Incorporating Nontumescent Ablation Into Your Practice

New techniques for superficial venous disease offer advantages, but reimbursement issues raise challenges for adoption.

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The US Food and Drug Administration (FDA) approved endothermal ablation (ETA) techniques (ie, radiofrequency, laser ablation) for the treatment of saphenous vein incompetence over 15 years ago. Since that time, these technologies have been rapidly adopted and are now the most common modalities used for treating superficial venous insufficiency.[1] ETA offers advantages over traditional high ligation and stripping, offering improvements in patient recovery, and most notably, a faster return to activities of daily living.[2] Both ETA techniques require tumescent anesthesia, and while this is generally well tolerated, it requires multiple needle sticks and can cause bruising and discomfort. A desire to simplify endovenous ablation procedures, eliminate the need for tumescent anesthesia, and improve the patient experience has lead to the development of nontumescent, nonendothermal technologies for the treatment of superficial venous insufficiency.

Three proprietary nontumescent technologies are currently offered in the United States for treating saphenous vein insufficiency:

- Clarivein (Vascular Insights) was approved as a proprietary infusion catheter in 2008. Although it does not have a specific indication for saphenous ablation, it is widely used. It combines mechanical rotation of a wire tip with injection of a liquid sclerosant of the provider's choice.[3] This technique is often referred to as "mechanochemical ablation" (MOCA).
- Varithena (BTG Internationl Ltd.) was approved by the FDA in November 2013 for the treatment of incompetence of the great saphenous vein (GSV) or accessory saphenous veins (ASVs) and their tributaries. It is a proprietary endovenous microfoam (PEM) consisting of 1% polidocanol and a very low nitrogen physiologic gas mixture. Because of FDA concerns of the neurologic effects of gas bubbles in the circulation, Varithena underwent extensive safety testing in patients with known patent foramen ovale prior to the pivotal trials that led to its approval.[4]
- Venaseal (Medtronic) obtained FDA approval for the treatment of saphenous vein insufficiency in February 2015. It is a proprietary cyanoacrylate with a delivery system that closes veins by coapting them with a medical adhesive.[5] Recent publications have referred to this technique as "cyanoacrylate closure" (CAC).[6]

These new technologies offer many potential advantages to providers and patients. No financial outlay in terms of an ETA generator is required, and clinical data show good outcomes. The largest current hurdle in terms of widespread adoption of these techniques is challenges with reimbursement, as they currently do not have their own current procedural terminology (CPT) code.

CLINICAL EVIDENCE

A selected and noncomprehensive list of peer-reviewed studies for MOCA, PEM, and CAC is shown in Table 1.[3,5-17] No head-to-head comparison studies of the three techniques have been performed. Because the studies may have had different mixes of patients, out-

come measures, and patient follow-up protocols, caution should be used when extrapolating and comparing results between trials. MOCA and CAC have both been compared to radiofrequency ablation (RFA) in a randomized fashion.[8,17] In both of these trials, duplex closure rates were noninferior compared to RFA, and patient postprocedure pain (MOCA), bruising (CAC), and return to work (MOCA) were superior to RFA. Return to work and normal activity was not specifically studied in the VeClose (CAC) trial, but the WAVES trial showed a return to work and normal activity of 0.2 ± 1.1 days and 2.4 ± 4.1 days, respectively. All three techniques show significant improvements in physician-determined venous clinical severity scores and patient quality-of-life measurements at all measured time points. Serious adverse events are rare, and the most common adverse event for all three techniques is superficial phlebitis.[7,9,17]

Reflux of the GSV is the most common anatomic pattern of superficial venous reflux; however, reflux of the ASV and/or the small saphenous vein (SSV) is not uncommon.[18] The treatment of the ASV was specifically included in the pivotal PEM trials[9,11] and is listed as an FDA-approved indication, and treatment of ASVs with CAC has been published.[6] Recent articles have described treatment of the SSV with MOCA[19,20] and with CAC.[6]

PATIENT CONSIDERATIONS

MOCA, PEM, and CAC all offer the option of varicose vein treatment without the use of tumescence or heat. Patient and clinical considerations may make the use of these techniques desirable. As heat is not used, the risk of thermal injury to the saphenous or sural nerve is avoided. This is a known complication of ETA,[21,22] one of particular concern when treating the GSV below the knee and the lower third of the SSV, as the sural nerve has significant variability in its course.[23] The techniques also offer advantages in terms of cutaneous burns in patients in whom adequacy of tumescence is a concern, such as patients with more superficial veins or those with lipodermatosclerosis in whom tumescence is difficult.

