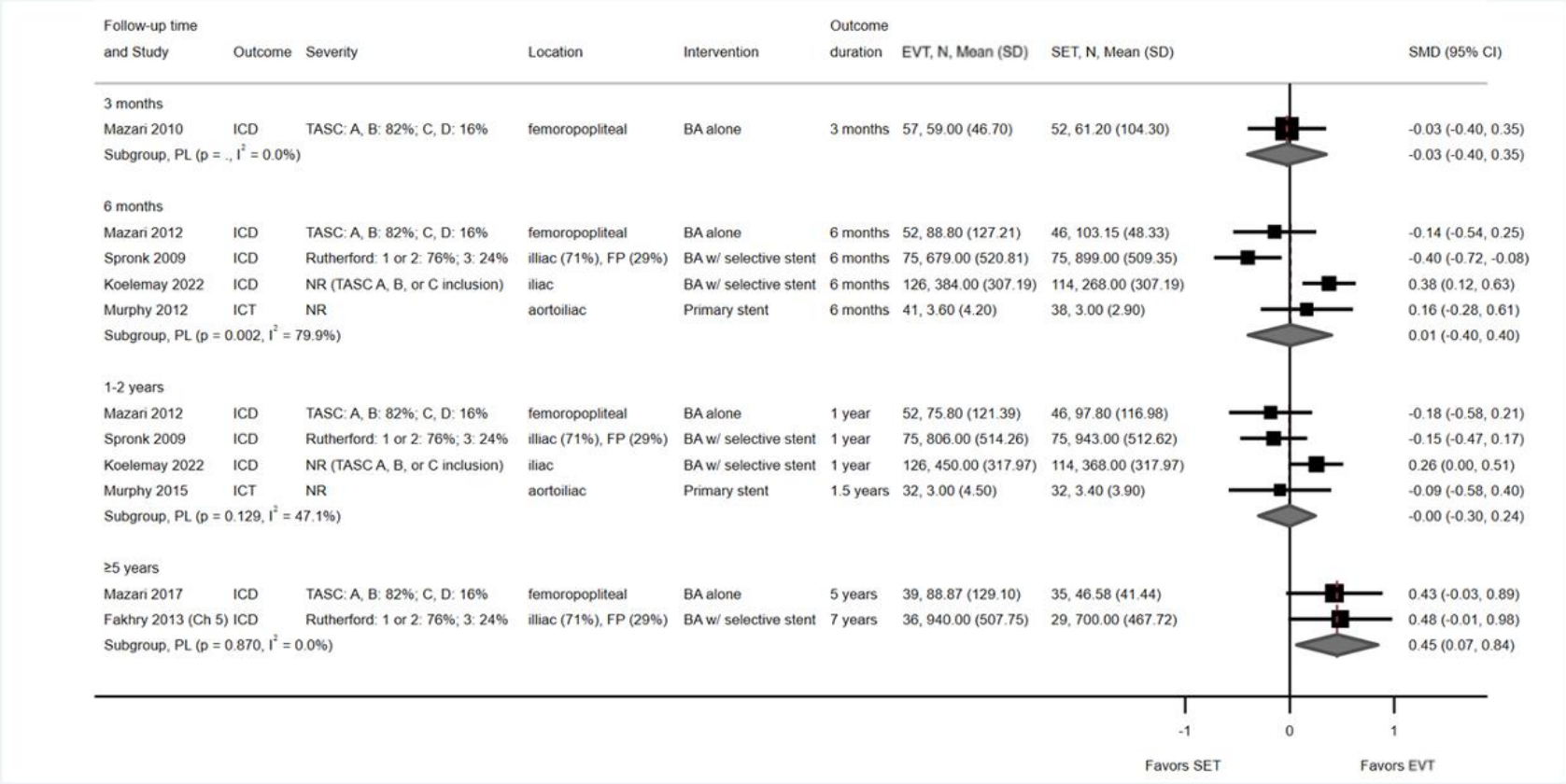
AI = aortoiliac; BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; MT = medical therapy; MWD = maximum walking distance; MWT = maximum walking time; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SFA = superficial femoral artery.
* Converted MWT to MWD using speed of 2 mph (3.2 km/hour); from Murphy et al.

Appendix Figure H6. Maximum walking distance (MWD) by longest follow-up using mean difference*: Endovascular intervention versus MT



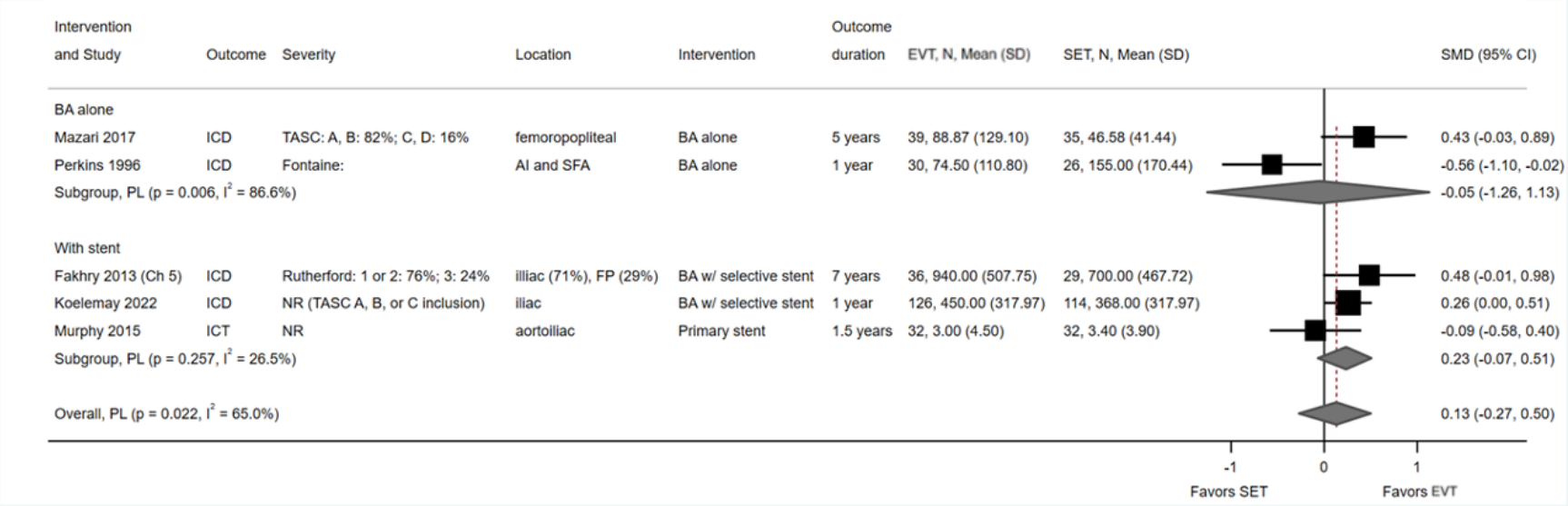
AI = aortoiliac; BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; MT = medical therapy; MWD = maximum walking distance; MWT = maximum walking time; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SFA = superficial femoral artery.
* Converted MWT to MWD using speed of 2 mph (3.2 km/hour); from Murphy et al.

Appendix Figure H7. Intermittent claudication distance (ICD) by timepoint excluding high risk of bias trial (Perkins 2009): Endovascular intervention versus SET



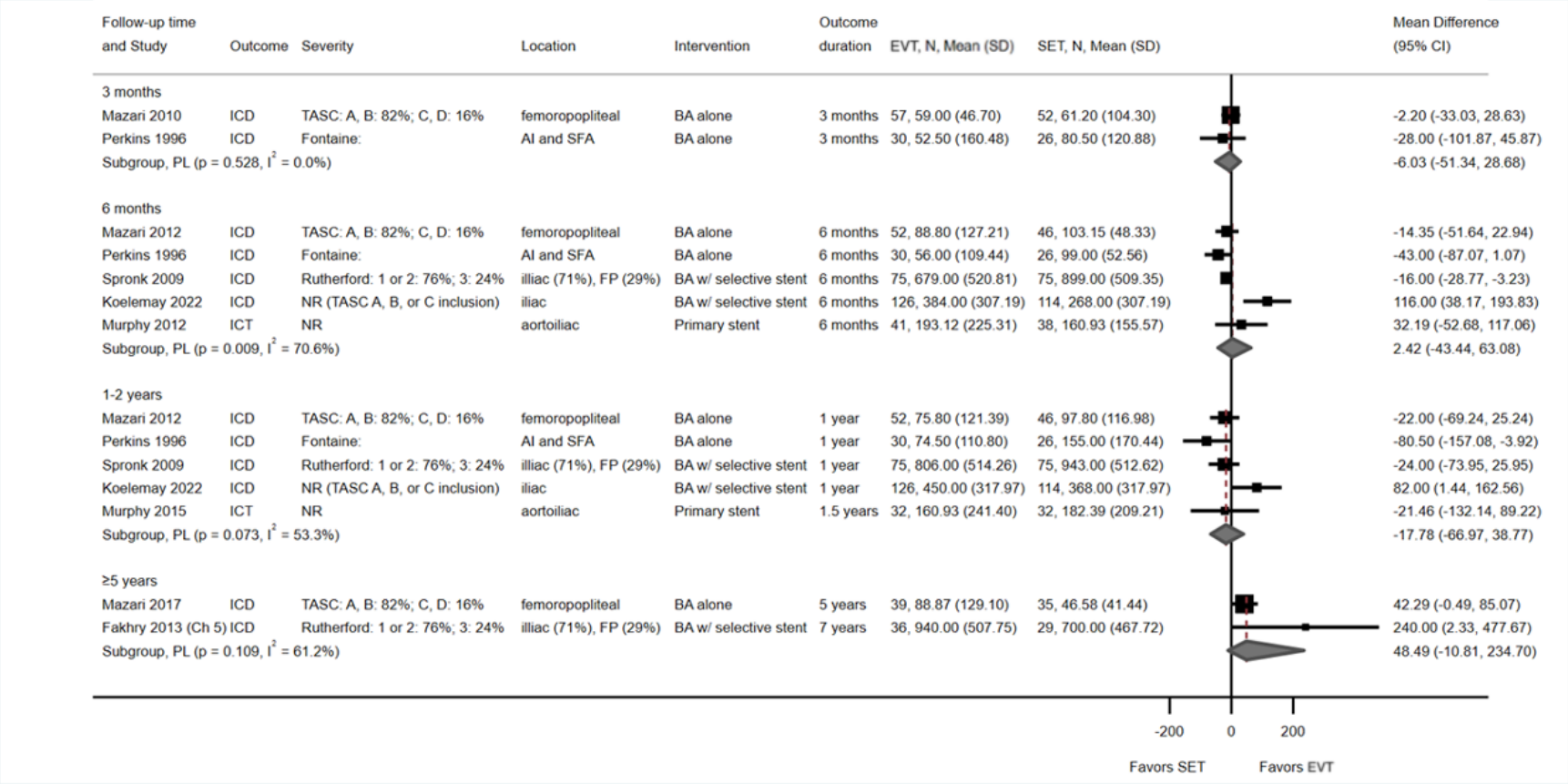
BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; ICD = initial claudication distance; ICT = intermittent claudication trial; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SET = supervised exercise therapy; SFA = superficial femoral artery; SMD = standardized mean difference; TASC = TransAtlantic Inter-Society Consensus.

Appendix Figure H8. Intermittent claudication distance (ICD) by longest follow-up: Endovascular intervention versus SET



AI = aortoiliac; BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; ICD = initial claudication distance; ICT = intermittent claudication trial; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SFA = superficial femoral artery; SET = supervised exercise therapy; SMD = standardized mean difference.

Appendix Figure H9. Intermittent claudication distance (ICD) by timepoint using mean difference*: Endovascular intervention versus SET



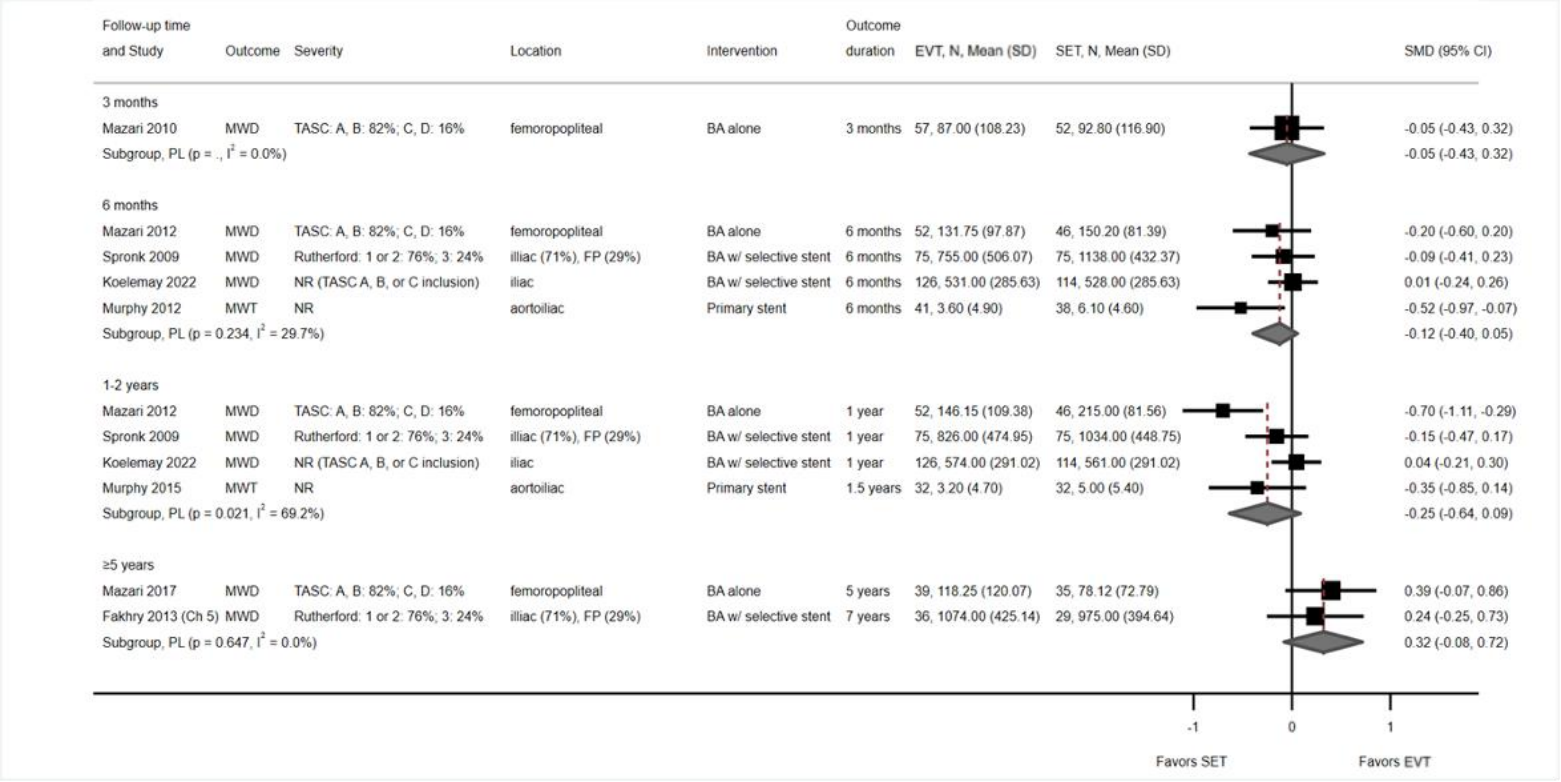
AI = aortoiliac; BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; ICD = initial claudication distance; ICT = intermittent claudication trial; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SFA = superficial femoral artery; SET = supervised exercise therapy; TASC = TransAtlantic Inter-Society Consensus.

* Converted ICT to ICD using speed of 2 mph (3.2 km/hour); from Murphy et. al.

Appendix Figure H10. Intermittent claudication distance (ICD) by longest follow-up using mean difference*: Endovascular intervention versus SET

AI = aortoiliac; BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; ICD = initial claudication distance; ICT = intermittent claudication trial; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SFA = superficial femoral artery; SET = supervised exercise therapy; TASC = TransAtlantic Inter-Society Consensus.
* Converted ICT to ICD using speed of 2 mph (3.2 km/hour); from Murphy et. al.

