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How We Incorporated the VenaSeal™ Closure System Into Our Vein Practice

Insights from one center's firsthand experience.

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The treatment of chronic venous insufficiency of the lower extremity secondary to saphenofemoral junctional valve incompetency has undergone significant changes with the advent of endovascular techniques. Through effective management and correction of valvular dysfunction via endothelial disruption or ablation in a minimally invasive fashion, both thermal and nonthermal platforms have evolved from a better understanding of disease mechanisms and evolution of early treatment technologies. With its published results and level of evidence, thermal ablation requiring tumescent anesthesia has been the standard of care and widely adopted in most clinical settings.[1-4] However, the reoccurring question is whether new techniques that incorporate nonthermal, nontumescent (NTNT) therapies such as cyanoacrylate-based medical adhesive (VenaSeal™ closure system, Medtronic), with clinical evidence demonstrating noninferiority as compared to radiofrequency ablation therapies, may have a role in the contemporary vein clinic.[5] The intent of this article is to provide perspective and considerations with respect to the incorporation of NTNT therapies through a patient empowerment model, incorporating patient education and frank discussion, thus allowing the patient to become an active participant in the management pathway.

In our clinic based in Canada (Eva Vein Care in Vancouver, British Columbia, Canada [www.evaveincare.ca]), the physician team consists of interventional radiologists and vascular surgeons, supported by dedicated phlebology nurses in a self-pay model. As current indications within our jurisdiction do not reimburse in the public sector or through private insurance, we have a very strong obligation to ensure that patients are not only receiving the best care, but also the best value for the expectations and presentations of their chronic venous insufficiency.

OVERVIEW OF TECHNOLOGY PLATFORMS

A variety of therapies are available for the treatment of chronic venous insufficiency secondary to saphenofemoral junction and lesser saphenous valvular incompetency. With the myriad of choices, it can be confusing to patients as to which therapy may be most appropriate. Device manufacturers are adept at direct patient engagement, but these efforts can result in a model that may not necessarily be driven by appropriateness of clinical presentation, and may potentially be affected by messaging through direct patient advertising.[6,7] A discussion of the individual technologies and their merits is beyond the scope and intent of this article; however, Table 1 summarizes our general experience and impression of the available technology platforms.

The decision to attempt to incorporate NTNT therapies into our practice was based on the following considerations:

1. Low overhead cost: No additional capital equipment costs are required to begin implementing NTNT.
2. Portable: Ability to perform procedures on a portable basis, with a minimal surgical suite footprint, allowing for rapid setup and breakdown.
3. Convenience: Although NTNT procedures generally take as much time as thermal-based ablations, not needing thigh-high compression or premixing tumescent anesthesia allows for faster room turnover.
4. Competitive market advantage: Implementing a "better/best" model and integrating all options in a "one-stop shop" provides the patient with more choices, and provides the clinic with greater catchment.

PATIENT PROFILES

In our iteration of a patient-empowered practice, we learn of the patient's expectations through an extensive evaluation that involves the standard physical exam,

review of clinical history, and ultrasonographic assessments in order to map and plan for therapy. A critical part of our management plan is a discussion with the patient about recovery, results, and cost, as these are key factors to understanding the needs of the individual and educating him or her on realistic expectations. Full disclosure of the literature (or lack thereof) and potential risks/benefits of an NTNT therapy versus a traditional thermal ablation strategy is essential. In our experience, specific patient populations have leaned toward the use of NTNT ablative strategies and are outlined below.

Early Adopters

This patient population arrives with a very clear expectation of receiving the latest technology. Through their own research, these patients may have some predispositions toward one technology over another, and for the most part, we remain agnostic with respect to the techniques we utilize and serve as a resource to the patient (as long as clinical outcomes are equivalent). Distinct patient populations can present with a knowledge base that is sufficient for them to make their own decisions between one technology platform and another. In these situations, we make our best attempt to review the alternatives but not discourage these patients from receiving the care that they expect (as long as it fits within the clinical paradigm, and the body of scientific evidence supports their preference).

Seasonality

A patient may present with a preference to be treated in a particular time of year that may prove difficult for the use of compression stockings. Patients presenting with severe symptoms during the summer months may find a trial of compression stockings unbearable, and the thought of wearing compulsory compression stockings during the recovery phase unacceptable.[8] These patients are typically expecting immediate ambulation with minimal bruising and may be ideally suited for NTNT-directed therapy. This is in contradistinction to patients presenting in the fall or winter, or in colder climates, as they are typically less concerned about a trial of compression stockings, or compression stockings during recovery. Thus, a distinct benefit to both the patient and clinic with respect to NTNT therapy is the ability to provide therapy at any time throughout the year.*

Need for Rapid Return to Baseline Activity

High-performance athletes, professionals who require a rapid return to normal activities, and individuals who would prefer minimal downtime have a tendency to place the convenience of an NTNT treatment as a priority. Dancers, physiotherapists, dentists, beekeepers, and physicians represent examples of professionals that demand minimal downtime that we have treated effectively with NTNT. Individuals with busy schedules, and those that value discretion during convalescence, also have a tendency to lean toward the most convenient and efficient option (Figure 1).

