

EDITORIAL COMMENT

Incentives for Clinical Decisions Where Evidence Is Lacking*



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There is concern that much of health care spending in the United States is wasteful given the poor correlation between cost of care and patient access, outcomes, and satisfaction. Hospitals are the usual targets for reducing unnecessary spending, given the large percentage of care provided to inpatients. Medicare often has succeeded in lowering hospital expenses through interventions such as paying hospitals a single lump sum for an episode of care (diagnostic-related group for hospitalization), penalizing hospitals for “excess” readmissions, and paying less for inpatient procedures if they can be performed in the outpatient setting. However, physicians control much of the cost of care through their treatment decisions, and the wide variety of physician incentives in place today makes it difficult to predict future resource use. The study by Jones et al. (1) in this issue of the *Journal* demonstrates how this physician “wild card” can change the balance sheet dramatically.

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The authors note that their study of peripheral vascular interventions (PVI) for peripheral arterial disease (PAD) was prompted by Medicare’s decision to increase reimbursement for outpatient PVI to reduce the number of inpatient procedures. They found that this change by Medicare had the intended effect of decreasing inpatient use. However, it also was followed by a large increase in the use of the more expensive atherectomy procedure. Overall costs were likely lower than without the change in reimbursement, but the rise in atherectomy use was likely unexpected and unintended.

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PAD has been a focus of Medicare given its high prevalence (15% to 20% among those patients >70 years of age) and the high cost of PVI. Over the past decade, there has been a large increase in the use of PVI. However, lower extremity disease has many challenges for percutaneous procedures including frequent chronic total occlusions and diffuse atherosclerotic burden. The limited technical ability of balloon angioplasty to improve these lesions has led to the development of new technologies using atherectomy. In the last few years, a large number of atherectomy-based technologies have been developed to improve the ability to open chronic total occlusions.

Unfortunately, there are limited data comparing the endovascular options, so we do not yet know which procedure is best for which patient. A 2010 systematic review could not find a significant clinical benefit of stenting compared with angioplasty, although technical success was higher with stenting (2). In 2014, the Cochrane Review identified only 4 small randomized trials of atherectomy for PAD (3). They concluded that the data were poor and that “there was no evidence for superiority of atherectomy over angioplasty on any outcome” (3). Given the limited data, it is perhaps not surprising that clinical practice guidelines for PAD are silent on which form of PVI to use. The recently created appropriateness criteria for treatment of PAD also do not provide guidance for use of atherectomy or other forms of PVI (4). They note that there were no controlled studies showing improvement in long-term patency or clinical outcomes with atherectomy.

If clinical trials are lacking, then what is the cause of the increase in atherectomy use? Some would argue that financial incentives will fill any outcome data vacuum. As the authors note, Medicare reimbursement rates have provided a clear incentive for practices to increase the use of outpatient procedures. However, physicians performing the procedure in hospital also have a financial incentive to perform atherectomy. For femoral/popliteal atherectomy

performed in a facility, Medicare pays the physician approximately \$650 for atherectomy, \$530 for stenting, and \$480 for angioplasty alone. The difference in facility fees between atherectomy and angioplasty is significantly greater, although it is unclear to what extent Medicare reimbursement is higher than actual practice cost.

An increase in Medicare reimbursement is usually followed by an increase in use. A study using Medicare price changes found that, on average, a 2% increase in reimbursement leads to a 3% increase in use (5). The effect of reimbursement on use was greatest for elective procedures, such as coronary angiography, and would likely apply to atherectomy in PAD.

However, there are noneconomic factors at work that may be even more important. A desire to be at the forefront of one's specialty is part of the culture for most physicians, and being proficient in the latest technology is highly desirable for specialists. Others have documented the importance of culture on resource use for generalists as well. Internists and family practitioners were more likely to order non-recommended cancer screening, see patients more frequently, and be more aggressive in ordering tests if they resided in areas of the country with a high spending "culture" (6).

The hospital or practice has its own economic incentive even if it is not felt by the individual physician. Patients often associate quality and best outcome with available technology. As with robotic surgery, hospitals and practices are often advertising their ability to provide the latest endovascular technologies.

Some will say that capitation will solve this problem, as physicians will no longer increase income by doing more expensive procedures. However, in the past, the economic effect of managed care capitation has been small. In a survey from 10 years ago, managed care only had small effects on the intensity of ordering tests when compared with other physician characteristics, such as board certification (less ordering), years in practice (more years, more ordering), and size of group (larger group, less ordering) (7).

Physicians should not be expected to choose the most cost-effective treatment for society. Both a lack of knowledge and a discomfort with making decisions on the basis of cost effectiveness (8) make this unrealistic for most physicians. The American College of Cardiology/American Heart Association

recently decided to report the published data on value (cost-effectiveness) alongside the recommendations for benefit in future guidelines (9). However, the main effect of the value information in the guidelines may be on payers who will decide which treatments should be first line.

What should be done in the absence of outcomes data? Although many authors have called for more randomized trials, there is little incentive to conduct them. Currently, there are 2 ongoing randomized trials of atherectomy where a patient outcome (symptom or event) is a primary outcome (although only 553 patients are expected to be enrolled across both trials). Unfortunately, for those trying to control cost, the U.S. Food and Drug Administration has a relatively low bar for approving devices. Occasionally, approved products are found to be harmful once patient outcomes are finally measured (e.g., metal-on-metal hip replacements). Even if patients are not harmed by new technology, Medicare cannot consider whether a new technology is a good or bad value. Furthermore, comparative-effectiveness studies funded by the government through the Patient Centered Outcomes Research Initiative, by law, cannot evaluate cost and value.

What Medicare can and should do is require a registry for all new technologies that are without sufficient randomized trial data demonstrating improved patient outcome. Such registries are required for implantable defibrillators and percutaneous aortic valve replacements despite better outcome data than for atherectomy. Although mandated registries are impractical for every procedure lacking in evidence, the substantial budgetary effect of PVI should make it a top priority.

For the foreseeable future, physicians will have strong incentives to use the latest atherectomy devices for PAD. Economics for the physician and practice are favorable, technical success keeps improving, and patients will always want the latest technology. Those paying insurance premiums and taxes can only hope that the benefits to patients will be worth the cost.

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