Radiofrequency ablation (RFA) for primary varicose veins: a feasible day-case procedure with good surgical and functional outcomes

El-Sayed A. Abd El-Mabood, Hussein G. El-Gohary, Atef A. Salem

Department of General Surgery, Vascular Unit, Benha University, Benha, Egypt

Correspondence to El-Sayed A. Abd El-Mabood, MD, Department of General and Vascular Surgery, Benha University Hospital, Benha, 13516, Egypt; Mob: 01065351802; e-mail: elsayedafifi@yahoo.com

Received 6 June 2017
Accepted 23 July 2017

The Egyptian Journal of Surgery
2017, 36:407–418

Objective
The aim of this study was to find out surgical and functional outcomes of the feasible day-case radiofrequency ablation (RFA) procedure for primary varicose veins (VV).
Background
Management of VV has changed rapidly in recent years. RFA being less invasive alternative to vein stripping can be done by percutaneous catheter-based closure without the necessity of incision.
Patients and methods
This prospective randomized controlled study was conducted on 26 patients (31 limbs) with primary VV; all patients were treated with RFA using VNUS closure under tumescent anesthesia. Patients were randomly allocated into two groups according to the performed RFA technique: group A: 'standard technique' [16 (51.6%) limbs] and group B: 'modified technique' [15 (48.4%) limbs]. Follow-up period was 6 months.
Results
There were satisfactory results with no complications in both groups at 3–6 months of follow-up (93.3% in group A and 86.7% in group B) and marked improvement of patients symptoms (P=0.011). The mean operative time was 62.9±5.4 min in group A and 51.8±3.2 min in group B. Patients in both groups were discharged within hours and returned to work within few days. On 1-week postoperative follow-up, minor complications were observed that disappeared with time, except for one (3.3%) limb with deep venous thrombosis, which was reported in group B.
Conclusion
Endovenous RFA and foam sclerotherapy, whichever is the performed technique, have shown to be very promising techniques as they are minimally invasive and highly effective, with high patient satisfaction and quality of life, better cosmetic results, and fewer days off work.

Keywords:
outcomes, primary varicose veins, radiofrequency ablation

Egyptian J Surgery 36:407–418

1110-1121

Introduction

Varicose veins (VV) are veins (usually in the legs) that have lost their elasticity and bulge with blood as a result. They occur if the valves in the veins become weak and let the blood go the 'wrong way' back through the veins. Over time, the veins become wider to cope with the extra blood, and this eventually leads to loss in elasticity. People with VV can feel pain in the affected area, their legs can feel tired and can swell, the skin can start to look different, and ulcers can appear in the area [1–3].

Chronic venous insufficiency (CVI) of the lower limbs is a common condition afflicting 25% of women and 15% of men, with venous reflux at the sapheno-femoral junction (SFJ) being the most common cause leading to VV. Long standing CVI can result in skin changes, including eczema, pigmentation, liposclerosis, and ulceration. Cosmetic concerns relate to the VV themselves and any associated skin changes. Surgical treatment of VV has been the gold standard for many years [4–6].

Multiple techniques for treating saphenous reflux have been developed over the years, including high ligation of the saphenous vein, saphenous vein stripping, and ultrasound (US)-guided sclerotherapy, as well as various combinations of these procedures. Most recently, endovenous thermal ablation has also been identified as a viable treatment option for patients with saphenous reflux [6,7].

Over the past decade, technological progress has enabled the development and application of new minimally invasive therapies such as VNUS closure

endovenous radiofrequency ablation (RFA) and endolaser [8–10].

RFA is a minimally invasive technology that provides efficacious treatment of venous reflux with minimal discomfort and 'downtime' for patients. One of the primary advantages of RFA is that the current procedure can be performed in an outpatient office setting with the use of local tumescent anesthesia [11]. The RFA technique has been used to treat VV, and it has several improvements over the original technology and features a 'segmental ablation' method using the Covidien (formerly VNUS) ClosureFAST catheter that is designed for treating both the great saphenous vein (GSV) and small saphenous vein (SSV). The ClosureFAST catheter is constructed with a 7-cm bipolar electrode affixed to its distal end [12–14].

RFA of a varicose vein involves using radiofrequency (RF) energy to heat the vein wall so that it collapses. Blood is redirected through nearby healthy veins as a result. For a varicose vein in the leg, the heating device is inserted either through a small cut in the skin made above or below the knee (depending on the area to be treated) or through a sheath that is run into the vein under the skin. Once in place in the vein, the device is slowly pulled back through the vein so that it heats and seals the vein as it goes [15,16].

The RFA mechanism is such that the electrode must make direct contact with the vein wall to deliver RF energy. Contact with the wall results in destruction of the endothelium, occlusion by contraction of vein wall collagen, and thrombus formation. Eventually, fibrosis occurs within the vein as well as the formation of new collagen matrix, which further constricts the vein lumen and successfully occludes the vein [17,18].

RFA of the GSV was described by [19]. The manufacturer suggests that the technique is suitable for ablation of a nontortuous GSV of less than 12 mm diameter and is thus applicable in 30–58% of patients with varicose vein. Although there are anecdotal reports of its use in larger veins, there is no published data to confirm that [19].

The current prospective study is aimed to find out surgical and functional outcomes of the feasible day-case RFA procedure regarding being less pain, early return to normal activities, fewer days off work, and better cosmetic results.

Patients and methods

After approval from the local ethical committee of Benha University, written fully informed consent was obtained from each patients. The current study was conducted at the Vascular Unit of General Surgery Department, Benha University, from October 2015 till June 2017 so as to allow 6-month follow-up period for last case operated on. This prospective randomized controlled study was conducted on 26 patients (31 limbs): 21 patients with unilateral limb and five patients with bilateral limbs with primary VV. All patients were treated with RFA using the VNUS RF generator and the ClosureFast catheter (VNUS Medical Technologies, San Jose, California, USA) under duplex scan guidance and by using tumescent anesthesia. Its safety limits were 30–35 mg/kg body weight. Patients were randomly allocated by using a computer generated random number table into two groups according to the performed RFA technique: group A: 'standard technique' [16 (51.6%) limbs] and group B: 'modified technique' [15 (48.4%) limbs].

