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Long-term results of endovenous laser ablation of saphenous vein reflux: Up to nine years of follow-up

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Abstract

Introduction: Endovenous laser ablation (EVLA) has become the gold standard for the treatment of saphenous vein reflux. We report the long-term clinical and ultrasound results of EVLA.

Methods: This study is a retrospective review of patients who underwent EVLA of saphenous vein over four years. Clinical results were assessed using venous clinical severity score (VCSS), and ultrasound results were classified according to Bush classification.

Results: Over a median follow-up time of 4.4 years, 168 EVLA-treated patients showed a drop in VCSS from 4.38 to 1.39. Ultrasound results of 140 treated great saphenous veins showed that 64% had one or more cause of recurrence. The presence of neovascularization correlated well with the lack of improvement of VCSS.

Conclusion: EVLA resulted in drop in VCSS from 4.38 to 1.39. Among 140 treated great saphenous veins, reflux in the anterior accessory saphenous vein was the primary cause (23.5%) of recurrence.

Keywords

Venous reflux, laser ablation, venous disease, saphenous vein

Introduction

Over the past decade, endovenous laser ablation (EVLA) with or without phlebectomy has overtaken high ligation and stripping (HLS) as the gold standard for the treatment of the saphenous vein reflux. Many studies have documented better early and midterm results in terms of post-operative pain score, hematomas, and early return to normal activity favoring EVLA.[1–4] Based on these results, recent guidelines recommended EVLA over surgery and over conservative management for the treatment of saphenous vein reflux.[5–7] Although the late clinical results of EVLA and surgery are similar, the anatomical causes of recurrence on duplex scanning are different.[8–12]

Recurrent varicose veins after surgery (REVAS) are classified as related to neovascularization at the groin and to progression of the disease itself.[13–15] But recurrent varicose vein after thermal ablation (REVATA) has many anatomical causes; furthermore, there has been no consensus on reporting of the duplex scanning results.[8,9] Bush et al. addressed this issue and reported on 164 patients who presented for REVATA and propose to classify these recurrences in five groups.[15,16]

Using his classification, we report the late results of a retrospective analysis of the cause of recurrence following EVLA in a large series of consecutively treated patients over a period of four years.

Material and method

This is a retrospective chart review of patients who underwent EVLA of the great or small saphenous veins (GSV, SSV) in an outpatient setting between 2006 and 2009. Patients' demographic data were prospectively collected upon clinical visit, as well as

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important details about the varicose vein condition including the clinical stage of the disease using the clinical, etiological, anatomical and pathological classification (CEAP), its severity using the venous clinical severity score (VCSS). Doppler ultra sound (DUS) was performed in standing position, leg in mild flexion, and external rotation with weight on the non-examined leg. Significant reflux was defined as lasting for more than 0.5 ms following distal manual compression. The size of the GSV at the groin and SSV at the popliteal fossa, the length of the treated vein, as well as the total energy delivered were also measured.

At early follow-up, physical examination and US were performed during routine office visits. We documented significant complications of the procedure such as deep or superficial vein thrombosis and also confirmed the occlusion of the treated vein. On late follow-up, patients were contacted and invited for an office visit for a clinical assessment using the VCSS. DUS evaluation in upright position was performed by the first author (BK) as per the protocol of the American Vein and Lymphatic Society.[17] Among patients who did not present for their late follow-up, the latest data in their medical records were considered. Ultrasound results were classified as recommended by Bush et al.:[15] (1) reflux in collateral at the groin, (2) more than 5 cm recanalization of the saphenous vein, (3) neovascularization at the groin, (4) new reflux in untreated ipsilateral saphenous vein, and (5) visible perforators of more than 3 mm at the thigh and/or legs.

All data were entered to SPSS Statistical software 24.0. All continuous data are displayed as mean ± standard deviation and categorical variables are presented in absolute numbers and percentages. The Mann–Whitney U and the Fisher exact tests were used to test the continuous and categorical variables, respectively. p values smaller than 0.05 were considered significant.

Procedure

The procedure is performed in an outpatient setting under local anesthetic using 1% lidocaine with or without sedation using sublingual midazolam. GSV was accessed at the most distal part of the refluxing segment using the regular 21-gauge echogenic tip needle. Over guidewire, the introduced catheter was parked 3.5 cm distal to the sapheno-femoral (SFJ) or saphenopopliteal junction (SPOPJ). The diomed 15/30 bare tip laser fiber (810 nm) was introduced in the catheter and positioned at 2.5 cm from the SFJ or SPOPJ. We use 0.1% lidocaine with adrenaline as the tumescent solution in the peri-saphenous space. Depending on the size of the proximal segment, we delivered 100 to 150 joules/cm to the proximal 15 cm segment of the saphenous vein and no less than 80 joules/cm for the rest of the vein in order to insure sufficient energy to destroy the endothelium. No phlebectomies were performed at the initial procedure; sclerotherapy was offered three months post procedure if varices remained visible. Class II compression stocking (20–30 mm Hg) were worn at the end of the procedure for three consecutive days and nights and then for three weeks only during the day. Walking exercise for 15 min under supervision was requested before discharge.

