Restenosis and the New Health Care Economy

The cost of freedom from restenosis and repeat intervention.

BY MARK W. BURKET, MD

When Charles Dotter initiated the revolutionary practice of percutaneous treatment of arterial blockages in 1964, his first target was the femoropopliteal segment in an elderly woman.[1] Nearly 50 years later, this arterial segment remains the focus of many procedures and research trials. Options for therapy have multiplied, with a dozen or more choices available to interventionists. Devices have often received FDA approval based on relatively small clinical trials, and for many procedures, long-term outcomes are uncertain. Few published studies report results of randomized trials comparing different devices in large patient cohorts, and even more rare is information pertaining to the long-term financial impact of selecting a particular option.

In a world of contracting resources and reimbursement, in which monetary issues grow increasingly important, the best question for a specific therapy is, "What is the long-term cost of this option?"

MEDICAL CONFERENCES AREN'T MEDICAL ANYMORE

A decade ago, medical conferences featured disease states and their diagnosis, prognosis, and treatment. Interventional meetings focused on clinical syndromes, imaging techniques, and how to accomplish the technical aspects of corrective procedures. There was ample discussion about a seemingly endless array of new devices to accomplish the goal of rectifying a pathologic process. The cost associated with these devices was typically a footnote, if it was considered at all. Physicians—those who determine what procedures would be done and what equipment would be employed—paid little or no attention to the cost of material. The magnitude of hospital charges for a trip to the interventional suite was a complete unknown. If money came into the discussion at all, it was usually in the context of teaching interventionists how to report and bill procedures properly to ensure that professional fees were commensurate with the work performed.

Those days are gone. In the current era, there is not a day that passes in any medical center without abundant discussion about revenue and expenses, and these talks are not limited to hospital administrators. At meetings that were previously purely medical in scope, it has become commonplace to include the costs associated with diagnostic testing, drugs, and other treatment options. As early as during medical school, students are becoming educated about generic drug savings, eliminating unnecessary testing, and how Medicare pays hospitals. The same applies to regional and national interventional meetings, where themes such as "value," "cost effectiveness," and "cost neutrality" are integrated into discussions that were formerly purely technical in nature.

ARE WE ASKING THE WRONG QUESTIONS?

As focus narrows from health care in general to peripheral vascular intervention, and even more specifically to the femoropopliteal segment, it quickly becomes obvious how limited health care professionals are by a paucity of good clinical and economic information. In order to make good choices, there is a need for good data, and good data only arise from asking the right questions.

In a world of contracting resources and reimbursement, in which monetary issues grow increasingly important, the best question for a specific therapy is, "What is the long-term cost of this option?" Placing that question at the forefront has an impact on trial design—on what treatments will be compared and what will be the primary endpoint.

In many femoropopliteal interventional trials, especially of stents, the primary efficacy endpoint has been primary

TABLE 1. THE IMPACT OF EQUIPMENT COSTS ON HOSPITAL PROFIT/LOSS CALCULATIONS[a]

Scenario	"Cheap" stent	Two PTFE stents	Three woven stents
APC	$8,109	$8,109	$8,109
Stent(s)	-$700	-$6,990	-$5,550
Balloon (1 or 2)	-$98	-$300	-$600
Crossing Catheter	N/A	N/A	-$115
Re-entry Device	N/A	N/A	-$2,400
Remaining	$7,311	$819	-$556

[a]Costs are actual purchase price figures for the University of Toledo Medical Center. The APC is the standard CMS value for outpatient femoral artery angioplasty and stent placement received by the hospital in 2013.

patency, often at the 6-month or 1-year mark.[2-5] This endpoint is helpful in that it allows meaningful comparison between balloon angioplasty and the stent in question. The comparison can be in the form of a randomized controlled trial, or by comparing stent patency to the benchmark of angioplasty patency derived from a variety of trials.[6]

Patency results are helpful in comparing stent treatment to angioplasty or in comparing one stent to another, but they produce no direct information about cost. Restenosis rates are determined, but it is important to recognize that there is no cost associated with restenosis. In financial terms, restenosis is free. No expense is incurred until restenosis is treated; that is, when target lesion revascularization (TLR) occurs.

Investigational trial designs that use restenosis (or its counterpart, primary patency) as the primary endpoint may prove helpful in the process of obtaining approval from the Food and Drug Administration (FDA). In the past, FDA approval virtually guaranteed payment from the Centers for Medicare & Medicaid Services (CMS) for procedures involving these devices. More recently, it has become obvious that this guarantee cannot be assumed. The most notable recent example has been with systems involving carotid stents and embolic protection devices: safety, efficacy, and equivalence to alternative therapies have been proven and FDA approval has been granted, but CMS only provides payment in a carefully regulated, small subset of treatable patients. The paclitaxel-coated Zilver PTX stent (Cook Medical, Bloomington, IN) received FDA approval in November 2012, allowing it to become commercially available. On August 2, 2013, CMS approved an add-on payment to hospitals when the device is used during an inpatient procedure. At present, hospitals do not receive extra payment when the Zilver PTX stent is used on an outpatient basis, which is how the majority of procedures are performed.

