

The Economic Impact of Drug-Coated Balloons in the SFA

From a financial standpoint, DCBs have become the most attractive endovascular option for treating atherosclerosis in the superficial femoral artery.

BY MARK W. BURKET, MD

It is well-recognized that peripheral artery disease (PAD) affects millions of individuals worldwide. In countries with an aging population, and with a growing prevalence of diabetes, there is an even greater growth of this malady. Although it has been common for PAD to be undiagnosed or misdiagnosed in the past, educational efforts by health care workers, professional societies, and industry have enhanced awareness in recent years.¹ Due to an increase in prevalence and awareness, greater numbers of patients with PAD are now being treated. This has led to an increase in financial expenditures related to PAD. In addition to this increase in patients being treated, new therapeutic options have become available, generally at a higher cost than older therapies. Thus, the overall expense associated with PAD is accelerating.

These increasing expenditures come at a time when scrutiny about funds spent on health care has become much more intense. Whereas “safety and efficacy” were the watchwords of the past, these terms are no longer good enough. In the current era, a proposed therapy must also impart value and cost effectiveness. Given the fact that disease of the superficial femoral artery (SFA) is the most common cause of claudication, it is of little wonder that there is now focused interest in determining the most cost-effective strategy for its treatment.

THE COSTLIEST OPTIONS

Although the focus of this discussion is cost effectiveness for endovascular treatment, it is vital to hold minimally invasive options within a broader perspective. Percutaneous therapy is often chosen as an alternative to surgical treatment, as the latter is typically associated with higher expenditures. For example, an uncomplicated femoropopliteal bypass operation produces hospital and physician fee costs of approximately \$20,000.²

Should the procedure be associated with infection or other perioperative complications, the expense would be dramatically higher.

Even worse than this is the option of amputation. Although in some ways this procedure may seem to be a simple and definitive solution to an intractable problem, it is not that at all. Patients have poor functional recovery, with many never achieving ambulatory status again. This is especially true after above-the-knee procedures. Dillingham et al reported that among patients undergoing amputation, 26% required an additional amputation, and 36% had died by 1 year.³ Furthermore, the financial cost is comparatively high, with first-year costs of \$40,000 to \$45,000 and structured rehabilitation doubling that cost.⁴

OTHER STRATEGIES

Of course, the simplest strategy for managing PAD consists of smoking cessation, structured exercise, antiplatelet therapy, lipid-lowering therapy, and cilostazol.⁵ As all three of the mentioned drug classes have become generic, the associated monthly expenditure has become reasonable for many patients. However, if drug side effects or lack of efficacy make conservative therapy untenable, then percutaneous treatment can be a more viable option. A hidden cost associated with medical therapy may lie in the associated physical disability. Patients suffering from intermittent claudication have a significant reduction in function and quality of life and may reduce the ability to sustain gainful employment.

When conservative therapy alone is abandoned, percutaneous options are typically pursued. In the 50 years since Dotter's use of a simple Teflon dilator to open a critical stenosis in the femoropopliteal segment of an elderly woman in 1964, there has been a deluge of devices designed to treat atherosclerotic peripheral arteries.⁶



Figure 1. Nitinol in-stent restenosis.

As new equipment and techniques were introduced into clinical use, they were initially assessed only in terms of their ability to safely restore circulation. As experience grew in the femoropopliteal segment, it became apparent that durability, typically measured by primary patency and target lesion revascularization (TLR), was just as important. It has been less than a decade since intense interest has also been placed on the cost effectiveness of SFA intervention. In recent years, virtually any thorough discussion concerning PAD treatment has included consideration of the economic impact of various treatment options. Given the wide variability in price attached to percutaneous treatment devices, as well as differences in outcomes, it is logical to critically compare therapies when considering health care costs. In essence, the goal is to achieve adequate limb perfusion for as long as possible and as cost effectively as possible.

An important concept in understanding expenditures associated with femoropopliteal intervention is that of commoditization. When products come to market with higher efficacy or other unique features in comparison to existing devices, a competitive edge exists, which allows for higher pricing. In contrast, when multiple vendors offer equipment that is nearly identical, price competition invariably follows. Access sheaths, diagnostic catheters, access guidewires, and simple balloons are examples of products that have become commodities.

