The 1470 radial endovenous laser ablation of the great saphenous vein larger than 12 mm: is it a good option? A single-center experience

Amr Elboushi[a], Mohamed Elsherbeni[a], Abdelrahman M. Gameel[a], Waleed Sorour[a], Mohamed Amin[b], A. Samir[a], A. Salem[a]

Departments of [a]Vascular Surgery, [b]Radiology, Faculty of Medicine, Zagazig University, Zagazig, Egypt

Correspondence to Abdelrahman M. Gameel, MD, Postal code: 123456. Tel: 0552366211; fax: 0552358540; e-mail: abdlgm2611@gmail.com

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Introduction
Endovenous ablation of varicose veins has been used to treat varicose veins and has gained popularity as one of the preferred techniques to treat axial reflux. Initially the diameter recommended was less than 8 mm, then gradually surgeons starting gaining the experience to treat larger veins. Treating larger veins has been on the controversial side with some surgeons recommending surgery versus others recommending endovenous ablation.
Patients and methods
The patients were divided to three groups according to the great saphenous vein diameter and follow-up duplex arranged at 3, 6, and 2 months. Visual analog scale was used at 1 week and 4 weeks to assess postoperative pain.
Results
In our study, there was no incidence of deep venous thrombosis (DVT) or nerve injury in any of our groups. At 1 month, there was significant difference between the groups, but at 4 weeks there was no significant difference regarding postoperative pain. There was no recanalization with an occlusion percentage of 100% in the 3-month duplex scan in all the groups. There is no significant statistical difference between the groups regarding recanalization at 6 and 12 months.
Conclusion
Our study showed good short-term results of endovenous laser therapy in the ablation of large-diameter great saphenous vein. The use of endovenous laser therapy has to be a dynamic process where you as an endovascular surgeon can change a variety of parameters to optimize the final results of the procedure.

Keywords:
endovenous laser therapy, large-diameter great saphenous vein, linear endovenous energy density, varicose veins

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Introduction

Chronic venous insufficiency is one of the public health concerns that have existed since the beginning of human civilization and has always caused an economic and social burden [1,2]. Great saphenous vein (GSV) disease is the cause of three-quarter of the cases of symptomatizing varicose veins [3].

Endovenous ablation of varicose veins has been used to treat varicose veins and has gained popularity gradually with vascular surgeons as one of the preferred techniques to treat axial reflux. Initially the diameter recommended was less than 8 mm, then gradually the surgeons started gaining the experience to treat larger veins. Treating larger veins has been on the controversial side with some surgeons recommending surgery versus others recommending endovenous ablation [4–6].

The goal of using endovenous laser therapy (EVLT) is to stop retrograde blood flow by permanently occluding the vein. This occurs by causing intima and media destruction by thermal injury causing fibrosis of the vein wall and fibrotic nonthrombotic blockage of the vein [7].

Using EVLT has shown good long-term results [8] and currently is one of the first lines to be provided for axial varicose vein reflux as recommended in the NICE guidelines in 2013 and which were confirmed and updated in February 2016 [9].

A total of 1470 wavelength is one of the wavelengths absorbed by water and the radial fiber design has the benefit of uniformingly distributing the energy to the vein wall with less incidence of perforation of vein wall

[10]. A total of 1470 radial laser fibers have shown good occlusion results with incidence of recurrence of about 2–5% [11].

Linear endovenous energy density (LEED) has been used by most authors as a method to measure energy delivery to the vein resulting in occlusion. The higher the LEED the more the energy delivered with increased destruction of vein wall and is associated with increased risk of complications and pain [12].

The aim of the study is to compare the efficacy and safety of using high-energy EVLT in large-diameter varicose veins.

Patients and methods

Patients

Patients included in this study were treated by five vascular surgeons in our center starting from February 2015 up to June 2017. BMI of all the patients was calculated after measuring their height and weight recorded in the outpatient clinic. Patients with controlled diabetes mellitus and hypertension were included in this study while patients who have uncontrolled diabetes mellitus, uncontrolled hypertension, peripheral vascular disease, recurrence after previous intervention, reflux in the small saphenous vein, active infection, and venous ulcer were excluded from this study.

