Combined stab high ligation with retrograde laser ablation compared to endovenous laser ablation in the treatment of symptomatic great saphenous varicose veins

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Objective
To compare reflux recurrences and complications after combined stab high ligation and retrograde laser ablation (SHL/ablation) with endovenous laser ablation (EVLA) of the great saphenous vein (GSV) varicosity.
Patients and methods
This study was designed as a single-center, nonblinded, randomized controlled trial; patients with symptomatic primary GSV varicosity with an incompetent saphenofemoral junction (SFJ) were randomized into two groups: the first was treated by high ligation of GSV with SHL/ablation and the second group was treated by EVLA, both groups received laser therapy using 120 J/cm of 980 nm diode laser. Patients with bilateral GSV insufficiency were randomized separately for each leg. The primary outcome was anatomic success with complete obliteration of the GSV. Secondary outcomes were sonographically determined reflux and clinical recurrence in the treated area after 1 year.
Results
Between March 2014 and December 2016, 280 legs in 257 patients were treated by SHL/ablation (n=140) or EVLA (n=140). The mean age, preoperative complain, mean GSV diameter, and treated length were comparable in both groups. There were no significant differences in postoperative complications or pain experience during or after the procedure in both treatments. The procedure time was significantly longer in SHL/ablation group (88.5±9.8 min) than EVLA (66.5±11.76 min). Twelve months after procedures, SHL/ablation limbs had no recurrence of clinical complaints or venous reflux while EVLA limbs showed venous reflux in 17 (12.1%) limbs and recurrence of limb edema and heaviness in 15 (10.7%) limbs with significant difference between the two groups ($P< 0.05$).
Conclusion
Combined high ligation through stab incision with laser ablation of GSV significantly decreases the risk of venous reflux and clinical recurrence after treatment of GSV varicosities.

Keywords:
endovenous laser ablation, great saphenous vein, SFJ, varicose veins

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Introduction

Varicose vein disease is one of the most common health problems faced by vascular surgeons worldwide affecting up to 23% of adult population [1]. In Western countries, the reported prevalence of varicose veins ranges from 20% in men to more than 25% in women. The majority of patients with primary varicose veins have great saphenous vein (GSV) insufficiency [2].

Along with affecting the quality of life of patients, it also causes physical symptoms such as achiness, swelling, and itching, with further worsening of the condition leading to skin changes and ulcerations. Proper treatment of varicose veins does, however, abolish these symptoms and improve the quality of life of patients [3].

Over the past decades, the gold standard treatment of the insufficient great saphenous vein (GSV) has been high ligation and stripping (HL/S) combined with phlebectomies; the results of this procedure are long lasting and have been shown to improve disease specifically and general quality of life of the patients with primary varicosis. However, HL/S is often performed as a day-case or inpatient operation [4].

In the last two decades and with the advent of the 'endovenous revolution, thermal endovenous ablation (EVA) of the great saphenous vein (GSV) or small saphenous vein by laser [endovenous laser ablation (EVLA)] or radiofrequency (RFA) has progressively become the principal therapy for VVs in the USA. It has increased in volume by 450-fold during the last decade [5].

EVLA represents the most commonly applied method within randomized controlled trials. EVLA and HL/S are comparably effective concerning improvement of disease severity and quality of life. In terms of clinical recurrence and saphenofemoral refluxes, HLS is superior to EVLA 5 years after treatment [6].

EVLA has the advantage of less pain, faster recovery to normal activities, and can be carried out as day-case or in an office-based setting under local anesthesia with or without sedation. Although technical success of EVLA is close to 100%, post-EVLA complications such as postprocedural pain, ecchymosis, tenderness, and phlebitis are common. One of the more concerning side effects is deep venous thrombosis (DVT), which has been reported in up to 7.7% of cases [7].

To reduce the risk of thrombosis, proper positioning of the laser tip, with a general distance of 1.5–2 cm below the SFJ, is essential. However, extension of the thrombus of the GSV into the common femoral vein has been reported; this phenomenon is called endothermal heat-induced thrombosis (EHIT) [8].

