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.

Method: 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;■:1-10.)

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.

METHOD

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

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