Figure 1. A preprocedural standing photograph showing a large anterior varicosity tracking along the anterior tibia to the ankle (A). After the VenaSeal™ procedure, there was minimal bruising and edema, with only a single puncture access site in the ankle (low access was performed to treat the lower GSV, demonstrating several branch reticular veins) (B). After the VenaSeal™ procedure, there was complete collapse of the varicosity due to decompression. The vein remained flaccid and palpable but did not require compression stockings, and the patient was discharged without bruising, compression, or pain (C). The patient will likely require follow-up sclerotherapy; however, immediate results were noted as a result of the change in hydrodynamic pressure.

Travel

In our clinic, patients who have anticipated air travel are generally advised to wait between 3 and 4 weeks after treatment before traveling to minimize the thromboembolic effects associated with hypobaric hypoxia.[9] All patients traveling are advised to wear, at minimum, knee-high (and ideally thigh-high) class II compression stockings and stretch frequently during air travel in order to minimize the risk of deep vein thrombosis, in addition to maintaining hydration and mobilization. Currently, no clear recommendations relating to the specific risk of venous thromboembolic disease in patients undergoing endovenous intervention has been established.[10] Administration

*Some patients may benefit from compression stockings post procedure.

of ASA or, in severe-risk patients, enoxaparin may warrant consideration based on LONFIT3 data.[11]

MEDICAL INDICATION

Specific medical conditions may require consideration when choosing the appropriate strategy for treatment of chronic venous insufficiency. Some presentations of greater and lesser saphenous insufficiency that we believe benefit from an NTNT strategy include:

Superficial or Epifascial Greater Saphenous Vein

The position of the greater saphenous vein may have implications on the selection as tumescent thermal ablative therapies in superficial, or epi/suprafascial locations may result in not only increased pain and discomfort, but also the possibility of skin burn.[12] Application of sclerosants within very superficial vessels may also result in superficial chemical phlebitis and the possibility of tissue breakdown. Therefore, consideration of an NTNT therapy, such as the use of cyanoacrylate-based medical adhesive becomes advantageous in these situations.

Low Pain Threshold or Concerns of Nerve Damage

Although optimized protocols for the use of tumescent anesthesia exist, multiple needle punctures and the application of the tumescent itself still result in moderate degrees of discomfort.[13] For patients who are squeamish or hesitant about receiving multiple needle punctures and sites of infiltration, they are usually reassured by the fact that options are available that do not require tumescent anesthesia or the potential pain and discomfort associated with compression stockings. In situations where lower access may be required (such as with large varicosities below the midcalf or access near the tibia), concerns with respect to thermal nerve damage[14,15] can be mitigated with an NTNT strategy.

Prominent Perforators Leading Into the GSV or SSV or Large Vessel

In situations where the vessel is of a larger diameter, the greater amount of tumescent anesthesia and a greater risk of thrombophlebitis requiring stab phlebectomy[16] may encourage the operator to consider technologies that allow for coaptation of the vessels from an endovascular/endoluminal standpoint (Figure 2) as opposed to relying on external compression and tumescent anesthesia to facilitate endoluminal inflammation and thus disruption.

TOPICS OF PATIENT DISCUSSION: DISCLOSURE AND ENGAGEMENT

In order to better focus the formal consultation with the patient prior to developing a therapeutic pathway, identification of the pathophysiologic mechanisms in addition to the general knowledge base/expectations of the patients is essential. Typically, our approach is to assess the patient based on the following:

