Whole-length great saphenous varicose veins thermochemical ablation, a novel technique: safety, efficacy, and mid-term follow-up results

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Background
Despite all advances in the treatment of varicose veins, recurrence rates are still high, and multiple factors have been incriminated. This study aims to evaluate the safety and efficacy of whole-length great saphenous vein ablation, starting flush with the saphenofemoral junction down to the ankle, using a new technique combining laser and chemical ablations.

Patients and methods
A prospective study was conducted that included patients with varicose veins who presented to the Vascular Surgery Department, Dr. Soliman Fakeeh Hospital, KSA, in the period from May 2016 to February 2018. All patients were treated with endovenous laser ablation of the whole great saphenous vein starting flush at the saphenofemoral junction using radial fiber combining low-level laser energy with truncal injection sclerotherapy for the below-the-knee vein segment with adjusted linear endovenous energy density. Patients were followed up for 18 months. Chronic venous disease quality of life questionnaire-20 (CIVIQ-20) was obtained before treatment and after 6–12 months.

Results
This study included 125 patients (132 limbs), their mean age was 40.4±11.8 years, male to female ratio was 1 : 2.4, Clinical, Etiological, Anatomical, Pathological (CEAP) classification was 2–6, the presentation was bilateral in seven (5.6%) patients, technical success was achievable in 99.3% of patients, need for extra-truncal treatment at the same time of ablation (laser, injection, or phlebotomy) in 64 (48.5%) patients, postoperative deep vein thrombosis was seen in 0%, saphenous nerve injury was seen in one (0.7%) case, recanalization at 6–12–18 months was seen in two (1.5%) cases, and improvement in CIVIQ-20 from 71.25±9.6 to 32.4 ±4.6 and 29.7±1.2 was seen at 6 and 12 months, respectively.

Conclusion
The use of the radial laser fiber allows safe flush thermal ablation of the great saphenous vein, with the anticipated decrease in groin recurrence, combined with thermochemical ablation of the below-the-knee segment has promising result in short-term and mid-term follow-up.

Keywords:
endovenous laser, great saphenous, radial fiber, sclerotherapy, thermochemical ablation, varicose veins

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Introduction

Varicose veins is considered one of the most common presentations at the vascular clinics; it affects both sexes and different age groups, with incidence of up to 40% of the population [1,2].

Traditionally, varicose veins was treated with Trendelenburg and stripping for many decades. Since the start of the nineties last century, a new technique was introduced with subsequent refinement and advance in technology [3–5].

Thermal ablation using either laser or radiofrequency is the method that has gained popularity and has good results comparable to open surgery with less pain and rapid recovery [6,7].

Endovenous laser ablation (EVLA) of varicose veins is a well-recognized treatment nowadays, with high efficacy and excellent results. Multiple refinements in the laser technology, type, wavelength and laser fiber design have led to a widespread use of this type of treatment [8,9].

The standard technique of EVLA includes treatment of the above-knee vein segment starting 1.5–2 cm away from the saphenofemoral junction (SFJ) to avoid thermal injury of the common femoral vein with subsequent risk of deep vein thrombosis (DVT). On the other hand, extending laser treatment to below-the-knee segment frequently results in saphenous nerve thermal injury with postoperative paresthesia or anesthesia of the medial aspect of the leg and foot, with too many patients failing to improve on long-term follow-up [10–12].

Most of the nonimprovement after laser treatment is owing to leaving dilated refluxing leg vein segment with multiple refluxing perforators on one hand, and on the other hand, recanalization of proximal great saphenous with subsequent recurrence after laser treatment referring to insufficient treatment or missing large vein joining the great saphenous proximally [13,14].

Thermal-induced deep venous thrombosis, nonoccluded vein, saphenous nerve injury, and groin recurrence are drawbacks in the traditional laser treatment [14].

In this study, we presented a new technique that addresses all these drawbacks. It involves whole great saphenous vein treatment starting at the SFJ down to the ankle.

Patients and methods

In this study, 125 patients (132 limbs) with varicose veins were included, who presented to our vascular clinic with CEAP classification 2–6 indicated for treatment. The patients were offered to be treated with EVLA of whole saphenous veins using the new technique.

Full clinical examination and colored duplex scan were done for all patients.

The duplex results with a detailed description of the limb venous anatomy, presence and extent of reflux with duration in seconds, average great saphenous vein diameter at the thigh and leg, distal point of reflux, bifurcated vein, dilated saphenous tributaries, and incompetent perforators all were documented.

All patients with primary varicose veins with SFJ incompetence and great saphenous vein reflux extended down to the leg with or without extra-truncal varicose veins, including unilateral or bilateral cases, were recruited.

