



## ORIGINAL ARTICLE

# MULTICENTER COMPARATIVE STUDY BETWEEN ENDOVENOUS RADIOFREQUENCY ABLATION AND ENDOVENOUS LASER THERAPY IN MANAGEMENT OF PATIENTS WITH PRIMARY VARICOSE VEINS

Wael El.Shimy,<sup>1</sup> Ashraf Eweda,<sup>2</sup> Mohamed Effat,<sup>1</sup> Abdelrahman M. Gameel,<sup>1</sup> Ahmad Tawfik,<sup>1</sup> Amro Elboushi,<sup>1</sup> Medhat Ellabody,<sup>1</sup> Hany Abd Momen Mohamed Hossein,<sup>2</sup> Mohamed Sagher,<sup>2</sup> Ehab Abdoh<sup>2</sup>

<sup>1</sup>Vascular and Endovascular Surgery Unit, Faculty of Medicine, Zagazig University, <sup>2</sup>Vascular and Endovascular Surgery Unit, Faculty of Medicine, Alazhar University, Egypt

Correspondence to: Wael El.Shimy, Email: wael.elshimy@yahoo.com

### Abstract

**Background:** The treatment of varicose (GSV) reduces the symptoms and the complications of venous insufficiency and increases the quality of life (2). Endovenous laser therapy (EVLT) and radiofrequency ablation (RFA) of the great saphenous vein (GSV) have been introduced as alternative and minimally invasive techniques for the treatment of truncal vein incompetence

**Purpose:** This prospective comparative study was conducted to evaluate the effectiveness of endovenous treatment of symptomatic varicose veins using the endovenous Laser therapy (EVLT) or radiofrequency ablation (RFA) and to describe the complications and short term outcome of patients follow up.

**Methods:** This is a multicenter, non-randomized, non-blinded prospective comparative study, was conducted in both the Zagazig university hospital as well as Elhoussein university hospitals between June 2010 and June 2012. The patients were divided into two groups; 60 patients in each group. The 1st group underwent endovenous Laser therapy while the 2nd group underwent endovenous radiofrequency ablation. Both procedures were performed under duplex scan guidance with foam sclerotherapy of incompetent perforators and superficial varicosities. The outcome of both groups was compared as regard pain and bruising and other complications, returning to normal activity, health related quality of life, and recurrence. Follow up will continue for at least 6 months.

**Results:** The number of treated patients was 120 patients 60 in each group with mean age  $29.2 \pm 5.8$  in the 1st group (EVLT) and mean age  $31.1 \pm 8.5$  in the 2nd group (RFA). There were 64 % females and 36 % males in the 1st group and there were 69% females and 31% males in the 2nd group. In the 1st group there were 68 limbs (11 bilateral and 57 unilateral, 65 GSV disease and 3 limbs with both GSV and SSV), while in the 2nd group there were 65 limbs (12 bilateral and 53 unilateral, with GSV disease in 61 and 4 limb showing both GSV and SSV disease). The overall number of complications encountered in the 1st group (EVLT) was 41%, while the overall number of complications encountered in the 2nd group (RFA) was 24%. 6 months postoperative DUS follow-up the totally occluded (TO) till the SFJ was 65 limbs (95.5%) in 1st Group and 61 limbs (93.8%) in 2nd Group.

**Conclusion:** Endovenous ablation in occluding incompetent GSV is a new effective and safe option in the treatment of varicose GSV.

**Keywords:** Endovenous, Radiofrequency, laser therapy.

## INTRODUCTION

Ligation of the great saphenous vein (GSV) and small saphenous vein (SSV) at their junctions with the deep venous system, stripping and removing the tributaries has been the standard of care for treatment of symptomatic varicose veins for many decades. However, this approach has a recurrence rate up to 40% at 5 years; 20% of all varicose vein operations are performed for recurrence.<sup>(1)</sup> The treatment of varicose (GSV) reduces the symptoms and the complications of venous insufficiency and increases the quality of life.<sup>(2)</sup>