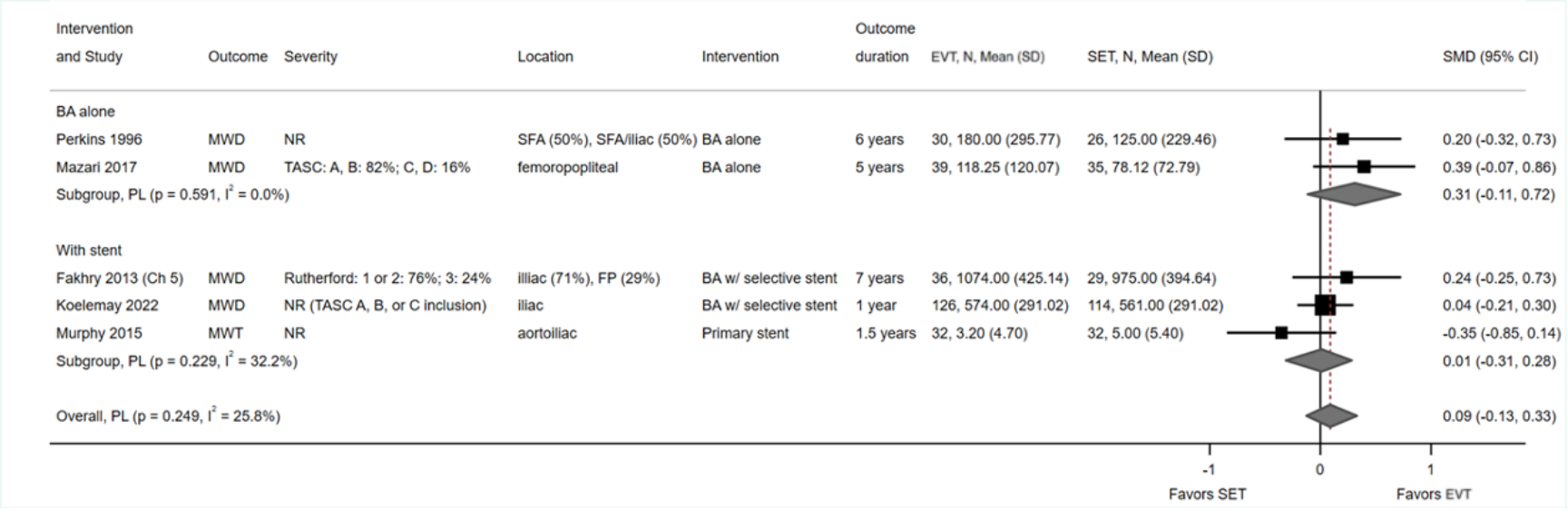
Appendix Figure H11. Maximum walking distance (MWD) by timepoint* excluding high risk of bias trial (Perkins 2009): Endovascular intervention versus SET



BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; MWD = maximum walking distance; MWT = maximum walking time; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SFA = superficial femoral artery; SET = supervised exercise therapy; SMD = standardized mean difference; TASC = TransAtlantic Inter-Society Consensus.

* Converted MWT to MWD using speed of 2 mph (3.2 km/hour); from Murphy et al.

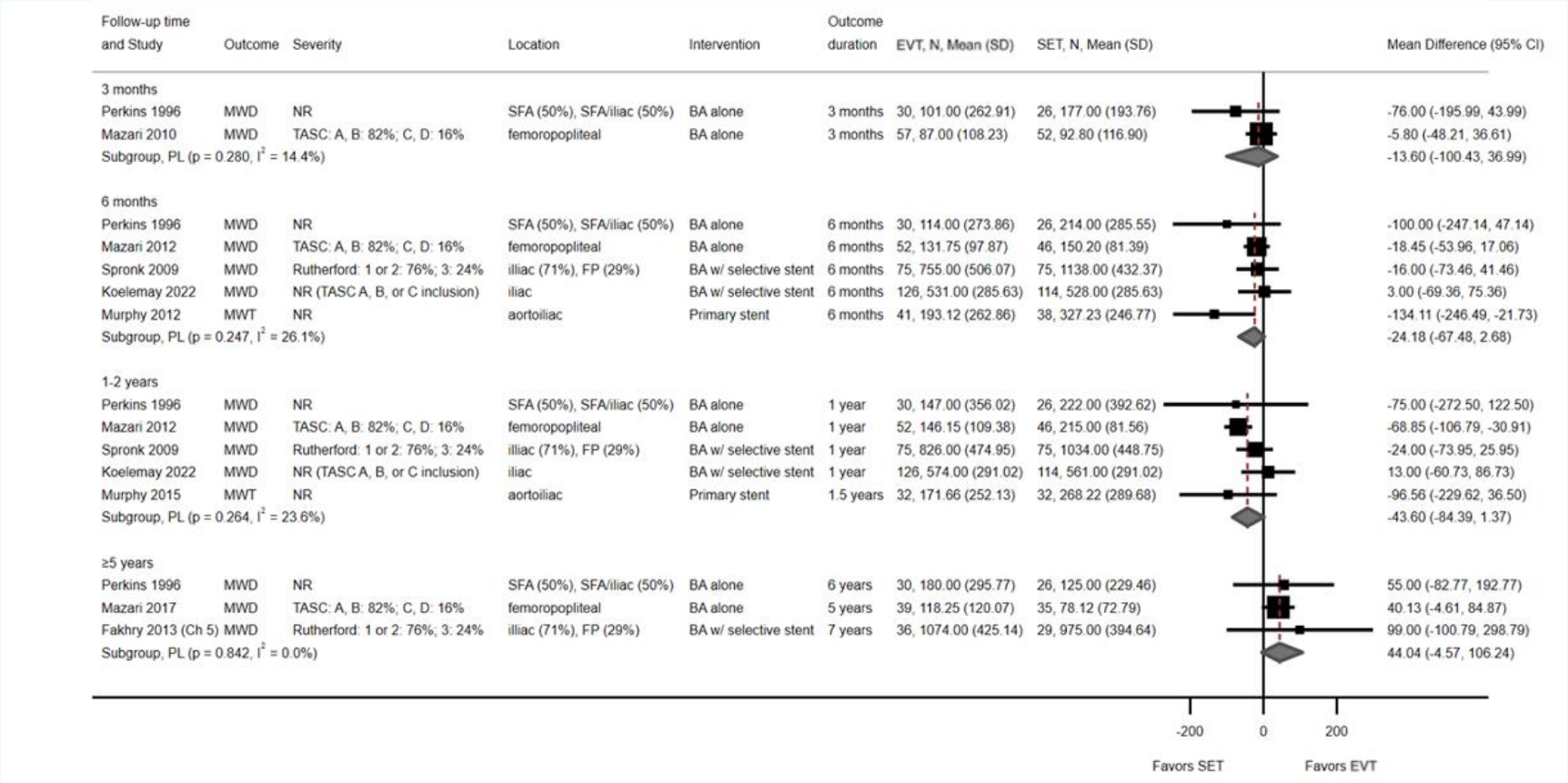
Appendix Figure H12. Maximum walking distance (MWD) by longest follow-up*: Endovascular intervention versus SET



BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; MWD = maximum walking distance; MWT = maximum walking time; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SFA = superficial femoral artery; SET = supervised exercise therapy; SMD = standardized mean difference; TASC = TransAtlantic Inter-Society Consensus.

* Converted MWT to MWD using speed of 2 mph (3.2 km/hour); from Murphy et al.

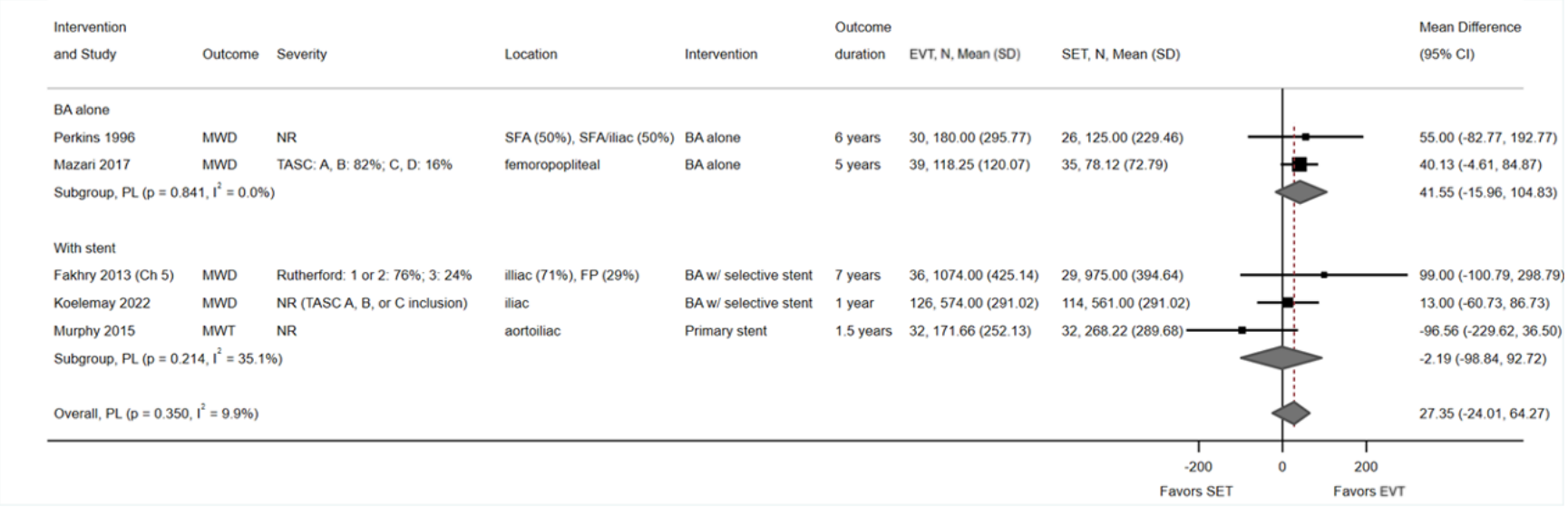
Appendix Figure H13. Maximum walking distance (MWD) by timepoint using mean difference*: Endovascular intervention versus SET



BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; MWD = maximum walking distance; MWT = maximum walking time; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SFA = superficial femoral artery; SET = supervised exercise therapy; TASC = TransAtlantic Inter-Society Consensus.

* Converted MWT to MWD using speed of 2 mph (3.2 km/hour); from Murphy et. al.

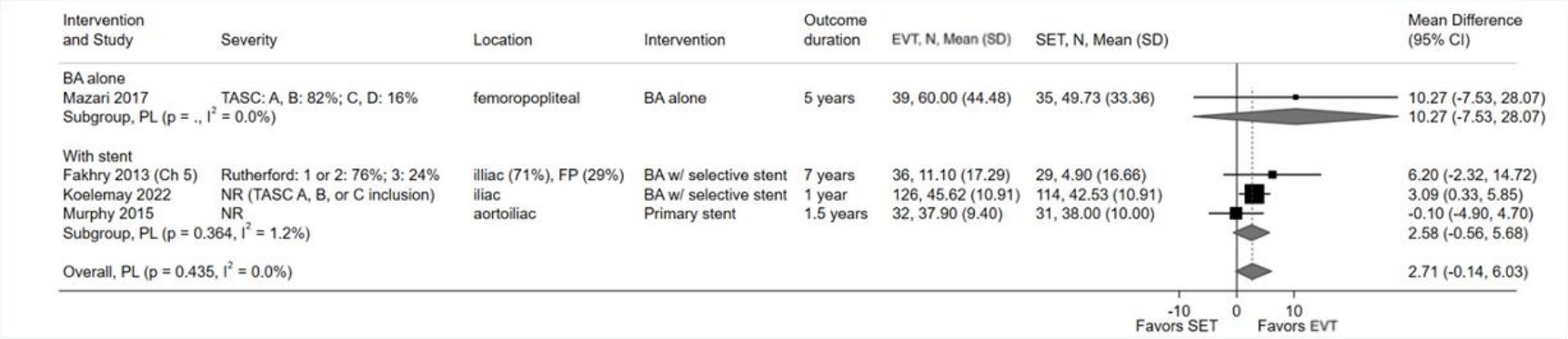
Appendix Figure H14. Maximum walking distance (MWD) by longest follow-up using mean difference*: Endovascular intervention versus SET



BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; MWD = maximum walking distance; MWT = maximum walking time; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SFA = superficial femoral artery; SET = supervised exercise therapy; TASC = TransAtlantic Inter-Society Consensus.

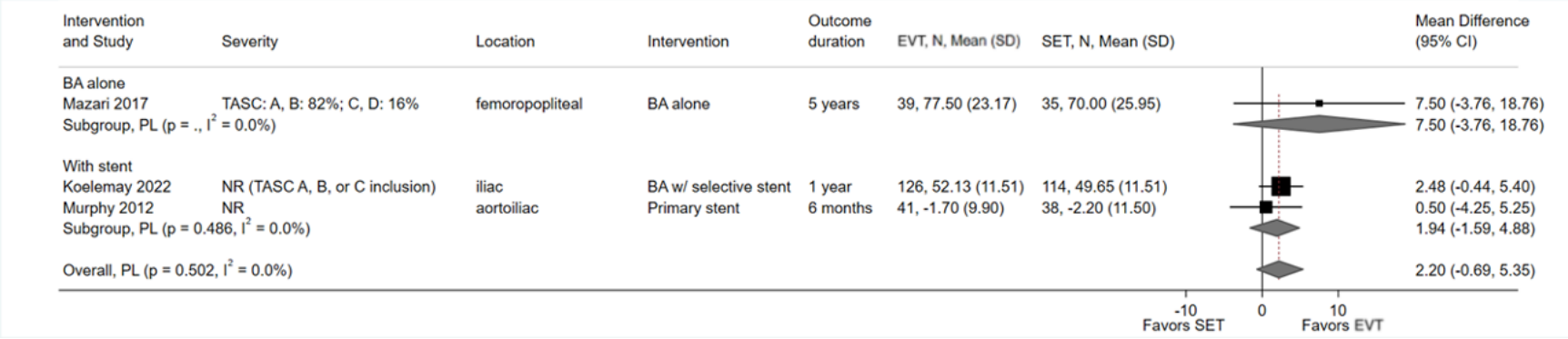
* Converted MWT to MWD using speed of 2 mph (3.2 km/hour); from Murphy et. al.

Appendix Figure H15. SF-36 PCS and PF scores (0-100 scale) by longest follow-up: Endovascular intervention versus SET



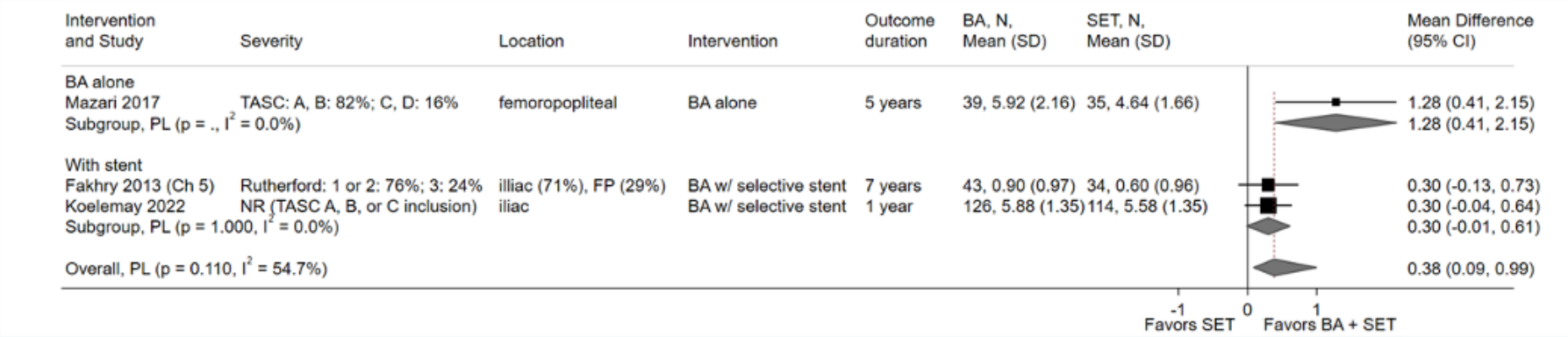
BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; NR = not reported; PCS = physical component score; PF = physical function; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SF-36 = 36-item Short Form Survey; SFA = superficial femoral artery; SET = supervised exercise therapy; TASC = TransAtlantic Inter-Society Consensus.