Patients with secondary varicose veins, recurrent varicose veins, SFJ incompetence without great saphenous reflux, history of DVT and hypercoagulable disorders were excluded.

Approval from the local ethical committee for the procedure was obtained. The technique was discussed in detail with the patient. Written informed consent was obtained, and the patients were scheduled for the procedure.

Preoperative CIVIQ-20 was obtained from all patients in Arabic or English, according to patient mother tongue, and marked as CIVIQ-20A.

Procedure was done in the operation room or a procedure room equipped with positionable table and vital sign monitoring.

At the beginning of the procedure, the patient was connected to standard vital signs monitoring.

The limb to be treated was prepared and draped as per standard way from above the inguinal ligament down to the foot.

The laser machine (Leonardo laser 1470; Biolitec, Jena, Germany) was turned on and radial fiber double-ring was connected and attached to the automatic pull-back device if it is to be used.

Using the ultrasound, we identified the great saphenous vein at the distal leg.

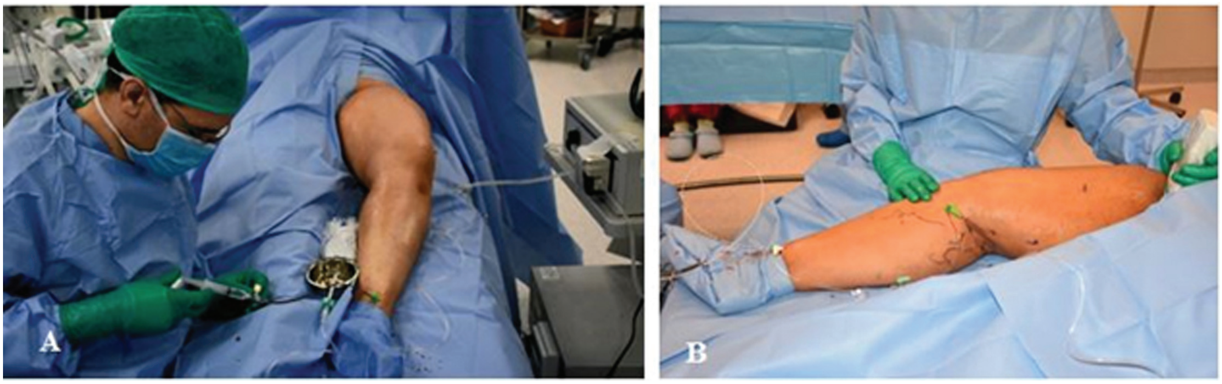
With the table in anti-Trendelenburg position to facilitates cannulation, infiltration of 2 ml lidocaine 1% was done at the determined puncture site, followed by introduction of a 6-F radial sheath into the great saphenous vein using standard Seldinger technique, assuring intralumen position, and after that any additional branches to be treated with laser were cannulated with separate radial sheaths as needed and left in place (Fig. 1).

Under ultrasound guidance, the laser fiber was introduced through the sheath in the great saphenous vein and advanced proximally till it passes to the common femoral vein, and then retracted back to position the tip just flush with the identified SFJ (Fig. 2).

The fiber at the sheath hob was marked, and its length was recorded.

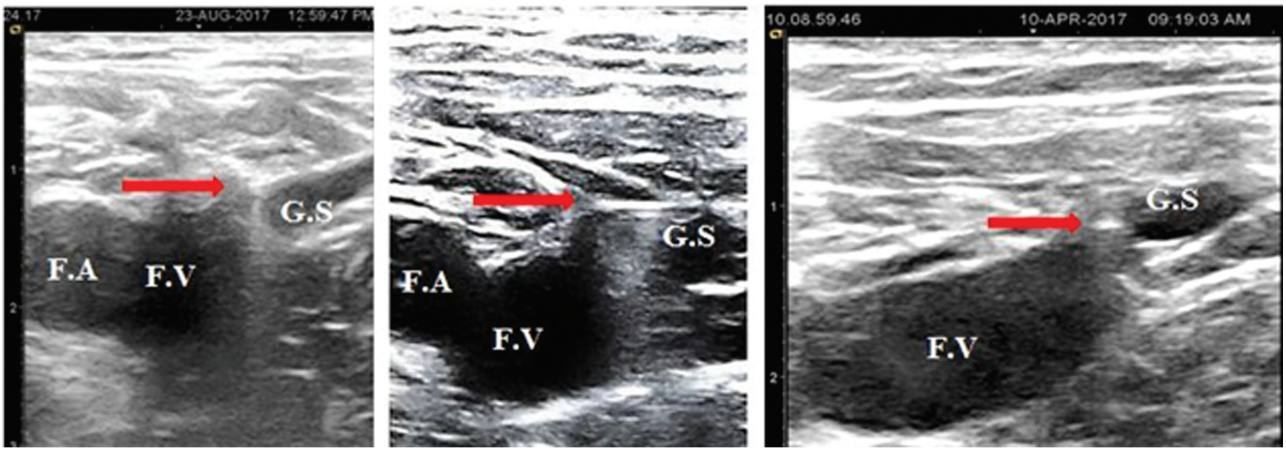
Injection of the tumescent anesthesia solution (500 ml cold normal saline, 35 ml lidocaine 2%, 10 ml sodium

