The Problem of Endovenous Overablation and Insufficiently Trained Operators

The need for increased regulation, accreditation, and better-defined appropriateness guidelines to promote sound ethical behavior and core values of professionalism in venous disease treatment.

BY MARC A. PASSMAN, MD

A 32-year-old woman recently came to see me at the vein clinic. She had an uncomplicated pregnancy and was 6 months postpartum after delivering a healthy baby. She was concerned about some spider and reticular veins that appeared along her right calf and ankle during pregnancy that have persisted after delivery. She had no symptoms or other venous findings on examination. She had never worn compression stockings. The patient reported that she had been seen at another vein clinic and was told that the spider veins were indicative of a much more severe venous issue.

A 10-minute ultrasound performed at the other vein clinic showed vein flow problems in her right leg as well as her left leg, and she was advised that she would need three separate vein closure procedures on each leg, which would be covered by her insurance, followed by sclerotherapy of the spider veins for which she would need to pay out of pocket. She was told that the endovenous ablation procedures had already been authorized by her insurance, the procedure should be performed as soon as possible to prevent the spider veins from degenerating into a venous ulcer, and the procedure should be scheduled the following week. She had a "funny" feeling at the other clinic and came to see me for another opinion.

On evaluation at our vein clinic, aside from some small spider veins along the medial aspect of her ankle, her legs had no additional venous findings. Repeat comprehensive venous ultrasound showed no evidence of reflux or obstruction in any vein segment. After some further discussion, she was relieved to know that the problem was not significant and intervention was not needed.

OVERUTILIZATION OF VENOUS PROCEDURES

Unfortunately, the described scenario is playing out across the United States in various iterations and is not uncommon. This is occurring seemingly in parallel to the expansion in volume of venous procedures being performed at a growing number of outpatient vein clinics by practitioners from a wide range of medical specialties, many of whom did not have formal venous-specific education or procedural training during their residencies or fellowships. Although this practice pattern has been evolving over the past decade, the issue of overutilization of venous procedures came to the forefront after publication of an article in *The New York Times* in January 2015, which mostly focused on arterial procedures but also highlighted a 586% expansion of venous procedural volume from 2005 to 2013 in one of the article's figures.[1]

In a recent query of the Medicare Provider Utilization and Payment Database, there was an annual increase

in the number of providers (10%) and ablations (26%) performed during a 4-year period of evaluation (2012–2015). Most ablations (64%) were performed by formally trained vascular surgeons, cardiologists, and general surgeons. Ablations per patient averaged 1.8 in the aggregate data set, and the number of ablations per patient were higher than average in specialties without any vascular training.[2]

Although expansion of procedural volume will usually occur with the introduction of new technology, the noted exponential growth of endovenous ablation volume over a short time frame is well beyond what would be expected, which has raised the concern for overutilization and inappropriateness. This concern was also echoed by the Centers for Medicare & Medicaid Services (CMS) during the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) panel (held July 20, 2016) on lower extremity chronic venous disease, which recommended a low confidence of evidence supporting current venous practice to CMS by MEDCAC.[3] In addition, there have been increased efforts directed at proposed policy coverage changes for endovenous ablation by Medicare's Local Coverage Determination and other health coverage carriers.

Outliers on Medicare claims are also being identified, and the number of Medicare fraud claims against venous practitioners has been on the rise in recent years. From these fraud cases, noted inappropriate practice patterns fostering this overutilization have included:

- Misrepresentation of leg complaints in the patient history
- Documentation of nonoperative measures such as compression stockings even though none had been used
- Overclassification of examination findings to higher severity categories
- Incomplete, focused ultrasound exams specifically performed to identify only venous reflux in the superficial system without evaluation of the deep system
- Nonaccredited venous ultrasound testing without use of defined venous duplex criteria
- Falsification of ultrasound results
- Financial incentives to ultrasound technologists to report reflux
- Aggressive intimidation tactics pushing operative corrections
- Staged, multiple endovenous ablations on both legs

Clearly, the increased volume of endovenous ablation procedures has paralleled the use of these inappropriate practice patterns.

THE NEED FOR APPROPRIATE TRAINING

Endovenous procedural volume expansion and inappropriate practice patterns have also followed the growth of outpatient vein clinics where oversight of clinical practice is variable and delivery of care is by venous practitioners from many different specialties with various educational backgrounds. Of the currently recognized American Board of Medical Specialties (ABMS) and subspecialties, general surgery, vascular surgery, interventional radiology, and cardiology have specific venous training. Yet, in the previously mentioned review of Medicare providers, one-third of endovenous ablations were performed by 41 other provider specialties. Although inappropriate endovenous ablation is being performed by practitioners in all specialties, and there are certainly excellent venous providers performing quality venous care independent of specialty training, there is a critical gap in what physicians may have learned during training versus the scope of practice for those performing venous interventions.