Appendix Figure H16. SF-36 MCS and MH scores (0-100 scale) by longest follow-up: Endovascular intervention versus SET



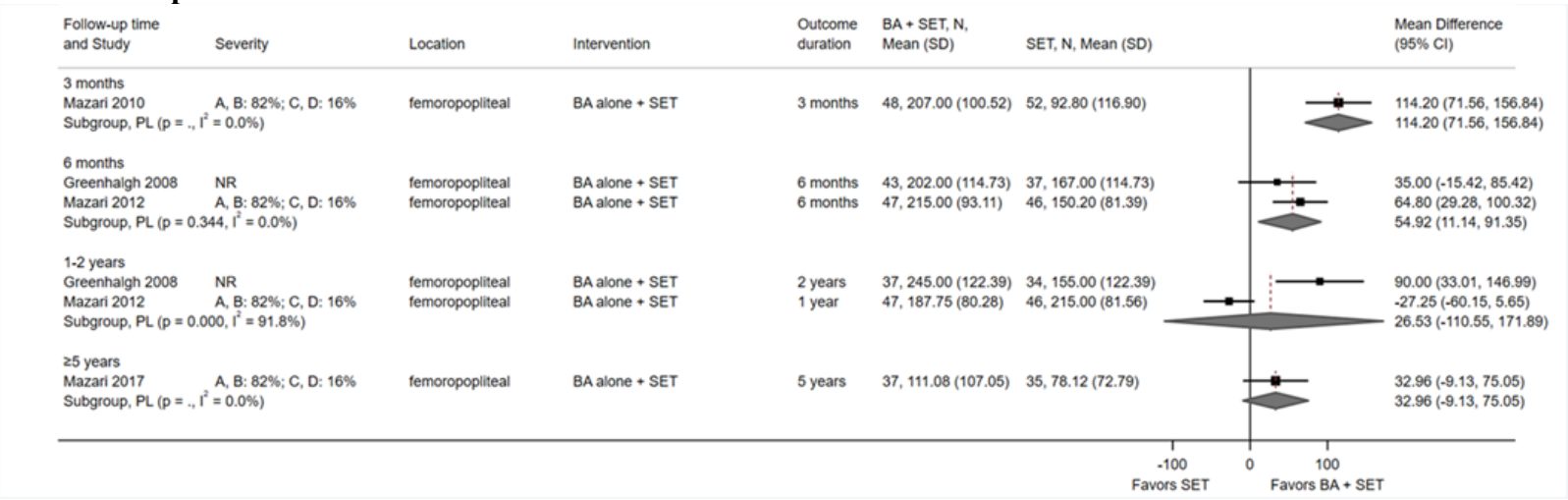
BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; FP = femoropopliteal; MCS = mental component score; MH = mental health; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SF-36 = 36-item Short Form Survey; SFA = superficial femoral artery; SET = supervised exercise therapy; TASC = TransAtlantic Inter-Society Consensus.

Appendix Figure H17. VascuQoL (1-7 scale) by longest follow-up: Endovascular intervention versus SET



BA = balloon angioplasty; CI = confidence interval; FP = femoropopliteal; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SFA = superficial femoral artery; SET = supervised exercise therapy; TASC = TransAtlantic Inter-Society Consensus; VascuQol = Vascular Quality of Life Questionnaire.

Appendix Figure H18. Maximum walking distance (MWD) by timepoint (excluding outlier trial): Combination endovascular intervention plus SET versus SET alone

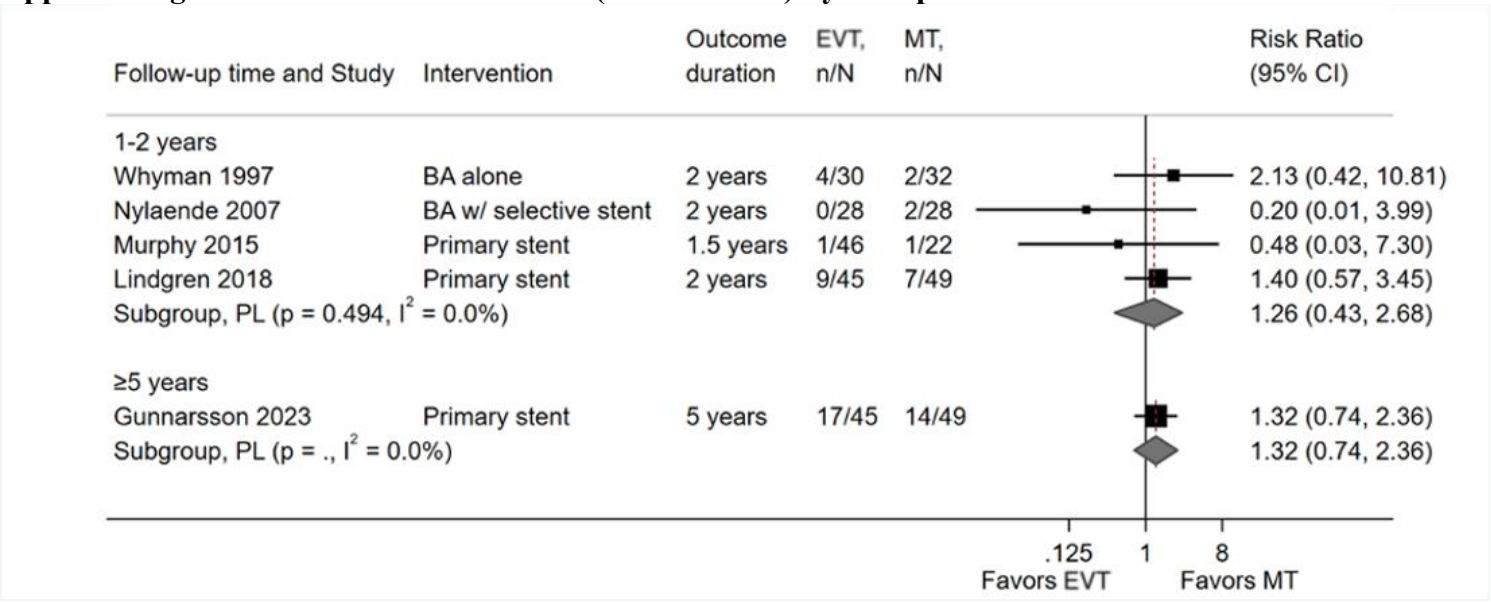


BA = balloon angioplasty; CI = confidence interval; FP = femoropopliteal; MWD = maximum walking distance; NR = not reported; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SFA = superficial femoral artery; SET = supervised exercise therapy; TASC = TransAtlantic Inter-Society Consensus.

Appendix Figure H19. SF-36 PCS and PF scores (0-100 scale) by longest follow-up: Combination endovascular intervention plus SET versus SET

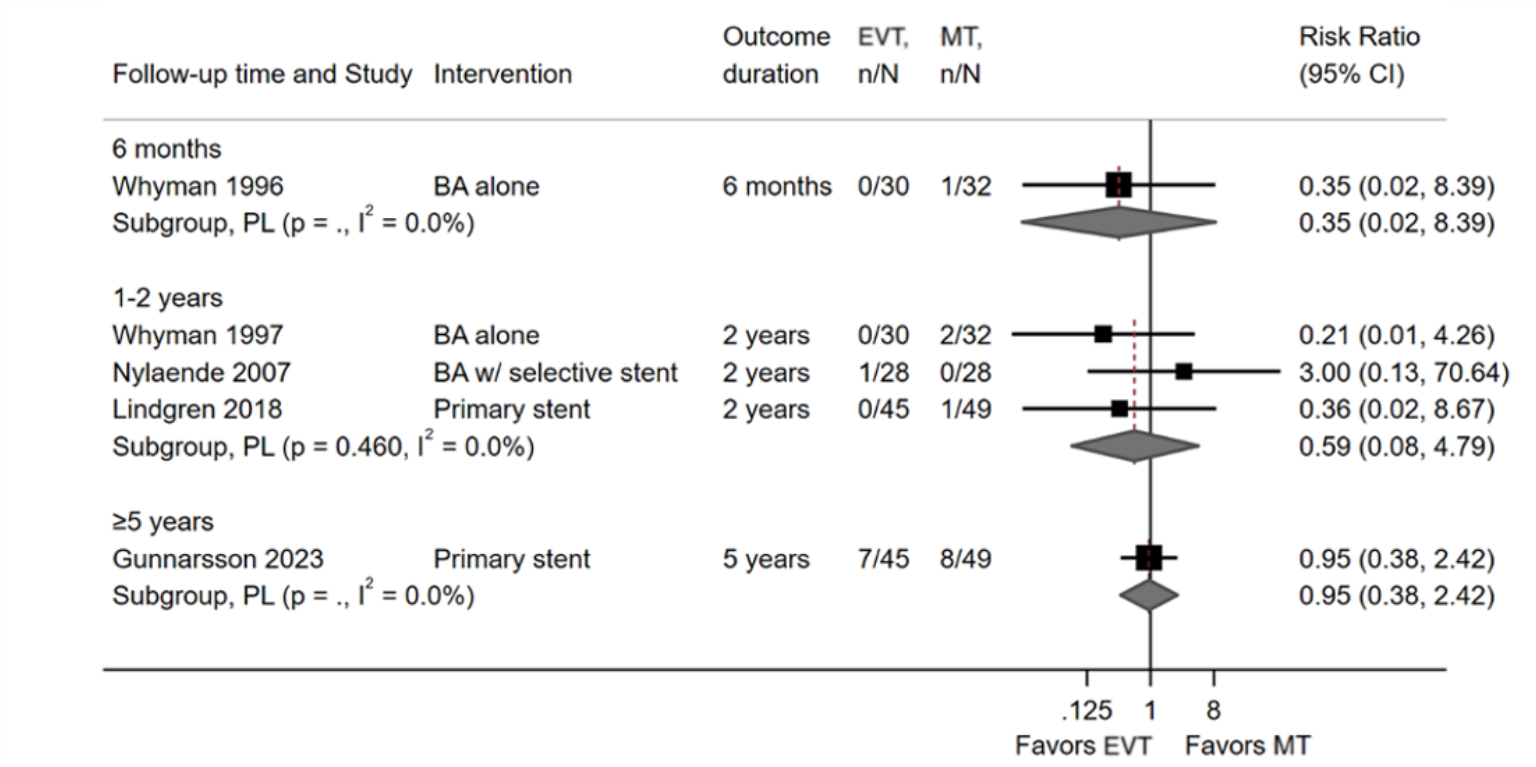
BA = balloon angioplasty; CI = confidence interval; FP = femoropopliteal; NR = not reported; PCS = physical component score; PF = physical function; PL = profile likelihood; RCT = randomized controlled trial; SD = standard deviation; SF-36 = 36-item Short Form Survey; SFA = superficial femoral artery; SET = supervised exercise therapy; TASC = TransAtlantic Inter-Society Consensus.

Appendix Figure H20. Second intervention (endovascular) by time period: Endovascular intervention versus MT



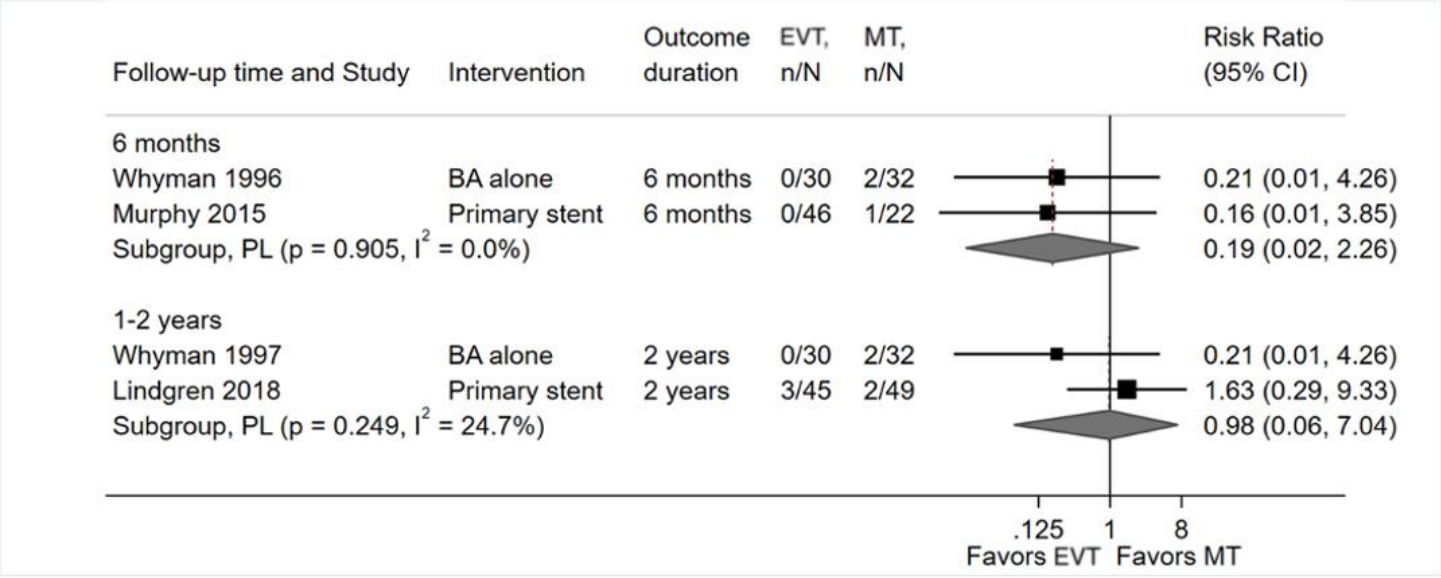
BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; MT = medical therapy; PL = profile likelihood.

Appendix Figure H21. Mortality by time period: Endovascular intervention versus MT



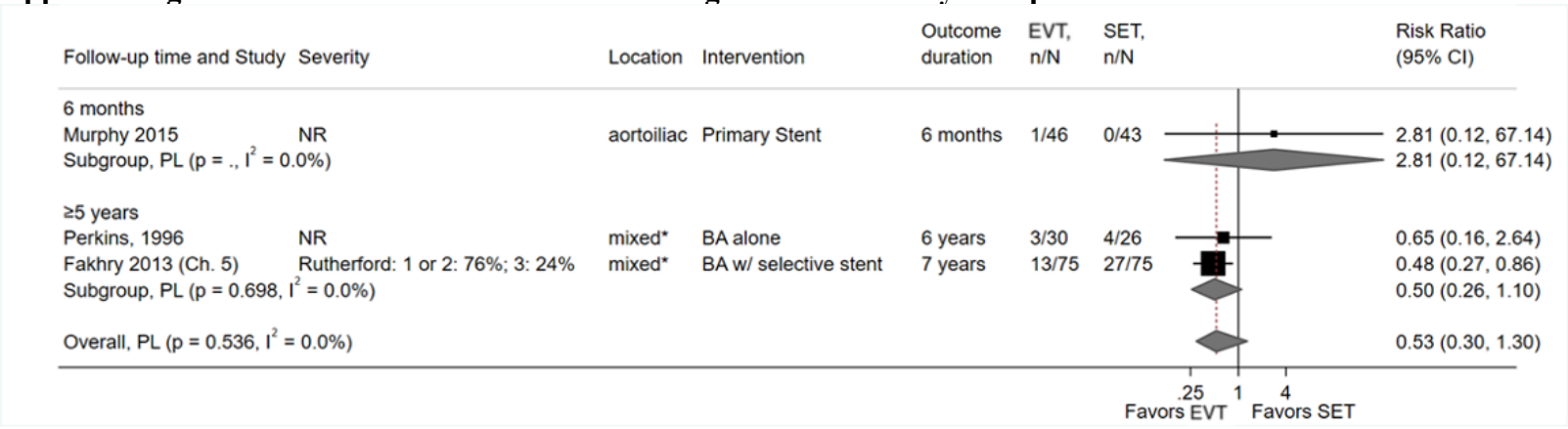
BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; MT = medical therapy; PL = profile likelihood.

Appendix Figure H22. MI by time period: Endovascular intervention versus MT



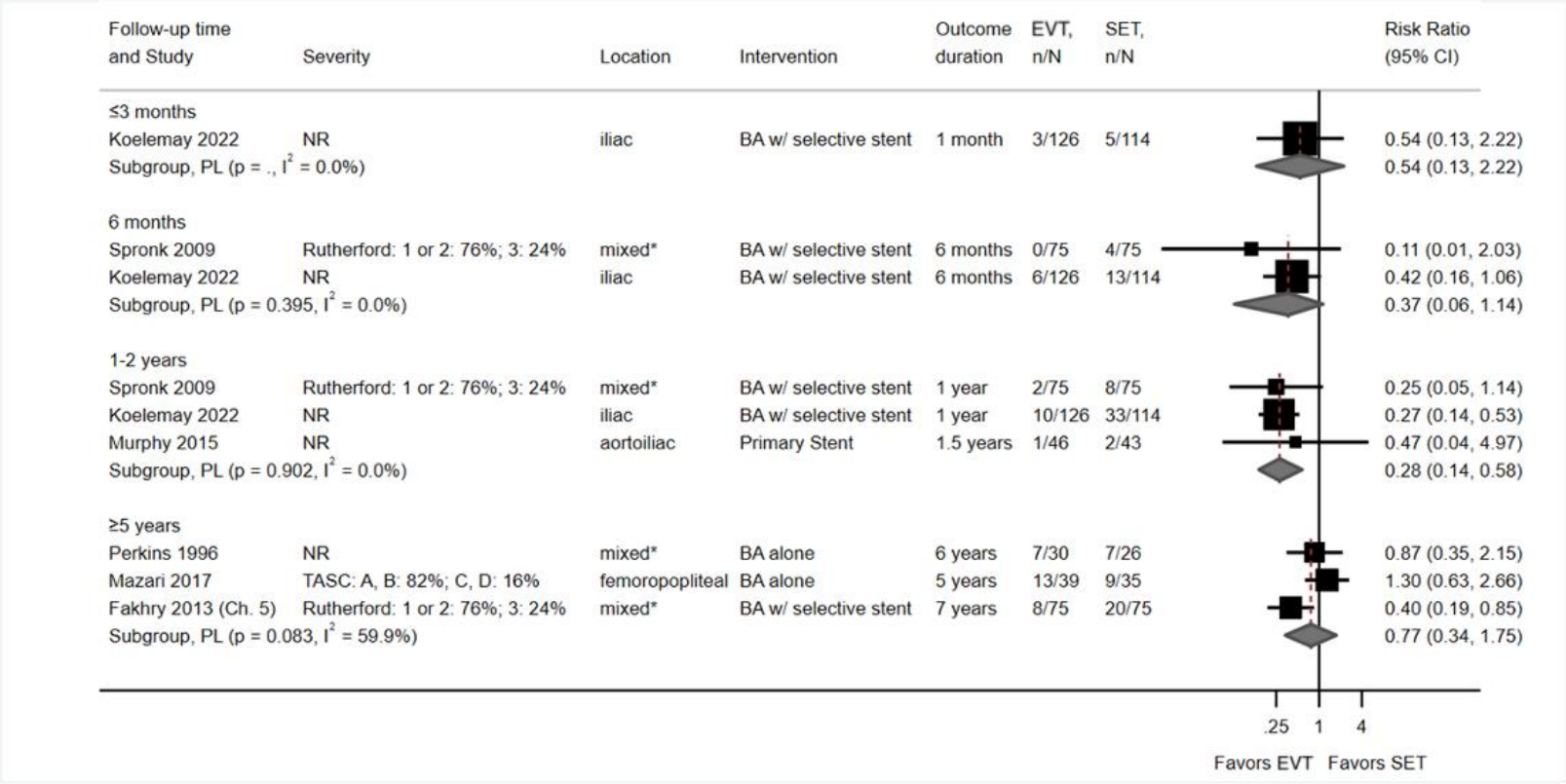
BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; MT = medical therapy; PL = profile likelihood.