Results

Between January 2006 and December 2009, we treated 202 incompetent saphenous veins in 168. Table 1 summarizes the demographic and the procedure data. Postoperative obliteration rate was 99%. Two GSV were completely patent on the first visit and were considered as a technical failure and were successfully retreated. One patient developed femoral deep venous thrombosis (DVT) and the other one popliteal DVT both were class C4 and were treated with three months of anticoagulation. Furthermore, four patients had superficial venous thrombosis.

Next, 164 (82%) limbs were followed up between 4 months and 9.2 years, with a median of 4.4 years and constitute the cohort for the analysis of late results. The remaining 18% of limbs were lost to follow-up

Table 1. Description of patient population and procedures.

Total number of patients	168
Total number of treated legs (%)	202
SSV	31 (15.3)
GSV	164 (81.2)
AASV	7 (3.5)
Bilateral (%)	34 (20)
Age (SD)	49.69 (11.94)
% Female	73.8%
CEAP C2	90.6%
CEAP C4–C6	9.4%
VCSS average mean (SD)	4.38 (1.9)
Energy joules/cm mean (SD)	
SSV	105.88 (20.45)
GSV	111.19 (28.50)
Length of treated vein cm: mean (SD)	
SSV	22.10 (8.17)
GSV	34.95 (11.70)
Diameter at the junction mean (SD)	
SSV	8.79 (2.75)
GSV	10.07 (3.4)

SD: standard deviation; AASV: anterior accessory saphenous vein; SSV: small saphenous veins; GSV: great saphenous veins; VCSS: venous clinical severity score; CEAP: clinical, etiological, anatomical and pathological classification.

either early after the first week post-operative visit (2/3) or between one week and four months of follow-up (1/3). The VCSS dropped from an average (standard deviation, SD) of 4.38 (1.9) before EVLA to 1.39 (1.5) at late follow-up.

Table 2 summarized the ultrasound results as classified by Bush et al.[15] Among the 140 limbs treated for GSV reflux, 51 (36%) had no abnormal ultrasound findings, while 89 (64%) limbs had one or more ultrasound finding. These abnormal findings are technical related in 35% and included neovascularization 7.9%, recanalization 5%, and reflux in groin collateral (mostly anterior accessory saphenous vein (AASV)) 23.5%. Abnormal findings associated with disease progression related failure such as newly incompetent SSV, thigh, and leg perforators were present in 8.6%, 16.5%, and 33% of treated limbs, respectively.

There was a highly significant positive correlation between the VCSS score at the late follow-up and the presence of neovascularization ($p = 0.006$); in the presence of neovascularization, the VCSS did not drop significantly. Another borderline correlation between the presence of reflux at the groin and the patient age was also found; the younger the patient, the more likely to develop late reflux at the groin with a p value of 0.049.

Discussion

This is a retrospective study of a cohort of consecutive patients with axial vein reflux and clinically apparent varicose veins, treated with EVLA. Late clinical results (median 4.4 years) showed a net improvement of VCSS with a drop of the average score from 4.3 before treatment to 1.3 at the time of follow-up. DUS results identified multiple causes of failure related to the technique, i.e., recanalization partial or total, neovascularization, and reflux in groin collateral in 35% of patients.

Table 2. Late ultrasound results.

	SSV, n = 24 (%)	GSV, n = 140 (%)
Neogenesis	1 (4)	11 (7.9)
recanalization	1 (4)	7 (5)
Reflux in collateral of the groin (AASV)	0	33 (23.5)
New reflux in untreated saphenous vein	2 (8)	12 (8.6)
Thigh perforators	1 (4)	23 (16.5)
Leg perforators	7 (29)	46 (33)
Normal ultra sound findings	12 (50)	51 (36)

Follow-up more than four months total 164 (83.6%); SSV 24 (77.4%); GSV 140 (85.4%). AASV: anterior accessory saphenous vein; SSV: small saphenous veins; GSV: great saphenous veins.

Another cause of Duplex failure related to progression of the varicose vein disease, i.e., new reflux in previously competent SSV, perforators of the thigh or legs in 45% of patients. Only 36% of our cohort had no abnormal ultrasound findings.