Although regimens vary significantly, it is standard practice that patients wear compression stockings or bandaging for some specified period of time after ETA.[24] Compression stockings were also mandated during the recovery period in studies of MOCA and PEM. In several CAC studies, no compression was used postprocedure,[5,6,14] and adverse event and closure rates were similar in patients who did not use compression compared to a CAC study in which compression was mandated.[17] Many patients find compression stockings difficult to wear, and compliance with compression regimens is notoriously poor.[25] Reasons patients may be noncompliant with stockings include poor fit (especially in the obese), difficulty donning the stockings (common in the elderly or those with arthritis in the hands or back), discomfort in warm climates, and skin reactions to compression material. As such, CAC may be desirable for patients who are intolerant of postprocedure compression.

Tumescent anesthesia is generally well tolerated by most patients. However, it can cause bruising and involves multiple needle sticks. Nontumescent techniques involve needle sticks only at the access site. These techniques may be especially attractive to patients with a low tolerance to pain or with a needle phobia.

All nontumescent techniques offer a rapid return to normal activity. In our practice, the main limitation on activity levels relates to whether compression is required after the procedure. Compression stockings or bandaging may slip, or the skin may become irritated with a vigorous workout after a venous procedure. For this reason, we may ask the patient to curtail these activities for a few days if they are wearing compression stockings. After CAC treatment, we allow our patients to return to normal activities immediately following their procedure, including vigorous exercise.

TECHNIQUE

Incorporating nontumescent techniques is straightforward for providers who are experts in endovenous heat ablation. Venous access is achieved in a similar fashion to access for laser or RFA therapy. Expertise with ultrasound-guided access and recognition of the saphenofemoral and/or popliteal junction is extremely important for safe use of these techniques. For novice providers of endovenous ablation, training in venous ultrasound is paramount, and competency in recognizing superficial and deep venous structures is a prerequisite for safe venous treatment.

For both MOCA and PEM, dose limits for sclerosant drugs must be respected. There is no specific dose limit of cyanoacrylate adhesive for CAC; however, the kit comes with 5 mL of adhesive, and 3.7 mL of this is usable because the dead space of the delivery catheter is 1.3 mL. Both MOCA and CAC can be performed by a single provider, with one hand holding the ultrasound probe and the other hand performing the ablation. PEM requires two individuals, with one person compressing the saphenofemoral junction with an ultrasound probe while the second person injects PEM while holding distal compression.