Figure 1



Step 1, (a) cannulation of great saphenous vein at the distal leg, (b) Cannulated great saphenous vein above the ankle and additional sheath inserted into large tributary at the knee level (different patient).

Figure 2



Step 2, positioning the laser fiber tip flush with the SFJ, fiber tip (red arrow). FA, femoral artery; FV, femoral vein; GS, great saphenous; SFJ, saphenofemoral junction.

bicarbonate 4.8% and 200 *mic* adrenaline) in the perisaphenous fascia was done using cannula needle and injection pump along the whole vein length. The patient was then positioned in Trendelenburg position (Fig. 3).

The fiber position was rechecked and confirmed. The laser power was set to 10 W and pull-back speed set for 0.5 mm/s for the first 5 cm of the vein.

Then the speed of pullback is increased to 1 mm/s and the power adjusted according to the original vein diameter aiming at linear endovenous energy density (LEED) of 60–120 J/cm till the knee.

Veins less than 8-mm diameter were treated with LEED 60–80 J/cm, veins with a diameter of 8–10 mm were treated with LEED of 80–100 J/cm, and veins with a diameter above 10 mm were treated with LEED of 100–120 J/cm.

LEED was calculated as follows:.

$$\text{LEED} = \text{time in second to pullback laser fiber for } 1 \text{ cm} \times \text{energy in Watts}$$

For example, if the vein diameter is 6 mm and we need to deliver 80 J/cm, we adjusted the laser power at 8 W and pull the fiber at 1 mm/s. So every cm of the vein will be treated for 10 s using 8 W, LEED=8×10=80 J/cm.

Manual fiber pullback can replace automatic pull-back device if not available throughout the procedure (Fig. 4).

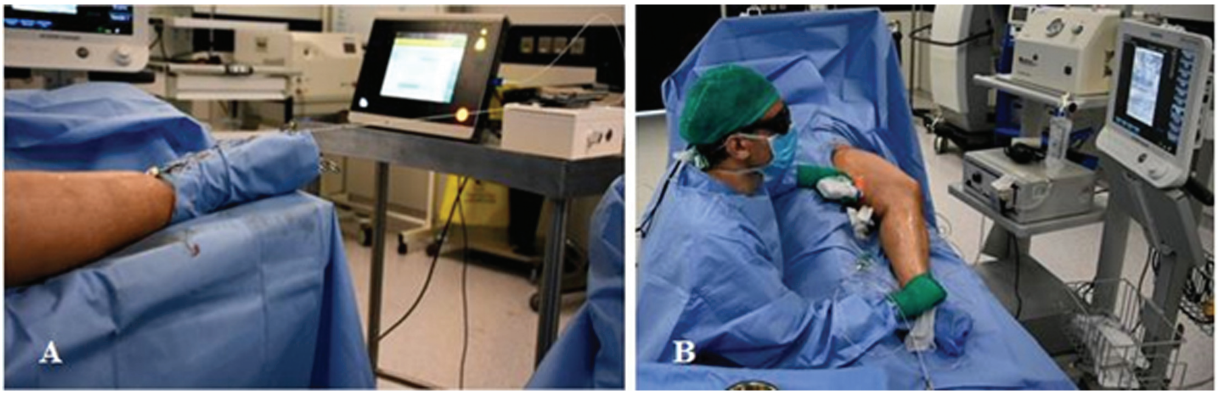
At the knee, the procedure was stopped, followed by sclerotherapy foam prepared from aethxoysklerol 3% mixed with air 1 : 4 ratio 20 times as per standard.

Through the side arm of the sheath, injection of the foam about 1 ml foam/5 cm of the vein length was done, with extra amount injected if the foam diffused

Figure 3

Step 3, injection tumescent anesthesia in the perisaphenous fascia.

Figure 4



Step 4, (a) ablation using automatic pull-back device and (b) manual pullback.

