A prospective randomized study comparing endovenous radiofrequency ablation and conventional surgery for primary great saphenous reflux

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Background
Over the last 10–15 years, percutaneous endovenous ablation has largely replaced ligation and stripping of the great saphenous vein, which has been associated with high success and low complication rates.
Objective
The goal of this study was to compare the effectiveness of endovenous radiofrequency ablation (RFA) of primary varicose veins with conventional surgery in terms of pain, complications, recurrence, quality of life, and return to normal activities using standard parameters.
Patients and methods
Both methods were used on a total of 63 limbs (54 individuals) with great saphenous vein reflux and lower-limb varicose veins. Clinical and duplex ultrasound examinations, as well as quality-of-life assessments, were performed as part of the follow-up.
Results
There were no significant differences between both groups as regards the demographic data. The pain score shows a significant difference between both groups (P<0.0001) in favor of the RFA group. Mean venous clinical severity scores improved from 5.73±3.194 to 3.45±2.279 at 1 month and 2.36±1.851 at 6 months in the conventional surgery group and from 5.97±3.538 to 3.10±2.657 at 1 month and 1.80±1.448 at 6 months in the RFA group. Complications represent 30.30% of patients in the surgical group compared with 16.67% of patients in the ablation group (P=0.5668). There was a statistically significant difference as regards returning to normal activity (7.21±1.634 days for the surgical group vs. 3.00±1.323 days for the ablation group).
Conclusion
The occlusion incidence and clinical recurrence of individuals who received radiofrequency thermoablation were equal to those who underwent saphenous vein stripping. Patients who received radiofrequency thermoablation, on the other hand, had a better quality of life, experienced less postoperative discomfort, had a lower complication rate, and missed work for a shorter period of time in comparison with those who underwent the traditional technique.

Keywords:
great saphenous vein reflux, radiofrequency ablation, stripping are all terms used to describe the treatment of varicose veins, varicose veins

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Introduction

Of all venous disorders, varicose veins were considered a common one that affects the great saphenous vein (GSV) and small saphenous vein. Depending on the degree of the disease, varicose veins can lead to pain, edema, pigmentation, itching, and ulceration [1].

A small array of a venous problem affects half of the adult population, and lower-extremity varicose veins affect around a quarter of the population. More than a quarter of persons with varicose veins have truncal vein insufficiency in their legs [2].

Surface venous insufficiency is a disorder that has a negative impact on patients' quality of life. Minimally invasive endovenous ablation techniques have emerged as a treatment that proved to be effective and safe, even though surgical treatment stood the test of time [3].

Interventional [a: traditional surgery, b: thermal ablation procedures such as radiofrequency ablation (RFA)

and endovenous laser ablation, and c: ultrasound-guided foam sclerotherapy] or supportive varicose vein treatment options are available (graduated compression elastic stocking) [4].

Conventional surgical (CS) intervention is associated with complications such as pain, wound infections, and nerve damage, in addition to a high rate of recurrence [5].

The use of general or epidural anesthesia, the presence of at least two long scars, postoperative downtime, and the risk of adverse events such as femoral artery and/or vein damage, wound infection, neurologic injury (about 7% in short to 40% in long GSV stripping), and lymphatic complications are all disadvantages of surgical therapy [2].

The existence of varicose veins in a lower limb previously operated on for varicosities, with or without adjuvant therapies, has been widely described and defined by Perrin in 2000 as 'existence of varicose veins in a lower limb previously operated on for varicosities, with or without adjuvant therapies.' The rate of occurrence is quite variable, ranging from 20 to 80% of instances, and it rises with time following intervention. A concurrent incompetence of the auxiliary saphenous vein or its direct confluence with the saphenofemoral junction (SFJ) may indicate that nonsurgical treatments (RFA or laser) should be used to prevent surgical ligation [6].

It is now known that a long residual saphenofemoral stump promotes recurrence [7]. It is also known that in endovenous procedures, recurrence preferentially occurs via the anterior accessory saphenous vein [8].

Following SFJ ligation and GSV stripping, recurrence was found in 60% of 125 limbs after a 34-year follow-up. Neovascularization, the double saphenous vein system, technical and tactical failure (up to 30%), and/or an inadequate procedure can all cause failure after surgery [2].

The purpose of this study was to compare the effectiveness of endovenous RFA of primary varicose veins with traditional surgery in terms of pain, complications, recurrence, quality of life, and return to normal activity.

Patients and methods

This was a randomized prospective study, in which we compared the short-term outcomes of endovenous RFA and traditional surgery in the treatment of patients with primary GSV reflux in the lower extremities.

