INTRODUCTION

Chronic venous disease (CVD) is a common malady of the peripheral vascular system and includes a wide spectrum of clinical presentations, which range from spider varicosities to varicose veins to severe venous ulceration. The manifestations of chronic venous disease may result from primary venous insufficiency or may be secondary to other disorders, the most common of which is deep vein thrombosis (DVT).[1] Varicose veins have long been considered a cosmetic problem that affected emotional well-being. Varicosities are frequently the cause of discomfort, pain, loss of working days, disability, and deterioration of health-related quality of life (QOL).[2] Severe CVD may also lead to loss of limb or loss of life.[3]

The prevalence of varicose veins is estimated to range from 2%-40% in the general population.[4] In the Edinburgh Vein Study 32% of women and 40% of men, in a cohort of 1566 randomly selected subjects, had trunk varicosities.[4] Other studies, generally of less stringent methodology, have found the gender difference reversed with a prevalence of 20–25% in women and 10–15% in men. In studies involving self reporting, women tend to be over-represented, as they are more likely to present with varicose veins and more likely to undergo treatment.[5]

The most frequent causes of CVI are primary abnormalities of the venous wall and the valves, and secondary changes due to previous venous thrombosis that can lead to reflux, obstruction, or both. The majority (70–80%) of varicose vein patients have an incompetent sapheno-femoral junction (SFJ) and long saphenous vein (LSV) reflux.[6]

For the diagnosis of CVD, duplex scanning is recommended as the first diagnostic test for all patients with suspected CVD.[7] Other non invasive tests such as measurement of venous refilling times (VRTs) using photoplethysmography (PPG)

are safe, cost-effective, and reliable. The principal application is to study blood flow and blood volume changes in the skin. PPG can be used for screening to detect CVI or to assess the overall physiological function of the lower limb veins.[8]

Although the pathogenesis of varicose veins is not fully understood, abolition of reflux appears crucial for successful treatment.[1] The optimum management of varicose veins requires accurate identification of the source of superficial venous incompetence. Subsequent treatment, specifically tailored to abolish venous reflux, should relieve any symptoms attributable to superficial venous incompetence, prevent complications, improve cosmesis, be associated with a low morbidity, low recurrence rates, and if possible, a short recovery time.[9] The treatment of varicose veins increases patient's health-related quality of life (HRQOL).[10]

Treatment for varicose veins can roughly be divided into four categories: compression therapy, surgical treatment, sclerotherapy, and endovenous thermal ablation. Surgical ligation of the junction with or without stripping has been the standard treatment of insufficient great and small saphenous veins for more than 100 years.[11] However, surgery has demonstrated to be associated with complications including hematoma, paresthesia, and recurrence. Surgical stripping has not been well accepted by patients who perceive the procedure as risky, disfiguring, requiring hospitalization, and requiring lengthy convalescence. The associated morbidity and patient dissatisfaction associated with this treatment have led to the development of alternative techniques.[12,13]

The latest innovations in minimally invasive therapies employ the delivery of thermal energy to the vein wall (via intraluminal means) to destroy the intima and denature collagen in the media. The result is fibrous occlusion of the vein. Thermal ablation of refluxing saphenous veins can be achieved with either radiofrequency or

laser energy.[13] Endovenous treatment modalities (laser ablation, radiofrequency ablation and foam sclerotherapy) have been readily accepted by both patients and doctors and in the last decade, these procedures have become the most frequently used therapy for saphenous varicose veins. Such minimally invasive techniques meet the demand for cosmetically superior, less invasive and more successful treatment modalities.[14] Since their introduction 12 years ago, these techniques have radically changed the treatment of varicose veins. The special advantages offered by endoluminal techniques include the less postoperative pain, fewer adverse events, quick return to everyday activities, an improved quality of life and shorter periods of disability.[15,16] The indications and contraindications for the endoluminal techniques correspond to those for classical vein surgery.[12] Previous techniques for controlling saphenous reflux, including sclerotherapy, ligation, and even stripping of the saphenous vein, are morbid procedures and, because of neovascularization at the saphenofemoral junction, have high recurrence rates. Endovenous techniques, by comparison, have low rates of complication and have not been shown to generate the same degree of neovascularization.[16,20]

The endoluminal treatment techniques described are designed for treating the trunk varicosis. The insufficient lateral branches are treated in the same session by means of mini-phlebectomy or foam sclerotherapy, since they do not degenerate completely after a treatment of the truncal varicosity alone and may cause pour-in effects and rechannelizations.[23] Foam sclerotherapy allows a smaller quantity of sclerosant to cover a greater surface area and to displace blood from the LSV, and hence is very effective for the treatment of varicosities and has fewer complications.[9] The Society of vascular surgery (SVS) and the American venous forum (AVF)

guidelines have recommended foam sclerotherapy for the treatment of reticular veins and branch varicosities.[37]

Percutaneous endovenous thermal ablation by radiofrequency (RF) (Closure; VNUS Medical) received Food and Drug Administration (FDA) approval in 1999 and the first reports were published in 2000.[25] Laser ablation therapy followed shortly thereafter, with FDA approval in 2002.[22] Endovenous radiofrequency ablation (Closure system: VNUS Medical Technologies Inc., Sunnyvale, CA) of the LSV was described by Goldman in 2000.[26] Experience with RFA rapidly accumulated, and several systems for radiofrequency ablation were developed. In the earlier years, RFA procedures were performed with the first-generation device, the VNUS Closure Plus system which was cumbersome to use.[17] In the last few years, two new RFA systems have been introduced: VNUS Closure Fast (segmental RFA) and radiofrequency induced thermotherapy (RFITT). The Closure Fast RFA catheter (VNUS Medical Technologies, San Jose, California), introduced in 2007, is more user-friendly, treatment with it is faster than with the first-generation device and is currently the most popular device being used.[36] The mechanism of action consists of a bipolar electrode which reaches a temperature of 120 degree C for 20 seconds and causes resistive heating of the vein and surrounding tissue which results in endothelial denudation, collagen denaturation and acute vein constriction.[27]

Puglisi first described endovenous laser ablation of the GSV in 1989.[28] The first successful results were reported by Bone in 1999 [29] and Navarro in 2001.[30] The endoluminal laser therapy has gone through many changes since its introduction. Laser wavelengths reported include 810 nm, 940 nm, 980 nm, 1064 nm, 1320 nm and 1470 nm.[31] Initially laser generators with wavelengths of between 810 and 980 nm were used. The current lasers use wavelengths from 1320 to 1470 nm. They

differ in their absorption behaviour.[32] Whereas the lasers with low wavelengths mainly have a good absorption in hemoglobin, the higher laser wavelengths are particularly well absorbed in water. Efficacy would be higher due to higher specificity for the interstitial water in the vessel wall of this laser and lower absorption by haemoglobin.[31,34]

Using a laser fiber with a modified tip (tulip or radial fiber) and avoiding a too high energy dose, reduces postoperative complications. A recent development was the introduction of the ELVeS Radial, a fiber with a radial emitting laser tip (Biolitec AG, Jena, Germany), which was proposed to decrease the amount of energy required to occlude the vein, thus decreasing pain and adverse effects of thermal ablations.[32] The mechanism of the laser is a thermal reaction after the laser exposure. The produced heat may reach up to 800°C at the tip of the fiber and results in the formation of steam bubbles. The bubbles cause the blood to boil and induce thermal injuries to the venous endothelium. Histological studies show that EVLA damages the endothelial and intimal layers, the internal elastic lamina and the media to some degree. The adventitia is rarely affected.[33,35]

Most of the previously published data on efficacy and safety of laser treatment arise from a laser with a wavelength between 810 and 1320 nm. The comparative trials of EVLA and RFA which have been published for endovenous treatment of GSV reflux have also included the previously used laser wavelengths, and have shown somewhat higher complication rates as compared to RFA. There are only a few studies comparing the safety and efficacy of EVLA with the recently introduced 1470 nm wavelength radial fibre,[32,33,34] and studies for its comparative effectiveness with RFA are lacking.

REVIEW OF LITERATURE

Evaluation of varicose veins has greatly progressed in the past 2 decades with the widespread availability of duplex ultrasonography. The treatment of varicose veins has also undergone dramatic changes with the introduction of percutaneous endovenous ablation techniques, including endovenous laser therapy (EVLA) radiofrequency ablation (RFA), and foam sclerotherapy.[37] Published guidelines have recommended use of the basic CEAP classification to document the clinical class, etiology, anatomy, and pathophysiology (CEAP) of CVD. The classification scheme is shown in Table 1.[38]

Table 1: CEAP Classification of Chronic venous disease

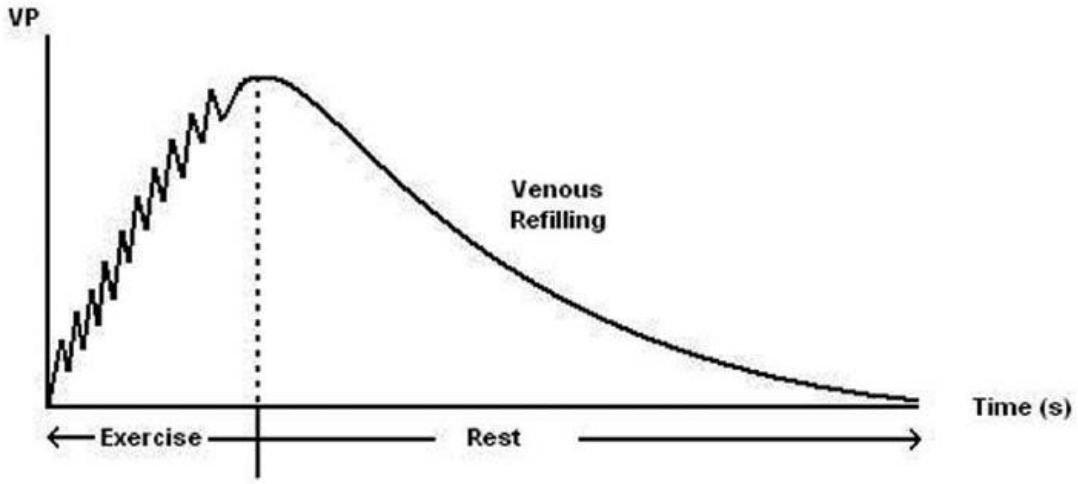
CEAP	*Description*
1. Clinical classification	
C_0	No visible or palpable signs of venous disease
C_1	Telangiectases or reticular veins
C_2	Varicose veins
C_3	Edema
C_{4a}	Pigmentation and/or eczema
C_{4b}	Lipodermatosclerosis and/or atrophie blanche
C_5	Healed venous ulcer
C_6	Active venous ulcer
C_S	Symptoms, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, as well as other complaints attributable to venous dysfunction
C_A	Asymptomatic
2. Etiologic classification	
E_c	Congenital
E_p	Primary
E_s	Secondary (postthrombotic)
E_n	No venous etiology identified
3. Anatomic classification	
A_s	Superficial veins
A_p	Perforator veins
A_d	Deep veins
A_n	No venous location identified
4. Pathophysiologic classification	
P_r	Reflux
P_o	Obstruction
$P_{r,o}$	Reflux and obstruction
P_n	No venous pathophysiology identifiable

Duplex ultrasound (DUS) is required to evaluate most patients with superficial venous insufficiency. It is advisable that all patients undergoing evaluation for varicose veins, edema, or venous skin changes (CEAP clinical stage 2-6) undergo an ultrasound of the superficial venous system to determine the patterns of incompetence prior to making treatment recommendations.[39] Colour flow duplex imaging provides instant visualization of blood flow and its direction and has decreased examination time and improved its accuracy.[40] In normal veins, cephalad flow phasic with respiration is indicated by the blue color in the lumen. This is enhanced with distal thigh or calf compression. On release of the compression, reflux is shown as red that lasts for 0.5 seconds.[41] Although the criteria of ≥0.5 second of retrograde flow has been used to identify pathological reflux, several seconds of retrograde flow is usually found in patients with incompetence.[39] According to the classification used by Puggioni et al[42], reflux in the great saphenous vein (GSV) was classified as grade 1 (0.5-1 seconds), grade 2 (1-2 seconds), grade 3 (2-3 seconds), or grade 4 (>3 seconds).