Endovenous laser therapy (EVLT) and radiofrequency ablation (RFA) of the great saphenous vein (GSV) have been introduced as alternative and minimally invasive techniques for the treatment of truncal vein incompetence.<sup>(3)</sup> These procedures were designed to ablate the (GSV) through a percutaneous approach to minimize the discomfort and complications associated with conventional stripping.<sup>(4)</sup> The RFA catheter delivers radiofrequency energy to achieve heat – induced venous spasm and collagen shrinkage, whereas EVLT releases thermal energy both to the blood and to the venous wall, causing localized tissue damage.<sup>(5)</sup>

**Aim of the work:** This prospective comparative study was conducted to evaluate the effectiveness of endovenous treatment of symptomatic varicose veins using the endovenous Laser therapy (EVLT) or radiofrequency ablation (RFA) and to describe the complications and short term outcome of patients follow up.

## MATERIAL AND METHODS

This is a multicenter, non-randomized, non-blinded prospective comparative study in which we evaluated short term results of both endovenous radiofrequency ablation & endovenous laser therapy in management of truncal varicosities in patients with lower extremity primary venous insufficiency. This study was conducted in both the Zagazig university hospital as well as Elhoussein university hospitals between June 2010 and June 2012.

The patients were divided into two groups; 60 patients in each group. The 1st group underwent endovenous Laser therapy in the form of 980nm wave length diode laser, powered up to 90 w and with pulse mode operation (Diod 90 w, LISA®, Germany) under duplex scan guidance. An adjunctive procedure associated at the time of treatment is foam sclerotherapy of incompetent

perforators and superficial varicosities.

The 2nd group underwent endovenous radiofrequency ablation using the VNUS® radiofrequency generator and the closure fast® catheter (VNUS Medical Technologies, San Jose, CA) under duplex scan guidance. An adjunctive procedure associated at the time of treatment is foam sclerotherapy of incompetent perforators and superficial varicosities.

Post procedural crepe bandage then compression stockings for several weeks were systematically proposed. All procedures are ambulatory, and patients do not have any physical activity restrictions. Non-steroidal anti-inflammatory drugs and analgesics were provided to the patients as needed.<sup>(7)</sup>

Pre-operative and post-operative duplex scans were assessed by two vascular technologists. Patients were matched in each group using the same inclusion and exclusion criteria. Inclusion criteria include; primary GSV incompetence confirmed by duplex scan, physical condition allowing ambulation after the procedure, patient able to give informed consent, requirement for intervention agreed between patient and the surgeon, availability of patients for all follow up visits.

Exclusion criteria are varicose veins without GSV or SSV incompetence on duplex scan, recurrent varicose veins, associated deep venous incompetence on duplex scan below common femoral vein, presence of an aneurysmal vein segment or tortuous GSV above the knee felt to be unsuitable for catheterization, GSV diameter <3 mm or >13mm in the standing position, thrombus in the GSV, patients with a pacemaker or internal defibrillator, patients on anticoagulants, concomitant peripheral arterial disease (ankle-brachial pressure index of <0.9), patient has a serious systemic disease or pregnancy.

**Pre-operative:** Before the procedure each patient was evaluated by taking full history, clinical examination of the limb, the CEAP classification and the venous clinical severity score (VCSS) were assigned by a surgeon skilled in the management of venous disease.

The VCSS is composed of 10 parameters (pain, varicose veins, edema, pigmentation, inflammation, induration, number of ulcers, duration of ulcers, size of ulcers, compressive therapy) that escalate in severity with increased area of the limb involved and are graded 0 to 3 (absent, mild, moderate, severe). In order to generate a dynamic score, VCSS categories are scored individually,

which adds emphasis to the most severe sequelae of venous disease that are likely to show the greatest response to therapy.<sup>(8)</sup> The VCSS has been evaluated in clinical practice and validated as an important instrument for longitudinal research to assess outcomes after treatment with low variability.<sup>(9)</sup> The VCSS has been demonstrated to increase with higher CEAP clinical class in a strong linear relationship.<sup>(10)</sup>

Duplex ultrasonography was undertaken in all patients preoperatively to assess the extent of venous disease. Reflux was assessed by response to a Valsalva maneuver in a reverse Trendelenburg position or with manual limb compression and release; with the patient in a standing position. The mean vein diameter was recorded in both groups.

In addition, each patient completed the 20-question Chronic Venous Insufficiency Questionnaire (CIVIQ2) quality of life questionnaire that has been validated for use in patients with chronic venous disease after being translated to Arabic.