Appendix Figure H23. Second intervention to the target vessel/lesion by time period: Endovascular intervention versus SET



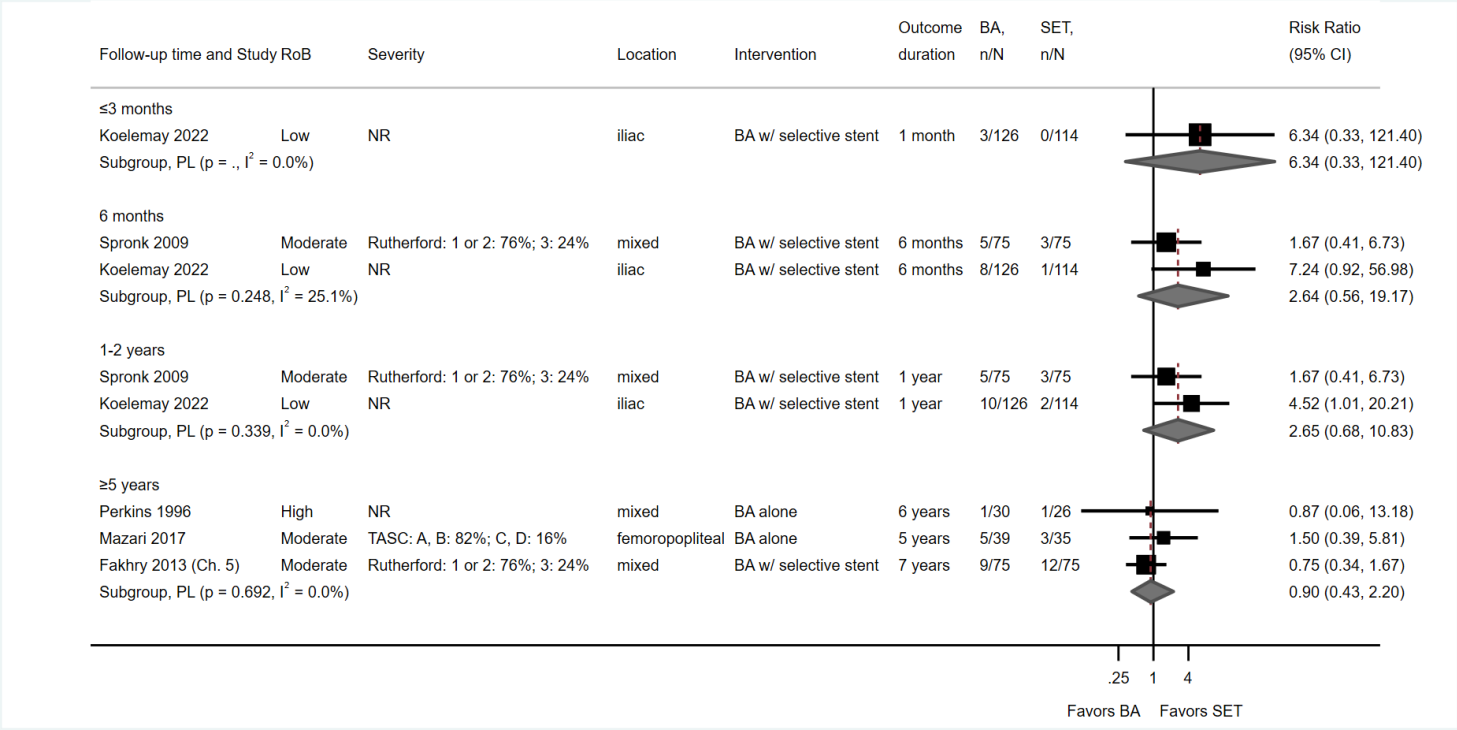
BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; PL = profile likelihood; SET = supervised exercise therapy.

Appendix Figure H24. Second intervention (endovascular) by time period: Endovascular intervention versus SET



BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; PL = profile likelihood; SET = supervised exercise therapy; TASC = TransAtlantic Inter-Society Consensus.

Appendix Figure H25. Second intervention (surgical/bypass) by time period: Endovascular intervention versus SET



BA = balloon angioplasty; CI = confidence interval; PL = profile likelihood; SET = supervised exercise therapy; TASC = TransAtlantic Inter-Society Consensus.

Appendix Figure H26. Mortality by time period: Endovascular intervention versus SET

BA = balloon angioplasty; CI = confidence interval; EVT = endovascular therapy; PL = profile likelihood; SET = supervised exercise therapy; TASC = TransAtlantic Inter-Society Consensus.

APPENDIX I. Differential Efficacy Analysis

Table I1. BA/Stent vs. SET: differential efficacy

Author, Year Intervention, Comparator	Follow-up	Outcome	Subgroup	BA* Mean (SD) or 95% CI	SET* Mean (SD) or 95% CI	MD (95% CI)	Test for Interaction
Perkins 1996 BA vs. SET	3 months	MWD (meters)	Iliac artery	141 (41) (n=15)	210 (74) (n=13)	NC	NR
	3 months	MWD (meters)	SFA	89 (39) (n=15)	165 (80) (n=13)	NC	NR
	6 months	MWD (meters)	Iliac artery	135 (33) (n=15)	195 (71) (n=13)	NC	NR
	6 months	MWD (meters)	SFA	121 (19) (n=15)	212 (84) (n=13)	NC	NR
	1 year	MWD (meters)	Iliac artery	183 (95) (n=15)	246 (98) (n=13)	NC	NR
	1 year	MWD (meters)	SFA	115 (23) (n=15)	365 (106) (n=13)	NC	NR
	1.25 years	MWD (meters)	Iliac artery	162 (124) (n=15)	362 (96) (n=13)	NC	NR
	1.25 years	MWD (meters)	SFA	150 (65) (n=15)	718 (121) (n=13)	NC	NR
	3 months	ICD (meters)	Iliac artery	59 (47) (n=15)	68 (42) (n=13)	NC	NR
	3 months	ICD (meters)	SFA	46 (35) (n=15)	93 (22) (n=13)	NC	NR
	6 months	ICD (meters)	Iliac artery	50 (21) (n=15)	73 (16) (n=13)	NC	NR
	6 months	ICD (meters)	SFA	62 (34) (n=15)	125 (13) (n=13)	NC	NR
	1 year	ICD (meters)	Iliac artery	80 (26) (n=15)	102 (38) (n=13)	NC	NR

Author, Year Intervention, Comparator	Follow-up	Outcome	Subgroup	BA* Mean (SD) or 95% CI	SET* Mean (SD) or 95% CI	MD (95% CI)	Test for Interaction
	1 year	ICD (meters)	SFA	69 (31) (n=15)	208 (55) (n=13)	NC	NR
	1.25 years	ICD (meters)	Iliac artery	49 (12) (n=15)	106 (57) (n=13)	NC	NR
	1.25 years	ICD (meters)	SFA	64 (26) (n=15)	331 (109) (n=13)	NC	NR
Koelemay 2022 Selective stenting (74%) vs. SET	1 month	MWD (meters)	Iliac artery + concomitant SFA	494 (95% CI 419 to 569) (n=59)	407 (95% CI 334 to 480) (n=58)	87 (95% CI -17.69 to 191.69)	NR
	1 month	MWD (meters)	Iliac artery only	492 (95% CI 428 to 555) (n=67)	420 (95% CI 346 to 494) (n=56)	72 (95% CI -24.96 to 168.96)	NR
	6 months	MWD (meters)	Iliac artery + concomitant SFA	507 (95% CI 434 to 580) (n=59)	525 (95% CI 450 to 598) (n=58)	-18 (95% CI -121.94 to 85.94)	NR
	6 months	MWD (meters)	Iliac artery only	550 (95% CI 487 to 612) (n=67)	535 (95% CI 458 to 612) (n=56)	15 (95% CI -83.12 to 113.12)	NR
	1 year	MWD (meters)	Iliac artery + concomitant SFA	585 (95% CI 510 to 659) (n=59)	555 (95% CI 480 to 630) (n=58)	30 (95% CI -75.71 to 135.71)	NR
	1 year	MWD (meters)	Iliac artery only	566 (95% CI 501 to 630) (n=67)	571 (95% CI 492 to 650) (n=56)	-5 (95% CI -105.96 to 95.96)	NR
	1 month	ICD (meters)	Iliac artery + concomitant SFA	287 (95% CI 211 to 363) (n=59)	202 (95% CI 129 to 275) (n=58)	85 (95% CI -20.42 to 190.42)	NR
	1 month	ICD (meters)	Iliac artery only	397 (95% CI 323 to 471) (n=67)	174 (95% CI 89 to 260) (n=56)	223 (95% CI 110.48 to 335.52)	NR
	6 months	ICD (meters)	Iliac artery + concomitant SFA	340 (95% CI 266 to 414) (n=59)	249 (95% CI 174 to 323) (n=58)	91 (95% CI -14.01 to 196.01)	NR

Author, Year Intervention, Comparator	Follow-up	Outcome	Subgroup	BA* Mean (SD) or 95% CI	SET* Mean (SD) or 95% CI	MD (95% CI)	Test for Interaction
	6 months	ICD (meters)	Iliac artery only	421 (95% CI 348 to 494) (n=67)	298 (95% CI 209 to 386) (n=56)	123 (95% CI 9.33 to 236.67)	NR
	1 year	ICD (meters)	Iliac artery + concomitant SFA	485 (95% CI 409 to 560) (n=59)	374 (95% CI 299 to 450) (n=58)	111 (95% CI 4.22 to 217.78)	NR
	1 year	ICD (meters)	Iliac artery only	414 (95% CI 338 to 489) (n=67)	368 (95% CI 277 to 460) (n=56)	46 (95% CI -71.54 to 163.54)	NR
Spronk 2009 Selective stenting (67%) vs. SET	6 months	Clinical success†	Iliac artery	NR	NR	NR	adjusted OR 3.70, 99% CI 0.7 to 18, p=0.03
	6 months	Clinical success†	Femoral artery	NR	NR	NR	adjusted OR 3.70, 99% CI 0.7 to 18, p=0.03
	1 year	Clinical success†	Iliac artery	NR	NR	NR	adjusted OR 0.8, 99% CI 0.2 to 3.3, p=0.71
	1 year	Clinical success†	Femoral artery	NR	NR	NR	adjusted OR 0.8, 99% CI 0.2 to 3.3, p=0.71
	6 months	Clinical success†	<6 cigarettes/day	NR	NR	NR	adjusted OR 0.52, 99% CI 0.1 to 4.4, p=0.43
	6 months	Clinical success†	≥6 cigarettes/day	NR	NR	NR	adjusted OR 0.52, 99% CI 0.1 to 4.4, p=0.43
	1 year	Clinical success†	<6 cigarettes/day	NR	NR	NR	adjusted OR 1.5, 99% CI 0.3 to 6.9, p=0.46
	1 year	Clinical success†	≥6 cigarettes/day	NR	NR	NR	adjusted OR 1.5, 99% CI 0.3 to 6.9, p=0.46

BA = balloon angioplasty; CI = confidence interval; ICD = intermittent claudication distance (i.e., pain-free walking distance); MD = mean difference; MWD = maximum walking distance; NC = not calculated; NR = not reported; OR = odds ratio; SD = standard deviation; SET = supervised exercise therapy; SFA = superficial femoral artery.

* Data was reported using the following statistical measures:

- Perkins 1996: median (standard error)
- Koelemay 2022: mean (95% CI)

† Clinical success as an improvement in at least one category in the Rutherford scale above the pretreatment level, measured after treadmill walking (3.5 km/h, no graded incline).

Table I2. BA/Stent vs. SET: Subgroup Analyses of Limb Survival by Assigned Intervention, Stratified by Lesion Location and Preoperative Symptom Category after Median 4 years of Follow-up (Wolf, 1993)

Subgroup	Balloon Angioplasty % (n/N)	Surgery % (n/N)	MD (95% CI)
Iliac – rest pain	74.8% (16*/22)	72.5% (16*/23)	MD 2.3% (95% CI -27.0% to 45.4%)†
Femoral/popliteal – Rest pain	90.9% (10*/11)	59.7% (10*/16)	MD 31.2% (95% CI -30.0 to 27.3%)†
Iliac – Claudication	90.5% (53*/59)	94.7% (56*/59)	MD -4.2% (95% CI -10.0% to 116.7%)†
Femoral/popliteal - Claudication	92.7% (35*/38)	85.1% (30*/35)	MD 7.6% (95% CI -16.9% to 66.5%)†

CI = confidence interval; MD = mean difference.

* n's back calculated.

† MD's and 95% CIs calculated by AAI using differences in percentages and standard deviations reported by authors.

APPENDIX J. Payer Policies and Clinical Guidelines

Table J1. Evidence Base for Payer Policies

Payer (year)	Policy
Premera Percutaneous Revascularization Procedures for Lower Extremity Peripheral Arterial Disease Number: 7.01.594 Last review: 5/26/2025	"For individuals who are adults with symptomatic lower extremity peripheral arterial disease who receive percutaneous revascularization with balloon angioplasty, stent procedures, or atherectomy, the evidence includes RCTs, observational studies, and systematic reviews. Multiple studies have demonstrated that percutaneous and surgical revascularization for chronic symptomatic PAD can improve symptoms and quality of life in individuals who have not responded to guideline directed medical treatment, including structured exercise. Guidelines recommend that the choice to proceed to revascularization and selection of procedure should be a shared decision-making process, based on clinical presentation, including severity of symptoms and anticipated natural history; degree of functional limitation and QOL impairment; response to medical therapy, including structured exercise; and the likelihood of a beneficial short- and longer-term outcome, balanced against potential short-term (e.g., bleeding, infection, major adverse cardiac events), and longer-term procedural risk. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome. For individuals who are adults with chronic limb-threatening ischemia (CLTI) who receive percutaneous revascularization with balloon angioplasty, stent procedures, or atherectomy, the evidence includes RCTs, observational studies, and systematic reviews. Relevant outcomes are overall survival, morbid events, functional outcomes, and treatment-related mortality and morbidity. Revascularization is considered the standard treatment for individuals with CLTI to minimize tissue loss and preserve a functional limb and ambulatory status. Both endovascular and surgical revascularization have been demonstrated to be effective treatments for preventing amputation in CLTI. In a systematic review of 13 studies of individuals with CLTI enrolled in medical and angiogenic therapy trials who did not receive revascularization, a 22% all-cause mortality rate and a 22% rate of major amputation at a median follow-up of 12 months were observed. The evidence is sufficient to determine that the technology results in an improvement in the net health outcome." See policy for relevant clinical practice guideline recommendations.
Aetna: Peripheral Vascular Stents Number: 0785 Last review: 11/12/24	"The American College of Cardiology/American Heart Association's guidelines for the management of patients with PAD (lower extremity, renal, mesenteric, and abdominal aortic) had the following statements (Hirsch et al, 2005): • Stenting is effective as primary therapy for common iliac artery stenosis and occlusions • Stenting is effective as primary therapy for external iliac artery stenoses and occlusions • Provisional stent placement is indicated for use in the iliac arteries as salvage therapy for a sub-optimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis greater than 50 %, or flow-limiting dissection)