Another test for the assessment of venous insufficiency is Photoplethysmography (PPG). It is a noninvasive test that uses a light-emitting diode and a photoelectric cell to detect changes in skin blood volume. During exercise, the amount of blood in the skin of the lower limb decreases as a result of venous emptying secondary to the action of the calf muscle pump. By placement of the PPG probe over the skin of the lower limb, the blood volume of the skin can be quantified and relates primarily to the effectiveness of the pump mechanism in clearing the leg of venous blood. The time taken for the skin to refill with blood after exercise is known as the venous refilling time (VRT). Digital PPG performed in the seated position in patients with isolated superficial venous reflux provides a reproducible

method for the noninvasive assessment of lower limb venous function for both clinical and research purposes. The refilling curve produced by digital PPG is shown in figure 1.[43]

Figure 1. Refilling curve produced by digital photoplethysmography machine



Sanjev Sarin et al[44] conducted a study to find out the effectiveness of photoplethysmography in detecting venous disease, defined clinically and by duplex scanning. They concluded that photoplethysmography readings are reproducible, noninvasive, and correlate well with the presence of clinical disease, and photoplethysmography remains useful in the assessment of venous dysfunction.

In practice, PPG is performed when venous reflux is suspected. Venous reflux is diagnosed if the venous RT (VRT) is abnormally short (<20 seconds in the sitting position).[45]

While evaluating any kind of treatment, the most important thing is to get the patient's opinion on the result of the treatment, or the health related quality of life. D.Reviki observed that *"the patient's perspective and patient reported HRQOL (Health related quality of life) is the ultimate outcome for health care interventions."* [46] Until recently, several vein specific QOL questionnaires such as the generic Short

Form-12 (SF-12;) and specific (CIVIQ - Chronic Venous Insufficiency Questionnaire, AVVQ - Aberdeen Varicose Vein Questionnaire) have been used, most of the time in association with each other, but no patient-reported outcome (PRO) is available which takes into account altogether symptoms, impairment of activities, appearance of the legs and concerns regarding health risk. Also, the administratrion of previous questionnaires is tedious and time consuming.[47] For this precise purpose, the SQOR-V (Specific quality of life and outcome response-venous) questionnaire was developed by Guex et al [48] (Appendix A). This avoids the administration of two or more forms, and initial results have demonstrated its validity for HRQOL measures, and improvement of sensitivity when compared to AVVQ. [47]

Regarding the treatment of varicose veins, endovenous thermal ablation techniques, which include radiofrequency ablation (RFA) or endovenous laser treatment (EVLA), are less invasive treatment options as an alternative to high ligation and stripping of the incompetent great saphenous vein (GSV), and the mid-term results of RFA and EVLA suggest that endovenous thermal ablation techniques are at least as effective and durable as traditional saphenous vein surgery.[49,50,51,52]

RFA and EVLA differ significantly in their mode of action of delivering thermal energy to the vein wall. For RFA, a segmental heating catheter of 7F diameter (ClosureFAST catheter, VNUS Medical Technologies Inc, San Jose, Calif) consisting of a 7-cm heating element is used, which reaches a temperature of 120° after 6 seconds and is applied for 14 seconds per term to the vein wall. The respective segment near the sapheno-femoral junction is treated twice. The treatment is carried through again in anti-Trendelenburg-position of the surgical table and with cooled tumescent solution that is injected under ultrasound guidance.[27] For one leg, 250–500 mL of solution is usually sufficient. The tumescense has three functions.[10]

1) It protects the perivenous tissue from the effects of heat via a cooling effect
2) It removes the blood from the lumen by collapsing the vein, increasing the effectiveness of the endovenous ablation
3) It increases the surface area of contact between the catheter tip and vein wall.

A comparative study of RFA with open surgery, the EVOLVeS study[53] (Endovenous Radiofrequency Obliteration [Closure] versus Ligation and Stripping) clearly demonstrated faster recovery times, less postoperative pain, fewer adverse events, and superior quality-of life scores in the RF obliteration group compared with the group that underwent saphenous vein stripping and ligation.

Proebstle TM et al[36] published that Radiofrequency ablation of saphenous veins with the ClosureFAST catheter had proven efficacy with an excellent side effect profile. This prospective, nonrandomized, multicenter study was conducted to evaluate the safety, feasibility, and early clinical outcomes of RFA of the GSV. A total of 194 patients with 252 GSVs with an average diameter of 5.7±2.2 mm (range, 2.0 to 18.0 mm) received RFA under tumescent local anesthesia. In 58 patients (29.9%), bilateral treatment (average length treated, 36.7±10.8 cm) was done. The average total endovenous procedure time was 16.4±8.2 minutes, and the average total energy delivery time was 2.2±0.6 minutes. The corresponding endovenous fluence equivalent delivered to the proximal 7-cm vein segment was 82±25 J/cm2 (range, 38 to 192). Follow-up at 3 days, 3 months, and 6 months was obtained from 250, 164, and 62 limbs, respectively. Occlusion rates were 99.6% for all three follow-up dates according to life-table analysis. The average Venous Clinical Severity Score was 3.4±1.2 at 3 days, 0.9±1.6 at 3 months, and 1.5±1.8 at 6 months compared with 3.9 ±2.0 at baseline. Thus, they concluded that Radiofrequency segmental thermal ablation is feasible, safe, and well tolerated.

In another prospective multicentre trial [54], Closure FAST RFA treated GSVs (n = 295) were followed for 24 months. Clinical control visits included flow and reflux analysis by duplex-ultrasound and assessment of treatment related side effects at all times. 280 of 295 treated GSVs (94.9%) were available for 24 months follow up. According to the method of Kaplan and Meier at 24 months after the intervention 98.6% of treated legs remained free of clinically relevant axial reflux. The average VCSS score improved from 3.9 ± 2.1 at screening to 0.7 ± 1.2 at 24 months follow-up ($p < 0.0001$). While only 41.1% of patients were free of pain before treatment, at 24 months 99.3% reported no pain and 96.4% did not experience pain during the 12 months before. At 24 months n=3 legs showed pigmentation along the inner thigh and one leg showed study-treatment related paresthesia. This concluded that Radiofrequency powered segmental thermal ablation Closure FAST showed a very moderate side-effect profile in conjunction with a high and durable clinical success rate.

EVLA mainly acts by laser light energy that is converted to heat when selectively absorbed by tissues within the vein. Heat-related damage to the vein endothelium leads to a focal coagulative necrosis and thrombotic occlusion of the treated vein. In contrast to treatment with RFA, the LSV does not shrink immediately, but gradually reduces in size over several weeks until it is no longer visible on ultrasound after about 6 months.[55,56] Whereas the radiofrequency ablation was performed according to a standard treatment protocol from the beginning, the endoluminal laser treatment has been subject to considerable changes since the first publications by Bone [29] in 1999 and Navarro [30] in 2001. The objective was to achieve a further reduction in side effects while ensuring a secure primary closure of the treated veins and permanent success of the treatment. A period of low energy output

to the vessel was followed by a phase of high energy application. Since then, several studies have since been published reporting different regimens for the energy per surface area (J/cm), pulse duration, and wavelength of the laser. The previously published data on efficacy and safety of laser treatment arise from lasers with a wavelength between 810 and 1320 nm and showed 90% to 100% occlusion.[51,52,57,58]

As the laser wavelengths were modified over time, it was possible to substantially reduce the number of side effects. Few years ago the radial emitting catheter with a laser ring (ELVeS radial™) was introduced in the treatment of truncal veins. Combined with the 1470-nm wavelength laser, the side effects of the laser treatment were further reduced. The first successful results were published by Pannier et al [59] in 2009. Especially the number of ecchymoses, the frequency of periphlebitis and post operative pain and paraesthesias (tenderness) were reduced considerably in comparison with the bare fiber and the lasers with a lower wavelength. At the same time the primary closure rates remained acceptable.[60]

A RCT by Doganci and Demirkilic compared early occlusion rates of two different laser fibers. The immediate occlusion rate was 100% for both the 980-nm laser and bare-tip fiber and the 1470-nm laser with the radial fiber.[32]

In addition to the laser wavelength, the linear endovenous energy density (LEED in Joules/cm) is also decisive for the efficiency of endoluminal laser therapy.[61] However, the data that are available suggest that higher laser energies per vein length (cm) are associated with less failure of EVLA. Furthermore, in a recent study, Proebstle et al [62] showed that the administered laser fluence, as calculated by cylindrical approximation of the proximal GSV segment, proved to be the most significant predictor of early EVLA failure in a multivariate statistical analysis. At first, energy densities as low as 25 J/cm were used. In order to optimize the results, the

energy doses were temporarily increased to 120 to 150 J/cm, which resulted primarily in an increase in side effects. This led to an energy density of 80-120 J/ cm being recommended.[18,19,63]

Studies have indicated that the administration of a linear energy density of ≥80 J/cm2 is usually sufficient to achieve an effective ablation during short-term follow-up. The rate of pullback with the laser technique is adjusted to maintain an energy transfer of 80–120 joules/cm within the vein.[22] Doganci et al applied laser energy using the laser's continuous mode and a constant pullback with a rate corresponding to 90 J/cm linear endovenous energy density (LEED).[32]

The amount of energy delivered depends on the wattage and duration of the laser energy over the surface of the vein wall. The use of 10–20 Watts is optimal, but wattages as high as 30 Watts have also been used. All wattages from 10 Watts to 30 Watts appear to be sufficient to achieve an adequate ablation. Most centers use continuous energy production of 12–14 Watts. Using the pulse mode or continuous mode usually does not influence the effectiveness of the outcome. The major advantage of the continuous mode is that duration of treatment is shorter.[10]

A recent literature search showed that EVLA had a significantly higher success rate when compared to surgery (94% vs. 48%) for the treatment of SSV insufficiency with similar complication rates. Until now, no randomized controlled trials have been performed comparing surgery and endovenous techniques for SSV insufficiency.[64]

The vast majority of complications occurring after EVLA are minor and transient. These include bruising, soreness, tenderness, and indurations along the treated vein segment. These complaints are most apparent in the first two weeks postoperatively and then gradually subside and disappear completely.[10]

Systematically studying all publications on EVLA showed that the most common side effects were ecchymoses and pain, with or without induration. Other less common side effects included: skin burns (<1%), dysesthesia (0-22%), superficial thrombophlebitis (0- 25%), deep vein thrombosis (DVT) (0-6%), nerve injury (<1%), and hematoma. Paresthesia is observed in 0% to 12% of cases and likely will be higher in patients with longer lengths of vein treated. Paresthesia also resolves spontaneously but may take weeks or months to achieve complete recovery.[11]

DVTs are a feared complication and are reported to occur in 0%– 8% of cases. A colour Doppler ultrasound (CDUS) examination a few days after EVLA to exclude DVTs or administering low molecular weight heparin for a week postoperatively has been recommended. However, the anticoagulation of all patients, even for a short period of time, is debatable, as the incidence of proven DVTs is usually less than 1%. Anticoagulation can be considered for patients who had a prior DVT.[10]

Data to support the routine administration of thromboprophylaxis with heparin are not available. Selected patients with a history of thrombophlebitis, DVT, known thrombophilia, or obesity are candidates for thrombosis prophylaxis. For high-risk patients, several interventionists use a single, preventive dose of low-molecular-weight heparin before or at the beginning of the procedure.[65]

Since a decade after its introduction, EVLA appears to be a safe and effective treatment of venous insufficiency. As a minimally invasive technique, it is a popular choice for both patients and physicians. The procedure has high immediate technical success, a short recovery time, and good cosmetic results. Minor complications are frequent but usually temporary and self-limited, and major complications are rare.

