

Five Must-Read Superficial Venous Publications

BY PETER F. LAWRENCE, MD

Use of the Clinical, Etiologic, Anatomic, and Pathophysiologic Classification and Venous Clinical Severity Score to Establish a Treatment Plan for Chronic Venous Disorders

Almeida JL, Wakefield T, Kabnick LS, et al. *J Vasc Surg Venous Lymphat Disord.* 2015;3:456–460.

SUMMARY/TAKE-AWAY POINTS

A measurement instrument for chronic venous disease (CVD) should be unbiased, fast, and consider severity of disease. This article describes the clinical, etiologic, anatomic, and pathophysiologic (CEAP) classification, which organizes CVD by etiology (ie, congenital, non-thrombotic, or postthrombotic), anatomic segments involved (ie, deep, superficial, or perforators), and pathophysiology (eg, reflux, obstruction). The Venous Clinical Severity Score is based on findings from CEAP and can be used to track clinical disease characteristics over time, especially after interventions (but the total score is biased with regard to advanced disease). Disease progression will be better predicted with the validation of more instruments that rely on patient-reported outcomes. The

Venous Clinical Severity Score and CEAP classification may be used in association with patient-reported outcomes to develop an ideal treatment plan for CVD.

WHY THIS ARTICLE IS IMPORTANT

This article emphasizes the critical role of classification systems to guide therapy and compare outcomes while managing patients with CVD. It argues that the CEAP classification is an excellent method to initially evaluate and classify patients with CVD and that the Venous Clinical Severity Score is the best method to longitudinally follow patients after treatment. Without systems that accurately classify and compare patients based on severity of venous disease, it is difficult to determine optimal treatments.

Report of the Society for Vascular Surgery (SVS) and the American Venous Forum (AVF) on the July 20, 2016 Meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) Panel on Lower Extremity Chronic Venous Disease

Gloviczki P, Dalsing MC, Henke P, et al. *J Vasc Surg.* In press.

SUMMARY/THE TAKE-AWAY POINTS

This dual society report from the SVS and AVF is a response to the 2016 MEDCAC meeting that took place in July 2016, which addressed questions related to chronic venous insufficiency and assessed the benefits and risks of currently used lower extremity CVD treatments and their effects on adult health outcomes in the United States. The main purpose of the meeting was to advise

the Centers for Medicare & Medicaid Services (CMS) on coverage determinations for interventions used for the treatment of CVD. After discussing critical issues, the panel voted for key questions (Table 1) and made recommendations to CMS regarding treatment and Medicare coverage.

The SVS/AVF report summarizes the evidence used to support the coalition's recommendations. These topics included important venous disease evidence gaps that have not suf-

TABLE 1. KEY QUESTIONS POSED AT THE JULY 2016 MEDCAC MEETING AND CONFIDENCE SCORES

Key Questions	Outcome in Patients With and Without Symptoms	Level of Confidence 1 = Low 3 = Intermediate 5 = High	
		MEDCAC	SVS/AVF
For adults with varicose veins and/or other clinical symptoms or signs of chronic venous insufficiency, how confident are you that there is sufficient evidence for an intervention that improves:	Immediate/near-term health outcomes in patients presenting with symptoms?	3.3	4
	Immediate/near-term health outcomes in patients presenting without symptoms but with physical signs?	2	1
	Long-term health outcomes in patients presenting with symptoms?	2.56	4
	Long-term health outcomes in patients presenting without symptoms?	1.33	2
For adults with chronic venous thrombosis and venous obstruction (including individuals with postthrombotic syndrome), how confident are you that there is sufficient evidence for an intervention that improves:	Immediate/near-term health outcomes in patients presenting with symptoms?	2.11	3
	Immediate/near-term health outcomes in patients presenting without symptoms but with signs?	1.44	2
	Long-term health outcomes in patients presenting with symptoms?	1.56	3
	Long-term health outcomes in patients presenting without symptoms but with signs?	1.22	2

Abbreviations: AVF, American Venous Forum; MEDCAC, Medicare Evidence Development and Coverage Advisory Committee; SVS, Society for Vascular Surgery.

ficiently been addressed, venous disease treatment disparities and how they may affect the health outcomes of Medicare beneficiaries, and mechanisms that might be supported by CMS to improve the evidence base to optimize the care of patients with lower extremity CVD. More research involving basic pathophysiology, standardization of care, and comparative studies, specifically randomized controlled trials (RCTs), would advance the care of patients with venous disease.

WHY THIS ARTICLE IS IMPORTANT

This article is a compendium of the literature and analysis related to the MEDCAC questions, with

evidence-based responses. These responses are in contrast to the responses of members of the MEDCAC committee, who were provided with limited data and information on the treatment of CVD and therefore may have come to conclusions that were not based on evidence. This article strongly supports the use of duplex ultrasonography to diagnose chronic venous insufficiency, endovenous ablation to treat symptomatic varicose veins, and a comprehensive program of ablation of incompetent superficial veins and dilatation of deep veins to treat deep venous stenosis and occlusion.

A Multi-Centre Randomised Controlled Trial Comparing Radiofrequency and Mechanical Occlusion Chemically Assisted Ablation of Varicose Veins—Final Results of the Venefit Versus Clarivein for Varicose Veins Trial

Lane T, Bootun R, Dharmarajah B, et al. *Phlebology*. 2017;32:89–98.

SUMMARY/TAKE-AWAY POINTS

In this multicenter RCT, the difference in pain during truncal ablation was compared using mechanical occlusion chemically assisted endovenous ablation (MOCA) versus radiofrequency endovenous ablation (RFA). One hundred seventy patients undergoing endovenous ablation for primary varicose veins were recruited over a 21-month period and were randomized to either MOCA or RFA. Pain scores were assessed using the 100-mm visual analogue scale (VAS) and number scale (0–10). Clinical scores, quality of life (QOL) scores, and results of duplex ultrasound of the treated leg were evaluated at 1- and 6-month follow-up.

