



A study comparing Endovenous laser ablation and Radiofrequency ablation of the great saphenous vein

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ABSTRACT

Background: Endovenous laser therapy (EVLT) and radiofrequency ablation (RFA) are new, minimally invasive techniques for ablation of the incompetent great saphenous vein (GSV). We reviewed saphenous closure rates and complications of both procedures.

Methods: Between June, 2012, and June 25, 2015, endovenous GSV ablation was performed on 130 limbs in 92 patients. RFA was the procedure of choice in 53 limbs over the first 24-month period of the study. This technique was subsequently replaced by EVLT, which was performed on the successive 77 limbs. According to the CEAP classification, 124 limbs were C2-C4, and six were C5-C6. Concomitant procedures included avulsion phlebectomy in 126 limbs, subfascial endoscopic perforator surgery in 10, and small saphenous vein ablation in 4 (EVLT in 1, ligation in 1, stripping in 2).

Results: Occlusion of the GSV was confirmed in 93.9% of limbs studied (94.4% in the EVLT [51/54] and 90.9% in the RFA group [10/11]). The distance between the GSV thrombus and the common femoral vein (CFV) ranged from -20 mm (protrusion in the CFV) to 50 mm (median, 9.5 mm) and was similar between the two groups (median, 9.5 mm vs 10 mm). Thrombus protruded into the lumen of the CFV in three limbs (2.3%) after EVLT. All three patients were treated with anticoagulation. One received a temporary inferior vena cava filter because of a floating thrombus in the CFV. Duplex follow-up scans of these three patients performed at 12, 14, and 95 days, respectively, showed that the thrombus previously identified at duplex scan was no longer protruding into the CFV. No cases of pulmonary embolism occurred. The distance between GSV thrombus and the sapheno-femoral junction after EVLT was shorter in older patients ($P=0.006$, $r=0.13$). The overall complication rate was 15.4% (20.8% in the EVLT and 7.6% in the RFA group, $P=0.049$) and included superficial thrombophlebitis in 4, excessive pain in 6 (3 in the RFA group), hematoma in 1, edema in 3 (1 in the RFA group), and cellulitis in 2. Except for two of the three patients with thrombus extension into the CFV, none of these adverse effects required hospitalization.

Conclusion: GSV occlusion was achieved in >90% of cases after both EVLT and RFA at 1 month. We observed three cases of thrombus protrusion into the CFV after EVLT and recommend early duplex scanning in all patients after endovenous saphenous ablations. DVT prophylaxis may be considered in patients >50 years old. Long-term follow-up and comparison with standard GSV stripping are required to confirm the durability of these endovenous procedures.

KEYWORDS : Endovenous laser therapy, Radiofrequency ablation, Saphenous reflux

INTRODUCTION

Endovenous laser therapy (EVLT) and radiofrequency ablation (RFA) of the great saphenous vein (GSV) have been recently introduced as alternative, minimally invasive techniques for the treatment of saphenous vein incompetence. These procedures were designed to ablate the GSV through a percutaneous approach to minimize the discomfort and complications associated with conventional stripping. The RFA catheter delivers radiofrequency energy to achieve heat-induced venous spasm and collagen shrinkage, whereas EVLT releases thermal energy both to the blood and to the venous wall, causing localized tissue damage. Relative simplicity and high patient satisfaction have made these procedures increasingly popular. Early reports on endovenous saphenous ablation demonstrate high occlusion rates and different patterns of complications related to these two different techniques. Reported complication rates range between 4% and 23% after RFA and between 0% and 10% after EVLT. Occlusion rates have been high with both techniques, but they have been somewhat higher after EVLT (98% to 100%) than after RFA (83% to 100%). To evaluate the early efficacy and side effects of these two techniques, we reviewed our experience.

METHODS

The clinical records of 92 consecutive patients who underwent endovenous GSV ablation over a 3-year period between June 1, 2012, and June 25, 2015, were retrospectively reviewed. Data on 130 extremities were included in the analysis. All patients had symptomatic varicose veins with documented GSV incompetence and were classified according to the CEAP (clinical, etiologic, anatomic, pathophysiologic) classification. Clinical data, operative

details, and postoperative course were recorded and analyzed.

