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VENASEAL™ CLOSURE SYSTEM

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Is Cyanoacrylate Safe for Peripheral Venous Applications?

Previous experience shows promise for a venous disease treatment that recently received FDA approval.

BY NICK MORRISON, MD, FACPH, FACS, RPHS

Traditional treatment of superficial venous incompetence changed little throughout most of the 20th century, during which time it consisted of high ligation of the saphenous vein and adjacent tributaries with stripping of the length of the vein. Some modifications of this surgical approach involved limiting the length of stripped saphenous vein to the more proximal portion (mostly to avoid sensory nerve injury) and a move away from the external stripping device to the development of an invagination (PIN) stripper to lessen perivenous tissue damage in an effort to enhance recovery.[1]

As with many other surgical procedures, minimally invasive techniques were developed beginning in the late 1990s. Endovenous ablation procedures for saphenous vein and other incompetent superficial nontruncal veins were technological breakthroughs that revolutionized the treatment of patients with chronic venous disorders. Within a few years, around the turn of the century, many new treatment methods were developed, especially in the United States and Western Europe, including foam sclerotherapy and endovenous thermal ablation (radiofrequency, laser, steam), all of which are performed under local anesthesia in an outpatient setting. These methods have been investigated thoroughly and found to be safe and efficacious, albeit with some drawbacks. Foam sclerotherapy has some limitations with regard to long-term efficacy. All of the thermal ablation techniques require the application of tumescent anesthesia, which requires considerable training and practice for the practitioner to become proficient in its use. Unfortunately, this is uncomfortable for patients, and many of them experience a variable degree of intraprocedural discomfort and postprocedural bruising. Moreover, even though the scientific evidence is weak, most practitioners recommend postprocedural compression hose for patients, which are limiting especially for patients in warm climates or for whom application of compression hose is difficult (diminished strength, painful joints, obesity, etc.).

TUMESCENTLESS THERAPIES

Many of these aforementioned shortcomings have led to technological developments intended to lessen or eliminate the necessity of tumescent anesthesia, patient discomfort, and the use of compression hose, and have been termed "tumescentless" techniques. With regard to the efficacy of foam sclerotherapy, it has been shown that the most commonly used detergent sclerosants (polidocanol and sodium tetradecyl sulfate) are much more active in the absence of blood.[2] Various techniques have been developed to minimize inactivation by blood within the vein, including the use of saline flush before foam injection[3] and the long catheter technique, which again requires the application of tumescent anesthesia for vein compression and blood evacuation.[4,5] Among the tumescentless treatment methods, mechanochemical ablation[6] was one of the first that eliminated the need for tumescent anesthesia, although perhaps not the recommendation for compression hose.

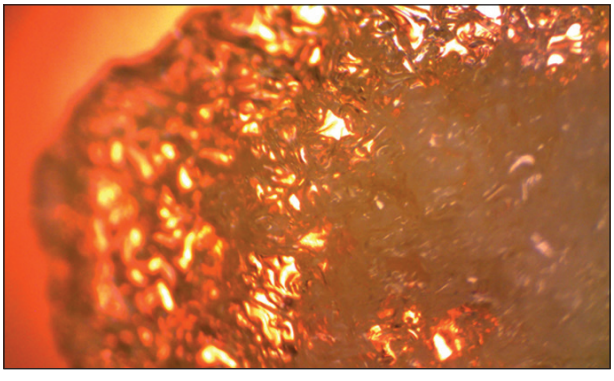

Figure 1. Microscopic view of the VenaSeal™ adhesive (Medtronic) polymerized in plasma.

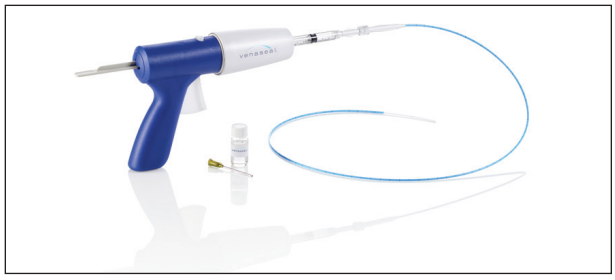

Figure 2. Delivery system for the VenaSeal™ procedure, which received US Food and Drug Administration approval in February 2015 and CE Mark approval in September 2011.

