

Comparison between Endovenous Laser and Endovenous Radiofrequency Thermal Ablation in Patients with Great Saphenous Vein Incompetence

Original Article

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ABSTRACT

Background: It is said that ultrasound-guided treatments, such as endovenous thermal ablation using two techniques—endovenous laser ablation (EVLA) and radiofrequency ablation (RFA)—have improved patient satisfaction and produced positive clinical outcomes. Comparing EVLA with RFA in patients with great saphenous vein (GSV) incompetence was the goal of this study.

Patients and Methods: A total of 38 patients of both sexes, ages 18–70, with incompetent sapheno-femoral junctions and GSV greater than 1s were included in this comparative investigation. Every patient had RFA and EVLA.

Results: The mean GSV diameter for laser ablation was 6.52 ± 1.271 in group I, while the mean GSV diameter for RFA was 7.12 ± 1.271 in group AA. Following surgery, the GSV diameter dramatically reduced, reaching a mean of 0.52 ± 0.252 in group I after 6 months of follow-up, and a mean value of 0.82 ± 0.252 in group II. We discovered a nonsignificant difference between the two treatments when we compared the GSV diameters of the two study groups after the surgery. Other for recurrence, which is higher in group II than in group I, there was no discernible difference in the main problems.

Conclusion: The effectiveness of EVLT and RF ablation in treating lower leg varicose veins and demonstrate that there are no appreciable differences between the two techniques in terms of procedure duration, clinical improvement, and postoperative GSV occlusion.

Key Words: Endo-Venous, Laser, Radio Frequency, Saphenous Vein Incompetence, Thermal Ablation.

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INTRODUCTION

At least 10% of the general population has varicose veins, which is a prevalent condition. Fine reticular varicosities, telangiectasia, and dilated and tortuous veins are some of the symptoms of varicose veins^[1].

Primary varicose veins are caused by intrinsic anomalies of the venous wall, while secondary varicose veins are linked to pelvic tumours, deep vein thrombosis (DVT), and other conditions^[2]. Individuals with varicose veins may have early tiredness, soreness, heaviness, pruritus, and an ugly look of the afflicted leg. Elevating the leg above the level of the heart relieves these sensations, which get worse with extended standing and sitting^[3].

For individuals with great saphenous veins (GSV) of extremely big diameter (>2cm), triple saphenectomy

(sapheno-femoral disconnection, GSV stripping, and stab avulsion) may be the recommended treatment^[4].

Endovenous thermal ablation (EVTA) is the result of complications related to GSV stripping and the development of minimally invasive methods for treating GSV reflux^[5]. EVTA is a more recent method that produces severe local heat in varicose or incompetent veins using a laser or high radiofrequency radiation. The target vessel is closed by applying heat using a catheter. In order to minimize bleeding and bruises, this procedure shuts the damaged veins while leaving them intact^[6].

Neovascularization is believed to be the result of angiogenesis after the tissue trauma of surgical dissection, while extravascular inflammation is thought to not occur

after EVTA^[7]. Neovascularization has been implicated as the leading cause of surgical recurrence in multiple studies, with rates as high as 52% at 2 years and 79% at 5 years.

In patients with acute DVT, acute infections at the puncture site, and deep vein occlusion when the target vein serves as a collateral, endovenous laser ablation (EVLA) is completely contraindicated. Additionally, certain technical issues such as tortuous veins, too wide sapheno-femoral junctions (SFJs) or GSVs, intraluminal webs, and pregnancy are relatively contraindicated. Additionally, ablation of veins closer to the skin after tumescent anesthesia may result in skin burns if the target veins are not at least 1cm deep to the skin dermis^[8].

This study compared the effects of EVLA and radiofrequency ablation (RFA) on patients with GSV incompetence. It also assessed the differences between EVLA and ERFA in terms of efficacy, early and long-term complications, and patient satisfaction with regard to cosmetic appearance and returning to normal activities.

PATIENTS AND METHODS:

A total of 38 patients of both sexes, ages 18–70, with incompetent SFJ and GSV greater than 1 s were included in this comparative investigation. After receiving clearance from the Suez Canal University Hospitals' Ethical Committee in Ismailia, Egypt, the study was conducted from March 2021 to 2023. The patients gave their signed, informed permission. Group I: EVLA and group II: RFA were the two equal groups into which the patients were split.

Those with DVT, pregnancy, breastfeeding, severe illness, recurring cases, and those with secondary varicose veins were excluded.

