

From the Vascular and Endovascular Surgery Society

Cost-effectiveness analysis of drug-coated therapies in the superficial femoral artery

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ABSTRACT

Objective: Drug-coated balloons (DCBs) may increase durability of endovascular treatment of superficial femoral artery (SFA) disease while avoiding stent-related risks. The purpose of this study was to use meta-analytic data of DCB studies to compare the cost-effectiveness of potential SFA treatments: DCB, drug-eluting stent (DES), plain old balloon angioplasty (POBA), or bare-metal stent (BMS).

Methods: A search for randomized controlled trials comparing DCB with POBA for treatment of SFA disease was performed. Hazard ratios were extracted to account for the time-to-event primary outcome of target lesion revascularization. Odds ratios were calculated for the secondary outcomes of primary patency (PP) and major amputation. Incorporating pooled data from the meta-analysis, cost-effectiveness analysis, assuming a payer perspective, used a decision model to simulate patency at 1 year and 2 years for each index treatment modality: POBA, BMS, DCB, or DES. Costs were based on current Medicare outpatient reimbursement rates.

Results: Eight studies (1352 patients) met inclusion criteria for meta-analysis. DCB outperformed POBA with respect to target lesion revascularization over time (pooled hazard ratio, 0.41; $P < .001$). Risk of major amputation at 12 months was not significantly different between groups. There was significantly improved 1-year PP in the DCB group compared with POBA (pooled odds ratio, 3.30; $P < .001$). In the decision model, the highest PP at 1 year was seen in the DES index therapy strategy (79%), followed by DCB (74%), BMS (71%), and POBA (64%). With a baseline cost of \$9259.39 per patent limb at 1 year in the POBA-first group, the incremental cost per patent limb for each other strategy compared with POBA was calculated: \$14,136.10/additional patent limb for DCB, \$38,549.80/limb for DES, and \$59,748.85/limb for BMS. The primary BMS option is dominated by being more expensive and less effective than DCB. Compared directly with DCB, DES costs \$87,377.20 per additional patent limb at 1 year. Based on the projected PP at 1 year in the decision model, the number needed to treat for DES compared with DCB is 20. At current reimbursement, the use of more than two DCBs per procedure would no longer be cost-effective compared with DES. At 2 years, DCB emerges as the most cost-effective index strategy with the lowest overall cost and highest patency rates over that time horizon.

Conclusions: Current data and reimbursements support the use of DCB as a cost-effective strategy for endovascular intervention in the SFA; any additional effectiveness of DES comes at a high price. Use of more than one DCB per intervention significantly decreases cost-effectiveness. (J Vasc Surg 2017;■:1-10.)

Peripheral arterial disease (PAD) affects one in five Americans by the age of 80 years according to recent epidemiologic data.¹ Because of increased awareness and an aging population, the incidence of PAD continues to increase worldwide.^{2,3}

The negative consequences of PAD on quality and length of life have been well reported,⁴ but the economic burden of this disease is often underestimated.³ The annual cost of treating PAD in the United States has been estimated to range from \$212 billion to \$389 billion, more than diabetes, coronary disease, or cancer.⁵⁻⁷ Much of this cost is billed to publicly funded insurance. In 2012, 71% of hospital discharges for PAD were billed to Medicare (Healthcare Cost and Utilization Project query; *International Classification of Diseases, Ninth Revision* diagnosis codes 440.20-29, 443.9, and 443.81). Moreover, an estimated 7% of all Medicare patients received treatment for PAD in a single year (2001), which represents a significant payer burden.^{3,8} Thus, it is imperative that health care providers have objective evidence to make cost-effective decisions with regard to treatment of PAD.

Advances in available percutaneous technology along with the associated lower morbidity and mortality (compared with bypass surgery) of endovascular therapy

From the Division of Vascular Surgery, University of Pittsburgh Medical Center. N.D.S. is funded as a trainee by a T32 grant HL098036.

Author conflict of interest: none.

Presented as a mini oral presentation at the Vascular and Endovascular Surgery Society Winter Annual Meeting, Steamboat Springs, Colo. February 2-5, 2017.

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The editors and reviewers of this article have no relevant financial relationships to disclose per the JVS policy that requires reviewers to decline review of any manuscript for which they may have a conflict of interest.