The severity and extent of GSV reflux were evaluated preoperatively with duplex scanning. All duplex scans were performed with a color duplex system. Reflux in the superficial (GSV and small saphenous vein) and deep (femoral vein and popliteal vein) venous systems was assessed with patients in the standing position by inflation/deflation of a calf plethysmographic cuff. Reflux was defined as reversed flow lasting 0.5 seconds. Presence of incompetent perforators was not routinely evaluated. Comparison between the two groups was performed with the Fisher's exact test or 2 test for categorical variables and the t test or Wilcoxon test for continuous variables, as appropriate. Linear regression analysis was used to assess the correlation between two continuous variables. $P=0.05$ was considered statistically significant. Before surgery, lower extremity varicosities were marked in the standing position in preparation for stab avulsions. These outpatient procedures were performed in the operating room under general or epidural anesthesia supplemented with local tumescent anesthesia. The patients were placed in the supine position, and under duplex ultrasound guidance, the GSV was punctured with an 18-gauge needle or, rarely, accessed by cutdown at the knee level. The unsheathed laser or radiofrequency catheter was advanced over a wire and its position confirmed to be distal to the saphenofemoral junction (SFJ), 1 cm below the confluence of the inferior epigastric vein. The saphenous subcompartment along the GSV was infiltrated with tumescent anesthesia (50 mL of 1% lidocaine and 1 mL of epinephrine [1:1,000] diluted in 1 L of normal saline) under duplex ultrasound guidance from knee to groin around the catheter. The patient was then placed in Trendelenburg position and the GSV was treated with either RFA

or EVLT. RFA was the procedure of choice over the first 24-month period of the study (53 limbs); a 6F radiofrequency catheter was used in 29 limbs (54.7%) and an 8F in 24 (45.3%). This technique was subsequently replaced by EVLT, which was performed on 77 successive limbs. Successful obliteration and absence of common femoral vein (CFV) thrombus were confirmed by intraoperative duplex ultrasound scans. Stab avulsion phlebectomies and other concomitant procedures were performed when indicated. At the completion of the operation a two-layer compressive dressing and ACE bandages was applied from toes to groin to be maintained for the following 2 days. Patients were discharged the same day upon recovery from the anesthesia with instruction to ambulate immediately. At time of discharge, all patients were prescribed a standard dose of analgesics. Postoperative pain was defined as excessive when this required an additional prescription refill or caused significant limitation of activities of everyday living. Thrombophlebitis was defined as the presence of an indurated cord at the site of the treated GSV associated with localized hyperemia, edema, and tenderness requiring treatment with anti-inflammatory agents. Edema was defined as the new onset of swelling in the treated lower extremity that was exacerbated by ambulation and relieved by leg elevation. Endovenous laser therapy. Veins of all sizes were treated with this procedure. After the GSV was cannulated with a 45-cm-long 5F angio sheath over a J-tip guidewire, an 810-nm diode laser fiber was inserted and advanced proximally. The veins were treated by delivering 14 W of continuous energy and withdrawing the laser fiber at a speed of 3 mm/s, until a distance of 2 cm above the knee access site was reached. Radiofrequency ablation. The Closure system (VNUS Medical Technologies Inc, San Jose, Calif) was used to treat veins from 2 to 12 mm in diameter. A 6F or 8F catheter was used. These were introduced in the GSV through a vascular sheath with the Seldinger technique.

The catheter was withdrawn at a rate of 2 to 3 cm/m, maintaining a temperature between 82°C and 90°C. Postoperative duplex evaluation. Routine early postoperative duplex scanning (1 month from surgery) was initiated at our institution only after the introduction of EVLT and publications on thrombotic complications after RFA. Successful obliteration was confirmed by the evidence of a noncompressible GSV with thickened walls and no flow on color duplex ultrasound analysis. The proximal extent of GSV thrombus was measured from the SFJ.

RESULTS

One hundred and thirty limbs in 92 patients were treated and represent the subjects of this study. Seventy seven patients were women (83.7%) and 15 were men (16.3%), with a mean age of 51.4 12.8 years (range, 23 to 84 years). One hundred and twenty-four limbs had symptomatic varicose veins, with or without skin changes (C2-C4), and six had a history of venous ulcers (C5-C6). Etiology was primary valvular incompetence in 126 limbs and post-thrombotic syndrome in four. Preoperative deep venous reflux was detected in 33 limbs (25.4%); this was localized in the femoral vein in 23 (17.7%) and in the popliteal vein in 20 (15.5%). Length of GSV treated by EVLT ranged between 10 and 45 cm (mean, 30.7 cm). A mean of 48.10 J/cm and 1452.374 J/limb (range, 500 to 2327 J) was delivered. Adjunctive procedures included avulsion phlebectomies in 126 limbs, small saphenous vein ablation in 4, and subfascial endoscopic perforator surgery in 10. Indications for subfascial endoscopic perforator surgery were a history of venous ulcers (C5-C6) in six limbs and advanced skin changes (C4) in four. Small saphenous vein reflux was abolished by EVLT in 1 case, sapheno popliteal ligation in 1, and stripping in 2. Immediate technical success was obtained in all (100%) of EVLT procedures and in 51 (96%) of 53 of RFA cases ($P=0.13$). In one case, spontaneous thrombosis of the GSV occurred after catheterization because of the small diameter of the vein. In another case, the procedure was aborted after numerous attempts to cannulate the GSV, and formal stripping was performed. RFA was deemed inadequate because of the presence of significant persistent flow in nine cases, thus necessitating repeated treatment during the same anesthesia, whereas EVLT was always successful (17% vs 0%, $P=0.002$). At the end of operation, duplex ultrasound

