ASK THE EXPERTS

Which Forces Most Drive Platform Adoption in Superficial Venous Care?

A panel discusses how they navigate the technologies available for treating superficial venous disease and the factors that influence widespread adoption.

WITH JULIANNE STOUGHTON, MD, FACS; THOMAS PROEBSTLE, MD; NEIL KHILNANI, MD, FSIR, FACPH; AND STEVE ELIAS, MD, FACS, FACPH

Julianne Stoughton, MD, FACS
Vascular Surgery
Massachusetts General Hospital
Harvard Medical School
Boston, Massachusetts
jstoughton@mgh.harvard.edu
Disclosures: None.

In 2018, the practitioner is faced with a difficult decision about which treatment is best for their patients with superficial venous disease when comparing and contrasting the numerous platforms available. There is some physician bias about which treatment may be preferable, but it would be optimal if the actual decisions were driven by available data. Because the current literature has demonstrated favorable clinical outcomes for almost all superficial venous treatments, we cannot draw firm conclusions about superiority of one treatment over another. Until we have more robust comparative data, the factor that should most drive platform adoption should be the consideration of specific patient characteristics and the analysis of safety and efficacy for the individual patient.

In my opinion, with regard to endovenous ablation of saphenous veins, the larger-diameter/higher-pressure veins are best treated with the standard thermal tumescent procedures to avoid the risk of failure, recurrence, or recanalization. Endovenous radiofrequency (RF) ablation with the segmental catheter has been a highly successful method and has had comparable anatomic and clinical success and outcomes when compared to the higher-wavelength endovenous laser treatments. However, both thermal ablation treatments require tumescent anesthesia, which makes the procedure more uncomfortable for the patients. Choosing between the two thermal technologies can be challenging, with nearly equivalent data supporting both treatments. When considering the costs and reimbursements, the net profits are similar as well. Clinicians should have at least one of these thermal tools in their armamentarium.

Alternatively, venous anatomy with close proximity to skin or nerves is best treated with one of the nonthermal methods to avoid injury to these structures. These nonthermal methods do not require the painful injection of perivenous tumescent anesthesia. Nonthermal methods include ultrasound-guided microfoam, cyanoacrylate glue, and mechanochemical ablation (MOCA), among others.

Foam has an obvious benefit for tortuous veins, whereas MOCA cannot be performed in veins with any webs or synechiae, and glue is promising but currently not covered by most insurers—and they all lack longer-term follow-up. The choice of which nonthermal method to employ will continue to evolve as the clinical outcomes are followed over time and as reimbursements become more established. For now, my opinion is to choose the best treatment for the individual patient's anatomy and history.

Some may argue the importance of cost and distribution of resources; thus, they would support the use of the least expensive treatment in all circumstances. This utilitarian approach may have some value in the future, but currently, the best decision for treatment of the individual patient should be based on comparative data and results from the literature (preferably from randomized controlled trials). The decision should also take into account the specific characteristics of the patient's anatomy, the results of diagnostic evaluations, and the presence of comorbid diseases. Of course, if all else is equal, then choosing the most economical treatment is acceptable.

In the long run, the least expensive treatment is the best and most appropriate treatment performed without complication. Because superficial venous disease is a complex and varied disease, we need to have multiple tools in our toolbox. One should at least be proficient in one thermal ablation platform and perhaps more than one nontumescent method. Also, one should be proficient in sclerotherapy, phlebectomy, or foam injection for the veins not amenable to catheter interventions.

Thomas Proebstle, MD
Department of Dermatology
University Medical Center Mainz
Mainz, Germany
Director and Owner
Private Clinic Proebstle
Mannheim, Germany
Vein Center Bellevue-Zurich
Zurich, Switzerland
info@privatklinik-proebstle.de
Disclosures: Speaker for Medtronic, Syneron Candela, and BTL.

The forces that accelerate or sometimes slow down the adoption of new technology in the treatment of superficial venous disease frequently remain mysterious. Certainly, there is one necessary key force for acceptance among physicians—the scientific evidence. Without studies comparing favorably to current gold standards, a new technology would hardly become attractive to venous specialists. This does not mean a superiority of a new technology in all dimensions; however, there must be at least one striking advantage such as the availability of outpatient treatment, fewer side effects, or eliminating the need for anesthesia when compared to the old standards. For example, abolition of saphenous reflux by endovenous cyanoacrylate glue does not require tumescent local anesthesia, induce paresthesia, or require compression stockings postprocedure, but delivers the same clinical results as endothermal procedures or high ligation and stripping.

