EDITORIAL

Atherectomy Overuse: Do Policy Solutions Exist?

Elizabeth L. George MD, MS; Todd H. Wagner PhD; Shipra Arya MD, SM

Lower extremity peripheral artery disease (PAD) affects >200 million people worldwide. In addition to being highly prevalent, PAD is a costly disease to treat. Estimates a decade ago priced annual PAD treatment costs in the United States to exceed $25 billion. Technology advancements and increased adoption of endovascular modalities to treat PAD as well as dramatically increasing numbers of interventions for PAD in the United States have only functioned to increase the cost of care. The prevalence of PAD is expected to increase for the foreseeable future, highlighting PAD as a major public health problem from both a societal and an economic perspective.

See Article by Brown et al.

The endovascular arsenal available to treat PAD is immense: percutaneous transluminal angioplasty balloons, drug-coated balloons, cutting balloons, intravascular ultrasound, reentry devices, drug-eluting stents, bare metal stents, intravascular lithotripsy, rotational atherectomy, directional atherectomy, and laser atherectomy, to name a few. Multiple studies have suggested that atherectomy is superior to balloon angioplasty alone, but the evidence is equivocal with regard to atherectomy’s performance compared with stenting, and at least one study suggests inferiority of atherectomy compared with other modalities. There is notably no non–industry-sponsored randomized controlled trial comparing atherectomy with angioplasty and/or stenting. Despite the minimal data to support the routine use of atherectomy, atherectomy use rates continue to increase over the less expensive stenting.

To combat the increasing costs of PAD treatment as referenced above, the Centers for Medicaid & Medicare (CMS) modified physician reimbursement by increasing reimbursement for office-based procedures, thereby shifting the incentive to treat PAD via peripheral vascular intervention through endovascular means as an outpatient. In this and subsequent CMS Final Rules for payment, atherectomy uniquely has higher reimbursement compared with other modalities, despite a lack of evidence about its effectiveness. It has been hypothesized that this incentive design (higher reimbursement for peripheral vascular intervention in office-based laboratories (OBLs) paired with higher reimbursement for atherectomy) may in part be responsible for the exponential increase in atherectomy volume in both absolute numbers and relative to other modalities over the past decade.

In this issue of the Journal of the American Heart Association (JAHA), Brown and coauthors describe a secondary data analysis of a retrospective cohort of 2019 Michigan Value Collaborative data comprising Blue Cross Blue Shield of Michigan Preferred Provider Organization and Medicare claims for all patients undergoing atherectomy for PAD in OBLs clustered at the provider level. They evaluated routine atherectomy providers (ie, who billed for at least 20 OBL atherectomies and at least 20 new patient evaluations during the study period). The inclusion criteria identified 59
providers operating on 4060 (86.9%) patients with atherectomy and 611 (13.1%) patients with stents. Strikingly, providers were performing atherectomy in an OBL 6 times as often as stenting. The authors found significant correlation of conversion percentage (the proportion of new patient evaluations billed that had a separate claim for OBL atherectomy within 90 days of their index evaluation), mean number of vessels, and mean number of treatments with total payment for OBL atherectomy at the provider level. Interestingly, this relationship did not exist for OBL stenting within the same data set, suggesting that atherectomy may be improperly financially incentivized in OBLs and this may be driving overuse.

PAD can be broken down into 2 levels of increasing severity: intermittent claudication (IC), where patients experience cramping lower extremity pain with activity; and the more advanced presentation of chronic limb-threatening ischemia (CLTI), where patients experience rest pain in their foot, tissue loss, or gangrene. The risk of limb loss is 1% per year for IC and 20% per year for CLTI; hence, the recommendations and goals of treatment are vastly different for each.5,12 The initial management of IC is supervised exercise therapy, smoking cessation, and medical optimization rather than procedural intervention.13,14 This is in contrast to CLTI, where treatment is much more aggressive and, in addition to smoking cessation and optimal medical therapy, intervention is performed expeditiously to prevent limb loss.5,12 As described in figure 4 in Brown et al, these OBL peripheral vascular intervention procedures are being done not only for limb salvage for CLTI, but also for IC. Particularly concerning is the high initial cost to procedural conversion that is happening for patients with IC by these providers. Unless IC is short distance or lifestyle limiting, there is little evidence to support use of invasive interventions as first-line therapy. In fact, there is contrasting evidence suggesting harm and progression to CLTI and increased risk of limb loss with early intervention.15,16

Given findings from another recent study of the broader national Medicare from Hicks et al, suggesting that patients with IC alone have 50% higher odds of receiving atherectomy as their index procedure compared with patients with CLTI, overuse of atherectomy bears a closer look.17 Although outside of the scope of this featured article, it will be important to link longer-term outcomes, such as reintervention and major amputation, with indications and modality of PAD treatment within data sources, such as the Michigan Value Collaborative. This type of cost-effectiveness analysis would provide more concrete evidence to the policy makers establishing the CMS reimbursement schedule. However, a cost-effectiveness analysis is only as good as its model inputs, and one of the major barriers at present is the lack of non–industry-sponsored randomized controlled trial data. Thus, an important next step will be to design and conduct a federally funded randomized controlled trial to determine the appropriateness of atherectomy in treating PAD and whether atherectomy is superior to other modalities to justify its costs. One possible solution in the short-term to curtail financial incentives is by eliminating multiple Current Procedural Terminology procedural terminology code submissions per single encounter or limiting the number of code submissions per encounter.18

