



Treatment of Superficial Venous Disease of the Lower Leg

Background

The diagnosis and treatment of venous disease has advanced more in the last 10 years than in the previous 2 centuries combined. Ultrasound, endovenous ablation devices, foam sclerotherapy and tumescent anesthesia have greatly improved patient care and have moved treatment from the operating room to the office or radiology suite. This has created challenges for insurers. Medical necessity policy for the treatment of chronic venous disease (CVD) has become fragmented and inconsistent across the U.S. among private insurers and Medicare. As with any medical specialty, those who are most committed to that specialty generally provide the best care. Commitment includes some form of training, a practice focused in that area and continuing education through attendance at meetings and other CME. The American College of Phlebology (ACP), the American Venous Forum (AVF), the Society of Interventional Radiology (SIR) and other organizations have been at the forefront of advancing education, research and appropriate treatment of venous disease.

In 2011, the Society for Vascular Surgery and the American Venous Forum undertook a comprehensive summary of all the available venous research and graded it by relevance and quality of data. Their goal was to analyze all the available evidence-based medicine and create rational guidelines for treatment of venous disease of the lower limbs and pelvis. This review, by Gloviczki et al, was well received by the medical community across specialties treating venous disease, as it built consensus over a variety of topics.

The American College of Phlebology has prepared this white paper with the goal of creating a summation document that reflects the evidence-based recommendations in the Gloviczki paper as well as many other current studies. Other recommendations are based on American College of Phlebology's consensus of experts where the evidence-based research is sparse, yet the therapy is considered standard of care.

We acknowledge that all carriers are free to determine coverage guidelines, etc., based upon their own independent review of the literature and resources like Cochrane and others. However, we suggest that evidence based medical necessity should not vary greatly based on geography or insurer. We would like to introduce the concept of "medically significant venous insufficiency" or "evidence-based medical significance." This eliminates confusion around terms like "cosmetic" or "not medically necessary." The medical evidence should determine the definition of medically significant venous insufficiency using a combination of CEAP and VCSS classifications (discussed below). We would propose that payers retain the evidence-based definition of medical significance, but choose at what level it becomes either a "covered benefit" or a "non-covered benefit." Insurers could establish different benefit levels for their various premium options. In this way, the evidence-based medical criteria would still be consistent across the industry. In the following pages are medical necessity guidelines in a summary format.

These recommendations have been determined by the method suggested by the Grading of Recommendations Assessment, Development and Evaluation system (GRADE) working group. (www.gradeworkinggroup.org)

For each guideline, the letter A, B or C marks the quality of current evidence as high, medium or low quality. The grade of recommendation of a guideline can be strong (1) or weak (2), depending on the risk and burden of a particular diagnostic test or a

therapeutic procedure to the patient vs. the expected benefit. The words, “we recommend,” are used for GRADE 1—strong recommendations—if the benefits clearly outweigh risks and burdens, or vice versa; the words, “we suggest,” are used for GRADE 2—weak recommendations—when the benefits are closely balanced with risks and burdens. Where current evidence is weak or lacking, the degree of consensus of the committee reflects the grade with the quality of the recommendation adjusted accordingly.

Table I. Grading Recommendations According to Evidence

Grade of Recommendation/Description	Benefit vs Risk and Burdens	Methodologic Quality of Supporting Evidence	Implications
1A. Strong recommendation, high-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs without important limitations or overwhelming evidence from observational studies	Strong recommendation; can apply to most patients in most circumstances without reservation
1B. Strong recommendation, moderate quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Strong recommendation; can apply to most patients in most circumstances without reservation
1C. Strong recommendation, low-quality or very low-quality evidence	Benefits clearly outweigh risk and burdens, or vice versa	Observational studies or case series	Strong recommendation but may change when higher quality evidence becomes available
2A. Weak recommendation, high-quality evidence	Benefits closely balanced with risks and burden	RCTs without important limitations or overwhelming evidence from observational studies	Weak recommendation; best action may differ depending on circumstances or patients' or societal values
2B. Weak recommendation, moderate-quality evidence	Benefits closely balanced with risks and burden	RCTs with important limitations (inconsistent results, methodologic flaws, indirect, or imprecise) or exceptionally strong evidence from observational studies	Weak recommendation; best action may differ depending on circumstances or patients' or societal values
2C. Weak recommendation, low-quality or very low-quality evidence	Uncertainty in the estimates of benefits, risks, and burden; benefits, risk, and burden may be closely balanced	Observational studies or case series	Very weak recommendations; other alternatives may be equally reasonable

