A systematic review and meta-analysis of revascularization outcomes of infrainguinal chronic limb-threatening ischemia

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ABSTRACT

Background: The optimal strategy for revascularization in infrainguinal chronic limb-threatening ischemia (CLTI) remains debatable. Comparative trials are scarce, and daily decisions are often made using anecdotal or low-quality evidence.

Methods: We searched multiple databases through May 7, 2017, for prospective studies with at least 1-year follow-up that evaluated patient-relevant outcomes of infrainguinal revascularization procedures in adults with CLTI. Independent pairs of reviewers selected articles and extracted data. Random-effects meta-analysis was used to pool outcomes across studies.

Results: We included 44 studies that enrolled 8602 patients. Periprocedural outcomes (mortality, amputation, major adverse cardiac events) were similar across treatment modalities. Overall, patients with infrapopliteal disease had higher patency rates of great saphenous vein graft at 1 and 2 years (primary: 87%, 78%; secondary: 94%, 87%, respectively) compared with all other interventions. Prosthetic bypass outcomes were notably inferior to vein bypass in terms of amputation and patency outcomes, especially for below knee targets at 2 years and beyond. Drug-eluting stents demonstrated improved patency over bare-metal stents in infrapopliteal arteries (primary patency: 73% vs 50% at 1 year), and was at least comparable to balloon angioplasty (66% primary patency). Survival, major amputation, and amputation-free survival at 2 years were broadly similar between endovascular interventions and vein bypass, with prosthetic bypass having higher rates of limb loss. Overall, the included studies were at moderate to high risk of bias and the quality of evidence was low.

Conclusions: There are major limitations in the current state of evidence guiding treatment decisions in CLTI, particularly for severe anatomic patterns of disease treated via endovascular means. Periprocedural (30-day) mortality, amputation, and major adverse cardiac events are broadly similar across modalities. Patency rates are highest for saphenous vein bypass, whereas both patency and limb salvage are markedly inferior for prosthetic grafting to below the knee targets. Among endovascular interventions, percutaneous transluminal angioplasty and drug-eluting stents appear comparable for focal infrapopliteal disease, although no studies included long segment tibial lesions. Heterogeneity in patient risk, severity of limb threat, and anatomy treated renders direct comparison of outcomes from the current literature challenging. Future studies should incorporate both limb severity and anatomic staging to best guide clinical decision making in CLTI. (J Vasc Surg 2018;68:624-33.)

Keywords: Revascularization; Severe limb ischemia; Critical limb ischemia; Bypass surgery; Endovascular treatment

Peripheral artery disease (PAD) is a common condition on a global level. In 2010, an estimated 202 million people were afflicted with PAD.[1] In the United States, lower extremity PAD prevalence was 5.9% in patients aged ≥40 years.[2] Among patients with lower extremity PAD, 1% to 2% present with chronic limb-threatening ischemia (CLTI). Approximately 20% of patients with CLTI will undergo amputations and 25% will die after 1 year.[3] Therefore, CLTI is a condition with important morbidity, mortality, and public health implications.

There are various treatment options for CLTI, including open and endovascular techniques of revascularization. Comparing these different options is best done using evidence from randomized controlled trials and comparative studies. However, a recent systematic review[4] of comparative studies commissioned by the Society for

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Vascular Surgery demonstrated a limited evidence base and a small number of studies that directly compared bypass surgery with endovascular revascularization in patients with CLTI. Only nine studies that enrolled 3071 subjects were included. There was no significant difference in mortality (odds ratio [OR], 0.72; 95% confidence interval [CI], 0.44-1.16) or amputation (OR, 1.2; 95% CI, 0.87-1.65). Bypass surgery was associated with higher primary patency (OR, 2.50; 95% CI, 1.25-4.99) and assisted primary patency (OR, 3.39; 95% CI, 1.53-7.51). The quality of this evidence was deemed low for mortality and amputation outcomes and moderate for patency outcomes.

Therefore, considering the lack of high-quality evidence from comparative studies and to support the initiative of a global vascular guideline on the management of these patients, we sought to evaluate noncomparative evidence derived from registries, trials, and prospective cohort studies meeting specified reporting criteria. The goal of this systematic review and meta-analysis is to provide decision makers and guideline developers with contemporary data on patient-important outcomes after infrainguinal revascularization, to facilitate decision making for patients with CLTI.

METHODS

The protocol was developed a priori by an expert panel charged with developing a global guideline on the management of CLTI. This report follows recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statements.[5]

Eligibility criteria. The search included comparative and noncomparative prospective studies that enrolled patients ≥18 years of age with critical or severe limb ischemia (Rutherford 4-6, Fontaine 3-4) undergoing infrainguinal (superficial femoral artery [SFA], popliteal artery, tibial artery, and pedal artery) revascularization (endovascular or bypass surgery). Outcomes had to be specifically reported based on the anatomic segment treated and the intervention used. We included studies that evaluated angioplasty/stent procedures (balloon with and without drugs, and stent with and without drugs), atherectomy, autogenous grafts, and nonautogenous grafts. A minimum of 1-year follow-up was required for inclusion. The outcomes of interest were mortality and major amputation at 30 days, 1 year and yearly thereafter up to 5 years; major adverse cardiovascular events (MACE) and reintervention/readmission at 30 days; patency (primary, primary assisted, and secondary), amputation-free survival (AFS), reintervention and amputation-free survival, quality of life, and wound healing at 1 year and yearly thereafter up to 5 years as available. All the outcomes were defined according to the study protocols. We extracted patency outcomes only if the bypass graft or treated vessel was assessed objectively using ultrasound or alternative imaging. We restricted the inclusion criteria to prospective cohorts with the sample size of at least 50 patients per endovascular or bypass surgery approaches, and at least 20 patients per subtype of intervention reported.

Exclusion criteria.

