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Comparative study between radiofrequency ablation and endovenous laser ablation in the management of primary great saphenous varicose veins

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ORIGINAL STUDY

Comparative study between radiofrequency ablation and endovenous laser ablation in the management of primary great saphenous varicose veins

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Abstract

Background: **Varicose veins are a common presentation of chronic venous disease. Multiple risk factors have been specified by epidemiological studies such as female sex, pregnancy, obesity, and prior deep venous thrombosis.**

Objective: **This is a prospective, comparative study to compare radiofrequency (RF) ablation versus endovenous laser ablation (EVLA) in the management of primary varicose veins of great saphenous vein (GSV).**

Patients and methods: **This study was conducted to 130 patients who had primary great saphenous varicose veins who attended to the vascular department of Ain Shams University Hospitals and El-Sahel Teaching Hospital. The study is a prospective comparative clinical trial.**

Results: **This study compares RF and EVLA in the management of primary GSV varicose veins. Age, sex, BMI, and comorbidities are of no clinical significance in this study. GSV diameter is a significant factor that is important in follow-up to detect the successfulness of the procedure and risk of recurrence. Three diameters of GSV were recorded preoperatively and compared at 1 week, 3 months, and 6 months postoperatively. Classification of varicose veins through the Clinical, Etiological, Anatomical, and Pathophysiological characters of varicose veins (CEAP) and venous clinical severity score (VCSS) were used for clinical assessment of the patients. Most of the cases presented with CEAP classification C2, VCSS score 9. Clinical improvement can be detected by the change of CEAP to C1 or C0, and the VCSS from score 9 to 2 in both study groups.**

Conclusion: **Both RF and EVLA are not significantly different as regards efficacy and complications, with more recurrence and superficial thrombophlebitis in the RF group.**

Keywords: Endovenous laser ablation, Primary great saphenous varicose veins, Radiofrequency

1. Introduction

Varicose veins are a common presentation of chronic venous disease. As regards sex, estimates of varicose veins prevalence are from 1 to 73% in women, and from 2 to 56% in men [1]. Etiology of the varicose veins can be classified as primary and secondary. Primary varices have no exact cause, but it seems to come from hereditary pathology of the vein wall [2], while postthrombotic secondary disease is an acquired inflammatory venous problem [3].

Discomfort, swelling, or ulcers are frequent complaints of chronic venous insufficiency [4]. Patients with varicose veins are usually asymptomatic and they are usually concerned about their cosmetic appearance [5]. To standardize the reporting and treatment of the diverse manifestations of chronic venous disorders, a comprehensive classification system called classification of varicose veins through the Clinical, Etiological, Anatomical, and Pathophysiological characters of varicose veins (CEAP) has been proposed to allow uniform

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diagnosis and comparison of patient populations [6]. Other clinical scoring systems were developed to provide a more dynamic assessment of patient status over time. The venous clinical severity score (VCSS) is the most widely used clinical scoring tool [7].

Duplex ultrasound is the gold standard technique used for evaluation of varicose veins. It can detect venous reflux that is defined as reverse flow occurring after the cessation of forward flow [8]. It is generally held to be significant if it lasts more than 0.5 s in the superficial veins, and more than 1 s in the deep veins [9].

High ligation of the great saphenous vein (GSV) is the conventional surgery used [10]. Although effective in management of tortuous veins, surgery can produce hematomas, superficial thrombophlebitis, and deep venous thrombosis (DVT) [11]. Both endovenous laser ablation (EVLA) and radiofrequency (RF) ablation are considered safe and efficacious and are recommended in preference to open surgery [12]. Endovenous ablation is suitable for superficial veins that lie subfacial, with minimal tortuosity, obese patients, and previous superficial thrombophlebitis [13].

RF ablation and EVLA are not significantly different. The 6-month follow-up showed recurrence only in the RF group, which was associated with large preoperative GSV diameter. No recurrence could be detected in the EVLA group. Age, sex, BMI, and comorbidities were not correlated to recurrence in our study and of no clinical significance.

2. Aim

In this study, we compared EVLA and RF, in terms of postoperative pain, endovenous heat-induced thrombosis (EHIT), DVT, skin burn and pigmentation, hematoma, neurological complications, superficial thrombophlebitis requiring analgesics for 2 weeks or no additional therapy, and recurrence.

3. Patients and methods

In total, 130 patients, 18 men and 112 women, with symptomatic GSV reflux, were treated by endovenous ablation and followed for 6 months. They were divided into two groups, first group 65 patients treated by RF, second group 65 patients treated by EVLA.

