



Physician Update

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Venous Insufficiency and Endovenous Radiofrequency Ablation of the Saphenous Vein



Therapeutic Hypothermia Improves Outcomes for Patients with Neurological Complications



By Kevin M. Kendall, M.D.

A 36-year-old man hit a home run in the seventh inning of a community baseball game. He ran the bases and returned to home plate. As he was bending over to pick up the bat, he collapsed. Bystander CPR was immediately initiated, and local EMS responders applied defibrillation within five minutes.

The automated external defibrillator shocked the patient a total of three times and he was transported to a local hospital. LifeFlight of Maine was called to transport the patient to a tertiary care center.

The flight team initiated the post-cardiac arrest therapeutic hypothermia protocol. By the time the patient arrived at Central Maine Medical Center, he had received two liters of cold normal saline and his temperature was 34°C. He was maintained at 33°C for 24 hours and an AICD was implanted after cardiologists determined that his cardiac arrest occurred secondary to a dysrhythmia. He was discharged on day nine and returned to work two days later with no neurological deficits.

In June of 2007, after an exhaustive review of the scientific literature, LifeFlight of Maine became one of a few air medical services in the nation to begin the cutting edge treatment of therapeutic hypothermia after cardiac arrest.

Throughout history, cold therapy has been used to treat myriad illnesses, but it wasn't until the 1960s that therapeutic hypothermia was first used to prevent ischemic brain injury after the return of spontaneous circulation (ROSC) after cardiac arrest.



When cardiac arrest occurs, cerebral oxygenation ceases within 20 seconds, leading to the associated loss of consciousness. If circulation does not begin immediately, the brain's energy substance, ATP, is depleted and exhausted within five minutes. A vicious cycle ensues that leads to cell and ultimately brain death unless therapeutic hypothermia is initiated.

Therapeutic hypothermia works by decreasing the overall metabolic demands of cells, thus minimizing the degrading cascade of events that leads to brain injury after cardiac arrest. Hypothermia also limits the cerebral

oxygen requirement, thus limiting the release of neurotoxic transmitters, leading to an overall suppression of inflammation and stability of neuronal cell membranes.

A variety of methods of therapeutic cooling have been developed during the last decade, allowing controlled hypothermia to be initiated not only in the hospital, but more importantly in the prehospital setting. LifeFlight of Maine uses a simplistic approach of cold packs over the large vessels in the neck, axilla and groin as well as 30 ml/kg of 4°C normal saline.

LifeFlight of Maine can begin this life-saving treatment not only for interfacility transfers going to cardiac referral centers in Maine, but also on patients who have had a cardiac arrest in the field and experienced ROSC. The sooner this treatment is initiated, the better the patient's neurological outcome.

To date, LifeFlight of Maine's statistics have been outstanding. Over 43 percent of patients undergoing therapeutic hypothermia after ROSC have had full neurological recovery; many of these patients also undergo

emergent cardiac catheterization and stent placement. LifeFlight's results parallel those from national studies at major cardiac centers. In addition, the use of this treatment has led not only to improved patient outcomes, but also to the initiation of therapeutic hypothermia in many rural community hospitals throughout Maine.

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Venous Insufficiency and Endovenous Radiofrequency Ablation of the Saphenous Vein



By Danielle R. George, P.A.-C.*

Over 80 million Americans suffer with venous insufficiency, including 25 to 50 million people with varicose veins. Venous disease is four to five times more common than arterial insufficiency and the incidence is expected to increase dramatically as the baby boomer generation grows older.

Surgical ligation and stripping has been the treatment standard for varicose veins for almost 100 years. However, a newer and more effective minimally invasive technique performed in the office settings is now replacing the previous standard. This new technique is making therapy an option to some who would not have considered surgical treatment or were deemed not to be candidates for surgery due to co-morbidities. Catheter-based endovenous radiofrequency ablation, the VNUS Closure Procedure, opens the door to treatment to many of these patients.