Figure 5

Step 5, below-the-knee injection through the side arm of the sheath.

to collateral VV, ensuring that all varicose veins of the leg get the foam inside (Fig. 5), and then the sheath was removed keeping the laser fiber in position.

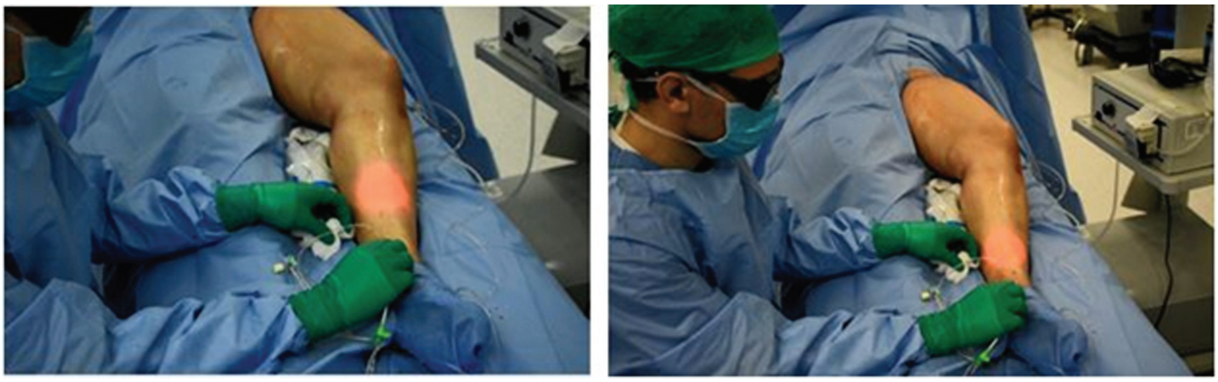
The laser power was decreased to 5 w and the pull-back speed increased to 2 mm/s aiming at LEED 25 J/cm regardless of vein diameter, and laser ablation was continued down to 2 cm from the puncture side. The exit site was compressed for 2 min and then covered with sterile Opsite (Fig. 6).

Extra-truncal varicose veins with straight venous segments that can be cannulated were treated using endovenous thermal ablation same way as great saphenous vein (Fig. 7a), short tortuous veins with diameter less than 4 mm were treated with injection using foam prepared of polidicanol 1–2%, and veins 4 mm or larger that are not feasible for laser treatment were stab avulsed (Fig. 7b).

Ablation time, the total energy in Joules, amount of tumescent anesthesia, and sclerosing agent used, all were recorded for each patient.

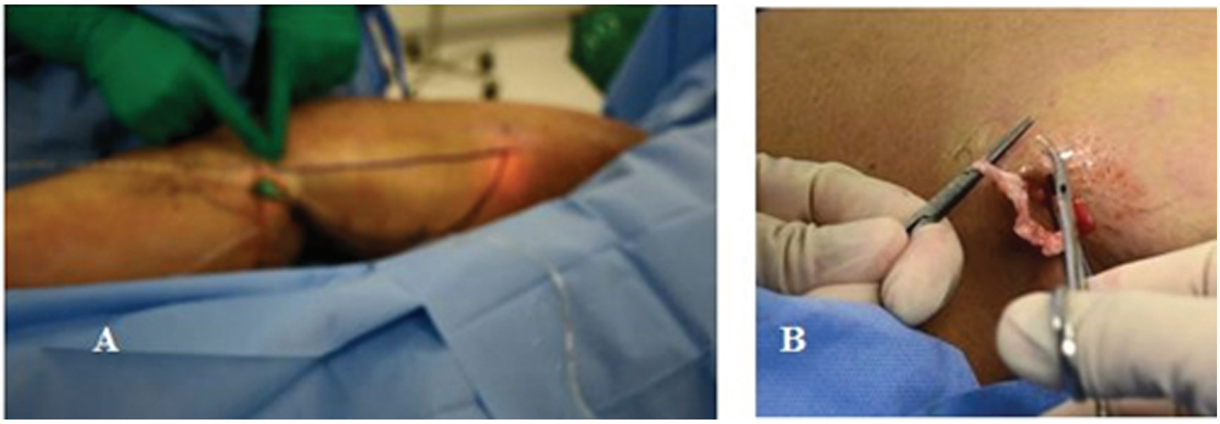
Eccentric compression over the great saphenous vein and class II graduated medical stocking 22–32 mmHg were applied. The patient returned back to a general ward room, instructed to walk for 15–20 min, and was discharged home after 1 h. The patient was instructed to keep stocking day and night for 7–10 days.

