Endovenous laser ablation vs conventional surgery in the management of superficial venous insufficiency

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Background and objective
Endovenous laser ablation (EVLA) of the great saphenous vein (GSV) is much more used as an alternative method of treatment instead of conventional surgery procedures. EVLA is thought to decrease postoperative morbidity with rapid recovery and early return to daily activity. The goal of this study was to compare the effectiveness, postoperative pain, complications, and patient satisfaction following either EVLA or conventional surgery for varicose veins of the lower limbs.
Patients and methods
This is a retrospective study that was conducted on 50 consecutive patients/60 limbs (10 bilateral and 40 unilateral) presented to Kasr Al Aini Hospitals, Cairo University and Asir Central Hospital Saudi Arabia from January 2015 to January 2018 with truncal varicose veins involving GSV. Patients were divided into two groups: group I (30 limbs) who underwent conventional surgery in the form of high ligation and striping and group II (30 limbs) who underwent EVLA.
Results
The EVLT group was associated with good patient satisfaction with early return to daily activities and work. Pain, paresthesia, ecchymosis, hematoma were significantly higher in group II ($P<0.05$), with low rate of recurrence in both groups with no statistically significant difference between both groups.
Conclusion
Both EVLT and conventional surgery techniques were performed well as regards efficacy with low rate of recurrence for incompetent GSV. Less postoperative pain and complications were observed with EVLT as compared with conventional surgery such as ecchymosis, hematoma, superficial thrombophlebitis, and paresthesia.

Keywords:
ablation, conventional surgery, endovenous laser, great saphenous vein

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Introduction

Chronic venous insufficiency of the lower limbs is one of the most common benign diseases with prevalence rates as high as 28–35% in adults [1]. The treatment goal is to eliminate pathological refluxes, thereby decreasing symptoms, avoiding long-term complications of venous insufficiency, and improving disease-related quality of life [2]. For several decades, high ligation and saphenous vein stripping (HLS) was the standard treatment for saphenous vein insufficiency [3]. The last decade has seen the evolution of minimally invasive methods of treatment for varicose veins, the endovenous laser ablation (EVLA) among them [3]. Fewer complications, less postoperative pain, better quality of life, and treatment satisfaction and early return to daily activities are the main advantages of these techniques if compared with surgery [4]. A reduced neovascularization in the groin may have an effect over the recurrence rates owing to absent dissection in the groin in these techniques [5]. In our study, we aim to compare the effectiveness, postoperative pain, complications, and patient satisfaction in patients with lower limb varicose veins who underwent EVLA or open surgery.

Patients and methods

This is a retrospective study for the analysis of two matched patient groups. Ethical committee was approved in our hospital. This study was conducted on 50 consecutive patients/60 limbs (10 bilateral and 40 unilateral) presented to Kasr Al Aini Hospitals, Cairo University and Asir Central Hospital, Saudi Arabia from January 2015 to January 2018 with truncal varicose veins involving great saphenous vein (GSV).

Patients were classified into two groups according to the inclusion criteria such as primary GSV

incompetence with clinical staging from C2 to C6 according to the CEAP classification [C2, varicose veins; C3, edema; C4, changes in skin and subcutaneous tissue (C4a, pigmentation, and/or eczema; C4b, lipodermatosclerosis and/or atrophie blanche); C5, healed venous ulcer; C6, active venous ulcer] and GSV diameters of 4–13 mm. Exclusion criteria included associated deep vein thrombosis (DVT), peripheral arterial disease, aneurysmal vein segment, severe tortuosity of GSV, thrombosed GSV, CEAP class 1 patients, short saphenous vein reflux, pregnancy, breast feeding, and refusal of consent.

Group I (30 limbs) underwent conventional surgery in the form of high ligation and striping and group II (30 limbs) underwent EVLA. Ligation for incompetent perforators and avulsion phlebectomies by direct mini incisions in both groups was done. Consent was taken from all patients for one of each technique. Full history talking, complete preoperative examination (including general examination, local examination), and routine investigations were done for all patients. Patient data: clinical, etiologic, anatomic, and pathophysiologic (CEAP) classification; details of the technique; and the post-procedural course with follow-up were documented.

