Endovenous laser ablation versus conventional surgery in treatment of primary truncal varicosities

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Aim of the Work
In this study we compare the outcome of laser ablation and conventional surgery in treatment of patients with primary trunkal varicose vein with a period of one year.
Background
It is estimated that varicose veins in the distribution of the great saphenous vein (GSV) are present in about 25% of women and 15% of men. Endovenous Laser Therapy (EVLT) is one of the most promising techniques in treatment of varicose veins.
Methods
This is a prospective randomized study. This study was conducted on 36 patients presented to our clinic in Mansoura university hospital (MUH) in the period from November 2015 to January 2017 with trunkal varicosities.
Results
In this study, female predominance was remarkable, with a 32 year old mean age. All patients in our study were presented by limb heaviness. Only 5 patients (13.8%) seeked intervention for varicose veins due to cosmetic issues. this study showed different results according to the operative time with 46 minutes difference in the mean operative time between both groups.
Conclusion
In our study we found that EVLA has the same results as surgical stripping regarding the efficacy and the recurrence rate, which was our primary outcome, so that we recommend EVLA as a main method for varicose vein treatment used in treatment of varicose veins with no scars or cosmetic discomfort.

Keywords:
aser ablation, cosmoses, stripping

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Introduction

Great saphenous vein (GSV) varicosities affect ~25% of women and 15% of men. It seems that the appearance and evolution of the disease occur owing to multiple factors but mainly the modern lifestyle, characterized by sedentarity, lack of exercise, and obesity [1].

Surgery is the gold standard in the treatment of varicose veins. For several decades, high ligation at the saphenofemoral junction and stripping of the GSV was the treatment of choice to eradicate the diseased vein. In the past years, in the era of minimally invasive surgery, new techniques in the treatment of varicose veins, such as the endovenous laser ablation (EVLA), have been introduced [2].

In this study, we compare the outcome of laser ablation and conventional surgery in the treatment of patients with primary truncal varicose vein with a follow-up period of 1 year.

Patients and methods

This is a prospective randomized study. This study was conducted on 36 patients with truncal varicosities who presented to our clinic in Mansoura University Hospital in the period from November 2015 to January 2017.

A total number of 175 patients visited the outpatient clinic in 2015, and one hundred of them were excluded as they did not match the criteria, whereas the other 75 patients were matched the inclusion criteria.

Moreover, 30 patients did not agree to the informed consent included in our study, and many of them claimed that the cost was too heavy on their pocket. In addition, nine patients were missed during the

follow-up, so eventually, we had 36 patients in our study, who were divided into two groups.

Inclusion criteria

Patients presented with varicose vein symptoms affecting their quality of life such as heaviness sensation, fatigability, pain, and cosmetic concerns, with or without presence of skin manifestations such as eczema, pigmentations, lipodermatosclerosis, and healed or active ulcers were included in the study.

Anatomical criteria are mainly listed as having remarkable reflux shown byduplex ultrasonography (DUS) examination (reflux >0.5 s), straight vein segment, any vein segment intrafascially or epifascially which has the same criteria as it can be moved away from the skin by using tumescent injection, great saphenous vein diameter ranges from 4 to 17 mm, and predicted availability of the patient for the follow-up investigations.

Exclusion criteria

Patients primarily aged less than 16 years or more than 65 years, pregnant females, patients experiencing mental incapacitation, patients with obstructed deepvenous system either recanalized or not, patients with GSV diameter more than 17 mm, patients presented with SSV reflux, and patients with deepvein reflux were excluded from the study. Moreover, patients with tortuous veins were also not included as it makes the passage of an endovenous device impossible.

Randomization

Randomization was done before beginning of the procedure using a coin by a nurse who was blinded to the process. The patients were divided into two groups. Group A underwent conventional surgery and group B underwent laser ablation.