1. Retrospective design or review article.
2. Common femoral artery, deep femoral artery, and aortoiliac arteries.
3. Claudication (Rutherford 1-3, Fontaine 1-2).
4. Non-FDA-approved devices (balloon-expandable absorbable metal stent).
5. Sample size <50 patients for either endovascular or bypass surgery, or <20 patients in any subintervention group.
6. The outcomes reported indistinctly in terms of the location of lesions or of the subinterventions of our interest.

Data sources and search strategies. A comprehensive search of several databases was conducted in any language from 1990 for bypass surgery and 2000 for endovascular procedures to May 7, 2017. The databases included Ovid Medline In-Process & Other Non-Indexed Citations, Ovid MEDLINE, Ovid EMBASE, Ovid Cochrane Central Register of Controlled Trials, Ovid Cochrane Database of Systematic Reviews, and Scopus. The search strategy was designed and conducted by an experienced librarian with input from the study principal investigator. Controlled vocabulary supplemented with keywords was used to search for prospective cohort studies and randomized controlled trials of critical limb ischemia revascularization. The detailed search strategy is available in the Appendix (online only).

Study selection and data extraction. After uploading all the identified references to Web-based software developed for systematic review data management (DistillerSR, Evidence Partners, Ottawa, Ontario, Canada), two reviewers screened all titles and abstracts independently to assess the eligibility of each article. The relevant references were retrieved in full text and screened against eligibility criteria. We solved disagreements by consensus. The final included studies were extracted using standardized forms created in DistillerSR. We extracted data from text and tables, and we used Web Plot Digitizer[6] as a measurement tool to extract data from graphs (Kaplan-Meier curves).

Methodologic quality and risk of bias. The goal of this analysis was to establish the best estimates for incidence rates of clinically important outcomes stratified by the anatomic level of disease treated. Therefore, outcome measures were derived from noncomparative data. Consequently, we derived risk of bias indicators (methodologic quality) from the Newcastle-Ottawa[7] instrument removing comparability items. We focused on outcome ascertainment (hemodynamic assessment at

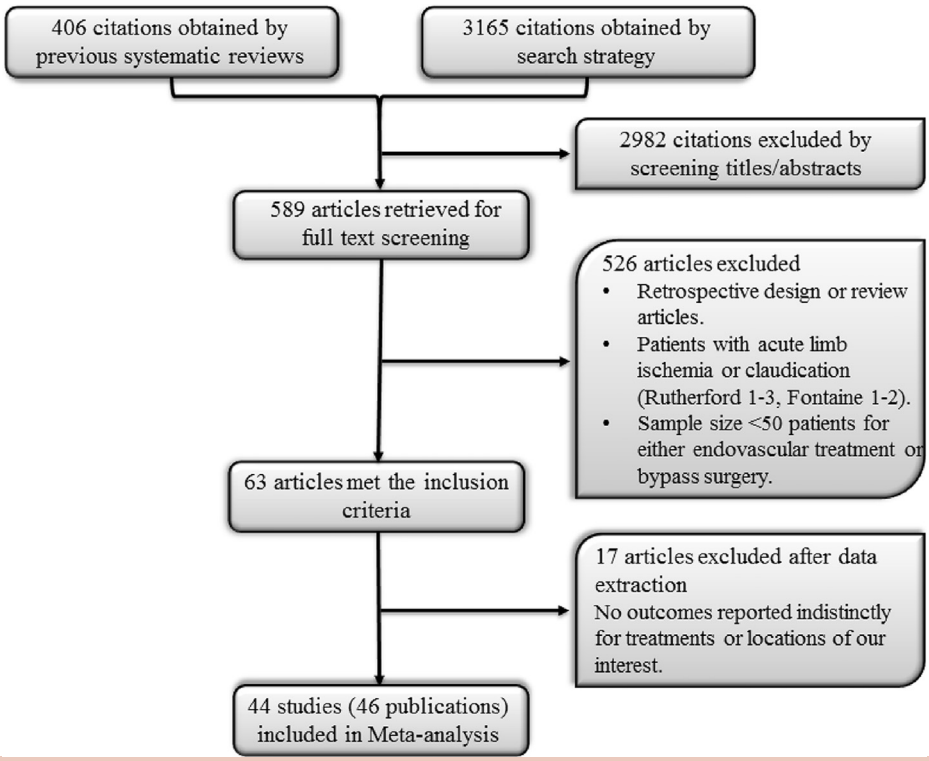

Fig 1. Process of studies selection.

baseline and follow-up, independent event adjudication, core lab imaging assessment) and adequacy of follow-up.

Analysis. We reported the outcomes from noncomparative studies as cumulative incidence rates with 95% CI estimated using the binominal distribution. Then, we pooled the log transformed rates using the DerSimonian and Laird random-effects model[8] and estimated heterogeneity using the Mantel-Haenszel model if possible. To evaluate heterogeneity, we calculated I^2 statistic,[9] where $I^2 > 50\%$ suggests high heterogeneity and not applicable (NA) suggests only one study available for analysis. We used STATA, version 14 (StataCorp LP, College Station, Tex) for conducting statistical analyses.

Whenever possible, we planned to stratify analysis by:

1. Location of disease (endovascular: SFA, popliteal, and infrapopliteal; bypass surgery: Fem-pop above the knee, fem-pop below the knee, infrapopliteal, and any infrainguinal location)
2. Direct vs indirect revascularization
3. Stent type-bare metal; balloon-expandable vs self-expandable
4. Endovascular techniques vs each other by location
5. Rest pain vs tissue loss
6. Diabetes status vs not
7. End-stage renal disease vs not
8. Multicenter vs single-center study.

We used the Global Limb-based Anatomic Staging System (GLASS; Table 1 in the Appendix, online only) to summarize the treated lesion distribution for the endovascular studies included in the review. We reported GLASS grades for femoropopliteal (FP) and tibioperoneal lesions separately using the location of the injured vessel, degree of stenosis, and the length of lesions as criteria for grading, based on data available from the published report of each study. Higher grade number (0-4) in GLASS represents a more severe lesion at each anatomic level.