Venous duplex was done for all cases before the procedure (to assess the extent of venous disease, reflux in response of Valsalva maneuver, measurement of vein diameter, ectatic areas, and presence of incompetent perforators), during the procedure, and immediately after the procedure to detect failed procedure. Follow-up duplex was done at 1 week, 1 month, 6 months, 1 year, and 2 years after the procedure to detect thrombophlebitis, recanalization or recurrence, and neovascularization.

Reflux in both superficial and deep venous systems was assessed with patients in the standing position. Reflux was defined as reversed flow greater than 0.5 s after calf compression.

All procedures in both groups were done under spinal anesthesia. In both groups, the time of procedures as well as the steps and any adjacent technique and any complications were recorded. Prophylactic antibiotics, ceftriaxone 1 g, was given just before the procedure.

In group I: the GSV is approached through a 1 cm incision in the groin crease medial to the common femoral pulse for adequate visualization of the saphenofemoral junction and its tributaries; the main trunk of GSV was identified. The dissection was extended till the saphenofemoral junction. Each of the main tributaries was ligated and divided. High ligation of GSV is performed close to the femoral vein with transfixing the proximal stump. With caution to avoid narrowing of the femoral vein and leaving long stump after ligation was performed, the caudal incision was made transversely and the vein was exposed and ligated distally and the stripper was passed in the GSV at or below the knee level according to the presence of the incompetent segment. Unless the caudal below knee saphenous vein is incompetent, there is no need for its removal to avoid injury to the saphenous nerve. This would result in less postoperative pain and bruising without compromising the outcome of surgery. Stripping was done by downward direction that is better for avulsion of tributaries and diminishes injury to the saphenous nerve. Leg was elevated to reduce ecchymosis and bleeding associated with stripping ligation for incompetent perforators and avulsion phlebectomies by direct mini incisions were performed for superficial varicosities. Skin incisions were closed by Prolene 3-0 sutures.

In group II, the GSV was cannulated below, at, or above the knee either in supine or reverse Trendelenburg position, and the catheter tip was positioned under ultrasound (US) guidance below the origin of the superficial epigastric vein 2 cm away from the saphenofemoral junction. Tumescent local anesthesia [25 ml 2% lidocaine,5 ml of sodium bicarbonate, and 0.5 ml of 1 : 10 000 adrenaline (epinephrine) in 500 ml normal saline] was infiltrated along the of GSV below the saphenous fascia and above the deep muscular fascia around the vein under US guidance.

The EVLA procedure was done using a 1470 nm diode laser (LEONARDO, 1470; Biolitec, Bonn, Germany) at signal mode with a laser power of 15 W with an energy interval from 70 to 90J/cm.

The laser fiber (ELVes radial 2 ring) was connected to the device and the fiber was activated and continually withdrawn with alarm of device with a pullback speed at 5 s/cm aiming at delivery of sufficient energy to the wall of the vein, allowing adequate thermal ablation of the GSV, manual external compression was applied on the treated segment of the vein. Laser catheter was withdrawn gradually, sheath was removed with dressing of puncture site ligation for incompetent perforators, and avulsion phlebectomies by direct mini incisions were done for superficial varicosities.

At the end of procedure, US was done to confirm shrinkage of the treated segment and to check patency of the deep venous system.

In both groups, after treatment, elastic stocking, class II was applied for at least 1 week. All patients were discharged on nonsteroidal anti-inflammatory drugs and recommended to be used when symptoms occurred. All patients were advised to start an early ambulation and return to their daily activities and work as early as possible. Degree of pain was judged according to the duration of analgesia needed.

Patients were followed up clinically and by US after 1 week, 1 month, 6 months, 12 months, and 24 months for assessing postoperative pain, patient satisfaction, early return to daily activities, and early postoperative complications (such as ecchymosis, hematoma, infection, burn, pigmentation, superficial thrombophlebitis, DVT, recurrence, and neovascularization).

Efficacy of vein obliteration was classified as follows: total vein occlusion (that was defined as vein with no flow), partially occluded vein (that was defined as ≤3 cm segment of flow within the GSV segment), and insufficient occluded vein (that was defined as >3 cm flow segment). Neovascularization in the groin was evaluated by duplex ultrasound (DUS) examination with multiple small veins in the groin reconnecting the proximal segment of the vein or its tributaries and the distal veins below.