The CIVIQ comprises 20 questions in four quality-of-life domains: physical (items 5, 6, 7 and 9), psychological (items 12–20), social (items 8, 10 and 11), and pain (items 1–4).<sup>(11)</sup> All questions have a 5-point response category, with higher scores reflecting more severe impairment. Higher scores represent lower health related quality of life (HRQOL) due to CVI or varicose veins.<sup>(12)</sup>

Before surgery, accurate mapping (cartography) should be done using the duplex-scanning method from the groin to the ankle to highlight tortuous veins stretches, ectasia areas, and incompetent, perforator, and varicose veins.

**Procedure:** The patient was placed in trendelenburg position after marking the varicosities in the standing position. Venous access was obtained with Seldinger technique just below the knee because of its relative larger diameter, less tortuous course and the smaller risk of nerve injury. After the entrance to the vein was established, a 7 fr 11 cm long sheath was introduced. (Fig. 1).

Tumescent anesthesia was given before the ablation procedure. We used a spinal anesthesia needle to administer tumescent anesthesia solution. The solution of tumescent anesthesia included 500 ml saline, 25ml 2% lidocaine, 10 ml 8.4% Sodium Bicarbonate and 1 ml adrenaline (1:1.000). Using ultrasound guidance the solution is infiltrated percutaneously below the saphenous fascia and above the deep fascia to surround the vein concomitant to a dose of 35 mg/kg is safe and effective. Some patients refused tumescent anesthesia thus spinal anesthesia was the alternative type of anesthesia used. All patients who had spinal anesthesia tumescent fluid were administered with the exception of lidocaine.

**In EVLT:** a catheter was inserted with its tip positioned to be 2 cm distal to the sapheno-femoral junction (SFJ), and a 600 mm laser fiber was inserted into the catheter, which was then withdrawn by 2.5 – 5 cm distal to the SFJ to allow the laser fiber to be protruded from the catheter tip. All the persons in the treatment room advised to wear the protective laser goggles, then Laser is activated the device used was a 980 nm wave length diode laser, high power up to 90 w, and pulse mode operation (Diod 90 w, LISA®, Germany). Depending on personal performance, pulse laser therapy was delivered from 2.5 – 5 cm below the SFJ and the fiber was drawn back 5mm every 3 pulses. At the end of the procedure, the laser was deactivated before withdrawal of the fiber from the sheath. Under duplex guidance closure of the vein was documented. (Fig. 2).

In RFA the closure fast catheter was inserted and by duplex US positioned to be about 2 cm distal to SFJ we used RFG2 generator which uses power ranged from 15 – 40 watts to reach the pre-established treatment temperature (120 c) during 20 seconds cycles. The closure fast catheter treats a 7 cm vein segment in every cycle (20 seconds). 2 cycles were done in the position 2 cm below SFJ, and then every 7cm distal segments were ablated by 1 cycle. In areas with vein-ectasia an additional cycle was advised. Venus closure system seen in Fig. 3.

**Post-operative:** All patients received a standard postoperative regimen; dressings were placed over the wounds and crepe bandages wrapped around the treated limbs. Patients were instructed to remove all dressings on the 3rd postoperative day, to shower and then to apply class II full length compression hosiery for 2 weeks.

Evaluation was done after 72hrs, one week, one month, and 6 month. Items to be evaluated will be: pain and bruising and other complications, returning to normal activity, health related quality of life, and recurrence. Follow up will continue for at least 6 months.

A 10 cm visual analogue scale (VAS) was used for self-assessment of pain with patients filling out a VAS for each leg treated. Scores were measured in centimeters. The respondents are asked to assess their pain intensity between the end-points of no pain to worst possible pain on the scale. They were asked to return to normal activity as soon as they wished.<sup>(13)</sup> During each patient's visit a standard set of information was collected. Physicians assessed patient's signs and symptoms utilizing VCSS classification and the patient were asked to complete another 20-question CIVIQ2 quality of life questionnaire.

We assessed patients' limbs for the presence of recurrent varicose veins. In cases where varicose veins were present, the question of whether varicosities were new or pre-existing was considered. New varicose veins below the knee were classified as recurrent varicosities.