Patients were recruited and followed up at Ain Shams University hospitals from the period of January 2019 to December 2020. A total of 54 individuals were randomly divided into two groups (using a computerized random number generator), with nine patients having bilateral lower-limb disease (total 63 legs). The first group (29 patients – 33 legs) underwent CS in the form of ligation of the SFJ with short stripping of GSV to just below the knee. The second group (25 patients – 30 legs) underwent endovenous RFA using the VNUS radiofrequency generator and the closure fast catheter (VNUS Medical Technologies, San Jose, California, USA) under duplex-scan guidance. Mini phlebectomies and triple ligation of incompetent perforators were done in the same setting in both groups. The inclusion and exclusion criteria were as follows.

Inclusion criteria

(1) Symptomatic patients 'C2s, 3, 4, 5, 6, Ep, As, Pr' according to CEAP classification.
(2) Duplex scan confirmed primary GSV incompetence.
(3) Age of at least 18 years up to 65 years.
(4) Ability to return for scheduled follow-up examinations for 12 months after treatment.
(5) Physical condition allowing ambulation after the procedure.

Exclusion criteria

(1) Nonpalpable pedal pulses (ABI<0.9).
(2) Varicose veins without SFJ incompetence on duplex scan.
(3) Patients with major comorbidities (ASA>2) or patients with coagulation disorders or on anticoagulation therapy.
(4) Patients with old or recent deep-vein thrombosis.
(5) Female patients during pregnancy, breastfeeding, or plans to become pregnant during participation in the study.
(6) Duplex ultrasound showing extremely tortuous GSV or superficial venous thrombosis or aneurysmal vein more than 1.3 cm in diameter.
(7) Patients with secondary varicose veins or recurrent GSV reflux or previous lower-limb surgery or presence of any other pathology affecting the target limb.

Preoperative preparation

Careful history taking, clinical examination, and duplex ultrasound were done, and patients were categorized according to CEAP classification. Also, patients were assessed according to venous clinical severity score (VCSS).

The VCSS is made up of 10 variables (pain, varicose veins, edema, pigmentation, inflammation, induration, number of ulcers, duration of ulcers, size of ulcers, and compression therapy) that are graded from 0 to 3 in severity as the area of the leg involved increases (absent, mild, moderate, and severe) [9].

In addition, after being translated into Arabic, each patient completed the 20-question Chronic Venous Insufficiency Questionnaire (CIVIQ2) quality-of-life questionnaire, which has been validated for use in patients with chronic venous illness. The CIVIQ is made up of 20 questions divided into four quality-of-life domains: physical (items 5, 6, 7, and 9), psychological (items 12–20), and social (items 12–20), (items 8, 10, and 11) and pain (items 1–4) [10].

Intraoperative procedures

The first group (conventional surgery)

Through a small incision positioned medial to the femoral pulsations 1 cm above and lateral to the groin crease, the SFJ was dissected and ligated with ligation of the tributaries. Triple ligation and mini phlebectomies were done before stripping of the GSV, to allow for immediate wrapping of the leg with crepe bandage after stripping.

The second group (radiofrequency ablation)

Under ultrasound guidance, a 7-F sheath was inserted into the GSV just below the knee. The catheter was positioned 2 cm below the SFJ. Tumescent was instilled around the GSV inside the saphenous compartment of deep fascia.

Two cycles (20 s each) were used to treat the first 7 cm of the vein, then one cycle for the rest of the segments associated with manual compression. We allowed for a 5-mm overlap between treated segments. Multiple veins were treated.

For patients with bilateral disease, the treatment was done bilaterally, with each limb getting the identical treatment. Each leg of the patients who received bilateral therapy was treated as a separate individual for statistical purposes.

Postoperatively

The bandage was removed on the third postoperative day, class II graduated-compression elastic stockings were prescribed for 2 weeks. Patients were followed up after 1 week, 1 month, and 6 months. They were evaluated for pain, ecchymosis, other complications, returning to normal activity, and recurrence. Pain was assessed on a scale of 0 (no pain) to 10 (worst imaginable pain).

During each patient's visit, we assessed patients' signs and symptoms utilizing VCSS classification, patients' limbs were assessed for the presence of recurrent varicose veins, and the patients were asked to complete another 20-question CIVIQ2 quality-of-life questionnaire.

Follow-up duplex ultrasound was done.

Definitions

Reflux was defined as reversal of flow more than 0.5 s in any treatment at the SFJ.