Patients included in this study were adults experiencing symptomatic primary VV, CEAP c_2 grade or above (Clinical, Etiological, Anatomical, Pathological classification), and either unilateral or bilateral VV. All were fit for regional/general anesthesia. Patients were excluded from this study if they had previously undergone varicose vein surgical stripping, were experiencing secondary VV or had vein diameter more than 1.2 cm or less than 0.2 cm, had tortuous veins that were considered to be unsuitable for RFA, had coagulation disorder, had peripheral arterial diseases, were pregnant, were unable to ambulate, or were extremely obese.

All patients presenting to the vascular unit of general surgery ward were admitted and underwent clinical evaluation, routine hematological tests, and venous duplex of both lower limbs to mark the highest point of reflux. After this, the patients were posted for intervention. On the day of the procedure, the patients were well hydrated to achieve maximum vein distention. The patients were kept warm, and the US gel was heated before placing it on the leg to avoid venospasm.

Radiofrequency ablation procedure

The procedure was performed under general, regional, or tumescent local anesthesia. The access site was detected ultrasonographically, and the procedure was initiated at or just below the popliteal area. In the reverse Trendelenburg's position, lidocaine was administered at the selected site, and a percutaneous

technique with Seldinger needle was used to gain access under U/S guidance. A small cutdown was used in few cases. A 0.035-inch guide wire was inserted into GSV and the needle was removed. Next, a 6F×10-cm or 8F×10-cm sheath was advanced over the wire and the VNUS catheter was inserted and advanced over the wire to the predetermined point. Optimal positioning of the catheter tip was 2 cm peripheral to the SFJ, which was done under U/S guidance.

Tumescent anesthesia was administered under US guidance using 22-gauge spinal needle connected to pump delivery system along the entire target treatment length to create a fluid layer around the GSV. Sufficient anesthesia was instilled to create a 10-mm diameter around vein, hence forming a distance of 10 mm between the targeted vein and the skin. A representative mixture includes 50 ml of 1% lidocaine with 1 ml epinephrine (1 : 100 000) in 450 ml of normal saline, neutralized with 5 to 10 ml of 8.4% sodium bicarbonate. Delivery of the tumescent anesthetic was helped by tourniquet application and was applied perivenously, and patient was placed in Trendelenburg's position to achieve maximum vein collapse.

Positioning of the catheter tip was reconfirmed with US before treatment is commenced. After that the generator was turned on. Then, either the "standard technique", where heating treatment is done at 85°C, in which the first 5.0 cm of saphenous vein was ablated at 1.0 cm per minute followed by the remainder of the GSV being ablated at 1 cm per 30 s, or "modified technique," in which the first 5.0 cm of saphenous vein was heated and ablated at 1.0 cm per minute with the generator set at 90°C after which the catheter is slowly and continuously pulled back at a rate 1 cm per 20 s that maintains a vein wall temperature of 90°C, was used. In both techniques, there was 0.5-cm overlap of each pair of segments and the pulled back was continuous until the desired vessel length was treated. When the final segment was treated, pulling of heating element of the catheter was avoided into the sheath because it might melt the sheath. The generator was turned off and sheath and closure catheter were then removed and hemostasis was obtained with manual compression over the access site.

Further treatment by US-guided sclerotherapy for the residual tributaries was performed immediately at the end of the RFA procedure. The sclerosant used in this study was aethoxysklerol (2%). The areas of concern were disinfected with a Povidone iodine solution 10%, then sclerosing agent solution was prepared for foam sclerotherapy (FS). It was aspirated in a 10-ml syringe and connected to a three-way cannula with a 10-ml syringe containing 7 ml of air; the syringes were rapidly depressed sequentially to create the foam sclerosant to air volume ratio (1 : 3).

A vein light was used to identify the reticular vein that was less than 5 mm, and a 26-G needle was placed into the vein with return of blood confirmed. The foam was injected through the needle while observing the foam displace the blood from the vein; the needle was removed at the end of the injection. In some cases, injection of the foam was done through multiple cannula inserted in the dilated tributaries. After all injections were completed, pressure dressings were placed on the veins treated, and simultaneously, the leg was elevated to achieve 90° of hip flexion. Thigh and knee were wrapped with an elastic compression bandage for 5 days continuously, taking it off only to shower. Thereafter, thigh high class II graduated compression stocking was applied for 2 weeks to minimize postprocedure bruising.

Clinical evaluation was performed for all patients at 1 week, 3 months, and 6 months. Patients were asked about symptomatic relief at follow-up visits, particularly improvement or resolution of lower extremity pain associated with venous insufficiency. Improvements in the appearance of the leg including reduction in visible varicosities, swelling, pigmentation, or other skin changes secondary to CVI were assessed by the patients, with direct comparison with pretreatment photographs obtained from all patients undergoing treatment. Patients were evaluated for possible adverse reactions caused by RFA at each follow-up visit. Minor complications were defined as those that had no significant clinical sequelae such as bruising. Major complications were defined as those necessitating an increased level of care, surgery, or hospitalization.

Outcome items

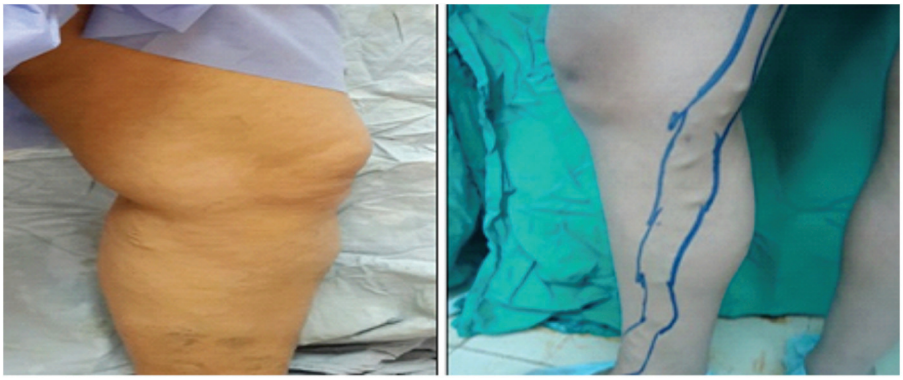
Patients were discharged 1–3 days after intervention and were followed up for 1 week for vessel perforation, nerve injury (manifesting as numbness, decreased or altered sensation or paresthesia), thrombosis [superficial thrombophlebitis or deep venous thrombosis (DVT)], thermal skin injury, and return to daily activities, and postoperative (PO) pain was evaluated using a Visual Analog Score (VAS). Patients ranked the level of pain from 0 (no pain) to 10 (very severe pain). Patients completed questionnaires dealing with analgesic use to detect the level of pain over the previous 24 h. Then, patient satisfaction and quality of life were evaluated using the Venous Clinical Severity Score (VCSS), which is composed of 10 parameters (pain, VV, edema, pigmentation, inflammation,

induration, number of ulcers, duration of ulcers, size of ulcers, and compressive therapy) and are graded 0–3 (absent, mild, moderate, and severe) [20]. To assess PO outcome, Duplex US examination was performed to confirm a successful obliteration procedure and to rule out any potential DVT or extension of thrombus from the saphenous vein into the femoral vein (Figs 1–6).