Ultrasound examination included characteristics of outflow and reflux. Special attention was paid to visualization of the GSV to detect recanalization of this vein and whether there was any residual flow in the GSV.

Efficacy of vein obliteration was categorized as follows: Totally occluded (TO) veins were defined as those with no evidence of flow. Partially occluded (PO) veins were defined as less than or equal to 3 cm segment of flow within the SFJ or an otherwise occluded vein trunk. Inefficiently occluded (IO) veins were defined as greater than 3 cm of flow in any treated vein segment.<sup>(14)</sup>

Reflux was defined as any evidence of reverse flow for more than 0.5 s in any treated vein segment or at the level of SFJ or SPJ.

The presence of neovascularisation in the groin was assessed by duplex ultrasound examination. This was defined as multiple small vessels in the groin reconnecting more proximal vein or its tributaries and the distal patent vein below the site of occlusion.

## RESULTS

**Statistical Analysis:** Data collected throughout history, clinical examination, DUS examinations, scores and questionnaires was coded, entered and analyzed using Microsoft Excel software. Data were then imported into Statistical Package for the Social Sciences (SPSS version 20.0) (Statistical Package for the Social Sciences) software for analysis.

According to the type of data, the following tests were used to test differences for significance;. Differences

**Post-operative Complications:** The overall number of complications encountered in the 1st group (EVL) was 41(%), while the overall number of complications encountered in the 2nd group (RFA) was 24 (%) .This is collected in Table 1.

Short-term technical success is defined as the successful occlusion of the vein lumen. Immediate vein occlusion with lack of spontaneous and augmented flow demonstrated by duplex ultrasound and vein wall thickening was achieved in 100% of the treated veins in our series. No cases of failure of closure were identified at the time of the procedure by the completion of a duplex ultrasound scan.

In the 2nd group there was one case (1.5%) of a perforation of the GSV 1 cm from the SFJ immediate exploration of the SFJ was done and ligation of the junction, the GSV and after closure of the wound RFA was completed as usual.

In both groups there was no incidence of Endothermal

between frequencies (qualitative variables) in groups were compared by Chi-square test. Differences between means (quantitative variables) in two groups were compared by Student's t-test, paired two groups by paired t test. P value was set at <0.05 for significant results.

**Demographic Data of Patients:** The number of treated patients was 120 patients 60 in each group with mean age  $29.2 \pm 5.8$  in the 1st group (EVL) and mean age  $31.1 \pm 8.5$  in the 2nd group (RFA). There were 64 % females and 36 % males in the 1st group and there were 69 % females and 31 % males in the 2nd group. Body mass index (kg/m<sup>2</sup>) was  $24.3 \pm 2.1$  in the 1st group and in  $26.9 \pm 2.3$  the 2nd group.

In the 1st group there were 68 limbs (11 bilateral and 57 unilateral, 65 GSV disease and 3 limbs with both GSV and SSV), while in the 2nd group there were 65 limbs (12 bilateral and 53 unilateral, with GSV disease in 61 and 4 limb showing both GSV and SSVdisease).

The distribution of CEAP classification in the 1st group was C2 13.2%, C3 55.1%, C4 27.4% and C5 4.3%. In the 2nd group the distribution was C2 17.6%, C3 53%, C4 29.4% and C5 0%. The mean vein diameter was  $7.9 \pm 2.8$  mm in the 1st group and  $8.3 \pm 2.2$  mm in the 2nd group.

**Operative Data of Patients:** Spinal anesthesia was used in 45% of cases and tumescent anesthesia in 55% of cases in the 1st group, while in the 2nd group only 34% of the cases took spinal anesthesia and 66 % took tumescent anesthesia. All patients who had spinal anesthesia Tumescent fluid was administered with the exception of lidocaine. The average treated length in the 1st group  $39.5 \pm 9.7$  cm and the average treated length in the 2nd group  $40.4 \pm 10.7$  cm.

Heat Induced Thrombosis (EHIT) which is a thrombus protruding into the common femoral vein. There was no incidence of Deep vein thrombosis (DVT). There was no incidence of pulmonary embolism in our study.