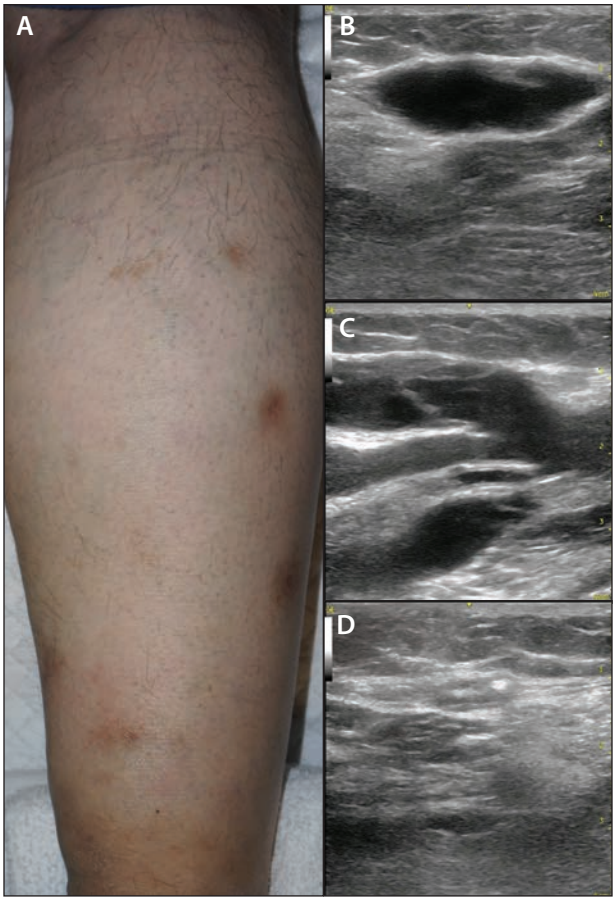

Figure 2. Baseline photograph showing enlarged lower calf after multiple failed attempts at visual sclerotherapy performed elsewhere (A). An ultrasonographic assessment of the small saphenous vein at the origin near the popliteal vein, measuring 19 mm (B) and longitudinal at the small saphenous vein origin (C). After NTNT with the VenaSeal™ procedure, there was coaptation of the vessel with no residual blood (D).

Is the primary indication medical, aesthetic, or both?

Patients with significant symptomology have much lower expectations for visual outcomes and appearances compared to those who are presenting with concerns regarding their aesthetics. Oftentimes, cosmetically motivated patients expect rapid turnaround and discrete recovery. The majority of these patients also require follow-up visual sclerotherapy, have an expectation of an expedient recovery, and will be subject to seasonal variation corresponding to the spring and fall

TABLE 1. COMPARISON OF AVAILABLE TREATMENTS FOR CHRONIC VENOUS INSUFFICIENCY

	FDA-Approved Foam Sclerotherapy (Varithena™ Foam, BTG International Inc.)	Mechanical-Assisted Foam Sclerotherapy (ClariVein™ Catheter, Vascular Insights LLC)	Endovenous Laser (various manufacturers)	Radiofrequency Ablation (ClosureFast™ Catheter, Medtronic)	Cyanoacrylate Ablation (VenaSeal™ Closure System, Medtronic)
Clinical evidence	More evidence	Less evidence	More evidence	More evidence	Some evidence
Indications	GSV, SSV, perf	GSV, SSV, perf	GSV, SSV	GSV, SSV, perf	GSV, SSV
Portability	More portable	More portable	Less portable	Less portable	More portable
Single session	No	Possible	Yes	Yes	Yes
Tumescent anesthesia	No	No	Yes	Yes	No
Thermal	No	No	Yes	Yes	No
Compression stocking	Yes	Yes	Yes	Yes	No
Required operator skill level	Less skilled	Skilled	More skilled	More skilled	Skilled
Disposable cost	More expensive	Expensive	Expensive	Expensive	More expensive
Capital cost	No	No	Yes	Yes	No
Return to activity	2 to 4 days	2 to 4 days	2 to 4 days	2 to 4 days	Immediate

Abbreviations: GSV, great saphenous vein; perf, perforator veins; SSV, small saphenous vein.

(ie, patients refer themselves in the spring in anticipation of the summer, as well as in the fall, when they do not need to wear compression stockings). We have found in our experience that this patient population has a general predisposition toward cyanoacrylate-directed therapy with associated visual sclerotherapy for cosmesis.

Patients presenting with concerns regarding the symptoms or risks associated with varicose veins will generally approach treatment with a very practical, pragmatic perspective and in general have a more cost-conscious approach to their management. Oftentimes, these patients will not be concerned about seasonality or visual appearance as long as symptoms can be controlled in an effective manner. These patients often opt for tumescent, thermal ablative strategies as a cost-conscious and/or established approach. Oftentimes, these patients will not seek visual sclerotherapy and present with permanent sequelae associated with their venous disease (blanche atrophy, lipodermatosclerosis, hemosiderin staining, healed or healing ulceration).

Is there a particular platform that you have preference toward or would like to discuss?

Within the self-pay model, patients either have an expectation of receiving full service, expert perspective, or a specific therapy based on their own research. Above all, efficacy of outcome should be the driving factor regarding the most appropriate course of treatment and management plan. However, as based on a combination of published literature and personal experience, there can be a number of pathways that can reach this objective.

What is your expectation of recovery?

Depending on the patient, expectations of recovery can range from immediate recovery, ambulation, and results, to an understanding of long-term medical prophylaxis with no significant change in visual appearances, potential bruising or pain, and complications associated with therapy.

