Why Drug-Eluting Stents Are Cost Effective in the Superficial Femoral Artery

The importance of cost effectiveness in health care is accelerating. Implanting drug-eluting stents in the superficial femoral artery may offer a safe, effective, and economically valuable solution.

BY MARK W. BURKET, MD

Consideration of cost and value has entered the field of medicine in an unprecedented fashion in recent years. As never before, concern over health care affordability pervades political rhetoric, corporate analysis, and family budgets. In the United States and elsewhere, the availability of more varied and expensive treatment options has fostered a situation in which health care costs consume a greater and greater proportion of the gross domestic product. This process has occurred simultaneously with economic slowdown in the United States and other countries, compounding the pain. It has become clear to any serious analyst that this is an unsustainable formula. It is therefore not surprising that treatment options are held to a higher standard than in years past. No longer is "safe and efficacious" sufficient; therapy must now provide value in measurable economic terms.

Although these principles apply in all fields of medicine, intense interest has recently been focused on the application of drug-delivering balloons and stents in the lower extremity vasculature. With US Food and Drug Administration (FDA) approval of the Zilver PTX stent (Cook Medical, Bloomington, IN) on November 14, 2012, it is hard to imagine a more relevant time for these discussions. Regulatory agencies in certain countries outside the United States had already approved this paclitaxel-eluting stent, as well as paclitaxel-coated balloons. Thus, health care providers have been grappling with the issues of cost and value of paclitaxel delivery for several years.

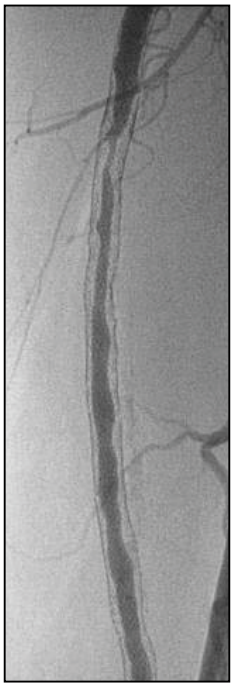

Figure 1. Bare-metal nitinol in-stent restenosis.

WINNERS AND LOSERS?

The efficiency of paclitaxel-coated stents in reducing restenosis is no longer a subject of debate.[1] By 24 months, the reduction in reintervention rates was 54% compared to bare-nitinol stents.[2] At first glance, a reduction in restenosis (and target lesion revascularization [TLR]) may seem to be a good thing for all involved parties. But this may not be the case. Without question, patients are the beneficiaries of coated stents. When this therapy is used, there is a lower chance of restenosis. This means that the patients may avoid recurrent painful symptoms, restriction of activity, and the inconvenience of returning for testing and treatment. If additional procedures are avoided, patients also completely sidestep any additional expenses and the potential for procedural risk. Winners indeed.

The next big winner is whoever foots the bill for TLR. This may be any or all of the following: Medicare, private insurance companies, or the patient. Each case of revascularization that doesn't occur represents 100% savings to those who would have paid.

For the physician, the effects of this new technology are mixed. On the one hand is the satisfaction that comes from knowing that optimal care has been delivered, providing the best chance of a favorable outcome. In economic terms, however, the physician may become a loser. Physician payment is the same for drug-eluting stent placement as for bare-metal stent placement. By passing up on a possible repeat

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intervention, the interventionist also passes up on any potential fee for service. Even in systems where doctors are salaried, their income may be tied to procedural volume. For physicians in training, a reduction in cases of restenosis translates into less hands-on experience, especially in those techniques closely associated with TLR, such as atherectomy, laser, embolic protection, and covered stent placement.

At first glance, paclitaxel-coated stents may represent an economic hardship for hospitals. The price premium for these stents is approximately 33% when compared to bare-metal stents of comparable size. Fortunately for hospitals, this premium is quite modest compared to what was seen with coronary drug-eluting stents when they were first introduced. At that time, the associated price premium was approximately 170%.[3] In striking contrast to what happened in 2003 with the advent of drug-eluting stents for the coronary arteries, Medicare is tracking peripheral DES usage with a special code to consider supplemental reimbursement in the future, and has not yet made provision to reimburse hospitals at a higher level for the use of drug-eluting stents in the femoral artery. Thus, the price premium, although more modest than that seen a decade ago, falls on the shoulders of the hospital budget.