In the both group; no cases of lignocaine toxicity occurred. Close observation of the patients was done, talking to the patient throughout the procedure to notice any suspicious symptoms of toxicity arising.

**1st Group:** At 6 months postoperative DUS follow-up the totally occluded (TO) till the SFJ was 65 limbs (95.5%). DUS follow-up of the other 3 limbs showed that 1 limb (1.4%) showed veins related to missed anterior accessory saphenous in one case and in 1 limb (1.4%) an incompetent thigh perforator connected to a superficial vein connected to the SFJ. 1 limb (1.4%) recanalization of the vein was found.

**2nd Group:** At 6 months postoperative DUS follow-up the totally occluded (TO) till the SFJ was 61 limbs (93.8%). DUS follow-up of the other 4 limbs showed that

2 limbs (3%) showed partially occluded (PO) veins related to missed anterior accessory saphenous. 2 limbs(3%) had inefficiently occluded (IO) vein related to recanalization of the vein.post operative results are concluded in Table 2.

In the 1st (EVLT) group there were 35 limbs (51.4%) presented with bruises and ecchymosis (without distinction between those due to treatment itself or due to tumescent injection or foam sclerotherapy) 2 limbs (2.9%) showed prolonged ecchymosis and local edema for one month, and 5 limbs (7.4 %) of paraesthesia. In the 2nd (RFA) group there were 12 limbs (18.5%) cases of bruises (without distinction between those due to treatment itself or due to tumescent injection or foam sclerotherapy), and 7 limbs (10.8 %) of paraesthesia.

Skin burn occurred in the form of mild erythema in 9

limbs (13.2%) in the first group and in 8 limbs (12.3%) in the second group which might be due to insufficient tumescent anesthesia and very superficial veins. All cases improved with conservative management.

**Table 1. Complications of both groups.**

Complications	G1%	G2%
Perforation of SFJ	0	1.5
Bruises and Ecchymosis	51.4	18.5
Nerve injury	7.4	10.8
Erythema	13.2	12.3
DVT	0	0
Pulmonary embolism	0	0
Recurrence	4.2%	6%

**Table 2. Post-operative findings are concluded in the following.**

Length of hospital stay (hour)	6.9±2.3	6.2±1.5	1.9	NS
Return to activities (d)	5.6±2.4	3.5±2.1	5.1	<0.001
Pain (VAS)	7.9±2.2	4.7±1.5	9.3	<0.001
VCSS	6.4±2.4	6.3±2.7	0.2	NS
6 m VCSS	2.7±2.1	2.6±2.1	0.26	NS
CIVIQ2	49.2±21.9	45±20.2	1.1	NS
6 m CIVIQ2	19.4±2	20.3±2.3	2.28	<0.05

## DISCUSSION

Endovenous techniques of saphenous vein ablation have been introduced as minimally invasive alternatives to high ligation and open surgical stripping of the incompetent saphenous vein. Stripping can lead to painful and prolonged post-operative recovery in some patients, with risks of infection, hematoma and nerve injury.<sup>(15)</sup> Conventional treatment generally entails general or spinal anesthesia. In many centers patients undergoing the operation are admitted at least 1 day.<sup>(16)</sup> The mechanism of action of EVLT and RFA are different. With laser energy, there is uniform, complete occlusion from intimal thermal damage caused by the steam bubble.<sup>(17)</sup> Some of the researches feel that adequate vein wall contact with the laser fiber is necessary to accomplish this intimal damage.<sup>(2)</sup> Radio frequency energy causes collagen shrinkage and fibrosis.<sup>(18)</sup> Published data give reliable occlusion rates for EVLT (97% to 100%)<sup>(2)</sup> and RFA (84% to 100%).<sup>(19)</sup> Successful occlusions of the GSV at the rate of over 90% immediately after EVLT were reported.<sup>(20)</sup> Heating the collagen of the venous walls results in contraction and destruction of the endothelium, the thickness of the wall increases and therefore, resulting in fibrosis of the

