Determinants and patterns of recurrence of primary varicose veins after Endovenous laser ablation

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Abstract

Background: The goal of this retrospective cohort study was to determine the different recurrence patterns, sites and determinants impacting primary varicose vein recurrence after endovenous laser ablation (EVLA).

Methods: 127 symptomatic patients (127 limbs) with great saphenous vein incompetence who underwent EVLA were followed up for recurrence. Twenty-seven patients were lost to follow-up, leaving 100 patients (100 limbs) for analysis.

Outcomes: Recurrence defined by venous clinical severity score (VCSS) or patterns of reflux on the duplex ultrasound examination. Assessments were done at 1, 6, 12 and 24 months after the procedure.

Results: Two-year life table analysis showed varicose vein recurrence in 9(7.1%) of limbs. Varicose vein recurrence was due to refluxing anterior accessory saphenous vein in 77.8% patients ($p < 0.001$, 95% CI 3.2 to 1669.1), re-canalization (66.6%), non-truncal varicosities (55.5 %) and incompetent perforators 77.8% patients ($p < 0.001$, 95% CI 2.7 to 69.3).

Recurrence was mostly seen owed to both incompetent perforators and accessory saphenous vein, BMI more than 30.5 kg/m² is noted in 77.8 % ($p < 0.001$, 95% CI 1.105 to 1.590) of recurrence patients.

Introduction

Lower limb venous incompetence is an extremely important issue affecting outcome and morbidity of patients and affecting 23% of adults¹. Incidence differs according to gender and with a percentage of 15% in males and 25% females. Great saphenous vein insufficiency contributes to the vast majority of venous incompetence.¹⁻³

Different treatment modalities have been proposed in the Management of GSV incompetence. These include surgery that is high ligation and stripping combined with phlebectomy⁵ and less invasive techniques such as EVLA and radiofrequency ablation current guidelines^{1,2} have favored endovenous laser ablation and other endovenous thermal ablation (EVTA) techniques over conventional surgery in terms of efficacy, complications and recurrence rates with a reported success rate of approximately 90%, in previous studies in the literature^{3,7}

Recurrence rates and patterns between Endovenous procedures have been thoroughly studied. However, the determinants of this recurrence are still poorly studied and understood.

Methods

127 patients were selected for this prospective cohort after assessing the sample size using the PASS® version 11 program, setting the type-1 error (α) at 0.05 and power at 80%.

Criteria for selection included all symptomatic patients with Primary varicose veins caused by SFJ incompetence with GSV reflux (< 0.5 seconds) on Valsalva, multiple incompetent perforators (midhigh, below the knee, above the knee and ankle perforators), diameter < 3.5 mm, incompetent SPJ, as demonstrated by duplex US imaging and age up to 65 years.

While Patients with preoperative recurrent GSV reflux with recanalized GSV or complicated v.v. like bleeding, non-healing venous ulcer or who received Combined therapy like injection foam sclerotherapy were excluded.

Written consents were taken from all patients who met the criteria and the study was approved by Ain-Shams university ethics committee. Patients were evaluated for symptomatic venous disease. Of the 127 patients, 73% of this number had been operated on by the participating surgeons in this study.

Laser ablation was performed via target linear endovenous energy density (LEED) of 80–100 J/cm using 1470-nm, continuous-mode diode laser via a 600- μ m bare-tip fiber pullback of 1 cm/10seconds.

After completing the study tool, the form was reviewed for accuracy and resulting data were given a numerical value. The data was entered the Statistical Package IBM© SPSS© Statistics version 26 (IBM© Corp., Armonk, NY) for statistical analysis.

Data was entered into 7 categories for each patient in the study: BMI, preoperative GSV diameter, preoperative incompetent perforators, postoperative residual incompetent perforators, preoperative accessory saphenous vein, pattern and time to recurrence were documented.

Patients were followed up for recurrence for 2 years which included re-evaluation of CEAP classification (Fig. 1), Venous Extremity Severity Score (Fig. 2) in addition to duplex scanning of the treated limb in the standing position seeking for reflux(< 0.5), partial or total occlusion of a segment or whole GSV (Fig. 3), patency of deep venous system, presence of residual perforators, presence of accessory saphenous vein.

