Key Developments in Superficial Venous Disease Management

A rundown of five significant advancements seen in the past year for the treatment and management of superficial venous disease.

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Symptoms of chronic venous insufficiency can have a significant effect on a patient's quality of life.[1] Despite high prevalence rates, awareness of venous disease is quite low. In the past decade, however, there has been an increase in the number of clinical trials and technologies designed to help improve the care of patients with venous disease. This article reviews the most noteworthy developments in the treatment and management of superficial venous disease in the past year.

EVIDENCE-BASED GUIDELINES UPDATED

An update to the *Handbook of Venous and Lymphatic Disorders* was published in January 2017 and includes important evidence-based, clinical practice guidelines to help manage various practical aspects of venous disease. In particular, 105 specific guidelines for the management of chronic venous disease are included; several updated guidelines related to thermal and nonthermal technologies are summarized in Table 1.[2]

DATA ON DURABILITY OF THERMAL ABLATION GROWS

A meta-analysis of three randomized controlled trials (RCTs) and 10 follow-up studies of RCTs with follow-up data ≥ 5 years compared surgical, thermal, and foam sclerotherapy of the great saphenous vein (GSV).[3] Ultrasound-guided foam sclerotherapy resulted in lower success rates of vein closure (34%; 95% confidence interval [CI], 26%–44%) compared with high ligation and stripping (83%; 95% CI, 72%–90%), laser ablation (88%; 95% CI, 82%–92%), and laser ablation with high ligation (88%; 95% CI, 17%–100%; $P \leq .001$ for all). In a 5-year comparative outcome study, both laser and radiofrequency ablation therapy demonstrated high GSV occlusion rates of 96.7% and 96.2% ($P = .81$), respectively. Freedom from symptomatic anterior accessory vein recurrence after 5 years was 85% after radiofrequency ablation therapy and 87% after laser ablation ($P = .50$). Venous Clinical Severity Score (VCSS) and Aberdeen Varicose Vein Questionnaire (AVVQ) scores also demonstrated durable improvements for both of these thermal techniques.[4]

These studies reinforce the effectiveness of thermal ablative therapies, which constitute the bulk of treatments for superficial venous disease, likely because of the lower cost of disposables for practices that own thermal generators, physician comfort with the procedures, and their durability (based on 5-year results). In late 2016, the US Food and Drug Administration approved the Venclose system (Venclose, Inc.), a new iteration of a radiofrequency ablation catheter that uses an adjustable-length catheter to deliver treatment to 10-cm and 2.5-cm vein sections with a single catheter. However, no public clinical data are available to assess the effectiveness of the Venclose system.

NONTHERMAL TECHNIQUES: THE NEW STANDARD OF CARE?

Although endothermal ablations replaced high ligation and stripping to become the new standard of care for superficial venous interventions over the past decade, the pursuit to make these already simple procedures simpler has led to the development of nonthermal, nontumescent (NTNT) technologies. The past year has seen consolidation of data that demonstrate the durability of these NTNT techniques.

Three-year results of the VeClose trial, a randomized controlled noninferiority trial, found a successful closure rate of 94.4%, which was noninferior to the radiofrequency ablation success rate of 91.9% at 3 years with cyanoac-

TABLE 1. AMERICAN VENOUS FORUM RECOMMENDATIONS UPDATE FOR USE OF ENDOVENOUS TREATMENT FOR SUPERFICIAL VENOUS DISEASE

Technique	Recommendation		Comments
	Level	Grade	
Endothermal ablation	1	B	Use for incompetent GSV over surgery
		C	Use for veins with diameter > 12 mm
MOCA/cyanoacrylate glue	2	B	Use for mildly tortuous incompetent GSV, below-knee incompetent GSV with C2 to C6 disease, SSV incompetence with diameter < 10 mm, and incompetent epifascial axial veins
PEM	2	B	Use for tortuous incompetent axial veins and incompetent branch varicosities with diameter < 6 mm
Nonthermal, nontumescent techniques	1	B	Overall recommendation; use MOCA, cyanoacrylate, and PEM for above-knee incompetent GSV with diameter < 12 mm
	2	B	Do not use with vein diameter > 12 mm
		C	Do not use for retreatment of recanalized veins
Ambulatory phlebectomy	1	B	Use as an outpatient procedure under local anesthesia for effective and definitive treatment after saphenous ablation; can be done during ablation or at a later stage
Transilluminated powered phlebectomy	2	C	An option for treatment of varicose veins

Abbreviations: GSV, great saphenous vein; MOCA, mechanochemical ablation; PEM, polidocanol endovenous microfoam; SSV, small saphenous vein.

rylate glue (VenaSeal Closure System, Medtronic) treatment.[5] Significant improvement in both VCSS and AVVQ scores was noted with both techniques.

