CLINICAL STUDY

Contemporary Systematic Review and Meta-Analysis of Early Outcomes with Percutaneous Treatment for Infrapopliteal Atherosclerotic Disease

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ABSTRACT

Purpose: The need for specialty devices to improve the technical outcome of endovascular interventions is dependent on the rate of early failure in such procedures. This meta-analysis assessed procedural outcomes of such interventions to elucidate the rate of early procedural failures and the need for such specialty devices.

Materials and Methods: MEDLINE and EMBASE were searched for contemporary studies (2000–2012) reporting procedural or short-term outcomes for revascularization of infrapopliteal atherosclerotic lesions. A random-effects metaanalysis was performed, which included post hoc comparisons among treatment groups.

Results: A total of 42 studies with 52 treatment arms representing 3,660 unique patients were included. Technical success rates were higher with bare metal stents (BMSs; 98.6%) than with atherectomy (92.2%; $P < .05$) or percutaneous transluminal angioplasty (PTA; 91.2%; $P = .01$), and higher with drug-eluting stents (DESs) than with PTA ($P < .001$). DES use had higher primary patency rates than atherectomy ($P < .05$), BMS use ($P < .001$), and PTA ($P < .01$). The 30-day rate of target lesion revascularization was significantly higher with PTA (8.1%) than with BMSs (2.2%; $P < .05$) and DESs (1.1%; $P < .05$). Thirty-day rates of major unplanned amputation (range, 1.5%–4.4%) and mortality (range, 0.9%–3.3%) were comparable among treatment groups. Significant heterogeneity among studies was noted for most PTA outcomes. Publication bias was evident for most PTA and DES outcomes.

Conclusions: Early failure of percutaneous therapies in patients with infrapopliteal atherosclerotic lesions is device- and technique-dependent. Specialty devices designed to reduce technical failure rates may therefore be of benefit in this selected group of patients. Study results are confounded by inconsistent data reporting, heterogeneity of treatment effects, and publication bias.

ABBREVIATIONS

BMS = bare metal stent, BTK = below the knee, CLI = critical limb ischemia, DES = drug-eluting stent, PTA = percutaneous transluminal angioplasty, TLR = target lesion revascularization

Revascularization is an integral part of the therapeutic plans for patients with critical limb ischemia (CLI). In view of the less invasive nature of endovascular approaches, coupled with advances in technology and techniques, they are used with increasing frequency in patients with CLI as well as intermittent claudication (1,2). Percutaneous transluminal angioplasty (PTA) alone is currently the most common method of endovascular therapy for below-the-knee (BTK) arteries (3). In addition to the long-term problem of restenosis, PTA alone is limited by recoil, dissection, and thrombosis early after the intervention (4). Multicenter prospective studies in the superficial femoral arteries have shown a relatively high rate of technical failure of PTA requiring placement of stents in patients with intermittent claudication (5,6). Similarly, some studies have reported a high rate of early failure of PTA in patients with CLI,

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Tables E1 and E2 and Figure E1 are available online at *www.jvir.org*.

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leading to repeat intervention and amputation in as many as 23.8% of patients within 30 days (7). Whether this is caused by an early compromise of flow or the nature of the underlying disease and poor general health of these patients is not well characterized.

Although the risks of late failure of various current endovascular therapies have been well studied and reported (8–10), the incidence of immediate (ie, on-table) and early (ie, < 30 d) failures for infrapopliteal arteries is less clear. In addition, the development and availability of specialty devices designed to reduce the rate of technical failure of PTA may improve early and late clinical outcomes, but their contribution to such is not well studied in BTK vessels (10). To determine the value of these new technologies requires a more accurate knowledge of early procedural outcomes of current therapies.

The present meta-analysis was undertaken to better understand the problem of early technical failures of endovascular therapies in BTK vessels and to assess the need for the use of more expensive devices designed to reduce recoil, dissection, and thrombosis, which are the root causes of early endovascular failure.

MATERIALS AND METHODS

Eligibility Criteria and Information Sources

The Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines (11) served as a template for this report. Studies that were eligible for consideration in this systematic review were randomized, nonrandomized, or single-arm studies indexed in MEDLINE or EMBASE and published in English-language journals between January 2000 and December 2012 on the effects of PTA, drug-eluting stents (DESs), bare metal stents (BMSs), or atherectomy for the treatment of infrapopliteal lesions. Publication dates of included studies were selected to ensure complete coverage of DES, BMS, and atherectomy studies while minimizing the influence of treatment period for PTA studies. DESs and BMSs were considered in separate categories as a result of the possibility of early thrombosis in one group versus the other. The complete search strategy is listed in **Table E1** (available online at *www.jvir.org*). We also sought references from experts in the field and handsearched the reference lists of included manuscripts.

Study Selection

One reviewer (L.E.M.) selected studies for inclusion in the review. Identified articles were assessed independently by a second reviewer (M.K.R.) to confirm eligibility. Disagreements were resolved by discussion and consensus. Titles and abstracts were screened to exclude all manuscripts published in non–English language journals. Next, review articles, commentaries, letters, case reports, animal or in vitro studies, studies with 15 or fewer patients receiving the indicated therapy, and obviously irrelevant articles were screened out. Full texts of the remaining manuscripts were retrieved and reviewed. Studies were excluded for the following reasons: any treated index lesions were above the distal popliteal artery; all treated lesions were submalleolar; laser atherectomy was performed; and studies exclusively included procedural successes or failures. Finally, kin relationships, defined as multiple publications describing the same or overlapping series of patients, were identified and, in each case, included only the publication with the largest sample size.

Data Collection Process and Data Items

A database was developed, pilot-tested, and subsequently refined to develop the final data extraction database. One reviewer (L.E.M.) extracted the data from included studies, and a second reviewer (M.K.R.) checked the extracted data for accuracy. Disagreements were resolved by discussion and consensus.

The following variables were recorded in a predesigned database: (i) general manuscript information; (ii) study characteristics (study design, sample size, number of centers, and treatment period), (iii) patient characteristics and comorbidities (sex, age, smoking status, diabetes mellitus, chronic renal failure, hypertension, hyperlipidemia, and Rutherford–Becker classification), (iv) lesion characteristics (number of lesions, lesion location, calcified lesions, occluded lesions, and percent stenosis), procedural outcomes (technical success, provisional stent placement, and dissection), and (v) 30-day outcomes (primary and secondary patency, major unplanned amputation, target lesion revascularization [TLR], and mortality). Outcome definitions followed the recommendations of Diehm et al (12) unless otherwise defined by individual investigators. Data were preferentially retrieved from article text and tables. Data were estimated from graphs if values were not reported elsewhere.

Data Analysis

Continuous variables are reported as mean (range), and categoric variables are reported as counts and percentages. A random-effects meta-analysis model was selected a priori based on the assumption that the true effect may vary among studies based on known differences in study design and patient and treatment characteristics. Denominators were adjusted when appropriate to include the number of patients, procedures, limbs, or lesions. For each outcome, the incidence and 95% confidence interval were calculated. When significant differences among treatments were identified by using the Q statistic, post hoc pairwise comparisons were conducted. We used the I^2 statistic to estimate heterogeneity of effects across studies with values of 25% or less, 50%, and 75% or greater representing low,