Statistical analysis

The statistical analysis of the data in this study was performed using the Statistical Package for the Social Sciences version 17. Statistical analysis was done using IBM SPSS statistics for windows, Version 23.0. Armonk, NY: IBM Corp. Numerical data were expressed as means ±SD and comparisons between groups were done. Description of quantitative variables such as means, SDs, and ranges; description of qualitative variables such as numbers and percentages; χ^2 test for comparisons of qualitative variables between the two groups; unpaired *t*-tests to compare quantitative data between the two groups. The difference was considered statistically significant if *P* value less than or equal to 0.05.

Result

This is a retrospective study that was conducted on 50 consecutive patients/60 limbs (10 bilateral and 40 unilateral) presented to Kasr Al Ainy Hospitals Cairo University and Asir Central Hospital Saudi Arabia from January 2015 to January 2018 with truncal varicose veins involving GSV.

Patients were classified into two groups; group I (30 limbs) underwent conventional surgery in the form of high ligation and striping and group II (30 limbs) underwent EVLA.

There was no significant difference between both groups regarding demography, age, sex, and in the distribution of CEAP classification in both groups (Table 1).

Table 1 Demographic and clinical presentation data in both groups

	Group I (*n*=30) [*n* (%)]	Group II (*n*=30) [*n* (%)]	*P* value
Age	34.8±6.9	33.7±1.3	0.8
Sex			
Male	8 (30.8)	6 (25)	0.1
Female	18 (69.2)	18 (75)	
Clinical presentation			
C2	19 (63.3)	21 (70)	0.8
C3	4 (13.3)	3 (10)	0.7
C4a	4 (13.3)	3 (10)	0.7
C4b	2 (6.7)	1 (3.3)	0.5
C5	1 (3.3)	0	0.3
C6	0	2 (6.7)	0.1
Side			
Right	17 (56.7)	15 (50)	0.4
Left	13 (43.3)	15 (50)	0.7
Site of incompetence			
GSV only	16 (63.3)	17 (56.7)	0.5
GSV+perforators	14 (46.7)	13 (43.3)	0.6

GSV, great saphenous vein.

All patients were C2–4, E (primary) A (GSV or GSV and perforator), P (reflux) (Table 1). All patients were treated for relief of symptoms and to prevent disease progression.

Demographic data

The number of treated limbs were 60 divided into two groups, 30 limbs in each one. In group I, there were eight (30.8%) men and 18 (69.2%) women, while there were six (25%) men and 18 (75%) women in group II (Table 1).

Age in both groups ranged from 18 to 50 years with a mean age of 34.8±6.9 in the surgery group and 33.7±1.3 in the laser group. There was nonsignificant difference between the two groups in age (Table 1).

Spinal anesthesia was used in all patients in both groups. Operative time in the surgery group ranged from 40 to 71 min with a mean time of 55±12.5 min, while it was between 26 and 48 min in the laser group with a mean time of 37±4.7 min. There was significant difference in operative time between both groups with *P* value less than or equal to 0.001

No cases of failure of vein occlusion (in the laser group) or saphenofemoral ligation (in the surgery group) were identified at the time of procedure by the completion of DUS scan.

Immediate technical success happened in 100% of cases in the EVLA group with immediate vein lumen occlusion, noncompressible thickened wall of GSV, lack of flow either spontaneous or augmented as demonstrated by DUS, and absence of common femoral vein thrombus by intraoperative venous US.

In the surgery group, hospital stay ranged from 24 to 48 h with a mean time of 36±9.2 h, while in the laser group hospital stay time ranged from 6 to 10 h with a mean time of 8±2.6 h. There was significant difference between both groups with *P* value less than or equal to 0.001

Also, there was a significant difference between both groups regarding return to daily activity with *P* value less than or equal to 0.001. In surgery groups, it took a time range of between 6 and 9 days with a mean time of 7.5 ±1.7 days, while this took a time range of between 1 and 3 days in the laser group with a mean time of 2±1.2 days.

