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Factors that influence perforator vein closure rates using radiofrequency ablation, laser ablation, or foam sclerotherapy

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Objective: **Perforator vein closure for the treatment of advanced chronic venous insufficiency has been shown to be effective using radiofrequency ablation (RFA), endovenous laser ablation (EVLA), or ultrasound-guided foam sclerotherapy (UGFS). The objective of the study was to compare these three modalities and attempt to identify factors that might predict treatment failure.**
Methods: **A retrospective review of a prospectively managed database of perforator vein treatments performed at a three centers within a single institution from February 2013 to July 2014. The modality for perforator closure was left to the discretion of the treating physician. A Duplex scan was performed at 2 weeks after the procedure. Standard statistical methods were used to compare subgroup characteristics. Univariate and multivariate analyses were performed using SAS v9.3.**
Results: **We performed 296 perforator ablations on 112 patients. Superficial venous reflux was appropriately treated before perforator ablation. Of the 296 procedures, 62 (21%) underwent EVLA, 93 (31%) RFA, and 141 (48%) UGFS. The indications for intervention in most patients were C5 and C6 disease (67%). At 2 weeks, closure rates were significantly lower for UGFS (57%) compared with RFA (73%; $P = .05$) but failed to reach significance compared with EVLA (61%; $P = .09$). When patients were first treated with UGFS and closure failed, thermal ablation was then successful in 85% ($P = .03$) of EVLA and 89% ($P = .003$) of RFAs as a secondary procedure, compared with initial closure rates. Systemic anticoagulation, perforator size, and presence of deep vein reflux did not affect closure rates for any modality. Factors that were predictive of failure were body mass index >50 with closure rates of only 37% for all modalities. There were five postprocedure deep venous thromboses found (5%). One patient had an isolated gastrocnemius thrombus after undergoing UGFS and the other four had focal tibial vein thrombosis without extension into the popliteal vein.**

Conclusions: **In this study we compared EVLA, RFA, and UGFS for the treatment of incompetent perforating veins. RFA was found to be the most reliable means of perforator closure and was significantly better than UGFS. Morbid obesity (body mass index >50) predicted failure of perforator closure in all groups. Failure of UGFS as an initial treatment led to increased perforator closure when thermal ablation was used as a secondary technique. (J Vasc Surg: Venous and Lym Dis 2016;4:51-6.)**

Chronic venous insufficiency (CVI) affects millions of people worldwide. Patients with venous ulceration often suffer for years without proper treatment. In addition to loss of work hours, patients can develop significant psychosocial issues surrounding chronic ulceration, because significant pain and disability can be associated with wounds and wound care. Genetic factors have been implicated in the development of CVI.[1] Other factors that increase risk of CVI include history of deep venous thrombosis, multiple pregnancies, and advanced age. Although compression has long been the primary treatment, aggressive procedures to relieve venous hypertension have been shown to improve wound healing and risk of recurrence.[2-6]

CVI arises from the venous hypertension caused by valvular incompetence. Increased venous pressure can cause aching, heaviness, fatigue, and pain. In the most severe cases, this can progress to inflammatory changes, lipodermatosclerosis, hemosiderosis, stasis dermatitis, and ultimately venous ulcers. With the advent of improved techniques to study flow and advances in the imaging capabilities of duplex ultrasonography, insufficiency within the superficial system and perforating veins has also become recognized as pathologic. Treatment of these veins helps to relieve venous hypertension and facilitates ulcer healing.[3,7]

Incompetent perforating veins (IPVs) play a role in the development of CVI and ulceration.[4,5] With improvements in technology, traditional open surgical options have been supplanted by minimally invasive techniques. Current societal recommendations include perforator closure in clinical

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Clinical, Etiologic, Anatomic, and Pathophysiologic (CEAP) 5 or 6 disease, through percutaneous thermal ablation of perforators, subfascial endoscopic perforator ligation (SEPS), open surgery, or sclerotherapy.[8,9] Closure rates for percutaneous thermal ablation of perforators are generally reported as 60% to 80%.[4,7,10,11] Higher rates of recanalization and de novo perforator formation have been reported after perforator treatment after thermal saphenous closure.[4] Ultrasound-guided foam sclerotherapy (UGFS) has shown promise in perforator closure and wound healing, but with widely variable success rates.[5,12] To date, there has not been an investigation into the short-term technical closure rates of these various modalities of perforator closure, success rates of each, and factors that influence perforator closure. Regardless of method used, successful closure of perforators appears predictive of wound healing with minimal morbidity.[4,5,12]

To our knowledge, this study is the first to compare early closure rates of IPVs using laser (1470 nm fiber), radiofrequency, and UGFS in an attempt to identify risk factors for failure in patients with advanced CVI. Patient comorbidities and anatomic factors were also assessed to describe demographic and procedural variables that influence closure rates.