After duplex examination by our team, the patients were divided into three groups: the first group included limbs with GSV segments of up to 12 mm; the second group included limbs with GSV segments ranging from 13 to 20 mm and the third group included limbs with GSV segments larger than 20 mm. All measurements were done in the standing position.

All steps of the intervention, including the type of anesthesia and possible complications which might be acquired were discussed carefully with all patients and written consents were obtained from all patients which were approved by the Institutional Review Board.

Procedure

The devices used were 1470 generator with radial tip laser catheter biolitec (Biolitec AG Jena, Germany).

Measurements of the GSV were done preoperatively in a standing position by duplex ultrasound (US) after confirming reflux greater than 500 ms. Skin marking of the GSV with diameters of each segment was recorded on the skin. All patients underwent the procedure under spinal anesthesia.

US-guided modified Seldinger technique was used to cannulate the GSV in the upper one-third of the leg and in case of marked tortuosity of the vein a second or third sheath was inserted at a higher level.

The laser fiber was inserted and the tip positioned 1.5 cm from the saphenofemoral junction. The position of the patient was changed to a head-down position and the tumescent fluid was injected around the vein and into the saphenous compartment.

Tumescent fluid injected was recorded with special care to have a heat sink 1.5–2 cm around the vein in segments of more than 12 mm and between the GSV and the femoral vessels in the upper thigh. In veins 12 mm or less the heat sink created by the tumescent fluid ranged from 1 to 1.5 cm. Cases with diameter more than 12 mm diameter cold saline was used to increase the efficacy of the heat sink.

Both continuous and pulsed modes were used in our study. The pulsed-wave mode was adjusted to one pulse per second with 0.5 s interval. Before starting the laser firing the probe of the US device is positioned to occlude the saphenofemoral junction by compression to reduce the risk of thermal energy going into the femoral vein.

For veins larger than 12 mm the power was adjusted to 10 W and the pullback was started. Speed of the pullback was slowed or advanced according to the sense of contraction of the vein wall on the catheter and obliteration of the vein by US. The multi-pass technique which was described by Dabbs *et al.* [12] was used in large veins where asymmetrical contraction occurred until complete occlusion.

Length of the treated GSV, amount of energy delivered in each segment, and intraoperative duplex findings were recorded. The procedure success is defined when no blood flow can be visualized in the treated segment.

Our end point is efficacy of occlusion at 12 months. A routine duplex scan was arranged after 1 week to exclude deep venous thrombosis (DVT). Postoperative pain was assessed by a visual analog score at 1 week and 4 weeks. The score has a range from 0 (no pain) and 100 (worse pain ever). The patients were assessed with duplex at 3, 6, and 12 months. Those who did not attend any of the arranged assessments were excluded from the postoperative

statistical analysis; seven, four, and two patients were excluded from group 1, group 2, and group 3, respectively.

Statistical analysis

Data were analyzed using SPSS statistics version 23 (SPSS Corp., Armonk, New York, USA). A *P* value was considered statistically significant if less than 0.05. Categorical variables were compared using Fisher's exact test 3×2 contingency table and numerical data were compared using analysis of variance with post-hoc analysis for in-group analysis when needed.

Results

Two hundred and fifty-nine limbs of 185 patients were included in our study. The demographic data is demonstrated in Table 1. There was no significant statistical difference ($P>0.5$) between the groups regarding sex, age mean, BMI, comorbidity, or clinical, etiological, anatomical, and pathological classifications.

There was significant difference between our groups in the intraoperative data as there was a significant difference in the tumescent fluid amount mean, tumescent fluid per centimeter, total joules and joules per cm reflecting the higher energy used and increased amount of tumescent used to compress the vein and create an appropriate heat sink. There was no significant difference between the groups in the length of vein treated. This data is demonstrated in Table 2.

Postoperative findings

In our study, there was no incidence of DVT, burn, or permanent paresthesia in any of our groups. Postoperative pain was assessed using the visual analog scale. At 1 month, there was significant difference between the groups but at 4 weeks there was no significant difference. After using post-hoc analysis looking into the in-group analysis the significant difference in postoperative pain was between group 1 and group 3 in the first week VAS score (Table 3).

There was no postoperative recanalization with an occlusion percentage of 100% in the 3-month duplex scan in all the groups.