CYANOACRYLATE ADHESIVE FOR EMBOLIZATION

One of the most recent developments has been the use of cyanoacrylate adhesive for embolization (CAE) and removal of the incompetent superficial veins of the leg from the venous circulation. Such endovascular use of CAE is not new, having been used in the United States in the treatment of intracerebral arteriovenous malformations since US Food and Drug Administration (FDA) clearance was granted in 2000. In studies leading to FDA clearance, cyanoacrylate adhesives were not found to be mutagenic, pyrogenic, hemolytic, sensitizing, irritating, or cytotoxic.[7] Other peripheral vascular conditions for which CAE has been used are gastrointestinal bleeding and tumors, genitourinary abnormalities, and postendovascular graft leaks.[8]

Rod Raabe, MD, an interventional radiologist from Spokane, Washington, had commonly used cyanoacrylate adhesives for various intravascular procedures, including ablation of intracerebral arteriovenous malformation. He wondered if a similar procedure could be developed for ablation of incompetent superficial truncal veins.

N-butyl cyanoacrylate was the most commonly used adhesive at the time and had characteristics that Dr. Raabe deemed unsuitable for use in leg veins, including reduced viscosity, slow polymerization with rigidity afterward, requirement of mixing to initiate polymerization, and adherence of the catheter to the vein wall in the presence of adhesive. These characteristics led Dr. Raabe and Monte Madsen, RVT, to convene a team of chemical, biochemical, and product engineers to develop a cyanoacrylate adhesive with different properties more appropriate for superficial leg veins. A better adhesive would include increased viscosity to prevent embolization by allowing adequate contact with the intima of the vein, rapid polymerization to avoid embolization, flexibility after implantation so patients would not experience discomfort upon leg movement, and development of a strong bond to the vein wall to prevent recanalization and eliminate the need for postprocedural compression.

Other important factors during the adhesive (Figure 1) and delivery system (Figure 2) development included a formula that would not change with sterilization, catheters that would not adhere to the vein wall in the presence of adhesive, and a long shelf life so the adhesive did not polymerize before its use.

Benchtop experiments began in 2008 and included development of a catheter with multiple air-filled channels in the catheter wall to allow for high visibility by ultrasound. A propulsion device ("glue gun") was also devised to precisely deliver very small volumes of adhesive. Endovenous animal studies conducted using CAE in rabbit veins were performed in 2009, which demonstrated a mild immunological response similar to that seen with suture material.[7] Caprine models showed a similar foreign body response without extension into perivenous tissue and complete occlusion at 6 months. CAE was then performed on superficial epigastric veins in porcine models followed by animal evaluation at 60 days.[9] Histologic examination of harvested veins showed a chronic foreign-body-type inflammatory response, which led to fibrosis and occlusion of the treated vein segment without evidence of perivenous extension of the inflammatory response, adhesive migration beyond 2 cm (no adhesive detected in pulmonary circulation), or recanalization of the vein.[9]

CONCLUSION

Over the past 2 decades, treatment of patients with chronic superficial venous disorders has progressed dramatically compared to the previous century of traditional surgical modalities. Endovenous techniques, initially with foam sclerotherapy, various methods of thermal ablation, and more recently with tumescentless procedures, have seen rapid development to less and less invasive technological methods of treatment. Previous experience with endovascular CAE for vascular malformations and other clinical disease states coupled with animal studies showing safety and efficacy for intravenous CAE using a modified form of cyanoacrylate adhesive have opened the way to human trials to be discussed in a later issue. ■

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Clinical Evidence Behind the VenaSeal™ Closure System

A review of the clinical trials that led to FDA approval of a novel treatment for saphenous vein reflux.

BY KATHLEEN GIBSON, MD, FACS, AND AZAH TABAH, PHD

In the United States, it is estimated that 30 million men and women are affected by chronic venous insufficiency (CVI).[1] CVI is often progressive and can lead to symptoms impacting patient quality of life such as aching, throbbing, and edema.[2] With time, CVI can lead to more serious medical problems such as irreversible skin changes and/or chronic ulceration.[3]

The most common anatomic pattern present in patients with superficial venous insufficiency is incompetence of the great saphenous vein (GSV).[4] In the United States, the previously favored treatment for incompetence of the GSV, surgical stripping, has largely been replaced by endothermal ablation, either with radiofrequency or laser energy.[5] Although endothermal techniques have led to improvements in patient recovery and offer earlier return to normal activities of daily living when compared to surgical stripping,[6] they require tumescent anesthesia and in some centers, are performed using sedation. Additionally, standard clinical practice after endothermal ablation requires the use of compression stockings or wraps for a physician-specified period of time during the recovery period. The VenaSeal™ closure system (VSCS, Medtronic) received CE mark approval in September 2011 and premarket approval from the US Food and Drug Administration (FDA) for closure of incompetent saphenous veins in February 2015. VSCS, utilizing a proprietary cyanoacrylate adhesive, offers a safe and effective method of treating refluxing saphenous veins without the need for tumescent anesthesia or postprocedure compression.*

In the March 2015 issue of *Endovascular Today*, Dr. Nick Morrison described the history of the development of cyanoacrylate adhesives for medical applications. This article outlines the clinical data leading to the premarket approval of the VenaSeal™ closure system.

