Superficial Venous Disease Data: What We Have, What We Need

Practical data we can use to treat the patient, not just the vein.

BY STEVE ELIAS, MD, FACS

In his book *The Power Broker*,[1] Robert Caro quotes Robert Moses and unknowingly crystalizes the history of the endovenous evolution by saying, "Majorities, of course, start with minorities." By the late 1900s and early 2000s, we had a lot of data supporting the 100-year-old treatment methods for superficial venous insufficiency. However, those data did not really address how the accepted treatments affected patients' quality of life.

We made incisions, pulled out veins, and never thought twice about how the patient felt. This is obviously so much different than the standards we insist upon for modern-day minimally invasive vein care, especially for the superficial system. The data we analyze now are patient-centric rather than procedure-centric. Our (vein specialist) evaluation and expectations of any procedure has evolved from discussions about closure rates, safety, and efficacy to the physician and patient-reported outcomes. It is about the patient; it is not about the vein. It is in this context that we analyze the data we have and the data we need to help the patient and not only treat the vein.

Those of us who were the early adopters of the minimally invasive management of vein disease were certainly in the minority. And as Robert Moses astutely stated, we are now the majority. Robert Moses, the architect of urban and suburban planning, had no idea that his radical, minority concepts would become the majority of thought when he had his vision for the transformation of New York City from an urban-oriented entity to a suburban landscape perceived as the "Promised Land." Let us now explore our promised land and the data both known and needed surrounding superficial venous disease.

WHAT DATA DO WE HAVE?

We finally have good data. We have 5-year data.[2,3] Endovenous ablation of the great saphenous vein utilizing thermal tumescent (TT) methods works, and it positively affects patients' quality of life. We all understand that vein disease is not an all-or-none event. We expect recurrences after 3 to 5 years, but we also expect some durability of treatment. We now have data that support our goals. We also know that we can tell our patients that TT methods of endovenous ablation are safe and effective, the procedure times are short, and they offer minimal recovery time. Isn't this what is important to patients?

As far as which ablation method is "better," we can't really answer this in an individual patient sense, but we can in a global way. Rasmussen et al[4] demonstrated that after a month and going forward, it really doesn't matter which technique is used to treat saphenous incompetence. Thus, all do equally well. These data followed patients up to 3 years. One must keep in mind that the great majority of patients in this study did have concomitant treatment of their visible varicosities. This may in fact be the equalizing element. This concept is discussed later in the *What Data Do We Need Next?* section of this article.

We have enough data that endovenous ablation should be considered as the first method of treatment. The NICE (National Institute for Health and Care Excellence) guidelines[5] from the United Kingdom and the Society for Vascular Surgery/American Venous Forum guidelines also express the same recommendations.[6] These guidelines have positively influenced payers, both government and third party, to cover these procedures. It is good to know that the treatments we offer patients have solid data behind them. This positive effect on a patient's quality of life is one of the strongest data to date regarding

superficial venous disease. The long-term data are based mostly on TT technologies, but one can expect that when longer-term data accumulate for nonthermal nontumescent (NTNT) technologies, these will also positively affect patients' quality of life. It is clear that an occluded incompetent axial vein, no matter what method used, will yield improvement in quality-of-life measures.

Because these technologies are relatively simple, many operators are performing a lot of superficial venous procedures. Sometimes, the wrong doctor is treating the wrong patient for the wrong reasons. These patients don't do well. The exponential rise in procedures is being noticed by insurers, notably CMS. The inappropriate treatment of patients was a recent topic in a roundtable discussion in *Vein Magazine*.[7] Ways to minimize these abuses are discussed in the *What Data Do We Need Next?* section.

The previous paragraphs elucidated that we have a lot of solid data to support treatment of axial vein reflux. Conversely and ironically, we also have very good data that support the idea that every refluxing axial vein doesn't need to be treated. I am speaking about the ASVAL (ambulatory selective varices ablation under local anesthesia) and CHIVA (conservative hemodynamic treatment for chronic venous insufficiency) methods.[8,9] Both seek to identify and treat those patients who can undergo a saphenous-sparing procedure with good results regarding quality of life and recurrence. In the right patient, not treating the axial reflux can be the right option. One should not dismiss these technologies without understanding them and the data that have been generated.

As a corollary, the data accumulated by Rasmussen et al[4] showed that in a large percentage of limbs, their branch varicosities were treated at the same time in each treatment group (laser, radiofrequency, foam sclerotherapy, and stripping). One can't help but wonder, what would have happened if only the varicosities were treated and the axial reflux was left untouched? Would the results still have been the same? This question brings us to the next section.

WHAT DATA DO WE NEED NEXT?