A meta-analysis of mechanochemical ablation (ClariVein, Vascular Insights) of the GSV and small saphenous vein demonstrated long-term closure rates ranging from 87% to 92%, which were comparable with thermal ablation therapies.[6] A multicenter, placebo-controlled RCT of polidocanol endovenous microfoam 1% (Varithena, BTG International) demonstrated significant reduction of visible varicosities and patient-reported outcomes as compared with placebo.[7] Duplex success, defined as elimination of reflux through the saphenofemoral junction or complete occlusion of the GSV or treated major accessory vein, was noted in 90% of patients.

Comparable outcomes with thermal ablation and demonstration of their durability make these NTNT techniques quite attractive, particularly to the early career venous practitioners.

NONTHERMAL TECHNIQUES RECEIVE CPT CODES

Until recently, for nonthermal technologies, physicians had to either charge patients an out-of-pocket fee or use an unspecified CPT code (37799: Unlisted vascular procedure). This required submission of additional documentation to describe the procedure to payers; however, reimbursement for this unlisted CPT code was variable and unpredictable and sometimes resulted in denials. This led to frustration and became an impediment to widespread adoption of these newer technologies. In early 2017, ClariVein became the first nonthermal technology to receive approval for separate CPT codes, which included (1) code 36473 for first vein treated—endovenous ablation therapy of incompetent vein, extremity, inclusive of all imaging guidance and monitoring, percutaneous, mechanochemical and (2) code 36474 for subsequent vein(s) treated in a single extremity, each through a separate access site. Seven of eight Medicare Administrative Contractors, which represents about 90% Medicare coverage, adopted coverage of these codes and agreed to pay for them by year end. Private payer coverage varies by state as coverage continues to grow.

In January 2018, the Centers for Medicare & Medicaid Services also approved CPT codes and assigned reimbursement rates for VenaSeal and Varithena. These developments in reimbursement should set the stage for increased adoption and utilization of the NTNT technologies.

CPT codes for VenaSeal cover endovenous ablative therapy of the incompetent vein of an extremity by transcatheter delivery of a chemical adhesive remote from the access site and covers intraprocedural imaging and moni-

toring. CPT code 36482 covers the first vein treated; and has an add-on code 36483, which covers subsequent veins in the same extremity. Local payer coverage is currently being pursued by Medtronic.

For the Varithena procedure, two new CPT codes cover the injection of noncompounded foam sclerosant with ultrasound compression maneuvers to guide dispersion of the injectate. CPT code 36465 is for a single incompetent extremity truncal vein and 36466 is for multiple incompetent truncal veins in the same leg.

Although we may not have reached the tipping point where nonthermal ablative therapies are favored over thermal ablative therapies, the accumulating scientific evidence and approval of reimbursements suggest a shift may be seen in the near future, which would be a significant development in superficial venous disease.

LATE-STAGE VENOUS DISEASE RECEIVES INCREASED RECOGNITION

Lipodermatosclerosis, stasis dermatitis, venous eczema, and atrophy blanche ulcers can result in significant disability and pain as well as create significant social isolation for the patient.[8] Despite high prevalence rates (approximately 600,000 in the United States[9]) and recurrence rates of venous leg ulcers (VLUs),[10] late-stage venous disease (CEAP C4–C6) has been largely ignored by the venous community. Most pivotal trials, including those evaluating thermal and nonthermal techniques, exclude patients with VLUs. The ESCHAR trial compared compression therapy with stripping and high ligation of the GSV and demonstrated no benefit of eliminating saphenous vein reflux on the speed of ulcer healing. Current guidelines recommend using saphenous vein ablative therapies only to reduce recurrence.[2]

There has been renewed interest in VLUs with both industry- and investigator-sponsored trials underway or completed, with the goal to reassess the role of contemporary ablative therapies in enhancing the speed of VLU healing. For example, the ongoing VIEW-VLU trial, a multicenter registry sponsored by BTG International, assesses wound healing as the primary endpoint after treatment with Varithena.[11] The EVRA trial (NCT03286140), a multicenter, prospective RCT, may be the most anticipated trial in this space and results are expected to be reported at the Charing Cross international symposium in April 2018.[12] EVRA randomized 450 patients to either early endovenous treatment of superficial venous reflux plus standard care or standard care alone. The trial is the first large RCT to report ulcer healing, quality of life, and cost-effectiveness of treating patients with VLUs with early superficial venous intervention.

SUMMARY

Although there have been significant developments in the management of superficial venous disease in the past year, we have discovered new controversies without clear answers and there is still much to learn. However, with combined efforts of cross-specialty investigators, government input, and industry research support, we can continue our attempts to solve these challenges to improve treatment of superficial venous disease. ■

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