Neovascularization was defined as multiple small vessels in the groin bridging between a proximal and distal patent vein below the site of interruption.

Analyzed outcomes

We analyzed demographic data, comorbidities, BMI, and postoperative complications (infection, phlebitis, and deep venous thrombosis). We also analyzed recanalization, neovascularization, pain, and return to normal activity.

Results

There was a nonsignificant difference in age, sex, and BMI between both groups, as shown in Table 1. Table 2 shows a nonsignificant difference between both groups as regards different variables mentioned in the table.

There is a high significant difference in the pain score between both groups (Table 3).

Table 4 shows that there was a nonsignificant difference in the VCSS between both patients' groups preoperatively and 6 months later. There was a high significant difference in the postoperative score of VCSS in comparison with preoperative scores in both groups. A repeated-measures analysis of variance determined that mean VCSS scores decreased significantly across three time points (F=93.806, P≤0.001) in the first group and F=81.265

Table 1 Demographic data of patients

	CS (*N*=29) (mean±SD)	RFA (*N*=25) (mean±SD)	*P* value
Age	41±11.913	39.56±12.063	0.662
BMI	29.4±4.56	28.5±4.90	0.473
	n (%)	*n* (%)	*P* value
Sex			
Male	13 (44.8)	11 (44.0)	1.000
Female	16 (55.2)	14 (56.0)	
Comorbidities			
DM	1 (3.4)	2 (8.0)	0.914
HTN	0	0	
Smoking	2 (6.4)	1 (4.0)	
Bronchial asthma	1 (3.4)	0	

CS, conventional surgery; DM, diabetes mellitus; HTN, hypertension; RFA, radiofrequency ablation.

Table 2 Descriptive data of patients

	CS (*N*=33) [*n* (%)]	RFA (*N*=30) [*n* (%)]	*P* value
Vein			
Right	10 (34.5)	8 (32.0)	0.871
Left	15 (51.7)	12 (48.0)	
Bilateral	4 (13.8)	5 (20.0)	
CEAP			
C2	9 (27.3)	9 (30.0)	0.991
C3	15 (45.5)	13 (43.3)	
C4	6 (18.2)	5 (16.7)	
C5	2 (6.1)	1 (3.3)	
C6	1 (3.0)	2 (6.7)	
	Mean±SD	Mean±SD	*P* value
GSV diameter	6.77±1.516	6.643±1.484	0.0740
CIVIQ2 questionnaire	38.2±13.9	35.7±11.2	NS

CIVIQ2, Chronic Venous Insufficiency Questionnaire; CS, conventional surgery; GSV, great saphenous vein; RFA, radiofrequency ablation.

Table 3 Pain score

Pain score	Postoperative (mean±SD)	Postoperative after 1 week (mean±SD)	Paired *t* test	*P* value
CS (*N*=29)	5.88±1.883	3.33±1.407	10.168	<0.001*
RFA (*N*=25)	3.00±1.722	0.90±0.995	10.832	<0.001*
P value	<0.0001*	<0.0001*		

CS, conventional surgery; RFA, radiofrequency ablation. *Statistically significant.

Table 4 Venous clinical severity score

VCSS	Preoperative (mean±SD)	After 1 month (mean±SD)	After 6 months (mean±SD)	Repeated-measure ANOVA (*F*)	*P* value
CS (*N*=33)	5.73±3.194	3.45±2.279	2.36±1.851	93.806	<0.001*
RFA (*N*=30)	5.97±3.538	3.10±2.657	1.80±1.448	81.265	<0.001*
P value	0.7781	0.5757	0.1891		

ANOVA, analysis of variance; CS, conventional surgery; RFA, radiofrequency ablation; VCSS, venous clinical severity score. *Statistically significant.

(*P*=<0.001) in the second group. A post-hoc pairwise comparison using the Bonferroni correction showed that there was a statistically significant decrease of VCSS score between the initial preoperative assessment and follow-up assessment after 1 month (5.73 vs. 3.45, respectively) (*P*≤0.001) in the first group and 5.97 versus 3.10, respectively (*P*≤0.001) in the second group. Also, the decrease in VCSS score was statistically significant when comparing the initial preoperative assessment with a second follow-up assessment taken 6 months after the original assessment (5.73 vs. 2.36, *P*≤0.001) in the first group and 5.97 versus 1.80, (*P*≤0.001) in the second group. Preoperatively, there was a nonsignificant difference in the CIVIQ2 questionnaire between both groups. But 6 months later, it was found that there is high significant difference between both groups as shown in Table 5.