3.1. Inclusion criteria

(1) Patients with primary GSV reflux (reflux: pathological retrograde flow of blood in the vein as a result of valve absence for more than 0.5 s on compression by duplex ultrasound) [14].
(2) C2, C3, C4, and C5 according to CEAP classification.
(3) Age from 18 to 60 years old.

3.2. Exclusion criteria

(1) Refusal of the patient to perform the procedure.
(2) History of recent or old DVT.
(3) Recurrent varicose veins.
(4) Patient is on anticoagulation.
(5) Females who are pregnant or breastfeeding.

3.3. Preoperative assessment

(1) History taking.

Personal history: age, sex, BMI, current occupation, and past medical and surgical history, including DVT, diabetes (DM), hypertension (HTN), and any previous lower limb surgery, drug history, including anticoagulation, presenting the symptom of primary GSV reflux.

(2) Clinical examination: based on CEAP and VCSS systems, inspection, and plapation.
(3) Laboratory investigations.

Venous duplex of the affected lower extremity describing patency and reflux of the common femoral and femoral veins, popliteal vein, and tibial veins. Patency, reflux, and diameter of the GSV (diameter measured at proximal, midthigh, and distal thigh). Patency and reflux of the small saphenous vein (SSV), sapheno-femoral junction (SFJ), sapheno-popliteal junction (SPJ), and accessory veins reflux.

3.4. Technique

3.4.1. Radiofrequency ablation

Patients were put in supine reverse Trendelenburg position, spinal or local anesthesia is used. Under the guidance of duplex ultrasound, access into the GSV below the knee using 18 G needle is done followed by 7 F sheath. The patient position is then changed to Trendelenburg position, closureFast Medtronic 7 × 100-cm catheter is used. The final position of the tip of the catheter was confirmed by ultrasound, typically 2 cm below the saphenofemoral junction. Injection of tumescent anesthesia around the target vein is done. After tumescent injection, ablation of the vein is started. During energy delivery, the catheter remains stationary for a period of 20 s.

Table 1. Comparison between radiofrequency group and endovenous laser ablation group according to baseline characteristics.

Baseline characteristics	RF group ($N = 65$)	EVLA group ($N = 65$)	Test value	P value
Age (years)				
Mean ± SD	33.28 ± 5.29	32.86 ± 6.34	$t = 0.406$	0.686
Range	23–47	20–47		
Age (group) [n (%)]				
18–35 (years)	47 (72.3)	48 (73.8)	χ^2=0.039	0.843
36–60 (years)	18 (27.7)	17 (26.2)		
Sex [n (%)]				
Female	57 (87.7)	55 (84.6)	χ^2=0.258	0.612
Male	8 (12.3)	10 (15.4)		
BMI [weight/(height)^2]				
Mean ± SD	25.77 ± 3.55	25.52 ± 3.25	$t = 0.170$	0.681
Range	20–35	20–35		
Comorbidity [n (%)]				
DM	2 (3.1)	3 (4.6)		
HTN	3 (4.6)	2 (3.1)	χ^2=0.400	0.819
Non	60 (92.3)	60 (92.3)		

χ^2, χ^2 test; EVLA, endovenous laser ablation; RF, radiofrequency; t, independent sample t test.
P value greater than 0.05, nonsignificant.

3.5. Endovenous laser ablation

Patients were put in supine reverse Trendelenburg position. Under the guidance of duplex ultrasound, access into the GSV below the knee using 18 G needle is done followed by 6 F sheath. EVLA catheter with radial tip is used. The final position of the tip of the catheter is confirmed by ultrasound, typically 2 cm below the saphenofemoral junction. After tumescent injection, ablation of the vein is

Table 2. Comparison between radiofrequency group and endovenous laser ablation group according to radiological and clinical findings preoperatively.

Preoperative	RF group ($N = 65$)	EVLA group ($N = 65$)	Test value	P value
Radiological				
Deep veins [n (%)]				
Patient, competent	65 (100.0)	65 (100.0)	χ^2=0.000	1.000
Diameter of the GSV (mm)				
Proximal thigh				
Mean ± SD	8.28 ± 1.04	8.25 ± 0.95	$t = 0.034$	0.854
Range	7–11	7–10.5		
Midthigh				
Mean ± SD	8.21 ± 0.96	8.27 ± 0.92	$t = 0.119$	0.730
Range	7–11	7–11		
Distal thigh				
Mean ± SD	7.91 ± 0.86	7.86 ± 0.79	$t = 0.130$	0.719
Range	7–10.5	7–10.5		
Reflux [n (%)]				
Reflux	65 (100.0)	65 (100.0)	χ^2=0.000	1.000
Clinical [n (%)]				
CEAP				
C2	47 (72.3)	48 (73.8)		
C3	10 (15.4)	10 (15.4)	χ^2=0.077	0.962
C5	8 (12.3)	7 (10.8)		
VCSS [n (%)]				
Score 7	10 (15.4)	7 (10.8)		
Score 8	12 (18.5)	9 (13.8)		
Score 9	26 (40.0)	24 (36.9)	χ^2=3.419	0.636
Score 10	15 (23.1)	20 (30.8)		
Score 11	2 (3.1)	4 (6.2)		
Score 12	0	1 (1.5)		