Postoperative complications

In the surgery group, two (6.7%) cases were complicated with post-stripping hematomas, which were managed conservatively; 22 (73.3%) cases were complicated with post-stripping ecchymosis that were managed conservatively. Two (6.7%) cases were complicated with superficial thrombophlebitis that was managed conservatively and one (3.3%) case of superficial groin wound infection occurred and was managed with antibiotic. On the other hand, in the laser group, six (10%) cases were complicated with post-stripping ecchymosis, which was managed conservatively. Two (6.7%) cases were complicated by pigmentations and burn in the form of mild to moderate erythema along the GSV, which might be due to insufficient tumescent injection and superficial segment of GSV. The two cases improved with conservative treatment and three (10%) cases were complicated with superficial thrombophlebitis which was managed conservatively. There was nonsignificant difference between both groups regarding postoperative complications except in ecchymosis, which was statistically significant. Regarding postoperative pain, all patients in both groups were managed by nonsteroidal anti-inflammatory drugs for 2–3 days. Patients in the surgery group also reported more pain over the first week that requires additional analgesia (63.33%, *n*=19) and (23.33%, *n*=7) for the EVLT group. There was statistically significant difference in postoperative pain between both groups (*P*=0.0037); in the surgery group four patients suffer from paresthesia for 1 month and might be caused by saphenous nerve affection during stripping (Table 2).

Patient satisfaction

Patient satisfaction was assessed by documentations of postoperative pain and complications such as hematomas, burn, pigmentations, superficial thrombophlebitis, and DVT.

We found that nine (30%) patients in the surgical group were not satisfied with the results due to

Table 2 Comparison between both groups regarding postoperative pain and complications

	Group I (*n*=30) [*n* (%)]	Group II (*n*=30) [*n* (%)]	*P* value
Ecchymosis	22 (73.3)	6 (20)	0.001
Hematoma	2 (6.7)	0	0.1
Infection	1 (3.3)	0	0.3
Superficial thrombophlebitis	2 (6.7)	3 (10)	0.8
Paresthesia	4 (13.3)	0	0.04
Burn	0	1 (3.3)	0.3
Pigmentation	0	1 (3.3)	0.3
Pain (need analgesia more than 3 days)	19 (63.3)	7 (23.3)	0.002

Table 3 Comparison between both groups regarding patient satisfaction

	Group I (*n*=30) [*n* (%)]	Group II (*n*=30) [*n* (%)]	*P* value
Satisfaction	21 (70)	25 (83.3)	0.7
Not satisfied	9 (30)	5 (16.7)	0.1

paresthesia that lasts for a relatively long time (four cases), hematoma along the course of stripped GSV (two case), superficial thrombophlebitis in two cases, and groin infection in one case, while there were five cases (16.7%) not satisfied with the results in the laser group due to pigmentations and burn in two cases and superficial thrombophlebitis in three cases (Table 3).

Follow-up

Follow-up was done at 1 month, 6 months, 12 months, and 24 months. This was done by clinical evaluation and DUS. There was statistically nonsignificant difference between both groups in recurrence rate.

Early postoperative venous duplex was done after a 1 month follow-up and showed no recanalization of GSV and no DVT in both groups, which was deemed as a satisfactory result (Table 4).

At a 6-month follow-up, recurrence was detected using DUS in the surgical group in one (3.3%) case. However, no recanalization was seen in the EVLA group at a 6-month follow-up (*n*=0) with remarkable improvement in manifestation in patients who underwent both surgery and laser procedures. At 12-month follow-up, recurrence was also detected using DUS, in two (6.7%) cases in the surgery group and two (6.7%) cases in the EVLA group. At a 24-month follow-up using DUS, recurrence was also detected, in four (13.3%) cases in the surgery group and three (10%) cases in the EVLA group (Table 4).

Discussion

Less invasive procedures are more popular for the management of GSV reflux. Endovenous thermal ablative techniques are recognized as less invasive alternatives to open conventional surgery procedures [6].

Also, patients nowadays prefer less invasive procedures as a line of treatment, as it is associated with rapid recovery and return to daily activity with low risks of infection and hematoma, especially in obese patients if compared with surgery [7].

In this retrospective study, we aimed at comparing the conventional surgery vs EVLA, regarding the early technical success, the complications of both techniques, especially postoperative pain and incidence of recurrence.

Table 4 Comparison between both groups regarding recurrence at follow-up periods

	Group I (*n*=30) [*n* (%)]	Group II (*n*=30) [*n* (%)]	*P* value
Recurrence after 1 month	0	0	0.9
Recurrence after 6months	0 (3.3)	1	0.8
Recurrence after 1 year	2 (6.7)	2 (6.7)	0.9
Recurrence after 2 years	4 (13.3)	3 (10)	0.8

Recently published studies have documented that there was no significant difference in the operative time between laser and surgical groups. Kalteis *et al.* [8] have published that the mean operative time was 67 min needed in laser ablation, while surgical intervention needs 65 min as a mean operative time. In January 2010, it was documented that there was no significant difference in the operative time between both groups with a mean time of 31 min in surgical procedure and 32 min in the laser group [9].