Statistical analysis

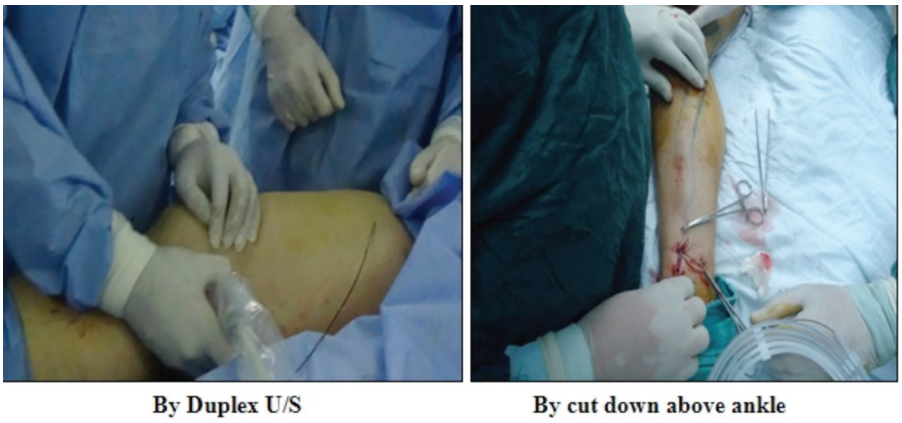
Analysis of data was done by using SPSS, version 16 (SPSS Inc., Chicago, Illinois, USA). Means of all

Figure 1



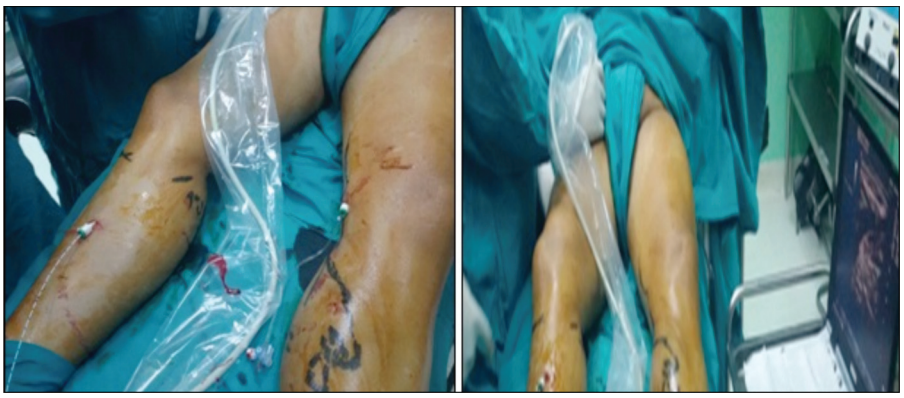
Preradiofrequency ablation photos.

Figure 2



Identification of the great saphenous vein.

Figure 3



Bilateral radiofrequency ablation (RFA) of great saphenous vein by sheath 6F: below right knee, above left knee; with identification of sapheno-femoral junction during introduction of RFA catheter to avoid deep vein injury.

continuous variables were compared by appropriate parametric or nonparametric tests (SD<50% mean). Categorical variables and proportions were analyzed using χ^2 and Fisher's exact tests. Results were expressed as medians, percentages, and mean±SD.

Steps of RFA of the GSV with immediate FS injection of the residual tributaries are shown in Figs 1–6.

Results

This prospective study was conducted on 26 patients with duplex US features of primary VV (31 limbs): 21 patients with unilateral limb and five patients with bilateral limbs. They were divided into two groups according to the performed RFA technique: group A: 'standard technique' [16 (51.6%) limbs] and group B: 'modified technique' [15 (48.4%) limbs]. Patients included 20 (76.9%) women and six (23.1%) men, with the following age strata – 25–35 years: seven (26.9%), 36–45 years: 14 (53.8%), and older than 45 years: five (19.3%) (Table 1 and Graph 1).

The most common symptoms were pain and visible veins which were present in almost all patients. Other

Table 1 Patients' demographic data

Data	Findings [*n* (%)]
Age (years)	
Strata	
25–35	7 (26.9)
36–45	14 (53.8)
>45	5 (19.3)
Sex	
Females	20 (76.9)
Males	6 (23.1)
Clinical categories	
C_2: varicose veins	17 (65.4)
C_3: varicose veins with edema	4 (15.4)
C_4: VV with skin changes without ulcer.	4 (15.4)
C_5: VV with healed ulcer.	1 (3.8)
C_6: VV with active ulcer.	0 (0)
Presenting symptoms	
Restless leg (heaviness)	26 (100)
Visible varicose vein	25 (96.2)
Skin discoloration	5 (19.3)
Night cramps	2 (7.7)
Bleeding	1 (3.8)
Total	26 (100)
Treated limbs (31)	
Right	9 (34.6)
Left	12 (46.1)
Bilateral	5 (19.3)
Total	31 (100)
Performed technique (limbs)	
Group A: 'Standard technique'	16 (51.6)
Group B: 'Modified technique'	15 (48.4)

VV, varicose veins.

Figure 4

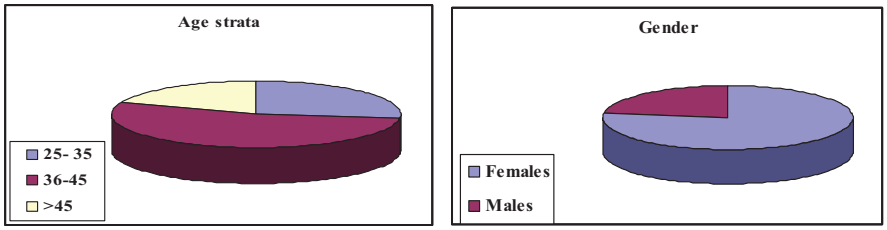
Radiofrequency apparatus VNUS type used in the present study.