Among providers in the OBL setting described by Brown et al, there was significant variation in average reimbursement per patient, which, on further investigation, raises concerns from an ethical standpoint. There is a clear cutoff between the top 10 highest grossing providers and the remainder of the pack: these top 10 providers accounted for >60% ($36,421,417) of the total payment received ($59,919,502). One possibility is that a small number of providers have fully optimized their billing procedures given the billing incentives in place for laterality, number of vessels, and catheter deployment in a single OBL session. Interestingly, these state-level data are mirrored on the national level, where 50% of all Medicare payments for atherectomy were received by only 1% of vascular surgeons and 98% of these procedures were completed in the OBL setting.19 Nevertheless, one of the biggest limitations of the article is that it only represents data from a single insurer. Thus, it remains possible that the high billing providers observed in the study may not solely be a function of provider behavior, but alternatively a function of insurance design. For instance, a provider may have negotiated a payment arrangement with Blue Cross Blue Shield to handle most of the regional cases at a higher reimbursement rate. It is also worth noting the unusual inversion of Medicare payments being greater than Blue Cross Blue Shield of Michigan Preferred Provider Organization payments in this study. Typically, Medicare payments are less than insurance payments, often by a 2:1 factor, so a situation where insurance payments are 3-fold less than Medicare payments is most uncommon and warrants further exploration.20

The findings of this study and others beg the question: From a policy standpoint, how do we discourage overuse by select providers and incentivize evidence-based care more broadly? Is there a role for CMS and other payers monitoring providers performing any given procedure several SDs outside of the mean in any given year? Rather than relying on individual hospitals, state medical boards, and professional societies alone, what if we partnered with those providing the reimbursement to identify these types of outliers? Instead of policing each individual procedure, the objective of such programs would be to monitor overall procedural volume and payments to providers through auditing. For instance, a possible expanded role for the Relative value scale Update...
Committee, a unique multispecialty committee dedicated to describing the resources required to provide physician services (which the CMS considers in developing relative value units) could be to identify outliers by evaluating reimbursement/current procedural terminology/provider distributions to ensure that patient-centered behavior is being incentivized.

The Society for Vascular Surgery appropriate use criteria for managing IC were published in the Journal of Vascular Surgery earlier in 2022. The criteria were created by a multidisciplinary rating panel consisting of 15 volunteers from 3 professional societies (the American College of Cardiology, the Society of Interventional Radiology, and the Society for Vascular Surgery) using the RAND appropriateness method, the only validated method for developing appropriate use criteria and a standardized method that combines the best available evidence from medical literature with expert opinion, using a modified Delphi process, and were published in the Journal of Vascular Surgery earlier in 2022. Key principles described in the article included exercise therapy as a mainstay of treatment; invasive therapy might provide a net benefit for selected patients who are nonsmokers, are taking optimal medical therapy, are considered low physiologic and technical risk, and are experiencing severe lifestyle-limiting or short-distance claudication. Most important, in the infrapopliteal segment, invasive intervention for the treatment of IC is of unclear benefit and could be harmful. In fact, revascularization of infrapopliteal disease for IC was rated as risk>benefit for all scenarios.

As mentioned above, first-line therapy for IC is exercise; however, it is poorly reimbursed in fee-for-service models, and prescribing a patient-supervised exercise therapy that meets insurance company standards is somewhat impractical, particularly in the community setting, thus making it challenging for providers to deliver evidence-based care. Exercise is also poorly captured in the coding/billing system, and it remains difficult to assess changes in prescribing behavior and patient activity levels; but promising strides have been made in the form of the digital health applications of supervised exercise therapy as it seeks Medicare and private insurance reimbursement. Although patients, clinicians, and payers often times struggle with its implementation, prior authorization was originally intended to facilitate the safe and guideline-adherent provision of new and potentially costly therapies. In this instance, atherectomy for PAD may be a good use case for how we might reimagine prior authorization under value-based contracts, as described by the American Heart Association Prior Authorization Learning Collaborative of the Value in Healthcare Initiative to deliver evidence-based care and decrease oversuse of atherectomy in the OBL setting. In addition, requiring prior authorization for atherectomy for IC in the OBL setting would help to ensure that the patient is on optimal medical therapy and had a trial of exercise therapy before intervention; and decrease the conversion rate from initial consult to intervention, as described in Brown et al. We now have an opportunity to examine the strength of financial incentives to perform atherectomy for IC in the setting of competing evidence-based recommendations. Regardless, it will be important to monitor for behavioral changes in response to the appropriate use criteria and whether atherectomy use, in particular infrapopliteal atherectomy use, decreases or whether financial incentives continue to drive overuse.

**ARTICLE INFORMATION**

**Affiliations**

Department of Surgery, Division of Vascular Surgery, Stanford University School of Medicine, Stanford, CA (E.L.G., S.A.); VA Palo Alto Health Care System, Surgical Service Line, Palo Alto, CA (E.L.G., S.A.); and Veterans Affairs Health Economic Resource Center, , Palo Alto, CA (T.H.W.).

**Disclosure**

None.

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