Widespread use of new technology, however, requires reimbursement. When looking at the situation in Europe, it becomes apparent that in countries with high payments for in-hospital saphenous vein stripping procedures, like Germany or Austria, the majority of procedures are still surgical stripping. In countries like The Netherlands or Great Britain, the situation changed a long time ago in favor of endothermal technology.

In situations when a vein specialist would like to make a change toward a new technology but reimbursement is not yet available, the tool of marketing needs to be engaged. Doctors need to use their multimedia channels to spread the information. Once approved, the medical companies also need to communicate the advantages of their new technologies. The introduction of VNUS Closure (Medtronic, formerly VNUS Medical Technologies) about 20 years ago is still a good example of how the introduction and achievement of widespread use of such a game-changing technology can be supported.

Neil Khilnani, MD, FSIR, FACPh
President, American College of Phlebology
Associate Professor of Clinical Radiology
Division of Vascular and Interventional Radiology
Weill Cornell Medical College
New York Presbyterian Hospital
New York, New York
(646) 962-9179;
nmkhilna@med.cornell.edu
Disclosures: None.

For better or worse, "superficial venous care" has become conflated with saphenous ablation. This neglects the importance of conservative and saphenous sparing tributary vein treatment but is a fact related to the economics of reimbursement. Ablation of the saphenous vein is reimbursed better than the other superficial venous treatments that we currently offer. Consequently, ablation tool development and validation have been the areas that physician entrepreneurs and industry have focused on. Currently, there are five commonly used, minimally invasive, US Food and Drug Administration–approved tools available in the United States to ablate saphenous veins. We have learned from the evidence that has been published to date that, more or less, they are all effective at what they are designed to do. There are some minor differences in surrogates for success, such as closure and the incidence of minor complications (eg, nontarget thrombosis), but there is no clear difference in patient-reported outcomes following each of these procedures in clinical trials.

The choice of tool is therefore based on a variety of factors, with the most common for the patient and the physician being economic and efficiency. For the majority of patients who seek care, being able to have the cost of the procedure covered by their insurance has been the most important issue. In addition, patients want to eliminate what they feel and what they see in one procedure. Until recently, only thermal ablation has been widely covered. Consequently, thermal ablation has been the primary approach used, with few differences in the outcomes for laser and RF ablation. In the self-pay market, nonthermal ablation has a larger share but is still not in great numbers.

In the last several months, wider coverage access for nonthermal ablation has theoretically been available in the United States and will likely lead to an increase in the number of these procedures. In addition, industry has begun to reduce the costs associated with the nonthermal devices in response to the valuations received from Medicare. However, the expected surge in use in our practice has not materialized. Persistent reimbursement uncertainties still exist for the patient and provider in the early part of 2018, limiting patients from accepting the financial risk to proceed with these procedures. In addition, patient concerns about long-term outcomes and side effects with the new procedures, with at most modest advantages to the patient, have limited nonthermal ablation utilization. As an example, patients have been more skeptical than anticipated regarding permanent implants and their biological outcomes in the long term. Also, the need to return for secondary procedures and trapped blood removal from larger tributaries after foam injections has limited other patients and physicians in our practice from embracing proprietary foam as a cost-effective and efficient alternative. Finally, based on the currently available evidence, larger-diameter veins are probably best addressed with thermal techniques. Consequently, for great saphenous vein (GSV) reflux above the knee and small saphenous vein (SSV) reflux above the musculotendinous junction of the gastrocnemius muscles, thermal ablation remains the most common procedure, often coupled with microphlebectomy for efficiency in patients with larger varicose veins.

