

# Devices, Data, and Economics: Decision Making in Today's Endovenous Environment

Venous expert Jose I. Almeida, MD, discusses the high mark set by current thermal ablation data, the forces affecting adoption of new therapies, and the economic realities facing today's venous practices.



## How would you summarize the current state of data supporting laser and radiofrequency ablation for treating superficial vein disease?

From my point of view, the study of the superficial venous system during the past 15 years (endovenous devices launched in 1999) has been very device-centric. It seems that most of the trials have focused on comparing endovenous devices to one another, with little attention paid to the actual disease process.

To date, we have seven randomized controlled trials (RCTs) comparing radiofrequency ablation to high ligation and stripping; 12 RCTs comparing endovenous laser ablation to high ligation and stripping; five RCTs comparing radiofrequency directly to endovenous laser; and six RCTs comparing foam sclerotherapy to high ligation and stripping. There is one recent RCT comparing four treatment arms: high ligation and stripping, radiofrequency, laser, and foam sclerotherapy. This represents a robust set of data in the form of RCTs (see *Body of Evidence Supporting Thermal Ablation* sidebar). Before these RCTs, there were numerous observational studies that looked at safety, closure rates, and side effects. We have plenty of data at this point, and in my opinion, no need for new trials evaluating thermal treatments of the incompetent saphenous vein.

## What is the current gold standard therapy, in your opinion?

It's clear that thermal ablation—and in that designation, I include endovenous laser and radiofrequency

together—is the gold standard. It has withstood the test of time.

Radiofrequency ablation has gone through one iterative change involving segmental instead of continuous pullback, with an increase in temperature, resulting in increased efficacy at a faster speed. Laser has progressed step-by-step to longer wavelengths: 810; 940; 980; 1,319; 1,320; and 1,470 nm. This increase has improved the procedure's side effect profile in terms of less pain and bruising. A 1,920-nm wavelength is soon to be launched.

These thermal ablation technologies are now well established. They're safe, and accepted well by patients; they clearly represent the gold standard to which we'll compare anything new.

## What do you consider to be the most promising next-generation therapies?

In general, the movement within the industry is from thermal to nonthermal technologies. These nonthermal technologies do not require tumescent anesthesia or capital expenditure in the form of a generator. Tumescent anesthesia still seems to be a problem: patients don't enjoy extra needle sticks along the medial thigh, and for some new doctors learning the procedure, placing the tumescent anesthesia is the most challenging piece to learn. Regarding capital outlay, a radiofrequency generator or laser console are \$30,000 pieces of equipment. There are three nonthermal technologies that are, or will be, coming to market very soon.

Mechanochemical ablation, which is a combination of sclerotherapy and a physical agitation of the vein with a

catheter–wire assembly, has been in use and is showing good results on saphenous veins < 12 mm in diameter. Cyanoacrylate glue is under investigation; it has currently finished its United States IDE (investigational device exemption) trial, and it seems to have good efficacy and a good side effect profile with the added benefit that, in the future, it may be applicable in other venous beds such as the pelvic circulation, perforators, or varicose tributaries. The new polydocanol endovenous microfoam has been in development for 14 years and is backed by 12 clinical trials. The product recently garnered FDA approval and should be commercially available by late spring 2014.

There's a fourth device that will not be pursued any further for the time being because the efficacy at 3 months started falling off in two clinical trials. This polyglycolic acid implant of the saphenous vein does not seem commercially viable because it has not met the standards set by thermal ablation.

### **What level of efficacy and patient outcomes must be met for new modalities to be considered on par with or better than today's therapies?**

In general, for efficacy, the primary endpoint we tend to look at is the closure rate. Thermal technologies have set the bar at 95% saphenous vein closure at 1 year; any new technologies should have comparable closure rates.

On balance, the new focus in venous disease is not so much on surrogate markers from physician-specified outcomes, but rather, the focus has shifted to patient-reported outcomes. More effort is being put into quality of life measurements reported by patients. We have certainly seen that small failures, such as a segmental recanalization of a vein, may not translate into worsening clinical symptoms. So even though the physician deems a recanalization of > 5 cm "a failure," the patient reports "a success" because he/she still feels well.

There will need to be a balancing of efficacy and patient-reported outcomes, and new devices may not require the stringent expectation of 95% percent closure, per se, as long as the patients are reported to be doing well. But, for a saphenous vein that has compelling reflux and needs to be treated, 95% closure at 1 year is a pretty good benchmark for new technologies to meet.

### **Do you think a randomized trial comparing the new therapies to existing platforms with proven track records will be required, or will the data produced for each technology on its own be sufficient? What kind of data or personal experience would it take to change your practice patterns?**

This is an excellent question without an easy answer. The RCT has become the Holy Grail because it removes the con-

### **THERMAL ABLATION CLINICAL TRIAL EVIDENCE**

- Seven RCTs comparing radiofrequency ablation to high ligation and stripping
- Twelve RCTs comparing EVLA to high ligation and stripping
- Five RCTs comparing radiofrequency directly to endovenous laser
- Six RCTs comparing foam sclerotherapy to high ligation and stripping
- Two RCTs comparing EVLA versus cryostripping
- Six RCTs comparing modifications of EVLA
- One RCT comparing high ligation and stripping versus RFA versus EVLA versus foam

*Courtesy of Bo Eklöf, MD, and Michel Perrin, MD.*

founders from the equation. However, the endovascular field changes rapidly, and by the time a RCT is completed, which takes great expense and a good amount of time, the next new instrument may already be in widespread use. The RCT data always lag behind technological developments in the endovascular space. In such a rapidly moving field, a good observational study demonstrating safety foremost, and efficacy second most, is fairly reasonable to get a new modality into use. Scientific purists tend to focus on head-to-head comparisons, so there will be people asking for RCTs. In my personal view, I'm happy with a couple of well-conducted observational studies showing safety and efficacy in a large number of patients.