EVLA is an efficient treatment method for the treatment of the GSV, the SSV truncal venous insufficiencies, achieving good short term and long-term results.[10]

Foam sclerotherapy of the saphenous vein is the least invasive of the endovenous ablation techniques. The European Consensus Meetings on Foam Sclerotherapy reported that foam was an effective, safe, and minimally invasive endovenous treatment for varicose veins with a low rate of complications.[66] The most popular technique used today was developed by Tessari et al [67] using a three-way stopcock connected with two syringes. Experts recommend a ratio of 1 part solution of Sodium Tetradecyl Sulphate or polidocanol to 4 or 5 parts of air. Mixing the drug with air using the two syringes and pushing the mixture from one syringe into the other 20 times results in an approximate bubble size of <100 μm.[68]

Coleridge-Smith [69] advised to cannulate the veins in supine patients and then elevate the limb 30° to inject the foam. Foam was prepared using 1% polidocanol, 1% Sodium tetradecyl sulphate (STD) or 3% STD. Ultrasonography was used to monitor the movement of foam in the veins. The saphenous trunk was injected first, followed by branch varicose veins if indicated. A maximum of 20 mL of foam was injected during one session.

Elastic bandages or class II (20–30 mmHg) graduated supporting stockings are recommended for one to three weeks following endovenous ablation with EVLA or RFA. Compressive stockings not only compress the vein and help to increase the effectiveness of the treatment, but they also decrease the patient's postprocedural discomfort.[10] In the published trials following EVLA or RFA, compression therapy with a graduated class II full length stockings at 30 to 40 mm Hg was initiated immediately following GSV ablation. Patients were to wear the stockings for 24 hours for 1 week, then during the day for a further 3 weeks.[10,15,17,70]

The early literature reports failure rates of approximately 10%, using either RFA or EVLA. Failure for endovenous treatments is defined as any recanalization (segmental or full length) of any ablated vein based on examination by ultrasound imaging. In most reported series, the failures seem to occur during the first 12 months.[71] There is enough published literature showing early, midterm and long term results of the two endovenous modalities separately. But only a few studies exist which have compared EVLA with RFA in terms of success rates, complications and quality of life issues.[74]

Van den Bos R et al [12] published a meta-analysis in 2009 after a systematic review of Medline, Cochrane Library, and Cinahl to identify studies on the effectiveness of the four therapies (endovenous laser therapy, radiofrequency ablation, and ultrasound guided foam sclerotherapy, surgical ligation and stripping) up to February 2007. All clinical studies (open, noncomparative, and randomized clinical trials) that used ultrasound examination as an outcome measure were included. Of the 119 retrieved studies, 64 (53.8%) were eligible and assessed 12,320 limbs. Average follow-up was 32.2 months. After 3 years, the estimated pooled success rates (with 95% confidence intervals [CI]) for stripping, foam sclerotherapy, radiofrequency ablation, and laser therapy were about 78% (70%-84%), 77% (69%-84%), 84% (75%-90%), and 94% (87%-98%), respectively. After adjusting for follow-up, foam therapy and radiofrequency ablation were as effective as surgical stripping (adjusted odds ratio [AOR], 0.12 [95% CI, –0.61 to 0.85] and 0.43 [95% CI, 0.19 to 1.04], respectively). Endovenous laser therapy was significantly more effective compared with stripping (AOR, 1.13; 95% CI, 0.40-1.87), foam therapy (AOR, 1.02; 95% CI, 0.28-1.75), and radiofrequency ablation (AOR,

0.71; 95% CI, 0.15-1.27). *This meta-analysis concluded that* EVLA is more effective than surgery, UGFS, and RFA.

In 2009, the results of the RECOVERY trial [74] by Almeida JI et al comparing Radiofrequency ClosureFAST ablation with endovenous laser ablation for the treatment of GSV reflux were published. The trial was prospective, randomized, single-blinded, and carried out at five American sites and one European site. 87 veins in 69 patients were randomized to Closure FAST or 980-nm EVL treatment of the GSV. Primary endpoints (postoperative pain, ecchymosis, tenderness, and adverse procedural sequelae) and secondary endpoints (venous clinical severity scores and QOL issues) were measured at 48 hours, 1 week, 2 weeks, and 1 month after treatment. The results showed that all scores referable to pain, ecchymosis, and tenderness were statistically lower in the Closure FAST group at 48 hours, 1 week, and 2 weeks. Minor complications were more prevalent in the EVL group, there were no major complications. Venous clinical severity scores and QOL measures were statistically lower in the Closure- FAST group at 48 hours, 1 week, and 2 weeks. This trial concluded that RF thermal ablation was significantly superior to EVLA as measured by a comprehensive array of postprocedural recovery and QOL parameters.

In 2010, Shepherd AC et al [75] published the results of the Randomized clinical trial of VNUS Closure FAST radiofrequency ablation versus laser for varicose veins. Consecutive patients with primary great saphenous vein reflux were randomized to EVLA (980 nm) or RFA (VNUS Closure FAST) at a single centre. The primary outcome measure was postprocedural pain after 3 days. Secondary outcome measures were quality of life at 6 weeks, determined by the Aberdeen Varicose Vein Questionnaire (AVVQ) and Short Form 12 (SF-12), and clinical improvement

assessed by the Venous Clinical Severity Score (VCSS). 131 patients were randomized to EVLA (64 patients) or RFA (67). Their results showed that mean(s.d.) pain scores over 3 days were 26·4(22·1) mm for RFA and 36·8(22·5) mm for EVLA (P = 0·010). Over 10 days, mean(s.d.) pain scores were 22·0(19·8) mm versus 34·3(21·1) mm for RFA and EVLA respectively (p=0·001). The mean(s.d.) number of analgesic tablets used was lower for RFA than for EVLA over 3 days (8·8(9·5) versus 14·2(10·7);p=0·003) and 10 days (20·4(22·6) versus 35·9(29·4) respectively;p=0·001).Changes in AVVQ, SF-12 and VCSS scores at 6 weeks were similar in the two groups: AVVQ (p=0·887), VCSS (p = 0·993), SF-12 physical component score (p = 0·276) and mental component score (p=0·449). They concluded that RFA using VNUS ClosureFAST was associated with less postprocedural pain than EVLA. However, clinical and quality-of-life improvements were similar after 6 weeks for the two treatments.

In the LARA study by SD Goode et al [76] published in 2010, Radiofrequency ablation (RFA) of the GSV was compared to Endovenous laser ablation (EVLA) to determine whether RFA was associated with less pain and bruising than EVLA. This was a randomised trial in which total 87 legs were treated. Limbs in the bilateral group were treated with RFA in one leg and EVLA in the other. In the unilateral group limbs were randomised to RFA or EVLA. RFA was performed using the Celon RFiTT system (Teltow, Germany). EVLA was performed using an 810 nm Laser (Biolitec AG, Germany). Primary endpoints were patient assessed pain and bruising measured by visual analogue scale (VAS). Secondary endpoints were patency assessed by duplex ultrasound at 6 weeks and 6 months. The results showed that in the bilateral group, RFA resulted in significantly less pain than EVLA on days 2-11 postoperatively. RFA also resulted in significantly less bruising than EVLA on days 3-

9. There were no significant differences in mean post operative pain, bruising and activity scores in the unilateral group. Both RFA and EVLA resulted in occlusion rates of 95% at 10 days postoperatively. They concluded that RFA was less painful for patients than EVLA and produced less bruising in the postoperative period with comparable success rates but there was no difference in the unilateral group.

In the randomized trial by Rasmussel et al [77] published in 2011, four treatments for varicose great saphenous veins were compared. Five hundred consecutive patients (580 legs) with GSV reflux were randomized to endovenous laser ablation (980 and 1470 nm, bare fibre), radiofrequency ablation, ultrasound-guided foam sclerotherapy or surgical stripping using tumescent local anaesthesia with light sedation. Miniphlebectomies were also performed. The patients were examined with duplex imaging before surgery, and after 3 days, 1 month and 1 year. The results showed that at 1 year, 7(5.8%), 6(4.8%), 20 (16.3%) and 4(4.8%) of the GSVs were patent and refluxing in the laser, radiofrequency, foam sclerotherapy and stripping groups. One patient developed a pulmonary embolus after foam sclerotherapy and one a deep vein thrombosis after surgical stripping. No other major complications were recorded. The mean (s.d.) postintervention pain scores (scale 0-10) were 2.58(2.41), 1.21(1.72), 1.60(2.04) and 2.25(2.23) respectively ($p<0.001$). The median (range) time to return to normal function was 2 (0-25), 1 (0-30), 1 (0-30) and 4 (0-30) days respectively ($p<0.001$). The time off work, corrected for weekends, was 3.6 (0-46), 2.9 (0-14), 2.9 (0-33) and 4.3 (0-42) days respectively ($p<0.001$). Disease-specific quality-of-life and Short Form 36 (SF-36) scores had improved in all groups by 1-year follow-up. In the SF-36 domains bodily pain and physical functioning, the radiofrequency and foam groups performed better in the short term than the others. The conclusions were that all treatments are equally

efficacious. The technical failure rate was highest after foam sclerotherapy, but both radiofrequency ablation and foam were associated with a faster recovery and less postoperative pain than endovenous laser ablation and stripping.

In 2011, Nordon IM et al [78] published their results of radiofrequency versus laser treatment of the great saphenous vein in patients with varicose veins. This was a prospective, double-blind randomized controlled trial in which consecutive patients with primary unilateral great saphenous vein (GSV) reflux undergoing endovenous treatment were randomized to RFA (VNUS ClosureFAST) or EVLT (810-nm diode laser). The primary outcome measure was GSV occlusion at 3 months after treatment. Secondary outcome measures were occlusion at 7 days, postoperative pain, analgesic requirement, and bruising, assessed at day 7 after Surgery. Quality of life (QoL) was assessed preoperatively and 3 months after surgery using the Aberdeen Varicose Vein Questionnaire (AVVQ) and EQ-5D. A total of 159 patients were randomized to RFA (79 patients) or EVLT (80 patients). Duplex scanning confirmed 100% vein occlusion at 1 week in both groups. At 3 months, occlusion was 97% for RFA and 96% for EVLT. Median percentage above-knee bruise area was greater after EVLT (3.85%) than after RFA (0.6%). Postoperative pain assessed at each of the first 7 postoperative days was less after RFA. Changes in the AVVQ and EQ-5D at 3 months were similar in both groups. They concluded that RFA and EVLT offer comparable venous occlusion rates at 3 months after treatment of primary GSV varices, with neither modality proving superior. RFA is associated with less periprocedural pain, analgesic requirement, and bruising.

Tesmann JP et al [79] published the results of their prospective, non-randomised study comparing RFITT (Radiofrequency Induced Thermotherapy) with EVLA in 2011. The comparison was done in terms of occlusion rates, side effects,

and patient's satisfaction. 133 patients with incompetent GSV or SSV were treated by RFITT (n=66) or EVLA (n=67). Follow up at days 1, 7, and months 3, 12 included duplex, digital photoplethysmography (DPPG), assessment of VCSS and patients' satisfaction. Both groups were balanced concerning clinical parameters. Occlusion rates were in trend in favour of EVLA (96.9%) *vs* RFITT (88.9%), p=0.093, at 12 months follow up. Functional outcome by digital PPG (venous refilling time: 30.8 *vs* 31.9 sec.), and side-effects were comparable apart from pain in the first postoperative week, which was more frequent in the EVLA group (0 *vs* 16.4%, p=0.001). Change in VCSS from baseline was advantageous for EVLA (89.9% *vs* 79.3%, p=0.005). Major complications did not occur. Both techniques provided excellent satisfaction results. Their conclusion was that after one year, RFITT is similarly as effective and safe as EVLT treatment of varicose insufficiency.