The mechanism of EHIT formation is not fully understood. Superficial venous thrombus is expected following thermoablation, whether this is by thrombotic vessel occlusion or local vessel injury from direct thermal damage or steam bubbles. Thrombus may form in the deep veins or propagate from treated superficial veins to the deep veins [9]. Some authors have suggested that changing the treatment distance from 2 cm to greater than or equal to 2.5 cm peripheral to the deep venous junction may result in a diminished incidence of EHIT [10].

Another rare complication of EVLA, reported by many authors, is external iliac arteriovenous fistula due to improper positioning of laser fiber tip in GSV [11–13].

One of the primary causes of recurrences after EVLA that was observed was reflux from a venous tributary in close proximity of the SFJ. While underreported in the literature, the frequency observed suggests that this reason for recurrence will likely increase as more EVLA are being performed and the duration of follow-up increases. The current recommendation of termination of EVLA at 2 cm from the SFJ may contribute to this cause of recurrence and warrants further evaluation [14].

Patients and methods

Patient selection

This study was designed as a single-center, nonblinded, randomized controlled trial at the Department of Vascular Surgery, Menoufia University. Adult patients with a symptomatic primary GSV incompetence at least above the knee and with an incompetent SFJ were eligible to participate. The incompetence of the GSV was defined as a reflux of 500 ms or more at color duplex ultrasound. Medical history, physical examination, duplex ultrasound (DUS), and CEAP classification were documented for all patients.

Exclusion criteria were previous treatment of the ipsilateral GSV, deep venous thrombosis or incompetence, agenesis of the deep system, vascular malformations, ipsilateral small saphenous vein incompetence, arterial insufficiency (defined as an ankle brachial index <0.7), pregnancy, heart failure, allergy for lidocaine, immobility, use of anticoagulation, known thrombophilia associated with a high risk of thromboembolism, and inability to provide written informed consent to trial participation.

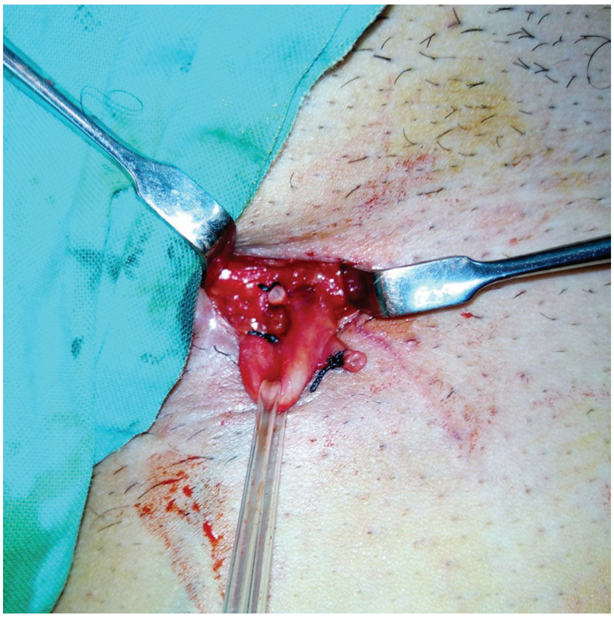
In this study, only the GSV in the thigh (from just below or above knee level) was treated. After written informed consent, eligible patients were randomized using a computerized list into two groups: the first group was treated by EVLA group; the second group was treated by stab high ligation with retrograde laser ablation (SHL/ablation) of the great saphenous vein group. Patients with bilateral GSV insufficiency were randomized separately for each leg.

Interventions

EVLA was performed under ultrasound guidance. In brief, venous access was obtained by puncturing the vein at the knee level, with a 16 or 18 G needle under ultrasound guidance; then a 0.35 guide wire was passed into the GSV up to the level of the SFJ. The needle was removed and a 5-inch introducer sheath was passed over the guide wire. Subsequently, the laser fiber was introduced after removing the guide wire. The laser fiber was positioned at 1.5–2 cm below the SFJ. About 250–500 ml of tumescent anesthetic solution was administered into the saphenous compartment under ultrasound guidance. Withdrawal of the laser fiber was performed in continuous mode, and it was attempted to deliver 100 J/cm.

