

Central Maine Medical Center
**Physician
Update**



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VENOUS INSUFFICIENCY AND ENDOVENOUS RADIOFREQUENCY ABLATION OF THE SAPHENOUS VEIN



By Carmine Frumiento, M.D.,
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Carmine Frumiento, M.D.

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 Boom Generation ages.

While research is mixed on whether males or females are more prone to venous insufficiency, it is clear that the incidence increases dramatically with 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 those between 60 and 69 years of age. Factors believed to contribute to venous disease include familial predisposition, multiple pregnancies, obesity, leg injury or previous surgery, and standing professions.

ETIOLOGY OF VENOUS INSUFFICIENCY AND VARICOSE VEINS

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 varicose vein development. While there is a definitive association between venous hypertension and varicose veins, pressure alone is likely an insufficient causative agent. Normal veins subjected to

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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 reveal a degeneration of cellular organization that is distinctly different than normal veins. These changes include vacuolated endothelium with pyknotic nuclei,

thinning and disorganized smooth muscle, fibrous degeneration of the media, and swelling and helical splitting of collagen fibers.

CLINICAL PRESENTATION

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. In addition, the edema may be pitting in the earlier stages but may progress to non-pitting with fibrosis.

Patients commonly complain of leg pain, most frequently describing it 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 pain described as “water being poured into the leg” that is experienced upon standing. 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.

DIAGNOSIS

In addition to a thorough history and physical, duplex ultrasound is critical to diagnosing and treating 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. Size, tortuosity and major branches or collaterals are also well visualized, perforator reflux can be assessed, and the presence of thrombus in the superficial veins and distance from the skin of pertinent veins can be studied.

Once the work-up is complete, patients can be stratified according to the CEAP Classification of Lower Extremity Venous Disease and treatment options can be discussed with the patient (see Table 1).

CONVENTIONAL TREATMENT

First line treatment for venous insufficiency is usually conservative management, including leg elevation, daily exercise, and, most importantly, graduated compression stockings. Compression therapy reduces edema, venous stasis, leg fatigue and pain. However, it does not address the underlying cause of the symptoms and patient com-

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); etiologic classification; anatomic distribution (superficial, deep, or perforator, singly or in combination); and pathophysiologic dysfunction (reflux and/or obstruction)

pliance with compression therapy is variable at best. Intervention 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.

Greater saphenous vein ligation and stripping has been a treatment standard for venous insufficiency for nearly 100 years and remains a practiced intervention. However, it is performed in an operating room setting, 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 drawbacks have dissuaded many patients from seeking therapy for their disease. Moreover, practitioners have felt that the dangers involved with an operate procedure, however unlikely, were not warranted in more “high risk” patients. For these reasons less invasive techniques and procedures were sought.

A NEW AND BETTER TREATMENT APPROACH

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 structure. Since that time, endovenous radiofrequency ablation has amassed the largest collection of published data -- including single center and multi-center randomized trials, and registry data -- and the longest follow-up of any endovenous procedure.

Endovenous radiofrequency ablation is a more effective minimally invasive technique that can be performed in an outpatient setting, making therapy an option for many who previously would not have considered surgical treatment or who were not considered candidates for surgery due to comorbidities.



OUTPATIENT PROCEDURE SUPERSEDES CONVENTIONAL SURGERY

Endovenous radiofrequency ablation patients routinely have the procedure performed in an outpatient setting with local anesthesia and a low dose oral sedative such as diazepam.

Using ultrasound guidance, the surgeon places a guide wire and small introducer sheath 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 with ultrasound guidance. The vein is “exsanguinated” using external compression or Trendelenburg position.

After tip position is reconfirmed, radiofrequency energy is delivered to the vein causing wall contraction and obliteration of the vein lumen. The catheter is withdrawn at a rate of one to two centimeters 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 a bandage applied to puncture site. With the patient still

in Trendelenburg position, thigh high compression stockings are applied. Compression therapy continues for three to four weeks post procedure. Patients can resume normal activities the following day and strenuous activity after one week.

EVOLVES STUDY

The EVOLVeS Study (endovenous obliteration versus ligation and stripping) was a randomized multi-center study comparing radio-frequency obliteration (RFO) to ligation and stripping (LS) performed by Lurie et al in 2003 involving patients with symptomatic venous insufficiency. There were no statistical differences between the groups with regards to mean age, gender, or CEAP clinical classification. Patients were followed up at three days, one week, three weeks, four months, one year and two years. The RFO group returned to normal activities after only 1.16 days versus 3.89 days for the LS group with a P value = 0.02. Return to work was 7.7 days faster for the RFO group versus the LS with a P value <0.05. Patients undergoing LS had significantly more pain post-op than the RFO group as measured by Quality of Life Pain Score, P<0.05. Fewer RFO patients had complications compared to the LS group overall P<0.05. The incidence of pain, ecchymosis, and hematoma, respectively, were all statistically lower in

the RFO group versus the LS group respectively P<0.05. There were no statistically significant differences in efficacy between the procedures in this study.