Figure 6



Step 6, laser ablation down to the ankle using low laser power to enforce vein occlusion.

Figure 7



Step 7: (a) Extra-truncal varicose vein laser ablation and (b) and stab avulsion.

All patients received prophylactic anticoagulation starting the same day of the procedure (clexane 40 IU once daily, Apixaban 2.5 mg twice daily, or Rivaroxaban 10 mg once daily for 5 days).

Follow-up was done at 1 week and at 1, 3, 6, 12, and 18 months (clinical and duplex assessment (Figs 8 and 9) for evaluation of vein occlusion, improvement of symptoms, and checking for DVT and other complications, with CIVIQ-20 reassessment repeated at 6–12-month duration marked as CIVIQ-20B1 and CIVIQ-20B2. Residual varicose veins after 3 months were treated by injection sclerotherapy sessions if indicated.

All data were collected and analyzed using IBM SPSS statistics 26.0 (IBM, Armonk, New York, USA).

Results

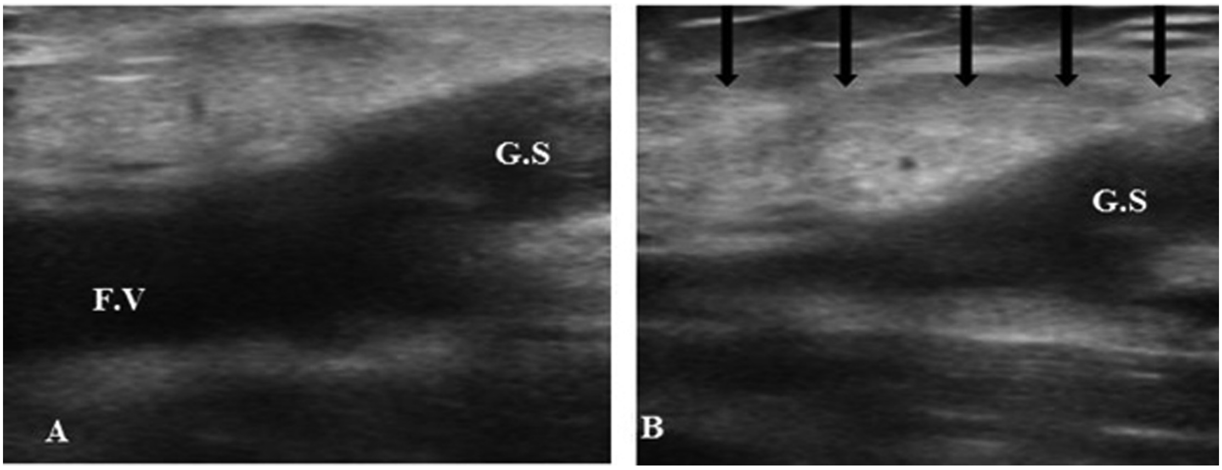
The total number of patients in this study was 125 patients, involving 132 limbs. There were 37 (29.6%) male and 88 (70.4%) female patients, with male to female ratio of 1 : 2.4. The main age was 40.4±11.8 years. A total of 32 (25.6%) patients were diabetic, 21 (16.8%) were hypertension, and six (4.8%) were smokers (Table 1).

Most of the cases were CEAP classification C2–3 with the collective number of 109 (82.6%) patients of both categories, and C4–6 represent 17.4% (23 patients) (Table 2).

A total of 118 (94.4%) cases were unilateral, and seven (5.6%) cases were operated for bilateral varicose veins. The average great saphenous vein diameter at the thigh and leg segments was 8.8±3.4 and 5.97±1.3 mm, respectively (Table 3).

