



Position Statement Endovenous Ablation

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Summary

Endovenous ablation therapy, using either laser or radiofrequency devices under imaging guidance and monitoring, is an effective treatment of extremity venous reflux and varicose veins.

Venous insufficiency is a very common condition resulting from valvular dysfunction and consequently poor venous return to the heart with pooling of blood in the leg veins (called reflux). These enlarged, swollen vessels are known as varicose veins and are a direct result of increased pressure from reflux. Although many people seek medical treatment for varicose veins because they find them unsightly, most people with varicose veins suffer from symptoms (1, 2). Left untreated, nearly 50% of patients with significant superficial venous insufficiency will eventually suffer from chronic venous insufficiency characterized by lower extremity swelling, eczema, pigmentation, hemorrhage, and ulceration (3).

Endovenous Ablation

Endovenous ablation has been performed in the United States for over five years. This minimally-invasive treatment is an outpatient procedure performed using imaging guidance. The physician inserts a catheter into the abnormal vein using ultrasound guidance and the ablation probe is guided up the great saphenous vein. Tumescant anesthetic is administered around the vein; again using ultrasound and radiofrequency or laser energy is then applied to the inside of the vein. This heats the vein and essentially seals the vein closed.

The ablative technologies are FDA-approved. FDA 510(k) approval/clearance was granted to VNUS Medical Technologies, Inc. (San Jose, CA) for radiofrequency (Closure) in March 1999. For endovenous laser, FDA approvals/clearances were granted to Diomed, Inc. (Andover, MA) in January 2002, to Biolitec, Inc. (East Longmeadow, MA) in August 2002, to Dornier MedTech (Kennesaw, GA) in November 2002, to Angiodynamics, Inc. in November 2002, and to Vascular Solutions Inc. (Minneapolis, MN) in June 2003.

Indications and Contra-Indications

Conservative measures can yield some non-durable symptomatic relief for reflux and varicose veins. The endovenous treatment of varicose veins may be medically necessary when:

1. One of the following indications (A - E) is present:
 - A. Persistent symptoms interfering with activities of daily living in spite of conservative/non-surgical management. Symptoms include aching, cramping, burning, itching and/or swelling during activity or after prolonged standing.
 - B. Significant recurrent attacks of superficial phlebitis
 - C. Hemorrhage from a ruptured varix
 - D. Ulceration from venous stasis where incompetent varices are a contributing factor
 - E. Symptomatic incompetence of the great or small saphenous veins (symptoms as in A above)
2. A trial of conservative, non-operative treatment has failed. This would include mild exercise, avoidance of prolonged immobility, periodic elevation of legs, and compressive stockings.
3. The patient's anatomy is amenable to endovenous ablation.

Duplex ultrasound is necessary to map the anatomy of the venous system prior to the procedure, and imperative during the procedure for correct catheter placement and for proper tumescent anesthetic administration to minimize potential complications. Duplex ultrasound also is necessary for follow-up after endovenous ablation.

Results

The scientific literature, consisting of case series and limited randomized studies to date, demonstrate that endovenous ablation is an effective treatment for venous reflux and varicose veins. (See attached list of references.) For more information on varicose veins and their treatment, please consult SIR's Web site (www.sirweb.org).

The success rate for vein ablation ranges from 90 - 95 percent. Long-term results demonstrate a recurrence rate of less than 7 percent at two-year follow-up. (4) These results are comparable or superior to those reported for the other options available for treatment of GSV reflux, including surgery or ultrasound-guided sclerotherapy. Lower rates of recurrence following endovenous ablation may be the result of more accurate targeting and treatment of only the abnormal incompetent venous segments using imaging guidance. This has resulted in the absence of neovascularization as is often seen following surgical ligation and stripping. Endovenous

ablation appears to offer these benefits with lower rates of complication and avoidance of general anesthesia. (4)

Citations

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