Table 5 Chronic Venous Insufficiency Questionnaire follow-up

CIVIQ2 questionnaire	Preoperative (mean±SD)	Postoperative after 6 months (mean±SD)	*P* value
CS	38.2 ± 13.9	19.3 ± 11.3	<0.001*
RFA	35.7 ± 11.2	15.4 ± 7.8	<0.001*
P value	0.4378	0.1196	

*Statistically significant.
CIVIQ2, 20-question Chronic Venous Insufficiency Questionnaire; CS, conventional surgery; RFA, radiofrequency ablation.

Table 6 Postoperative complications

Postoperative complications	CS (*N*=33) [*n* (%)]	RFA (*N*=30) [*n* (%)]
Ecchymosis	4 (12.1)	2 (6.7)
Hematoma	3 (9.1)	0
Thrombophlebitis	0	2 (6.7)
Paresthesia	1 (3.0)	1 (3.3)
Infection	2 (6.1)	0
Skin burn	0	0
DVT-PE	0	0
Total	10 (30.30)	5 (16.67)

CS, conventional surgery; DVT, deep venous thrombosis; RFA, radiofrequency ablation.

Table 7 Return to normal activities

	CS (*N*=29) (mean±SD)	RFA (*N*=25) (mean±SD)	*t* test	*P* value
Return to work	7.21 ± 1.634	3.00 ± 1.323	10.287	<0.001*

*Statistically significant.

CS, conventional surgery; RFA, radiofrequency ablation.

The incidence of complications was higher in the first group (Table 6). All complications were treated conservatively, except for one patient in the surgical group, who presented with secondary wound infection, needed hospitalization for antibiotic therapy (the patient presented with grade fever, severely infected wound with an underlying abscess that needed surgical evacuation of the abscess, and surgical debridement of the wound). There was no statistically significant difference between both groups (*P*=0.5668).

There was a statistically significant difference between both groups as regards to return to work. Patients in the CS group reported a longer time of absence from work or from house activities than those in the RFA group as shown in Table 7.

The overall technical failure rate was 6.6%, with one recanalization and one missed perforator in the RFA group, and three surgical failures in the first group (9.1%). In the latter, there were two cases of missed perforators, and one case of neovascularization (Table 8).

The clinical recurrence of varicose veins in 1 year was not significantly different in the two groups (*P*=0.0851).

Table 8 Recurrence rate

Recurrence	CS (*N*=33) [*n* (%)]	RFA (*N*=30) [*n* (%)]	*P* value Fisher's exact
Recanalization	0	1 (3.3)	
Missed AASV	5 (15.15)	0	
Perforators	2 (6.1)	1 (3.3)	
Neovascularization	1 (3.0)	0	
Total	8 (24.24)	2 (6.6)	0.0851

AASV, anterior accessory saphenous vein; CS, conventional surgery; RFA, radiofrequency ablation.

Discussion

In our study, the second group showed significantly lesser pain scores associated with less need for analgesic intake. Also, we found that there was a decrease in the time to return to normal activities in the second group (3.00 ± 1.323) compared with the first group (7.21 ± 1.634). These results are consistent with other studies [11,12].

The VCSS score preoperatively in the first was 5.73 ± 3.194 and 6 months postoperatively was 2.36 ± 1.851, while in the second group, RFA was 5.97 ± 3.538 preoperatively and 1.80 ± 1.448 6 months postoperative, which indicates significant improvement in both groups with no statistically significant difference between both groups. Vasquez *et al.* [9], in their study examining 682 limbs treated with RFA, the overall mean baseline for VCSS was 8.8 and 3.6 at the last follow-up visit. Proebstle *et al.* [12] reported the average VCSS score to be 1.5 ± 1.8 at 6 months compared with 3.9 ± 2.1 preoperatively. Sincos *et al.* [13] reported the average VCSS score to be 4.00 (2.91–5.09) at 1 year compared with 7.58 (6.37–8.79) preoperatively for the RFA group, while the average VCSS score was 4.35 (3.56–5.13) at 1 year compared with 7.78 (6.52–9.04) preoperatively for the surgical group. Sevil *et al.* [3] reported the average VCSS score to be 1 (1–3) at 1 year compared with 5 (1–9) preoperatively. Tamura and Maruyama [14] showed that VCSS improved from 5.31 ± 0.60 (at the baseline) to 1.10 ± 0.13, 0.39 ± 0.09, 0.14 ± 0.06, and 0.06 ± 0.03 at 1, 3, 6, and 12 months, respectively.