Hospitals take a second hit financially in that the loss of TLR cases represents a loss of revenue. In essence, the more effective an antiproliferative therapy is, the more potential revenue the hospital loses.

The financial impact on hospitals for adopting drug-eluting stents may not be all negative. Hospitals that offer treatment with coated stents will clearly have an edge in marketing their services to savvy customers who appreciate the definite benefit offered in terms of less restenosis. This provides the potential of growth in patient volume. Encouraged by the possibility of better outcomes, physicians may also be willing to perform interventions on patients who would have been managed medically in the past. Reimbursement models are in rapid flux, with a clear emphasis on tying outcomes to reimbursement, such as is seen in heart failure, myocardial infarction, and pneumonia. Drug-eluting technologies fit well into these efforts to align incentives among payers, caregivers, and patients. This strategy is perfectly consistent with the accountable care organization (ACO) model.

COST ESCALATION TO TREAT RESTENOSIS

One of the most underappreciated aspects of femoropopliteal intervention is the degree to which treatment cost increases on second and subsequent procedures. Nearly everyone who treats peripheral vascular disease has an appreciation for the diffuse nature of atherosclerosis affecting the femoral artery. Similarly, it is common knowledge that mechanical stresses on this vessel can lead to stent disruption and loss of patency. These characteristics result in some of the highest restenosis and reocclusion rates of any commonly treated vessel (Figure 1). What is surprising is the void of knowledge that exists about the cost of treatment.

Few interventionists can cite the cost of initial or subsequent treatment of femoropopliteal disease with confidence. We have evaluated representative costs in our institution (University of Toledo Medical Center) and have found that for a typical, straightforward angioplasty and stent placement, the cost is approximately $7,000 to $8,000. These figures are based on actual hospital cost (not charges), plus calculated overhead for such things as nursing care, housekeeping, utilities, etc. Physician reimbursement at Medicare rates is included. Costs change extensively based on patient, physician, and hospital variables. Transatlantic Intersociety Consensus (TASC) type D disease treatment consumes much more interventional equipment than a simple type A stenosis. Physicians may prefer angioplasty, stent placement, or atherectomy as a primary treatment strategy, with progressively increasing costs.

Until recently, the dramatic escalation of cost to treat in-stent restenosis has been unappreciated. Increases come at nearly every phase of reintervention. There is wide variation among operators with

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regard to treatment strategies, but most United States operators will choose a method other than balloon angioplasty as the initial treatment. In every case, anything other than balloon angioplasty is much more expensive. In the current era, balloons have become commodities, with prices now typically around $150, a fraction of what they were in the past. In contrast, devices used to debulk in-stent lesions have price tags that are approximately 20 times as high. Prices vary with individual hospital contracts, but approximate costs for debulking tools range from $2,400 for a simple laser catheter (with an extra $500 for the "Turbo Booster" option) to about $3,200 for directional atherectomy or Jetstream atherectomy catheters (Bayer, Warrendale, PA). With any of these options, it has now become commonplace to use embolic protection devices, which cost roughly $1,650.[4] Cutting or scoring balloons may also be used to disrupt the integrity of neointimal hyperplasia, rendering it more amenable to final treatment.

Debulking is viewed by many operators as necessary but not sufficient to fully treat in-stent restenosis. After debulking, some operators choose to reline the vessel with bare-nitinol stents, although there are significant concerns about the durability of this approach. Rarely is it possible to limit stent length to what was originally used. Often, more or longer stents are used, bringing a higher stent cost on repeat procedures as well as worse outcomes that have been associated with adding more stented length.[5] Another popular approach has been to debulk the restenosis, then reline the vessel with a polytetrafluoroethylene (PTFE)-covered stent. This was the basis of the SALVAGE trial (A Prospective, Multicenter Trial to Evaluate the Safety and Performance of Spectranetics Laser With Adjunct PTA and Gore Viabahn Endoprosthesis for the Treatment of SFA In-Stent Restenosis), initiated by VIVA Physicians, Inc. In this study, laser treatment was followed by placement of Viabahn PTFE-covered stent grafts (Gore & Associates, Flagstaff, AZ). Viewed from a financial perspective, this treatment carries a huge cost, as stent grafts cost in excess of $3,000 apiece. In SALVAGE, 27 patients were enrolled, compared to an original target of 100.[6] One-year primary patency (based on a peak systolic velocity ratio of 2) was 48%.