χ^2, χ^2 test; EVLA, endovenous laser ablation; GSV, great saphenous vein; RF, radiofrequency; t, independent sample t test; VCSS, venous clinical severity score; z, Mann–Whitney U test.
P value greater than 0.05, nonsigificant.

Table 3. Comparison between radiofrequency group and endovenous laser ablation group according to complications.

Complications	RF group ($N = 65$) [n (%)]	EVLA group ($N = 65$) [n (%)]	Test value	P value
DVT	0	0	0.000	1.000
EHIT	3 (4.6)	2 (3.1)	0.208	0.648
Skin burn and pigmentation	2 (3.1)	2 (3.1)	0.000	1.000
Incomplete obliteration	0	0	0.000	1.000
Neurological complications	5 (7.7)	5 (7.7)	0.000	1.000
Hematoma/ecchymosis	18 (27.7)	20 (30.8)	0.149	0.700
Superficial thrombophlebitis	2 (3.1)	0	2.031	0.154
Postoperative pain	9 (13.8)	7 (10.8)	0.285	0.593
Recurrence	2 (3.1)	0	2.031	0.154

χ^2, χ^2 test; DVT, deep venous thrombosis; EVLA, endovenous laser ablation; EHIT, endovenous heat-induced thrombosis; RF, radiofrequency.
P value greater than 0.05, nonsigificant.

started. Laser fiber is then withdrawn at a rate of 1–3 mm/10 s, more slowly for the proximal 10 cm and more quickly distally.

3.6. Postoperative assessment

All patients were assessed clinically and radiologically by duplex ultrasound at 1 week, 3 months, and 6 months postoperatively.

Follow-up included clinical examination, including reevaluation by CEAP and VCSS classifications, duplex ultrasound at 1 week, 3 months, and 6 months postoperatively.

3.7. Statistical analysis

Recorded data were analyzed using the Statistical Package for Social Sciences, version 23.0 (SPSS Inc., Chicago, Illinois, USA). The quantitative data were presented as mean ± SD and ranges. Also, qualitative variables were presented as number and percentages. Data were explored for normality using Kolmogorov–Smirnov and Shapiro–Wilk test. P value less than 0.05 was considered significant, P value less than 0.001 was considered as highly significant, and P value greater than 0.05 was considered insignificant.

4. Results

Tables 1–7 and Figs. 1 and 2.

5. Discussion

Lower limb varicose vein treatment has changed over the last years, and endovenous ablation was found to be less invasive with optimal results procedure. This study is carried out to compare the RF group and EVLA group in the management of primary GSV varices. Both groups were matched regarding age ($P = 0.843$), sex ($P = 0.612$), and BMI ($P = 0.681$). CEAP classification, VCSS, and radiological follow-up over 6 months were the major determinants for comparison.

All patients demonstrated complete occlusion of the GSV. A clinical improvement of the patients' condition can be detected by the decreasing CEAP classification and VCSS over a 6-month period, with 66.2% at C1 and 33.8% at C0 in RF group, 69.2% at C1 and 30.8 at C0% in EVLA group. VCSS also showed improvement along the follow-up period as score 9 representing the highest percentage preoperatively (40% in RF, 36.9% in EVLA), while score 2 is the highest percentage among patients at 6 months in both RF and EVLA groups (49.2% in RF, 47.7% in EVLA).

Table 4. The mean great saphenous vein diameter at proximal, midthigh, and distal thigh, documented at preoperative, postoperative, 1 week, 3 months, and 6 months in the radiofrequency group.