Do we have enough data to know when to treat visible varicosities in conjunction with axial reflux—whether concomitantly or staged? There have been two good studies that seem to answer this question.[10,11] However, just as there are patients who don't need their axial reflux treated but rather only the visible varicosities, there are patients who don't need their varicosities treated, only their axial reflux. In the recent United States VeClose trial, the design was such that even those patients with visible varicosities would not receive concomitant phlebectomy at the time of saphenous ablation. The goal of trial designs such as this is to keep the data focused and within parameters reflecting only the saphenous ablation being evaluated. Although not a major endpoint, in analyzing the data, more than 50% of patients who had saphenous reflux did not require further intervention regarding their varicosities, and they did not receive it per the constructs of the trial. If the trial were to have followed the belief that concomitant phlebectomy should be performed at the time of any form of saphenous ablation, then a portion of those patients could theoretically have had an unnecessary procedure. I don't believe we have data to definitively answer this issue yet.

There is a movement among payers and vein specialists that reimbursement should be based on treating the disease (ie, venous insufficiency, varicose veins), not a piecemeal approach. The idea of getting a one-time, one-sum reimbursement to "treat a leg" may change how a physician chooses to treat the patient. Why do a phlebectomy at the same time if at least 50% of patients would have been happy without one? This is a question that is still not completely vetted. I believe it comes down to a detailed discussion with each individual patient in terms of what they want to accomplish and in what time frame they want to achieve their goal. We know that to get full maximum results from axial ablation, one needs to wait at least 6 weeks and up to 2 to 3 months. This may be okay with some patients, but not others.

Although we need longer-term data for the NTNT technologies, the short-term data[12-14] for these methods parallel those of the short-term data for the TT methods. The longest reported data thus far have been on mechanochemical ablation.[14] I believe the results will be comparable, but we just don't have the data yet.

It is counterintuitive, but the smaller the vein is, the harder it is to treat, and with less predictable results. We need methods that can improve spider vein treatment. This is an area that is quite variable regarding results and patient–physician satisfaction. There is dermatologic literature that purports to show decent data for transcutaneous laser treatment. Most vein specialists treating small veins are not completely satisfied with any method (sclerotherapy, transcutaneous laser, or ohmic treatments). We need a better, easier way to treat these types of veins, and we need a better, easier way of collecting and quantifying data.

Although we have some data regarding progression of disease,[15,16] we don't really have scientific criteria that tell us which individual patients (such as those with C2 disease) will progress to more advanced disease and/or ulceration. Much of medicine is focused on the "preemptive" strike. For example, we can confidentially tell a patient with a 6-cm aortic aneurysm that the data sup-

port intervention. Similarly, a patient with a 95% carotid stenosis will benefit from an endarterectomy. Do we really have similar data for the majority of vein patients, most of whom have C2 disease? I don't believe we do. Some practitioners may convince C2 patients as to the merits of preemptive treatments aimed at preventing progression to C4 through C6 disease. Again, we don't have the data to identify who will progress and who will not, which we need to help us with decisions on whether to intervene. Almeida et al[17] have alluded to this dilemma. Currently, treatment is best based on a discussion with the patients as to how much their venous symptoms affect their individual quality of life. In the great majority of cases, prophylactic vein treatment is probably not warranted, even though some "vein specialists" are taking this approach in C2 patients without good data.

Finally, one of the areas in which we don't have good data is determining what metrics we need to help us understand who is qualified to treat venous disease and who is qualified to treat which types of venous disease. The reality that superficial vein disease treatments are relatively simple, short, safe, and pay well has led to some abuse and misuse, as previously alluded to in *Vein Magazine*.[7] It is good for our patients that superficial procedures are simple, short, and safe, but it is these very qualities that have gotten us to where we are now. Yet, we don't have data (eg, outcomes or prospective data) to differentiate a qualified vein specialist from an unqualified one. There have been attempts by insurers to not reimburse certain specialists. Societal accreditation bodies, such as the Intersocietal Accreditation Commission, have set minimal standards for vein centers. There are boards in phlebology. Although, conceptually, some of these ideas would seem to improve vein care, do we have reason to believe that show that outcomes are better, patients are more satisfied, and complications are less if a vein specialist has passed phlebology, vascular surgery, or interventional radiology boards and works at an accredited vein center? I think the answer is yes, but we still need data to support this premise.

CONCLUSION

Superficial vein treatment is hot and ubiquitous, and those involved cross many surgical and medical specialties. We have morphed into a patient-centric specialty in which some subspecialties have pioneered the concept of "How does my intervention affect the patient?" This is a good thing, and the data support intervention to help the patient live a better life. Vein care practitioners must not stretch or extrapolate data to increase procedural volume without supportive proof that they are preventing progression or ulcer. This is a slippery slope. Most decisions on treatment should be data driven with a side of clinical equipoise.

The informed vein specialist manages each individual patient using existing data and acknowledging that we don't have all the data to allow us to treat every patient. We need to be aware of what we solidly know, what we sort of know, and what we don't know. Being cognizant of all three data sets will allow for the honest and best management of patients with superficial vein disease. "Majorities, of course, start with minorities." ■

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