Results

Of the 127 patients entered into the study, 45 patients were females (35.4%) and 82 patients were males (64.6%). The mean age was 41 ± 12 years (21-65). Patients had a mean BMI of $29.3 \text{ kg/m}^2 \pm 4.5$ (21 – 42). GSV was dilated (≤ 5.5 mm) in 79(62.2%) patients (**table 1**)

27 patients (21.3%) were lost during the two-year follow-up. Recurrence occurred in 9 limbs (7.1%) during a two-year follow-up (**figure 4**)

Of the recurrences, 2 were females (22.2%) while 7 were males (77.8%). The mean age of recurrence was $44.9 \text{ years} \pm 8.4$ compared to $41.1 \text{ years} \pm 12.2$ in the non-recurrent patients. The mean BMI was $34.1 \text{ kg/m}^2 \pm 5.3$ ($P=0.001$) in recurrent patients. Age, sex and preoperative GSV diameter (≥ 5.5 mm) were not statistically significant in both groups ($P=0.152$) (**table 2**).

7 of the 9 recurrent patients (77.8%) had patent refluxing anterior accessory saphenous vein ($P < 0.001$) and 7 of them (77.8%) had postoperative residual incompetent perforators ($P < 0.001$) (**table 2**).

Recurrence patterns included 5 patients (55.6%) with non-truncal tributaries: 3(33.3%) with incompetent perforators and 4(44.4%) with patent AASV. In addition to 6 patients (66.6%) with partial recanalization of GSV: 5(55.6%) with incompetent perforators and 5(55.6%) with patent AASV. No anterior accessory saphenous vein was found and only 22 patients (19%) had residual incompetent perforators in the non-recurrent group (**table 2**).

BMI, accessory SV, and postoperative incompetent perforators were compared in both recurrent and non-recurrent patients and were found to be statistically significant in the determination of recurrence (**figures 5,6,7**).

The median time to recurrence in patients with accessory saphenous vein was 12 months but it could not be determined in patients without accessory saphenous vein. Difference between both Kaplan-Meier curves is statistically significant (**hazard ratio = 73.1, 95% CI 3.2 to 1669.1, Mantel-Cox log-rank chi-squared = 116.080, df = 1, P-value < 0.001**) (**figure 8**).

The median time to recurrence in patients with or without postoperative incompetent perforators could not be determined in either group. Difference between both Kaplan-Meier curves is statistically significant (**hazard ratio = 13.7, 95% CI 2.7 to 69.3, Mantel-Cox log-rank chi-squared = 18.983, df = 1, P-value < 0.001**) (**figure 9**).

BMI, accessory SV, and postoperative incompetent perforators were selected based on statistically significant relation to recurrence by further bivariate analysis. Of these variables, BMI was the only independent predictor for recurrence that is retained by backward binary logistic regression (odds ratio = 1.325, 95% CI = 1.105 to 1.590, P-val = 0.002) (**table 3**). BMI has fair to good predictive value for recurrence with an area under the ROC curve (AUC) of 0.766 (95% CI = 0.605 – 0.926, P-value = 0.001). Best cutoff is a BMI >30.5 kg/m² (sensitivity = 77.8%, specificity = 61.0%, J-index = 0.388) (**figure 10**).

Discussion

Primary varicose veins are due to either predisposed weakness in the mesenchymal tissue or due to valve incompetence that is presumed idiopathic or potentiated by physical and lifestyle factors of the patients. Owing to their impact on the affected populations different management modalities have been proposed for intervention in primary varicose veins either surgical or less invasive techniques that proved to be of the upper hand in terms of efficacy, less complications, less hospital stay and most importantly with a reported success rate of approximately 90%, in previous studies in the literature [3–7] and declined recurrence rates [8, 9, 10] long-term durability of a procedure is the main factor of choosing one intervention over the other and the most important key outcome to assess this durability is recurrence [11, 12]. The great saphenous receives blood from three main vessels which are the superficial epigastric, superficial circumflex and superficial external pudendal which are normally ligated during surgical

interventions for primary varicosities however in EVLA management is targeted only for catheter ablation of the great saphenous ,many studies have denoted a hydrostatic backflow in these draining veins following the ablation of the great saphenous vein in EVLA leading to their enlargement and incompetence .though this drawback of EVLA in comparison to surgery could increase incidence of recurrence. total risk of recurrence after EVLA compared to surgery is markedly lower [13–15].