RESULTS

Study identification

The search strategy yielded 3165 citations, and manual search of previous systematic reviews added an additional 406 citations. We explained the study selection process in Fig 1. After excluding all irrelevant studies, we included 44 studies in the meta-analysis enrolling 8602 patients. Fig 2 depicts the subcategories of data sources used by the revascularization technique, anatomical location, and conduits types. The characteristics of the included studies are summarized in the Supplementary Tables in the Appendix (Table 2.1 for endovascular studies and Table 2.2 for bypass surgery studies, online only). The criteria used to assess the risk of bias showed that most of the studies appeared to have moderate to high risk of bias (Table 4 in the Appendix, online only).

Several key limitations of the available data are readily apparent from the summary tables, defining major gaps in quality evidence for the field. For FP disease, there were no studies that could be included on stenting

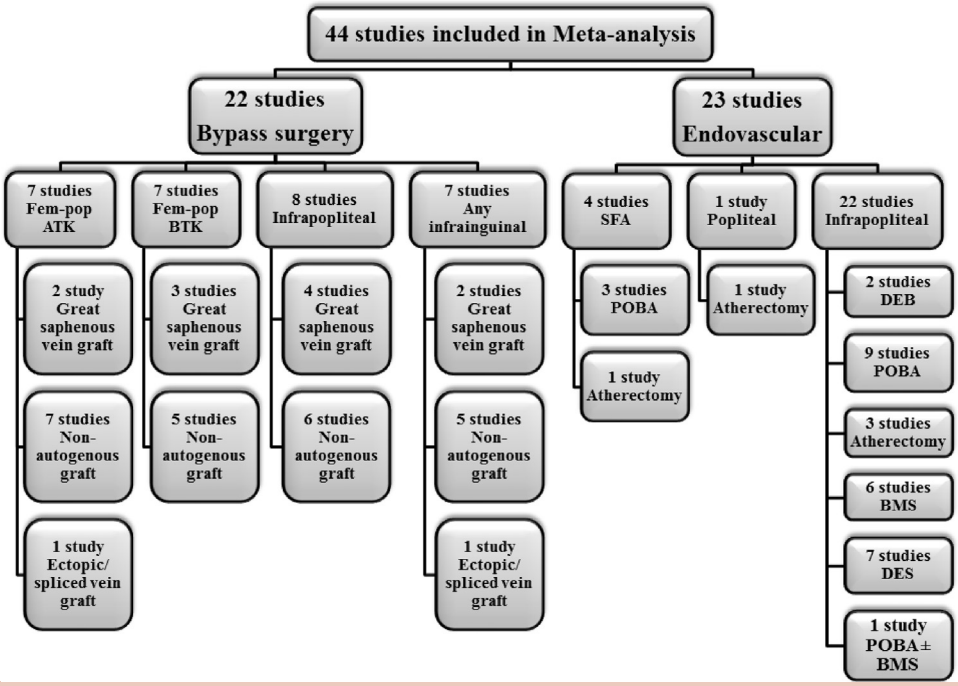

Fig 2. Subcategories of data sources used by the revascularization technique, anatomical location, and conduits types. Some studies contained data in more than 1 category. *BMS,* Bare-metal stent; *DEB,* drug-eluting balloon; *DES,* drug-eluting stent; *Fem-pop ATK,* femoropopliteal above the knee; *Fem-pop BTK,* femoropopliteal below the knee; *POBA,* plain old balloon angioplasty; *SFA,* superficial femoral artery.

despite the highly prevalent use of stents for this level of disease. This reflects the fact that regulatory trials and prospective studies of stenting for FP disease have focused primarily on subjects with moderate lesion severity, predominantly those with claudication, often mixing in small percentages of patients with CLTI (rest pain) without clearly separating the outcomes by indication. Overall, the endovascular data are also quite limited in terms of the spectrum of anatomic severity treated, both above and below the knee (eg, no studies included GLASS grade 4 IP disease). For open FP bypass surgery, there were more studies included of prosthetic conduits than of autogenous vein, likely because the superiority of autogenous vein bypass has long been considered as established. Finally, the number of patients included with data available beyond 2 years was also a notable limitation.

Outcomes

In the Appendix (Tables 3.1-3.6, online only), we summarize the results of meta-analyses of the included 44 studies for all available procedure types per time point of interest. Figs 3-7 depict overall outcomes as proportions and associated 95% CI for endovascular and open bypass surgery in the first year and the third year of follow-up according to the location of lesions. An overview summary is provided in the following text. Data were insufficient to conduct several a priori planned subgroup analyses such as diabetes status, a diagnosis of ESRD, certain technical aspects, lesion severity, and number of study centers.

Periprocedural events

Perioperative mortality (1%-7%) rates were similar across treatment types and lesion locations. MACE (1%-7%) and major amputation (0%-7%) rates were likewise similar between endovascular interventions and vein bypass surgery. Early amputation rates after nonautogenous bypass grafting were notably higher than great saphenous vein bypass and ectopic/spliced vein bypass (up to 14%).

Mid- to long-term outcomes

Endovascular. At 1 year, primary patency of percutaneous transluminal angioplasty (PTA) and atherectomy in patients with SFA lesions were 0.86 (95% CI, 0.70-1.00; I^2 = 84.1%) and 0.73 (95% CI, 0.58-0.85; I^2 = NA), respectively. As noted above, there were no data available for stent outcomes in the FP position. In patients with infrapopliteal artery lesions, primary patency at 1 year was as follows: bare-metal stent (BMS): 0.50 (95% CI, 0.42-0.60; I^2 = 41.4%); drug-eluting stent (DES): 0.73 (95% CI, 0.65-0.81; I^2 = 68.1%); atherectomy: 0.78 (95% CI, 0.72-0.85; I^2 = 0%); and PTA: 0.66 (95% CI, 0.51-0.85; I^2 = 84.1%).