Table 2 Vein characteristics: (*N*=31 limbs in 26 patients)

Data	Findings *n* (%)/mean±SD (range)
Anatomical	
GSV along the whole length	17 (54.8)
GSV above the knee	13 (41.9)
SSV	1 (3.3)
Vein reflux	
GSV reflux	30 (96.7)
SSV reflux	1 (3.3)
Diameter of GSV (mm)	
At 3 cm Below SFJ	10.2±0.4
At Mid-thigh	7.3±0.2
GSV puncture	
At the level of the knee	20 (64.5)
At the level of the ankle	10 (32.3)

GSV, great saphenous vein; SSV, small saphenous veins.

Graph 1



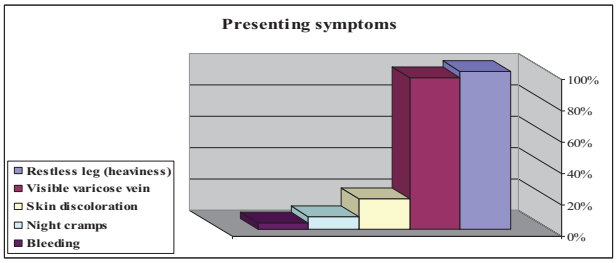
Patients' demographic data (age and sex).

symptoms included night cramps, bleeding, and skin discoloration. The studied patients were classified according to CEAP classification, which entails clinical, etiological, anatomical, and pathophysiological classification (Table 1, Graphs 2 and 3).

Upon review of characteristics of the affected veins, anatomical classification of VV of the studied 26 patients (31 limbs) was mainly seen in GSV reflux using duplex US that was used also to determine the site of puncture of GSV at either the level of the knee or the ankle and to detect site of SFJ (Table 2).

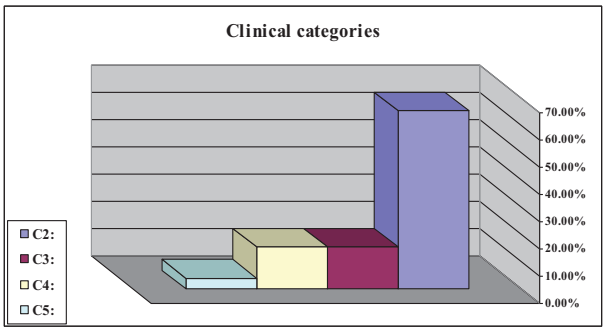
Tumescent anesthesia was used in all patients beside general or spinal anesthesia especially in irritable patients. All patients passed uneventful intraoperative course without complications. Mean operative time was 62.9±5.4 in group A, with a range of 51–87 min, and 51.8±3.2 in group B, with a range of 45–72 min.

Graph 2



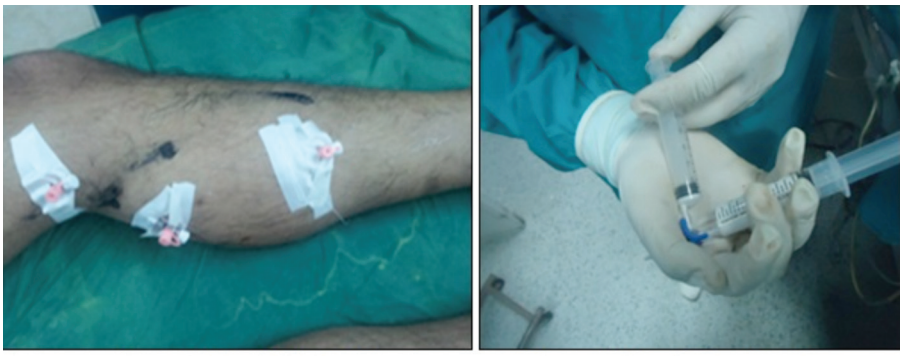
Presenting symptoms.

Graph 3



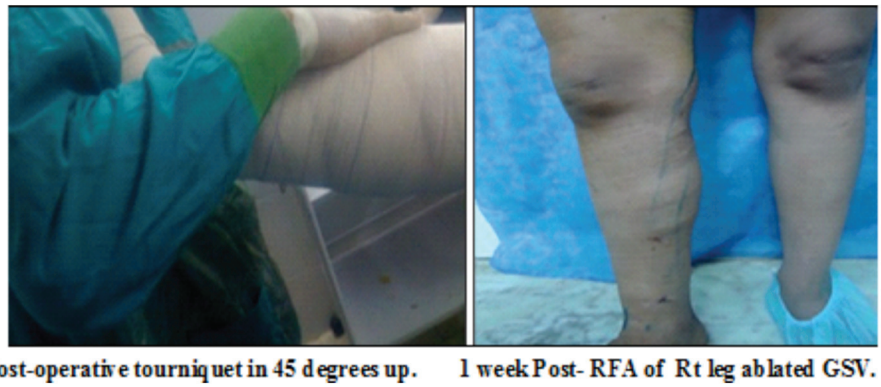
Clinical categories.

Figure 5



Technique for foam sclerotherapy injection.

Figure 6



Postoperative photos: immediate and after 1 week.

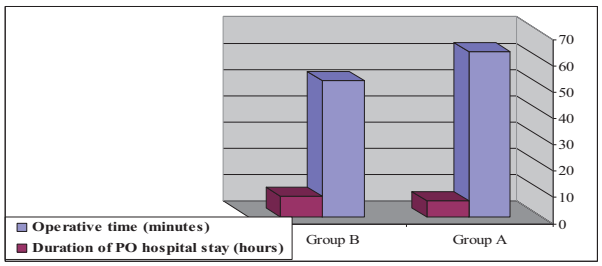
Patients in group A were discharged 6.2±1 h PO, whereas in group B, they were discharged 7.9±2 h PO (Table 3 and Graph 4).

Chemical sclerotherapy was performed for some patients of this study with residual dilated tributary after RFA. This was usually performed in the same session of RFA; the rate of injection in patients is shown in Table 4.

On using a VAS, patients in both groups experienced significantly less PO pain on first 2 days (VAS: 2.09 ±0.3 vs. 3.05±0.01; *P*=0.001) and seventh day (VAS: 0.9±1.1 vs. 1.51±0.9; *P*=0.001) (Table 5 and Graph 5).