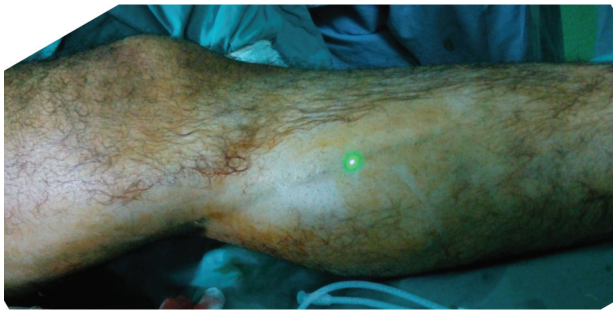
SHL/ablation was performed under tumescent anesthesia. An incision measuring 1 cm was performed at the site of premarked SFJ; ligation of all tributaries was followed

Figure 1



Saphenofemoral junction with ligated tributaries.

Figure 2



Laser fiber tip at the level of knee joint.

Figure 3

Proximal segment ablation.

by flush SFJ ligation (Fig. 1), after saphenofemoral disconnection, a 0.35 guide wire was passed into the GSV to the knee level. Then a 5-inch introducer sheath was passed over the guide wire. Subsequently, the laser fiber was introduced after removing the guide wire (Fig. 2). About 250–500 ml of tumescent anesthetic solution was administered into the saphenous compartment under ultrasound guidance. Withdrawal of the laser fiber was performed in continuous mode, and it was attempted to deliver 100 J/cm (Fig. 3). Ligation of proximal end of the GSV was performed after completion of ablation. The cribriform fascia, superficial fascia, and skin were closed.

Patients received laser therapy with a 980 nm diode laser (12 W; ARC Laser, Nuremberg, Germany), using a bare fiber in continuous mode under duplex guidance. The tumescent anesthetic solution included 500 ml saline, 25 ml 2% lidocaine, and 10 ml 8.4% sodium bicarbonate. Tumescent anesthetic solution was administered along the perivenous space of the GSV under duplex guidance with a 19 G needle.

After both treatments, an ambulatory compressive bandage was applied for 48 h, followed by therapeutic full-thigh compression stockings (20–30 mmHg) for 4 weeks. All patients were observed for at least 1 h after treatment. Patients were encouraged to mobilize and to resume their usual activities as soon as possible. All patients were discharged on the day of the procedure and NSAIDs were prescribed for pain to all the patients. The pain score was measured using a visual analog scale ranging from 0 (no pain) to 10 (most severe pain).

Delivered total energy, GSV diameter, treated GSV length, procedure time, energy in joules per length of GSV in centimeters, and delivered tumescent volume were recorded for each limb. The treated limbs were evaluated as separate treatment events.

Follow-up examinations

Patients were evaluated clinically and by DUSs on the first 48 h, first week, first month, 6 month, and 12 month after the procedure. The presence of flow in the previously ablated vein, symptoms of CVI, ecchymosis, skin burn, paresthesia, induration, swelling, hyperpigmentation, DVT, wound infection, and complaints related to EVLA were recorded as complication.

Outcomes

The primary outcome was anatomic success according to duplex ultrasound evaluation. This was defined as complete obliteration, without flow or reflux, of the GSV. Secondary outcomes were the sonographically determined reflux and clinical recurrence in the treated area after 1 year; the type and frequency of complications of both treatments were reported.

Statistical analysis

Statistical analysis was performed using SPSS version 24.0. (IBM Corp., Armonk, New York, USA). Discrete variables were presented as numbers (counts) and percent. Continuous variables presented as mean and SD. Student's *t*-test was used for intergroup comparisons to test the significance of difference between two different variables. *P* value of less than 0.05 was considered statistically significant.