scans demonstrated residual minimal flow in 16 limbs (12%), representing 11.3% of RFA and 13% of EVLT procedures ($P=0.99$). However, this finding was not considered clinically significant, and no further intervention was deemed necessary. Early postoperative duplex ultrasound scans were performed in 65 limbs (50%) (54/77 [70%] of the EVLT group and 11/53 [20.8%] of the RFA group) between 1 and 23 days (median, 7 days). These studies revealed early partial GSV recanalization in four limbs (6.1%). Of these, 5.6% (3/54) were in the EVLT group, and 9.1% (1/11) were in the RFA group of patients who received an early postoperative duplex scan. One of these patients had recurrent symptomatic leg varicosities, and GSV stripping with phlebectomies was performed 7 months later. The other three patients remained asymptomatic, and no further intervention was performed. A comparison of intraoperative and early postoperative duplex ultrasound scans revealed that postoperative recanalization had occurred in one (9%) of 11 limbs with minimal GSV flow at the end of procedure (EVLT group), and in three (5.5%) of 55 limbs, with intraoperative evidence of complete GSV occlusion (2 in the EVLT and 1 in the RFA group). Postoperative duplex scans revealed protrusion of the GSV thrombus into the CFV in three (2.3%) asymptomatic patients, all in the EVLT group; no case was identified in the RFA patients studied with duplex ultrasound scanning. None of these patients had a history of previous DVT or a known hypercoagulable state. Treatment consisted of subcutaneous low-molecular-weight heparin in two cases and unfractionated intravenous heparin in one. In one case, a temporary inferior vena cava filter was also inserted because protruberant thrombus appeared to be floating in the CFV. Two weeks later, the thrombus previously identified at duplex ultrasound scan was seen no longer to protrude into the CFV, and the filter was removed. No thrombus was identified in the filter, and patient remained asymptomatic during a 3-month follow-up. Similarly, thrombus completely resolved in the other two patients on duplex ultrasound scans performed 12 and 95 days later. The distance between the proximal GSV thrombus and the SFJ ranged between -20 mm (protrusion into the CFV) and 50 mm (median, 9.5 mm) and was similar between the EVLT and RFA groups (median, 9 vs 10 mm). After EVLT, the distance between the GSV thrombus and the SFJ was significantly shorter in older patients (r^2 0.13, $P=.0064$) but not after RFA ($P=0.39$). When EVLT patients were grouped by age, we found that the mean age of those whose GSV thrombus extent was 2 mm from the SFJ (66%) was 56 years, whereas mean age was 49.1 years ($P=0.63$) in those whose distance was 2 mm (33%). The overall complication rate was 15.4% (20.8% after EVLT and 7.6% after RFA, $P=0.039$) and included thrombus protrusion in the CFV in 3, urinary retention in 1, superficial thrombophlebitis in 4, excessive pain in 6, hematoma in 1, edema in 3, and cellulitis in 2. None of the patients had bilateral edema. No cases of clinically evident pulmonary embolism or thermal skin injury occurred. Except for two of those with thrombus extension into the CFV, hospitalization was not required for any of these patients.

DISCUSSION

Endovascular techniques of saphenous vein ablation have been introduced as minimally invasive alternatives to high ligation and open surgical stripping of the incompetent saphenous vein. Although stripping can lead to painful and prolonged postoperative recovery in some patients, with risks of infection, hematoma, and nerve injury reports of endovenous procedures claim earlier return to work and decreased postoperative pain. Encouraging results after RFA and EVLT have been reported in several studies. This retrospective review compared the early success and complications of two endovenous procedures of GSV ablation performed at a single institution during two consecutive study periods. A drawback of this study was that duplex scanning after RFA was performed only in the later period of the study, thus data relative to early recanalization and thrombus progression in this group are limited and were not statistically analyzed. We have recently described the three cases of progression of GSV thrombus into the CFV after EVLT in detail. This study found a higher need for repeated treatment of the saphenous vein during the same operation in the RFA group compared with the EVLT group (17% vs 0%) because of duplex