Summary of Guidelines for Treatment of Venous Disease

Indications for Treatment

Compression therapy is an effective method for the management of symptoms related to superficial disease but it does not correct the source of reflux. When patients have a correctable source of reflux definitive treatment should also be offered unless it is contraindicated or unwanted. GRADE 1A (1,8,9,10,11)

We recommend against compression therapy as a prerequisite therapy for symptomatic venous reflux disease when other definitive treatments such as endovenous ablation are appropriate. GRADE 1A (1,8,9,10,11)

After interventional treatment, we recommend the use of a compression garment in the postoperative period. There is extra benefit to the patient in the form of reduced pain after use of compression. The compression dosage and duration is at the discretion and clinical judgment of the treating physician. GRADE 2B

Superficial venous insufficiency is a chronic disease and as such we recommend that patients with this disease be counseled to wear a compression garment even after definite treatment has been provided. The compression dosage is at the discretion and clinical judgment of the treating physician GRADE 2C

We suggest the treatment of some CEAP C2 patients with isolated varices, by medical compression hose alone may be an acceptable form of treatment. A short 1-2 week trial of compression hose may be appropriate where an alternative etiology of symptoms is considered, e.g. musculoskeletal pain or neuropathy (spinal stenosis, sciatica, hip or knee arthritis, diabetic neuropathy etc). GRADE 2C (2,8,9,10,11)

Indications for treatment include pain or other discomfort (ie, aching, heaviness, fatigue, soreness, burning), edema, varix hemorrhage, recurrent

superficial phlebitis, stasis dermatitis or ulceration. We recommend patients should be evaluated using the CEAP classification and the Venous Clinical Severity Score (VCSS). We would define medically necessary as a CEAP classification of C2 or higher. GRADE 1A (1)

In addition

We recommend all patients being considered for treatment must have a duplex ultrasound of the superficial venous system and, at a minimum, evaluation of the common femoral vein and popliteal vein for patency and competence. The exam should ideally be done in the standing position. GRADE 1A (1,3,4,5,6)

We suggest all noninvasive vascular diagnostic studies be performed by a qualified physician or by a qualified technologist under the general supervision of a qualified physician. GRADE 1C (2)

We recommend that named veins (Great Saphenous Vein (GSV), Small Saphenous Vein (SSV), Anterior Accessory of the Great Saphenous Vein (AAGSV), Posterior Accessory of the Great Saphenous Vein (PAGSV), Intersaphenous Vein (Vein of Giacomini)) must have a reflux time > 500 msec, regardless of the reported vein diameter. GRADE 1A (1,7,6)

Treatment of Named Saphenous Veins

We recommend endovenous thermal ablation (laser and radiofrequency) is the preferred treatment for saphenous and accessory saphenous (GSV, SSV, AAGSV, PAGSV) vein incompetence. GRADE 1B (1,15)

We suggest Mechanical/chemical ablation (Clarivein Device) may also be used to treat truncal venous reflux. GRADE 2B (2)

We recommend open surgery is appropriate in veins not amenable to endovenous procedures but otherwise is not recommended because of increased pain, convalescent time, and morbidity. GRADE 1B (1)

We suggest when open surgery of the great saphenous vein is performed it should include high ligation and invagination stripping to the level of the knee. GRADE 2B (1)

We recommend when open surgery of the small saphenous vein is performed it include high ligation and selective invagination of the proximal portion. GRADE 1B (1)

Treatment of Circumflex Veins and Other Non-Truncal Veins

The treatment of other non-truncal, tributary varicose vein reflux (circumflex veins anterior and posterior thigh) is more complex. The medical record should reflect that these veins are incompetent and note their size, presence or absence of tortuosity, and depth relationship to the skin, i.e. accessible or not accessible by phlebectomy.

