Fate of minor lower limb varicosities after Endovenous Thermal Ablation in patients with lower limb Varicose veins with incompetent Sapheno-femoral Junction

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Received: 7 March 2023
Revised: 20 March 2023
Accepted: 26 March 2023
Published: 11 August 2023

The Egyptian Journal of Surgery 2023, 42:509–515

Objectives
This was an open-label randomized comparative two arms study to assess the efficacy and clinical outcome of endovenous thermal ablation on reticular veins and telangiectasias in patients with lower limbs varicose veins with incompetent Sapheno-femoral Junction.

Patients and methods
A total of 40 patients [15 (37.5%) males and 25 (62.5%) females] with reflux of the long saphenous vein were subjected to radiofrequency ablation (RFA). 20 patients had RFA alone while the other 20 patients underwent RFA and injection sclerotherapy. Then patients were followed up on 1 week after the procedure, 3 months, 6 months, and 1 year by duplex and clinically using venous clinical severity score.

Results
There were 37.5% males and 62.5% females. There was a statistically significant difference in both groups regarding patients' symptoms (pain, heaviness, and swelling) before and after serial times of follow-up, which was assessed by the VCSS, denoting marked improvement of patients' symptoms. Also, there was a statistically significant difference ($P<0.001$) concerning duplex results regards the reflux before and following RFA. Reticular veins follow-up, we found that in group A they were present among 35% of patients on 1-week follow-up. This increased to reach 70% after 1 year of follow-up, however, in group B they were absent among all patients on 1 week follow-up. They were present among 15% of patients after 1 year of follow-up.

Conclusion
RFA with concomitant sclerotherapy for the associated minor veins have proved to be safe, cost-effective and more patient satisfaction than RFA without concomitant sclerotherapy.

Keywords:
minor veins, radiofrequency ablation, sclerotherapy, great saphenous vein

Egyptian J Surgery 42:509–515

1110-1121

Introduction

Chronic venous disorders (CVD) are a common health problem that has presented since the very earliest times and are a significant socio-economic problem [1].

It is known that up to 40% of the population complains from CVD, recently estimates that 60% to 70% of the population has some degree of CVD according to the CEAP classification, the incidence of varicose veins has been estimated to be about 2% per year [2].

Varicose veins are a public problem worldwide [3]. Varicose veins commonly occur in the superficial veins of lower extremities due to their lack of muscular support in comparison with deep veins; specifically, the greater and lesser saphenous veins and their accessories and tributaries [4].

Manifestations of CVD are commonly telangiectasias, reticular veins, and varicose veins. Chronic venous insufficiency (CVI) represents the more advanced forms of venous disorders of lower limbs, with persistent ambulatory venous hypertension that cause diverse pathologies, ranging from pain, edema, skin changes e.g hyperpigmentation, venous eczema, lipodermatosclerosis, atrophy blanche, up to healed or active ulcers [5].

Treatment goals are to eliminate symptoms, improve appearance, and prevent deterioration. Many options

available include compression stocking, sclerotherapy, ambulatory phlebectomy, surgical stripping, surgical ligation, and radiofrequency ablation (RFA), either singly or in combination [6].

Endovenous thermal ablation (EVTA) is a minimal invasive and efficacious technique for the treatment of saphenous reflux [7]. Thermal ablation was considered to be superior to surgery [8].

Endovenous ablation techniques have become increasingly common, these methods are based on the principle of destruction of the vessel using very high energy produced inside the vessel during the procedure. Tumescent anesthesia is essential to avoid damaging surrounding tissues with thermal energy [9]. After RFA, if there are significant residual veins, adjunct sclerotherapy is an additional modality that helps to reduce residual varicosities, adjunct sclerotherapy was done on the same anesthesia which was cost-effective due to no repetition of the procedure in the form of sclerotherapy was needed [10].

This study aims to evaluate of efficacy and clinical outcome of EVTA on reticular veins and telangiectasias in patients with lower limbs varicose veins with incompetent Sapheno-femoral Junction (SFJ).