evidence of patency after the first pass of the Closure catheter. This finding was more than the usual intraoperative residual flow and was considered as inadequate closure, necessitating repeated obliteration during the same anesthesia. Most data available in literature about early success of endovenous saphenous ablation procedures pertain to the early postoperative period, but few authors report on immediate intraoperative success. Although the successful immediate retreatment of an incompletely obliterated venous segment with RFA may not be considered relevant in terms of outcome, when two different procedures are compared, it is important to report in detail not only the clinical but also the technical results, as all of these factors might affect the preference of one procedure over the other one. The Endovenous Radiofrequency Obliteration (Closure) Versus Ligation and Stripping in a Selected Patient Population (EVOLV) study was designed to compare RFA with stripping of the GSV. Immediate success on the day of treatment was reported for 95% (42/44). A scan obtained 72 hours after the procedure showed flow in the proximal GSV in 16.3% (7/44) of limbs. Five of these segments had reflux in the open segment. Two of these closed at 1 week, and an additional segment closed at 3 weeks. Our data confirm these observations. When we compared intraoperative with postoperative duplex ultrasound findings, we found no apparent correlation between the presence of minimal GSV flow at the end of procedure and recanalization. Noncompliance with postoperative compression could have been one of the causes of early recanalization, but we were unable to monitor this. Previous reports have also reported slightly higher occlusion rates with EVLT (98% to 100%)^{4,5} than with RFA (83% to 100%). In our series, early recanalization was infrequent in both groups; most patients remained asymptomatic and required no further treatment. Evidence of minimal residual flow at the end of procedure was not associated with premature recanalization of the GSV. Although we did not monitor closely compliance with postoperative compression, we believe that this may be a contributing factor for recanalization. It is possible that this variability in occlusion rates is due to the different mechanism of action between these two techniques. RFA of the target vein is obtained by heat induced venous spasm and collagen shrinkage, whereas EVLT causes both heating of blood components and thermal damage to the endothelium. Therefore, adequate vein emptying by leg elevation, the use of perisaphenous infiltration with tumescent solution, and maintenance of an adequate probe temperature are probably more crucial with the RFA technique. This could be the subject of future studies.

The higher occurrence of painful thrombophlebitis and cellulitis with the EVLT technique is probably due to the incomplete vein emptying with intraluminal thrombus and surrounding inflammation. Absence of flow proximal to the inferior epigastric vein at postoperative duplex scans is most likely due to the presence of thrombotic material that forms in the stump of the GSV above the treated area. Routine postoperative duplex scanning was initiated at our institution only after recent publications of thrombotic complications after RFA. Current rates of DVT pooled from large series are considered similar between EVLT and RFA (0.3% vs 0.4% to 2.1%)^{14,15} and stripping (5.7%). Occurrence of proximal thrombus extension after EVLT is low. In our experience, three patients were observed with saphenous thrombus protrusion into the CFV. Although two of these three patients clearly could not be classified as having a classic DVT, anticoagulation was introduced and was effective in all three, with complete resolution of the thrombus on duplex scans performed 2 to 12 weeks later. No case of pulmonary embolism has been reported with the EVLT technique, but two cases of this serious complication have been described after RFA. It is possible GSV thrombi caused by laser energy have different characteristics from those occurring after RFA. Pathologic examination of veins treated by EVLT shows homogeneous thrombotic occlusion of the vessel due to generation of steam bubbles, whereas RFA causes collagen shrinkage and fibrosis. There are reports indicating that activation of the coagulation cascade in RFA ablation procedures is not related to the delivery of energy but to the placement of intravascular catheters and to the prolonged

duration of the ablation procedure. Another significant finding was the inverse correlation observed between the distance of GSV thrombus from the SFJ and patients age in the EVLT group; this observation has not been reported previously. In particular, most of patients who developed an extension of GSV thrombus to 2 mm from the SFJ were 50 years old. Previous studies demonstrated a significant increase in occurrence and propagation of spontaneous DVT in the older population. From these data, it can be argued that patients 50 years old undergoing endovenous procedures are at the greatest need for thromboprophylaxis in the perioperative period. Only prospective randomized studies will answer this question. Our initial enthusiasm for the RFA technique was tempered by the need for repeat treatment of the saphenous vein during the same operation in some cases, the need for continuous monitoring of catheter temperature, and the need for an irrigation system used for the ablation. EVLT laser fiber is less expensive than the RFA catheter, the pullback treatment time is shorter, and the saphenous obliteration rates are likely higher.

CONCLUSION

The overall success rate of endovenous ablation techniques in occluding incompetent GSVs was 94% at 1 month. EVLT was associated with somewhat higher occlusion rates, but postoperative complications in our experience were more frequent after EVLT than after RFA. Compression treatment after endovenous saphenous ablation may be important. All patients who receive endovenous procedures should undergo early postoperative duplex scanning to rule out proximal extension of thrombus, confirm occlusion, and exclude more distal DVT. Our data suggest that older patients tend to develop more proximal GSV thrombi after ablation; thus DVT prophylaxis may be considered in patients 50 years old.

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