At 3 years, in patients with infrapopliteal artery lesions, primary patency of DES was 0.49 (95% CI, 0.31-0.79; I^2 = 79.8%), and that of BMS was 0.10 (95% CI, 0.03-0.23; I^2 = NA). No data were available for PTA alone at this time point. Data on major amputation and mortality in patients with infrapopliteal disease were not significantly different for various endovascular techniques at 1 and 3 years of follow-up.

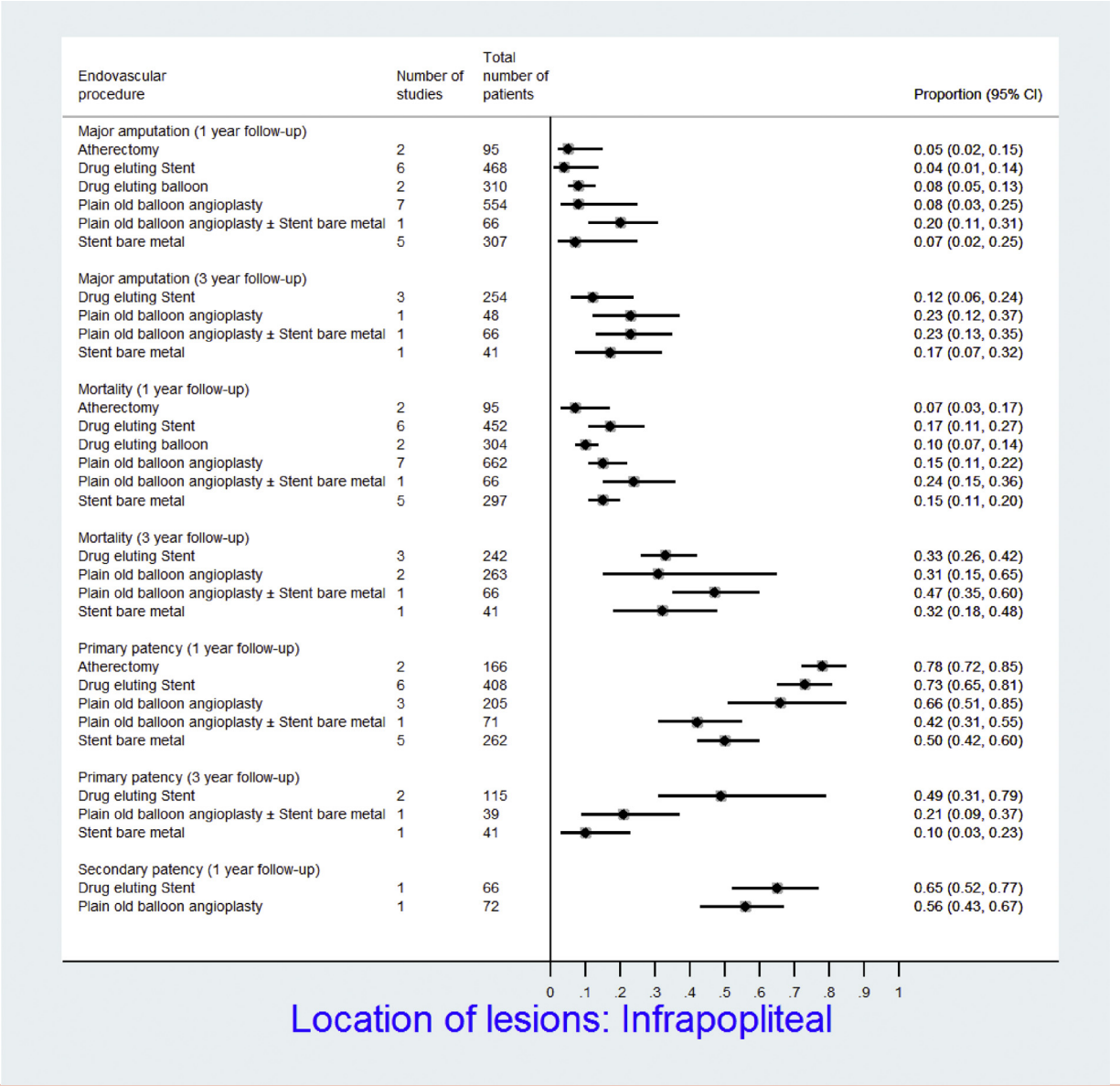

Fig 3. Forest plot represents the overall outcomes' proportions and associated 95% confidence intervals (*CIs*; *horizontal lines*) for each endovascular technique at 1 year and 3 years of follow-up in patients with infrapopliteal arteries lesions.

Bypass surgery. For bypass surgery to any infrainguinal target, the incidence rate of major amputation within 1 year was 0.11 (95% CI, 0.09-0.13; I^2 = NA) in great saphenous vein graft, 0.24 (95% CI, 0.14-0.42; I^2 = 76.8%) in nonautogenous graft, and 0.16 (95% CI, 0.12-0.21; I^2 = NA) in ectopic vein or spliced arm vein graft. On the other hand, primary patency at 1 year was 0.77 (95% CI, 0.71-0.82; I^2 = 0%) in nonautogenous grafts, 0.64 (95% CI, 0.61-0.67; I^2 = NA) in great saphenous vein grafts, and 0.45 (95% CI, 0.39-0.51; I^2 = NA) in ectopic vein or spliced arm vein graft. At 2 years and beyond, superior patency (primary and secondary) and limb salvage rates for great saphenous vein over nonautogenous and ectopic vein conduits were evident and increasingly amplified. Mortality was similar for the three types of bypass grafts. Data on MACE, reintervention/readmission, AFS, reintervention and amputation-free survival, quality of life, and wound healing were limited.