While research is mixed on whether males or females are more prone to venous insufficiency, it is clear the incidence increases dramatically as we age. Studies have found that up to 10 percent of individuals between ages 20 and 29 have varicosities, but varicosities are present in up to 72 percent of individuals between the ages 60 and 69. In addition, other factors believed to contribute to presence of venous disease include a very strong familial predisposition, multiple pregnancies, obesity, leg injury or surgery, and standing professions.

There are conflicting theories as to the exact etiology of venous insufficiency and varicose veins. Classically it has been thought that valvular incompetence and venous hypertension are the primary processes in the development of varicose veins. While there is a definitive associa-

tion between venous hypertension and varicose veins, pressure alone is likely an insufficient causative agent. Normal veins subjected to high intramural pressures, such as in an arterial bypass, tend to become hypertrophied or "arterialized" with a thickened wall and not varicose. It is likely that an intrinsic abnormality of the veins leads to dilatation and subsequent venous insufficiency. Both light and electron microscopy of varicose veins revealed a degeneration of cellular organization, which is distinctly different than normal veins. These changes included vacuolated endothelium with pyknotic nuclei, thinning and disorganized smooth muscle, fibrous degeneration of the media, and swelling and helical splitting of collagen fibers.

The clinical presentation of patients with venous insufficiency ranges from complaints of cosmetically displeasing appearance to cellulitis and ulcerations. Venous dilatation along with mild edema is the first symptom of the disease. Dilatation of the small subcuticular venules just below the medial malleolus is pathognomonic for venous insufficiency. As the disease progresses, veins become more tortuous and elongated. Edema may progress to mid calf with advancing disease. Usually the metatarsal area is spared in edema from venous insufficiency. In addition, the edema may be pitting in the earlier stages but may progress to non-pitting with fibrosis. Patients commonly will complain of leg pain as well. Most frequently it is

Table 1
CEAP* CLINICAL CLASSIFICATION OF CHRONIC LOWER EXTREMITY VENOUS DISEASE

Class 0
No visible or palpable disease
Class 1
Telangiectases, reticular veins
Class 2
Varicose veins
Class 3
Edema without skin changes
Class 4
Skin changes due to CVI
Class 5
Skin changes with healed ulcers
Class 6
Skin changes with active ulcers

* CEAP - Clinical signs (classes 0 through 6); etiological classification; anatomic distribution (superficial, deep, or perforator, singly or in combination); and pathophysiologic dysfunction (reflux and/or obstruction)

described as heaviness or aching that occurs after prolonged standing. The pain is usually over the calf area and may ease with walking. Occasionally patients complain of pain specifically along the dilated varicosity. A less frequent presentation is that of a bursting type pain on standing that is described as "water was being poured into the leg". This is due to deep venous insufficiency, which is almost always associated with concomitant superficial incompetence. Additional clinical manifestations include brownish hemosiderin deposits, eczematous dermatitis, cellulitis, lipodermatosclerosis, and ulcerations.

In addition to a thorough history and physical, duplex ultrasound is critical to the accurate diagnosis and treatment of venous disease. It allows accurate assessment of the deep system for thrombosis and/or reflux. In the superficial system we can identify specific areas of venous reflux or incompetence to target those areas for treatment. Size, tortuosity and major branches or collaterals are also well visualized. In addition, perforator reflux can be assessed, and presence of thrombus in the superficial veins and distance from the skin of pertinent veins is studied.

Once all the information from the history and physical as well as the duplex study is known, patients can be stratified according to the CEAP Classification of lower extremity venous disease and treatment plans and options can be discussed with the patient.

First line treatment for venous insufficiency is almost always conservative management. This includes leg elevation, regular daily exercise, and, most importantly, graduated compression stockings. Compression therapy acts to reduce edema, venous stasis, leg fatigue and leg pain. However it treats the symptoms of the disease while compression stockings are in use and it is not a cure. It does not address the underlying cause of symptoms and patient compliance with compression therapy is variable at best. Interventions for venous stasis disease is appropriate when a patient has failed conservative management, continues to have symptoms of venous insufficiency, and has ultrasound-proven venous reflux.