veins.<sup>(22)</sup> We did not find any variability in occlusion rates with either EVLT & RFA techniques, as was seen in Mayo clinic study.<sup>(23)</sup> We emphasized the importance of performing these procedures under tumescent anesthesia, collapsing the vein, and minimizing the trauma by not introducing the RFA or EVLT catheter into the common femoral vein. This is our opinion as surgeons, of course, but there are many physicians performing these ablation who are not vascular surgeons or interventionists.<sup>(23)</sup> In our study, performed by vascular surgeons immediate closure of the vein is reported as reported in all reviewed literature. In our 6 months follow up, the success rate was 95.5% in the EVLT group and 93.8 in th RFA group. Our findings are comparable with the previous studies. In min et al., who used a similar techniques for GSV varicosities, reported that 93% of 499 GSV were occluded 2 years after therapy.<sup>(2)</sup> An Italian work group reported a success rate of 97% in 1000 patients with a follow up of 3 years.<sup>(24)</sup> Another large study with more than 1250 limbs treated showed, a success rate of approximately 95%.<sup>(25)</sup> Sharif et al., reported long saphenous vein occlusion in 100% and 96% at 3 and 12 months after EVLT.<sup>(26)</sup> Absence of neovascularity in the groin with the presence of physiological drainage is an added advantage of

endovenous treatment. Avoiding the ligation of all the tributaries in the groin and performing high ligation of the GSV prior to stripping contributes to the neovascularity and recurrence seen with conventional ligation and stripping.<sup>(27)</sup> Technical problems such as difficult access, problems in advancing the catheter or a tortuous GSV may also lead to recurrence. Lohr and Kulwicki stated that neovascularization, though less frequent with endovenous ablation than surgery, is also considered a cause and has been seen in 2.8 – 7% of cases.<sup>(28)</sup> However, it seems that it could protect against neovascularization by preserving physiological drainage of the abdominal wall.<sup>(29)</sup>

There were no significant differences between the RFA & EVLT techniques in our study. It is possible GSV thrombi caused by laser energy have different characteristics from those occurring after RFA.<sup>(23)</sup> Deep vein thrombosis (DVT) after endovenous ablation is extremely rare and indeed most case series and trials show no evidence of DVT at all.<sup>(30)</sup>

For safety, the manufactures recommended the tip of the ablation catheter should be at least 2 cm from the saphenofemoral junction. In our series the catheter tip is positioned to be 2 cm distal to SFJ in EVLT and 2 cm distal to SFJ in RFA. Thrombosis of GSV was expected but was at least 3 cm away from the SFJ.<sup>(30)</sup>

Concomitant SSV or transluminal occlusions of perforators with endovenous ablation have been considered risk factors for calf DVT<sup>(31)</sup> although it is not evident in our study.

Studies have reported low rates of skin staining, to avoid and decrease incidence of skin burns and pigmentation is the very generous use of tumescent fluid under duplex ultrasound guidance and making sure that at least 1 cm of fluid is surrounding the treated vein all around. Also it is wise to manage very superficial veins by other modalities rather than endovenous ablation.<sup>(32)</sup>

The most common self-limited or minor complications included slight pains minor burning, bruising and abnormal skin sensation.

Using of A 10 cm visual analogue scale (VAS) for self-assessment of pain showed that pain is more significant postoperative in the EVLT Group than the RFA group. Bruising was more evident in the EVLT group in comparison with the RFA group most due to vein perforations by the laser beam.

The serious complications of endovenous ablation are few saphenous nerve injury following endovenous ablation is rare.<sup>(33)</sup> Our patients had none of the serious complications.

In conclusion endovenous ablation in occluding incompetent GSV is a new effective and safe option in

the treatment of varicose GSV. Selection of endovenous ablation as a treatment alternative to conventional surgery depends on the cost of equipment and disposables and operator experience. The advantages of endovenous ablation are far greater than its associated risks. Tumescent anesthesia should be instilled below the saphenous fascia and confirming by duplex that at least 1 cm of fluids is surrounding the treated vein to avoid unpleasant minor complications. Catheter tip must be at least 2cm from SFJ to avoid extension of the thrombi to deep venous system. After endovenous ablation, patients can immediately return to their daily routine life works.

Further long term follow up studies are needed to confirm absence of recurrence and to more establish the techniques.



**Fig 1. Sheath N. 7 inside the GSV by seldenger tech.**



**Fig 2. Duplex U/S showing the catheter inside the GSV.**



**Fig 3. Venus closure system for V.V.**

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