Ultimately, a new therapy needs something more than just a good study to be widely adopted into our system. It must be a good fit for a practice—meaning, well accepted by patients, reimbursement with CPT codes, and financial viability. For example, laser ablation has the allure of a high-tech device, and as such, it is very attractive to patients, whereas a technology that's not as high tech and "sexy" may not get the same traction, even with good clinical data.

### **How will the iterative advancements in thermal ablation technologies be evaluated against their own previous generations?**

As far as laser and the iterations of wavelength go, we're currently seeing the greatest popularity with wavelengths longer than 1,320 nm; now there is a 1,920-nm wavelength that's starting to get attention. I suspect that the laser community will want to see some head-to-head data that a 1,920-nm fiber makes sense. Because when you're running a practice, displacing a \$30,000 investment that works quite

well will require more than a small improvement over a comparable technology to justify the cost. At this point, radiofrequency and laser are mainstream devices with very good results, so an iterative advancement will probably require a substantial trial with compelling data to displace a proven option—or, a markedly less expensive device with clinical equipoise.

### **And this challenge is distinct from what it might take for an entirely new option, though?**

I think the hurdle to acceptance will be lower for technologies that don't require substantial investment in a new piece of equipment. If there is a good observational study showing that a new option is safe and efficacious with an acceptable side effect profile, translating to a better patient experience, and it does not require more money out of the physician's pocket, I believe such an option will have an easier time penetrating the marketplace with a smaller trial than would a new expensive thermal iteration.

### **What is the likelihood that the emergence of new options results in some therapies—either existing platforms or new ones—being found to be best suited to either niche applications or challenging anatomies, thereby broadening the offering available to endovenous specialists and their patients?**

For a doctor like myself who only does venous work in a very competitive environment, if there's something out there that may help me get an edge, I may go ahead and invest in a new piece of equipment if I feel the return is reasonable. But for someone whose practice is 5% venous disease, he or she will be less motivated to adopt a new technology to fill a small need.

For example, there may be a niche where, anatomically, I can't do something with thermal ablation that I can do with glue, and if I want to be a "one-stop shop," I need to have everything in my office. If that's the type of practice I want, the investment may enhance the practice brand. That type of investment may not be the right fit for other practices. So, for busy venous practices, the addition of new technologies may broaden the offering as opposed to simply displacing the old.

### **The global health care environment is increasingly cost-conscious. In your experience, how cost effective are the current endovenous ablation options?**

In comparison to the United Kingdom, none of the United States trials have focused on cost effectiveness. In general, traditional stripping surgery is done in the hospital under general anesthesia in an operating room. Those are costly procedures just because of the facility. A procedure

that can be done in the office environment is a leaner, more cost efficient operation, and it's more attractive to patients. My overall impression is that catheter-based technologies in the office setting are more cost effective than traditional surgery in a hospital. However, there's much more to the cost equation than a comparison between therapies.

Venous disease exists in a wide spectrum from CEAP class 1 to class 6. For advanced disease, class 4 through class 6, I don't think there is any question that these patients are debilitated by their disease, and that the loss of work days to society is in the billions of dollars. For a less-advanced class 2 patient with bulging varicose veins, it may just be a cosmetic problem, although they are on the course of disease progression. The issue is, we can't yet identify exactly which class 2 patient will go on to develop an ulcer versus which one will not. As a society with limited resources, we need to draw lines and allocate resources appropriately.

If the insurance industry offers more coverage benefits, this will require higher premiums to be paid by the risk pool. The healthy risk pool always subsidizes the sick folks; and we therefore have to ask ourselves, "If the 20 million people in the United States with class 2 varicose veins mobilize to go see a doctor to have their veins treated—and these costs are absorbed by the insurance industry—will healthy patients consent to higher premiums to cover these costs?" Given that these procedures can be done in a physician's office with catheter-based technology at a relatively reasonable out-of-pocket expense, society may consider omitting class 2 disease as a covered insurance benefit.

As far as how reimbursement affects practices, unfortunately, medicine has become monetized. We have increasing regulatory requirements to deal with, HIPAA, EMR, PQRS, etc., and other things that the government mandates, all requiring more overhead and more full-time employees just to keep us in compliance. Our expenses are going up, and reimbursement is going down. Like any small business, once margins start dwindling, a medical practice has a hard time surviving. That's just reality. If expenses are higher than reimbursement revenue, then obviously, it becomes a problem to keep a practice afloat.

These are just some of the broader questions for which we as a society don't yet have answers to at the present time. With the all of the moving parts that come with the new Affordable Care Act, it's hard to say how things will ultimately play out. ■

*Jose I. Almeida, MD, is Director of the Miami Vein Center and Voluntary Associate Professor of Surgery at the University of Miami Miller School of Medicine in Miami, Florida. He has disclosed no financial interests related to this article. Dr. Almeida may be reached at dralmeida@mac.com.*