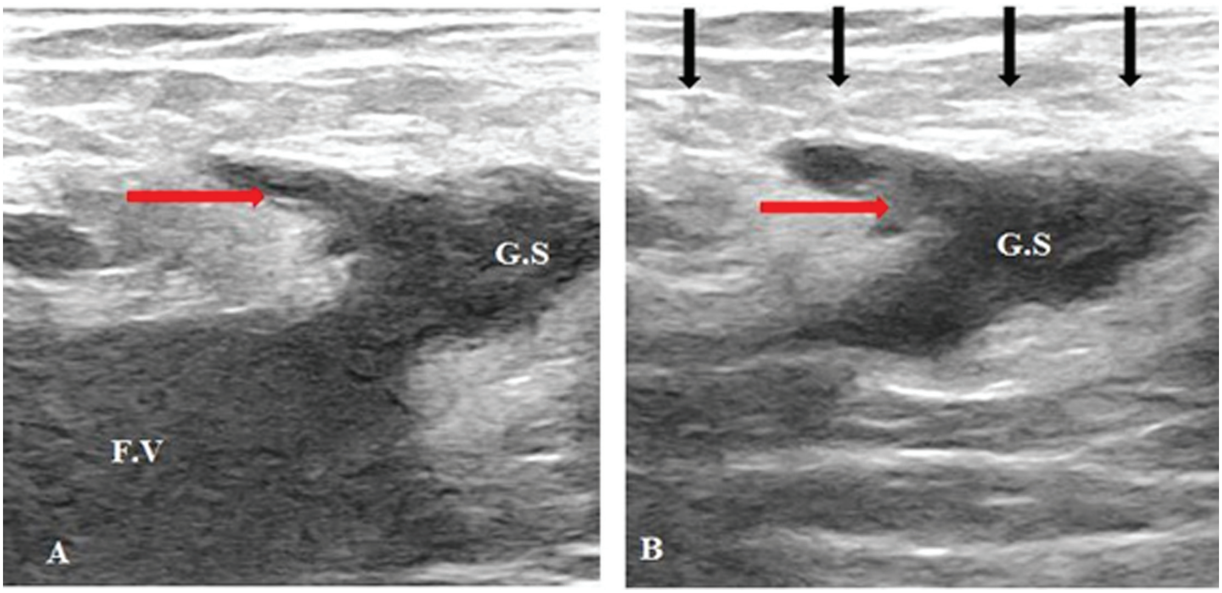
The total operative time was 43±17 and 93±12.7 min for unilateral cases and bilateral cases, respectively; time to establish single sheath was 37±15 s; the treated great saphenous vein segment length was 70.45±3.8 cm; the average amount of tumescent anesthesia was 400 ±50 ml; per limb, laser energy 5950±730 J with ablation time of 8.7±0.6 min (Table 4).

Figure 8



One-week postablation ultrasound showed patent (a) compressible (b) femoral vein with occlusion of great saphenous (GS) flush at the junction.

Figure 9



One-week postablation ultrasound showed patent compressible femoral vein with occlusion of great saphenous (GS) flush at the junction with thermal ablation extended to the first tributary (red arrow).

Table 1 Patient demographic data

Patients demographic data		
Total number of patients	125	1 : 2.4
Male	37	29.6%
Female	88	70.4%
Mean age	40.4±11.8	–
Diabetes	32	25.6%
Hypertension	21	16.8%
Smoking	6	4.8%

Table 2 CEAP classification of the patients

CEAP classification	*n* (%)
C2	66 (50)
C3	43 (32.6)
C4	15 (11.4)
C5	5 (3.8)
C6	3 (2.2)

The patients who needed extra-truncal treatment were 64 (48.5%). In most of them, laser ablation of big tributary of the great saphenous vein (25 cases, 18.9%) was done, with average laser energy of 960±46 J and added ablation time of 1.6±0.23 min. Separate injections were needed for 19 (14.5%) cases, most of them for thigh varicosities, where 2–4 ml of liquid polidicanol 1% transformed to foam was used for each case. A small number of phlebectomies (10 cases, 7.6%) were done in this study. A total of 17

(12.9%) cases needed separate injection sclerotherapy for persistent extra-truncal minor varicose veins after 3 months. Most of them were for cosmetic concern, with average of one to two sessions (Table 5).

Postoperative follow-up at 1 week showed great saphenous vein complete occlusion of 131 (99.3%) limbs; one (0.7%) case of primary failure with vein diameter of 18 mm at the proximal segment showed segmental nonocclusion, with improvement of symptoms on long-term follow-up; 10 (7.6%) cases had minor skin ecchymosis, which resolved in 1–2 weeks without any additional treatment; mild postoperative pain was seen in 23 (17.4%) cases, which improved on oral paracetamol; and one (0.7%) case presented with numbness over the medial aspect of the lower leg and foot, with mild improvement over the next months. No cases of skin burn, DVT, or PE were seen on serial follow-up, and two (1.5%) cases showed short segmental great saphenous recanalization over the next 6 months without recurrence of symptoms (Table 6).