Payer (year)	Policy
	• Stents can be useful in the femoral, popliteal, and tibial arteries as salvage therapy for a sub-optimal or failed result from balloon dilation (e.g., persistent translesional gradient, residual diameter stenosis greater than 50 %, or flow-limiting dissection) • Primary stent placement is not recommended in the femoral, popliteal, or tibial arteries • The effectiveness of stents for the treatment of femoral-popliteal arterial lesions (except to salvage a suboptimal result from balloon dilation) is not well-established • The effectiveness of uncoated/uncovered stents for the treatment of infra-popliteal lesions (except to salvage a suboptimal result from balloon dilation) is not well-established." "In a systematic review, Mwipatayi et al (2020) compared studies reporting the outcomes of the use of covered balloon-expandable (CBE) stents for the treatment of aorto-iliac occlusive disease. … All studies showed high rates of technical success and patency over the course of 12 months. Long-term data were only available for the iCast/Advanta V12 device, which had a primary patency rate of 74.7 % at 5 years. The authors concluded that CBE stents are a viable therapeutic option for patients with complex aorto-iliac lesions because of their high rates of technical success and favorable patency across all devices at 12 months. However, long-term data are only available for a single device, the iCast/Advanta V12. The results of using this device were favorable over the course of 5 years. Moreover, these researchers stated that further robust comparative studies with long-term data will provide more information. "The National Institute for Health and Clinical Excellence's guideline on "Lower limb peripheral arterial disease: Diagnosis and management" (2012) recommended the use of bare metal stents where stenting is indicated for intermittent claudication because of a lack of evidence of superior clinical outcomes with DES." "Guidelines on management of peripheral artery disease from the American College of Cardiology (Hirsch et al, 2006), discussed in greater detail below, conclude that primary stent placement is not recommended in the femoral, popliteal, or tibial arteries. In addition, the guidelines state that the effectiveness of stents for the treatment of femoral-popliteal arterial lesions (except to salvage suboptimal results from balloon dilation) is not well established, and the effectiveness of uncoated/uncovered stents for the treatment of infra-popliteal lesions (except to salvage a suboptimal result from balloon dilation) is not well-established. … The Agency for Healthcare Research and Quality's technology assessment of "invasive interventions for lower extremity peripheral artery disease" and systematic review of "studies comparing stent placement to other interventions" (Balk et al, 2008) reached the following conclusions: (i)The cited aorto-iliac surgery studies did not describe the pre-operative anatomy and no clinically relevant outcomes were reported. The majority of the studies cited for endovascular treatment of the aorto-iliac segment did have anatomical descriptions of the studied patients; however, none used the Trans-Atlantic Society Consensus (TASC) classification; (ii) There is a dearth of trials of patients with either aorto-iliac or infra-popliteal disease. The newer nitinol stents were used by only 3 of the trials (plus 1 RCT of stent versus bypass and 2 RCTs comparing different stents). The predominant primary outcome of the trials remain patency (variously defined), which has not been adequately demonstrated to be an excellent predictor of clinical outcomes. True clinical outcomes have frequently been inadequately or incompletely reported and analyzed.

Payer (year)	Policy
	… An UpToDate review on "Percutaneous interventional procedures in the patient with lower extremity claudication" (Zaetta et al, 2016) states that 'Although PTA in the femoro-popliteal segment is associated with restenosis, a clear advantage to primary stenting has not been definitively demonstrated in meta-analyses of randomized trials. In general, longer lesions probably benefit from stenting, but whether a self-expanding metal stent or covered stents should be used remains debated. Local delivery of medical therapies aimed at preventing stenosis using drug-eluting stents has also been tried, as well as the use of biodegradable stents. The use of drug-eluting stents should be considered experimental therapy'." "Chu and colleagues (2017) examined the published literature on the use of biodegradable stents in the treatment of PAD. Technical success rates were 100 %. These studies had a short-to-medium follow-up period up to 58 months. The primary and secondary patency rates were 60.8 % (range of 32 to 77 %) and 88.4 % (range of 79 to 97 %) respectively. There were also 4 on-going studies internationally. The authors concluded that contemporary published literature suggested that biodegradable scaffold/stent is safe and effective in the treatment of PAD, but these studies were heterogeneous and were limited by their study design, relatively small sample size, and short follow-up period; and therefore did not produce a high enough level of evidence to show superiority that leads to a change in current treatment guidelines."

ACC = American College of Cardiology; AHA = American Heart Association; AHRQ = Agency for Healthcare Research and Quality; BA = balloon angioplasty; CBE = covered balloon-expandable; CLTI = chronic limb-threatening ischemia; DES = drug-eluting stent; FDA = Food and Drug Administration; IC = intermittent claudication; NICE = National Institute for Health and Care Excellence; PAD = peripheral artery disease; PTA = percutaneous transluminal angioplasty; QOL = quality of life; RCT = randomized controlled trial; SDM = shared decision-making; TASC = TransAtlantic Inter-Society Consensus; USD = United States Dollar.

Table J2. Summary of Clinical Practice Guidelines for Endovascular Treatments in Patients with Peripheral Artery Disease

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
Society for Vascular Surgery 2025 Society for Vascular Surgery Clinical Practice Guideline on the Management of Intermittent Claudication: Focused Update Conte et al United States	Intermittent claudication	None cited.	• In patients with IC, we recommend a supervised exercise program consisting of walking a minimum of three times per week (30-60 min/session) for at least 12 weeks as first-line therapy. • For patients who have undergone revascularization for IC, we suggest the continued use of exercise therapy post-intervention (supervised or home-based).	Grade: 1 Level of evidence: A Grade: 2 Level of evidence: C

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
			• For patients who have undergone revascularization for IC, we suggest the continued use of exercise therapy post-intervention (supervised or home-based).	Grade: 2 Level of evidence: C
			• We recommend against performing revascularization in patients with asymptomatic peripheral artery disease or IC based solely on hemodynamic measurements or imaging findings. There is no evidence to support the use of revascularization for modifying disease progression.	Grade: 1 Level of evidence: C
			• In patients with IC who are selected for an endovascular intervention to treat femoropopliteal disease and have lesions exceeding 5 cm in length, we recommend the use of either bare metal stents or drug eluting devices (drug-coated balloons or drug-eluting stents) over plain balloon angioplasty to reduce the risk of restenosis and need for reintervention.	Grade: 1 Level of evidence: B
ACC/AHA/AACVPR/APMA/ABC/ SCAI/SVM/SVN/SVS/SIR/VESS 2024 Guideline for the Management of Lower Extremity Peripheral Artery Disease: A Report of the American College of Cardiology/American Heart Association Joint	Claudication (chronic symptomatic PAD)	1 RCT, 5 observational study	<u>Revascularization for Claudication: Initial Decision-Making</u> • In patients with functionally limiting claudication who are being considered for revascularization, potential benefits with respect to QOL, walking performance, and overall functional status should be weighed against the risks and	Class of recommendation: 1 Level of evidence: B-NR

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
Committee on Clinical Practice Guidelines (Gornik et al) United States	Chronic limb-threatening ischemia (CLTI)		durability of intervention and possible need for repeated procedures.	
		1 meta-analysis, 1 systematic review, 6 RCTs	• In patients with functionally limiting claudication and an inadequate response to GDMT (including structured exercise), revascularization is a reasonable treatment option to improve walking function and QOL.	Class of recommendation: 2a Level of evidence: B-NR
		None cited.	• In patients with claudication who have had an adequate clinical response to GDMT (including structured exercise), revascularization is not recommended.	Class of recommendation: 3 (No benefit) Level of evidence: C-EO
			<u>Revascularization for Claudication: Aortoiliac Disease and Femoropopliteal Disease (Excluding Common Femoral Artery Disease)</u>	
		1 meta-analysis, 1 systematic review, 19 RCTs, 1 review	• In patients with functionally limiting claudication and hemodynamically significant aortoiliac or femoropopliteal disease with inadequate response to GDMT (including structured exercise), endovascular revascularization is effective to improve walking performance and QOL.	Class of recommendation: 1 Level of evidence: A
		2 meta-analyses, 1 observational	• In patients with functionally limiting claudication and hemodynamically significant aortoiliac or femoropopliteal disease with	Class of recommendation: 2a Level of evidence: B-NR

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
			inadequate response to GDMT (including structured exercise), surgical revascularization is reasonable if perioperative risk is acceptable and technical factors suggest advantages over endovascular approaches.	
			<u>Revascularization for Claudication: Common Femoral Artery Disease</u>	
		2s systematic reviews with meta-analysis, 2 RCTs, 4 observational studies	• In patients with functionally limiting claudication and hemodynamically significant common femoral artery disease with inadequate response to GDMT (including structured exercise), endovascular approaches may be considered in those at high risk for surgical revascularization and/or if anatomical factors are favorable (ie, no adverse effect on profunda femoris artery pathways).	Class of recommendation: 2b Level of evidence: B-R
		1 systematic review, 3 RCTs, 1 case-controlled study, 8 observational studies, 1 review	• In patients with CLTI, surgical, endovascular, or hybrid revascularization techniques are recommended, when feasible, to minimize tissue loss, heal wounds, relieve pain, and preserve a functional limb.	Class of recommendation: 1 Level of evidence: B-R
		6 systematic reviews with meta-analysis, 1 observational study	• In patients with CLTI and nonhealing wounds or gangrene, revascularization in a manner that achieves in-line blood flow or maximizes perfusion to the wound bed can be beneficial.	Class of recommendation: 2a Level of evidence: B-NR

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
		2 observational studies	• In patients with CLTI with ischemic rest pain (ie, without nonhealing wounds or gangrene) attributable to multilevel arterial disease, a revascularization strategy addressing inflow disease first is reasonable.	Class of recommendation: 2a Level of evidence: C-LD
Society for Vascular Surgery Society for Vascular Surgery practice guidelines for atherosclerotic occlusive disease of the lower extremities: management of asymptomatic disease and claudication 2015 Conte et al United States	Patients with intermittent claudication	None cited.	• We recommend EVT or surgical treatment of IC for patients with significant functional or lifestyle-limiting disability when there is a reasonable likelihood of symptomatic improvement with treatment, when pharmacologic or exercise therapy, or both, have failed, and when the benefits of treatment outweigh the potential risks. • We recommend an individualized approach to select an invasive treatment for IC. The modality offered should provide a reasonable likelihood of sustained benefit to the patient (>50% likelihood of clinical efficacy for at least 2 years). For revascularization, anatomic patency (freedom from hemodynamically significant restenosis) is considered a prerequisite for sustained efficacy.	Grade: 1 Level of evidence: B Grade: 1 Level of evidence: C
	Aortoiliac occlusive disease in intermittent claudication	3 meta-analyses, 1 systematic review	• We recommend endovascular procedures over open surgery for focal AIOD causing IC. • We recommend endovascular interventions as first-line	Grade: 1 Level of evidence: B Grade: 1 Level of evidence: B

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
			revascularization therapy for most patients with common iliac artery or external iliac artery occlusive disease causing IC.	
			• We recommend the selective use of BMS or covered stents for aortoiliac angioplasty for common iliac artery or external iliac artery occlusive disease, or both, due to improved technical success and patency.	Grade: 1 Level of evidence: B
			• We recommend the use of covered stents for treatment of AIOD in the presence of severe calcification or aneurysmal changes where the risk of rupture may be increased after unprotected dilation.	Grade: 1 Level of evidence: C
			• For patients with diffuse AIOD (e.g., extensive aortic disease, disease involving both common and external iliac arteries) undergoing revascularization, we suggest either endovascular or surgical intervention as first-line approaches. Endovascular interventions that may impair the potential for subsequent AFB in surgical candidates should be avoided.	Grade: 2 Level of evidence: B
			• We recommend direct surgical reconstruction (bypass, endarterectomy) in patients with reasonable surgical risk and diffuse AIOD not amenable to an	Grade: 1 Level of evidence: B

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
			endovascular approach, after one or more failed attempts at EVT, or in patients with combined occlusive and aneurysmal disease.	
	Femoropopliteal occlusive disease in intermittent claudication	4 meta-analyses, 1 RCT	• We recommend endovascular procedures over open surgery for focal occlusive disease of the SFA artery not involving the origin at the femoral bifurcation.	Grade: 1 Level of evidence: C
			• For focal lesions (<5 cm) in the SFA that have unsatisfactory technical results with balloon angioplasty, we suggest selective stenting.	Grade: 2 Level of evidence: C
			• For intermediate-length lesions (5-15 cm) in the SFA, we recommend the adjunctive use of self-expanding nitinol stents (with or without paclitaxel) to improve the midterm patency of angioplasty.	Grade: 1 Level of evidence: B
			• We recommend surgical bypass as an initial revascularization strategy for patients with diffuse FP disease, small caliber (<5 mm), or extensive calcification of the SFA, if they have favorable anatomy for bypass (popliteal artery target, good runoff) and have average or low operative risk.	Grade: 1 Level of evidence: B
			• For intermediate-length lesions (5-15 cm) in the SFA, we recommend the	Grade: 1 Level of evidence: B

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
			adjunctive use of self-expanding nitinol stents (with or without paclitaxel) to improve the midterm patency of angioplasty. • We recommend surgical bypass as an initial revascularization strategy for patients with diffuse FP disease, small caliber (<5 mm), or extensive calcification of the SFA, if they have favorable anatomy for bypass (popliteal artery target, good runoff) and have average or low operative risk.	Grade: 1 Level of evidence: B
Canadian Cardiovascular Society Canadian Cardiovascular Society 2022 Guidelines for Peripheral Arterial Disease 2022 Abramson et al Canada	Intermittent claudication CLTI	None cited.	• We suggest that revascularization may be considered in patients with intermittent claudication affecting vocational, recreational, or daily living activities who have an acceptable risk profile, reasonable expectation for function and life expectancy, and in whom a trial of nonoperative therapy with an exercise program and medical therapy has failed. • We recommend that in patients with chronic limb-threatening ischemia, endovascular, open, or hybrid revascularization should be considered on the basis of the anatomical pattern of disease, degree of ischemia, expected durability of the procedure, perioperative risk, and patient life expectancy.	Weak Recommendation Moderate-Quality Evidence Strong Recommendation Low-Quality Evidence

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
	Endovascular procedures		• We recommend endovascular therapy in appropriately selected patients with claudication or chronic limb- threatening ischemia. • We recommend against performing endovascular therapy in the common femoral or profunda femoris arteries.	Strong Recommendation Low-Quality Evidence Strong Recommendation Low-Quality Evidence
European Society of Cardiology 2024 ESC Guidelines for the management of peripheral arterial and aortic diseases: Developed by the task force on the management of peripheral arterial and aortic diseases of the European Society of Cardiology (ESC) Endorsed by the European Association for Cardio-Thoracic Surgery (EACTS), the European Reference Network on Rare Multisystemic Vascular Diseases (VASCERN), and the European Society of Vascular Medicine (ESVM) 2024 (Mazzolai et al) Europe	Interventional treatment of asymptomatic and symptomatic PAD (general) Interventional treatment of patients with symptomatic PAD	1 RCT, 1 observational study 2 observational studies, 2 reviews 1 RCT, 1 observational study 2 meta-analyses, 2 RCTs 1 RCT, 1 observational study, 1 guideline, 1 guideline companion document	• In patients with symptomatic PAD and impaired PAD-related quality of life after a 3 month period of MT and exercise therapy, revascularization may be considered. • In patients with PAD, revascularization is not recommended if the reason is to solely prevent progression to CLTI. • In femoropopliteal lesions, drug-eluting treatment should be considered as the first-choice strategy. • In iliac lesions, balloon angioplasty with or without stenting in external iliac arteries, or primary stenting in common iliac arteries, should be considered. • In femoropopliteal lesions, if revascularization is indicated, endovascular therapy should be considered.	Class of recommendation: IIb Level: B Class of recommendation: III Level: B Class of recommendation: IIa Level: A Class of recommendation: IIa Level: B Class of recommendation: IIa Level: B

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
		1 guideline, 1 guideline companion document	• In femoropopliteal lesions, if revascularization is indicated, an open surgical approach should be considered when an autologous vein (e.g. GSV) is available in patients with low surgical risk.	Class of recommendation: IIa Level: C
		1 prognostic study, 1 guideline supplement 1 RCT, 1 survival prediction model	• In patients with severe IC undergoing endovascular femoropopliteal revascularization, treatment of BTK arteries may be considered in the same intervention.	Class of recommendation: IIb Level: C
	CLTI	1 survival prediction model	• For limb salvage in patients with CLTI, revascularization is recommended.	Class of recommendation: I Level: B
	Interventional treatment of CLTI	None cited.	• In CLTI patients, it is recommended to perform revascularization as soon as possible.	Class of recommendation: I Level: B
		2 RCTs, 1 survival prediction model. 2 RCTs, 1 survival prediction model.	• In multilevel vascular disease, it is recommended to eliminate inflow obstructions when treating downstream lesions.	Class of recommendation: I Level: C
			• In CLTI patients with good autologous veins and low surgical risk (<5% peri-operative mortality, >50% 2 year survival), infra-inguinal bypass may be considered.	Class of recommendation: IIb Level: B
			• In CLTI patients, endovascular treatment may be considered as first-line therapy, especially in patients with	Class of recommendation: IIb Level: B