Diameter of the great saphenous vein (mm)	Preoperative	Postoperative (1 week)	Postoperative (3 months)	Postoperative (6 months)	F test	P value	η^2
Proximal thigh	8.28 ± 1.04A	5.18 ± 0.41B	4.65 ± 0.39C	4.15 ± 0.38D	847.000	<0.001**	0.929
Midthigh	8.21 ± 0.96A	5.11 ± 0.45B	4.54 ± 0.45C	4.01 ± 0.42D	985.547	<0.001**	0.939
Distal thigh	7.91 ± 0.86A	5.15 ± 0.42B	4.49 ± 0.44C	3.90 ± 0.39D	1056.173	<0.001**	0.943

Repeated measurements analysis of variance about Bonferroni. Means that do not share the same letter are significantly different at P value less than 0.05. **$P \leq 0.01$.
P value greater than 0.05, non-significant.
P value less than 0.05, significant.
P value less than 0.001, highly significant.

Table 5. The mean great saphenous vein diameter at proximal, midthigh, and distal thigh, documented at preoperative, postoperative, 1 week, 3 months, and 6 months in the endovenous laser ablation group.

Diameter of the great saphenous vein (mm)	Preoperative	Postoperative (1 week)	Postoperative (3 months)	Postoperative (6 months)	*F* test	*P* value	η^2
Proximal thigh	8.25 ± 0.95A	5.16 ± 0.46B	4.72 ± 0.43C	4.19 ± 0.40D	822.051	<0.001**	0.928
Midthigh	8.27 ± 0.92A	5.11 ± 0.44B	4.62 ± 0.40C	4.06 ± 0.40D	868.769	<0.001**	0.931
Distal thigh	7.86 ± 0.79A	4.95 ± 0.37B	4.41 ± 0.40C	3.87 ± 0.40D	878.034	<0.001**	0.932

Repeated measurements analysis of variance about Bonferroni. $^{**}P \leq 0.01$.
Means that do not share the same letter are significantly different at *P* value less than 0.05.
P value greater than 0.05, nonsignificant.
P value less than 0.05, significant.
P value less than 0.001, highly significant.

Table 6. Percentage of the C class of CEAP classification at preoperative and postoperative, 1 week, 3 months, and 6 months of the radiofrequency group.

CEAP	Preoperative [*n* (%)]	Postoperative (1 week) [*n* (%)]	Postoperative (3 months) [*n* (%)]	Postoperative (6 months) [*n* (%)]	Test value	*P* value
C0	0	0	0	22 (33.8)		
C1	0	57 (87.7)	65 (100.0)	43 (66.2)		
C2	47 (72.3)	0	0	0	346.012	<0.001**
C3	10 (15.4)	0	0	0		
C4	0	8 (12.3)	0	0		
C5	8 (12.3)	0	0	0		

χ^2, χ^2 test. $^{**}P \leq 0.01$.
P value greater than 0.05, nonsignificant.
P value less than 0.05, significant.
P value less than 0.001, highly significant.

This is supported by Mishra et al. [15] study, which detected the clinical improvement of patients who performed endovenous ablation on follow-up, which can be documented by VCSS value improvement.

A significant decrease in the treated GSV diameter is noticed over the 6-month period. In a nonrandomized prospective study by Pannier et al. [16], patients who performed endovenous ablation for varicose vein treatment showed higher initial vein diameter when compared with the successfully treated vein, with a reduction of about 50% of diameter.

In this study, two cases of the RF group complained of superficial thrombophlebitis after 4 days of the procedure. Local ointment and close follow-up were sufficient to treat it. Tolva et al. [17] documented a number of cases of superficial thrombophlebitis after endovenous ablation, which were managed either spontaneously or by local anti-inflammatory cream.

In our study, hematoma and ecchymosis represent the most common complications in both RF and EVLA groups, with more incidences in the EVLA group, by 27.7 and 30.8%, respectively. This is followed by postoperative pain. In a previous randomized controlled study by Hamann et al. [18], it was found that pain represents the most common complication

Table 7. Percentage of the C class of CEAP classification at preoperative and postoperative, 1 week, 3 months, and 6 months of the endovenous laser ablation group.

CEAP	Preoperative [*n* (%)]	Postoperative (1 week) [*n* (%)]	Postoperative (3 months) [*n* (%)]	Postoperative (6 months) [*n* (%)]	Test value	*P* value
C0	0	0	0	20 (30.8)		
C1	0	58 (89.2)	58 (89.2)	45 (69.2)		
C2	48 (73.8)	0	0	0	320.525	<0.001**
C3	10 (15.4)	0	7 (10.8)	0		
C4	0	7 (10.8)	0	0		
C5	7 (10.8)	0	0	0		

$\chi 2$, $\chi 2$ test. $^{**}P \leq 0.01$.
P value greater than 0.05, nonsignificant.
P value less than 0.05, significant.
P value less than 0.001, highly significant.