Recurrence incidence increases with the length of time after the procedure [16–18]. Recurrence after EVLA mostly occur in several tributaries veins of GSV below the saphenofemoral junction (SFJ), one of which is the anterior accessory vein (AASV) or in the perforators [8, 21].

Possible explanations for new AASV insufficiency are that once the GSV is ablated, flow is then directed to the AASV either with its inherited defects in the vein wall or valves causing insufficiency [19, 20] or causing recanalization of the previously treated GSV [14].

Moreover, a true relationship between recurrent GSV insufficiency and incompetent postoperative calf perforators was documented in the **REVATA** study and concluded that ablation should begin at the mid-calf level below these perforators to reduce the chance of future new insufficiency in untreated segments in addition to ablation of calf perforators [19].This reinforces our findings that preoperative patent AASV and postoperative residual perforators could play a major role in the prediction of recurrence through new retrograde flow in AASV after GSV ablation and enlargement of calf and thigh perforators "arterialization" [19] mainly which enhances GSV recanalization rates and new GSV reflux [22].

Medium-term follow-up studies suggested equivalent recurrence rates and quality of life at 2 to 5 years after treatment between different management modalities [19], Neovascularization has been reported more frequently following surgery [23] ;on the other hand, recanalization was reported more with EVLA demonstrating that recanalization of the GSV occurred in 29% of limbs [20]. Determinants of this recurrence after EVLA have not been studied in previous literature. In Our study, Effects of variable determinants on the recurrence rates and patterns after EVLA during midterm (2-year) follow-up. Age, Gender, BMI, pre-operative dilated GSV (≥ 5.5 mm), preoperative AASV and postoperative remaining perforators were the major determinants studied in each patient and the patients were standardized to the same device (1470 nm diode laser, 15 W) and used a standard LEED (linear endovenous energy density) for ablation. VCSS and CEAP classification were used for perioperative clinical assessment.

Although no evidence was found in the literature to explain the male predominance in the risk of recanalization, it could be hypothesized that the vein wall of males is thicker than the vein wall of females. Also although pre-operative dilated GSV (≥ 5.5 mm) was seen 88.6% of recurrent patients compared to 66.7% of non-recurrent patients in our study, it was found to be statistically insignificant, and it became a controversial issue to treat patients with very large GSV diameter(> 12 mm) using EVLA, However GSV diameter may predict the risk of early recanalization after the EVLA especially if the diameter < 10 mm [24–27].As we used standard LEED for above-knee GSV segment (100 j/cm) and for the below-knee segment (80 j/cm) and one of the two patients with preoperative GSV diameter < 8 mm

developed recurrence in our study, we suggest that large GSV diameter could play a role in recanalization rates after EVLA although it was not confirmed in our study.

Upon assessment of the BMI of patients in our study, it was found to have fair to good predictive value for recurrence after EVLA with cutoff $< 30.5 \text{ kg/m}^2$. In the comparison of this statistically significant finding in our study to previous studies: A retrospective cohort study by **Merchant and Pichot** documented an association between high body mass index (BMI) and recurrence after five years. The mechanism by which a high BMI results in anatomical failure remains unclear [28] while it can be due to increased femoral venous pressure [29] or increase in intraabdominal pressure [30], On the other hand, **Theivacumar et al.** reported no influence of BMI on early truncal occlusion rates after laser ablation [23].

The presence of AASV and postoperative residual thigh and calf perforators in addition to BMI $< 30 \text{ kg/m}^2$ are major determinants of recurrence after EVLA and are documented in most previous studies. The gender and preoperative GSV diameter are still controversial and need to be addressed in further studies, also Optimum prevention of recurrence in a previously ablated GSV is tailored to the identification of many potential risk factors: higher VCSS score, GSV diameter, saphenofemoral junction reflux, length of the ablated vein, type of device & male sex have all been reported to increase risk of Recurrence. However, most studies of endovenous ablations neither report potential risk factors for reflux recurrence nor identify significant differences in recurrence rates of both endovenous and surgical ablations [25, 26]. The question of whether these specific determinants impact a certain recurrence pattern should be assessed and further studies should be undertaken either to study determinants of recurrence and their potential impact on rates and patterns of recurrence to formulate recurrence prevention guidelines by addressing those determinants.