Complete history taking, clinical examination, laboratory tests (complete blood count, FBS, glycated hemoglobin, HbA1c, prothrombin time, PTT, international randomized ratio, and serum creatinine), and radiological tests (duplex ultrasound, US, color-flow Doppler, and gray-scale B-mode) were performed on all patients.

Operative technique

Both procedures EVLA and RFA was done in the operating room. The whole procedure was be performed under US guidance. Spinal or tumescent anesthesia. Tumescent anesthesia [lignocaine (20ml 2% lignocaine with 1:100,000 Adrenaline mixed with 480ml normal saline)], adding 10ml of sodium bicarbonate was used to decrease the irritation that might happen by the acidic lignocaine. The knee joint, or just below it, is the intended access point. Access was started using a micro-access set (20-gauge needle and 6F sheath in EVLA group and 7F sheath in RFA group). To calculate the quantity of energy to be delivered by the laser generator, the diameter of

the long saphenous vein is measured using the US. The generator is then modified to aim for a goal energy delivery of 60–80Joules/centimetre (J/cm) of vein length. After that, the generator is attached to the laser catheter, the aiming beam is activated to aid see the fibre tip beneath the skin, the laser catheter is inserted, and its placement—which is confirmed by US to be 2cm below SFJ—is verified. Tumescent anesthesia is prepared for administration; a 22- or 25-gauge hypodermic needle is used to inject the drug perivenously. Administration was done via pump, syringe refill system, or manual delivery. Before starting the process, the laser fibre tip's position is verified again. A laser wavelength of 1470nm was employed. Catheter withdrawal was done continuously until the puncture point was close to the skin's surface exit.

When it came to tumescent anesthesia injection, catheter tip placement, and vein access, RFA treatments were carried out in the same way. Then, in distinct 20s cycles separated by 6.5–7cm, heat energy (1200C) was applied segmentally. At the beginning point, which was 2cm distal to the SFJ, two successive 20s cycles were administered; one cycle was applied to each of the other segments. A sterile 2-inch gauze pad was used to cover the entrance site, and a half-inch piece of Steri-Strip (3M, St. Paul, MN) was cut into thirds.

For the first week, patients were equipped with a graded bandage that was 30–40mmHg. They were also ordered to wear the stockings constantly throughout the day, and for the second week, they were not allowed to sleep. To encourage the vascular occlusion process and lower the risk of DVT, patients start walking right away.

Postoperative care and follow-up examination

The patient was discharged on the same day. Clinically, evaluation was assessed on the: one week after the procedure patient is checked to assess pain, skin and diameter of GSV is taken by duplex US. The patient was seen in the outpatient clinic 1 month following the treatment to check for paraesthesia, discomfort, residual symptoms, and any ecchymosis. To determine the extent of venous blockage, patients had duplex US scanning three months following the surgery. Any occlusion that was shorter than the entire duration of treatment was rated as partially occluded and categorized as follows: a brief section that was fully opened and less than 5cm. Long section fully expanded over 5cm. No portions were opened. GSV diameter measurements were obtained using an outpatient duplex US and a 6 month follow-up visit.

Statistical analysis

SPSS v26 was used for statistical analysis (IBM Inc., Chicago, Illinois, USA). The mean and SD of the quantitative variables were shown, and the unpaired Student's *t*-test was used to compare the two groups. When applicable, the χ^2 or Fisher's exact test was used to analyze the qualitative variables, which were shown as frequency

and percentage (%). Statistical significance was defined as a two-tailed *P* value less than 0.05.

RESULTS:

The average age was 36.4 ± 6.17 , 28(73.7%) patients had a standing employment, 30(79.0%) patients were married, and 22(51.9%) cases were female. Eight (21.1%) patients had discomfort and leg heaviness, four (10.5%) patients experienced ulcers, and 26(68.4%) patients experienced disfigurement. 34(89.5%) patients had SPJ that was competent (Table 1).

Table 1: Demographic data, complaint, SFJ and SPJ competence of the studied patients:

| N= 38 | | |
|-------------------------|---------|-----------|
| Age (years) | | 36.4±6.17 |
| Sex | Male | 16(42.1%) |
| | Female | 22(57.9%) |
| Marital status | Married | 30(79.0%) |
| | Single | 8(21.0%) |
| Job | | 28(73.7%) |
| Complain | | 26(68.4%) |
| Disfigurement Ulcer pin | | 4(10.5%) |
| | | 8(21.1%) |
| SFJ competence | | 0(0.0%) |
| SPJ competence | | 34(89.5%) |

Data are presented as mean±SD or frequency (%); SFJ: Sapheno-Femoral Junction; SPJ: Sapheno-Popliteal Junction.