In economic terms, what matters is TLR. It is with repeat intervention that additional cost is incurred. Trial design with a primary endpoint of TLR, such as the recently published RESILIENT trial, provides the most helpful information in economic terms.[7] Knowing the TLR rate, as well as the cost for repeat procedures, allows for the calculation of long-term cost.

Meaningful financial comparisons can be derived if TLR rates are known for different devices or therapies. This information stands out as more important than the cost of initial therapy. An expensive treatment with TLR rates similar to cheaper options should be abandoned; on the other hand, an expensive device may prove to be a bargain if it results in significantly lower rates of TLR.

CAN INCENTIVES BE ALIGNED?

"Broken," "expensive," and "inefficient" are adjectives often used to describe health care delivery in the United States. A contributing factor is the poor alignment of financial incentives between the parties involved; at times, different participants have opposing objectives. Shared objectives can't solve every problem, but they could go a long way to help. Looking at the motivations of various stakeholders is a helpful starting point.

For a patient with full insurance coverage, the most durable treatment is desired, regardless of cost. However, for the payer (eg, self-pay patient, CMS, or insurance company) the ideal treatment strategy is the one that entails the lowest long-term cost. This means that a higher initial treatment cost is completely acceptable, provided it is for a durable treatment that incurs lower expenses in the future.

When physicians receive a salary based on relative value units (RVU) or under a fee-for-service model, they are economically incentivized to perform the largest number of procedures possible, each of which carries the

highest compensation or RVU. Physicians are ethically obligated to pursue the most durable result by the most economical means, but there is no direct financial motivation toward that end.

When hospital economics enter the picture, conflicting incentives become strikingly apparent. The financial wellbeing of the hospital is enhanced by incurring the lowest possible equipment cost per procedure. Hospital administrators seek to provide no money-losing interventions, while at the same time performing the highest number of profitable procedures.

Understanding payment schemes to hospitals helps to clarify this mentality. In the case of femoral artery percutaneous interventions, most CMS payments come in the context of the Ambulatory Payment Classification (APC), a fixed payment for a specific type of procedure. When the physician completes the procedure using a minimal amount of inexpensive equipment, the hospital is left with a surplus. From this surplus, the hospital can pay for the additional supplies used in the procedure, staff salaries, and hospital overhead. What is left over is profit.

Table 1 is based on the 2013 APC for femoral artery angioplasty and stent placement. Equipment costs are based on actual costs to the University of Toledo Medical Center, rather than list prices; there will undoubtedly be some variation in cost between health care systems. In the first scenario, in which the most economical nitinol tube stent is used in conjunction with a low-priced peripheral balloon, the hospital has $7,311 left over to pay for all additional equipment and overhead. In the second scenario, which assumes operator choice of two 15-cm, PTFE-covered stents, as well as a more expensive balloon, the surplus shrinks dramatically. The third scenario, which is not uncommon for long, calcified femoral occlusions, includes three woven wire stents, two balloons, an end-hole crossing catheter, and a re-entry device to accommodate for a distal subintimal guidewire position. In this setting, the hospital has already spent more on equipment than it will receive from CMS. There is no mechanism to recoup the loss.

Given these realities, it is little wonder that hospital administrators have scrambled to contain the cost of equipment. Consequently, there has been the rapid spread of regulatory committees in hospitals throughout the country. They carry various names, such as "Value Added Committee," and have variable memberships, but their goal is always the same: restrict the inflow of devices available to physicians. It is a truism that if expensive equipment is kept off of the interventional lab shelf, it won't be used in procedures. In addition, hospitals have continuously endeavored to negotiate with suppliers to achieve the lowest possible device cost.

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It is apparent that the parties giving, receiving, and paying for health care services do not have the same financial incentives. No problem arises when a new therapy is both more effective and less costly, a so-called "dominant" treatment in cost-effectiveness terms;[8] all groups will favor adoption. There will be increasing pressure to abandon treatment options that are more costly, but have not been proven to be more effective. Perhaps the most challenging situation, and one that is not uncommon, is when a new option is both more effective and more costly. Examples in the femoropopliteal segment include paclitaxel-coated balloons and paclitaxel-coated stents. Both have been shown to be more effective (in terms of TLR) than their uncoated counterparts.[9,10] As mentioned previously, CMS has approved higher hospital payments when the Zilver PTX drug-coated stent is used for inpatient procedures. There is no such provision for the more common outpatient use of this stent, nor is there any assurance that drug-coated balloons will trigger higher payments. Thus, from a purely economic perspective, hospitals may resist the adoption of paclitaxel technologies. As CMS and other payers offer more compensation to hospitals to use these devices, motivation will be provided and incentives will become aligned.