Patient and method

After taking written consent from patients and approval from the ethical committee of Aswan University Hospital, 40 patients were included in this study, 20 patients per group (15 Males and 25 females). Group A, underwent RFA of great saphenous vein (GSV) only and group B, underwent RFA of GSV plus same sitting injection sclerotherapy. This study was approved by the ethical committee of Aswan University Hospital. These patients were admitted in Aswan University Hospital, Aswan, Egypt in the period between July 2021 and August 2022.

Inclusion criteria

The following were the inclusion criteria:

(1) Patients with primary varicose veins with incompetent SFJ.
(2) Patient's age 18–60 years.
(3) Patient with dilated GSV (exceeding 6 mm in diameter 2 cm below SFJ)
(4) Patients with symptomatic moderate to severe varicosities (CEAP classification C2-C6)
(5) Patients with incompetent GSV, with reflux time of >0.5 s assessed in the standing position with duplex ultrasound.

Exclusion criteria

The following were the exclusion criteria:

(1) Patients with secondary varicose veins.
(2) Patients with deep venous thrombosis.
(3) Patient with prior surgery for varicose veins.
(4) Patients with acute superficial thrombophlebitis.
(5) Patients with duplication of saphenous trunk, accessory GSV.
(6) Patients with poor general health (cardiac, renal failure, systemic and local infection).
(7) Patients with hypercoagulability status.
(8) Pregnant or lactating patients; planning to become pregnant during participation in the investigation.
(9) Patients with extremely tortuous GSVs.
(10) Patients with an impalpable pedal pulse; inability to ambulate.
(11) Declined informed consent.

Methods

All patients were subjected to detailed history taking regarding symptoms (pain, heaviness, swelling) and their duration, and occurrence of complications, followed by full body examination, and then detailed vascular examination for the pulses and site of varicosities. Laboratory investigation were done, such as a complete blood picture, prothrombin time, and international normalized ratio. Radiological investigations were done in the form of a colored duplex examination to detect reflux at SFJ and to exclude recent or old DVT.

Technique

Patients were divided randomly into two groups: group A, who underwent RFA of GSV only and group B, who underwent RFA of GSV plus same sitting injection sclerotherapy. In the operating theater, preoperative marking of the varices and photography were performed with the patient standing upright.

Group I: a 7-cm Closure Fast^{TM} (Covidien, VNUS Medical technology, San Jose, Cal, US) system was used. Local anesthesia was applied at the puncture site using 2 ml xylocaine 2%. The leg was positioned in the dependent position. Insertion of 7 F sheath, the RFA closurefast^{TM} catheter placed till the starting point for ablation (2 cm distal to SFJ or just distal to superficial epigastric vein). Administer tumescent anesthesia (500 ml normal saline with 25 ml 2% lidocaine and

25 ml 8.4% sodium bicarbonate) with ultrasonographic guidance after the patient has been placed into the trendelenberg position to help drain the vein. 2-therapeutic cycles were delivered to first segment of GSV, then one cycle was delivered to other venous segments. Gauze application was done at the puncture site followed by compression using class II elastic stocking for one week. (Fig. 1).

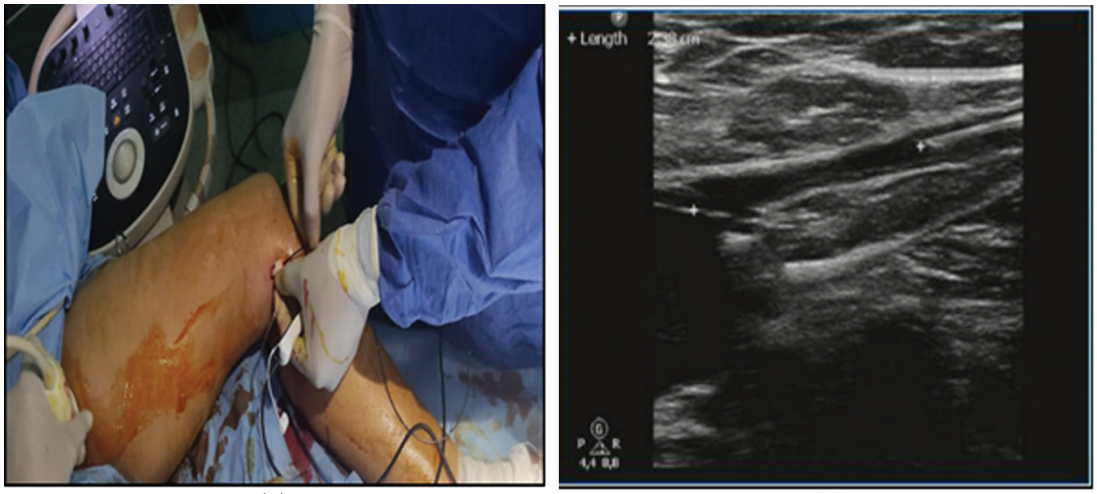
Group II: the same as group I with Adjunctive treatment, compression sclerotherapy for telangiectasia and reticular veins in the same session using ethanolamine oleate 5% either liquid or foam sclerotherapy 'Tessari method' followed by compression using class II elastic stocking for one week. (Fig. 2).