Quality of the evidence

Using the GRADE approach (Grading of Recommendations, Assessment, Development and Evaluation),[10] the current evidence warrants low confidence as it was derived from noncomparative studies at moderate to high risk of bias. This applies to all outcomes of interest addressed in this review.

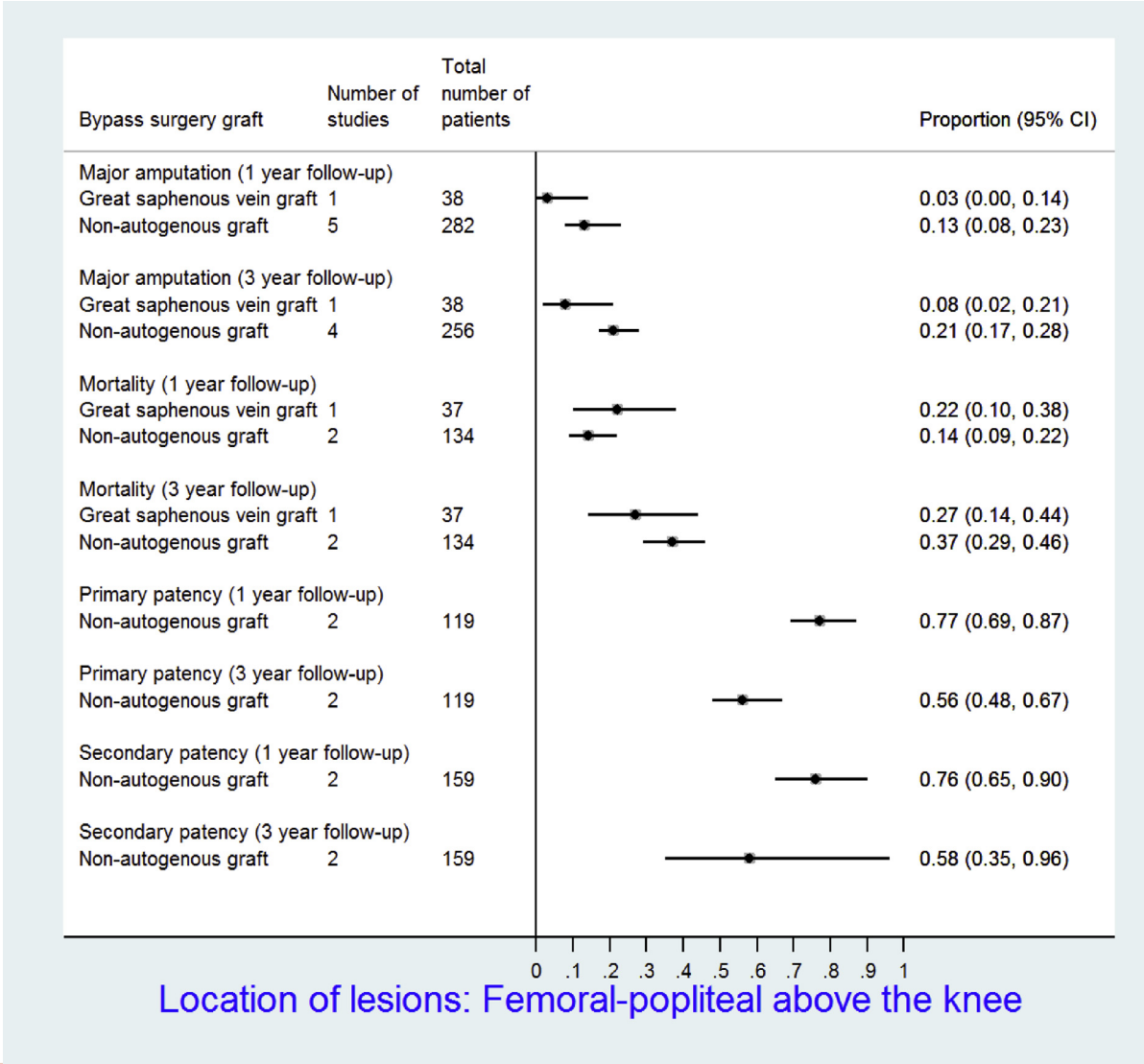

Fig 4. Forest plot represents the overall outcomes' proportions and associated 95% confidence intervals (*CIs*; *horizontal lines*) for nonautogenous graft at 1 year and the third year of follow-up in patients with femoropopliteal (FP) above-the-knee lesions.

DISCUSSION

This systematic review and meta-analysis provides incidence rates of several patient important outcomes for patients with infrainguinal CLTI requiring either open surgical or endovascular intervention. This information, along with surgical expertise, can support shared decision making and possibly populate decision aids that facilitate conversations taking place during the clinical encounter. However, there are notable limitations to the current state of evidence in CLTI that are re-emphasized by this review. Commonly employed procedures such as stent placement for FP lesions have not been adequately studied in a prospective manner in the CLTI population. Lesion severity in the endovascular cohorts is greatly limited by the regulatory nature of many of the reported studies, focused on subjects with more favorable lesions, and thus lacking generalizability to a large segment of the real-world population with CLTI. Moreover, these studies universally lack information on both patient risk and the severity of limb threat (eg, SVS threatened limb classification system) that is likely of major importance in key outcomes such as survival and major amputation. With these numerous important confounders, any direct comparisons of outcomes must be considered highly speculative and the importance of high-quality, appropriately stratified randomized controlled trials is stressed.