These examples highlight how rapidly cost escalates with repeat femoropopliteal intervention. Not only is the price of each piece of equipment a multiple of the simpler initial tool, but these more expensive devices are typically used in combination, exponentially driving up cost. For the most part, these aggressive strategies lack clinical trial results proving efficacy. Although they seem logical, they are unproven.

WORST CASE SCENARIOS

Most physicians familiar with treating femoral disease has had the experience of treating patients with repeated episodes of treatment failure. Initial intervention is followed by restenosis or occlusion, prompting a second, more complex procedure. This may then fail in a shorter time interval, initiating what amounts to a cascade of events, with repeated interventions of increasing difficulty separated by shorter and shorter times. Robinson has shown that early failure is predictive of additional failure.[7]

The outcomes of these cascades are uniformly unfavorable. Some patients will be left with continued symptoms from chronic occlusion. Others will require bypass surgery, with hospital costs far in excess of percutaneous procedures. We recently reviewed the cost of repeat interventions in our hospital, for example, and found that a representative case in which bypass surgery was required carried an actual hospital cost (not charge) of $11,035. When coupled with unavoidable overhead costs (eg, nursing services, housekeeping, utilities, etc.) of $6,747 and physician Medicare reimbursement of $1,540, the total came to $19,322. Because this price is added to all previous percutaneous treatment, it clearly highlights an onerous cumulative cost. Furthermore, this assumes an uncomplicated hospital course. When wound infection or other untoward events occur, this burden is increased in multiples.

Even worse than all of the previously described scenarios are those that end in amputation. Although on first glance this may appear to represent a solution to intractable vessel occlusion, it comes at a horrific cost. Dillingham found that of patients who underwent

amputation, 26% required an additional amputation, and 36% had died by 1 year.[8] Major amputation is associated with first-year costs of $40,000 to $45,000, with structured rehabilitation doubling the cost.[9] It is clear that whereas the operative procedure may appear simple, the financial and functional fallout is awful and should be minimized if at all possible.

AN OUNCE OF PREVENTION

If the ancient adage "an ounce of prevention is worth a pound of cure" applies in any medical context, it certainly does in the treatment of the superficial femoral artery. What the previous discussion has shown is that the cost of retreatment of this vessel dwarfs the cost of the first procedure. Any mechanism by which a second procedure can be avoided multiplies financial savings. The Zilver PTX stent has been shown to reduce TLR by more than 50%, at a cost premium of approximately 33%. Therefore, for a relatively modest increase in purchase price, extremely expensive follow-up care may potentially be avoided.

It may be helpful to put this topic in the context of coronary artery disease. When drug-eluting stents first became available, the associated price premium was approximately 170%. Despite this cost increase, studies have supported their cost-effectiveness.[10] At the same time, treating coronary in-stent restenosis is typically relatively straightforward. Unlike femoral in-stent restenosis treatment, there is almost never use of laser atherectomy, embolic protection, or stent grafts. Thus, coronary drug-eluting stents came at a strikingly higher price premium than their femoral counterpart, preventing a problem that is much easier and cheaper to treat and yet still had favorable economics. How much more favorable is a stent that comes at a lower incremental cost and effectively prevents the need for exceptionally expensive treatment?

SUMMARY

With FDA approval of the Zilver PTX stent, physicians have received an effective tool to help minimize one of peripheral intervention's most vexing and costly problems. This can bring substantial economic and quality-of-life value to patients and has the potential to reduce overall expenditures in the management of peripheral arterial disease. ■

Mark W. Burket, MD, is Chief, Division of Cardiovascular Medicine, University of Toledo Medical Center in Toledo, Ohio. He has disclosed that he receives research support and is a speaker for Cook Medical and receives research support and serves as a consultant to Biotronik. He has also disclosed that he receives research support from Bard and serves as a consultant to Gore & Associates and Abbott. Dr. Burket may be reached at (419) 383-4087; mark.burket@utoledo.edu.

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