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
			increased surgical risk or inadequate autologous veins.	
European Society for Vascular Surgery (ESVS) European Society for Vascular Surgery (ESVS) 2024 Clinical Practice Guidelines on the Management of Asymptomatic Lower Limb Peripheral Arterial Disease and Intermittent Claudication 2024 Europe	Intermittent claudication	2 observational studies	• For fit patients with disabling intermittent claudication at low risk of groin complications and with common femoral artery bifurcation stenosis or occlusion undergoing revascularization, open surgery is recommended due to expected higher long term patency rates compared with endovascular approaches.	Class of recommendation: I Level: C
		Consensus	• For patients with disabling intermittent claudication and a hostile groin (e.g., prior ipsilateral common femoral endarterectomy, morbid obesity, or previous regional radiotherapy to the groin region) undergoing revascularization, endovascular treatment of steno-occlusive disease of the femoral bifurcation may be considered over open surgery due to the lower risk of surgical wound complications.	Class of recommendation: IIb Level: C
		1 RCT, 2 observational studies	• For patients with disabling intermittent claudication due to femoropopliteal steno-occlusive disease, a careful selection for revascularization is recommended where the treatment indication is weighed against the degree of disability, results of non-invasive therapies, concomitant comorbidities, procedural risks, and expected procedural patency, due to	Class of recommendation: I Level: C

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
			remaining uncertainty about sustained clinical benefits and risks.	
		1 meta-analysis	• For patients with disabling intermittent claudication undergoing revascularization who have Trans-Atlantic Inter-Society Consensus Document II A/B femoropopliteal lesions, the adjunctive use of paclitaxel coated balloon angioplasty should be considered after optimal balloon angioplasty without the need for stenting.	Class of recommendation: IIa Level: A
		1 meta-analysis, 5 RCTs	• For patients with disabling intermittent claudication undergoing revascularization, selective drug eluting stent placement should be considered if femoropopliteal plain balloon angioplasty leads to suboptimal results i.e., residual stenosis or dissection.	Class of recommendation: IIa Level: B
		2 RCTs	• In the extreme scenario of highly selected patients with disabling intermittent claudication, where endovascular revascularization of below the knee lesions is deemed necessary, balloon angioplasty with selective drug eluting stent placement may be considered.	Class of recommendation: IIb Level: C
European Society for Vascular Medicine Guideline on peripheral arterial disease 2019	Aortoiliac lesions	None cited.	• For the treatment for aortoiliac lesions, classified according to TASC II guidelines as A to D lesions, endovascular therapy should be considered or may be considered	Class of recommendation: Level of evidence:

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
Frank et al Europe			according to anatomical picture and comorbidities.	
	Femoropopliteal lesions		• In femoropopliteal lesions, endovascular intervention is recommended over treatment with synthetic and vein graft bypass surgery in the presence of increased surgical risk.	Class of recommendation: I Level of evidence: A
			• When treating femoropopliteal lesions, endovascular procedures are recommended as the treatment of choice.	Class of recommendation: IIa Level of evidence: B
			• Bypass procedures should be considered in the presence of long occlusions (TASC D > 25 cm), recurrent femoropopliteal disease, non-increased surgical risk, non-substantially limited life expectancy (> 2 years) and donor-vein availability.	Class of recommendation: IIa Level of evidence: B
	Stents		• Balloon angioplasty with optional stent implantation is preferentially recommended for treatment of lesions of the popliteal artery as standard care for limb symptom improvement.	Class of recommendation: I Level of evidence: C
	Drug-eluting balloons		• Treatment of (longer and more complex) femoropopliteal lesions with drug-eluting balloons after pre-dilatation is recommended as standard of care.	Class of recommendation: II Level of evidence: B

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
			• It is recommended that stenting be restricted to focal stenting in regions of recoil after balloon angioplasty with or without drug eluting balloons, relevant dissection or eccentric calcification with severe recoil.	Class of recommendation: I Level of evidence: B
			• Open surgery should be considered in the presence of low surgical risk and a suitable autologous vein.	Class of recommendation: IIa Level of evidence: B
			• In treating critical ischemia accompanied by ischemic tissue defects, it is recommended that the crural artery supplying the relevant region (angiosome) be preferentially revascularized. If direct revascularization proves unfeasible, indirect revascularization, (possibly with retrograde PTA via the plantar arch), is recommended. The short-term clinical outcome may be improved by revascularizing even more than one crural artery.	Class of recommendation: IIa Level of evidence: B
			• In patients with CLI, rapid and efficient revascularization regardless of treatment techniques applied, is recommended.	Class of recommendation: I Level of evidence: B
			• In vascular multilevel disease, it is recommended that eliminating inflow obstructions take priority over treating downstream lesions.	Class of recommendation: I Level of evidence: B/C

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
			• In patients with critical ischemia, endovascular treatment is recommended to be employed initially for inflow lesions and subsequently for outflow lesions, if possible.	Class of recommendation: I Level of evidence: C
Multi-society Guideline The Diagnosis and Treatment of Peripheral Arterial Vascular Disease 2016 Lawall et al Europe	Peripheral arterial occlusive disease (PAOD)	None cited	• For patients with intermittent claudication, the efficacy of supervised exercise programs to increase the distance the patient can walk is comparable to that of an endovascular or vascular surgical procedure. • An endovascular procedure should be offered to a patient with intermittent claudication only after the patient has been thoroughly informed about the benefits of risk factor modification and structured walking exercises, and if the stenotic or occlusive lesion seems amenable to endovascular treatment. • An open vascular surgical procedure should be offered to a patient with intermittent claudication only if the condition causes considerable suffering and an endovascular procedure is not appropriate or has been attempted unsuccessfully, or else surgery seems to be a more suitable treatment for the patient. • Stenoses and occlusions of the aortoiliac arteries should be treated endovascularly at first, whatever the TASC stage. The patient's	Grade: A Level of evidence: 1 Grade: Consensus Level of evidence: 2 Grade: Consensus Level of evidence: GCP Grade: B Level of evidence: GCP

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
			accompanying illnesses and personal preferences should be considered, along with the local availability of high-quality vascular surgical and/or endovascular interventional care.	
			• Vascular surgery is appropriate when endovascular treatment fails or when vascular surgery appears to be a more reasonable option for the patient.	Grade: B Level of evidence: 2
			• The endovascular treatment of aortoiliac TASC II C and D lesions should preferably be performed with primary stent angioplasty.	Grade: B Level of evidence: 2
			• Stenoses and occlusions at the bifurcation of the common femoral a. should primarily be treated surgically.	Grade: A Level of evidence: GCP
			• Stenoses and occlusions of the femoropopliteal arteries, regardless of their TASC classification, should primarily be treated endovascularly. A bypass is preferable if the following criteria are met: long-segment occlusion (TASC D), no elevation of surgical risk, life expectancy at least two years, and availability of a donor vein.	Grade: B Level of evidence: 2
			• Primary stent angioplasty with nitinol stents is preferred for the endovascular treatment of long and	Grade: B Level of evidence: 2

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
			intermediate- length femoropopliteal lesions. • If, in the endovascular treatment of a femoropoliteal lesion, the treating physicians consider it highly important for clinical angiological reasons to lessen the risk of re-stenosis and reintervention after angioplasty, then paclitaxel-coated balloons should be used for the angioplasty. • Lesions of the popliteal artery should be treated primarily by balloon angioplasty.	Grade: B Level of evidence: 2 Grade: B Level of evidence: 2
Joint guidelines of the Society for Vascular Surgery, European Society for Vascular Surgery, and World Federation of Vascular Societies Global vascular guidelines on the management of chronic limb-threatening ischemia 2019 Conte et al Global	CLTI	None cited 6 RCTs 1 meta-analysis	• Do not perform revascularization in the absence of significant ischemia (WIfI ischemia grade 0) unless an isolated region of poor perfusion in conjunction with major tissue loss (eg, WIfI wound grade 2 or 3) can be effectively targeted and the wound progresses or fails to reduce in size by ≥ 50% within 4 weeks despite appropriate infection control, wound care, and offloading. • Do not perform revascularization in very-low-risk limbs (e.g., WIfI stage 1) unless the wound progresses or fails to reduce in size by ≥ 50% within 4 weeks despite appropriate infection control, wound care, and offloading. • Offer revascularization to all average-risk patients with advanced limb-	Good practice statement Grade: 2 (Weak) Level of evidence: C (Low) Grade: 1 (Strong)

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
			threatening conditions (e.g., WIfI stage 4) and significant perfusion deficits (e.g., WIfI ischemia grades 2 and 3).	Level of evidence: C (Low)
		None cited	• Consider revascularization for average-risk patients with intermediate limb threat (e.g., WIfI stages 2 and 3) and significant perfusion deficits (e.g., WIfI ischemia grades 2 and 3).	Grade: 2 (Weak) Level of evidence: C (Low)
		4 observational studies	• Consider revascularization in average-risk patients with advanced limb threat (e.g., WIfI stage 4) and moderate ischemia (e.g., WIfI ischemia grade 1).	Grade: 2 (Weak) Level of evidence: C (Low)
		None cited	• Consider revascularization in average-risk patients with intermediate limb threat (e.g., WIfI stages 2 and 3) and moderate ischemia (e.g., WIfI ischemia grade 1) if the wound progresses or fails to reduce in size by ≥ 50% within 4 weeks despite appropriate infection control, wound care, and offloading.	Grade: 2 (Weak) Level of evidence: C (Low)
		1 meta-analysis, 1 systematic review, 1 observational study	• Use an endovascular-first approach for treatment of CLTI patients with moderate to severe (e.g., GLASS stage IA) aortoiliac (AI) disease, depending on the history of prior intervention. • Consider surgical reconstruction for the treatment of average-risk CLTI patients with extensive (e.g., GLASS stage II) AI disease or after failed endovascular intervention.	Grade: 1 (Strong) Level of evidence: B (Moderate)

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
		1 meta-analysis, 1 systematic review, 1 RCT	• Consider endovascular treatment of significant CFA disease in selected patients who are deemed to be at high surgical risk or to have a hostile groin.	Grade: 2 (Weak) Level of evidence: C (Low)
		1 RCT, 3 observational studies	• Avoid stents in the CFA and do not place stents across the origin of a patent deep femoral artery.	Grade: 2 (Weak) Level of evidence: C (Low)
		None cited	• In average-risk CLTI patients with infrainguinal disease, base decisions of endovascular intervention vs open surgical bypass on the severity of limb threat (eg, WIfI), the anatomic pattern of disease (eg, GLASS), and the availability of autologous vein.	Good practice statement
		1 meta-analysis	• Offer endovascular revascularization when technically feasible for high-risk patients with advanced limb threat (e.g., WIfI stage 4) and significant perfusion deficits (e.g., WIfI ischemia grades 2 and 3).	Grade: 1 (Strong) Level of evidence: C (Low)
		None cited	• Consider endovascular revascularization for high-risk patients with intermediate limb threat (e.g., WIfI stages 2 and 3) and significant perfusion deficits (e.g., WIfI ischemia grades 2 and 3).	Grade: 2 (Weak) Level of evidence: C (Low)
		None cited	• Consider endovascular revascularization for high-risk patients with advanced limb threat (e.g., WIfI	Grade: 2 (Weak) Level of evidence: C (Low)

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
		1 meta-analysis, 4 observational studies	stage 4) and moderate ischemia (e.g., WIfI ischemia grade 1) if the wound progresses or fails to reduce in size by ≥50% within 4 weeks despite appropriate infection control, wound care, and offloading, when technically feasible.	Grade: 2 (Weak) Level of evidence: C (Low)
		None cited	• Consider endovascular revascularization for high-risk patients with intermediate limb threat (e.g., WIfI stages 2 and 3) and moderate ischemia (e.g., WIfI ischemia grade 1) if the wound progresses or fails to reduce in size by ≥ 50% within 4 weeks despite appropriate infection control, wound care, and offloading, when technically feasible.	Grade: 2 (Weak) Level of evidence: C (Low)
		None cited	• Consider open surgery in selected high-risk patients with advanced limb threat (e.g., WIfI stage 3 or 4), significant perfusion deficits (ischemia grade 2 or 3), and advanced complexity of disease (e.g., GLASS stage III) or after prior failed endovascular attempts and unresolved symptoms of CLTI.	Grade: 2 (Weak) Level of evidence: C (Low)
		1 meta-analysis, 4 RCTs	• In treating femoropopliteal (FP) disease in CLTI patients by endovascular means consider adjuncts to balloon angioplasty (e.g., stents, covered stents, or drug-eluting technologies) when there is a technically inadequate result (residual stenosis or flow- limiting dissection) or	Grade: 2 (Weak)

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
			in the setting of advanced lesion complexity (e.g., GLASS FP grade 2-4).	Level of evidence: B (Moderate)
National Institute for Health and Care Excellence (NICE) Peripheral arterial disease: diagnosis and management. London **2012**	Intermittent claudication	None cited.	• Offer angioplasty for treating people with intermittent claudication only when: ○ advice on the benefits of modifying risk factors has been reinforced (see recommendation 3) and ○ a supervised exercise program has not led to a satisfactory improvement in symptoms and ○ imaging has confirmed that angioplasty is suitable for the person. • Do not offer primary stent placement for treating people with intermittent claudication caused by aortoiliac disease (except complete occlusion) or femoropopliteal disease. • Consider primary stent placement for treating people with intermittent claudication caused by complete aortoiliac occlusion (rather than stenosis). • Use bare metal stents when stenting is used for treating people with intermittent claudication. CLI • Offer angioplasty or bypass surgery for treating people with critical limb ischemia who require	Unspecified

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
			revascularization, taking into account factors including: ○ Comorbidities ○ pattern of disease ○ availability of a vein ○ patient preference. • Do not offer primary stent placement for treating people with critical limb ischemia caused by aortoiliac disease (except complete occlusion) or femoropopliteal disease. • Consider primary stent placement for treating people with critical limb ischemia caused by complete aortoiliac occlusion (rather than stenosis). • Use bare metal stents when stenting is used for treating people with critical limb ischemia.	

AACVPR = American Association of Cardiovascular and Pulmonary Rehabilitation; ABC = Association of Black Cardiologists; ACC = American College of Cardiology; AFB = aortofemoral bypass; AHA = American Heart Association; AI = aortoiliac; AIOD = aortoiliac occlusive disease; APMA = American Podiatric Medical Association; BMS = bare metal stents; BTK = below-the-knee; CFA = common femoral artery; CLI = critical limb ischemia; CLTI = chronic limb-threatening ischemia; EVT = endovascular therapy; FP = femoropopliteal; GCP = good clinical practice; GDMT = guideline directed medical therapy; GLASS = Global Limb Anatomic Staging System; GSV = great saphenous vein; IC = intermittent claudication; MT = medical therapy; NR = not reported; PAD = peripheral artery disease; PTA = percutaneous transluminal angioplasty; QOL = quality of life; RCT = randomized controlled trial; SCAI = Society for Cardiovascular Angiography and Interventions; SFA = superficial femoral artery; SIR = Society of Interventional Radiology; SVM = Society for Vascular Medicine; SVN = Society for Vascular Nursing; SVS = Society for Vascular Surgery; TASC = Trans-Atlantic Inter-Society Consensus; VESS = Vascular & Endovascular Surgery Society; WIfI = Wounds, Ischemia, and foot Infection

Table J3. Summary of Society for Cardiovascular Angiography and Interventions (SCAI) Clinical Practice Guidelines

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
Society for Cardiovascular Angiography and Interventions (SCAI)	**PTA with Uncoated Balloons -** Focal CIA	None cited.	<u>Aortoiliac (Ao-I) disease</u> Recommended as the intended definitive therapy in the aortoiliac interventions.	Class of recommendation: IIa (Moderate)

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
SCAI guidelines on device selection in Aorto-Iliac arterial interventions 2020 Feldman et al United States	lesion, Focal EIA lesion, ISR, focal lesion, ISR, diffuse lesion			Level of evidence: B-R, C-LD
	PTA with Uncoated Balloons - Aortoiliac bifurcation, Diffuse CIA lesion, Diffuse EIA lesion, Moderate to severe calcified, focal lesion, Moderate to severe calcified, diffuse lesion, Chronic total occlusion, focal lesion, Chronic total occlusion, diffuse lesion		Recommended as the intended definitive therapy in the aortoiliac interventions.	Class of recommendation: IIb (Weak) Level of evidence: B-R, B-NR, C-LD
	PTA with Specialty Balloons – (All lesions)		Not recommended as the intended definitive therapy in the aortoiliac arterial intervention	Class of recommendation: III (No benefit) Level of evidence: C-LD, C-EO
	Bare Metal Balloon Expandable Stents - Aortoiliac bifurcation, Focal CIA lesion, Diffuse CIA lesion		Recommended as the intended definitive therapy in the aortoiliac interventions.	Class of recommendation: I (Strong) Level of evidence: B-R, B-NR
	Bare Metal Balloon Expandable Stents - Focal EIA lesion, Diffuse EIA lesion, Moderate to severe calcified, focal lesion, Moderate to severe calcified, diffuse lesion, Chronic total		Recommended as the intended definitive therapy in the aortoiliac interventions.	Class of recommendation: IIa (Moderate) Level of evidence: B-R, B-NR