Follow-up of the patients by duplex was done to detect occlusion, partial occlusion, or recanalization of the saphenous vein and the degree of reflux, and also change in the diameter of the vein was measured. Improvement of symptoms was assessed by VAS, VCSS. Clinical follow-up of the patients and fate of telangiectasia and reticular veins was done, as well as assessment by the VAS and VCSS at one day after the procedure, 3 months, 6 months, and 1 year later.

Statistical analysis

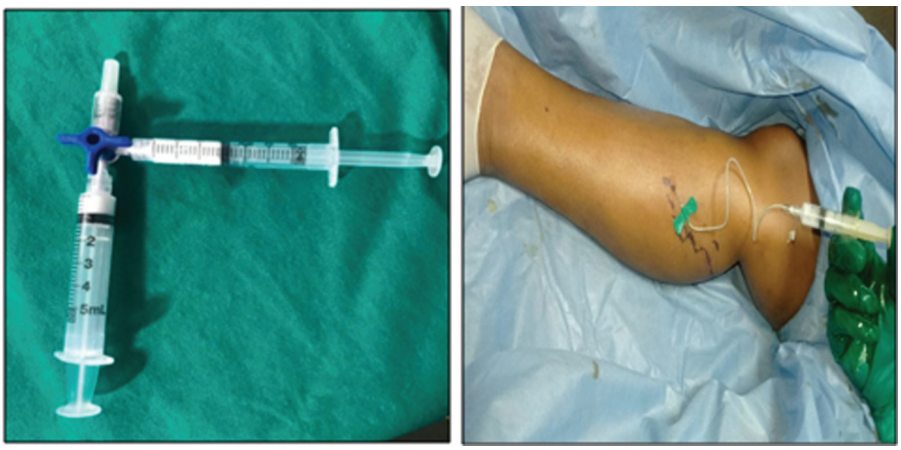
Data were fed to the computer and analyzed using IBM SPSS software package, version 20.0. (IBM Corp., Armonk, New Yo.rk, USA). The Kolmogorov–Smirnov test was used to verify the

Figure 1



(a) RFA using Closure FastTM catheter, (b) duplex image show tip of catheter 2cm distance from SFJ.

Figure 2



Injection sclerotherapy after RFA in same cession.

Table 1 Difference between both groups concerning associated sociodemographic characteristics, clinical examination, incidence of complications, and their clinical staging

Variable	Group A (*n*=20)	Group B (*n*=20)	*P* value
Age	37.2±11.5	35.9±8.87	0.691 T
Sex			
Male	8 (53.3%)	7 (46.7%)	1.00 C
Female	12 (48%)	13 (52%)	
BMI	27.77±4.21	29.17±3.69	0.270 T
Clinical presentation			
Heaviness	11 (52.4%)	10(47.6%)	1.00 C
Dilated veins	20 (50%)	20 (50%)	NA
Ankle swelling	11 (57.9%)	8 (42.1%)	0.527 C
Skin pigmentation	11 (73.3%)	4 (26.7%)	0.048 C
Skin eczema	8 (57.1%)	6 (42.9%)	0.741 C
Skin ulcer	4 (66.7%)	2 (33.3%)	0.661 C
CEAP classification			
C2	5 (25%)	11 (55%)	0.17 C
C3	5 (25%)	4 (20%)	1.00 F
C4	6 (30%)	2 (10%)	0.235 F
C5	1 (5%)	1 (5%)	1.00 F
C6	3 (15%)	2 (10%)	1.00 F
Minor complication			
Paresthesia	2 (10%)	1 (5%)	1.00 F
Thrombophlebitis	1 (5%)	3 (15%)	0.605 F
Skin pigmentation	0	2 (10%)	0.487 F
Ecchymosis	2 (10%)	1 (5%)	1.00 F
Edema	1 (5%)	1 (5%)	1.00 F
Skin burn	0	0	NA