AVOIDING TLR LIKE THE PLAGUE

The key to understanding femoral artery economics is to recognize the staggering cost of TLR, especially for in-stent restenosis. When this is appreciated, several additional facts become clear. First, it is worth going to great lengths to avoid TLR. Second, therapy proven to avoid TLR accrues major economic benefit over time, and it makes sense to pay more for this therapy than for one that has an unknown effect on TLR or is known to have a higher rate. Finally, in the current era, it makes little sense to design a clinical trial for femoropopliteal treatment that does not allow for comparison of TLR rates of the new therapy versus comparable modalities. Without proof of lower TLR, it is nearly impossible to justify paying a higher price for the new device or technique, regardless of the acute results.

It is important to be cognizant of the differences between femoral artery reintervention and that which

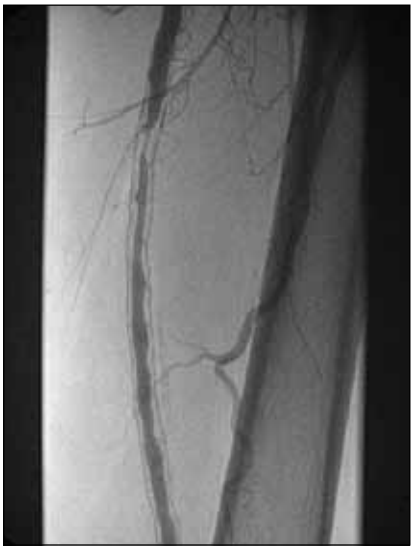

Figure 1. ISR in a nitinol stent.

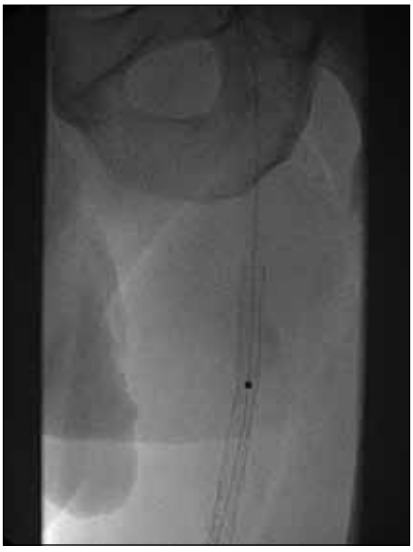

Figure 2. Excimer laser debulking within femoral ISR.

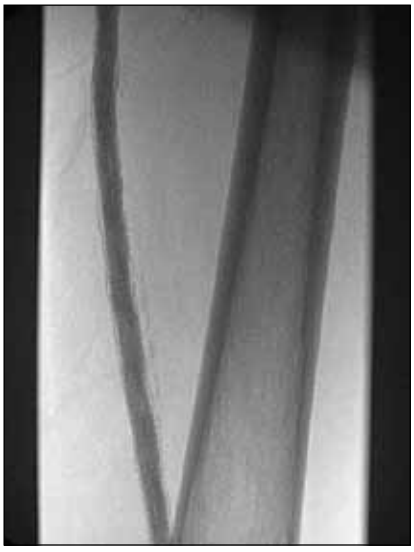

Figure 3. A restenotic femoropopliteal segment after treatment with a PTFE-covered stent.

occurs in other vessels. For example, if a coronary stent develops restenosis, the standard therapy is to introduce a new drug-eluting stent inside it. The cost of a second intervention is typically comparable to the index case. In this setting, no thought is given to embolic protection, a PTFE-covered stent, or laser, directional, or rotational atherectomy. In contrast, any of these modalities may be considered in the setting of femoral in-stent restenosis (Figures 1 through 3), and each carries a cost that can be measured in multiples of that of the lowest-priced nitinol stent. We evaluated the actual hospital cost (not charge) in our institution of typical cases of treating in-stent restenosis, and found it to be approximately $10,000. Thus, avoiding even a single case constitutes a notable savings. However; this is not as simple as preventing a single episode of TLR because one failure is often predictive of a second, the second a third, and so on;[11] costs become rapidly additive. The process sometimes culminates in femoropopliteal bypass surgery, with a cost of approximately $17,000.

CONCLUSION

While in the past, the discipline of endovascular intervention focused almost entirely upon technical aspects, cost and value carry equivalent importance in the current era. Low TLR rates impart value in any vascular space, but particularly in the femoral artery, where the cost of repeat procedures escalates exponentially. One of the best ways to assess the relative value of therapies is to know how their TLR rates compare to one another. In the femoropopliteal space, new devices have often received FDA approval and CMS reimbursement without convincing TLR data to support their use. From the standpoint of payers, who appear to have an increasing degree of sovereignty in the practice of medicine, it makes sense to pay more for treatments with proven low TLR and to neglect those lacking such proof. ■

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