

EDITORIAL COMMENT

Good Intentions, Unintended Consequences?*



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Peripheral artery disease (PAD) in the United States has been estimated to affect about 8.5 million adults, or 5.9% of the population of the United States (1,2). The disease is concentrated among older adults, with a prevalence of 29% found in subjects ≥ 70 years or ≥ 50 years of age with histories of diabetes mellitus or smoking (3). The care of patients with PAD is dually focused: reduction in cardiovascular events and improvement in leg function. Although medical therapy is the cornerstone of treatment to prevent cardiovascular morbidity and mortality, the impact of medical therapy in relieving symptoms of claudication is limited. Until supervised exercise therapy is reimbursed, revascularization is the only covered modality to improve life-style-limiting claudication and critical limb ischemia (4). With improvements in endovascular techniques and the advent of new technologies, endovascular therapy for PAD has surpassed surgical revascularization as the dominant treatment modality (5). The cost of a first endovascular treatment for PAD has been estimated to be $> \$15,000$ per patient, with 86.8% of PAD-related cost attributable to hospitalizations (6). Major cardiovascular societies now recommend endovascular treatment as the primary revascularization approach for most PAD lesions (4,7), although the best first modality of revascularization of critical limb ischemia remains unclear and is under study in the BEST-CLI (Best Endovascular vs. Best Surgical Therapy in Patients With Critical Limb Ischemia) trial.

The choice of first modality within the endovascular armamentarium remains undefined. Recent

advances have provided a panoply of tools, including balloon angioplasty, drug-eluting balloon angioplasty, stent implantation, drug-eluting stent implantation, and atherectomy. Drug-eluting balloons (8) and drug-eluting stent implantation (9) have been compared with their drug-bare modalities, but in general, these tools have not been compared with each other. The data for atherectomy are limited compared with the other modalities (10,11). The lack of comparative effectiveness trials combined with a broad set of anatomic variants and clinical situations has created a heterogeneous interventional approach among providers.

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In this issue of *JACC: Cardiovascular Interventions*, Turley et al. (12) demonstrate the variability in practice and provide an estimate of recent outcomes. Using a 100% national sample of fee-for-service Medicare beneficiaries from 2010 to 2012, the investigators determined 30-day and 1-year all-cause mortality, amputation, repeat revascularization, and hospitalization rates for 218,858 patients who underwent index peripheral vascular intervention. These analyses were stratified by clinical care location of the peripheral intervention: inpatient, outpatient, or office-based settings. The investigators found significant variation in clinical care location. Some of the changes were wholly predictable: patients with more advanced illness constituted a greater share of inpatient procedures than those who were outpatient or office-based. As would be expected, the sicker inpatient population also had higher rates of cardiovascular morbidity and mortality. More interesting is the variation that would not necessarily have been predicted. For example, the use of atherectomy was dramatically higher in the office-based setting than in the other 2 care settings. Moreover, use of this device was not associated with better outcomes. Despite a lower comorbidity

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burden, patients receiving care in the office-based setting had a significantly higher rate of repeat revascularization compared with the other 2 locations. Compared with the use of other technologies, atherectomy has the most limited evidence base, so other factors are likely driving its use in the office-based setting. One factor may be the generous reimbursement for atherectomy in the office-based setting (13). These investigators have previously reported increases in the rates of atherectomy after changes in Medicare reimbursement, and it is notable that the trend continues unabated.

Two significant trends illustrated by this work include the ongoing poor intermediate-term outcomes for patients with PAD requiring intervention, with a 1-year cumulative all-cause mortality rate of 15.7%. Similar to the work published by this same group of investigators first detailing the shift in practice pattern and location after the 2008 change in Medicare reimbursement for peripheral interventions as described earlier (14), and despite the lack of evidence favoring the efficacy of atherectomy over balloon angioplasty or stenting (10), the use of atherectomy is associated with worse procedural outcomes and higher cost. Perhaps the publication of multispecialty appropriate use criteria, now in process, will help rationalize technology use in this clinical arena until comparative effectiveness trials can be performed.

We do not argue that the shift to outpatient and office-based laboratories is a mistake. Indeed, we recognize that these settings provide greater convenience for patients, greater access in rural and hospital-poor regions, and an efficient and less costly setting for care, all with similar safety. However, it is unlikely that the changes in reimbursement rates for peripheral interventions made in 2008 by the Centers for Medicare and Medicaid Services were intended to result in this variability in practice. Specifically, although the reduction in inpatient procedures was likely planned, the 2-fold increase in the use of atherectomy in the outpatient setting and a 50-fold increase in use in the office-based clinic setting from 2006 to 2011 likely were not (14).

Good intentions can often lead to unintended consequences. PAD is a costly disease, and the number of interventions in the periphery exceed those in the coronary arteries (15). We believe that care reimbursement should be determined when evidence is available. Efforts for cost containment are necessary, with ongoing refinements in policy decisions needed to adjust to the current environment and needed care of these complex patients (and lesions).

As with all studies using Centers for Medicare and Medicaid Services administrative data, there are limitations to this study, including the inability to apply findings outside of the Medicare population, dependence on International Classification of Diseases-Ninth Revision diagnoses to adequately describe patient populations, the limited clinical information available at the patient level, particularly basic descriptors of lesion characteristics that may be driving interventional decisions, and lack of information regarding concomitant medical therapy.

Despite these limitations, the investigators provide an important bird's-eye view of current practice patterns and outcomes of peripheral vascular interventions performed on Medicare beneficiaries in the United States. As they state, this study should serve as a call to action for practitioners of vascular disease across the United States to work collaboratively in fostering the development of high-quality randomized controlled trials to determine the most clinically effective and most cost-effective treatment options for patients with PAD. Until that evidence base exists, the community must also continue collaborations in developing and disseminating appropriate use criteria, guidelines, and standards based on the high-quality data we have now.

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