C, Chi square test; F, Fissure exact test; NA, Not applicable; T, Independent sample *T* test.

normality of the distribution of variables. Comparisons between the different stages for categorical variables were assessed using McNemar–Bowker, whereas Friedman test was assessed for comparison between different periods s for abnormally distributed quantitative variables and followed by a post-hoc test (Dunn's) for pairwise comparison. The significance of the obtained results was judged at the 5% level.

Results

This study included 40 patients, comprising 15 (37.5%) males and 25 (62.5%) females. Their mean age was 36.55±10.17 years old (37.2±11.5 and35.9±8.87 respectively), their mean BMI was 28.47±3.97 kg/m^2(27.77±4.21 and 29.17±3.69 respectively), presented with heaviness, dilated veins, ankle swelling, skin pigmentation, skin eczema and skin ulcers. (Table 1).

There was a statistically significant difference in both groups regarding patients' symptoms (pain, heaviness, and swelling) before and after serial times of follow-up, which was assessed by the VCSS, denoting marked improvement of patients' symptoms. (Fig. 3).

Comparing the results of duplex for the 40 patients who underwent this study, there was a statistically significant difference in both groups ($P<0.001$)) between the reflux before and following RFA).

Concerning reticular veins, we found that in group A they were present among 35% of patients on 1 week follow-up. This increased to reach 70% after 1 year of follow-up, (Fig. 4); however in group B they were absent among all patients on 1 week follow-up. They were present among 15% of patients after 1 year of follow-up. (Fig. 5, Table 2).

Discussion

Varicose veins are dilated, elongated, tortuous veins of the lower limb. Superficial varicosities of the lower limb were considered one of the chronic common venous problems affecting 35% of women and 15% of men. Patients may present with ankle edema, disfigurement, chronic eczema, disability, ulceration, bleeding, foot deformities, and impairment in quality of life [11,12].

Endovascular ablation techniques such as laser ablation and RFA are associated with less frequent pain,

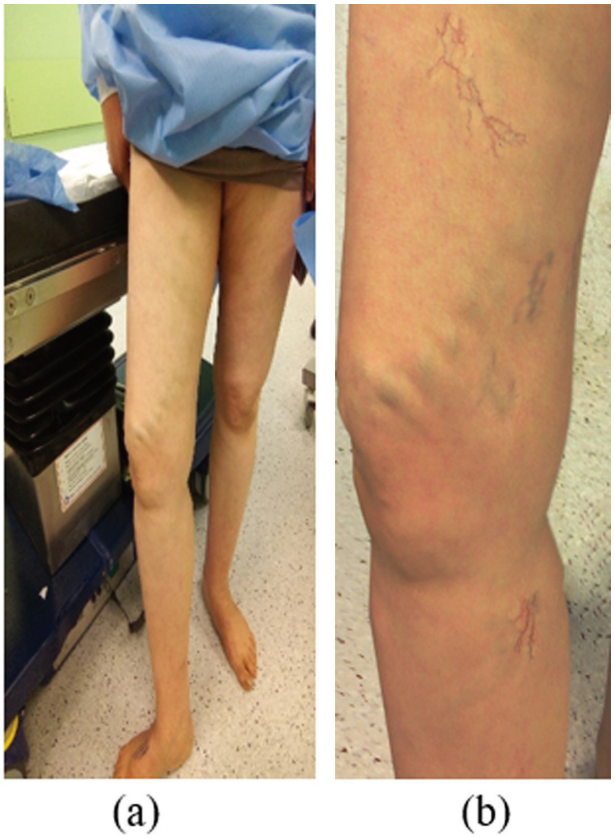
reported as 1% after 1 month in a report after using RFA [11,12]. Various chemical agents (liquid or foam preparations) may be injected during sclerotherapy to close varicose veins. In foamed sclerotherapy, the chemical agent achieves direct contact with the epithelial layer of the vein because the gas mixture inside the foam causes the expulsion of the blood [13]. In RFA, thermal energy is produced using radiofrequency waves which damages the endothelial layer and seals the valve which is incompetent [14].