Traditional therapy for superficial venous insufficiency has been greater saphenous vein ligation and stripping. This is still a practiced intervention today. However, it is performed in an operating room setting, it is relatively invasive and disfiguring and has a rather slow recovery time. In addition, five-year failure rates are as high as 30 percent. These problems have resulted in many patients not seeking therapy for their disease. In addition, practitioners may also have felt that the risks involved with an operate procedure were not warranted in their more "high risk" patients suffering with venous insufficiency.

For these reasons less invasive treatment techniques and procedures were sought.

In 1999 the FDA approved a catheter-based system to deliver radio frequency energy to the endothelium of the vein, thus resulting in contraction of the vein wall and

fibrotic obliteration of the vein. Since that time endovenous radiofrequency ablation has amassed the largest collection of published data, including single center, multi-center randomized trials, and registry data regarding endovenous therapy as well as the longest follow-up of any endovenous procedure.

Patients deemed to be candidates for endovenous radiofrequency ablation routinely have the procedure performed in the office setting with local anesthesia and a low dose oral sedative such as valium. Using ultrasound guidance a guide wire and small introducer sheath are placed within the greater saphenous (long saphenous) vein at about the level of the knee. The radio frequency catheter is passed over the wire through the sheath with the tip positioned just distal to the superficial epigastric vein near the sapheno-femoral junction. Position is confirmed with ultrasound. Tumescence anesthesia utilizing a very dilute lidocaine solution is infiltrated along the vein tract again with ultrasound guidance. The vein is "exsanguinated" using eternal compression or Trendelenburg position. After again confirming final tip position, radiofrequency energy is delivered to the vein causing wall contraction and obliteration of the vein lumen immediately. The catheter is withdrawn at a rate of about 1 to 2 cm per minute until the tip reaches the sheath at which point it is completely removed. Ultrasound is again performed to confirm vein obliteration and the sheath is then removed and band-aid applied to puncture site. With the patient still in Trendelenburg position thigh high compression stocking are applied. The compression therapy continues for approximately three to four weeks post procedure. Patient can resume normal activities the following day and strenuous activity after one week.

The recovery trial was a prospective, multi-center, randomized study designed to determine if differences between radiofrequency and laser treatment for varicose veins existed, particularly in relation to patient recovery and short-term outcomes. The trial was a single blinded randomized trial involving six centers that performed

ClosureFAST versus endovenous laser. A total of 69 patients were studied, totaling 87 limbs (46 to ClosureFAST and 41 to endovenous laser). The study included short-term follow up at two, seven, 14, and 30 days from procedure. Conclusions drawn from the study included statistically significant differences — less pain, less tenderness, less bruising, and overall fewer adverse events in the ClosureFAST patients when compared to the endovenous laser patients. There were no statistically significant differences in efficacy between the procedures in this study.

Summary

Endovenous radiofrequency ablation is a viable minimally invasive alternative to traditional ligation and stripping for patients with symptomatic venous insufficiency. This procedure alone will, of course, not treat all forms of venous insufficiency, but it can and is replacing ligation and stripping. In addition to being applicable to any relatively straight veins, it can also be utilized for perforator vein incompetence. Endovenous radiofrequency ablation in combination with the adjuvant therapies of ambulatory microincisional phlebectomy and sclerotherapy now allows most patients suffering with venous insufficiency to receive comprehensive treatment completely in an outpatient office setting. This should broaden the appeal of treatment to patients who would have previously not considered therapy or were deemed not to be candidates.

For further information on this procedure or to refer a patient for evaluation, call the Central Maine Heart and Vascular Institute at 207-753-3916.

**This article was prepared by Carmine Frumiento, M.D., in 2007 and updated recently by Danielle R. George, P.A.-C.*

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