We recommend varicose (visible) symptomatic tributary veins can be treated by stab phlebectomy, liquid sclerotherapy or foam chemical ablation. GRADE 1B (1, 2, 13)

We recommend (non visible) symptomatic tributary veins be treated by ultrasound-guided liquid sclerotherapy or foam chemical ablation. GRADE 1B (1, 2, 12,14)

Treatment of Perforator Veins

We suggest treatment of incompetent perforating veins located beneath a healed or open venous ulcer. They should have outward flow of 500 ms, with a diameter of 3.5 mm. GRADE 2B (1)

We suggest, in patients with perforator reflux as the primary or only source of disease, treatment of the perforator with endovenous thermal ablation, ligation or ultrasound guided sclerotherapy. Subsequent or simultaneous treatment of symptomatic varicosities arising from the incompetent perforator is also considered best practice. GRADE 2B (2)

References

The American College of Phlebology guidelines are based on consensus documents and research. These consensus documents, as well as other materials reviewed in forming the ACP guidelines included but were not limited to:

1. Gloviczki P, Comerota AJ, Dalsing MC, Eklof BG, Gillespie DL, Gloviczki ML, Lohr JM, McLafferty RB, Meissner MH, Murad MH, Padberg FT, Pappas PJ, Passman MA, Raffetto JD, Vasquez MA, Wakefield TW. The care of patients with varicose veins and associated chronic venous diseases: Clinical practice guidelines of the Society for Vascular Surgery and the American Venous Forum. *J Vasc Surg* 2011 Volume 53, Issue 5, Supplement , Pages 2S-48S
2. ACP Consensus Opinion
3. Malgaor, Labropolous, Diagnosis & Follow-up of VVs with Duplex US, *Phleb* 2012;27 suppl 1:10-15
4. Foldes M, et al: Standing Versus Supine Positioning in Venous Reflux Evaluation: *The Jour for Vasc Ultrasound* 1991;15(6):321-24
5. Fowler, Zygmunt, Ramirez, Kolluri, Venous Insufficiency Duplex Scanning, *Jour for Vasc Ultrasound*, Vol 38, No 1, 2014
6. Zygmunt J, Pichot O, Dauplaise T, *Practical Phlebology: Venous Ultrasound*, CRC Press London 2013
7. Caggiati A, Bergan J, Gloviczki P, et al, Nomenclature of the veins of the lower limb: Extensions, refinements, and clinical application, *J of Vasc Surg* 2005; 41: 719-24
8. Moneta GL, Partsch H. Compression therapy for venous ulceration. In: Gloviczki P, ed. *Handbook of venous disorders: guidelines of the American Venous Forum*. 3rd ed ed. London: Hodder Arnold; 2009:348-58.
9. Amsler F, Blattler W, Compression therapy for occupational leg symptoms and chronic venous disorders: a meta-analysis of randomised controlled trials. *Eur J Vasc Endovasc Surg* 2008;35(3):366-72.
10. Michaels JA, Brazier JE, Campbell WB, MacIntyre JB, Palfreyman SJ, Ratcliffe J. Randomized clinical trial comparing surgery with conservative treatment for uncomplicated varicose veins. *The British journal of surgery* 2006;93(2):175-81.
11. Michaels JA, Campbell WB, Brazier JE, et al. Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial). *Health Technol Assess* 2006;10(13):1-196.
12. Rabe E, Breu FX, Cavezzi A, Coleridge Smith P, Frullini A, Gillet JL, Guex JJ, Hamel-Desnos C, Kern P, Partsch B, Ramelet AA, Tessari L, Pannier F and for the Guideline Group. European guidelines for sclerotherapy in chronic venous disorders. *Phlebology* published online 3 May 2013
13. Rigby KA, Palfreyman SJ, Beverley C, Michaels JA. Surgery versus sclerotherapy for the treatment of varicose veins. *Cochrane Database Syst Rev* 2004:CD004980.
14. Tisi PV, Beverley C, Rees A. Injection sclerotherapy for varicose veins. *Cochrane Database Syst Rev* 2006:CD001732.
15. Carradice D, Mekako AI, Mazari FA, et al. Randomized clinical trial of endovenous laser ablation compared with conventional surgery for great saphenous varicose veins. *Br J Surg*. 2011 Apr;98(4):501-10

Disclaimer

Adherence to these guidelines will not ensure successful performance. Furthermore these guidelines should not be deemed inclusive of all proper methods of treatment or exclusive of other protocols reasonably directed to obtain the same results. The physician and patient must make the ultimate judgment regarding the propriety of any performance and interpretation of studies in light of all the circumstances presented by the individual patient.

These guidelines reflect the best available data at the time it was prepared; the results of future research or technology may require alteration of the minimum standards and reporting as set forth in this guideline.