Taken as a whole, endoluminal treatment techniques today play an essential role in the treatment of varicosis. The early and mid-term treatment results achieved by endoluminal laser therapy and radio wave therapy with ClosureFast™ are at least as good as those of the traditional stripping operations, not to mention the considerably lower complication rates and a greater patient comfort. Although these two treatment techniques are used in a standardized manner, they, too, are subject to further developments. The objective is to further enhance patient comfort and to achieve permanently optimal closure rates of the treated veins.[27]

AIMS AND OBJECTIVES

The aim of this study was to assess the outcomes after the two endovenous procedures (Radiofrequency Ablation-RFA and Endovenous Laser Ablation-EVLA) for varicose veins / chronic venous insufficiency, and their comparison in terms of:

1. Imaging outcome (GSV occlusion / recanalisation status): Post-operative and during follow up visits

2. Physiological outcome (Venous refilling times): Preoperative, postoperative and at follow up visits

3. Quality of life (SQOR-V Questionnaire): Preoperative, postoperative and at follow up visits.

MATERIALS AND METHODS

This was a single centre, non randomized, prospective, longitudinal, open ended study. The study population consisted of patients presenting to our Jain Institute of Vascular sciences (JIVAS), Bhagwan Mahaveer Jain Hospital, Bangalore with varicose veins, who underwent treatment with either of the two endovenous procedures (RFA or EVLA). The total study period was one and a half years from April 2013 to October 2014 which included 1 year of patient recruitement and 6 months of follow up. All selected patients fulfilled the following inclusion criteria:

1. Patients of age 18 years and above
2. Willing to give consent
3. Doppler evidence of an incompetent SFJ and GSV reflux
4. Appropriate GSV diameter (3 mm - 12 mm)

The patients who had any of the following exclusion criteria were not included in our study:

1. Only SPJ incompetence or only SSV reflux
2. Deep venous reflux
3. Superficial thrombophlebitis
4. Iliac vein stenosis / occlusion on basis of doppler examination
5. Non-palpable pedal pulses with ABI < 0.8
6. Women who were pregnant or nursing (based on history)

All patients underwent a thorough clinical examination on presentation and the important parameters were documented which were age, sex, clinical indication for treatment, any comorbities and the CEAP (Clinical, Etiological, Anatomical and Pathological) classification of disease (Appendix I). As all the included patients had the same etiology (primary), anatomy (GSV and/or SSV) and pathology (reflux), only the clinical (C) classification was recorded.

After history and clinical examination, patients were evaluated by Colour Duplex Ultrasonography (CDU) at our institute with the GE™ LOGIQ E ultrasound machine using the 12L-RS (5-13 Mhz) linear probe. The superficial (GSV and SSV), perforating and deep venous systems (including Iliac veins) were evaluated with the patient in upright position. The GSV diameter was measured at a location 3 cm below the Sapheno-femoral junction (SFJ) and recorded. The SFJ and GSV reflux were recorded along with the grading. Reflux was defined as retrograde flow lasting for more than 0.5 seconds, and was classified as grade 1 (0.5-1 seconds), grade 2 (1-2 seconds), grade 3 (2-3 seconds), or grade 4 (>3 seconds). Only the patients with grade 2 reflux or above underwent endovenous treatment.

The venous refilling times (VRTs) were recorded with the UNETIXS™ Digital Photoplethysmography system. Photoplethysmography (PPG) was done with the patient sitting on the edge of examination table with legs in dependant position. The

tranducer of the PPG system was fixed on calf just cephalad to medial malleolus and the baseline tracing was recorded**.** Patient was asked to dorsiflex the foot ten times to exercise the calf muscle pump and empty the venous reservoir in the calf and skin**.** The time required for the PPG tracing to return to 90% of baseline after cessation of exercise was recorded as the venous refilling time (abnormal < 20 seconds).

The quality of life evaluation was done using the standard - Specific Quality of Life and Outcome Response – Venous (SQOR-V) Questionnaire, and the scores recorded (Appendix II). The questionnaire consisted of 46 items grouped in 5 dimensions (physical discomfort, appearance, activity restriction, emotional problems, risk and threat to health). Each item had 5 values (Scores 1 to 5) where 1 corresponded to no symptoms and 5 as severe symptoms. Each dimension was weighed to a maximum value of 20, yielding an overall maximum score of 100 per patient. The magnitude of score was inversely related to quality of life.

All patients were alternately planned for either of the two endovenous procedures (Endo Venous Laser Ablation or Radio Frequency Ablation), after written informed consent of the patient (Appendix III). All procedures were done under general or spinal anesthesia. A standard and uniform regimen of pre-operative antibiotics was followed for all patients. Percutaneous access to the GSV was obtained at appropriate level under ultrasound guidance, and the level of puncture was classified as above knee or below knee. Above knee puncture was done only in patients where a below knee puncture failed.

Endovenous laser ablation was done by the Biolitec™ Diode Endovenous Laser system. In all treated patients the 1470 nm radial fibre was used for ablation. After achieving GSV access, the fibre was passed proximally into the GSV and the

tip of the fibre was positioned 1-2cm distal to the SFJ. Then cold normal saline was infiltrated along the whole length of the vein being treated in order to provide tumescence. After adequate tumescence, ablation of the vein was done proximal to distal. The wattage of the machine and pullback time of the fibre was adjusted so as to deliver 80-100 Joules of energy per centimetre of the treated vein. The parameters recorded were the length of the vein treated (cms), the total energy deposited (Joules) and the linear endovenous energy deposited (LEED). The LEED was calculated as total energy deposited divided by the length of the vein treated (Joules/cm).

Radiofrequency ablation was done with the Covidien ClosureFast™ Endovenous Radiofrequency Ablation system. After achieving GSV access, the RFA catheter system was passed proximally into the GSV and the tip of the fibre was positioned 1-2cm distal to the SFJ. Then cold normal saline was infiltrated along the whole length of the vein being treated in order to provide tumescence. After adequate tumescence, ablation of the vein was done by sequential heating of the vein at 7-cm intervals, heating the vein to 120°C in each 20-second cycle. The first segment was treated twice. The length of the vein treated was recorded.

In the patients having SSV reflux on preoperative duplex, cannulation of the SSV was done at the appropriate level and ablation done with the same modality as was used for the GSV. In addition to either of the two endovenous procedures, all patients with branch varicosities received foam sclerotherapy with 3% sodium tetradecyl sulphate (STD). The foam was prepared using the Tessary method by mixing STD and air in a 1:4 ratio and injected under ultrasound guidance. The quantity of foam used was recorded. Intraoperative complications, if any, were recorded (Appendix IV).

At the end of procedure, all patients received a single prophylactic dose of unfractionated or low molecular weight Heparin. Patients were mobilised early on the same day, depending on the type of anaesthesia received. Graduated class II full length stockings for the treated legs were advised to all patients, starting from the immediate postoperative period for duration of three weeks, after which they changed to below knee stockings. On the first postoperative day, duplex examination of the treated legs was done to check for GSV/SSV occlusion and any evidence of DVT and the findings were recorded. All patients were discharged on the next day of procedure with a standard and uniform regimen of analgesics. Follow up was advised after 1 month, 3 months and 6 months. Within the 1 month period, patients were advised to report immediately in case they experienced any kind of symptom/discomfort due to complications. All complications occurring within 1 month of the endovenous procedure were recorded. Similarly, complications between 1 to 3 months and 3 to 6 months were recorded (Appendix V).

At the 1 month, 3 months and 6 months follow up visits, clinical examination, duplex scanning, VRT measurements and quality of life assessment were done for all patients and recorded. Parameters recorded on duplex were the status of GSV (occluded/recanalised) and presence/absence of reflux. Recanalisation was defined as patency of any segment/length of the GSV which was ablated. VRTs and quality of life evaluation were done with the same method as preoperatively.

Statistical comparison of the data were performed by using the Chi-square analysis, Fischer's exact test, Student's T test for paired and unpaired samples as appropriate and the Spearman's rank correlation analysis.

RESULTS

During the period of 1 year from April 2013 to April 2014, a total number of 94 patients (124 legs) with varicose veins who fulfilled all the inclusion criteria were included in the study with an intent to treat. All included patients underwent endovenous ablation in the form of EVLA or RFA at our institute. The study population was divided into two groups, one who underwent EVLA and the other who underwent RFA. A total of 46 patients (60 legs) underwent EVLA and 48 patients (64 legs) underwent RFA. The age, sex and limb distribution of the population is shown in Table 2.

Table 2. Age, Sex and limb distribution (n=94)

Parameters	EVLA	RFA	P value*
Age(yrs)	49.09 ± 13.84	46.98 ± 11.25	0.419
Sex(M,F)	28,18	29,19	1 .000
Side(UL,BL)	32,14	32,16	0.827

*P values (two-tailed) calculated using Fisher's exact test

The presenting symptoms were recorded as prominent veins, swelling, pain, discoloration, ulceration, bleeding and itching. The most common symptom on presentation was prominent veins (85; 68.54%), followed by swelling (53; 42.74%). The distribution of symptoms is shown in Table 3.

Table 3. Presenting symptoms (n=124)

Presenting symptoms	No. of legs (%)
V (Prominent veins)	85 (68.54)
S (Swelling)	53 (42.74)
P (Pain)	40 (32.26)
D (Discoloration)	37 (29.83)
U (Ulcer)	28 (22.58)
B (Bleeding)	10 (8.06)
I (Itching)	8 (6.45)

All major comorbidities were recorded such as diabetes, hypertension, smoking, coronary artery disease and others. Hypertension was the most common comorbidity recorded which was present in 20 (21.28%) patients, followed by Diabetes in 18 (19.15%) patients. The distribution of other comorbidities is depicted in Table 4.

Table 4. Distribution of co-morbidities (n=94)

Co-Morbidities	No. of patients (%)
No co-morbidities	52 (55.32)
Diabetes	18 (19.15)
Hypertension	20 (21.28)
Smokers	13 (13.82)
Coronary artery disease	8 (8.51)
Hypothyroidism	4 (4.26)
Atrial Fibrillation	1 (1.06)
Chronic liver disease	1 (1.06)

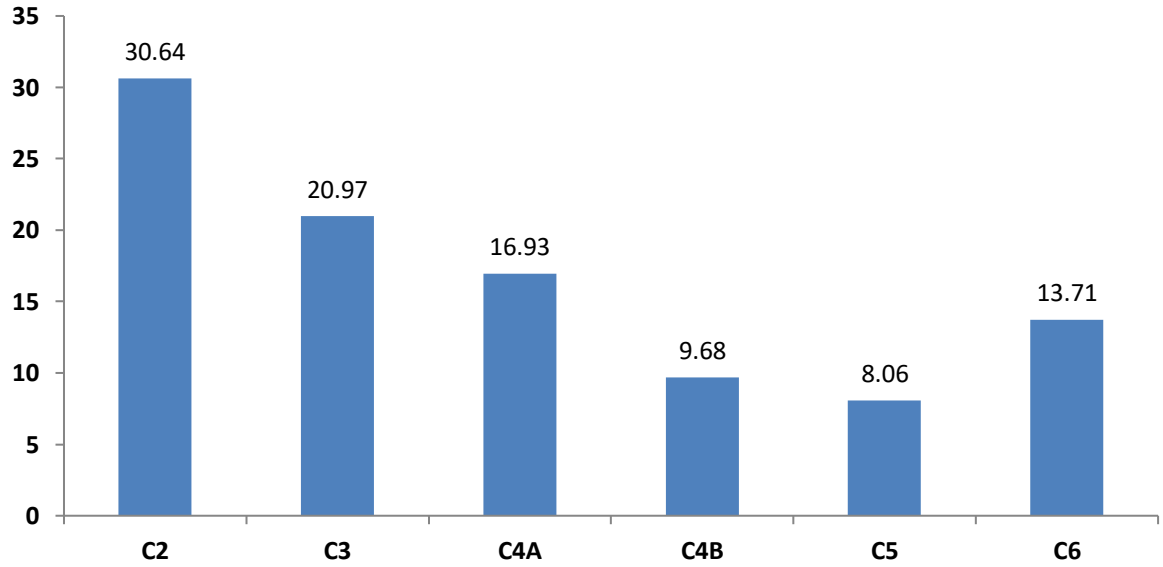
Considering the CEAP classification, all included patients (legs) were classified as clinical (C2-C6), etiology (primary), anatomical (superficial) and

pathology (reflux). Most of the patients (legs) had C2 disease on presentation (38; 30.64%) followed by C3 disease (26; 20.97%). The distribution of the C stage of disease is shown in Table 5 and Figure 2.