CONCLUSION

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

NEW RESEARCH VALIDATES LONG-TERM SAFETY, EFFICACY OF BARIATRIC SURGICAL PROCEDURES



By Jamie Loggins, M.D., Chief, Bariatric Surgery, Central Maine Medical Center



Jamie Loggins, M.D.

It has been almost two years since the Centers for Medicare and Medicaid Services (CMS) acknowledged that severe obesity is a lethal disease, and mandated coverage for its treatment. Yet today, most insurance companies do not cover bariatric

surgery as part of a standard benefits package. Many insurance companies that do cover bariatric surgery place non-evidence-based barriers to discourage or delay patients from obtaining potentially lifesaving surgical treatment.

The appropriateness of the CMS action regarding bariatric surgery was confirmed recently by two landmark studies published in the August 23, 2007 issue of the *New England Journal of Medicine*. These studies show that patients who underwent bariatric surgery had a significant survival benefit over non-surgically treated morbidly obese patients.

The first study – the Swedish Obese Subjects Study – is a prospective, controlled study of bariatric surgery matching severely obese patients with a BMI ≥ 34 kg/m² who underwent bariatric surgery with equally obese patients who did not have surgery.

This study was conducted over a 13.4-year period and surveyed over 4,000 patients with a 10.9-year average follow up (range 4.75 to 18.2 years) and a 99.9 percent follow-up rate. Weight loss was up to 25 percent of initial weight in the surgical group versus two percent in the control group. The surgery group experienced a 29 percent survival advantage compared to the non-surgical group.

While these studies demonstrate powerful evidence of improved health and mortality reduction following bariatric surgery, perhaps what makes these results even more impressive is that both studies predate major advances in bariatric surgery, including the advent of laparoscopic surgery. It is reasonable to surmise present survival benefits are likely even greater.

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The research proved the long-term sustainability of weight loss in the surgical group.

The second study was a retrospective cohort study out of Utah performed over an 18-year period from 1984 to 2002. This study included over 15,000 subjects; this time matching patients who had undergone the Roux-en-Y gastric bypass procedure to non-surgically treated morbidly obese patients. The average follow up period of this study was 7.1 years. The results were even more impressive. In the surgical group, death from all causes was reduced by 40 percent, from diabetes by 92 percent, from coronary artery disease by 56 percent, and from cancer by 60 percent.

With over 100 million obese Americans, including some 15 million severely obese individuals, what we can conclude from this evidence is that with operative mortality rates less than one percent, obesity is far more dangerous than bariatric surgery. These results support the contention that it is unethical for insurance carriers to deny patient access to bariatric surgery. Finally, the significant mortality reduction of surgery demonstrated in a group that included patients with a BMI < 35 kg/m² suggests the need to reassess standard indications for bariatric surgery which currently exclude patients with a BMI < 35 .

Central Maine Bariatrics
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“CULTURAL BROKER” HELPS HEALTHCARE PROVIDERS BETTER SERVE IMMIGRANT POPULATION



By Reggie Albert, Administrative Director, Central Maine Family Medicine Residency

The communities of Lewiston and Auburn, located on opposite shores of the Androscoggin River in south-central Maine, have seen a heavy influx of immigrants over the past several years. Some 4,000 East Africans, primarily from Somalia, seeking to escape the ravages of a long civil war, have relocated in the area, presenting healthcare providers with both interesting challenges and unique rewards.



Fowsia Musse, Cultural Broker

The Central Maine Medical Center Family Medicine Residency Program, established in the late 1970s as a training program for family doctors, has become an important healthcare

resource for the immigrant community. In fact, nearly 25 percent the program’s patient population is comprised of Somalis.

Because the Somali language has only been written for about 30 years, many of the immigrants do not read their native tongue. Even for those who do read the language, there are many adaptations required to convey Ameri-

can English linguistic concepts into Somali. For some time, the residency program employed the services of translators to communicate with the immigrants. Not

the residency program’s overall ability to provide care for the immigrant community. The residency program’s collective knowledge – the ability to understand people,

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long ago, however, the program introduced a “cultural broker” to improve communications.

The residency’s cultural broker, an Ethiopian-born female immigrant who spent many years living in Somalia, was located through a Somali community organization. She provides an array of benefits for the program’s East African patients, most arising from interpreting-translation services. She makes reminder calls to patients, accompanies them to service locations, and works to assure that details are appropriately tended to. She has been instrumental in developing various pertinent signage, handouts and letters.

A great benefit that the cultural broker provides to residency staff members, including all care providers and support staff, is education regarding Somali culture. Understanding the customs and traditions of the Somali people has significantly improved

their history, and their traditions – is enhanced on a daily basis. The program’s compassion has improved, not only for this immigrant community, but for all patients. The educational opportunity that has been provided to the CMMC Family Medicine Residency Program is immeasurable.

The Central Maine Medical Center Family Medicine Residency Program operates from facilities at the Oscar Treat Turner Family Medicine Center, located adjacent to the Medical Center. Since its inception in 1978, the residency program has graduated over 150 family physicians who practice from Maine to California, and in Hawaii, Alaska, Canada, New Zealand and Norway. Many residency graduates have established practices in Maine, including the central Maine area. Among its graduates have been physicians from throughout the world.

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