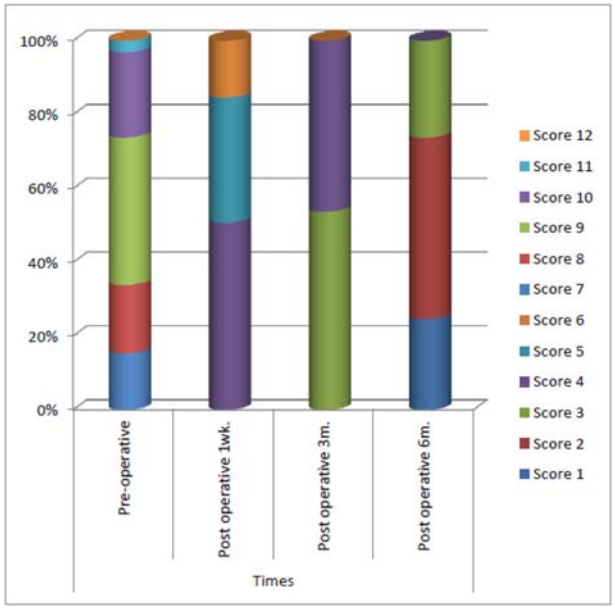

Fig. 1. VCSS at preoperative, postoperative, 1 week, 3 months, and 6 months of the RF group. RF, radiofrequency; VCSS, venous clinical severity score.

of both RF and EVLA groups, followed by hematoma and ecchymosis in contrast to our study.

One of the least-presenting complications in this study is skin burn and pigmentation, only 3.1% of both RF and EVLA groups experienced skin burn and pigmentation. Merchant et al. [19] reported a 4.2% rate of skin burn and pigmentation in half the

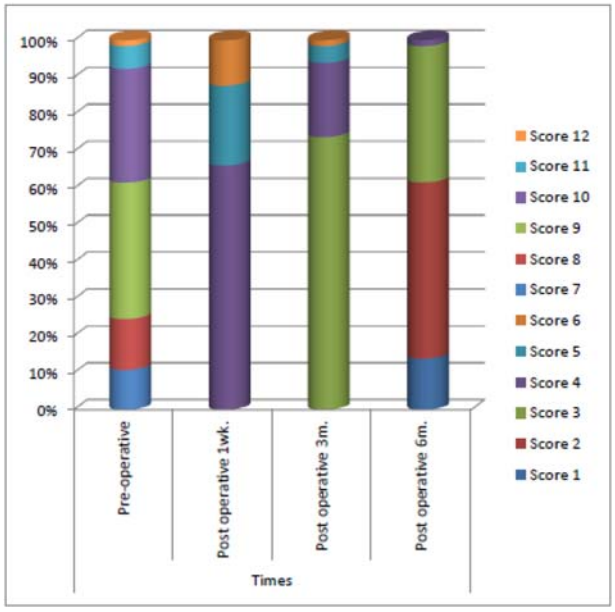

Fig. 2. VCSS at preoperative, postoperative, 1 week, 3 months, and 6 months of the EVLA group. EVLA, endovenous laser ablation; VCSS, venous clinical severity score.

number involved in the study after endovenous ablation, which then decreased after better use of tumescent anesthesia.

No DVT could be detected in our study either in the RF group or the EVLA group. In Van Den Bos et al. [20], DVT incidence ranges from 0 to 5% of cases, and usually affects gastrocnemius veins. About 4.6% of RF-group and 3.1% of EVLA-group patients developed EHIT that could be detected at 1-week follow-up. Pugioni et al. [21] show that 2.3% of patients involved in the study suffer from EHIT and were all after EVLA, so they were recommended routine duplex evaluation after endovenous ablation.

In this study, only two cases of recurrence could be detected and both occurred in the RF group after 6 months of ablation of a large-diameter GSV. According to the recurrent veins after thermal ablation (REVATA) study, RF shows more incidence of recurrence than EVLA, but diseased perforators are responsible for the majority of varicose recurrence [22].

5.1. Conclusion

The two methods are not significantly different in postoperative pain, pigmentation, EHIT, neurological complications, hematoma, and clinical improvement of the patient. The 6-month follow-up showed recurrence only in the RF group, which was associated with large preoperative GSV diameter. No recurrence could be detected in the EVLA group. Age, sex, BMI, and comorbidities were not correlated to recurrence in our study and of no clinical significance. In addition, superficial thrombophlebitis was reported in the RF group.

Conflict of interest

There are no conflicts of interest.

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