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
	occlusion, focal lesion, Chronic total occlusion, diffuse lesion			
	Bare Metal Balloon Expandable Stents - ISR, focal lesion, ISR, diffuse lesion		Recommended as the intended definitive therapy in the aortoiliac interventions.	Class of recommendation: IIb (Weak) Level of evidence: C-LD
	Bare Metal Self-Expanding Stents - Diffuse CIA lesion, Focal EIA lesion, Diffuse EIA lesion		Recommended as the intended definitive therapy in the aortoiliac interventions.	Class of recommendation: I (Strong) Level of evidence: B-NR
	Bare Metal Self-Expanding Stents - Aortoiliac bifurcation, Focal CIA lesion, Moderate to severe calcified, focal lesion, Moderate to severe calcified, diffuse lesion, Chronic total occlusion, focal lesion, Chronic total occlusion, diffuse lesion		Recommended as the intended definitive therapy in the aortoiliac interventions.	Class of recommendation: IIa (Moderate) Level of evidence: B-R, B-NR
	Bare Metal Self-Expanding Stents - ISR, focal lesion, ISR, diffuse lesion		Recommended as the intended definitive therapy in the aorto-iliac interventions.	Class of recommendation: IIb (Weak) Level of evidence: C-LD
	Drug-Eluting Stents - (all lesions)		Not recommended as the intended definitive therapy in the aorto-iliac arterial intervention	Class of recommendation: III (No benefit) Level of evidence: C-EO

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
	Drug Coated Balloons - ISR, focal lesion, ISR, diffuse lesion		Recommended as the intended definitive therapy in the aorto-iliac interventions.	Class of recommendation: IIb (Weak) Level of evidence: C-EO
	Drug Coated Balloons - Aortoiliac bifurcation, Focal CIA lesion, Diffuse CIA lesion, Focal EIA lesion, Diffuse EIA lesion, Moderate to severe calcified, focal lesion, Moderate to severe calcified, diffuse lesion, Chronic total occlusion, focal lesion, Chronic total occlusion, diffuse lesion		Not recommended as the intended definitive therapy in the aortoiliac arterial intervention	Class of recommendation: III (No benefit) Level of evidence: C-EO
	Covered Balloon Expandable Stents - Aortoiliac bifurcation, Focal CIA lesion, Diffuse CIA lesion, Moderate to severe calcified, focal lesion, Moderate to severe calcified, diffuse lesion		Recommended as the intended definitive therapy in the aortoiliac interventions.	Class of recommendation: I (Strong) Level of evidence: B-R, B-NR, C-LD
	Covered Balloon Expandable Stents - Focal EIA lesion, Diffuse EIA lesion, Chronic total occlusion, focal lesion, Chronic total occlusion, diffuse lesion, ISR, focal		Recommended as the intended definitive therapy in the aortoiliac interventions.	Class of recommendation: IIa (Moderate) Level of evidence: B-R, B-NR, C-LD

Developer/Guideline/Year	Clinical Subset of PAD or Endovascular Procedure	Evidence Base	Recommendation	Strength of Recommendation
	lesion, ISR, diffuse lesion **Covered Self-Expanding Stents -** Aortoiliac bifurcation, Focal CIA lesion, Diffuse CIA lesion, Focal EIA lesion		Recommended as the intended definitive therapy in the aortoiliac interventions.	Class of recommendation: IIb (Weak) Level of evidence: C-LD
	Covered Self-Expanding Stents - Diffuse EIA lesion Moderate to severe calcified, focal lesion, Moderate to severe calcified, diffuse lesion, Chronic total occlusion, focal lesion, Chronic total occlusion, diffuse lesion, ISR, focal lesion, ISR, diffuse lesion		Recommended as the intended definitive therapy in the aortoiliac interventions.	Class of recommendation: IIa (Moderate) Level of evidence: C-LD

CIA = common iliac artery; EIA = external iliac artery; ISR = in stent restenosis

APPENDIX K. Outcome Definitions

Appendix Table K1. Definitions for Magnitude of Effects, Based on Mean Between-Group Differences

Outcome	Slight/Small	Moderate	Large/Substantial
Symptoms	5–10 points on a 0-to 100-point VAS or the equivalent*	>10–20 points on a 0-to 100-point VAS or the equivalent*	>20 points on a 0-to 100-point VAS or the equivalent*
	0.5–1.0 points on a 0-to 10-point numerical rating scale or the equivalent	>1–2 points on a 0-to 10-point numerical rating scale or the equivalent	>2 points on a 0-to 10-point numerical rating scale or the equivalent
	1-2 points on 0-20 scale	2-4 points on 0-20 scale	>4 points on 0-20 scale
Function	5%-10% change in MWD	>10%-20% change in MWD	>20% change in MWD
	5%-10% change in ICD	>10%-20% change in ICD	>20% change in ICD
	5%-10% change in MWT	>10%-20% change in MWT	>20% change in MWT
	5%-10% change in COT	>10%-20% change in COT	>20% change in COT
	5%-10% change in WIQ Walking Distance	>10%-20% change in WIQ Walking Distance	>20% change in WIQ Walking Distance
	5– 10 points on SIP scale	>10– 20 points on SIP scale	>20 points on SIP scale
Pain or function	0.2–0.5 SMD	>0.5–0.8 SMD	>0.8 SMD
	1.2 to 1.4 RR/OR	1.5 to 1.9 RR/OR	≥2.0 RR/OR

COT = claudication onset time; ICD = intermittent claudication distance; MWD = maximum walking distance; MWT = maximum walking time; WIQ = walking impairment questionnaire; SIP = sickness impact profile; SMD = standardized mean difference; VAS = visual analogue scale
*Includes WIQ pain severity scale and PAQ symptoms scale

Appendix Table K2. Walking Outcome Definitions and Treadmill Protocols for Randomized Trials Comparing Endovascular Therapy Versus Medical Therapy or Supervised Exercised Therapy

Intervention, Comparator	Author, year	ICD definition	MWD definition	Treadmill protocol	Notes
Endovascular therapy vs. MT	Nylaende, 2007	The patients indicated when the onset of pain occurred (i.e., PFWD) during treadmill testing and then proceeded to walk up to MWD	The patients indicated when the onset of pain occurred (PFWD) and then proceeded to walk up to absolute claudication distance (MWD) during treadmill testing	fixed load treadmill test, 3 km/h at 10° incline	The PFWD and MWD were recorded for the primary limiting side up to a maximum of 600m (12min), although some patients were able to walk further. In these cases, the PFWD and MWD were equaled to 600m
	Whyman 1996, 1997	Time to onset of claudication, up to a maximum of 10 minutes; converted to distance: treadmill onset claudication distance	Time to cessation of walking due to claudication. Converted to distance: treadmill maximum walking distance	standard treadmill test, 4 km/h at 10° incline, up to a maximum of 10 minutes.	Significant improvement was arbitrarily taken as the ability to walk 667 m (10 min) on the treadmill free of pain where this was not possible before.
	Murphy 2012, 2015 ***and vs. SET***	Claudication onset time was defined as the treadmill time when calf muscle discomfort was first noticed	Peak walking time was defined as the maximal time a participant could walk during the graded treadmill test	graded treadmill test: Gardner protocol (not otherwise specified)	For those individuals who did not experience any claudication symptoms during follow-up testing, COT was considered to be the same as the PWT
	Nordanstig, 2014	Covered distance until onset of intermittent claudication symptoms	MWD on treadmill (no other information provided)	Treadmill test with increasing workload due to progressively increasing slope (0% to 12%) and speed	None
	Lindgren, 2018	NR	Absolute walking distance measured by a standardized treadmill test (no other information provided)	3 km/h, without incline, maximum duration 20 minutes or 1000 meters	Report on the proportion that walk the maximum distance (1000 m) on treadmill; no mention of symptoms (i.e., walking pain-free or with claudication pain)

Intervention, Comparator	Author, year	ICD definition	MWD definition	Treadmill protocol	Notes
Endovascular therapy vs. SET	Mazari 2010, 2012, 2017 ***and combo endovascular + SET vs. SET alone***	ICD (not further defined)	MWD (not further defined)	fixed-load treadmill testing at 2·5km/h and 10° incline; maximum 215 m or 5 minutes	patient reported walking distance (PRWD, up to a maximum of 1000 m),
	Spronk, 2009; Fakhry, 2013	PFWD (not further defined) on treadmill testing	MWD (not further defined) on treadmill testing	3.5 km/h, no graded incline	None
	Perkins, 1996	Claudication distance (not further defined)	MWD (not further defined)	3 km/h and 10° incline, up to a maximum of 750 m (equivalent to 15 min walking)	None
	Koelemay, 2022	PFWD was defined as the distance covered on treadmill without any pain	MWD was defined as the maximum distance covered on treadmill testing	3 km/h and 10° incline; up to maximum of 800 m (15 minutes).	None
Combination endovascular therapy + SET vs. SET alone	Fakhry, 2015; Klaphake, 2022	PFWD (not further defined)	MWD (not further defined) had to be between 100 and 500 meters on treadmill	graded treadmill test: Gardner protocol (not otherwise specified).; maximum duration 30 minutes	A mean difference of 30% in treadmill MWD (corresponding to an approximately 150 m difference) between the 2 groups was considered as a relevant effect size.
	Greenhalg, 2008	ICD, defined as the distance the patient walks on the treadmill before onset of claudication pain.	Absolute walking distance (AWD) is defined as the maximum distance that patients can walk on the treadmill before they must stop either due to claudication pain or for any other reason such as breathlessness or fatigue	4 km/h and 10° incline, up to a maximum of 15 min (i.e., 1000 m).	None

ICD = intermittent claudication distance; MWD = maximum walking distance; PFWD = pain-free walking distance.

APPENDIX L. FDA Approved Devices

Table L1. Devices Used Across Endovascular Revascularization Randomized Controlled Trials

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
Balloon Catheters	Amphirion Deep 0.014 OTW PTA Balloon Catheter	Medtronic	03/13/2009 K083919	"The Amphirion™ Deep PTA Balloon Dilatation Catheter up to 120mm balloon length is intended to dilate stenoses in the iliac, femoral, iliofemoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The Amphirion Deep PTA Balloon Dilatation Catheter in 150mm and 210mm balloon lengths is intended to dilate stenosis in the femoral, popliteal, and infra-popliteal arteries."	Not specified.
	AngioSculpt PTA Scoring Balloon Catheters	Philips	02/14/2024 K150634	"The AngioSculpt PTA scoring balloon catheter is intended for dilatation of lesions in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neuro-vasculature."	"None known for percutaneous transluminal angioplasty (PTA) procedures."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	Armada 35 Balloon Dilation Catheter	Abbott Laboratories (Chicago, IL, USA)	10/03/2011 K111899	"The device is intended for dilatation of lesions in the renal, iliac, femoral, popliteal, tibial, and peroneal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature."	• "Inability to cross lesion with a guide wire • Use in the coronary arteries"
	EverCross 0.035 OTW PTA Dilatation Catheter	Medtronic	04/23/2019 K190753	"The EverCross 0.035" OTW PTA dilatation catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infrapopliteal, and renal arteries, and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. This device is also indicated for stent post-dilatation in the peripheral vasculature."	Not specified.
	Mustang Balloon Dilation Catheter	Boston Scientific (Marlborough, MA, USA)	03/22/2011 K103751	"The Mustang Balloon Dilatation Catheter is indicated for Percutaneous Transluminal Angioplasty (PTA) in the peripheral vasculature, including iliac, femoral, popliteal, tibial, peroneal, subclavian, and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The Mustang Balloon Dilatation Catheter is also indicated for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature. Mustang Balloon Dilatation Catheters with balloons up to 120 mm in length are indicated for the treatment of biliary strictures."	"None known."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	OPTA PRO PTA Dilatation Catheter	Cordis (Miami Lakes, FL, USA)	5/20/1998 K981407	"The OPTA PRO PTA catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae."	"None known for PTA procedure. The OPTA PRO PTA catheter is contraindicated for use in coronary arteries."
	Oscar Peripheral Multifunctional Catheter system	Biotronik	07/11/2024 K241711	"The Oscar Peripheral Multifunctional Catheter system is indicated for percutaneous transluminal interventions in the peripheral vasculature to provide support during access into and to dilate stenoses in femoral, popliteal and infrapopliteal arteries. The product is also intended for injection of radiopaque contrast media for the purpose of angiography."	"All general contraindications for percutaneous transluminal angioplasty (PTA) are contraindications for this device. Contraindications for this device and peripheral dilatation catheters in general are: • Lesions that cannot be reached or treated with the system • Uncorrected bleeding disorders • Sepsis Furthermore, all general PTA and procedure-related contraindications as described in the national and international guidelines of the respective medical associations apply."
	Passeo-18 Peripheral Dilation Catheter	Biotronik (Berlin, Germany)	10/08/2015 K151744	"The Passeo-18 peripheral dilatation catheter is indicated to dilate stenosis in the femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae."	"Contraindications for this device and peripheral dilatation catheters in general are: • Inability to cross the target lesion with a guide wire • Bleeding diathesis"

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	Passeo-35 Xeo Peripheral Dilatation Catheter	Biotronik	02/16/2023 K222065	"The Passeo-35 Xeo peripheral dilatation catheter is indicated to dilate stenosis in the iliac, femoral, popliteal and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Passeo-35 is also recommended for post-dilatation of balloon expandable and self-expanding stents in the peripheral vasculature."	"Passeo-35 Xeo is contraindicated for use in patients with: • A lesion that cannot be reached or treated with the dilatation catheter. • Large amounts of acute or sub-acute thrombus at the target lesion. • Perforated vessels. • A lesion that lies within or adjacent to an aneurysm. • Uncorrected bleeding disorders. • A renal insufficiency or an allergy to contrast media. Furthermore, all general PTA and procedure-related contraindications as described in the national and international guidelines of the respective medical associations apply."
	PowerFlex Pro PTA Catheter	Cordis (Miami Lakes, FL, USA)	06/14/2012 K121442	"The PowerFlex Pro PTA catheter is intended to dilate stenoses in iliac, femoral, ilio-femoral, popliteal, infra popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. The device is also indicated for post-dilation of balloon-expandable and self-expanding stents in the peripheral vasculature."	"None known for PTA procedure. The PowerFlex Pro PTA catheter is contraindicated for use in coronary arteries."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	Serranator PTA Serration Balloon Catheter	Cagent Vascular (Wayne, PA, USA)	05/04/2022 K220704	"The Serranator® PTA Serration Balloon Catheter is intended for dilatation of lesions in the iliac, femoral, iliofemoral, popliteal, and infrapopliteal arteries and for the treatment of obstructive lesions of native or synthetic arteriovenous dialysis fistulae. Not for use in the coronary or neurovasculature."	"None known."
	VascuTrak PTA Dilation Catheter	Bard Peripheral Vascular, Inc. (Tempe, AZ, USA)	12/13/2010 K103459	"The VascutrakTM PTA Dilation Catheter is intended to dilate stenoses in the iliac, femoral, ilio-femoral, popliteal, infra-popliteal and renal arteries and for the treatment of obstructive lesions of native or synthetic arterioveneous dialysis fistulae. The device is also recommended for post-dilation of balloon expandable stents, self-expanding stents, and stent grafts in the peripheral vasculature."	"The VASCUTRAK® PTA Catheter is contraindicated: • where there is the inability to cross the target lesion with a guidewire • for use in the coronary or neuro vasculature"