The assessment of patency of revascularization and the relationship between patency and important clinical end points in CLTI such as reintervention, major adverse limb events, and amputation represent areas of inconsistent reporting and controversy in the literature, and among vascular specialists. Maintained patency of the bypass graft or endovascular intervention is unarguably a

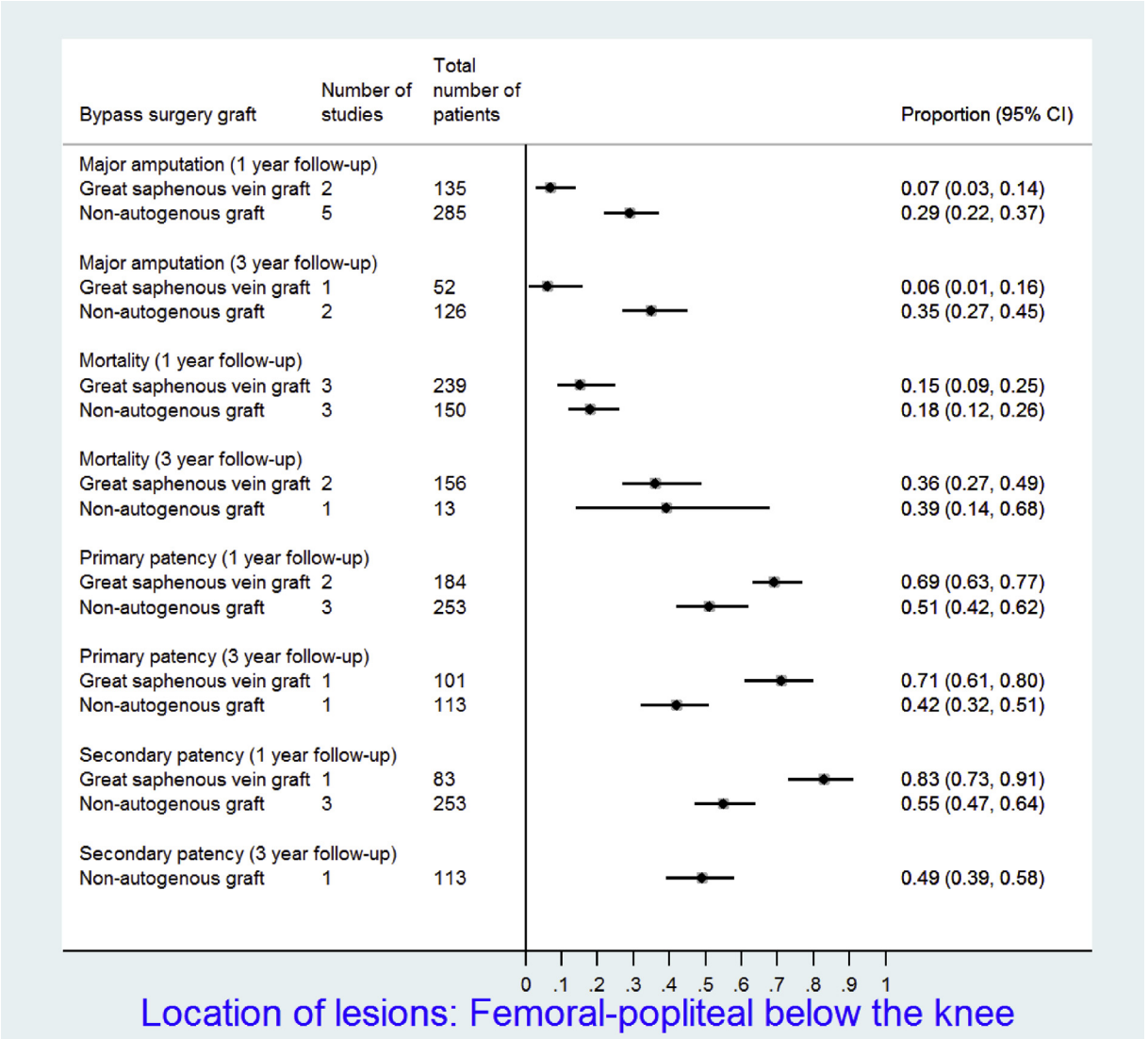

Fig 5. Forest plot represents the overall outcomes' proportions and associated 95% confidence intervals (*CIs*; *horizontal lines*) for each bypass surgery graft at 1 year and 3 years of follow-up in patients with femoropopliteal (FP) below-the-knee lesions.

desired outcome for any revascularization, reducing the likelihood of recurrent symptoms, repeated procedures and hospitalizations, and downstream major adverse limb events. Surveillance protocols, assessment of vessel patency, and approach to reinterventions for endovascular procedures and bypass grafts vary across studies and greatly influence the reported outcomes. For example, prophylactic reinterventions for vein bypass graft lesions identified on ultrasound surveillance are commonly performed with the goal of maintaining long-term primary assisted patency, resulting in reduced midterm primary patency rates in comparison to prosthetic grafts. Despite these caveats, a global assessment of primary, primary assisted, and secondary patency provides an important lens into the expected anatomic durability of the given reconstruction.

This contemporary evidence review was designed to inform a comprehensive practice guideline on the management of CLTI, and thus the criteria we employed for study inclusion are uniquely tuned to that need. Accordingly, studies with inadequate numbers of patients or procedures, limited follow-up, or where the outcomes reported were indistinct in relation to the anatomic level of disease and the specific procedure performed were excluded. These strict inclusion criteria may have led to a smaller body of evidence on stenting. In clinical practice, specialists are faced with an array of choices and an estimate of risk/benefit for each is based on specific patient factors such as general health, anatomic pattern of disease, and conduit availability. Other recent registry studies and reviews examining outcomes of endovascular intervention or surgery have employed different study designs