In our study, the mean operative time in the surgical group was 55 min, while in the laser group it was 37 min. This result can be explained by an accurate preoperative assessment of the vein by DUS by well-trained and skilled surgeons, who can perform accurate and rapid venous cannulation under US guidance and revolution happened in devices abilities that can perform sufficient venous ablation in less time. Patient satisfaction was assessed by documentations of postoperative pain and complications. such as hematoma, pigmentations, burn, wound infection superficial thrombophlebitis. and DVT.

In our study, in the surgery group, there were two cases complicated with post-stripping hematomas, 22 cases complicated with post-stripping ecchymosis, two cases complicated with superficial thrombophlebitis which were managed conservatively. In one case superficial groin wound infection occurred and was managed with antibiotic.

On the other hand, six cases in the laser group were complicated with post-stripping ecchymosis, three cases were complicated with superficial thrombophlebitis, which were managed conservatively. Two cases were complicated by pigmentations and burn in the form of mild to moderate erythema along the GSV, which might be

due to insufficient tumescent injection and superficial segment of GSV. The two cases improved with conservative treatment; no case suffered from DVT in both groups.

In 2012, Siribumrungwong and his colleagues reported that patients treated with surgical ligation of SFJ had higher rates of hematoma compared with who were treated with laser ablation [10], which is comparable to our study.

Regarding postoperative pain, all patients in both groups were managed by nonsteroidal anti-inflammatory drugs for 2–3 days. Patients in the surgery group also reported more pain over the first week, 63.33% (n=19) and 23.33% (n=7) for EVLT. There was statistically significant difference in postoperative pain between both groups (P=0.0036). Four patients suffered from paresthesia for 1 month and might be caused by saphenous nerve affection during stripping. There was significant difference in postoperative pain between the two groups.

In 2012, Siribumrungwong *et al*. [10] reported that postoperative pain was less severe in EVLT than surgical intervention. It is announced that wound infection is less in the laser ablation group by 60% if compared with an incidence of infection in patients who underwent surgical ligation of SFJ and stripping. This is comparable to our study that showed a lower incidence of infection and pain in early postoperative days following the procedure in EVLT than in conventional surgery.

In our study significant differences were found as regards hospital stay with a mean time of 36±9.2 h in the surgical group, while in the laser group the mean time was 8 ±2.6 h. Also, there was a significant difference between both groups in return to daily activity. In surgery groups, it took a mean time of 7.5±1.7 days, while in the laser group the mean time was 2±1.2 days which was comparable to other studies.[11]

There was no statistically significant difference as regards patient satisfaction between two groups which was comparable to other studies [8].On the contrary, most recent studies have shown that both lines of treatment have the same quality of life postoperatively, with same satisfactory rates, with minimal advantage toward EVLA due to better cosmetic appearance [8].

In our study, in the EVLA group recanalization occurred in one case at postoperative sixth month, in two cases at 1 year postoperatively and in three cases at 2 years postoperatively. In the surgery group, recanalization occurred in two cases at 1-year postoperatively and in four cases at 2 years postoperatively. There was no statistically significant difference between both groups in the rate of recanalization and recurrence. Our results were comparable to other publications who report 7% recanalization after a 24 month follow-up besides publications reporting 10% recanalization ratios in 12 months for the cases in whom ablation was performed by the EVLA method [12,13].

Conclusion

Conventional surgery has been used for a long time as the standard treatment of varicose veins with variable degrees of complications. EVLA is a less invasive procedure which can be used as a safe and effective technique in the treatment of varicose veins. In our study, we documented that EVLA has the same outcome as surgical ligations and stripping as regards efficacy and recurrence rate. Less postoperative pain and complications were documented with EVLT as compared with the conventional surgery, Finally, according to our study results we recommend EVLA as a modern, safe, and effective procedure of treatment of varicose veins.

Limitation of study

The results of this study were derived out of a two-center experience with one technique of less invasive procedures being routinely used. The selection of techniques with its own limitations may differ largely from centers with another experience with another technique of less invasive procedures. Additionally, a larger number of patients are needed to make a firm conclusion with different less invasive treatment modalities, in comparison with each other and with surgery.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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