0741-5214

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Table I. Cost-effectiveness definitions

Term	Definition
Cost	Reimbursement per procedure
Effectiveness	Patency at end of time period
ICER	Difference in payer costs divided by the difference in patencies at the end of the time period between two strategies
ICER, Incremental cost-effectiveness ratio.	

have made endovascular-first management of femoral-popliteal disease increasingly attractive and widespread.⁹ Moreover, there is evidence that endovascular therapy first may be cost-effective, although long-term data are lacking.^{10,11} Emerging therapies of significance include drug-coated balloons (DCBs) and drug-eluting stents (DESs), which have the potential to improve patency rates of percutaneous interventions on the basis of the initial trials.¹² DCBs may specifically offer improved patency rates without stent-associated risks, such as fracture or in-stent restenosis. However, there is a scarcity of cost-effectiveness evidence to support this decision-making process.

The goal of our study was twofold. First, we sought to perform a meta-analysis of the growing body of high-quality literature for drug-coated therapies. We then applied these pooled data to a decision model to compare the cost-effectiveness of different index endovascular treatment modalities for superficial femoral artery (SFA) disease using a clinically relevant effectiveness outcome of patency rates. We hypothesized that drug-coated therapies would be cost-effective from a payer perspective on a per-patient basis.

METHODS

Methods overview. This study was conducted with approval of the Institutional Review Board of the University of Pittsburgh. We conducted a systematic literature search for randomized clinical trials reporting primary patency (PP) or target lesion revascularization (TLR) for DES or DCB compared with any alternative therapy in the SFA or popliteal artery. Meta-analysis was performed first. Second, results from these studies were pooled and aggregated with additional literature-based parameter estimates to create a decision model to simulate cost-effectiveness of index therapy options (plain old balloon angioplasty [POBA], bare-metal stent [BMS], DCB, or DES) for SFA-popliteal disease. Effectiveness was defined as patency for our model. Other important definitions are summarized in Table I.

Literature search. To summarize the current evidence on DES and DCB, PubMed and Embase were systematically searched in December 2016 for all English-language, randomized clinical trials that compared DES or DCB with another mode of endovascular therapy for

the SFA or popliteal artery. Studies were included if they reported either PP or TLR results at any time point. To focus on the highest quality data, studies were excluded if they were retrospective or observational or focused on treatment of restenotic lesions after a primary endovascular intervention. Single-arm studies were excluded.

Meta-analysis. Time-to-event outcomes, such as TLR, are most appropriately analyzed using hazard ratios, which account for the number and timing of events as well as censoring of patients lost to follow-up.¹³ Odds ratios (ORs) or relative risks can be compared only when results are reported at specific time points for multiple studies (ie, 6 months or 1 year) and should not be combined for variable follow-up times.¹³ Using ORs for meta-analysis excludes much of the available data on drug-eluting interventions because trials to date have variable lengths of follow-up reported. To maximize the available data, TLR hazard ratios were carefully extracted by recreating published Kaplan-Meier curves using the methodology described by Tierney et al.¹³ The number of events and number of patients censored at each time point were estimated from the reported Kaplan-Meier curves and number at risk. When Kaplan-Meier curves were unavailable, ORs were calculated. This was done for the secondary outcomes of PP, major amputation, and death for DCBs at 1 year. Whereas two DES trials met our inclusion criteria, meta-analysis could not be performed on DES trials because of the lack of a consistent comparator between the two trials (ie, BMS or balloon angioplasty). Meta-analysis was performed using Stata 14 (StataCorp LP, College Station, Tex). The random-effects model was used to perform meta-analysis, allowing that the true effect size might differ from study to study on the basis of the characteristics of the patient and lesion.

Decision analytic model. A state transition decision analysis model was used as the primary method to simulate, by index procedure strategy, patency and associated costs. Index procedure options were POBA with bailout stenting, primary BMS, DES, and DCB (with bailout stenting). Several important assumptions were made in our model. First, open surgery (such as bypass surgery) was not an option because the available randomized controlled studies for drug-eluting therapies, from which our clinical parameters are derived, focused on short lesions and primarily Rutherford class 2 and 3 disease, for which a bypass is less likely to be chosen as the primary intervention.¹⁴ In addition, atherectomy was not an index therapy option because of a lack of solid evidence to support its use as a primary treatment strategy in SFA disease.¹⁵ No patients suffered limb loss in the model. Amputations are already known to be extremely costly, there is no evidence that these strategies differ with respect to amputation rates, and amputation was expected to be rare during the short follow-up time of the model.^{12,16}

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