Largely because of commoditization, percutaneous transluminal angioplasty (PTA) is a procedure that can be provided at very modest equipment costs. A typical price for a balloon catheter is \$100, a small fraction of what was charged in the 1990s. For straightforward lesions, ancillary equipment costs are negligible, giving

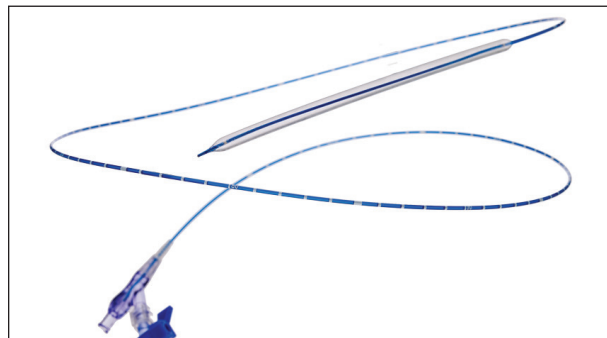


Figure 2. The LUTONIX® drug-coated balloon.

an initial impression that PTA may be an economically desirable option. The hidden cost of angioplasty comes during follow-up in the form of TLR. Studies of PTA outcomes have revealed disappointing primary patency rates, as low as 33% at 1 year and TLR rates in excess of 50% at 2 years.^{7,8} An analysis performed at the University of Toledo Medical Center determined that the estimated 2-year follow-up cost after successful PTA is \$3,915.⁹

The next step up in procedural complexity and expense is associated with placement of a bare-metal nitinol stent, a practice that is commonplace in the current era. Assuming that a “commodity-type” stent is used, which can provide a \$48 higher physician Medicare reimbursement, there is an initial increase in procedural cost of \$748 over PTA, as estimated by the University of Toledo model. The increased cost, however, was shown by the model to be offset by a lower rate of TLR.¹⁰ Although there is no consensus about the optimal therapy to treat SFA in-stent restenosis (Figure 1), some form of ablative therapy, such as laser or atherectomy, is commonly employed, which could drive up the cost per TLR. Using the previously described model, and including the \$748 initial excess, the resultant 2-year cost is estimated at \$3,778, which is slightly less than balloon angioplasty. Thus, the higher procedural cost can be completely offset by downstream savings. This benefit, however, is lost if the stent cost increases by as little as \$200.

With US Food and Drug Administration approval of the LUTONIX® paclitaxel-coated balloon (Bard Peripheral Vascular, Inc.) in October 2014 (Figure 2) and its subsequent commercial availability, as well as the In.Pact paclitaxel-coated balloon (Medtronic), the economic landscape for SFA treatment has notably changed. These devices come at a significant increase in price, yet due to a low rate of TLR and the fact that no in-stent treatment is required in this TLR algorithm, the 2-year total cost is much lower at \$2,827, which is roughly \$1,000 less than the aforementioned options.

The next option is that of paclitaxel-coated nitinol stent placement (Zilver PTX, Cook Medical), also a

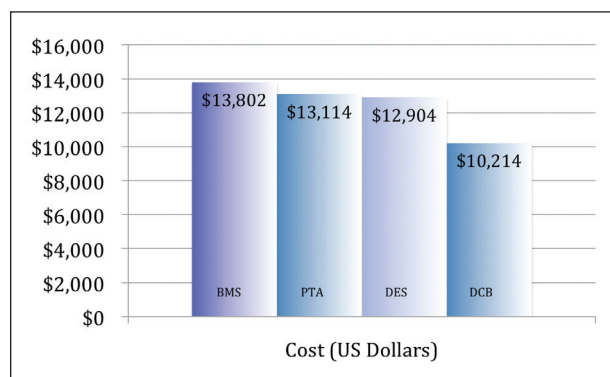


Figure 3. Two-year total cost for various treatment strategies for the SFA. Data derived from Pietzsch JB et al. *Catheter Cardiovasc Interv.* 2014;84:546–554.¹⁰

recent addition to United States health care practices after its US Food and Drug Administration approval in November 2012.¹¹ As with the drug-coated balloon (DCB), the addition of paclitaxel to a nitinol stent was associated with a dramatic reduction in TLR to 13.4% at 2 years. Given the higher TLR expense associated with in-stent restenosis as compared to treatment in the absence of a prosthetic device, the 2-year cost estimate in the University of Toledo model was \$3,288, which is 16% higher than with a DCB.

Among the treatment options that are commonly employed in the SFA, atherectomy is estimated to be the costliest by a wide margin.⁹ Using the average price of popular atherectomy devices and assuming the use of an embolic protection device, this procedure can cost up to \$4,718 more than simple angioplasty. Even if the follow-up expense is moderate, the estimated 2-year cost is more than twice as much as that of a DCB. The initial outlay is so high, in fact, that even if TLR rates were reduced to zero, atherectomy would still be the most expensive treatment option.