Our results are slightly different from those reported by Bush et al.[15] in his REVATA study where he classified 164 clinical recurrences in four groups and found that the groin recurrence (24.4%) was less but partial or total recanalization (28.6%) was more than in our cohort. Moreover, Bush et al. found that reflux in the short saphenous vein was the cause of recurrence in 14.6% which was higher than in our population (8.6%). Thigh and leg perforators were frequent in both studies 64% versus 78%. Unfortunately, he has no mention of neovascularization as a cause of failure post EVLA.

The incidence of neovascularization observed is possibly due to the higher energy delivered per cm of treated vein (110 joules/cm) which could cause vein perforation and hematoma and later neovascularization. But the advantage of this high level of delivered energy might have accounted for the low recanalization rate observed in our study. Although there is no consensus on the appropriate energy delivered by centimeter of vein, most authors used between 70 and 100 joules/cm of treated vein and report low level of neovascularization but higher incidence of recanalization.[5,9,10]

Neovascularization is the formation of new thin wall veins in the groin following surgical trauma, this phenomenon is well documented[13,14] and causes 18% of recurrence after surgery but only 2% after EVLA as reported by O'Donnell in his meta-analysis.[18] In this meta-analysis recanalization (32%) and reflux in AASV (19%) were the main cause of recurrence following EVLA.[18]

The strong correlation between the presence of neovascularization and the lack of improvement in the VCSS found in our study ($p = 0.006$) is in line with the fact that neovascularization at the groin is progressive and associated with severe clinical recurrence as documented in a multicenter retrospective study looking at 279 limb with recurrent varicose vein. In this study, Geier et al.[13] found that most patients had experienced a symptom-free interval of a mean duration of 7.4 years, and recurrence became apparent and symptomatic on average 8.5 years following the initial surgery. In our study, a significant portion of our patients had seven years of follow-up, although the median follow-up time was 4.4 years. This long follow-up might explain the recurrence rate documented in our population.

We found no correlation between recanalization and the initial size of the GSV or the energy delivered per

cm, and similarly, no correlation between reflux in AASV and the initial size of the GSV at the groin ($p = 0.9$); this absence of correlation was also reported by Proebstle and Möhler[19] who found 32% of treated GSV developed new reflux in AASV two years following EVLA but also found no correlation between the late new reflux and the initial size of the vein.[19] To find the cause of late AASV reflux post EVLA, a prospective study documenting the status of the saphenofemoral valve at the time of treatment and comparing it to the late development of reflux in AASV is needed.

New reflux in previously normal vein constituted 15% of the cause of recurrence of 164 patients evaluated by duplex scanning by Bush et al.[15] in the REVATA study and was the case in 13.6% in our cohort. Finally, the last cause of recurrence are perforator veins, mostly the thigh ones, those thigh perforators are usually treated at the initial procedure. Therefore, when apparent on late ultrasound, they become a significant cause of recurrence. On the other hand, the presence of leg perforators may already be present initially and were never treated. New reflux in SSV and recent development of perforators are purely related to the progression of varicose vein disease well known and reported to occur in 3% to 5% yearly in the Bonn and Edinburg vein study.[20,21]

A total of 31 SSV were treated and 24 were available for follow-up. Among those, this good result of treatment of SSV by EVLA has been recently confirmed by Boersma et al.[22] in a meta-analysis of all published data on the treatment of SSV incompetence. He found 98.5% of 2950 SSV treated by EVLA were occluded with 4.5% neurologic complication and no deep vein thrombosis.

The retrospective nature is clearly a weakness in this study; however, this was compensated by the long follow-up and the significant number of patient examined seven years after the EVLA. The information presented here along with the REVATA study and the study by Winokur et al. call for a consensus on reporting duplex recurrence following EVLA.[15,16] This will enable us to perform a more meaningful meta-analysis and help modulate patient's expectation of the treatment of varicose vein disease. The main cause of failure of non-surgical treatment of GSV incompetence is reflux in previously competent AASV. The second cause of failure remains the progression of the disease itself. Therefore, a life-long follow-up is strongly recommended. Moreover, in order to identify the predictive factors for the late development of AASV reflux, a prospective study comparing the initial status of the SFJ and confluent (size, competence) to the late development of AASV reflux is needed.

Conclusion

In this study, we were able to follow 84% of the EVLA treated limbs and up to nine years. The clinical improvement is evident and supported by the drop of average VCSS. The DUS findings were classified and regrouped as technical-related failure and disease progression-related failure; those outcomes and this classification help in modulating the patient's expectation from this procedure. Reflux in the AASV remains the main cause of failure (23.5%) of EVLA in treating GSV reflux.

Declaration of Conflicting Interests

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Guarantor

BK.

Contributorship

BK conceived the idea and did the procedure. FH helped develop the protocol. HN, KA, and MM did the literature review and wrote the manuscript. RJ did the data analysis. All authors reviewed and edited the manuscript and approved the final version of the manuscript.

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