Table 5. C classification (n=124)

Class (C)	No.of legs (%)
2	38 (30.64)
3	26 (20.97)
4A	21 (16.93)
4B	12 (9.68)
5	10 (8.06)
6	17 (13.71)

Figure 2. C-staging of legs (%)



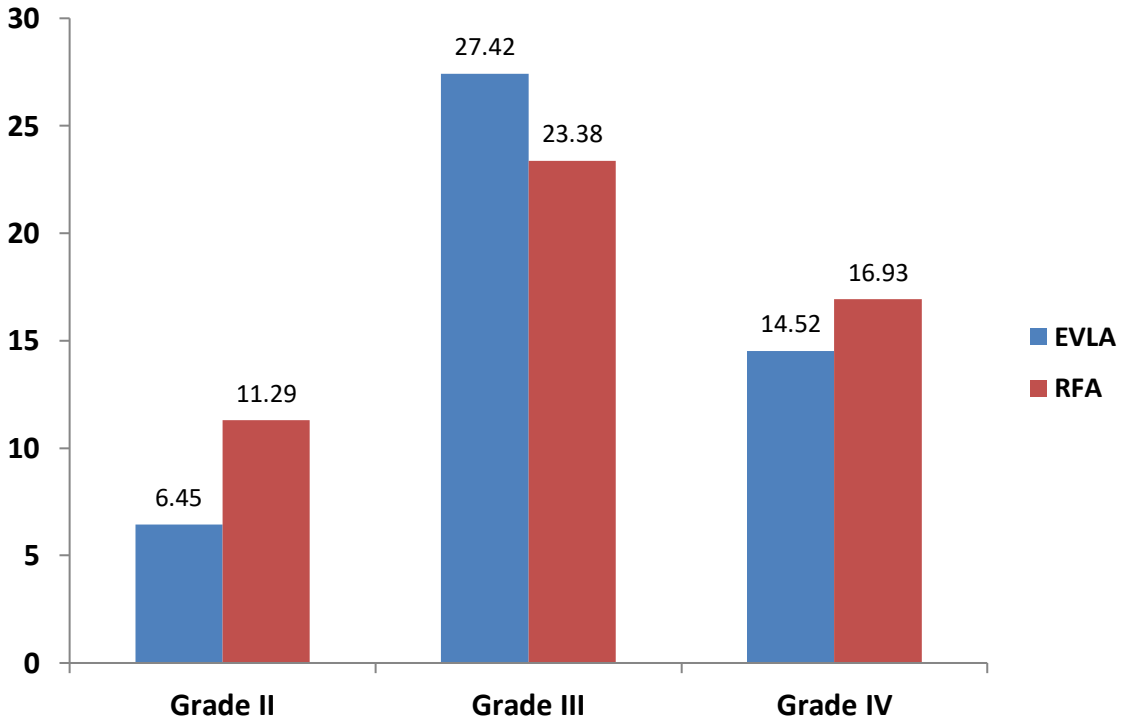
On duplex examination, maximum number of legs (63, 50.8%) had a grade III reflux in the GSV. The distribution of the three grades of reflux in both groups is shown in Table 6 and Figure 3.

Table 6. Grading of GSV reflux (n=124)

Duplex (Reflux grade)	EVLA (n=60)	RFA (n=64)	P Value*
II	8(6.45)	14(11.29)	0.246
III	34(27.42)	29(23.38)	0.215
IV	18(14.52)	21(16.93)	0.847

*P values (two-tailed) calculated using Fisher's exact test

Figure 3. Grading of GSV Reflux (%)



The mean GSV diameter on duplex was 7.41 ± 1.16 mm in the EVLA group and 7.32 ± 1.01 mm in the RFA group (p=0.675). The short saphenous vein (SSV) had significant reflux on duplex in 14 legs and was planned for ablation along with the primary procedure.

The preoperative venous refill times (VRTs) ranged from 3.6 seconds to 17.4 seconds with a mean of 9.22 ± 3.62 seconds in the EVLA group. In the RFA group, the times ranged from 3.2 seconds to 16.6 seconds with a mean of 9.03 ± 3.47 seconds. The difference in the mean preoperative VRTs between the two groups was not significant at p=0.764.

The preoperative quality of life evaluation with the SQOR-V questionnaire had scores ranging from 36.8 to 78.4 with a mean of 52.72 ± 9.87 in the EVLA group and a range of 36.8 to 82.4 with a mean of 53.43 ± 10.12 in the RFA group. The difference was not statistically significant at p=0.734. The preoperative VRTs and SQOR-V scores for both groups are mentioned in Table 7.

Table 7. Preoperative VRT and SQOR-V scores

	EVLA	**RFA**	**P value***
SQOR-V Scores	. 52.72 ± 9.87	53.43 ± 10.12	**0.734**
VRT Scores	9.22 ± 3.62	9.03 ± 3.47	**0.764**

*P values (two-tailed) calculated using unpaired t-test

Out of 94 patients, 80 patients received spinal anesthesia and 14 patients received general anesthesia. In 124 legs, percutaneous GSV access was taken through below knee puncture in 111 legs and above knee puncture in 13 legs. The distribution of anesthesia and access is shown in Table 8 and Table 9.

Table 8. Distribution of anesthesia (n=94)

Anesthesia	SA	GA	P value*
EVLA (n=46)	39	7	1 .000
RFA (n=48)	41	7	

*P value (two-tailed) calculated using Fisher's exact test

Table 9. GSV access (n=124)

Access	BK	AK μ	P value*
EVLA (n=60)	54	6	1 .000
RFA (n=64)	57	7	

μ Above knee access was taken only in patients where below knee access failed

* P value (two-tailed) calculated using Fisher's exact test

In the EVLA group, the total length of the vein treated ranged from 26 cm to 52 cm with a mean of 42.38 ± 5.79 cm. The total energy deposited ranged from 2320 Joules to 4750 Joules with a mean of 3812.33 ± 529.26 Joules. The linear endovenous energy deposited (LEED) ranged from 82.14 Joules/cm to 96.36 Joules/cm with a mean of 89.99 ± 3.37 Joules/cm. In the RFA group, the total length of vein treated ranged from 22 cm to 50 cm with a mean of 41.47 ± 7.13. The volume of foam used for sclerotherapy ranged from 5 ml to 20 ml with a mean of 9.24 ± 4.59 in EVLA and 9.79 ± 4.72 in RFA group. The above parameters were recorded as in Table 10.

Table 10. Intraoperative parameters

Parameter	EVLA	RFA	P value*
GSV Diameter (mm)	7.41 ± 1.16	7.32 ± 1.01	0.675
Treated GSV Length (cm)	42.38 ± 5.79	41.47 ± 7.13	0.436
LEED (Joules/cm)	89.99 ± 3.37	-	-
Volume of foam used (ml)	9.24 ± 4.59	9.79 ± 4.72	0.567

*P value (two-tailed) calculated using unpaired t-test

In the EVLA group, 4 SSV's were ablated in addition to the GSV. In the RFA group, SSV ablation was done in 10 legs in addition to GSV as shown in Table 11. This difference was not significant (p=0.258)

Table 11. Distribution of SSV ablation

Vein Treated	GSV	SSV	P value*
EVLA (n=60)	60	4	0.258
RFA (n=64)	64	10	

*P value (two-tailed) calculated using Fisher's exact test

No intraoperative complications were observed in both groups. Post procedure, duplex scanning on the 1st postoperative day showed a 100% success rate with all GSVs and SSVs occluded with no recanalisation or reflux. After discharge, the number and nature of complications occurring anytime within the 1st postoperative month were recorded. The recorded complications included minor complications which were bruising/ecchymosis, erythema, phlebitis, paresthesias, skin burns, hematoma and local infection and major complications which were deep vein thrombosis and pulmonary embolism. Only few minor complications were

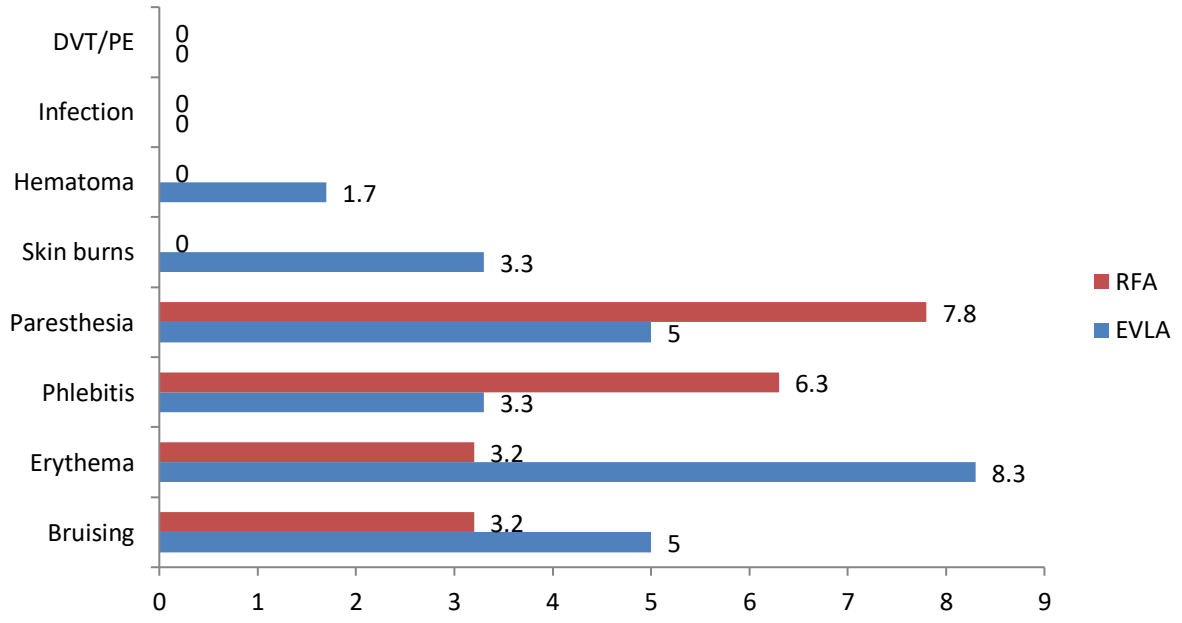
observed in both groups with no major complications. All complications were managed conservatively. The complications occurring in both groups were analysed as shown in Table 12 and Figure 4.

Table 12. Complications within 1 month

Complication	EVLA (%)	RFA (%)	P value*
Bruising	3(5)	2(3.2)	0.673
Erythema	5(8.3)	2(3.2)	0.262
Phlebitis	2(3.3)	4(6.3)	0.68
Paresthesia	3(5)	5(7.8)	0.719
Skin burns	2(3.3)	0	0.232
Hematoma	1(1.7)	0	0.484
Infection	0	0	-
DVT/PE	0	0	-

*P value (two-tailed) calculated using Fisher's exact test

Figure 4. Distribution of complications within 1 month(%)



All 94 treated patients returned back after 1 month for the first follow up. Duplex scanning at 1 month showed a 100% success rate in both groups with all GSVs occluded and no recanalisation or reflux. The quality of life evaluation at 1 month showed SQOR-V scores ranging from 23.2 to 41.6 with a mean of 33.23 ± 4.82 in the EVLA group and a range of 22 to 41.6 with a mean of 32.13 ± 5.29 in the RFA group (p=0.298). The VRT at 1 month ranged from 21.5 seconds to 50.6 seconds with a mean of 34.04 ± 8.16 seconds in the EVLA group and range of 22.1 seconds to 52.4 seconds with a mean of 34.53 ± 8.25 seconds in the RFA group (p=0.739). Both SQOR-V scores and VRTs at showed significant improvement in both groups at 1 month after treatment as shown in Table 13. The analysis for SQOR-V and VRT at 1 month is shown in Table 14.

Table 13. SQOR-V and VRT comparison before and after intervention

	Preoperative	**1 month**	**P value***
SQOR-V	53.08 ± 9.95	32.67 ± 5.07	p<0.0001
VRTs	9.12 ± 3.53	34.29 ± 8.18	p<0.0001

*P values (two-tailed) calculated using paired t-test

Table 14. SQOR-V and VRTs (EVLA vs RFA) at 1 month follow up

1 month	**EVLA**	**RFA**	**P value***
SQOR-V	33.23 ± 4.82	32.13 ± 5.29	0.298
VRTs	34.04 ± 8.16	34.53 ± 8.25	0.739

*P values (two-tailed) calculated using unpaired t-test

At the 3rd month following endovenous ablation, 4 patients did not return for follow up. Patients lost to follow up included 2 from the unilateral EVLA group, 1 from the unilateral RFA group and 1 from the bilateral RFA group. At the 6th month evaluation another 4 patients were lost to follow up, in addition to the previous 4 patients. These included 1 patient from the unilateral EVLA group, 1 from bilateral EVLA, 1 from unilateral RFA and 1 from bilateral RFA groups. The distribution of patients and legs at the 3rd and 6th month follow up visits is depicted in Table 15.