MODELING THE EFFECT OF DCBs

Three recent publications have assessed the economic impact of DCBs in various health care systems.^{10–13} Pietzsch and colleagues constructed a model to estimate the 2-year cost for four commonly employed SFA treatment strategies. As with any model, numerous assumptions had to be made about lesion complexity, device cost, patient mix, etc. Notably, the model allows for only one TLR during the entire 2-year period. TLR rates for each of the proposed therapies were derived from a literature review. Within this construct, the lowest total expenditure in the United States was found with DCB therapy, followed by drug-eluting stents (DES) and then simple balloon angioplasty (Figure 3). The most expensive option was treatment with

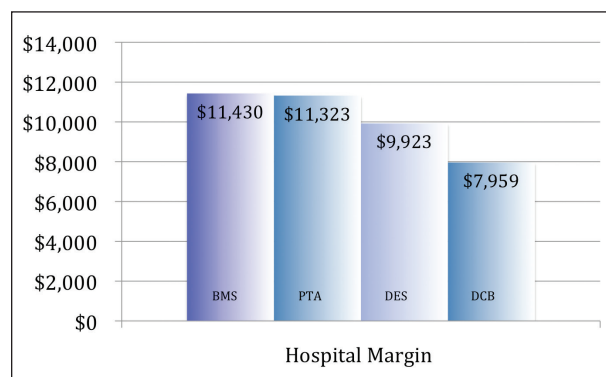


Figure 4. Two-year hospital profit for various treatment strategies for the SFA. Data derived from Pietzsch JB et al. *Catheter Cardiovasc Interv.* 2014;84:546–554.¹⁰

a bare-metal stent (BMS). The same ranking was found in the German health care system. Ironically, hospital profit was exactly the opposite: lowest with DCBs and highest with BMS procedures (Figure 4). Thus, when considering financial incentives, payers (Medicare, private insurance, self-pay patients) benefit most from DCB treatment, whereas hospitals profit most from bare stents.

Diehm et al found that nearly identical forces come into play in Switzerland.¹² They constructed a model similar to Pietzsch et al, using a literature review to estimate TLR. A comparison of simple PTA to DCB therapy showed that the latter was associated with lower cost. As with the United States and German models, Swiss hospitals and physicians saw more financial benefit from PTA.

A British model confirmed these findings in yet another health care system.¹³ In this study, a wide variety of treatment options was entertained: PTA, PTA with bailout DES, DCBs, DES alone, BMS, brachytherapy, and stent grafts. As with every other model discussed so far, the lowest cost was found with DCBs. The next best option was PTA with bailout DES.

THE PROBLEM OF INCENTIVES

Under ideal circumstances, the financial incentives of patients, health care providers, and payers would be identical. As the previous discussion has made clear, these incentives are not just poorly aligned; in some cases, they are polar opposites. Historically, hospitals have made the most money on the therapies that make the least financial sense. The same can be true for United States physicians, who are reimbursed more liberally for atherectomy (the costliest option) than for DCB use (the most economical). In addition, both hospitals and physicians profit from TLR, which payers and patients wish would never happen. Significant efforts have been made to correct this misalignment. A step in the right direction was made when

Medicare agreed to reimburse hospitals at a higher rate when DES were used on inpatients. The same practice for outpatient procedures would be logical, but has not yet been accomplished. This is especially important because most femoropopliteal interventions are performed as outpatient procedures. Medicare did, however, take a major step forward by approving a pass-through for outpatient DCB use effective April 1, 2015. Initially, this provided a limited incremental payment to the hospital for the first DCB, with full reimbursement for additional DCB use. In June 2015, the Medicare position was changed to an even more favorable one, in which the full cost of all DCBs was paid to hospitals, retroactive to April 1, 2015. This largely eliminates financial disincentives for DCB use and represents a huge benefit to patients. As of August 2015, and going into effect on October 1, 2015, Medicare approved an add-on payment for DCBs under the Medicare hospital inpatient prospective payment system to help cover additional costs incurred by hospitals treating Medicare beneficiaries with this product.

SUMMARY

Among the wide variety of options to treat atherosclerosis of the SFA, the lowest cost appears to be associated with DCBs. This observation applies across multiple health care systems. Adequate reimbursement from payers for DCBs (and DES) encourages providers in supplying optimum care. ■

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