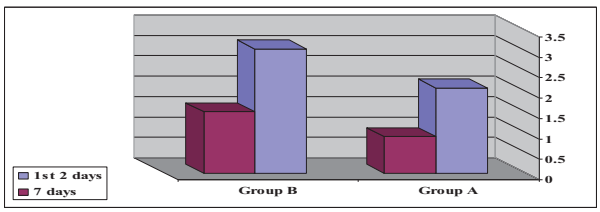
No mortality was recorded; however, one patient of SSV reflux did not come for follow-up, and data collection was applied on 25 patients (30 limbs) only, with 15 limbs in each group. At 1-week PO, erythema, hematoma, and bruising and ecchymosis were present in group A in one (3.3%), one (3.3%), and two (6.6%) limbs, respectively, versus two (6.6%),

Graph 4



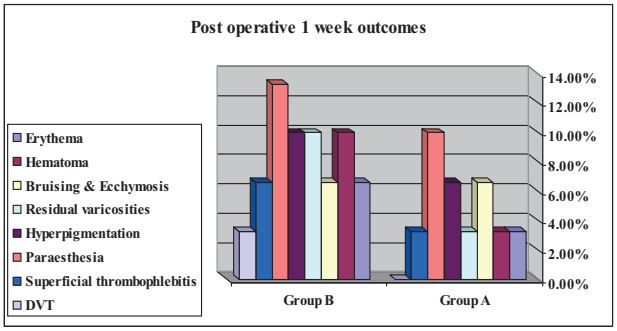
Operative and immediate postoperative (PO) data.

Graph 5



Postintervention pain assessment using a Visual Analog Score.

Graph 6



Postoperative 1-week outcomes. DVT, deep venous thrombosis.

Table 3 Operative and immediate postoperative data

Variables	Group A [16 (50.6%)]	Group B [15 (48.4%)]	*t*	*P* value
Operative time (min)				
Mean±SD	62.9±5.4	51.8±3.2	3.6	0.000 (HS)
Range	51–87	45–72		
Duration of PO hospital stay (h)				
Mean±SD	6.2±1	7.9±2	4.6	0.001 (HS)
Range	5–12	6–14		

HS, highly significant; PO, postoperative. Statistically significant difference was observed using unpaired *t*-test.

Table 4 Sclerotherapy in the studied patients: (*N*=31 limbs in 26 patients)

Types of varicose vein	Type of procedure	*n* (%)
GSV reflux without dilated tributary	RFA alone	24 (77.4)
GSV reflux with dilated tributaries	RFA with injection sclerotherapy	6 (19.3)
SSV reflux without dilated tributary	RFA alone	1 (3.3)

GSV, great saphenous vein; RFA, radiofrequency ablation; SSV, small saphenous veins.

Table 5 Pain assessment using a visual analog score

Variables	Mean±SD		*t*	*P* value
	Group A [16 (50.6%)]	Group B [15 (48.4%)]		
First 2 days	2.09±0.3	3.05±0.01	4.6	0.001 (HS)
7 days	0.9±1.1	1.51±0.9	3.9	0.001 (HS)

HS, highly significant. Statistically significant difference was observed using unpaired *t*-test.

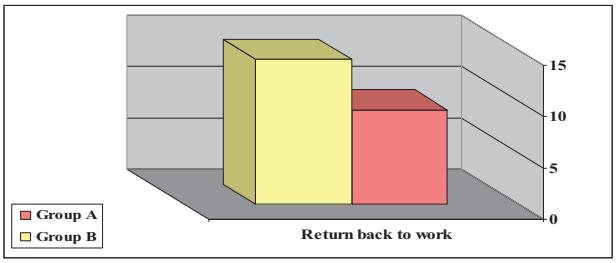
three (10%), and two (6.6%) limbs, respectively, in group B. Residual varicosities that appeared in both groups were treated immediately by FS. Thermal skin burn and superficial thrombophlebitis was observed in three (10%) limbs: one (3.3%) in group A versus two (6.6%) in group B. Only one (3.3%) limb with DVT was reported in group B. Hyperpigmentation and paresthesia were observed in two (6.6%) and three (10%) limbs in group A versus three (10%) and four (13.3%) limbs in group B (Table 6 and Graph 6).

The mean time to return to work in group A was 9.2 ±1.7 days and in group B was 14.1±1.6 days. Group B had slightly longer duration till return to work (Table 7 and Graph 7).

At 3–6-month postoperative follow-up, skin discoloration (pigmentation) was noticed in three (10%) limbs: one (3.3%) in group A versus two (6.6%) in group B. Residual varicosities was noticed only in two (6.6%) limbs in group B and treated by FS. Recurrence was noticed only in one (3.3%) limb in group A. Paresthesia was markedly declined and observed in three (10%) limbs: one (3.3%) in group A versus two (6.6%) in group B. The overall complications were less in group A [14, 93.3%) limbs] (Table 8 and Graph 8).

Patient satisfaction and quality of life were evaluated using the VCSS preoperative, third month and sixth month. There were marked improvement of patients' preoperative symptoms by 3 months after treatment and more significant improvement in the appearance of VV by 6 months after initial treatment; χ^2=5.391, *P*=0.011 (Table 9 and Graph 9).

Graph 7



Return to work.

Table 6 Postoperative 1-week outcomes: (*N*=30 limbs in 25 patients)

Variables	Group A [15 (50%)]	Group B [15 (50%)]	χ^2	*P* value
Erythema	1 (3.3)	2 (6.6)	21	0.01 (Significant)
Hematoma	1 (3.3)	3 (10)		
Bruising and Ecchymosis	2 (6.6)	2 (6.6)		
Residual varicosities	1 (3.3)	3 (10)		
Hyperpigmentation	2 (6.6)	3 (10)		
Paresthesia	3 (10)	4 (13.3)		
Superficial thrombophlebitis	1 (3.3)	2 (6.6)		
DVT	0 (0)	1 (3.3)		
Thermal Skin burn	1 (3.3)	2 (6.6)		
No complications	12 (80)	11 (73.3)		

Data are presented as *n* (%) and by using χ^2-test. DVT, deep venous thrombosis.

Table 7 Return back to work

Variables	Group A [15 (50%)]	Group B [15 (50%)]	*t*	*P* value
Mean±SD	9.2±1.7	14.1±1.6	8	0.001 (HS)
Range (days)	7–14	10–17		

HS, highly significant. Statistically significant difference was observed using unpaired *t*-test.