Table 15. Distribution of patients and legs at the 3rd and 6th month follow up visits

Follow up visits	1 month	3 months	6 months
UL EVLA (n=32)	32	30 (2 LTFU)	29 (3 LTFU)
UL RFA (n=32)	32	31 (1 LTFU)	30 (2 LTFU)
BL EVLA (n=14)	14	14 (0 LTFU)	13 (1 LTFU)
BL RFA (n=16)	16	15 (1 LTFU)	14 (2 LTFU)

UL – Unilateral, BL – Bilateral, LTFU – Lost to follow up

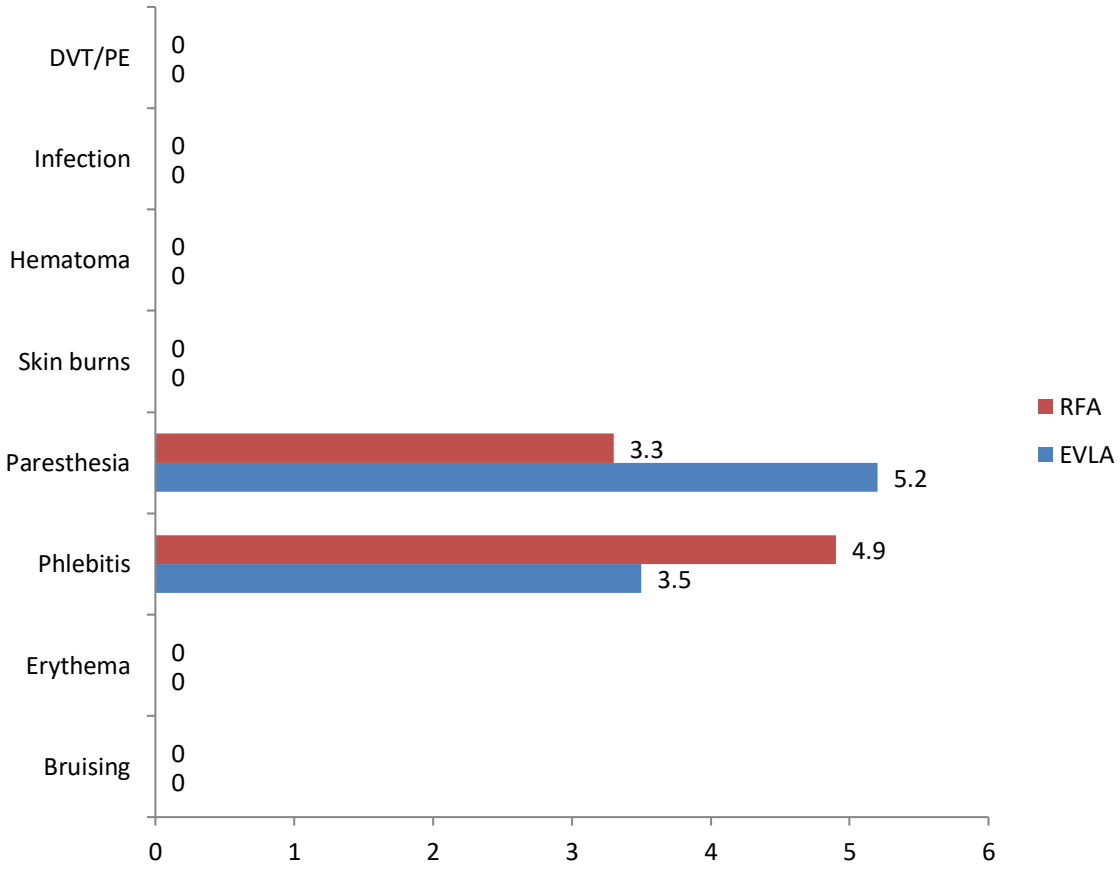
At the 3rd month follow up, clinical examination was followed by duplex examination, quality of life and VRT evaluation were done. All complications which were present between 1 and 3 months were recorded. No major complications were observed and only few minor complications seen. All complications were managed conservatively. The distribution of complications is shown in Table 16 and Figure 5.

Table 16. Complications between 1-3 months

Complications (1-3m)	EVLA (n=58)	RFA (n=61)	P value*
Bruising	0	0	-
Erythema	0	0	-
Phlebitis	2(3.5)	3(4.9)	1 .000
Paresthesia	3(5.2)	2(3.3)	0.674
Skin burns	0	0	-
Hematoma	0	0	-
Infection	0	0	-
DVT/PE	0	0	-

*P values (two-tailed) calculated using Fisher's exact test

Figure 5. Distribution of complications between 1-3 months (%)



The duplex scanning showed 2 GSV recanalisations in the EVLA group and 3 in the RFA group. In the EVLA group, one patient who had a right GSV ablation was found to have segmental recanalisation of GSV on lower thigh region. The other patient had undergone bilateral GSV ablation and developed a segmental recanalisation of the left GSV on the mid-thigh region. Similarly, in the RFA group, two patients of left GSV RFA had lower thigh segmental recanalisations and one patient of bilateral RFA had a right GSV mid and lower thigh segmental recanalisation. Thus the success rate of EVLA and RFA as seen at 3 months were 96.55% and 95.08% respectively, which was not statistically significant (p=1.000) as shown in Table 17.

Table 17. Success rates of EVLA and RFA at 3 months

Duplex at 3 months	GSVs recanalised	GSVs occluded	Success rate (p=1.000)	P value*
EVLA (n=58)	2	56	96.55%	1.000
RFA (n=61)	3	58	95.08%	

*P values (two-tailed) calculated using Fisher's exact test

The quality of life evaluation at 3 months showed SQOR-V scores ranging from 21.6 to 32.8 with a mean of 25.27 ± 3.0 in the EVLA group and range of 20.8 to 32.8 with a mean of 24.65 ± 3.3 in the RFA group. This difference was not significant at p=0.354.

The VRTs at 3 months ranged from 8.6 seconds to 51.2 seconds with a mean of 34.81 ± 8.39 seconds in the EVLA group and range of 12.1 seconds to 51.3 seconds with a mean of 35.92 ± 8.37 seconds in the RFA group. The difference was

not statistically significant at p=0.469. The SQOR-V scores and VRTs at 3 months are shown in Table 18.

Table 18. SQOR-V and VRTs (EVLA vs RFA) at 3 months follow up

3 months	EVLA	RFA	P value*
SQOR-V	25.27 ± 3.0	24.65 ± 3.3	0.354
VRTs	34.81 ± 8.39	35.92 ± 8.37	0.469

* P values (two-tailed) calculated using unpaired t-test

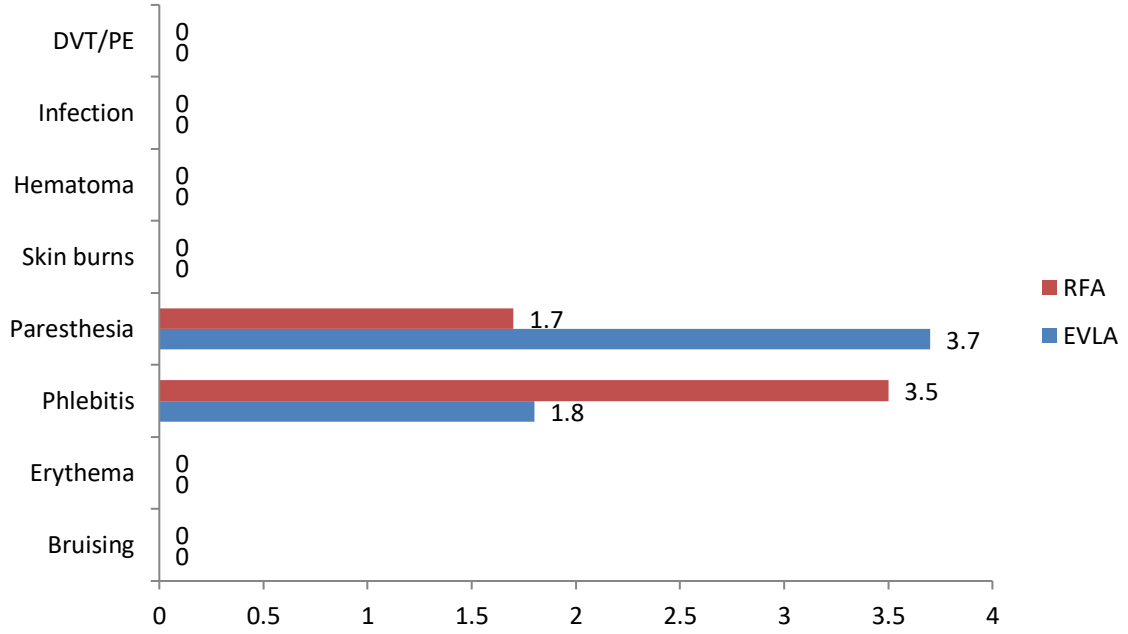
At the 6th month follow up, clinical examination was followed by duplex examination, quality of life and VRT evaluation were done. All complications which were present between 3 and 6 months were recorded. No major complications were observed and only few minor complications seen. All complications were managed conservatively The distribution of complications is shown in Table 19 and Figure 6.

Table 19. Complications between 3-6 months

Complications (3-6m)	EVLA (n=55)	RFA (n=58)	P value*
Bruising	0	0	-
Erythema	0	0	-
Phlebitis	1(1.8)	2(3.5)	1 .000
Paresthesia	2(3.7)	1(1.7)	0.612
Skin burns	0	0	-
Hematoma	0	0	-
Infection	0	0	-
DVT/PE	0	0	-

*P values (two-tailed) calculated using Fisher's exact test

Figure 6. Distribution of complications between 3-6 months (%)



The duplex scanning at 6 months showed 2 more GSV recanalisations in the EVLA group and 2 more in the RFA group, in addition to the previous 5 recanalisations, making the total number of recanalised GSVs to 9. In the EVLA group, one patient who had a left GSV ablation was found to have segmental recanalisation of GSV on lower thigh region. The other patient had undergone bilateral GSV ablation and developed a segmental recanalisation of the right GSV on the mid-thigh region. Similarly, in the RFA group, two patients of bilateral RFA had segmental recanalisations, one on the mid and lower thigh region, right leg and the other on the lower thigh region, left leg. Thus the success rate of EVLA and RFA as seen at 6 months were 92.72% and 91.38% respectively, which was not statistically significant (p=1.000) as shown in Table 20.

Table 20. Success rates of EVLA and RFA at 6 months

Duplex at 6 months	GSVs recanalised	GSVs occluded	Success rate (p=1.000)	P value*
EVLA (n=55)	4	51	92.72%	1.000
RFA (n=58)	5	53	91.38%	

*P values (two-tailed) calculated using Fisher's exact test

The quality of life evaluation at 6 months showed SQOR-V scores ranging from 20 to 27.2 with a mean of 21.16 ± 1.72 in the EVLA group and range of 20 to 25.6 with a mean of 21.01 ± 1.47 in the RFA group. This difference was not significant at p=0.659.

The VRTs at 6 months ranged from 7.6 seconds to 50.5 seconds with a mean of 35.40 ± 10.05 seconds in the EVLA group and range of 7.4 seconds to 52.2 seconds with a mean of 36.57 ± 9.85 seconds in the RFA group. The difference was not statistically significant at p=0.535. The SQOR-V scores and VRTs at 6 months are shown in Table 21.

Table 21. SQOR-V and VRTs (EVLA vs RFA) at 6 months follow up

6 months	EVLA	RFA	P value*
SQOR-V	21.16 ± 1.72	21.01 ± 1.47	**0.659**
VRTs	35.40 ± 10.05	36.57 ± 9.85	**0.535**

* P values (two-tailed) calculated using unpaired t-test

A compilation of the SQOR-V scores and the VRTs in the preoperative, postoperative periods and follow up visits is shown for both groups in Table 22 and Table 23.