METHODS

A retrospective review of a prospectively maintained database was performed in three centers within a single institution after approval by the institutional review board. No patients were prospectively enrolled and therefore no informed consent was needed for the study. Patients were evaluated with duplex ultrasound using the GE Logiq S8 machine (Fairfield, Conn), with a 9-MHz linear transducer in a standing position, with no weight-bearing on the affected limb. The presence of perforating veins near the superficial pathology with a diameter >3.5 mm and reflux time >0.5 seconds of reflux were treated. Perforator characteristics including length from the deep veins, tortuosity, diameter at the fascia, and the visual appearance of pulsatility on ultrasound were noted. Table I shows the specific symptoms in each CEAP class that would indicate treatment. The distance from the malleolus and the tibial ridge were measured and were used to identify the exact position of the perforating vein. More than one perforator could be treated at a sitting if clinically indicated. Patients with untreated saphenous reflux were excluded from the study. All patients who underwent treatment of IPVs from February 2013 to July 2014 were enrolled. Patient comorbidities, CEAP classification, anatomic factors, and treatment details were analyzed. Perforator closure modality was at the discretion of the treating physician.

Laser ablation. A 1470-nm, 400-um microfiber (Angiodynamics, Latham, NY) was directly inserted into the pathologic perforator through a 21-gauge needle. The perforator was imaged in the longitudinal view and the laser tip was passed below the fascia and to the deep venous junction if possible. The laser was then pulled back to 2 to 3 mm from the deep venous junction. One percent lidocaine was then infiltrated below and above the perforator down to the deep veins. The generator was set at 6 W and the vein was then treated with 50 to 100 joules per 2 mm segment for the length of the perforator (Fig 1, *A1-3*). The leg was then compressed with ace bandages or a multilayer ulcer wrap.

Table I. Superficial pathology located near the pathologic perforating veins

Patients considered for perforator closure	
CEAP 2	Focal pain in the area of the IPV and associated varicose veins
CEAP 3	Focal swelling or pain in the area of IPV
CEAP 4	Focal skin irritation and/or discoloration over the IPV
CEAP 5	IPVs near the area of a previous ulcer
CEAP 6	IPVs in the area of an active ulcer

CEAP, Clinical, Etiologic, Anatomic, and Pathophysiologic; *IPV,* incompetent perforating vein.

RFA. A radiofrequency stylet catheter (Closurefast radiofrequency stylet; Medtronic, Minneapolis, Minn) was directly inserted into the pathologic perforator. This was done either with direct puncture using the stylet, or more frequently using a Seldinger technique over a 0.035-inch wire. The perforator was imaged in the longitudinal view and the radiofrequency catheter was passed below the fascia and to the deep venous junction if possible. The catheter was then pulled back to 2 to 3 mm from the deep venous junction. One percent lidocaine was then infiltrated below and above the perforator down to the deep veins. The vein was then treated for 30 seconds in four quadrants. The catheter was pulled back 3 to 5 mm and treated again in four quadrants. This was repeated for the length of the perforator (Fig 1, *B1-3*). The leg was then compressed with ace bandages or a multilayer ulcer wrap.

UGFS. The perforator was imaged in transverse and longitudinal views and a varicosity approximately 5 cm away from the perforator was selected. The vein was cannulated with a 23-gauge butterfly needle. One cc of 1% polidocanol (Asclera; Merz Aesthetics, Greensboro, NC) was agitated with 4 cc room air for approximately 10 seconds until a visually homogenous foam was created. The foam was immediately injected into the varicosity and manually directed with visualization using ultrasound into the perforator (Fig 1, *C1-4*). When the perforator was filled with foam, pressure was held over the junction of the perforator to the deep veins. Pressure was held for 2 minutes. A maximum of 10 cc of foam was used per treatment event. The leg was then compressed with ace bandages or a multilayer ulcer wrap.

Follow-up. Patients were instructed to wear daily compression of at least 20 to 30 mm Hg or their standard compressive wound therapy after any perforator treatment. Patients were seen at 2 weeks for an ultrasound examination, sooner if there were any complications, or for wound care. The pretreatment measurements were used to identify the area of the treated vein. Closure was reported as