Table 8 Post-operative 3–6 months outcomes: (*N*=30 limbs in 25 patients)

Variables	Group A [15 (50%)]	Group B [15 (50%)]	χ^2	*P* value
Paresthesia	1 (3.3)	2 (6.6)	20	0.01 (Significant)
Skin pigmentation	1 (3.3)	2 (6.6)		
Residual varicosities	0 (0)	2 (6.6)		
Recurrence	1 (3.3)	0 (0)		
No complications	14 (93.3)	13 (86.7)		

Data are presented as *n* (%) and by using χ^2-test.

Discussion

During the past decade, new less invasive methods have been developed as alternatives to conventional high ligation/excision in the treatment of GSV incompetence, including RFA, endovenous laser therapy, and FS [21].

RFA involves the use of high-frequency alternating current delivered by a bipolar catheter, placed intraluminally under duplex guidance, to obliterate the vein lumen. The current causes ionic agitation and local heating, resulting in venous spasm and irreversible denaturation of collagen with intimal destruction [22].

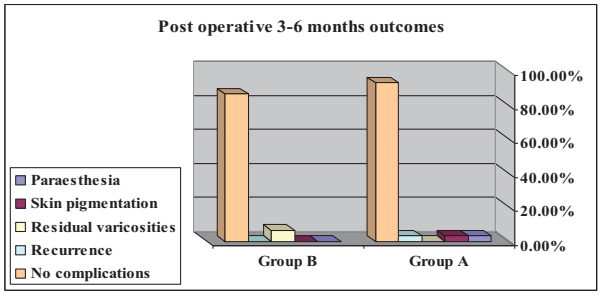
This produces a fibrotic luminal seal with minimal thrombus formation. Proper administration of tumescent anesthesia was a critical component of the procedure, because it not only serves as an anesthetic but also compresses the vein around the catheter and protects the surrounding tissue from heat damage. For the closure procedure, a bloodless field is desirable, as the closure catheter works by conducting RF energy through the vein wall. Blood within the field can coagulate on the tines of the closure catheter, increasing the impedance and diminishing the effectiveness of the heat deposition [23].

The present study was performed using VNUS closure as a closure system under tumescent anesthesia. It included 26 patients (31 limbs) divided into two groups according to the technique performed, and the mean follow-up period was 6 months. It included 20 (76.9%) women and six (23.1%) men, with the following age strata: 25–35 years: seven (26.9%), 36–45 years: 14 (53.8%), and older than 45 years: five (19.3%). This was a smaller study than the one done by Merchant *et al.* [13] who studied 858 limbs with RFA using ClosurePLUS catheter (Covidien, Mansfield, Massachusetts, USA). However, the sample size was similar to the study done by Dzieciuchowicz *et al.* [24] who performed their study on 161 limbs in 154 patients, including RFA in 43 extremities, and was similar to an earlier study done by Almeida [25], who performed his study on 69 patients, including RFA in 43 extremities.

In this study, classification of VV was based on CEAP classification by Bergan *et al.* [26] and revision of the CEAP classification by Eklöf *et al.* [27]. According to the clinical part of the CEAP classification, patients with CVI were categorized in percentage as done by Dzieciuchowicz *et al.* [24]. Moreover, our CEAP classification was comparable to another study published by Michael *et al.* [28].

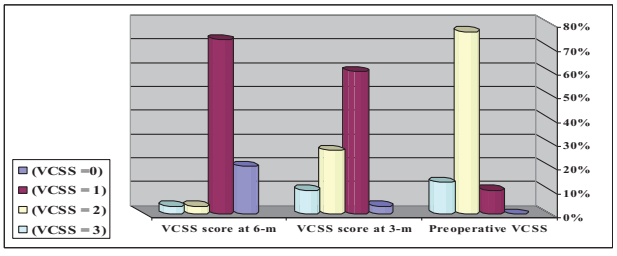
The presenting symptoms of patients were as follows: pain [26 (100%)], visible varicose vein [25 (96.2%)], night cramps [two (7.7%)], bleeding [one (3.8%)], and skin discoloration [five (19.3%)]. This was comparable to the study done by Halil *et al.* [29] that was performed on 90 patients and showed the following data: 90 (100%) patients complained of pain, 64 (71%) patients complained of night cramps, 12 (13%) patients

Graph 8



Postoperative 3–6 months outcomes.

Graph 9



Venous Clinical Severity Score (VCSS) at third and sixth month postoperatively.

Table 9 Venous Clinical Severity Score; at third m and sixth month postoperation

Descriptive items of VCSS	Preoperative VCSS	VCSS score at 3 m	VCSS score at 6 m
Absent (VCSS=0)	0 (0)	1 (3.3)	6 (20)
Mild (VCSS=1)	3 (10)	18 (60)	22 (73.4)
Moderate (VCSS=2)	23 (76.7)	8 (26.7)	1 (3.3)
Severe (VCSS=3)	4 (13.3)	3 (10)	1 (3.3)
Statistical analysis		χ^2=5.391, *P*=0.011	

Data are presented as *n* (%) and by using χ^2-test. VCSS, Venous Clinical Severity Score.

complained of edema, 14 (15.5%) patients complained of skin discoloration, two (2%) patients complained of bleeding, and six (6.5%) patients complained of varicose ulcer. Many patients reported more than one main symptom, so the total percentage exceeds 100%.

Duplex US was performed for all the studied patients. GSV reflux was found in 30 (96.7%) limbs, and SSV reflux was found in one (3.3%) limb. Similar ratios were obtained by Dzieciuchowicz *et al.* [24] who managed 147 of 185 (79.5%) GSV, 23 (12.5%) SSV, one (0.5%) Giacomini vein, eight (4.3%) anterior accessory saphenous vein, and six (3.2%) dilated thigh tributaries of GSV in 154 patients (171 limbs and 185 veins).

In the present study, despite the mean operative time being relatively long owing to time consumed during marking the course of the GSV under duplex guidance (62.9±5.4, range: 51–87 min, in group A and 51.8 ±3.2, range: 45–72 min, in group B), patients' hospital stay was short (in group A, patients were discharged 6.2±1 h PO, and in group B, they were discharged 7.9±2 h PO. This was mentioned by De Maeseneer [30]. The total theater time (between entry into and exit from the theater suite) was significantly longer for RFA.