Procedure

The basic equipment and supplies for endovenous laser ablation (ELA) were prepared as follow: operating table which can move up and down with tilting to Trendelenburg and reverse Trendelenburg; DUS using transducer with 7.5 MHz; sterile gowns, gloves, masks, drapes, and gauze; ultrasonographic KY gel with sterile probe using wire shields; local anesthesia; scalpel blade (11); 18-G needle, blade (15), or punch biopsy device; 18–21-G needle for skin puncture; 21–25-G needle for tumescent injection; syringes; normal saline; elastic stockings; an EVLA device (Ceralas 1470 nm); and a catheter (ELVeS Radial, Bioletic, Bonn, Western Germany).

Preoperative preparation

All patients were subjected to provide a written consent with complete history taking. After that, full general and local examination was done, which was followed by full laboratory investigations and preoperative duplex scanning.

Treatment modalities

In the group that underwent EVLA, venous access was obtained while the patient lied in the supine position. In some cases, reverse Trendelenburg position was used to increase the venous hydrostatic pressure.

Spinal anesthesia was used in all patients. Skin nicking was done just to help the introduction of the sheath. We used an ELVeS Radial catheter in all cases. A specific mark on the tip of the catheter is usually present. After that, we fix the laser fiber manually and expose ~3 cm ofthe fiber by pulling the sheath backward. Then, weadjust the whole system according to the beginning point ofthermal ablation.

The second group that was subjected to surgical stripping was managed preoperatively as usual. Then spinal anesthesia was used in all patients. A small transverse incision of 2 cm in width was done in the groin just medial to the palpable femoral pulsation. Delivery of the GSV and ligation of the tributaries was done surgically. A second small infragenicular incision was made handbreadth from the knee. Delivery of the vein was done surgically.

The stripper then was introduced from below upward. We used disposable metallic strippers. Then stripping was done by pulling the stripper from the incision below the knee.

The follow-up then was done with DUS 1 week later, and then follow-up was done at 1 month, 3 months, and 1 year postoperatively.

The primary outcome of the study was the recurrence rate documented by duplex ultrasound examination 6 months after the operation. The secondary outcomes were assessment of the patient satisfaction according to presence of failure rate, complications, postoperative scars, and the hospital stay as well as ambulation time that allows patients to return to normal activities they used to do before the procedure. Scars were defined by presence of any skin incisions more than 2 cm in the limb.

Patient satisfaction was assessed by Aberdeen Varicose Veins Questionnaire. A total of 13 questions were asked to all patients. The scoring system ranges from 0 point,

which means no affection on patient's quality of life, to 100 points, which means severe affection.

Statistical analysis

Data analysis was performed using statistical package for the social sciences, version 21. Qualitative data was expressed as number and percent, and comparison between groups was done using χ^2-test. The quantitative data were expressed as mean±SD. Independent sample *t*-test was used to compare two groups. Kaplan–Meier method was used for survival curves. *P* value of less than 0.05 was considered to be statistically significant (Figs. 1–8 and Tables 1–4).

Results

Demographic data

Our study was conducted on 36 patients presented with primary varicose veins, with 14 (38%) males and 22 (62%) females. The age of our patients ranged from 17 to 45 years old with mean age of 31 years for the laser group and 35 years for the surgical group.

Clinical presentation

All patients presented with heaviness sensation in the lower limb, 30 patients experienced lower limb pain, only four patients had ulcer, 23 patients had edema, and only five patients complained of cosmetic issues.

Operative techniques

There was a significant difference in the operative time in both groups, as the mean time in the laser group was 49.72±27.78 min and in the surgical group was 96.67± 33.43 min, with *P* value less than 0.001.

Figure 1

Assessment of the saphenofemoral junction.

Postoperative hospital stay and complications

In the laser group, the hospital stay ranged from 1 to 2 days, but in the surgical group, it ranged from 2 to 3 days, except for one case, which stayed for only 1 day.

Moreover, there was a significant difference in the ambulation time after intervention in both groups. In laser group, ambulation after surgery was within 2 days, but in the surgical group, it ranged from 2 to 10 days.

Quality of life

Quality of life was assessed by documenting postoperative complications.

Figure 2

Insertion of 6 Fr sheath into the GSV.