TABLE 1. SELECTED STUDIES

	Study Name	Date	Design	N	Outcomes
Clarivein					
Elias and Raines[3]	–	2012	Single center, cohort	29	Duplex closure of 96.7% at 6 months, safety and efficacy established
Van Eekeren et al[7]	–	2014	Single center, cohort	106	Duplex closure of 88.2% at 1 year, significant improvement in VCSS and QOL ($P < .001$)
Lane et al[8]	–	2016	Randomized vs RFA	170	Similar occlusion rates, average pain score less in MOCA group ($P = .002$)
Varithena					
Todd and Wright[9,10]	VANISH-2	2014, 2015	Randomized vs placebo, primary treatment	232	Improvement in symptoms (VVSymQ*) and appearance compared to placebo $P < .0001$
King et al[11]	VANISH-1	2015	Randomized vs placebo, primary treatment	279	Improvement in symptoms (VVSymQ*) and appearance compared to placebo $P < .0001$
Vasquez and Gasparis[12]	VARITHENA 017	2016	Randomized vs placebo, branch treatment	117	Improvement in appearance ($P = .001$) and need for additional treatment ($P < .05$) compared to placebo
Venaseal					
Almeida et al[5,13]	–	2013, 2015	Single center, nonrandomized cohort	38	Duplex closure of 92% at 12 and 24 months, VCSS significantly improved ($P < .0001$)
Proebstle et al[14-16]	eScope	2013, 2014, 2015	Multicenter, nonrandomized cohort	70	Duplex closure rate of 92.9% at 12 months, AVVQ significantly improved ($P < .0001$)
Morrison et al[17]	VeClose	2015	Randomized vs RFA	222	Duplex closure of 99% for cyanoacrylate and 96% for RFA at 3 months, ($P < .01$ for noninferiority. Significant improvement in VCSS and AVVQ ($P < .001$)
Gibson and Ferris[6]	WAVES	2016	Single center, nonrandomized cohort	50	Duplex closure 100% at 1 month, VCSS and AVVQ significantly improved ($P < .001$)

Abbreviations: AVVQ, Aberdeen Varicose Vein Questionnaire; MOCA, mechanochemical ablation; QOL, quality of life; RFA, radiofrequency ablation; VCSS, venous clinical severity score.
*BTG International Ltd.

With PEM, both the truncal veins and the side branches can be treated in one session, up to a 15-mL limit. MOCA and CAC treat truncal veins only, and the decision whether to treat side branches with either microphlebectomy or sclerotherapy is physician dependent. In our practice, we typically perform concomitant side branch procedures when a patient is treated with ETA; however, with CAC, we usually stage branch treatment for several reasons, including because the procedure requires cash payment and many patients prefer to "wait and see" if their side branches resolve, and we tend to see greater branch resolution with CAC than with ETA. We have found PEM to be particularly advantageous in patients with recurrent varicose veins, as these veins can be tortuous, making catheter passage with other techniques impossible.

REIMBURSEMENT

Currently, without unique CPT codes, reimbursement for these new techniques can be challenging. Insurance coverage of both PEM and MOCA is highly dependent on region and insurance carrier. Both BTG and Vascular

Insights have resources to help guide practices through preauthorization/predetermination. As with approval for any venous procedure, good documentation of the venous disease's impact on the patient's quality of life and activities of daily living is important. Documentation of vein diameters, reflux times, and compliance with conservative management is necessary in crafting a letter of medical necessity. In communication with the insurance provider, it is helpful to indicate why the new technology will be particularly beneficial to that specific patient. Need for peer-to-peer review and appeals can be expected. CAC is currently not covered by insurance carriers and is offered as a cash payment choice. In our region, depending on the plan, some patients can use flexible spending accounts to cover their treatment.

APPROACH TO PATIENTS

In our practice, all patients who are anatomically and clinically suitable for nontumescent techniques are offered those options along with traditional ETA. The advantages and disadvantages of each approach, including the anticipated out-of-pocket costs, are discussed with every patient. The risk of each technique is discussed, as are the data regarding efficacy and patient outcomes. Patients are informed that long-term data are not available with these techniques as compared with ETA. Finally, we are upfront with our patients about challenges we may have with payor coverage.

It is my belief that patients should be made aware of all the available techniques for their venous treatment. I do not make assumptions about what they may or may not be willing to spend out of pocket for medical expenses. After presenting the pros and cons of each treatment with the patient in an open and unbiased fashion, it is ultimately the patient's decision as to whether they want to undergo treatment with ETA versus a nontumescent technology. I point out that all available treatments should provide an excellent outcome, and they all have a common goal in improving venous health.

SUMMARY

Nontumescent ablation technologies offer intriguing new tools in the treatment of superficial venous disease. MOCA, PEM, and CAC all have potential advantages for practitioners and patients, with data showing good patient outcomes. Performance of these techniques is straightforward, but until insurance coverage is more widespread, their adoption may be slowed by reimbursement and cost issues. As is common in the United States health care system at large, reimbursement often lags behind the launch of exciting new technologies. ■

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