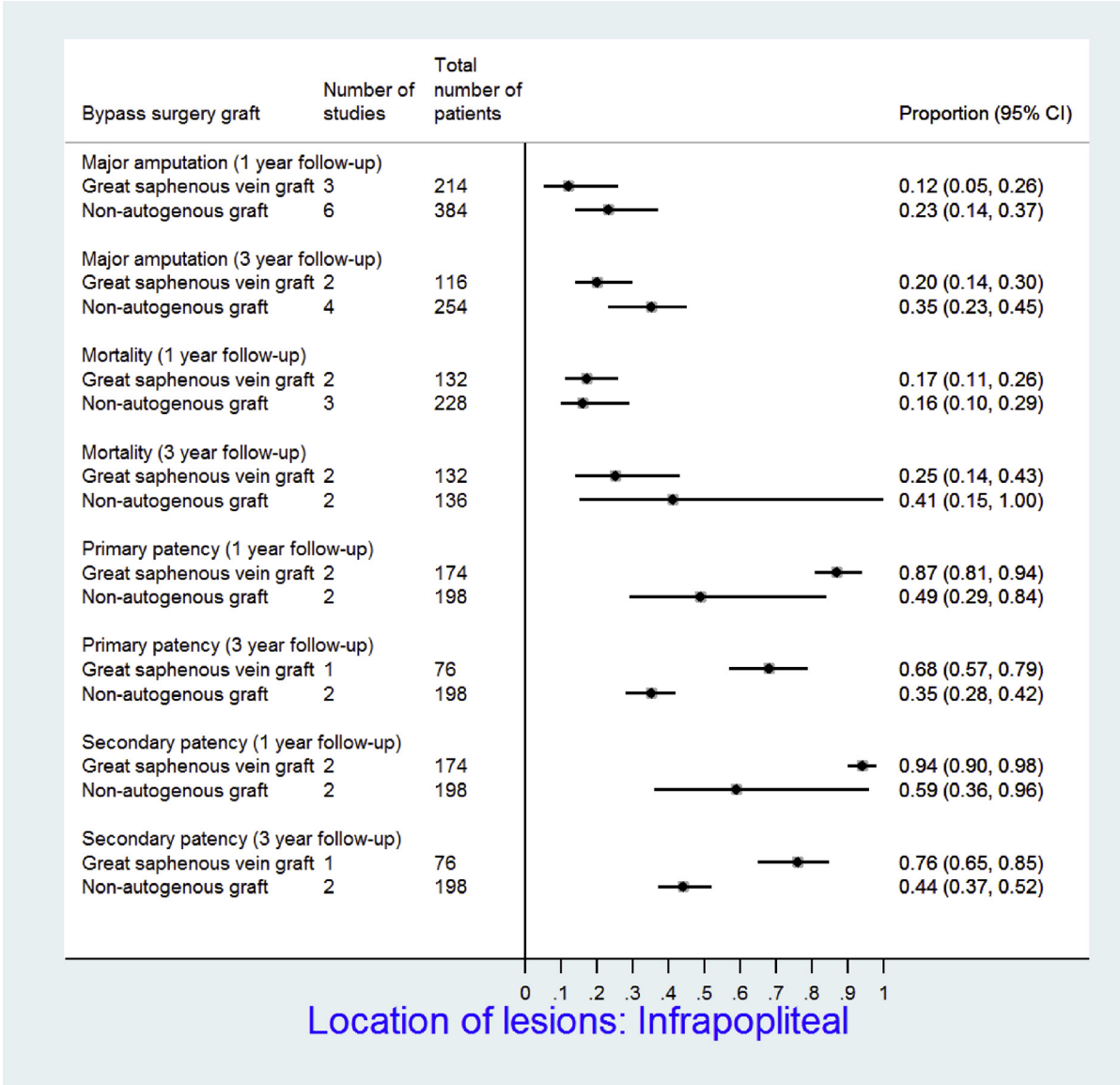

Fig 6. Forest plot represents the overall outcomes' proportions and associated 95% confidence intervals (*CIs*; *horizontal lines*) for each bypass surgery graft at 1 year and 3 years of follow-up in patients with infrapopliteal arteries lesions.

for alternative purposes.[11-13] Of note, although employing different and less restrictive inclusion criteria, a recent meta-analysis of infrapopliteal PTA reported very similar 1-year point estimates of primary patency (0.63 vs 0.66 [95% CI, 0.51-0.85] this study), major amputation (0.15 vs 0.08 [95% CI, 0.03-0.25] this study), and mortality (0.15 vs 0.15 [95% CI, 0.11-0.22] this study).[14] Only 2 studies included in that report involved tibial lesion lengths >88 mm, although multiple studies included patients with tibial occlusions. The referable GLASS IP grades encompassed in that meta-analysis are predominantly 1 and 2, with few if any IP grade 3 or 4 lesion patterns represented.

Despite these key limitations, the available data suggest that periprocedural risks are broadly similar across both open and endovascular interventions for CLTI in current practice. For endovascular interventions, there is little evidence to support favoring any one technique in the treatment of CLTI for most anatomic patterns commonly encountered. DES appears to offer improved outcomes over BMS for short infrapopliteal lesions, and may thus be a preferred bailout option for flow-limiting dissection or PTA failures in this group. Bypass surgery with autogenous vein offers the best mid- and long-term patency and limb salvage outcomes, particularly for below-knee targets. Open bypass with nonautogenous conduits has inferior patency and limb salvage outcomes at all time points.

Clinical implications. CLTI is a highly morbid condition and successful treatment requires safe and effective