In this study, six (19.3%) patients received foam sclerosant placed into them appropriately in the same session of RFA. Residual varicosities was noticed only in two (6.6%) limbs and treated by another session of sclerotherapy at third month. Ho *et al.* [31] similarly performed sclerotherapy in three (12.5%) patients of his 24 patients at eight week of follow-up and in one (4.1%) patient at sixth month.

Given the concern of postoperative pain, by using a VAS, patients in both groups reported significantly less PO pain at first 2 days (VAS: 2.09±0.3 vs. 3.05±0.01, P=0.001) and seventh day (VAS: 0.9±1.1 vs. 1.51±0.9, P=0.001). The results were to those obtained by Proebstle and Herdermann [18] who reported that the average pain score was 1.7±1.6 during the first 3 days. For patients who experienced limb pain at any time during the follow-up period, the maximum pain score was 2.8±1.6.

On review of the results in this study, at 1-week PO, erythema, hematoma, and bruising and ecchymosis were present in group A in one (3.3%), one (3.3%), and two (6.6%) limbs, respectively, versus two (6.6%), three (10%), and two (6.6%) limbs, respectively, in group B, which improved spontaneously in the follow-up. Residual varicosities appeared in both groups and were treated immediately by FS. Thermal skin burn and superficial thrombophlebitis was observed in three (10%) limbs (topical anti-inflammatory was prescribed and rapid improvement was noticed in the follow-up): one (3.3%) in group A versus two (6.6%) in group B. Only one (3.3%) limb with DVT was reported in group B. Hyperpigmentation and paresthesia were observed in two (6.6%) and three (10%) limbs, respectively, in group A versus three (10%) and four (13.3%) limbs, respectively, in group B. The reported figures for DVT were significantly superior to that obtained by Hingorani *et al.* [32] who reported that DVT subsequently developed in 16% of limbs treated with the ClosurePLUS catheter [32].

On the contrary, the results were comparable to Proebstle and Herdermann [18] who initially reported comprehensive findings from 6-month data showing a low rate of adverse effects: ecchymosis 6.4%, paresthesia 3.2%, hyperpigmentation 2.0%, hematoma 1.6%, erythema 1.6%, and phlebitis 0.8%. Thermal skin injury and DVT were not observed in the trial.

Patients were more comfortable with the earlier return to work following the intervention, but it remains a costly procedure. The mean time to return back to work was significantly more quickly following RFA: in group A, 9.2±1.7days, and in group B, 14.1±1.6 days. Group B had slightly longer duration, as the cause mentioned by De Maeseneer [30].

At 3–6-month post-operative follow-up, skin discoloration (pigmentation) was noticed in three (10%) limbs: one (3.3%) in group A versus two (6.6%) in group B. Residual varicosities were noticed only in two (6.6%) limbs in group B and were treated by FS. Recurrence was noticed only in one (3.3%) patient who was old and had large veins in group A). Paresthesia was markedly declined and observed in three (10%) limbs: one (3.3%) in group A versus two (6.6%) in group B. The overall complications were less in group A [14 (93.3%) limbs]. Similar results were published by Proebstle and Herdermann [18].

Residual varicosities and recurrence remain a significant problem after either RFA or open surgical ablation. Tielliu *et al.* [33] explained the cause of recurrence as follows: large veins may be less effectively treated by radiofrequency obliteration, and in elderly patients, possible alterations of the collagen fibrils' response

owing to the age of the patient might limit success of treatment. Neovascularization, presence of incompetent tributaries, and connection between remaining segment of GSV and new vessels or incompetent tributaries are another possible causes of recurrence [34].

The most important outcome for the patient with primary VV is satisfaction and quality of life. The current study indicates that RFA is an effective treatment for primary VV. Patient satisfaction and quality of life were evaluated using the VCSS. The components of the VCSS provide outcome analysis on many levels, including technical, patient reported, and clinical. The present study reported that there were marked improvements of patients' preoperative symptoms (χ^2=5.391, P=0.011). The obtained results coincided with that reported in literature, wherein Vasquez and Munschauer [35] examined the results of RFA on venous clinical severity score in 682 limbs treated with RFA. Overall mean baseline venous clinical severity scores were 8.8 at baseline and 3.6 at last follow-up visit, with $P<0.05$.

Proesbstle *et al.* [5] reported the average VCSS score was 1.5±1.8 at 6 months compared with 3.9±2.0 preoperatively. Kapoor and Mahajan [36] reported significantly reduced post-treatment VCSS scores at 3 months.

The reported PO results for RFA were better and showed a lower overall complication rate. Moreover, RFA was less invasive than the surgical approach. The present study showed a primary occlusion rate of 29/30 (96.7%). This is comparable to previous reports where Hingorani *et al.* [32] reported a 96% primary occlusion rate and Puggioni *et al.* [2] reported a 100% occlusion rate.

Conclusion

Endovenous, RFA, and sclerotherapy, whichever is the performed technique, have shown to be very promising techniques as they are minimally invasive and highly effective, with high patient satisfaction and quality of life, better cosmetic results, and fewer days off work. The most important thing is to choose the optimum one for each case to have good outcomes.

Financial support and sponsorship
Nil.

Conflicts of interest
There are no conflicts of interest.

References

1 Rautio T, Ohinmaa A, Perälä J. Endovenous obliteration versus conventional stripping in the treatment of primary varicose veins: a randomized controlled trial with comparison of the costs. J Vasc Surg 2003; 35:958–965.

2 Puggioni A, Kalra M, Carmo M, Mozes G, Gloviczki P. Endovenous laser therapy and radiofrequency ablation of the great saphenous vein: analysis of early efficacy and complications. J Vasc Surg 2005; 42:488–493.

3 Rasmussen L, Lawaetz M, Bjoern L, Blemings A, Eklof B. Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins. Br J Surg 2011; 98:1079–1087.

4 Marsden G, Perry M, Kelly K. Diagnosis and management of varicose veins in the legs: summary of NICE guidance. BMJ 2013; 347:f4279.

5 Proebstle T, Alm J, Göckeritz O. European Closure Fast Clinical Study Group. Three-year European follow-up of endovenous radiofrequency powered segmental thermal ablation of the great saphenous vein with or without treatment of calf varicosities. J Vasc Surg 2011; 54:146–152.

6 Rabe E, Pannier F, Ko A, Berboth G, Hoffmann B, Hertel S. Incidence of varicose veins, chronic venous insufficiency, and progression of the disease in the Bonn Vein Study II. J Vasc Surg 2010; 51:791.