Table 22. SQOR-V Scores

SQOR-V Score	EVLT	RFA	P value
Preoperative	52.72 ± 9.87	53.43 ± 10.12	0.734
1 month	33.23 ± 4.82	32.13 ± 5.29	0.298
3 months	25.27 ± 3.00	24.65 ± 3.30	0.354
6 months	21.16 ± 1.72	21.01 ± 1.47	0.659

Table 23. Venous refilling times (VRTs)

VRT (sec)	EVLT	RFA	P value
Preoperative	9.22 ± 3.62	9.03 ± 3.47	0.764
1 month	34.04 ± 8.16	34.53 ± 8.25	0.739
3 months	34.99 ± 7.87	35.92 ± 8.37	0.533
6 months	35.70 ± 9.29	36.53 ± 9.95	0.646

A subanalysis was done for the recanalised legs to correlate the quality of life and venous refill times with the recanalisation of the ablated GSV at any period of time. The SQOR-V scores and VRTs for the recanalised patients were compiled separately and comparison done for both variables before and after recanalisation during follow up visits. On the 3rd followup visit, duplex examination had showed segmental recanalisation in 5 patients. The SQOR-V scores and VRTs of these patients at 1 month and 3 months were compared. The SQOR-V scores were in the range of 25.2 to 28.4 with a mean of 26.48 ± 1.31 at 1 month and range of 30.4 to

32.8 with a mean of 31.68 ± 1.07 at 3 months. This increase in the scores was statistically significant at p=0.002. Similarly, VRTs at 1 month were in the range of 27.1 to 31.5 with a mean of 29.22 ± 2.06 seconds and a range of 8.6 to 14.3 with a mean of 11.72 ± 2.15 seconds at 3 months. This decrease in VRTs was also statistically significant at p=0.0002. These comparisons were done as shown in Table 24.

Table 24. Analysis of SQOR-V scores and VRTs in recanalised patients between 1 to 3 months

	1 month	**3 months**	**P value***
SQOR-V	26.48 ± 1.31	31.68 ± 1.07	0.002
VRTs (seconds)	29.22 ± 2.06	11.72 ± 2.15	0.0002

*P values (two-tailed) calculated using paired t-test

In a similar manner, the SQOR-V scores and VRTs of 4 patients who developed GSV recanalisation between 3 months and 6 months were compiled separately. The SQOR-V scores ranged from 21.6 to 24.4 with a mean of 22.6 ± 1.24 at 3 months and a range of 23.6 to 26 with a mean of 25.2 ± 1.13 at 6 months. This increase in scores was statistically significant at p=0.012. The VRTs ranged from 24.7 to 33.8 seconds with a mean of 28.6 ± 3.99 seconds at 3 months and a range of 8.5 to 13.4 seconds with a mean of 10.68 ± 2.25 seconds at 6 months. This decrease in VRTs was statistically significant at p=0.004. These comparisons were done as shown in Table 25.

Table 25. Analysis of SQOR-V scores and VRTs in recanalised patients between 3 to 6 months

	3 months	6 months	P value*
SQOR-V	22.6 ± 1.24	25.2 ± 1.13	0.012
VRTs (seconds)	28.6 ± 3.99	10.68 ± 2.25	0.004

*P values (two-tailed) calculated using paired t-test

Lastly, a correlation analysis was done to measure the correlation between the GSV recanalisation, quality of life scores and VRTs. The SQOR-V scores and VRTs of the 5 recanalised patients between 1 and 3 months showed a strong negative correlation with a Pearson correlation coefficient of -0.92245 which was statistically significant at p=0.0258. Similarly, the SQOR-V scores and VRTs of the 4 recanalised patients between 3 and 6 months showed a strong negative correlation with a Pearson correlation coefficient of -0.95328 which was statistically significant at p=0.047. These results are compiled in Table 26 and Table 27.

Table 26. Correlation analysis of SQORV scores and VRTs at 3 months

	3 months	PCC$^{\mu}$	P value*
SQOR-V	31.68 ± 1.07	**-0.92245**	**0.0258**
VRTs (seconds)	11.72 ± 2.15		

$^{\mu}$ Pearson correlation coefficient

* P value (two-tailed) calculated using Spearman's rank correlation analysis

Table 27. Correlation analysis of SQORV scores and VRTs at 6 months

	6 months	PCC$^{\mu}$	P value*
SQOR-V	25.2 ± 1.13	**-0.95328**	**0.047**
VRTs (seconds)	10.68 ± 2.25		

$^{\mu}$ Pearson correlation coefficient

* P value (two-tailed) calculated using Spearman's rank correlation analysis

DISCUSSION

Present study included 94 patients (124 legs) divided into two groups – EVLA group and RFA group. A total of 46 patients (60 legs) underwent EVLA and 48 patients (64 legs) underwent RFA. The mean age was 49.09 ± 13.84 in the EVLA group and 46.98 ± 11.25 in the RFA group. Number of males predominated with a M:F ratio of 57:37. The most common symptom on presentation was prominent veins (85; 68.54%) and Hypertension was the most common comorbidity recorded which was present in 20 (21.28%) patients. Majority of the patients (legs) had C2 disease on presentation (38; 30.64%) and maximum number of legs (63, 50.8%) had a grade III reflux in the GSV on duplex scanning. In all previous studies,[74,75,76] duplex examination was used for the documentation of GSV reflux and GSV diameters. Goode SD et al [76] had recorded a GSV diameter of 7.5 ± 2.5 mm in the EVLA group and 8.1 ± 2.6 mm in the RFA group by duplex. Almeida JI et al [74] observed GSV diameters of 5.1 ± 2.3 mm in the RFA group and 6.0 ± 2.8 in the EVLA group. In our study, we observed a mean GSV diameter of 7.41 ± 1.16 mm in the EVLA group and 7.32 ± 1.01 mm in the RFA group (p=0.675) by duplex examination.

In our EVLA group, the total length of the vein treated ranged from 26 cm to 52 cm with a mean of 42.38 ± 5.79 cm. This was almost similar to the length of GSV treated by Almeida JI et al [74], which was 42.2 ±14.0 cm. Goode SD et al [76] had documented the length of GSV treated as 46 cm (IQR 44-49). In our study, the total energy deposited in the EVLA group ranged from 2320 Joules to 4750 Joules with a mean of 3812.33 ± 529.26 Joules. The linear endovenous energy deposited (LEED) ranged from 82.14 Joules/cm to 96.36 Joules/cm with a mean of 89.99 ± 3.37 Joules/cm. This was in accordance with the recommendation of using 80-120 Joules/cm for adequate ablation of the GSV.[18,19,63] Doganci et al [32] had reported the

outcomes of EVLA with the 1470 nm radial fibre, where they had used the laser's continuous mode and a constant pullback with a rate corresponding to 90 J/cm linear endovenous energy density (LEED) in the vein.

RFA was performed according to the standard protocol as mentioned in previous publications.[15,17,20,36] The volume of foam used for sclerotherapy ranged from 5 ml to 20 ml in accordance with the earlier publications [67,68,69] with a mean of 9.24 ± 4.59 in EVLA and 9.79 ± 4.72 in RFA group. As a general observation, volume of foam used was more in the patients with bilateral disease.

Evaluation of quality of life in our patients was done using the venous specific SQOR-V questionnaire. Shepherd AC et al [80] had observed a strong correlation between the AVVQ and SQOR-V disease specific quality of life questionnaires, and this correlation was stronger than that seen with the SF12, supporting the use of the SQOR-V as a valid and responsive disease specific questionnaire. In the majority of their study patients, changes in post procedure AVVQ scores correlated with the changes in the SQOR-V scores. The SQOR-V questionnaire was specifically designed to allow more sensitive evaluation of the functional impact of venous disease in patients in CEAP classes C1-C6. The results from their study were able to support the use of the SQOR-V in patients with venous insufficiency. In their study, a baseline mean score of 45.60 (36.54 - 57.17) was observed and at 6 weeks following treatment in the form of surgery or endovenous procedures, a mean score of 33.53 (25.64 - 42.11) was observed. This decrease in the SQOR-V score corresponded to a better quality of life following treatment. The mean scores in patients with C2 disease at presentation were 46.496 while in C6 disease the mean scores were 55.014, which showed that the quality of life was poor in patients with C6 disease as compared to patients with C2 disease.[80]

Guex JJ et al [48] observed a significant increase of the SQOR-V global scores between patients belonging to CEAP classes C1– C2 and classes C3–C6. The global score and the physical impact were also higher in symptomatic patients. Thus, SQOR-V scores discriminated according to the severity of the disease. Exploring the impact of the symptomatology in the global score of the SQOR-V, they observed that asymptomatic patients had lower global SQOR-V scores than those who were symptomatic (36.1 ± 8.5 vs. 44.8 ± 10.9; P<0.001). The SQOR-V global score, according to CEAP classification was also analyzed using an analysis of variance (ANOVA). This revealed that the global score significantly differed between C4 and C1 patients (< 0.001) and between C3 and C1 patients (P = 0.02). They concluded that the SQOR-V can be used in longitudinal studies and clinical practice, and can be used to demonstrate efficacy of different treatments, even in patients belonging to CEAP classes C0 - C3, since the outcome is very sensitive to physical and psychosomatic variations.[48]

In our study, the preoperative quality of life evaluation with the SQOR-V questionnaire had scores ranging from 36.8 to 78.4 with a mean of 52.72 ± 9.87 in the EVLA group and a range of 36.8 to 82.4 with a mean of 53.43 ± 10.12 in the RFA group (p=0.734). The quality of life evaluation at 1 month showed SQOR-V scores ranging from 23.2 to 41.6 (33.23 ± 4.82) in the EVLA group and a range of 22 to 41.6 (32.13 ± 5.29) in the RFA group (p=0.298). At 3 months, SQOR-V scores ranged from 21.6 to 32.8 (25.27 ± 3.0) in the EVLA group and range of 20.8 to 32.8 (24.65 ± 3.3) in the RFA group (p=0.354). Evaluation at 6 months showed SQOR-V scores ranging from 20 to 27.2 (21.16 ± 1.72) in the EVLA group and range of 20 to 25.6 (21.01 ± 1.47) in the RFA group (p=0.659). These results showed a significant improvement in the quality of life in all patients (p<0.0001) following endovenous

treatment with either of the two modalities, RFA or EVLA. The patients in whom the duplex examination at follow up visits showed complete occlusion of the GSV had further improvements in their quality of life at 3 months and 6 months. However, the subanalysis for patients having recanalisation by duplex at follow up visits at 3 months and 6 months showed a significant deterioration in their quality of life. This was evident from the finding that patients having recanalisation at 3 months had SQOR-V scores in the range of 25.2 to 28.4 (26.48 ± 1.31) at 1 month and range of 30.4 to 32.8 (31.68 ± 1.07) at 3 months. This increase in the scores, and hence decrease in quality of life was statistically significant at p=0.002. Similarly, patients having recanalisation at 6 months had SQOR-V scores ranging from 21.6 to 24.4 (22.6 ± 1.24) at 3 months and a range of 23.6 to 26 (25.2 ± 1.13) at 6 months. This increase in scores was also statistically significant at p=0.012. These findings suggested a correlation between the GSV recanalisation on duplex imaging at follow up visits and the poor quality of life in these patients following recanalisation.