To close this educational gap, numerous venous courses have come into existence, but the quality of these courses can vary, with some promoting similar inappropriate practice patterns as previously noted. The American Board of Venous & Lymphatic Medicine (ABVLM) (www.abvlm.org) was established in 2007 to improve the standards of medical practitioners and the quality of patient care related to the treatment of venous disorders; however, the ABVLM is not currently recognized by the ABMS, and although standards are promoted for practitioners, implementation of these standards into clinical practice is not regulated.

The Intersocietal Accreditation Commission for Vein Centers (IAC-Vein Center) (www.intersocietal.org/vein) was established in 2015 to provide standards for accreditation for facilities performing vein center treatment and management, but adaptation of these standards has only been limited to a few hundred vein centers at this time, and the IAC-Vein Center does not enforce a specific penalty regarding licensure or credentialing except to withhold accreditation from a facility.

Although state medical boards are responsible for provider licensure, they do not provide enough oversight specific to venous care expertise and only respond when there is a complaint from a patient, documented fraud, or some other issue that might threaten the licensure of that provider. In short, currently, there is

a gap between appropriately trained and accredited practitioners performing venous interventions and the location where these services are provided, a void that is being filled by inappropriate venous practice patterns.

APPROPRIATENESS GUIDELINES FOR ENDOVENOUS ABLATION

Although joint clinical practice guidelines from the Society for Vascular Surgery and American Venous Forum and other sources exist for treatment of varicose veins and venous ulcers and include recommendations for use of endovenous ablation, these evidence-based reviews are solely intended to guide clinical decision-making.[4,5] How widely adapted these guidelines are used in clinical practice is variable and does not necessarily dictate appropriateness. The assumption is that if a practitioner follows evidence-based guidelines, then care will be appropriate. This may be true to some extent, but decision-making can still be appropriate when care needs deviate from these guidelines.

What is lacking are specific appropriateness guidelines for endovenous ablation. Much like an evidence-based guideline, the concept of appropriateness refers to the balance between benefits and harms of a procedure. However, the concept of appropriateness extends beyond clinical practice guidelines—an appropriate procedure is one in which the expected health benefits exceed the expected negative consequences by a sufficiently wide margin such that the procedure is worth doing exclusive of cost. Although an appropriateness statement may be linked to evidence or a clinical practice guideline statement, it then applies a judgment about what a provider should or should not do regarding what is appropriate or not. It is not graded like an evidence-based statement for strength of the recommendation; it may have absolutes (clearly appropriate or inappropriate) but can have an uncertain gray zone in between in which it may be appropriate or inappropriate in certain situations. Establishing appropriateness guidelines and following quality measures for outcomes can close the gap between evidence and appropriateness.

Currently, efforts are underway to leverage the Vascular Quality Initiative Varicose Vein Registry into these appropriateness questions. The American Venous Forum is also in the process of leading a collaborative effort to create specific appropriateness guidelines for endovenous ablation using a similar validated methodology as developed by the RAND Corporation/University of California Los Angeles.[6] Collaboration with other like-minded venous organizations will be required for wider adaptation of these guidelines to better implement quality and appropriate care for patients requiring endovenous ablation.

CONCLUSION

There has been a deviation from evidence-based clinical practice and appropriateness regarding endovenous ablation, and this has led to an exponential growth in venous procedural volume, practitioners performing venous interventions, and locations of venous service. Although increased regulation and accreditation as well as better-defined appropriateness care algorithms are needed, ultimately, the burden of providing quality care to our venous patients falls to the individual practitioner. Promoting sound ethical behavior and core values of professionalism should be fundamental to all clinical care decisions. The call to action for all who provide venous care is for individual reflection: Are you providing the utmost quality, evidence-driven, and appropriate care to your patients? We have that obligation to our vein patients. ■

Marc A. Passman, MD, is immediate Past President of the American Venous Forum. This article includes excerpts adapted from his Presidential address entitled, "The American Venous Forum—Where Evidence, Ethics, and Professionalism Converge," which was presented on February 23, 2018, at the 30th Annual Meeting of the American Venous Forum.

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