Conclusion

Varicose vein recurrence patterns after EVLA was found to be mostly due to re-canalization (66.6%), non-truncal varicosities (55.5 %) and incompetent perforators 77.8% patients ($p < 0.001$, 95% CI 2.7 to 69.3). determinants of recurrence were found to be mostly owed to the presence of AASV and postoperative residual thigh and calf perforators. In addition, BMI $< 30 \text{ kg/m}^2$ was found to be a single independent major determinant of recurrence after EVLA. Age, sex and preoperative GSV diameter ($\geq 5.5 \text{ mm}$) were not statistically significant in both groups. Whether these determinants have an impact on a specific recurrence pattern and addressing them as a protocol in recurrence prevention after EVLA or not remains a question and further studies should be undertaken with larger study populations to assess this link. Further studies with larger populations must be done.

Declarations

Ethics approval and consent to participate: The cohort study was performed in accordance with the declaration of Helsinki and approved by Ain-Shams university hospitals ethics committee- Ain Shams institute- according to the international guidelines and ethics.

Consent to publish: Written consents were taken from the all participants.

Availability of data and material: All data generated or analyzed during this study are included in this published article and its supplementary information files.

Conflict of interests: All authors declared no conflict of interests.

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Authors' contributions: All the authors have shared work in collecting, analyzing, and writing the research paper. AA, SE were major contributors in writing manuscript. All authors read and approved the final manuscript.

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Tables

Table (1): Characteristics of the whole study population

Variable	Value
Sex	
<i>F</i>	45 (35.4%)
<i>M</i>	82 (64.6%)
Age (years)	41 ± 12 (21 – 65)
BMI (kg/m ²)	29.3 ± 4.5 (21 – 42)
Preoperative dilated GSV (more than 5.5 mm)	79 (62.2%)
Patent refluxing Anterior Accessory SV	7 (5.5%)
Partial recanalization of GSV	6(4.72%)
Non-truncal varicosities(neovascularization)	5(3.93%)
Postoperative incompetent perforators	29 (23.2%)
Recurrence	9 (7.1%)

Data are number (%) or mean ± SD and range.

Table (2): Comparison table between recurrent and non-recurrent group.

<i>Variable</i>	<i>No recurrence (n=118)</i>	<i>Recurrence (n=9)</i>	<i>P-value*</i>
Sex			0.490
<i>F</i>	43 (36.4%)	2 (22.2%)	
<i>M</i>	75 (63.6%)	7 (77.8%)	
Age (years)	41.1 ± 12.2	44.9 ± 8.4	0.365§
BMI (kg/m ²)	28.9 ± 4.2	34.1 ± 5.3	0.001§
Preoperative dilated GSV	71 (60.2%)	8 (88.9%)	0.152
Accessory SV	0 (0.0%)	7 (77.8%)	<0.001
Postoperative incompetent perforators	22 (19.0%)	7 (77.8%)	<0.001
Partial recanalization of GSV	0(0.0%)	6(66.7%)	<0.001
Non truncal varicosities(neovascularization)	0(0.0%)	5(55.6%)	<0.001
Postoperative incompetent perforators+ Partial recanalization of GSV	0(0.0%)	5(55.6%)	<0.001
Accessory SV+ Partial recanalization of GSV	0(0.0%)	5(55.6%)	<0.001
Postoperative incompetent perforators+ Non truncal varicosities	0(0.0%)	3(33.3%)	<0.001
Accessory SV+ Non truncal varicosities	0(0.0%)	4(44.4%)	<0.001

Data are number (%) or mean ± SD.

*Fisher's exact test unless otherwise indicated.

§Unpaired t-test.

Table (3): Results of backward binary logistic regression analysis for the prediction of recurrence.