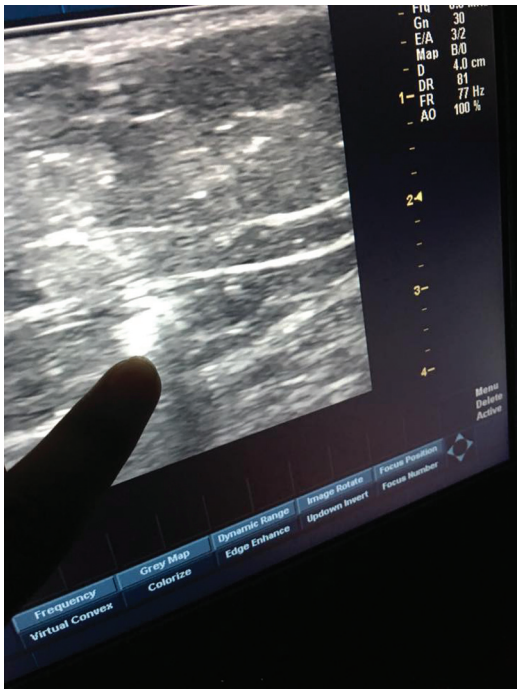
Figure 3

Introduction of the laser fiber through the sheath.

Figure 4

Thermal ablation of GSV.

Figure 5



Another case for thermal ablation of GSV.

Discussion

In our study, female predominance was remarkable, as it represented ~61.1% of patients. This may be because of cosmetic point of views. These data are nearly similar to those of all recent studies.

Figure 6

The light mark at the tip of the catheter, which can be visualized through skin.

Figure 7

During removal of the sheath to start ablation for the infragenicular segment of GSV.

The mean age in our study was 32 years in patients underwent EVLA and 35 years in the surgical group. This was to some extent lower than most studies. In 2010, Christenson *et al.* [3] published their study on 200 limbs, with 100 limbs in each group, and the mean age was 45 years in the laser group and 46 years in the surgical group. There is no definite cause for this discrepancy between studies, but it may be related to social awareness about self-medications and periodic scanning about varicose veins [4].

All patients in our study were presented by limb heaviness. Lower limb pain was documented in 72% of patients who underwent laser ablation, and 95% of patients experienced pain in the surgical group. Only five (13.8%) patients seeked intervention for varicose veins owing to cosmetic issues, with four of them being female and only one male.

There was no significant difference in the operative time between laser and surgical groups in most of the studies published recently. Kalteis *et al.* [5] presented that the mean time was 67 min in laser ablation, which is more than the mean time of surgical group at 60 min only. In Jan 2010, *Jan et al.* also documented that there was no remarkable difference in the treatment time between both groups, with a mean time of 31 min in the high ligation surgery and 32 min in the laser ablation.

However, our study showed different results regarding the operation time. In the laser group, the actual mean time was 50 min, whereas in the surgical group it was 96 min.

Unlike most of the studies, significant differences were recorded in our study according to hospital stay. The mean time in the laser group was 1.28 days, whereas in the surgical group, it was 2.11 days, with *P* value less than 0.001.

Although recent studies showed no difference between surgery and EVLA in the ambulation time, there was a significant difference in our study. Patients who underwent EVLA regained their normal activities after 1–2 days, with mean of 1.5 days, whereas in the surgery group, they returned to their work again after 7–9 days (7.39). *P* value was less than 0.001. This obvious variation may be owing to cultural factors, as

Figure 8

Postoperative case after endovenous laser ablation.

Table 1 Demographic data and clinical presentation in patients with varicose veins

	Laser group (*N*=18)	Surgery group (*N*=18)	*P*
Age	31.33±9.62	35.56±6.39	0.131
Male [*n* (%)]	6 (33.3)	8 (44.4)	0.494
Female [*n* (%)]	12 (66.7)	10 (55.6)	0.494
Clinical presentation [*n* (%)]			
Pain	13 (72.2)	17 (95)	0.306
Edema	10 (55.6)	13 (72.2)	
Ulcer	1 (5.6)	3 (16.7)	
Heaviness	18 (100)	18 (100)	
Cosmetic	3 (16.7)	2 (11.1)	