FEASIBILITY STUDY

The cyanoacrylate adhesive utilized in the VSCS first underwent proof of concept in the rabbit, swine, and goat models.[7,8] Additionally, animal models were used to research biocompatibility, mechanism of action, safety, and effectiveness. In a first-in-man feasibility study published[9] and presented by Dr. Jose Almeida at the American Venous Forum, 38 patients with symptomatic reflux of the GSV were treated with catheter-delivered cyanoacrylate adhesive under ultrasound guidance. No adjunctive procedures were allowed for 6 months, and the post-procedure regimen did not include the use of compression. The primary outcome measure was duplex-verified closure of the GSV at follow-up intervals of 48 hours, 1, 3, 6, and 12 months. Secondary outcome measures were rates of adverse events and change in the Venous Clinical Severity Score (VCSS). A second article reporting follow-up out to 2 years by the same authors in 2014 showed that GSV closure immediately after the procedure and at 48 hours was 100%.[10] Closure rates at 1, 3, 6, and 12 months were 92%. At 2 years, 24 of the original 38 patients were available for follow-up, and the occlusion rate remained at 92% (Table 1). The mean VCSS at the start of the study was 6.1 ± 2.7, and 1.3 ± 1.1, 1.5 ± 1.4, and 2.7 ± 2.5 at 6, 12, and 24 months, showing maintenance of clinical benefit.

A mild and self-limited phlebitis, responding to nonsteroidal analgesia, was reported in 15.8% of patients. Thread-like thrombus extensions into the common femoral vein were seen on duplex ultrasound in eight patients (21.1%). These thrombus extensions resolved without the use of anticoagulants. In this study, the catheter was placed 1.5 to 2 cm caudal to the saphenofemoral junction for the delivery of adhesive. Additionally at this location, two injections of the adhesive were administered. Because of the thrombus extensions seen in the patients in this early

*Some patients may benefit from compression stockings postprocedure.

TABLE 1. DUPLEX CLOSURE RATES	
Clinical Study	**Closure Rates**
FEASIBILITY study[9,10]	12 months: 92% 24 months: 92%
eSCOPE study[13]	6 months: 94.3% 12 months: 92.9%

trial, the technique was changed in the subsequent trials, and the tip of the catheter was positioned farther caudally, 5 cm from the saphenofemoral junction, and the first two injections were delivered 1 cm apart. With this change in technique, no thrombus extensions were seen in subsequent clinical trials.[11,12]

eSCOPE STUDY

The European multicenter study, eSCOPE,[11] was a nonrandomized, prospective trial to evaluate the safety and efficacy of the VSCS in the treatment of symptomatic refluxing GSVs. Seventy patients were treated, and follow-up assessments occurred at 48 hours, 1, 3, 6, and 12 months, and ongoing follow-up at 24 and 36 months. Technique and outcome measures were similar to the feasibility study, with the exception of the more caudal catheter placement, and the allowance of adjunctive measures at 3 months rather than 6 months. No compression therapy was used after the procedures. GSV closure rates were 94.3% at 6 months and 92.9% at 1 year (Table 1); 36-month data have not yet been published. Adverse events included a mild, self-limited phlebitic reaction in 11.4% of patients. No thrombotic events or paresthesias were observed.

VeClose STUDY

The United States pivotal trial, VeClose, was a prospective trial with a 1:1 randomization comparing VSCS to radiofrequency ablation (RFA, ClosureFast™ catheter, Medtronic).[12] The trial was conducted at 10 sites throughout the United States. No adjunctive therapies were permitted for 3 months. To avoid confounding effects, both groups received postprocedure compression. The study objective was to demonstrate the safety and efficacy of VSCS in the treatment of lower extremity truncal reflux by showing noninferiority to RFA