The mean GSV diameter for laser ablation was 6.52 ± 1.271 in group I, while the mean GSV diameter for

RFA was 7.12 ± 1.271 in group 'A'. By the 12th month of follow-up visits, two patients in groups I and II experienced recanalization of short-segment (below 5cm) occlusion, one and two experienced recanalization of long-segment occlusion, and one and two experienced recurrent varicose veins (Table 2).

GSV diameter dropped dramatically after surgery, reaching a mean of 0.52 ± 0.252 in group I after 6 months of follow-up, and a mean of 0.82 ± 0.252 in group II. We discovered a nonsignificant difference between the two treatments when we compared the GSV diameters of the two study groups after the surgery (Table 3).

There was no significant difference in the major complications except in recurrence, which is more in group II than group I, however, two groups are close in the minor and short-term complications (Table 4).

Table 2: Pre-operative diameter of GSV and evaluation of treatment failure in two study groups:

| | Group I(n=19) | Group II (n=19) |
|---|------------------|------------------|
| GSV diameter (4.50 – 9.50mm) | 6.52 ± 1.271 | -- |
| GSV diameter (5. 50 – 10.0mm) | -- | 7.12 ± 1.271 |
| Evaluation of treatment failure | | |
| Recanalization of short segment (below 5cm) occlusion | 2(10.526%) | 2(10.526%) |
| Recanalization of long segment (above 5cm) occlusion | 1(5.263%) | 2(10.526%) |
| Recurrent varicose veins by 12 th month | 1(5.263%) | 2(10.526%) |

Data are presented as mean±SD or frequency (%). GSV: great saphenous vein.

Table 3: Evaluation of GSV diameter preoperatively and postoperatively after EVLA and RFA ablation:

| | | Follow-up | | | |
|----------------------------|------------|--------------|------------|------------|------------|
| | | Preoperative | 1 week | 1 month | 3 months |
| After EVLA ablation | | | | | |
| GSV diameter | 6.52±1.271 | 5.31±1.273 | 3.50±1.070 | 1.88±0.731 | 0.52±0.252 |
| After RFA ablation | | | | | |
| GSV diameter | 7.12±1.271 | 5.31±1.273 | 3.50±1.070 | 2.28±0.731 | 0.82±0.252 |

Data are presented as mean±SD; GSV: Great Saphenous Vein; EVLA: Endovenous Laser Ablation; RFA: Radio-Frequency Ablation.

Table 4: Complications in the two study groups:

| | Group I (n=19) | Group II (n=19) |
|-----------------------------------|----------------|-----------------|
| Postoperative pain | ++ | + |
| Paresthesia | 0(0.0%) | 1(5.26%) |
| Transient ecchymosis and bruising | 8(42.11%) | 5(26.32%) |
| Permanent pigmentation | 0(0.0%) | 1(5.26%) |
| DVT | 0(0.0%) | 0(0.0%) |
| Recanalization | 1(5.26%) | 2(10.53%) |
| Recurrence | 1(5.26%) | 2(10.53%) |

Data are presented as frequency (%). DVT: deep venous thrombosis.

DISCUSSION

For a long time, high ligation at the sapheno-femoral junction and GSV stripping were the preferred methods of managing sick veins, and surgery was thought to be the gold standard for treating VV. Additionally, stripping and SPJ ligation were used as surgical treatments for SSV reflux^[9].

Every patient in our research had a leg ulcer or discomfort from skin deformity. Eight patients had discomfort and heaviness, four patients experienced leg ulcers, and 26 patients experienced skin disfigurement due to varicosities. According to Jan T. *et al.*, who recorded 200 limbs, 89% of them experienced heaviness, and all of them complained of discomfort.

About 20% of patients who have EVLA and surgical stripping present primarily with deformity and seek help [10]. In their study, Mozafar and Khashayar found that 85% of patients had highligation surgery, and 92.3% of patients in the thermal ablation group had cosmetic problems that required treatment.

Recently published studies documented that there was no significant difference in preoperative diameter of GSV, in our study it ranged between 4.50 and 9.50mm, with a mean value of 6.52 ± 1.271 in group I for Laser ablation and between 5.50 and 10.0mm, with a mean value of 7.12 ± 1.271 in group II for RFA, Bozoglan *et al.*,^[11] showed the GSV diameter in two groups and there was no significant difference.