Table 3 Vein criteria

Vein criteria	
Unilateral cases [*n* (%)]	118 (94.4)
Bilateral cases [*n* (%)]	7 (5.6)
Average vein diameter (thigh) (mm)	8.8±3.4
Average vein diameter (leg) (mm)	5.97±1.3

Table 4 Operative data for great saphenous

Operative data for great saphenous	
Total number of treated limbs	132
Operative time unilateral cases (min)	43±17
Operative time bilateral cases (min)	93±12.7
Access insertion time (s)	37±15
Treated vein length for one great saphenous (cm)	70.45 ±3.8
Amount of tumescent anesthesia for one great saphenous (ml)	400±50
Laser energy used for one great saphenous (J)	5950 ±730
Ablation time for one great saphenous (min)	8.7±0.6

CIVIQ-20 score showed marked improvement over the follow-up period with the average score of 71.3±9.6 at the initial preoperative assessment to 32±4.6 after 6 months with more improvement on 12-month assessment (29.7±1.2); this reflects a good improvement in the quality of life after the treatment (Table 7) (Figs 10 and 11).

Discussion

In this study, we introduced in detail a new technique for great saphenous varicose veins ablation with the aim to improve the outcome of varicose veins therapy, using the advantage of the development of the radial emitting laser fiber combined with below-the-knee thermochemical ablation.

Incomplete surgery at the groin without ablation of all superficial branches drain to the great saphenous vein is one of the most common causes of recurrence of varicose veins. Gad *et al*. [13] estimated up to 19.8% rate of all recurrence owing to incomplete surgery at the groin and proximal thigh. The saphenous vein at the upper thigh has many tributaries that may be

Table 6 Postoperative complications

Postoperative	*n* (%)
Skin burn	0
Ecchymosis	10 (7.6)
Postoperative pain	23 (17.4)
DVT	0
Saphenous nerve injury	1 (0.7)
Primary failure of occlusion	1 (0.7)
Segmental recanalization at 6 month	0
Recanalization at 18 month	2 (1.5)

DVT, deep vein thrombosis.

Table 7 CIVIQ-20 preoperative and postoperative

CIVIQ-20 preoperative and postoperative	
Preoperative CIVIQ-20A	71.3±9.6
6 months postoperative CIVIQ-20B1	32.4±4.6
12 months postoperative CIVIQ-20B2	29.7±1.2

Table 5 Extra-truncal vein treatment

Extratruncal vein treatment		
Total number of patients who needed extratruncal treatment	64	48.5%
Number of cases needed extra-truncal Laser ablation	25	48.5%
Tumescent used	130±23 ml	
Laser energy	960±46 J	
Ablation time	1.6±0.23 min	
Number of cases needed extra-truncal Injection sclerotherapy	19	14.5%
Amount of sclerosing used for one great saphenous	2–4 ml	
Number of cases needed phlebectomy	10	7.6%
Injection sclertotherpy after 3 months	17	12.9%

Figure 10

(a) Preoperative and (b) 2-week postoperative, thermochemical ablation with stab avulsion.

Figure 11

(a) Preoperative and (b) 3-month postoperative, thermochemical ablation with stab avulsion.

incriminated in the pathogenesis of varicose recurrence after laser ablation; the first few centimeters of great saphenous vein has more than five tributaries [15].

Traditionally EVLA starts 1.5–2 cm from the SFJ for fear of extending the thermal injury to the deep system with subsequent occurrence of DVT [14,16,17]; this leaves most of the groin tributaries of the great saphenous patent to give a high chance of recurrence [13,15,18].

With most of the recurrence after laser ablation occurs at the groin due to recanalization, the concept of missing big refluxing tributary at the proximal segment necessitates the evaluation of the more proximal thermal ablation.

In our study, we performed safe ablation starting flush at the SFJ (endovenous thermal crossectomy) ablating the most crucial segment of the vein, draining all the tributaries at the groin without any recorded DVT thanks to the radial laser fiber.

Itoga *et al.* [19] reported an incidence of DVT after endothermal ablation of around 1.9 and 3.2% at 7 and 30 days after the procedure, respectively. Shutze *et al.* [20] found a higher incidence of 5.1% of DVT in their study, whereas in our study, no DVT occurred in all cases.

For the thigh segment, the use of radial laser fiber with postoperative prophylactic dose anticoagulation for 5 days and adjusted LEED allows thermal ablation of great saphenous vein flush with the SFJ, and it results in an excellent occlusion rate, without complications. Our study has shown that it is a highly safe procedure. Other laser fibers with end tip laser emission cannot be used for the purpose, as the risk of injury to the deep veins is great.

Calculation of the needed energy for effective treatment has no standard guidelines, with the most widely used method being LEED. Many investigators found that using LEED power less than 60–80 J/cm was associated with the high primary failure rate. Adapted power of 80–150 J/cm has shown to be very effective [21,22].

Adding the vein diameter to the calculation helps getting the highest occlusion rate with minimal complication.