The areas where nonthermal tools seem most likely to be selected by patients is with GSV ablations below the knee (or SSV below mid-calf), because anecdotally, they may reduce the already infrequent sensory nerve injuries found with thermal ablation. The other reason is that these longer ablations are somewhat more painful to the patient related to the tumescent anesthetic delivery, which is tedious for the operator to perform and is also associated with more postprocedure discomfort, particularly across the knee. Retrograde access to ablate the lower calf GSV under lipodermatosclerosis in patients with venous ulcers will likely become popular even though evidence to support its value is only anecdotal at this point.

In summary, treatment cost and efficiency as well as scientific evidence guide the selection of tools used for saphenous ablation. As reimbursement for nonthermal ablation procedures becomes routine, there will be a shift toward their utilization. More evidence will settle some of the other lingering concerns of their efficacy, side effects, and complications and will likely increase the nonthermal share of the market. Laser and RF will likely remain a popular procedure for the near future for those who have invested in the generators and garnered significant experience because they work well and the advantages of the nonthermal procedures are limited to certain anatomy. However, I suspect that new providers and offices will not be investing in expensive thermal generators and will gravitate toward the nonthermal devices sooner due to their lower upfront cost. This shift may also occur for those who already own generators if the cost of the nonthermal tools can be brought down further, as we are beginning to see in the early part of 2018.

Steve Elias, MD, FACS, FACPh
Director, Center for Vein Disease
Englewood Hospital and Medical Center
Englewood, New Jersey
Founder, Expert Venous Management course
veininnovations@aol.com
Disclosures: None.

Long question, short answer: "Sooner or later it all comes down to money" as sung by Bruce Springsteen in "The Big Muddy." This answer may seem cynical or simplistic, but most physicians don't adopt a new platform or technology unless there is something in it for them—intellectual stimulation, notoriety, novelty, or remuneration. Most people don't work at their job without compensation. We have seen this movie before many times. In fact, in superficial vein care, we are now realizing the algorithm of care that answers the question, "What forces most drive platform adoption in superficial vein care?" is often, "Because I can get paid." Money talks and now some vein specialists are doing too many procedures because they can get paid. This is an issue that has been discussed in this publication and others, as well as at societal meetings. We are working on solutions. Another topic for another day.

Currently, we have reimbursed platforms that are safe, efficacious, durable, and relatively patient friendly for treating superficial venous disease. One need not feel as if they are providing inferior or substandard care to most patients most of the time with currently covered and available platforms. Yet, there are new nonreimbursed technology platforms that have some inherent advantages to patients and physicians. Some people are using them. The why and how may help answer the posed question.

We can divide physicians, and specifically surgeons and proceduralists, into three categories: (1) early adopters, (2) secondary adopters, and (3) reluctant adopters. Most proceduralists are not driven to change as long as what they are using seems to be working for them and for their patients. Most are not comfortable with feeling uncomfortable, except the early adopters. Most will adopt new platforms only if they need to or if they get paid. Yet, there are early adopters who simply embrace the new. These are the ones involved in clinical trials and platform development so that they can gain experience for their patients and themselves. They are the first wave. Reimbursement may not be an issue because their experience and their patients' experience are gained by clinical trial support. However, these cases are the minority.

The great majority of physicians are secondary adopters. They wait for data, demand, and reimbursement. This is what drives their adoption. They wait and they wait, but their patience usually pays off for their patients and themselves. Their patients get treated with procedures, technologies, or platforms that are proven and reimbursed. Although this approach may not be as interesting or stimulating as the early adopters' approach, it is the standard safe approach that is time-proven.

Luckily, reluctant adopters are the minority. By the time the reluctant adopters consider using new platforms, most of them have been vetted by research, time, and results. The losers of the reluctant adopter approach are both patients and physicians. The patients more than physicians because good care and new platform technology has been withheld longer by these physicians for their patients than most other patients.

It is the nature of medicine and surgery to progress and change. We all want to improve patient care. It is also the nature of new platforms to take time for data, results, and reimbursement to accumulate. There is at least a 3-year lag time from market entry to successful reimbursement for most platforms. Forces driving platform adoption are linear. Who adopts and at what point along the line of the "adoptive path" depends on the "adoptive attitude" of each individual practitioner. Some are early adopters, most are secondary adopters, and a few are reluctant adopters. But in reality, for most, the forces that drive platform adoption is the Jerry Maguire mantra, "Show me the money." Not cynical or simplistic, merely realistic. ■