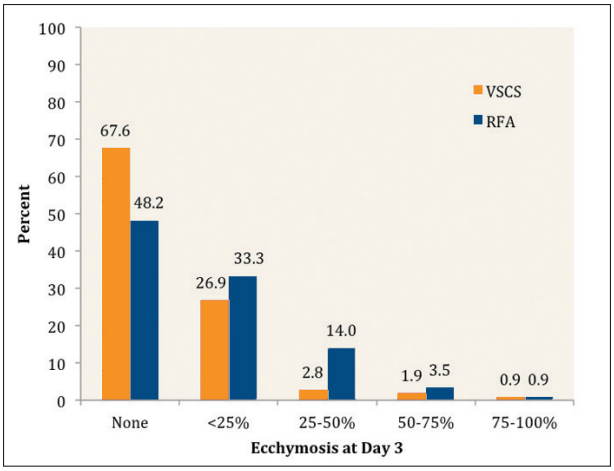

Figure 1. Ecchymosis assessed with a 5-point scale on day 3 by treatment group. Patients treated with VSCS had less ecchymosis at day 3 compared with those treated with RFA ($P < .01$).

at 3 months. There were 242 patients enrolled with 20 roll-in/training cases; 108 patients were treated with VSCS and 114 with RFA. The primary study endpoint was duplex ultrasound closure of the GSV, and secondary endpoints were intraoperative pain, ecchymosis (at day 3), and adverse events (at 1 month). VCSS, Aberdeen Varicose Vein Questionnaires (AVVQ), and EQ-5D were collected at baseline and at follow-up evaluations. Follow-up assessments occurred at day 3, 1 and 6 months, 1 and 2 years, and will conclude at 3 years.

The two treatment groups were well matched in regards to age, gender, body mass index, vein diameter, length of vein treated, and baseline AVVQ. There was no significant difference in intraprocedural pain between the two groups, but there was significantly less ecchymosis in the treated limb at 3 days in the VSCS group ($P = .0013$). No ecchymosis was present in 67.6% of the VSCS patients compared to 48.2% of the RFA patients. When present, the severity of ecchymosis was lower in the VSCS group (Figure 1). In terms of the primary endpoint, the study protocol defined complete closure to mean duplex ultrasound closure along the entire treated segment of the target vein with no discrete segments of patency exceeding 5 cm in length, which also included segments that were compressible, even if they showed

TABLE 2. CLOSURE RATES FROM VeCLOSE STUDY			
Duplex Closure Rate	**VSCS (n = 108)**	**RFA (n = 114)**	***P* Value**
3 months	99%	96%	< .0001
6 months[13]	99%	94%	< .0001

TABLE 3. CHANGE IN VCSS AND AVVQ SCORES BY VISIT AND TREATMENT TYPE

	Treatment	Baseline	1 Month	3 Months	6 Months
VCSS mean (SD)	RFA	5.6 (2.6)	2.6 (2)	2 (2)	1.6 (1.9)
	VSCS	5.5 (2.6)	2.3 (1.7)	1.9 (1.6)	1.5 (1.8)
AVVQ mean (SD)	RFA	19.4 (9.9)	12.6 (8.3)	10.7 (8.6)	9.1 (6.9)
	VSCS	18.9 (9)	11.9 (7.5)	11.6 (7.5)	10.2 (7.2)

no flow with color imaging. Vein closure was adjudicated by an independent core laboratory (VasCore) for the 3-month visit. Closure rates (Table 2) at 3 months and 6 months were 98.9% and 98.9% for VSCS, and 95.4% and 94.3% for RFA, a highly statistically significant finding for noninferiority at these time points ($P < .0001$).[13] There was complete agreement between the core laboratory and the investigator findings. The core laboratory was blinded to the investigator findings.

There were no deep vein thromboses or pulmonary emboli reported in either treatment group. Phlebitis occurred in 20% of VSCS-treated patients and 14% of RFA-treated patients ($P = .36$). In both groups, the majority of the cases of phlebitis were mild and transient, and were successfully treated with anti-inflammatory medications such as ibuprofen. The reaction within the VSCS cohort was seen in all three studies, and it has a presentation that is different in terms of both physical signs and duration and quality of symptoms compared to phlebitis that can occur following endothermal heat ablation. Whereas phlebitis after endothermal ablation typically presents as a firm and focally tender cord along the course of the treated vein that may take weeks to resolve, patients with symptoms following VSCS presented with a rosy cutaneous erythema in the medial thigh, with mild diffuse tenderness that dissipated over several days. Some patients with phlebitis presented without symptoms, having only the visual appearance.

It is increasingly recognized that the use of surrogate outcome measures (such as duplex closure of the GSV) to judge the success or failure of a treatment for venous disease is insufficient if they are not accompanied by demonstration of improvement in a patient's symptoms/quality of life. The improvements seen in VCSS and the AVVQ in the VeClose trial therefore are critically important findings. In the two treatment groups, the VCSS and AVVQ showed significant and sustained improvement. There were no differences in the improvement in VCSS and AVVQ in patients treated with VSCS compared with those treated with RFA (Table 3). Data collection in this trial is ongoing and will continue for 36 months after treatment.