At 6 months the percentage of recanalization in the first group was 1.3% (two cases) while in the second group it was 1.5% (one case) and in the third group it was 9.1% (two cases). There was no significant between the groups.

Table 1 Demographic data of the patients

	Group 1 (*N*=165) [*n* (%)]	Group 2 (*N*=70) [*n* (%)]	Group 3 (*N*=24) [*n* (%)]	*P* value
Mean age (mean±SD) (years)	37.5±12.8	38.9±13.7	34.6±10.7	0.361 (NS)
BMI (mean±SD)	28.5±4.9	28.3±5.5	29.58±5	0.129 (NS)
Sex				
Male	53 (32.1)	19 (27.1)	9 (37.5)	0.59 (NS)
Female	112 (67.9)	51 (72.9)	15 (62.5)	
HPN	11 (6.7)	3 (4.3)	1 (4.2)	0.937 (NS)
DM	25 (15.2)	10 (14.3)	3 (12.5)	
CEAP				
CEAP2	34 (20.6)	12 (17.1)	3 (12.5)	0.65 (NS)
CEAP3	49 (29.7)	16 (22.9)	5 (20.8)	
CEAP4	50 (30.3)	27 (38.6)	9 (37.5)	
CEAP5	32 (19.4)	15 (21.4)	7 (29.2)	

CEAP, clinical, etiological, anatomical, and pathological classification; GSV, great saphenous vein; SSV, small saphenous vein.

Table 2 Intraoperative data

	Group 1: GSV<13 mm (mean ±SD)	Group 2: GSV=13–20 mm (mean ±SD)	Group 3: GSV>20 mm (mean ±SD)	*P* value
GSV diameter	9.37±1.65	16.39±2.39	24.08±2.16	0.000
Length of GSV treated	42.5±12.67	42.9±12.4	45.17±9.91	0.625
Tumescent fluid (cm^3)	677.61±170	780.50±130	1123.46±222	0.000
T/cm (cm^3)	17.67±7.9	20.05±7.8	26.29±8.5	0.000
Total joules	3448±636	4710±626	5450.29±733	0.000
LEED	89.5±34	121.57±46	126.13±31	0.000

GSV, great saphenous vein; LEED, linear endovenous energy density.

Table 3 Postoperative pain

	Group 1: GSV<13 mm (mean±SD)	Group 2: GSV=13–20 mm (mean±SD)	Group 3: GSV>20 mm (mean±SD)	*P* value
VAS first week	23.2±14.5	26.1±11.8	31.8±11.3	**0.01**
VAS 4 weeks mean±SD	10.2±5.2	10.85±6.8	12.8±5	0.13
Post-hoc analysis				
VAS 1 week		GSV<12 mm	GSV=13–20 mm	0.476
			GSV>20 mm	**0.018**
		GSV=13–20 mm	GSV<12 mm	0.476
			GSV>20 mm	0.263
		GSV>20 mm	GSV<12 mm	**0.018**
			GSV=13–20 mm	0.263
VAS 4 weeks		GSV<12 mm	GSV=13–20 mm	1.000
			GSV>20 mm	0.145
		GSV=13–20 mm	GSV<12 mm	1.000
			GSV>20 mm	0.510
		GSV>20 mm	GSV<12 mm	0.145
			GSV=13–20 mm	0.510

GSV, great saphenous vein; VAS, visual analog scale.

Table 4 Recanalization at 3, 6, and 12 months

	Group 1: GSV<13 mm	Group 2: GSV=13–20 mm	Group 3: GSV>20 mm	*P* value
Recanalization at 3 months	0	0	0	NA
No reflux (%)	100	100	100	
Recanalization 6 months [*n* (%)]	2 (1.3)	1 (1.5)	2 (9.1)	0.08
No reflux	98.7	98.5	90.9	
Recanalization 12 months [*n* (%)]	4 (2.5)	2 (3)	2 (9.1)	0.3
No reflux	97.5	97	90.9	

GSV, great saphenous vein; NA, not applicable.

At 12 months the total number of recanalization is 2.5% (four cases) in the first group, 3% (two cases) in the second group, and 9.1% (two cases) in the third group. These figures did not show any significant statistical difference between the groups regarding recanalization (Table 4).