As compared with the RFA group, patients in the MOCA group experienced significantly less pain during the procedure, as assessed by the VAS (median for MOCA, 15 mm [interquartile range, 7–36 mm] vs RFA, 34 mm [interquartile range, 16–53 mm]; $P = .003$) and number scale (median for MOCA, 3 [interquartile range, 1–5] vs RFA, 4 [interquartile range, 3–6.5]; $P = .002$). Mean pain scores were also signifi-

cantly lower in the MOCA group. At 1 and 6 months, occlusion rates, clinical severity scores, and QOL scores (both disease-specific and generic) were similar between groups. The authors concluded that there is less pain secondary to truncal ablation with MOCA as compared with RFA. Technical, QOL, and safety outcomes are similar in the short term.

WHY THIS ARTICLE IS IMPORTANT

Nonthermal, nontumescent ablation techniques will become the standard of care for superficial venous incompetence if they result in less perioperative pain, have similar success rates related to closure of the truncal veins, and have similar recurrence and recanalization rates. This is one of the first studies to compare MOCA with thermal ablation. It shows that there is less pain related to the MOCA procedure; however, outcomes (ie, occlusion rates, clinical severity scores, and QOL) were similar between the two procedures.

ClariVein®—Early Results From a Large Single-Centre Series of Mechanochemical Endovenous Ablation for Varicose Veins

Tang TY, Kam JW, Gaunt ME. *Phlebology*. 2017;32:6–12.

SUMMARY/TAKE-AWAY POINTS

The patient experience associated with and effectiveness of the ClariVein endovenous occlusion catheter (Vascular Insights, LLC) for varicose veins were assessed in 300 patients who underwent treatment at a single private hospital in the United Kingdom. Of 300 ClariVein-treated patients, 184 had great saphenous vein (GSV) incompetence, 62 had bilateral GSV, 23 had short saphenous vein (SSV), 6 had bilateral SSV, and 25 had combined unilateral GSV and SSV. Two months postprocedure, patients underwent clinical examination, and duplex ultrasound (including color and spectral Doppler and B-mode imaging) was performed. Postoperative complications were recorded, and patient satisfaction was assessed using a 10-point scale satisfaction score. All 393 procedures were successfully completed under local anesthetic. Ultrasound evaluation immediately

after ClariVein treatment showed all treated veins were completely occluded. However, at 8-week follow-up, partial obliteration was found in 3.3% of veins, which were all successfully treated with ultrasound-guided foam sclerotherapy. Procedures were well tolerated (mean pain score, 0.8 [range, 0–3]), with no significant complications reported. The authors concluded that long and short saphenous varicose veins can be safely and effectively treated with ClariVein on an ambulatory basis. Bilateral veins and multiple veins in the same leg can be successfully treated and the procedure is well tolerated. Early results are promising, but further evaluation and longer-term follow-up are required.

WHY THIS ARTICLE IS IMPORTANT

Nonthermal, nontumescent treatment of incompetent axial veins is very well tolerated by patients and does not

require concomitant tumescent anesthesia. However, outcomes are only available for a small number of patients, and results of the procedures have not been compared with those of thermal ablation techniques. This study describes the outcomes in patients from a single center

and is one of the first to report early results of nonthermal ablation. Longer-term studies and comparisons with thermal ablation will be required to determine if nonthermal ablation will replace thermal ablation as the treatment of choice for patients with superficial venous incompetence.

Recurrence of Varicose Veins After Endovenous Ablation of the Great Saphenous Vein in Randomized Trials

O'Donnell TF, Dermody M, Tangney E, Iafrati MD. *J Vasc Surg Venous Lymphat Disord.* 2016;4:97–105.

SUMMARY/TAKE-AWAY POINTS

The authors performed a systematic review and meta-analysis of RCTs to define the overall recurrence rate of varicose veins after surgery for GSV and to determine sites and causes of reflux for endovenous ablation. A database search was conducted for RCTs published between January 2000 and July 2014 that evaluated endovenous ablation of GSV incompetence using either endovenous laser ablation or RFA. RCTs were excluded if they had ≤ 2 years follow-up, postoperative duplex scans were not performed, the incidence of recurrent varicosities

after GSV ablation was not clearly reported, and small saphenous or anterior accessory saphenous veins were treated.

Twenty RCTs were identified, and eight had a follow-up of ≥ 2 years (one study was excluded due to lack of information). The remaining seven trials provided eight comparisons: three used RFA and five used endovenous laser ablation. Overall, 22% of patients developed recurrent varicose veins after ablation. There was no difference in the incidence of recurrent varicose veins versus the ligation and stripping group (22%), based on the number of limbs available at the time of recurrence for both groups. The incidence of recurrent varicosities was dependent on the length of follow-up after initial treatment. In two studies with serial follow-up, the recurrence of varicose veins after surgery almost doubled over time for both endovenous ablation and ligation and stripping; however, the cause of recurrence was different between the two methods (neovascularization occurred in 2% after ablation vs 18% in the ligation and stripping group). For ablation, the most common cause of recurrence was recanalization (32%), followed by the development of anterior accessory saphenous vein incompetence (19%), whereas incompetent calf perforating veins were an infrequent cause of recurrence (7%) in contrast to previous reports.

WHY THIS ARTICLE IS IMPORTANT

There is no difference in the incidence of recurrence for endovenous ablation versus ligation and stripping, regardless of whether RFA or laser ablation is used. However, the causes of recurrence are different, which has important implications for treatment. ■

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Disclosures: None.