CONCLUSION

The three described clinical trials demonstrate that VSCS is a safe and effective therapy for the closure of incompetent truncal veins. The closure rates across all of the trials have been consistently demonstrated. Side effects were minor and well tolerated. There have been no documented cases of deep venous thrombosis or pulmonary embolism in any trial. As shown in the feasibility and eSCOPE trials, patients treated with VSCS do not require post-procedure compression stockings.* Additionally, VSCS does not require use of tumescent anesthesia. The FDA approval of VSCS for the treatment of superficial venous insufficiency gives physicians a new and important tool to treat their patients suffering from symptoms caused by varicose veins. ■

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**Some patients may benefit from compression stockings postprocedure.*

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

Insights from one center's firsthand experience.

BY DAVID M. LIU, MD, FRCPC, FSIR; DARREN KLASS, MD, FRCPC, PHD; JOHN CHUNG, MD, FRCPC; AND JOEL GAGNON, MD, FRCPC

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).

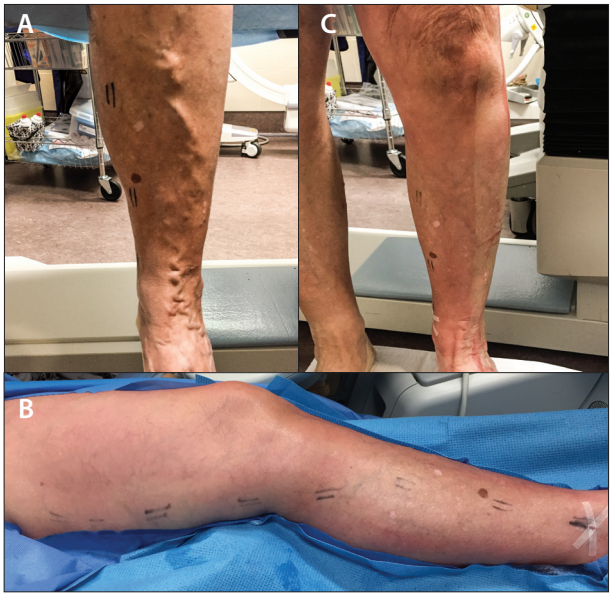

Figure 1. A preprocedural standing photograph showing a large anterior varicosity tracking along the anterior tibia to the ankle (A). After the VenaSeal™ procedure, there was minimal bruising and edema, with only a single puncture access site in the ankle (low access was performed to treat the lower 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:

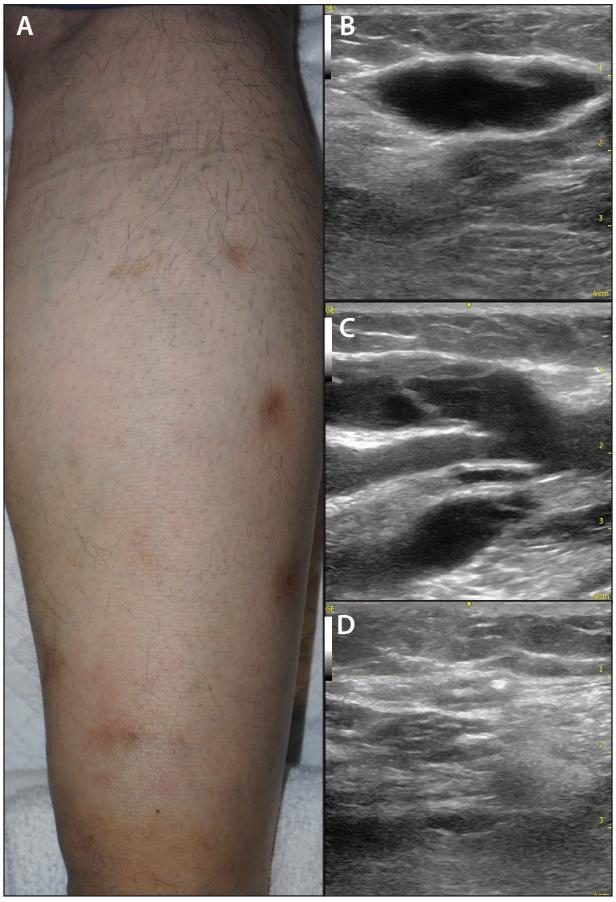

Figure 2. Baseline photograph showing enlarged lower calf after multiple failed attempts at visual sclerotherapy performed elsewhere (A). An ultrasonographic assessment of the small saphenous vein at the origin near the popliteal vein, measuring 19 mm (B) and longitudinal at the small saphenous vein 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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