Discussion

The key factor to decrease recurrence in EVLT is to understand the mechanism of recurrence to design an optimum strategy to decrease it.

Some studies that advised that EVLT is ineffective in comparison with open surgery when treating incompetent varicose veins over 8 mm in diameter is due to incomplete suboptimal ablation of the vein leading to thrombus formation which has the risk to propagate to cause a DVT or become a bed for migrations of cells from the media leading to recanalization [4–6,13,14].

But this was not the conclusion of our study as we showed similar results regarding occlusion and recanalization with other studies that advise using EVLT in the treatment of larger saphenous vein diameter [12,15]

Multiple studies confirmed the association between less thermal injury to the vein wall with increased risk of recanalization [6,16].

We agree with the concept of Dabbs *et al.* [12] that transmural vein wall death is the key concept to prevent recanalization of EVLT-treated varicose vein as it will lead to fibrotic occlusion while thrombophlebitis associated with inadequate exposure of the inner wall of the vein to the thermal effect of the laser energy is a good media for migration of cells from the media and later recanalization of the vein resulting in recurrence.

Cowpland *et al.* [17] reviewed the clinical evidence affecting optimal LEED in a very interesting publication in 2016 and determined the different factors that affect the optimal LEED including the vein diameter, the design of the fiber, wavelength of the laser, rate of pullback, and mode of laser delivery.

Increasing the LEED alone in hugely dilated veins is not sufficient to expose all of the vein wall layers to the

thermal injury that is why we applied multiple passes of the fiber guided by US (this technique was described by Dabbs *et al*. [12] in their study) to the unoccluded parts of the vein resulting in fibrotic nonthrombotic occlusion and less risk of recurrence in our study. This is aided by a sufficient amount of tumescent fluid to adequately compress the vein and a proper head-down position to empty the vein.

The fiber tip design is another important factor. The radial fiber distributes the laser energy in a 360° direction which leads to better distribution of the injury to the vein wall with less energy. The dual radial tip is already showing promising results [11] and so is the ball-tipped catheter design [18] with good occlusion rates and less LEED.

Another factor affecting the outcome is using a fixed pullback rate without sensing the contracture of the vein wall and not visualizing the proper occlusion by US. The pullback can also increase or decrease the injury delivery simply by increasing or decreasing the rate of pullback without the need of using maximum energy. This is also highlighted in an experimental study done by Ignatieva *et al*. [19] and published in 2017 showing that the rate of pullback and power arbitrate the temperature and the degree of collagen framework degradation.In our study, we did not compare using pulsed mode versus continuous mode but we did notice almost always lack of carbonization of the tip of the catheter. Some studies confirmed that pulsed-wave mode delivers sufficient energy without causing excessive carbonization or vein wall perforation in comparison with continuous or discontinuous mode [20,21].

Laser wavelengths targeting water (1320, 1470, and 1510 nm) achieved better occlusion rates in comparison to shorter wavelengths in multiple studies with a lower mean LEED [22–25].

Pain in the postoperative period was initially significant in the larger than 20 mm group but in a month's time this significance disappeared with no cases of parathesia.

Putting different EVLT wavelengths and technologies in one basket and concluding that it is unsuitable to treat large-diameter varicose vein is unfair to the patients and to an evolving technique and we encourage an EVLT first strategy in all axial varicose vein disease putting in mind that modifying different parameters is a dynamic process that can accommodate different case scenarios.

Our study has limitations as it is a nonrandomized short-term study with five vascular consultants doing the procedures and with no surgery group as a control group in large vein diameter. Further RCTs and long-term studies are needed to confirm the advantages of EVLT in hugely dilated varicose veins [26].

Conclusion

Our study showed good short-term results of EVLT in the ablation of large-diameter GSV. Using appropriate LEED and multi-pass technique are good tips in improving the occlusion of the vein and inducing fibrosis of the vein wall. The use of EVLT has to be a dynamic process where you as an endovascular surgeon can change a variety of parameters like energy, pullback speed, multiple passes, and the amount of tumescent fluid injected to optimize the final results of the procedure. This should encourage us to change the concept that EVLT is not suitable for varicose veins larger than 12 mm.

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Conflicts of interest

There are no conflicts of interest.

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