Results

Between March 2014 and December 2016, according to the eligibility criteria 280 legs in 257 patients were randomized to SHL/ablation (n=140) or EVLA (n=140).

Baseline patient characteristics are shown in Table 1. The two groups were comparable with regard to demographic characteristics, CEAP classification of the treated legs, GSV diameter, and complaints of chronic venous disease at randomization.

Technical success was achieved in all procedures of both groups; the mean length of treated GSV and procedure time were significantly longer in the SHL/ablation group; however, the amount of total energy delivered and the tumescent anesthetic volume were comparable in both groups as shown in Table 2. There were no significant differences in pain experience during or after the procedure in both treatments. The procedure time was significantly longer in the SHL/ablation group (88.5±9.8 min) than EVLA (66.5±11.76 min). Treated patients resumed their normal daily activities after few days with no significant difference between the two groups.

No major complications such as skin burn, deep vein thrombosis, persistent pain, persistent bruising, allergy, or anesthetic complications were encountered. Wound infection was seen in two patients after SHL/ablation and needed oral antibiotics to control. Other complications such as ecchymosis, hematoma, phlebitis, induration, hyperpigmentation, and transient paresthesia were higher in the EVLA group but with no significant statistical differences (Table 3).

Table 1 Baseline patient characteristics

	SHL/ablation (n=140)	EVLA (n=140)	*P* value
Male/female (*n*/*N*)	91/49	77/63	0.112
Age			0.62
Range (years)	17–48	18–51	
Mean±SD	31.22±6.88	30.8±7.3	
Diameter of GSV 2 cm from SFJ	1.34±0.28	1.39±0.24	0.1
Diameter of GSV at knee level	0.9±0.18	0.94±0.22	0.09
Preoperative complaints [*n* (%)]			
Pain	62 (44.2%)	56 (40%)	0.54
Heaviness	95 (67.8%)	81 (57.8%)	0.1
Calf cramps	31 (22.1%)	40 (28.5%)	0.27
Edema	42 (30%)	33 (23.5%)	0.28
Skin changes	7 (5%)	11 (7.8%)	0.45
Venous ulcer	5 (3.5%)	7 (5%)	0.76
CEAP classification			
C2	95 (67.8)	102 (72.8)	0.43
C3	42 (30)	33 (23.5)	0.28
C4	7 (5)	11(7.8)	0.45
C5	1	0	1
C6	5 (3.5)	7 (5)	0.76

EVLA, endovenous laser ablation; GSV, great saphenous vein; SHL/ablation, stab high ligation and retrograde laser ablation.

Table 2 Procedure data and results in both groups

	SHL/ablation (mean±SD)	EVLA (mean±SD)	*P* value
Length of treated vein	44.75±2.83	43.51±3.77	0.002
Total laser energy (J)	4853.3±375.9	4759.7 ±446.9	0.058
Laser energy (J/cm)	108.43±4.3	109.38±4	0.08
Procedure time	88.5±9.8	66.5±11.76	0.0001
Tumescent volume	400.5±30.1	392.1±43.4	0.06
Pain during procedure	3.8±1.13	3.7±1	0.43
Postoperative pain	4.2±0.89	4.35±0.91	0.16
Pain after 48 h	5.55±0.99	5.35±1.2	0.13
Pain after 7 days	3.51±0.88	3.32±0.95	0.08
Daily activity	4.91±1.2	5.11±1.2	0.16
Time needed for ulcer healing (days)	35–70 (52 ±13.5)	42–71 (54.1±11.2)	0.15

EVLA, endovenous laser ablation; SHL/ablation, stab high ligation and retrograde laser ablation.

Table 3 Postoperative complications

Postoperative complications	SHL/ablation [*n* (%)]	EVLA [*n* (%)]	*P* value
Skin burn	0	0	1
Ecchymosis	19 (13.5%)	25 (17.8%)	0.41
Hematoma	0	2 (1.4%)	0.49
Infection	2 (1.4%)	0	0.49
Phlebitis	2 (1.4%)	5 (3.5%)	0.44
Induration	22 (15.7%)	29 (20.7%)	0.35
Persistent pain	0	0	1
Hyperpigmentation	0	1	1
Thromboembolism	0	0	1
Allergy	0	0	1
Persistent bruising	0	0	1
Anesthetic complication	0	0	1
Sensory disturbance	0	3 (2.1%)	0.24

EVLA, endovenous laser ablation; SHL/ablation, stab high ligation and retrograde laser ablation.