Based on our practice and available published data, we divided varicose veins into three groups: veins less than 8 mm, veins with diameter 8–10 mm, and veins larger than 10 mm. We adjust the LEED according to the vein diameter to get the best result. In our study, the use of LEED of 60–80, 80–100, and 100–120 J/cm results in 100% occlusion in respective vein diameter.

The leg vein segment usually has varicose reflux with many tributaries and incompetent perforators that need further separate treatments. Overall, 48.3% of distal varicose veins recurrence was owing to incomplete treatment at the legs [13].

The use of laser for the below-the-knee vein segment with the recommended LEED (60–80 J/cm) is usually associated with the high incidence of saphenous nerve injury; this leads to avoiding thermal ablation for this segment [23].

On the contrary, the use of low laser power (LEED<60 J/cm) has resulted in the failure of obtaining occlusion of the vein in most of the cases [21].

Truncal injection sclerotherapy alone has a high rate of recanalization with some study estimated recurrence up to 29% at 5 years [23].

In our study, we combine low laser energy (25 J/cm) with truncal sclerotherapy (thermochemical ablation) at the same time for the below-knee vein segment. This new method resulted in 100% occlusion with less risk to the saphenous nerve injury and persistent occlusion on mid-term follow-up.

Below-the-knee thermochemical ablation has the advantage of safe treatment of the leg saphenous vein, dilated tributaries, and perforators at the same time, with much easy and rapid technique, reducing operative time and complication.

Truncal injection through the sheath at the lower leg has the advantages of distributing the foam in the refluxing leg tributaries and perforators connected to the saphenous main trunk, and when followed by low energy laser thermal ablation, it gives solid occlusion of the main saphenous trunk with a potential decrease in the number of subsequent treatment sessions.

In our study, the below-the-knee thermochemical ablation is associated with 100% sustained occlusion rate of the main saphenous vein, and a small number of patients needed subsequent treatment sessions (15%). The incidence of saphenous nerve injury was 0.7% only, with improvement in 3 months.

Ablation of the extra-truncal varicosities decreased the incidence of recurrent varicose veins and fastened the clinical improvement [13,24,25]. In our study, we performed laser ablation – when indicated – of accessory saphenous vein and dilated tributaries connected to the great saphenous vein that can be cannulated with access sheath and at least have 10 cm straight segment; this seems to affect long-term persistent occlusion of the saphenous vein and good patient satisfaction owing to rapid disappearance of limb varicosities.

Regarding the laser fiber design, the introduction of new designs for laser fibers has a great effect on our results. The availability of the radial double-ring laser fiber in our experience gives the best results. Theoretically, slitting the laser power into two rings at the fiber tip has two advantages: first, it splits the laser power, which decreases the incidence of vein perforation and skin complication, and second, it makes a double effect on the vein wall, where the first ring (far from the tip) emits laser which makes the vein contract around the fiber, and then the same segment is retreated by the second ring laser (at the fiber tip) with direct contact with the vein wall.

Accessing the veins at the lower leg is much easier than the lower thigh or upper leg, as it becomes superficial at the distal leg.

Fiber introduction from the distal leg may be challenging in some cases as the fiber may easily pass in a dilated branch or fail to pass a tortious saphenous segment.

Most of the time, manipulating the fiber tip combined with external skin compression, stretching the skin over the vein, flexion of the knee joint, and flexion abduction of the hip will succeed in pushing the fiber upward. Minor cases will need another sheath insertion and treating in two segments.

Postprocedure prophylactic anticoagulation is a common practice that is largely different between centers, mostly given for 3–10 days. Keo *et al.* [26] found no difference in both regimens. In our study, we adopt 5-day therapy, with great saphenous vein occlusion rate of 99.3 and 0% DVT.

The rate of complication in our study was considered very low. Excluding minor ecchymosis and mild postoperative pain, the incidence of DVT (0%), saphenous nerve injury (0.7%), primary failure (0.7%), and recanalization on follow-up (1.5%) was all less than documented in previous studies [7,11,12].

Conclusion

With the recent advances in laser technology and introduction of radial fiber, it becomes safe to perform laser ablation starting at the SFJ (endovenous thermal crossectomy) avoiding missing proximal refluxing tributaries at the upper thigh and groin improving the mid-term outcome, with no increase in the incidence of thermal-induced deep venous thrombosis.

Combining low laser energy and sclerotherapy (thermochemical ablation) for the below-the-knee long saphenous varicosities offers a very successful method to extend the treatment down to the foot, decrease the incidence of saphenous nerve injury, decrease the number of treatment session and recurrence, with promising short-term and mid-term follow-up results.

Extra-truncal laser thermal ablation if applicable has excellent effect on both short-term and long-term treatment results.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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