Table 2 Operative time, intraoperative (IO) complications, hospital stay, and ambulation time

	Group [*n* (%)]		*P*
	Laser group (*N*=18)	Surgery group (*N*=18)	
Intraoperative complications			
No	16 (88.9)	17 (94.4)	0.387
Failed infragenicular access with inaccessible cut down, and ligation with new supragenicular access	1 (5.6)	0 (0.0)	
Cut down	1 (5.6)	0 (0.0)	
Bleeding	0 (0.0)	1 (5.6)	
Operative time (min)	49.72±27.78	96.67±33.43	<0.001
Stay (days)	1.28±0.46	2.11±0.47	<0.001
Ambulation time (days)	1.50±0.51	7.39±2.30	<0.001

Table 3 Postoperative pain, complications, and assessment of quality of life

	Group [*n* (%)]		*P*
	Laser group (*N*=18)	Surgery group (*N*=18)	
Postoperative complications			
No	13 (72.2)	8 (44.4)	0.178
Multiple scars	0 (0.0)	2 (11.1)	
Hematoma	0 (0.0)	1 (5.6)	
Edema	3 (16.7)	3 (16.7)	
Burn	2 (11.1)	0 (0.0)	
Scars	0 (0.0)	1 (5.6)	
Postoperative pain	3 (16.7)	12 (66.7)	0.002
Quality of life			
Not satisfied	2 (11.1)	9 (50.0)	
Satisfied	9 (50.0)	8 (44.4)	0.003
Very satisfied	7 (38.9)	1 (5.5)	

Table 4 Follow-up

	Group [*n* (%)]		*P*
	Laser group (*N*=18)	Surgery group (*N*=18)	
Follow-up DUS at 3 months			
No recurrence	17 (94.4)	17 (94.4)	1.000
Recurrence	1 (5.6)	1 (5.6)	
Follow-up DUS at 6 months			
No recurrence	17 (94.4)	17 (94.4)	1.000
Recurrence	1 (5.6)	1 (5.6)	
Follow-up DUS at 12 months			
No recurrence or symptoms	16 (88.9)	16 (88.9)	0.261
Recurrence (radiologically)	1 (5.6)	2 (11.1)	

DUS, duplex ultrasonography.

patients consider any wound as a major surgery and they must have longer time for rehabilitation.

In our study, follow-up was done by DUS for 1 year. For the first 6 months, identical results were obtained from both groups. Only one case showed recurrence by duplex examination with mild edema.

On 12-month follow-up, only one patient treated by EVLA has recanalization of the proximal half of GSV. On the contrary, two patients treated with surgical stripping complained of recurrent varicosities demonstrated by DUS with minimal edema and no significant manifestations.

In a prospective, nonrandomized study, Proebstle *et al.* [6] demonstrated that recanalization rate of GSV was less than 10% in cases treated with EVLA. Min *et al.* [7] also showed similar results with recurrence rate less than 7%.

In our study, only 11 patients were not satisfied regarding their limbs, with two of them being treated by laser ablation, and this dissatisfaction was owing to presence of superficial burns which needed longer time for follow-up. Nine patients treated by surgery were not satisfied regarding their results, as some of them were seeking for better cosmetic appearance, and the others did not accept the presence of complications, which led them to more delayed return to their usual activities.

On the contrary, most recent studies have documented that both lines of treatment have similar quality of life postoperatively, with similar satisfactory rates, with minimal privilege toward EVLA owing to better cosmetic appearance [5].

Conclusion

In our study, we found that EVLA has similar results as surgical stripping regarding the efficacy and the recurrence rate, which was our primary outcome. Therefore, we recommend EVLA as the main method for varicose vein treatment, with no scars or cosmetic discomfort.

Postoperative pain and complications are less severe in EVLA than surgical stripping. Moreover, EVLA is associated with shorter time in hospital stay than surgery, allowing patients to return more rapidly to their normal activities.

Although EVLA can be named as the main line of treatment in VV, surgical stripping is still considered a cornerstone in VV treatment owing to many obstacles found during our study, mainly its use in skinny patients as they are more liable to be burnt during thermal ablation.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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