Dr. Rastan and colleagues are to be congratulated for performing a well-designed multicenter, prospective, randomized, controlled trial comparing primary stenting with provisional stenting for moderate-length (≈42 mm) popliteal artery stenoses in primarily claudicators (79%) with one third having total occlusions. The Endovascular Treatment of Atherosclerotic Popliteal Artery Lesions—Balloon Angioplasty Versus Primary Stenting (ETAP) trial confirms, for what seems to be the bazillionth time, that provisional stenting, properly performed, achieves functional and patency outcomes equal to those of primary stenting. This has been shown for femoral lesions in multiple trials that often included lesions extending into the popliteal artery, and now it has been shown for the isolated popliteal disease. Although not reported in this article, we would expect a cost analysis to demonstrate that provisional stenting, for appropriate indications, would be resource sparing compared with primary stenting.

The popliteal segment was thought to be a hostile environment for stents as a result of repeated flexion, extension, and torsion at the knee joint, but this trial and others have dispelled that myth. As always, there is the caveat that total occlusions and longer, more complex lesions are more difficult to treat with endovascular techniques. This was confirmed by ETAP, with a multivariate logistic regression analysis revealing target lesion length (<30- versus >60-mm lesion length; odds ratio, 0.26; 95% confidence interval, 0.09–0.68; \(P=0.007\)) and total occlusions (stenosis versus occlusion; odds ratio, 0.39; 95% confidence interval, 0.18–0.87; \(P=0.02\)) as independent predictors of restenosis.

However, this study and many others like it fail to provide the clinician the information that he or she really needs to manage symptomatic popliteal arterial disease. Clinicians need to know which stent offers the best outcomes for patients. Of the many femoral-popliteal stents available, are there any that offer better outcomes or fewer complications than their competitors? We will never know this information without head-to-head stent trials.

This seems like a no-brainer. Would the need to demonstrate a competitive advantage for a stent not be self-evident to medical device industry executives? If a company develops or acquires a new stent design that is fracture resistant, is coated with a new drug to reduce restenosis, or has some other feature that gives the stent a theoretical advantage over its competitors, would that company not want to demonstrate the value of this stent by showing it to be superior to its competitors, thereby justifying its market share and a premium price? Why have companies not competed for the top spot in femoral-popliteal stents? Could it be that they lack confidence in winning a direct comparison with another stent? In direct-comparison medical device trials, there are 3 outcomes: win, lose, or draw. Unfortunately, the medical device industry considers 2 of these outcomes, losing or tying, to be bad for business, and they do not like those odds.

Despite manufacturers’ protestations of an excellent and superior product, no companies seem willing to put their money where their marketing is. No company does head-to-head comparator trials because there has been no requirement to do so. Medical device companies have avoided the ignominy of spending their own money on a clinical trial that proves that their stent is disadvantaged. How have they avoided the need to demonstrate value? Although the wholesale purchasers of these devices are hospitals, which then resell the devices at retail rates to third-party payers, it is actually the physician who plays the dominant role in selecting which device a hospital purchases. Hospitals have been able to pass these increased costs onto third-party payers and therefore have not been as sensitive to the costs of devices as they should be. Hospitals that do not provide the favored devices of a physician find that the physician will take his patient to a hospital that will provide his or her preferred equipment.

Why would physicians demand to use more costly devices without objective evidence of some patient-related outcome advantage? Well, it would appear that some of us are lazy, some of us are gullible, and some of us are conflicted. By lazy, I mean that some physicians may not take the time to educate themselves on the various properties, costs, and peer-reviewed data on a specific device, relying on information provided by vendors. By gullible, I mean that some physicians may be seduced by compliments from the sales force or duped by pseudoscientific marketing information into using a more expensive device when a less expensive one would do just as well. By conflicted, I mean that a physician’s decision making about which device to use may be influenced by factors that are not directly related to patient...
outcomes. One such factor could be the self-serving personal aggrandizement of using the latest and greatest equipment, even if it is not better than what it replaced. Performance issues such as one device being easier to use but not measurably improving outcomes may play a role. In addition, research interests might reasonably influence equipment choices. Finally, there have been rare reports of physicians using or promoting medical devices for personal financial gain. The medical device industry has become very facile at exploiting these lazy, gullible, or conflicted physicians to encourage hospitals to purchase medical devices that have never been required to demonstrate value.

The good news for healthcare consumers is that this lack of comparative data commoditizes the femoral-popliteal stent market, so price becomes the only product differentiator that matters. Why pay a higher price without receiving measurable value in return? This is the lesson that is finally coming to US hospitals as cost reduction, rather than increased revenues, becomes the only way to survive the fiscal constraints imposed by healthcare reform. With reduced reimbursement, it is becoming very difficult for hospitals to increase productivity (ie, to encourage overuse) to balance their budgets. Their only alternative is to deeply slash expenses. As hospitals look for ways to cut costs, they will increasingly look for classes of devices that can be treated as commodities and then simply look for the low bidder. This concept of value-based purchasing will revolutionize the way that American hospitals do business and will be transformative for the medical device industry. Never before has industry had to sell its products in such a price-sensitive market. Yet, here manufacturers are, stuck with mountains of noncomparative data, none of which demonstrate the value of their device relative to their competitors’ less expensive device. This will finally force stent manufacturers, which want to charge a premium for their device, to demonstrate improved outcomes. Currently, there does not appear to be a large difference in outcomes among the multitude of femoral-popliteal stents. It follows that the process of commoditizing these expensive devices will assist in lowering healthcare costs.

Disclosures

None.

Reference


Keywords: Editorials • peripheral arterial disease • stents
Brave New World: Value-Based Purchasing for Peripheral Vascular Stents Is Coming to a Hospital Near You
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Circulation. 2013;127:2475-2476; originally published online May 21, 2013;
doi: 10.1161/CIRCULATIONAHA.113.003491
Circulation is published by the American Heart Association, 7272 Greenville Avenue, Dallas, TX 75231
Copyright © 2013 American Heart Association, Inc. All rights reserved.
Print ISSN: 0009-7322. Online ISSN: 1524-4539

The online version of this article, along with updated information and services, is located on the World Wide Web at:
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