We concluded that the two treatment techniques were beneficial since the two study groups demonstrated relief of symptoms following the operation, particularly leg discomfort and heaviness, and the major clinical findings of the treatments did not differ between the two groups. In agreement, Guangzhi *et al.*,^[12] came to the same conclusions on this issue. In our investigation, the two groups' postoperative pain scores were similar and did not differ significantly. Tofigh *et al.*,^[13] reported pain scores both during and after the two operations, and there was no discernible difference between the two groups on this issue.

One of the most crucial aspects of patient satisfaction is getting back to his regular daily activities. We found that there was no difference between the two study groups and that it took anywhere from five to ten days, depending on the patient's desire and will to resume his daily activities. Additionally, Ahadiat *et al.*,^[14] found no discernible difference in the speed at which the two treatment groups returned to work.

Major adverse events, such as DVT, did not significantly vary between the two treatment groups in the current research.

Impaired superficial sensation due to saphenous nerve damage is a rather common side effect after GSV stripping; it has been reported to happen in 23–40% of patients undergoing whole saphenectomy and 7–19% of those undergoing partial saphenectomy (above the knee). Our research revealed that saphenous nerve neuralgia was similar in RFA and EVLA. Only one patient in the RFA group had saphenous nerve neuralgia by the third month. Despite using a different sample size, Ewida *et al.*,^[15] obtained the same outcome.

Regarding skin pigmentation and postoperative ecchymosis, we found that In EVLA group there were eight patients suffering from transient skin ecchymosis and bruising during the first week while only one patient complicated with persistent skin hyperpigmentation. In RFA group only five patients were suffering from transient skin ecchymosis and bruising by the first week, but one patient complicated with persistent skin hyperpigmentation. According to our study sample size RFA is superior on EVLA concerning skin bruising and sin ecchymosis which resolves completely by the second week without any remnants. Shepherd *et al.*,^[16] reported that there was no significant difference between treatment groups in skin ecchymosis, bruising and pigmentation.

There were no recorded cases complicated with persistent saphenous nerve damage in the groups of study. Mohammadi *et al.*,^[13] reported the same results as our study.

The GSV diameter in the current research dropped considerably following surgery, reaching a mean of 0.52 ± 0.252 in the EVLA group after 6 months of follow-up, and a mean value of 0.82 ± 0.252 in the RFA group. This data indicates that there was no significant difference between the two methods; nonetheless, there was a noticeable drop in GSV diameter in both groups. Similar findings with a notable reduction in GSV width and no discernible difference between treatment groups during the same follow-up time were reported by Shepherd *et al.*,^[16]

We discovered that two patients in the EVLA group experienced recanalization of short segment (below 5cm) occlusion, one patient experienced recanalization of long-segment occlusion, and one patient experienced recurrent varicose veins. Two patients in the RFA group experienced recanalization of short-segment (less than 5cm) occlusion, two patients experienced recanalization of long-segment occlusion, and one patient experienced recurrent varicose veins. Although the recanalization of the short segment of GSV was shown to be greater in the EVLA group than in the RFA group, Ewida *et al.*,^[15] observed results that

were similar to our study in terms of the recanalization of the long-segment.

With the exception of one patient who had saphenous nerve neuralgia during the RFA operation, which resolved three months after the surgery without any issues, we discovered that both treatment groups in our research were happy with the outcomes. According to Dermody *et al.* patients who had either EVLA or RFA experienced the same positive outcomes. Additionally, several studies have shown that both methods had comparable satisfaction rates and the same quality of life after surgery. According to several meta-analysis studies, such as the one by Luebke *et al.*,^[17] EVLA has a longer-lasting positive impact on “occlusion recanalization, recurrence, phlebitis, DVT, and paraesthesia” than RFA.

In the current study, we did not find any fundamental difference between the two treatment methods, and neither procedure is superior on the other in absolute term, but we find that RFA is better in postoperative pain and skin bruising and ecchymosis while EVLA is better in recanalization and recurrence results.

CONCLUSION

The effectiveness of RFA and EVLT in treating varicose veins in the lower limbs. They further demonstrate that there are no appreciable differences between the two approaches in terms of operation duration, clinical improvement, and postoperative GSV occlusion. There is no difference in serious complications or postoperative discomfort, according to the results of the 1-year follow-up. Although the RFA group experienced a recurrence, several studies have found no discernible difference in recurrence rates between the two treatments. Laser catheters are preferable in terms of handling and manipulation, and the light at the tip of the catheter can be seen in the groin and along the vein, which makes it easier for the operator to inspect the area. Additionally, throughout the treatment, we may carefully examine vein obliteration using a laser catheter.

CONFLICT OF INTEREST

There are no conflicts of interest.

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