7 Gohel MS, Epstien DM, Davies AH. Which treatments are cost-effective in the management of varicose veins. Phlebology 2013; 28(Suppl 1):153–157.

8 Roland L, Dietzek A. Radio-frequency ablation of the great saphenous vein performed in the office: tips for better patient convenience and comfort and how to perform it in less than an hour. Pers Vasc Surg Endovasc Ther 2007; 19:309–314.

9 Darwood R, Theivvacumar N, Dellagrammatics D, Mavor D, Gough M. Randomized clinical trial comparing endovascular ablation with surgery for the treatment of primary great saphenous vein. Br J Surg 2008; 95:294–301.

10 Roth SM. Endovenous radiofrequency ablation of superficial and perforator veins. Surg Clin North Am 2007; 87:1267–1284.

11 Mark DI, Thomas FO, O'Donnell JR. Varicose veins: endovenous ablation and sclerotherapy in Rutherford's vascular surgery. 8th ed. By Lowell S. and Mikel S.; Printed in China; 1 (58): 2014. pp. 887–901.

12 VNUS Medical Technologies, Inc. VNUS ClosureFAST Radiofrequency brochure. San Jose, CA: VNUS Medical Technologies, Inc; 2006.

13 Merchant RF, Pichot ON, Myers KA. Four-year follow-up on endovascular radiofrequency obliteration of great saphenous reflux. Dermatol Surg 2008; 31:129–134.

14 Pichot O, Creton D, Merchant R, Schuller-Petroviae S, Chandler J. Duplex ultrasound scan findings two years after great saphenous vein radiofrequency endovenous obliteration. J Vasc Surg 2004; 39:189–195.

15 Weiss RA, Weiss MA. Controlled radiofrequency endovenous occlusion using a unique radiofrequency catheter under duplex guidance to eliminate saphenous varicose vein reflux: a 2-year follow-up. Dermatol Surg 2002; 28:38–42.

16 Goldman MP. Closure of the greater saphenous vein with endoluminal radiofrequency thermal heating of the vein wall in combination with ambulatory phlebectomy: preliminary 6-month follow up. Dermatol Surg 2002; 26:452–456.

17 Lurie F, Creton D, Eklof B. Prospective randomized study of endovenous radiofrequency obliteration (closure) versus ligation and vein stripping (EVOLVes): two-year follow up, Eur J Vasc Endovasc Surg 2005; 29:67–73.

18 Proebstle T, Herdermann S. Treatment of the incompetent great saphenous vein by endovenous radiofrequency powered segmental thermal ablation: first clinical experience. J Vasc Surg 2008; 47:151–156.

19 Carroll C, Hummel S, Leaviss J. Clinical and cost effectiveness of minimally invasive techniques to manage varicose veins: a systemic review and economic evaluation. Health Techno Assess 2013; 17:i–xvi.

20 Meissner M, Natiello C, Nicholls C. Performance characteristics of the venous clinical severity score. J Vasc Surg 2002; 36:889–895.

21 Perkowski P, Ravi R, Gowda R, Rodriguez-Lopez J. Endovenous laser ablation of the saphenous vein for treatment of venous insufficiency and varicose veins: early results from a large single-center experience. J Endovasc Ther 2004; 11:132–138.

22 De Maeseneer MG, Van Schil PE, Philippe MM, Vanmaele RG, Eyskens EJ: Is recurrence of varicose veins after surgery unavailable. Acta Chir Belg 2006; 95:21–26.

23 Sharif MA, Soong CV, Lau LL, Hannon RJ. Endovenous laser treatment for long saphenous vein incompetence. Br J Surg 2006; 93:831–835.

24 Dzieciuchowicz L, Espinosa G, Grochowicz L. Evaluation of ultrasound-guided femoral nerve block in endoluminal ablation of the greater saphenous vein. Ann Vasc Surg 2011; 24:930–934.

25 Almeida JI. Radiofrequency endovenous closure FAST versus laser ablation for the treatment of great saphenous reflux: a Multicenter, Single blinded, Randomized Study (Recovery Study). J Vasc Interv Radiol 2009; 20:752–759.

26 Bergan J, Eklof B, Kistner R, Moneta G, Nicolaides A the International ad hoc committee of the American Venous Forum. Classification and grading of chronic venous disease in the lower limbs. A consensus statement. Vasc Surg 1996; 30:5–11.

27 Eklöf B, Rutherford RB, Bergan JJ, Carpentier PH, Gloviczki P, Kistner RL for the American Venous Forum International ad hoc committee for the revision of the CEAP classification. Revision of the CEAP classification for chronic venous disorders: consensus statement. J Vasc Surg 2004; 40:1248–1252.

28 Micheal HL, Juan JN, Peter FL, Brian GD, David AR, Hugh AG, Steven MF. Management of endovenous heat induced thrombus using classification system & treatment algorithm following segmental thermal ablation of SSV. J Vasc Surg 2013; 58:427–432.

29 Halil B, Cemalettin A, Yasin A, Bekir I, Hasan E, Cemil G, Mehmet B. Endovenous laser ablation versus high ligation and stripping (HL/S): two years follow up. East J Med 2012; 17:83–87.

30 De Maeseneer M. The role of postoperative neovascularization in recurrence of varicose veins: from historical background to today's evidence. Acta Chir Belg 2004; 104:283–289.

31 Ho P, Jensen T, Cho S, Grace C, Yuen W, Stephen K, Cheng W Day surgery varicose vein treatment using endovenous laser. Hong Kong Med J 2009; 15:39–43.

32 Hingorani A, Ascher E, Markevich N, Schutzer R, Kallakuri S, Hou A. Deep venous thrombosis after radiofrequency ablation of greater saphenous vein: a word of caution. J Vasc Surg 2004; 40:500–504.

33 Tielliu I, De Maeseneer M, Van Schil P, De Hert S, Eyskens E. Multicentre 3-year results with VNUS closure. Phlebology Eur J 2004; 14:118–122.

34 De Medeiros CA. Comparison of endovenous laser therapy vs. conventional stripping of the great saphenous vein: midterm results. J Vasc Bras 2006; 5:277–287.

35 Vasquez MA, Munschauer CE. Venous Clinical Severity Score and quality-of-life assessment tools: application to vein practice. Phlebology 2008; 23:259–275.

36 Kapoor A, Mahajan G. Endovenous ablation of saphenofemoral insufficiency: analysis of 100 patients using RF closure fast technique. Indian J Surg 2010: 72:458–462.