The previous studies comparing the quality of life between treatment with EVLA or RFA show variable results. Results of the RECOVERY trial by Almeida JI et al [74] showed that the venous clinical severity scores and quality of life measures were statistically lower in patients who underwent treatment with RFA at 48 hours, 1 week, and 2 weeks, as compared to patients who underwent EVLA. Shepherd AC et al [80] published the results of their randomized clinical trial of VNUS Closure FAST radiofrequency ablation versus laser for varicose veins in which they concluded that RFA using VNUS ClosureFAST was associated with less postprocedural pain than EVLA. However, clinical and quality-of-life improvements were similar after 6 weeks for the two treatments. The results of the LARA study by Goode SD et al [76] comparing RFA with EVLA showed that RFA was less painful for patients than EVLA

and produced less bruising in the postoperative period, hence patients undergoing RFA had a better quality of life. In the randomized trial by Rasmussel et al [77] four treatments for varicose great saphenous veins were compared. This trial concluded that both radiofrequency ablation and foam sclerotherapy were associated with a faster recovery and less postoperative pain than endovenous laser ablation and stripping. Nordon IM et al [78] concluded in their double-blind randomized controlled trial of radiofrequency versus laser treatment that RFA is associated with less periprocedural pain, analgesic requirement, and bruising and hence better quality of life. In our results, we found that there were no significant differences in the quality of life between patients who underwent RFA or EVLA during the 1month, 3 month and 6 month follow up visits.

Physiological evaluation in our study patients was done by measuring the VRTs preoperatively, postoperatively and at follow up visits. Sarin S et al [44] had concluded in their study that photoplethysmography readings are reproducible, noninvasive, and correlate well with the presence of clinical disease, and photoplethysmography remains useful in the assessment of venous dysfunction. Sam RC et al [43] evaluated the effectiveness of measuring the VRTs in patients with venous reflux and their study showed that median interquartile range (IQR) VRT in patients with venous disease was 13.5 seconds (8.5 - 22.0 seconds), with a significantly lower VRT in limbs with clinically worse disease (C2/3 - 15 seconds; C4-6 - 7.5 seconds; P<.0001). The patients in the study by Shepherd AC et al [80] had baseline mean VRT values of 19.33 (11.00-25.50), which increased to a mean value of 25.73 (17.00-33.00) at 6 weeks following treatment in the form of surgery or endovenous ablation (p<.001). However, further studies using VRTs for measuring the physiological outcome following treatment for venous disease are lacking. In our

study, the preoperative VRTs ranged from 3.6 seconds to 17.4 seconds (9.22 ± 3.62) in the EVLA group, and 3.2 seconds to 16.6 seconds (9.03 ± 3.47) in the RFA group (p=0.764). VRTs at 1 month ranged from 21.5 seconds to 50.6 seconds (34.04 ± 8.16) in the EVLA group and 22.1 seconds to 52.4 seconds (34.53 ± 8.25) in the RFA group (p=0.739). The VRTs showed significant improvement in both groups at 1 month after endovenous treatment (p<0.0001) with either of the two modalities, RFA or EVLA. VRTs at 3 months ranged from 8.6 seconds to 51.2 seconds (34.81 ± 8.39) in the EVLA group and range of 12.1 seconds to 51.3 seconds (35.92 ± 8.37) in the RFA group (p=0.469). 6 month VRTs ranged from 7.6 seconds to 50.5 seconds (35.40 ± 10.05) in the EVLA group and 7.4 seconds to 52.2 seconds (36.57 ± 9.85) in the RFA group (p=0.535). Above findings showed no significant differences between the physiological outcome after endovenous treatment with EVLA or RFA.

The patients who had no GSV recanalisation by duplex at follow up visits had an improvement of physiological outcome as evident by the upward trend of VRTs during subsequent visits. However, the subanalysis of patients in whom GSV recanalisation had occured, showed poor physiological outcomes as evident by a significant drop in the VRTs during follow up visits. In patients who were found to have recanalised at 3 months, the VRTs at 1 month were in the range of 27.1 to 31.5 (29.22 ± 2.06) seconds and a range of 8.6 to 14.3 (11.72 ± 2.15) seconds at 3 months (p=0.0002). In patients with recanalised GSV at 6 months, the VRTs ranged from 24.7 to 33.8 seconds (28.6 ± 3.99) at 3 months and a range of 8.5 to 13.4 seconds (10.68 ± 2.25) at 6 months (p=0.004). Above findings showed a correlation between recanalisation of the GSV by duplex imaging and the physiological outcome at follow up visits.

Shepherd AC et al [80] had evaluated the relationship between disease-specific quality-of-life and venous refilling times, but they did not observe any correlation between the venous refill time in patients with unilateral disease and either AVVQ or SQOR-V questionnaires. (Spearman coefficients -0.042 and 0.043; p=.606 and p= .065, respectively). But in present study, we observed a strong correlation between the quality of life and physiological outcome in the subanalysis for patients with recanalisation at follow up visits. This was evident from the findings that in the recanalised patients, the SQOR-V scores increased (QOL decreased) and the VRTs decreased. The SQOR-V scores and VRTs of the 5 recanalised patients between 1 and 3 months showed a strong correlation with a Pearson correlation coefficient of -0.92245 which was statistically significant at p=0.0258. Similarly, the SQOR-V scores and VRTs of the 4 recanalised patients between 3 and 6 months showed a strong correlation with a Pearson correlation coefficient of -0.95328 which was statistically significant at p=0.047. Hence our results showed a strong correlation between the poor quality of life and poor physiological outcome in patients who had developed recanalisation of the GSV during follow up.

The procedural success rates of EVLA and RFA also vary among the different studies. The randomised controlled trial of RFA versus EVLA by Nordon IM et al [78] showed a 100% vein occlusion by duplex scanning at 1 week in both groups. At 3 months, occlusion was 97% for RFA and 96% for EVLT (P = 0.67). In the LARA study, Goode SD et al [76] compared the occlusion rates with RFA and EVLA in a randomised controlled trial. A postoperative duplex examination at 10 days showed 95% occlusion with both RFA and EVLA. After a period of 9 months, duplex showed 78% occlusion with EVLA and 74% with RFA. The meta-analysis by Van den Bos R et al [12] showed that success rates after 3 years for radiofrequency ablation and laser

therapy were about 84% (75%-90%), and 94% (87%-98%). In the randomized trial by Rasmussel et al,[77] all patients were examined with duplex imaging before procedure, and after 3 days, 1 month and 1 year. The results showed that at 1 year, 7(5.8%) and 6(4.8%) of the GSVs were patent and refluxing in the laser and radiofrequency groups. Tesmann JP et al [79] published that occlusion rates were in favour of EVLA (96.9%) *vs* RFA (88.9%), p=0.093, at 12 months follow up. Our study results had a 100% occlusion by duplex in both patient groups immediately after procedure and at 1 month. At 3 months, occlusion rates were 96.55% (56/58) with EVLA and 95.08% (58/61) with RFA (p=1.000). After 6 months, the occlusion rates were 92.72% (51/55) with EVLA and 91.38% (53/58) with RFA (p=1.000). Hence no significant differences were observed between the procedural success with RFA and EVLA at 1, 3 and 6 months.

The distribution of minor as well as major complications following endovenous procedures also varies among the previous studies. Shepherd AC et al [80] in their randomised control trial comparing RFA with EVLA observed two major complications. One patient randomized to RFA suffered a pulmonary embolus 2 weeks after intervention and one patient in the EVLA group developed a lymphatic leak from the cannulation site. Minor complications included wound infection (4.6%), haematoma (1.5%), thrombophlebitis (6.1%), saphenous nerve paraesthesia (9.9%) and skin staining (6.1%). The distribution of complications in the RFA group versus laser group were wound infection (6% vs 3%), hematoma (0 vs 3%), thrombophlebitis (7% vs 5%), paraesthesia (12% vs 8%), skin staining (9% vs 3%), seroma (3% vs 2%) and pulmonary embolism (1% vs 0). Results of the RECOVERY study by Almeida JI et al [74] showed that the complications were statistically more prevalent in the EVLA group than the RFA group (22.0% vs 4.4%; *P* = .0210). In this

study, the complications were recorded in both RFA and EVLA groups at 48 hours, 1 week, 2 weeks and 1 month. The overall incidence of complications at any follow up in the RFA vs EVLA group were hyperpigmentation (2.2% vs 0), Phlebitis (0 vs 14.6%), paraesthesia (2.2% vs 4.9%), erythema (0 vs 9.8%), infection (0) and PE/DVT (0 vs 2.4%). The incidence of complications was higher in the EVLA group, with significantly higher phlebitis (p=0.009) and erythema (p=0.045). In our study, complications observed within the first month, between 1-3 months and between 3-6 months were recorded. No major complications such as deep venous thrombosis (DVT) or Pulmonary embolism (PE) were observed in any of our patients in the postoperative period or during follow up. Minor complications which occurred within 1 month in the EVLA group vs RFA group were bruising/ecchymosis (5% vs 3.2%; p=0.673), erythema (8.3% vs 3.2%; p=0.262), phlebitis (3.3% vs 6.3%; p=0.68), paraesthesia (5% vs 7.8%; p=0.719), skin burns (2% vs 0; p=0.232), and hematoma (1.7% vs 0; p=0.484). Between 1 to 3 months, the only complications seen in few patients were phlebitis and paraesthesia. The distribution of complications in the EVLA vs RFA group were phlebitis (3.5% vs 4.9%; p=1.00) and paraesthesia (5.2% vs 3.3%; p=0.674). During the 3-6 months period, the complications observed in the EVLA vs RFA group were phlebitis (1.8% vs 3.5%; p=1.000) and paraesthesia (3.7% vs 1.7%; p=0.612). Hence, we observed that no major complications occurred following either of the endovenous procedures. Only minor complications occurred after both procedures and no significant differences were observed. The minor complications such as bruising, erythema, skin burns and hematoma were mostly observed within the first month following the endovenous procedure. Other complications such as phlebitis and paraesthesia were observed even during the 3 months and 6 months follow up in addition to the postoperative 1 month period. But

none of the complications were significantly different between the two procedures, which suggested that both were comparable to each other.

All above observations in our study showed no significant differences in the two modalities in terms of GSV occlusion rates, physiological outcome, quality of life changes and procedure related complications.

CONCLUSIONS

Our study assessed the outcomes after the two endovenous procedures (Radiofrequency Ablation-RFA and Endovenous Laser Ablation-EVLA) in patients having varicose veins / chronic venous insufficiency. All the observations were documented and compared between the two endovenous procedures.

The duplex imaging on postoperative day 1 and after 1 month showed 100% GSV occlusion in both groups. At 3 months, occlusion rates were 96.55% (EVLA) and 95.08% (RFA); p=1.000. At 6 months, occlusion rates were 92.72% (EVLA) and 91.38% (RFA); p=1.000. Hence we concluded that there is no significant difference in the imaging outcome between the two treatment modalities postoperatively and at 1, 3 and 6 months.

The physiological evaluation with VRTs showed no significant differences between the two modalities preoperatively (p=0.764), at 1 month (p=0.739), 3 months (p=0.533) and 6 months (p=0.646). The physiological outcome correlated with the imaging outcome as the patients who developed GSV recanalisation by duplex had lower VRTs (poor physiological outcome) as compared to patients with GSV completely occluded. Hence we concluded that there is no significant difference in the physiological outcome between the two treatment modalities at 1, 3 amd 6 months. Also, measuring the physiological outcome with VRTs is an excellent method for monitoring the success of the endovenous procedures during follow up visits.

The health related quality of life evaluation with the SQOR-V questionnaire also showed no significant differences between the two modalities preoperatively (p=0.734), at 1 month (p=0.298), at 3 months (p=0.354) and at 6 months (p=0.659).

The QOL evaluation also correlated with the imaging outcome as the patients who developed GSV recanalisation by duplex had higher SQOR-V scores (poor QOL) as compared to patients with GSV completely occluded. Hence we concluded that there is no significant difference in the quality of life after treatment with the two modalities at 1, 3 amd 6 months. Also, measuring the HRQOL using the SQOR-V questionnaire is an excellent method for monitoring the success of the endovenous procedures during follow up visits.

The subanalysis of patients having recanalisation on follow up visits showed that there was a significant correlation between the physiological outcome and quality of life at 3 months ($p=0.0258$) and at 6 months ($p=0.047$).

We did not observe any major post-operative complications. Among the minor complications, none were significantly different among the two treatment groups.

Hence we concluded that EVLA with the newer available systems (1470nm wavelength, Radial fibre) is as effective as RFA (Closure Fast) for the treatment of GSV/SFJ reflux with no significant differences in terms of procedural success rates, physiological success, quality of life changes and complication rates at 1, 3 and 6 months.

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