This study is an open-label randomized comparative two arms study that included 40 patients presented with varicose veins with Incompetent Saphenofemoral junction, conducted at vascular surgery department, Aswan University Hospital, Aswan, Egypt.

The current study found that GSV was occluded in 100% of patients in both groups after 1 week. Whereas after 1 year follow-up, it was found that 83.3% of patients in group A and 76.5% in group B had GSV occluded. Concerning reticular veins, we found that they were present among 35% of patients in group A while absent in group B on 1 week follow up. This increased to reach 70%, 15% respectively after 1 year of follow-up. Also, major complications were absent either on admission or discharge in both groups. Concerning minor complications, they were present among 30%, 40% of patients 1 week postoperatively. This decreased to reach 0%, 5% after 1 year of follow-up.

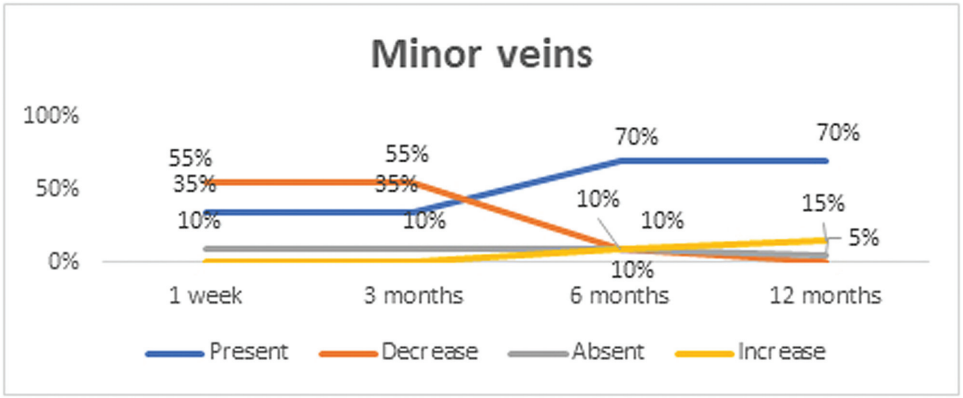
Alvandfar *et al.* [15] in their study involved 100 patients with varicose vein randomly allocated to receive RFA and sclerotherapy in one session (Group A) or two sessions with a two weeks interval (Group B). This study detected that the frequency of ecchymosis, infection, paresthesia, pain and VAS score decreased on 1, 3, 7, 14, and 28 days after surgery. Hyperpigmentation were increased in this period. Although the incidence of complications in group A was lower than group B. There was no significant difference between the two groups regarding the incidence of hematoma, ecchymosis and thrombophlebitis. However, the incidence of

Figure 3



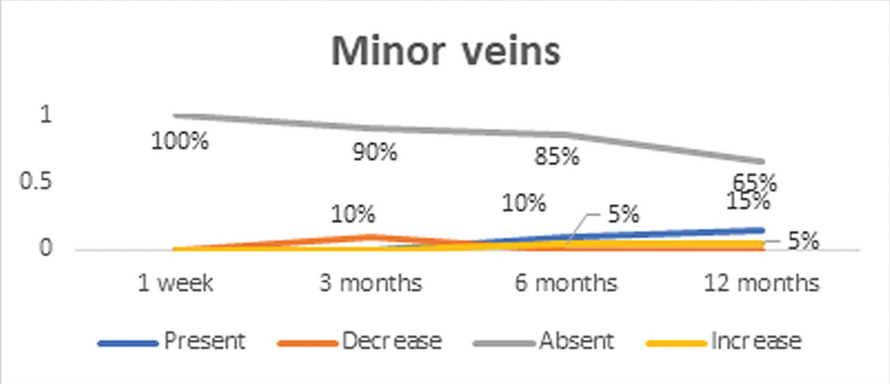
(a) preoperative photo of patient with incompetent SFJ with minor veins, (b) follow up picture after 1 year.