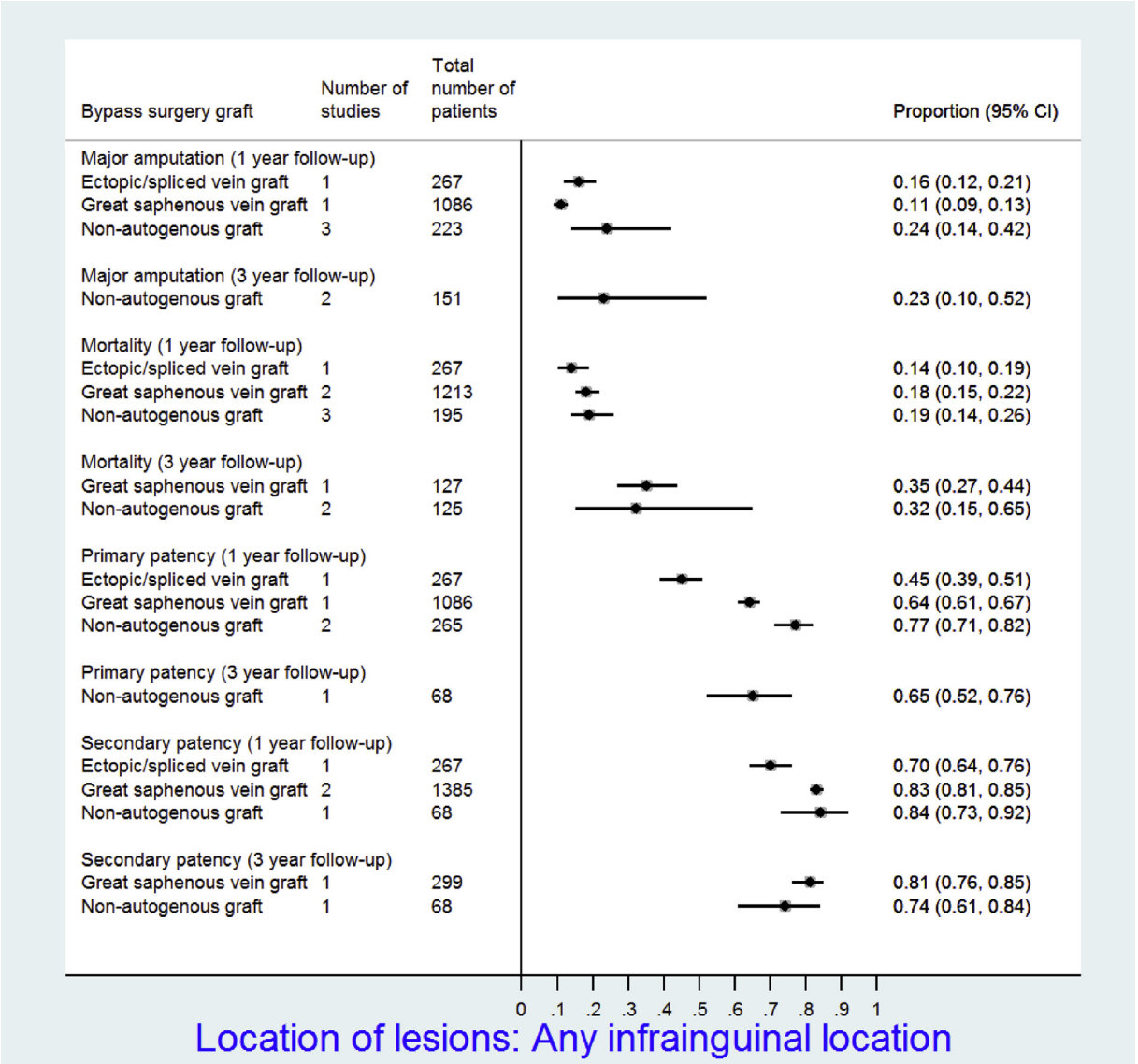

Fig 7. Forest plot represents the overall outcomes' proportions and associated 95% confidence intervals (*CIs*; *horizontal lines*) for each bypass surgery graft at 1 year and 3 years of follow-up in patients with any infrainguinal artery lesions.

limb revascularization. There is a broad range of patient risk, limb threat and anatomic severity in this population, and a lack of high-quality comparative trials. In current practice, specialists should be familiar with the full range of endovascular and open surgical techniques for revascularization. Although overall survival and AFS are largely similar across studies applying various modalities in selected patients, significant differences in anatomic durability of interventions are apparent beyond 1 to 2 years. These factors should be taken into account when undertaking clinical decision making in this population. Overall, it seems that major adverse events seen in patients with CTLI did not importantly differ between endovascular and open bypass. Increased patency did not always correlate with a significant effect on survival and risk of amputation, which may be a limitation of the available evidence.

Strengths and limitations. This systematic review is the most comprehensive and up to date addressing this topic. The strengths of this review relate to a priori design that restricted inclusion to studies that were prospective with adequate follow-up and procedures, the comprehensive search that included multiple databases, the rigorous approach of study selection and appraisal by pairs of independent reviewers, and collaboration with clinical experts tasked with developing a global guideline on CLTI.

The limitations of this review relate to the nature of data available and our inability to stratify results by several clinically important characteristics that restricts the ability of providing patients with individualized risk assessment specific to their lesion and clinical context. Other sources of data such as institutional and multi-institutional registries may be of value, particularly for hard objective end points such as mortality and amputation, but are fraught with less rigorous inclusion criteria, inconsistent follow-up assessments and reporting of outcomes specific to the anatomy treated or procedure employed, and significant proportions of subjects with missing data. Further efforts should focus on improving data quality in prospective registries and comparative effectiveness studies in this growing population with advanced PAD. The quality of evidence supporting the care of patients with CLTI remains low, and the choice of approach remains heavily dependent on patients' values, morbidities, provider bias, and the availability of endovascular and surgical expertise wherever they are treated.

CONCLUSIONS

Multiple revascularization techniques are currently available for the treatment of CLTI. Optimal selection of interventions requires the understanding of the current evidence within the context of the individual patient's clinical status, disease severity, and anatomic pattern. Results from current large-scale randomized trials[15,16] will be of great value in moving toward true evidence-based revascularization for CLTI.

AUTHOR CONTRIBUTIONS

Conception and design: JeA, LP, MC, MM
Analysis and interpretation: JeA, AB, PK, MC, MM
Data collection: JeA, JaA, NA, SL, MA
Writing the article: JeA, LP, MC, MM
Critical revision of the article: JeA, JaA, NA, SL, MA, LP, AB, PK, MC, MM
Final approval of the article: JeA, JaA, NA, SL, MA, LP, AB, PK, MC, MM
Statistical analysis: JeA
Obtained funding: AB, PK, MC, MM
Overall responsibility: MM

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