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
Paclitaxel-coated Balloons	Chocolate Touch Paclitaxel Drug-Coated PTA Balloon Catheter	Genesis MedTech (Singapore)	08/16/2023 P210039/S001	"The Chocolate Touch® (Paclitaxel Coated PTA Balloon Catheter) is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo or restenotic lesions up to 180 mm in length in native femoral or popliteal arteries with reference vessel diameters of 4.0 mm to 6.0 mm."	• "Use in the coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries • Lesion is unable to be crossed with a guidewire. • Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy • Patients with known allergies or sensitivities to paclitaxel • Pregnant or breast-feeding women or women who are intending to become pregnant, or men intending to father children."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	IN.PACT 018 Paclitaxel-Coated Percutaneous Transluminal Angioplasty (PTA) Balloon Catheter	Medtronic	11/22/2024 P140010/S086	"The IN.PACT Admiral Paclitaxel-coated PTA Balloon Catheter and IN.PACT 018 Paclitaxel-coated PTA Balloon Catheter are indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo, restenotic, or in-stent restenotic lesions with lengths up to 360 mm in superficial femoral or popliteal arteries with reference vessel diameters of 4–7 mm."	"The IN.PACT Admiral DCB and IN.PACT 018 DCB are contraindicated for use in: • Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries • Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy • Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system • Patients with known allergies or sensitivities to paclitaxel • Women who are breastfeeding, pregnant, or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	IN.PACT Admiral Paclitaxel-Coated Percutaneous Transluminal Angioplasty Balloon Catheter	Medtronic	10/21/2024 P140010/S085	"The IN.PACT Admiral Paclitaxel-coated PTA Balloon Catheter is indicated for percutaneous transluminal angioplasty, after pre-dilatation, of de novo or restenotic lesions up to 180 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-7 mm."	"The IN.PACT Admiral DCB is contraindicated for use in: • coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries • patients who cannot receive recommended antiplatelet and/or anticoagulant therapy • patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system • patients with known allergies or sensitivities to paclitaxel • women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and whether there is a potential for adverse reaction in nursing infants from paclitaxel exposure."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	Lutonix Drug Coated Balloon PTA Catheter	BD (Franklin Lakes, NJ, USA)	09/07/2023 P130024/S043	"The Lutonix 035 Drug Coated Balloon PTA catheter is indicated for percutaneous transluminal angioplasty, after pre-dilatation, of de novo or restenotic lesions up to 150mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-6mm."	"The LUTONIX® Catheter is contraindicated for use in: • Patients who cannot receive recommended anti-platelet and/or anticoagulant therapy. • Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. It is unknown whether paclitaxel will be excreted in human milk and there is a potential for adverse reaction in nursing infants from paclitaxel exposure. • Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	Ranger™ Paclitaxel-Coated Balloon Catheter	Boston Scientific (Marlborough, MA, USA)	07/23/2024 P190019/S033	"The Ranger Drug-Coated Balloon (DCB) is indicated for percutaneous transluminal angioplasty (PTA) of *de novo* or restenotic lesions up to 180 mm in length located in native superficial femoral and proximal popliteal arteries (SFA/PPA) with reference vessel diameters of 4 mm to 7 mm."	"Use of the Ranger DCB is contraindicated in: • Patients with known hypersensitivity to paclitaxel (or structurally-related compounds). • Patients who cannot receive recommended antiplatelet and/or anticoagulation therapy. • Women who are breastfeeding, pregnant or men intending to father children. • Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system. • Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	Stellarex 0.035 OTW Drug-Coated Angioplasty Balloon	Philips	08/07/2024 P160049/S025	"The Stellarex™ 0.035" OTW Drug-coated Angioplasty Balloon is indicated for percutaneous transluminal angioplasty (PTA), after appropriate vessel preparation of de novo or restenotic lesions up to 180 mm in length in native superficial femoral or popliteal arteries with reference vessel diameters of 4-6 mm."	"The Stellarex™ 0.035" OTW Drug-coated Angioplasty Balloon is contraindicated for use in: • Patients with known hypersensitivity to paclitaxel or structurally related compounds. • Patients who cannot receive recommended antiplatelet and/or anticoagulation therapy. • Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. • Coronary arteries, renal arteries, and supra-aortic/cerebrovascular arteries. • Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	Surmodics Surveil Drug-Coated Balloon	Surmodics (Eden Prairie, MN, USA)	08/20/2024 P210025	"The SurVeil DCB is indicated for percutaneous transluminal angioplasty, after appropriate vessel preparation, of de novo or restenotic lesions (0 mm in length) in femoral and popliteal arteries having reference vessel diameters of 4 mm to 7 mm."	"The SurVeil DCB is contraindicated for use in: • Patients who cannot receive recommended antiplatelet and/or anticoagulant therapy • Patients with known hypersensitivity to paclitaxel or structurally related compounds. • Patients judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the delivery system. • Women who are breastfeeding, pregnant or are intending to become pregnant or men intending to father children. • Coronary, renal and supra-aortic/cerebrovascular arteries."
Bare Metal Stents	Absolute Pro Vascular Self-Expanding Stent System	Abbott Vascular	01/31/2023 P110028/S023	"The Absolute Pro™ Vascular Self-Expanding Stent System is indicated for improving luminal diameter in patients with de novo or restenotic atherosclerotic lesions in the native common iliac artery and native external iliac artery with reference vessel diameters between 4.3 mm to 9.1 mm and lesion lengths up to 90 mm."	"There are no known contraindications."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	Astron Peripheral Self-Expanding Nitinol Stent System	Biotronik	07/20/2023 P140030/S016	"The Astron stent system is indicated for improving luminal diameter in patients with iliac atherosclerotic lesions in vessel reference diameters between 4.3mm and 9.5mm and lesion lengths up to 105 mm."	"There are no known contraindications."
	Astron Pulsar, Pulsar-18, Pulsar-18 T3	Biotronik	07/20/2023 P160025/S017	"The Astron Pulsar stent system is indicated for improving luminal diameter in patients with symptomatic de novo, restenotic or occlusive lesions located in the superficial femoral or proximal popliteal arteries in vessel diamters between 3.0 mm and 6.0 mm and lesion lengths up to 190 mm."	• "Patients with known hypersensitivity to nickel or amorphous silicon carbide. • Patients with uncorrected bleeding disorders and contraindication to antiplatelet and/or anti-coagulation therapy."
	E-Luminexx Vascular Stents	BD	11/23/2021 P080007/S026	"The Bard® E-LUMINEXX™ Vascular Stent is indicated for the treatment of illiac occlusive disease in patients with symptomatic vascular disease of the common and/or external iliac arteries up to 126 mm in length with a reference vessel diameter of 5 to 9 mm."	"There are no known contraindications."
	Epic Vascular Self-Expanding Stent System	Boston Scientific	03/13/2024 P110035	"Epic Vascular Self-Expanding Stent System is indicated for the improvement of luminal diameter in patients with de novo or restenotic symptomatic atherosclerotic lesions up to 120 mm in length In the common and/or external iliac arteries, with a reference vessel diameter between **5** and **11** mm."	"There are no known contraindications."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	EverFlex Self-Expanding Peripheral Stent System	Covidien/Medtronic	05/09/2025 P110023	"The EverFlex Self-Expanding Peripheral Stent System is intended to improve luminal diameter in the treatment of symptomatic de-novo or restenotic lesions up to 180mm in length in the native Superficial Femoral Artery (SFA) and/or proximal popliteal arteries with reference vessel diameters ranging from 4.5-7.5mm."	"Patients in whom anticoagulant and/or antiplatelet therapy is contraindicated. • Patients with known hypersensitivity to nickel titanium. • Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system."
	LifeStent Vascular Stent System	Bard	07/27/2023 P070014/S065	"The Bard® LifeStent® Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic de novo or restenotic lesions up to 240 mm in length in the native superficial femoral artery (SFA) and popliteal artery with reference vessel diameters ranging from 4.0 – 6.5 mm."	"The LifeStent® Vascular Stent System is contraindicated for use in: • Patients with a known hypersensitivity to nitinol (nickel, titanium), and tantalum. • Patients who cannot receive recommended anti-platelet and/or anti-coagulation"

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	LifeStent™ 5F Vascular Stent Systems	Bard	02/02/2023 P070014/S064	"The LifeStent™ 5F Vascular Stent System is intended to improve luminal diameter in the treatment of symptomatic de novo or restenostic lesions up to 240 mm in length in the native superficial femoral artery (SFA) and popliteal artery with reference vessel diameters ranging from 4.0 - 6.5 mm."	"The LifeStent™ 5F Vascular Stent System is contraindicated for use in: • Patients with a known hypersensitivity to nitinol (nickel-titanium), and tantalum. • Patients who cannot receive recommended anti-platelet and/or anti-coagulation therapy. • Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	MISAGO RX Self-expanding Peripheral Stent System	Terumo Medical Corporation (Somerset, NJ, USA)	11/14/2024 P140002/S028	"The Misago RX Self-expanding Peripheral Stent is indicated to improve luminal diameter in symptomatic patients with de novo or restenotic native lesions or occlusions of the superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters ranging from 4 mm to 7 mm and lesion length up to 150 mm."	• "Patients who exhibit angiographic evidence of severe thrombus in the target vessel or lesion site before/after undergoing Percutaneous Transluminal Angioplasty PTA procedure. • Patients with contraindication to antiplatelet and/or anticoagulation therapy. • Patients who are judged to have a lesion that prevents proper placement or deployment of the stent. • A lesion that is within an aneurysm or an aneurysm with a proximal or distal segment to the lesion. • A lesion through which a guide wire cannot pass."
	Omnilink Elite Vascular Balloon-Expandable Stent System	Abbott Vascular	09/20/2024 P110043/S014	"The Omnilink Elite Stent System is indicated for the treatment of atherosclerotic iliac artery lesions with reference vessel diameters of $\geq$ 5.0 mm and $\leq$ 11.0 mm, and lesion lengths up to 50 mm."	"There are no known contraindications."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	PALMAZ GENESIS Peripheral Stent	Cordis (Miami Lakes, FL, USA)	12/20/2022 P890017/S023	"The PALMAZ GENESIS Peripheral Stent is indicated for use in the treatment of atherosclerotic disease of peripheral arteries below the aortic arch and for palliation of malignant neoplasms in the biliary tree."	"Peripheral Artery Stent Implantation Generally, contraindications to percutaneous transluminal angioplasty (PTA) are also contraindications for stent placement. Contraindications include, but may not be limited to: • Patients with highly calcified lesions resistant to PTA • Patients with a target lesion with a large amount of adjacent acute or subacute thrombus • Patients with uncorrected bleeding disorders or patients who cannot receive anticoagulation or antiplatelet aggregation therapy. • Patients with perforated vessels evidenced by extravasation of contrast media • A lesion that is within an aneurysm or an aneurysm with a proximal or distal segment adjacent to the lesion."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	SMART Nitinol Self-Expanding Stent	Cordis	8/12/2003 P020036	"The S.M.A.R.T.™ Nitinol Stent System (hereinafter called the SMART stent system) and the S.M.A.R. T. TM Control™ Nitinol Stent System (hereinafter called the SMART Control stent system) are indicated for improving luminal diameter in patients with symptomatic atherosclerotic disease of the common and/or external iliac arteries up to 126 mm in length, with a reference vessel diameter of 4 to 9 mm, and angiographic evidence of a patent profunda or superficial femoral artery."	None known.
	Supera Peripheral Stent System	Abbott Vascular	1/17/2024 P120020/S031	"The Supera™ Peripheral Stent System is indicated to improve luminal diameter in the treatment of patients with symptomatic de novo or restenotic native lesions or occlusions of the superficial femoral artery (SFA) and / or proximal popliteal artery with reference vessel diameters of 4.0 to 7.5 mm, and lesion lengths up to 140 mm."	"The Supera™ Peripheral Stent System is contraindicated in: • Patients who are judged to have a lesion that prevents complete inflation of an angioplasty balloon or proper placement of the stent or stent delivery system. • Patients who cannot receive antiplatelet or anticoagulation therapy. Based on in vivo thrombogenicity testing, the device should not be used in patients who cannot be anticoagulated as there may be some thrombus formation in the absence of anticoagulation."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
Drug-eluting Stents	Eluvia Drug-Eluting Vascular Stent System	Boston Scientific	09/27/2024 P180011/S061	"The ELUVIA Drug-Eluting Vascular Stent System is indicated for improving luminal diameter in the treatment of symptomatic de-novo or restenotic lesions in the native superficial femoral artery (SFA) and/or proximal popliteal artery with reference vessel diameters (RVD) ranging from 4.0-6.0 mm and total lesion lengths up to 190 mm."	• "Women who are pregnant, breastfeeding, or plan to become pregnant in the next 5 years should not receive an Eluvia Drug-Eluting Stent. It is unknown whether paclitaxel will be excreted in human milk, and there is a potential for adverse reaction in nursing infants from paclitaxel exposure. • Patients who cannot receive recommended anti-platelet and/or anti-coagulant therapy. • Patients judged to have a lesion that prevents proper placement of the stent or stent delivery system."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	Esprit™ BTK Everolimus Eluting Resorbable Scaffold System	Abbott	08/28/2024 P230036/S006	"The Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is indicated for improving luminal diameter in infrapopliteal lesions in patients with chronic limb-threatening ischemia (CLTI) and total scaffolding length up to 170 mm with a reference vessel diameter of ≥ 2.5 mm and ≤ 4.00 mm."	"The Esprit™ BTK Everolimus Eluting Resorbable Scaffold System is contraindicated for use in: • Patients who cannot tolerate, including allergy or hypersensitivity to, procedural anticoagulation or the post-procedural antiplatelet regimen. • Patients with hypersensitivity or contraindication to everolimus or structurally related compounds or known hypersensitivity to scaffold components poly(L-lactide), poly(D, L-lactide), and platinum."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	Zilver® PTX® Peripheral Drug-Eluting Stent	Cook Medical (Bloomington, IN, USA)	09/22/2023 P100022/S042	"The Zilver PTX Drug-Eluting Peripheral Stent is indicated for improving luminal diameter for the treatment of *de novo* or restenotic symptomatic lesions in native vascular disease of the above-the-knee femoropopliteal arteries having reference diameter from 4 mm to 7 mm and total lesion lengths up to 140 mm per limb and 280 mm per patient."	• "Women who are pregnant, breastfeeding, or plan to become pregnant in the next 5 years should not receive Zilver PTX Drug-Eluting Peripheral Stent. It is unknown whether paclitaxel will be excreted in human milk, and there is potential for adverse reaction in nursing infants from paclitaxel exposure. • Patients who cannot receive recommended anti-platelet and/or anticoagulant therapy. • Patients judged to have a lesion that prevents proper placement of the stent or stent delivery system."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
Covered (Endovascular Grafts) Stents	GORE® VIABAHN® Endoprosthesis	Gore Medical (Flagstaff, AZ, USA)	09/10/2024 P040037/S166	"The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery de novo and restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 7.5 mm. The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in superficial femoral artery in-stent restenotic lesions up to 270 mm in length with reference vessel diameters ranging from 4.0 – 6.5 mm. The GORE® VIABAHN® Endoprosthesis is indicated for improving blood flow in patients with symptomatic peripheral arterial disease in iliac artery lesions up to 80 mm in length with reference vessel diameters ranging from 4.0 – 12 mm. The GORE® VIABAHN® Endoprosthesis is also indicated for the treatment of stenosis or thrombotic occlusion at the venous anastomosis of synthetic arteriovenous (AV) access grafts."	"The GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface is contraindicated for non-compliant lesions where full expansion of an angioplasty balloon catheter was not achieved during pre-dilatation, or where lesions cannot be dilated sufficiently to allow passage of the delivery system. Do not use the GORE® VIABAHN® Endoprosthesis with Heparin Bioactive Surface in patients with known hypersensitivity to heparin, including those patients who have had a previous incidence of Heparin-Induced Thrombocytopenia (HIT) type II."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	GORE VIABAHN VBX Balloon Expandable Endoprosthesis	Gore	06/27/2024 P160021/S045	"The GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis is indicated for the treatment of de novo or restenotic lesions found in iliac arteries with reference vessel diameters ranging from 5 mm - 13 mm and lesion lengths up to 110 mm, including lesions at the aortic bifurcation."	"Do not use the GORE® VIABAHN® VBX Balloon Expandable Endoprosthesis in patients with known hypersensitivity to heparin, including those patients who have had a previous incident of Heparin-Induced Thrombocytopenia (HIT) type II."
	iCast Covered Stent System	Atrium Medical Corp (Hudson, NH, USA) (Getinge?)	08/07/2024 P120003/S005	"The iCast covered stent system is indicated for improving luminal diameter in patients with symptomatic atherosclerotic disease of the native common and/or external iliac arteries up to 110 mm in length, with a reference vessel diameter of 5 to 10 mm."	"The iCast covered stent is contraindicated for use in: • Patients with uncorrected bleeding disorders. • Patients who cannot receive recommended antiplatelet and/or anticoagulation therapy. • Patients who are judged to have a lesion that prevents full expansion of the implant. • Lesions in which the lumen diameter post-balloon angioplasty is insufficient for the passage of the endovascular system. • Lesion locations subject to external compression."

Type of Device	Device Name	Manufacturer	FDA Approval Date/Number	Indications for Use	Contraindications
	LifeStream™ Balloon Expandable Vascular Covered Stent	BD	08/23/2022 P160024/S012	"The LifeStream™ Balloon Expandable Vascular Covered Stent is indicated for the treatment of atherosclerotic lesions in common and external iliac arteries with reference vessel diameters between 4.5 mm and 12.0 mm, and lesion lengths up to 100 mm."	"The LifeStream™ Balloon Expandable Vascular Covered Stent is contraindicated for use in: • Patients with uncorrected bleeding disorders • Patients who cannot receive recommended antiplatelet and/or anticoagulation therapy • Patients who are judged to have a lesion that prevents full expansion of the implant • Lesions in which the lumen diameter post balloon angioplasty is insufficient for the passage of the endovascular system • Lesion locations subject to external compression."

AWD = absolute walking distance; FDA = Food and Drug Administration; ICD = intermittent claudication distance; km/h = kilometers per hour; MWD = maximum walking distance; NR = not reported; OTW = over-the-wire; PAD = peripheral artery disease; PFWD = pain-free walking distance; PRWD = patient-reported walking distance; PTA = percutaneous transluminal angioplasty; PWT = peak walking time; QoL = quality of life; RCT = randomized controlled trial; SFA = superficial femoral artery; SET = supervised exercise therapy; USD = United States dollar.

APPENDIX M. Clinical Expert Peer Review

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APPENDIX N. Appendix References

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