<i>Variable*</i>	<i>B</i>	<i>SE</i>	<i>Wald</i>	<i>P-value</i>	<i>Odds ratio</i>	<i>95% CI</i>
BMI (kg/m ²)	0.282	0.093	9.182	0.002	1.325	1.105 to 1.590
Constant	-11.437	3.115	13.479	<0.001		

B = regression coefficient, Wald = Wald statistic, 95% CI = 95% confidence interval.

*Variables removed by backward regression: Accessory SV and Postoperative incompetent perforators.

Figures

Clinical Classification		Anatomic Classification	
C0	No visible or palpable signs of venous disease	As	Superficial veins
C1	Telangiectasies or reticular veins	Ap	Perforator veins
C2	Varicose veins	Ad	Deep veins
C3	Edema	An	No venous location identified
C4	Pigmentation or eczema		
C5	Healed venous ulcer		
C6	○Active venous ulcer		
S	Symptomatic: ache, pain, tightness, skin irritation, heaviness, muscle cramps		
Etiologic Classification		Pathophysiologic Classification	
Ec	Congenital	Pr	Reflux
Ep	Primary	Po	Obstruction
Es	Secondary (postthrombotic)	Pr, o	Reflux, obstruction
En	No venous cause identified	Pn	No venous pathophysiology identifiable

Figure 1

CEAP classification for chronic venous disorders developed in 1994 as a descriptive classification and incorporated into "Reporting standards" in venous diseases.

Attribute	Absent = 0	Mild = 1	Moderate = 2	Severe = 3
Pain	None	Occasional, not restricting activity or requiring analgesics	Daily, moderate activity limitation, occasional analgesics	Daily, severe limiting activities or requiring regular use of analgesics
Varicose veins*	None	Few, scattered: branch VV's	Multiple: GS varicose veins confined to calf or thigh	Extensive: thigh and calf or GS and SS distribution
Venous edema†	None	Evening ankle edema only	Afternoon edema, above ankle	Morning edema above ankle and requiring activity change, elevation
Skin pigmentation‡	None or focal, low intensity (tan)	Diffuse, but limited in area, and old (brown)	Diffuse over most of gaiter distribution (lower 1/3) or recent pigmentation (purple)	Wider distribution (above lower 1/3) and recent pigmentation
Inflammation	None	Mild cellulitis, limited to marginal area around ulcer	Moderate cellulitis, involves most of gaiter area (lower 1/3)	Severe cellulitis (lower 1/3 and above) or significant venous eczema
Induration	None	Focal, circumalleolar (< 5 cm)	Medial or lateral, less than lower third of leg	Entire lower third of leg or more
No. of active ulcers	0	1	2	> 2
Active ulceration, duration	None	< 3 mo	> 3 mo < 1 y	Not healed > 1 y
Active ulcer, size§	None	< 2-cm diameter	2- to 6-cm diameter	> 6-cm diameter
Compressive therapy¶	Not used or not compliant	Intermittent use of stockings	Wears elastic stockings most days	Full compliance: stockings + elevation

Figure 2

venous clinical severity scores (VCSS) The VCSS includes 9 hallmarks of venous disease, each scored on a severity scale from 0 to 3. Compression therapy was added to the scoring system with higher scores

representing greater compliance. Absence of venous disease if score ≤ 3 and score ≥ 8 denotes severe disease.

Fig. 1 Anatomical patterns of recurrent varicose veins in the groin. SFJ, saphenofemoral junction; DEP, deep external pudendal; O, scar tissue from previous attempted saphenofemoral ligation

Figure 3

Anatomical patterns of recurrent varicose veins in the groin. SFJ, saphenofemoral junction; DEP, deep external pudendal vein; O, scar tissue.

Figure 4

Recurrence rate in the study population.

Figure 5

Mean BMI in patients with or without recurrence. Error bars represent the standard error (SE).

Figure 6

Percentage of patients with accessory SV among those who suffered or did not suffer a recurrence.

Figure 7

Percentage of patients with postoperative incompetent perforators among those who suffered or did not suffer a recurrence.

Figure 8

Kaplan-Meier curves for the time to recurrence in patients with or without accessory SV

Figure 9

Kaplan-Meier curves for the time to recurrence in patients with or without postoperative incompetent perforators.

Figure 10

Receiver-operating characteristic (ROC) curves for prediction of recurrence using BMI.