Clinical and duplex examination of treated limbs 6 months after the procedure showed maintained obliteration of the GSV treated segment in both groups. Venous reflux was detected at SFJ to tributary veins in the femoral region in 17 (12.1%) limbs treated by EVLA; on the other hand, no reflux was detected in limbs treated by SHL/ablation ($P<0.05$). Twelve months after the procedures, recanalization of GSV was higher in limbs treated by EVLA [seven (5%) limbs] than limbs treated by SHL/ablation [two (1.4%) limb], but still was statistically insignificant ($P=0.17$). Limbs treated by SHL/ablation had no recurrence of clinical complaints or venous reflux; on the other hand, EVLA limbs showed persistence of venous reflux in the 17 (12.1%) limbs and recurrence of limb edema and heaviness in 15 (10.7%) limbs, with significant difference between the two groups ($P<0.05$).

Discussion

Surgery remained the standard treatment of varicose vein disease for centuries until its thrown had been threatened by EVA techniques, including laser ablation, during the last two decades. Being minimally invasive with less pain and earlier ambulation than surgery gave these procedures preference to vascular surgeons and patients.

However, these procedures are not complication free. Efforts had been made to minimize the incidence of recurrence, EHIT or even the rare arteriovenous (AV) fistula complications. In this study, the refluxing GSV was treated by classic EVLA procedure or by high ligation of GSV through stab incision combined with retrograde ablation of the vein; stab incision with minimal dissection was found to minimize the risk of wound infection to 1.4% of cases when compared with 6% of cases reported in the literature [15]. Insertion of the laser fiber retrogradely through the proximal cut end of GSV was found to be feasible and gives alternative to GSV access which in some cases may be difficult and needs a cut down to achieve.

There is some debate about the necessity of high ligation of GSV with EVA procedures; in this work, high ligation of GSV combined with laser ablation had a significant lower clinical and duplex-detected recurrence rate than EVLA (*P*?0.05). Flessenkämper *et al.* [16], compared EVLA with and without high ligation and surgery and reported that in EVLA without high ligation reflux developed in all side branches, not only in the anterior accessory GSV; on the other hand, there was no major difference between the clinical outcomes of the three therapeutic strategies after a median follow-up of 4 years. Disselhoff *et al.* [17] also concluded similar recurrent rates in EVLA with and without high ligation. Both studies of Flessenkämper *et al.* [16] and Disselhoff *et al.* [17] described neovascularization as an explanation for recurrence with high ligation. High ligation through stab wound with minimal dissection in our work may explain lower incidence of recurrence; this explanation is supported by the lower recurrence and recanalization rate of combined pinhole high ligation and EVLA published by other authors [18]. Packing up the role of high ligation in minimizing recurrence, Rass *et al.* [6], reported that even with different mechanisms of recurrence, high ligation and stripping is superior to EVLA with respect to long-term duplex and same site clinical recurrence.

Another advantage of high ligation is that it may ameliorate the debate about the proper distance between the laser fiber tip and SFJ. While some authors recommend decreasing this distance to decrease the rate of recurrence after EVLA [14], others advocate increasing this distance from 2 to 2.5 cm peripheral to the deep venous junction may result in diminished incidence of EHIT [10].

Conclusion

Combined high ligation through stab incision with laser ablation of GSV significantly decrease the risk of venous reflux and clinical recurrence after treatment of GSV varicosities

Recommendation

Combined stab high ligation with retrograde laser ablation can offer a minimally invasive ablative procedure for great saphenous varicose vein. Large-scale studies with a longer follow-up period may be needed before recommendation of the proper first-line treatment of varicose veins.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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