Figure 4



Change in minor veins prevalence over follow up period among patients in group A (*n*=20).

Figure 5



Change in minor veins prevalence over follow up period among patients in group B (*n*=20).

Table 2 The change in study outcomes over follow up period among patients in both groups

	1 week		3 months		6 months		12 months	
Outcomes	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
Duplex of GSV								
Occlusion	20 (100%)	20 (100%)	19 (95%)	18 (90%)	18 (90%)	17 (85%)	14 (70%)	13 (65%)
Recanalization	0 (0%)	0 (0%)	1 (5%)	2 (10%)	2 (10.5%)	3 (15%)	4 (20%)	4 (20%)
Reticular veins								
Present	7 (35%)	0	7 (35%)	0	14 (70%)	2 (10%)	14 (70%)	3 (15) %
Decrease	11 (55%)	0	11 (55%)	2 (10%)	2 (10%)	0	0	0
Absent	2 (10%)	20 (100%)	2 (10%)	18 (90%)	2 (10%)	17 (85%)	1 (5%)	13 (65%)
Increase	0	0	0	0	2 (10%)	1 (5%)	3 (15%)	1 (5%)
Major complications	0	0	0	0	0	0	0	0
Minor complications	6 (30%)	8 (40%)	3 (15%)	3 (15%)	1 (5%)	2 (10%)	0	1 (5%)
VSCC	10.4±1.96	9.5±2.26	8.85±1.4	7.9±1.9	7.9±1.4	6.2±1.8	5.9±1.53	4.76±1.64

Data described in terms of frequency (percentage).

hematoma and ecchymosis was lower in group A. None of the patients in the two groups were observed deep vein thrombosis, and hemorrhage and hematoma damage.

Memon *et al.* [16] included patients with symptomatic varicosities treated with RFA and Concomitant Sclerotherapy. This study reported that 99% (*n*=101) of the legs had complete occlusion of the GSV confirmed by duplex ultrasound on their first post-procedural visit. Duplex ultrasonography demonstrated complete vein occlusion in 100% of SSVs (*n*=26) and 97% for GSVs (*n*=75) at 6 months (mean time 188 days±33.1). Two cases of recanalization were documented in refluxing GSVs with flow segments of 20–22 cm and 15–17 cm from SFJ to occlusion stump at day 2 and 13 months, respectively. No cases of pulmonary embolism or venous thromboembolism (VTE) were documented according to our 6-month follow-up. In total, 51% (*n*=52) of patients complained of pain and tenderness at 24 h, followed by bruising at the site of catheter insertion (17.6%). One patient reported persistent pain at the 30-day follow-up. The pain was in the posterior mid-thigh region of their operated limb. Moreover, 6.8% (*n*=7) of patients reported paresthesia, while 2.9% (*n*=3) reported thrombophlebitis. No sign of infection or burns was seen.

Aherne T. M. *et al.*, [17] compared outcomes of concomitant vs. Staged Treatment of Varicose Tributaries as an Adjunct to Endovenous truncal Ablation. It is a systematic review and meta-analysis. Outcomes assessed included rates of re intervention, complications, and thrombotic events. Quality of life (QOL) and disease severity were also analyzed. Fifteen studies (6915 limbs) were included for analysis. Re-intervention rates were significantly lower in the concomitant group (6.3% vs. 36.1%) when compared with staged intervention (relative risk [RR] 0.21 [95% CI 0.07e0.62], *P*=0.004. Reported complications (RR 1.14 [95% CI 0.67e1.93], *P*=0.64) and rates of deep venous thrombosis (RR 1.41, *P*=0.31) were similar in each group. Overall disease severity (Venous Clinical

Severity Score) was lower in the concomitant group (P=0.005), while QOL, assessed using the Aberdeen Varicose Vein Questionnaire, favored concomitant treatment when measured at less than three months (P=.050) and between three and 12 months (P=0.020).

Conclusion

RFA with concomitant sclerotherapy has proved to be safe, cost-effective and more patient satisfaction. Some of the minor veins diminished, disappeared after RFA alone procedure, while it reappeared or increased again in follow-up.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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