In a typical consultation, we advise the patients undergoing thermal ablation that they may have the standard complications associated with ablation (nerve damage, bruising, thrombophlebitis), in addition to potential erythema that may last from 4 to 6 weeks. We will not pursue further treatment with sclerotherapy until at least 3 to 6 months following the completion of the initial treatment session. Patients who are undergoing cyanoacrylate ablation are advised that ambulation and recovery is almost immediate; however, they should be aware of the potential for a mild inflammatory dermatitis (which is

self regulating, typically presenting at 10 to 14 days) and the potential feeling of subdermal tightness secondary to the cyanoacrylate polymer, which also self resolves after approximately 3 to 6 months.[5] None of these presentations or courses of recovery should result in significant limitations in ambulation.

Regardless of which modality and pathways are chosen, we can still assure patients that all endovenous options will allow them to enjoy a much faster recovery as compared to traditional surgical stripping and ligation. As such, all treatments will result in the same outcome.[1,3,5] The variation in recovery, however, is based on the modality chosen, which may be driven by patient preference.

CONCLUSION

As clearly indicated by the prevalence of venous disease, challenges remain with respect to patient education and activation. A consolidated approach that incorporates the patient as a key stakeholder in his or her therapeutic pathway has the potential to increase engagement and activation of this population in need. ■

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1. Brittenden J, Cotton SC, Elders A, et al. Clinical effectiveness and cost-effectiveness of foam sclerotherapy, endovenous laser ablation and surgery for varicose veins: results from the Comparison of Laser, Surgery and Foam Sclerotherapy (CLASS) randomised controlled trial. Health Technol Assess. 2015;19:1-342.
2. Kayssi A, Pope M, Vucemilo I, Werneck C. Endovenous radiofrequency ablation for the treatment of varicose veins. Can J Surg. 2015;58:85-86.
3. van der Velden SK, Biemans AA, De Maeseneer MG, et al. Five-year results of a randomized clinical trial of conventional surgery, endovenous laser ablation and ultrasound-guided foam sclerotherapy in patients with great saphenous varicose veins. Br J Surg. 2015;102:1184-1194.
4. Witte ME, Reijnen MM, de Vries JP, Zeebregts CJ. Mechanochemical endovenous occlusion of varicose veins using the ClariVein(R) device. Surg Technol Int. 2015;26:219-225.
5. Morrison N, Gibson K, McEnroe S, et al. Randomized trial comparing cyanoacrylate embolization and radiofrequency ablation for incompetent great saphenous veins (VeClose). J Vasc Surg. 2015;61:985-994.
6. Gardner DM, Mintzes B, Ostry A. Direct-to-consumer prescription drug advertising in Canada: permission by default? CMAJ. 2003;169:425-427.
7. Mackey TK, Cuomo RE, Liang BA. The rise of digital direct-to-consumer advertising? Comparison of direct-to-consumer advertising expenditure trends from publicly available data sources and global policy implications. BMC Health Serv Res. 2015;15:236.
8. Bakker NA, Schieven LW, Bruins RM, et al. Compression stockings after endovenous laser ablation of the great saphenous vein: a prospective randomized controlled trial. Eur J Vasc Endovasc Surg. 2013;46:588-592.
9. Matarasso A. Air travel, surgery, and thromboembolic disease: the surgical flight syndrome. Aesthet Surg J. 2002;22:364-365.
10. Blackhurst H. Towards evidence based emergency medicine: best BETs from the Manchester Royal Infirmary. BET 1. Flight deep vein thrombosis prophylaxis in lower limb injury. Emerg Med J. 2009;26:289.
11. Cesarone MR, Belcaro G, Nicolaides AN, et al. Venous thrombosis from air travel: the LONFLIT3 study—prevention with aspirin vs low-molecular-weight heparin (LMWH) in high-risk subjects: a randomized trial. Angiology. 2002;53:1-6.
12. Ertuğul I, Karagöz T, Aykan HH. A rare complication of radiofrequency ablation: skin burn. Cardiol Young. 2015:1-2.
13. Zerweck C, von Hodenberg E, Knittel M, et al. Endovenous laser ablation of varicose perforating veins with the 1470-nm diode laser using the radial fibre slim. Phlebology. 2014;29:30-36.
14. Doganci S, Yildirim V, Demirkilic U. Does puncture site affect the rate of nerve injuries following endovenous laser ablation of the small saphenous veins? Eur J Vasc Endovasc Surg. 2011;41:400-405.
15. Yilmaz S, Delikan O, Aksoy E. Saphenous nerve injury after endovenous laser ablation of incompetent greater saphenous vein: An electroneuromyography study [published online ahead of print January 12, 2015]. Phlebology.
16. Varnagy D, Labropoulos N. The issue of spontaneous arteriovenous fistulae after superficial thrombophlebitis, endovenous ablations, and deep vein thrombosis: an unusual but predictable finding. Perspect Vasc Surg Endovasc Ther. 2006;18:247-250.