The CIVIQ is a reliable questionnaire because it has an excellent clinical validity due to reproducibility in

all dimensions and the ability to show change over time concerning pain relief [15]. Both groups showed improvement in the CIVIQ2 questionnaire, which was more significant in the second group compared with the surgical group after 6 months. This was due to the minimally invasive nature of the second group compared with the first.

In our series, we achieved a 100% occlusion rate of the treated veins. No cases of failure of closure were identified at the end of the procedure by duplex ultrasound. One patient showed saphenous vein recanalization at 6 months with 95.8% occlusion rate consistent with the results of other studies [12,13].

In our study, three (9.1%) patients developed hematomas, four (12.1%) patients developed ecchymosis (12.1%) in the surgical group, while in the radiofrequency group, none developed hematomas, and two (6.7%) patients developed ecchymosis, showing nearly the same results of other studies [4,11,12].

Two (6.7%) patients in the radiofrequency group developed phlebitis that was consistent with other studies [16,17]. Another study reported the incidence of superficial venous thrombosis to be only 3% [3].

In the second (RFA) group, there was no incidence of endothermal heat-induced thrombosis. Also, there were no cases of deep-vein thrombosis in both groups. The results of no thromboembolic complications were reported by other studies [11,18,19], while Sevil *et al.* [3] reported a rate of 1%.

Mendes *et al.* [4] reported no incidence of skin burn or hyperpigmentation as we showed in our study.

Pigmentation was observed in 3.1% of cases in another study [11]. Another study reported skin pigmentation during phlebitis or ecchymosis to be 2% that decreased to 0.4% at 36 months [12].

Paraesthesia or numbness may arise following RFA, but in most cases improves later after a few weeks [20]. In both groups, nerve damage (paraesthesia) occurred in two limbs, one in each group, along the distribution of the saphenous nerve, both of them improved after 6 months with no residual paraesthesia. The median rate of paraesthesia has been reported as high as 13% [21] with another reporting it to be 4.8–12% [22]. Other studies reported lower rates, being as low as 2–3.4% [3,11,12].

Recurrence remains a major problem after either endovenous ablation or open surgical intervention. After classic surgical intervention, neovascularization in the subcutaneous tissue around the SFJ can lead to recurrence [23]. In a decreasing frequency, the three most important factors associated with recurrence included recanalized treated veins, new or recurrent perforating veins, and new anterior accessory GSV reflux [24]. RFA maintains patent epigastric vein, which was considered earlier a cause of recurrence. However, it seems that it could protect against neovascularization by preserving physiological drainage of the abdominal wall [25]. Neovascularization seems to be less frequent with endovenous ablation, but it may lead to recurrence in 2.8–7% of cases [22].

Impaired preoperative venous function is another contributing factor for recurrence. Preoperative venous-filling index of more than 2 s was present in 58% of patients with late recurrence. Also, reflux of perforators and deep venous reflux were present in 83% of limbs showing recurrence [26].

Overall, it appears that recurrence is a complex process and no technique deals with all potential causes. Xenos *et al.* [27] concluded that further long-term studies were needed to determine which intervention is superior.

Whiteley *et al.* [28], in their long-term trial of RFA, reported that there was no recurrence in the previously treated veins and recurrence occurs in de novo veins that were previously competent. Also, the clinical and anatomical success with using RFA was maintained in the majority of patients at 5 years of follow-up [29].

In their meta-analysis on long-term outcomes for endovenous procedures, Kheirelseid *et al.* [30] showed that there was no statistical difference in the recurrence rate of RFA versus surgery or endovenous laser ablation.

Although the cost of the catheter is relatively high but with the extended use and governmental mass, purchase of the cost per patient is decreasing in our country. Other studies believe that the RFA is cost-effective because it is an outpatient-based procedure that helps in freeing the operating theater for other surgical interventions [31].

Also, part of the cost-effectiveness of RFA is due to rapid return to work [32].

If we considered the available literature and our findings, RFA therapy may be considered better than a surgical option, especially regarding the reduction in pain, return to normal activity, and frequency of complications as compared with classical surgery. However, although a minor complication, paresthesia has been reported to be more frequent with RFA. In the current study,

only one patient had paresthesia; however, multicenter studies with a higher number of patients are necessary to determine the actual frequencies of these minor complications using ablation.

Conclusion

The occlusion incidence and clinical recurrence of patients who received radiofrequency thermoablation were comparable to those who underwent saphenous vein stripping. Patients who received radiofrequency thermoablation, on the other hand, reported an improvement in their quality of life, less postoperative pain, a lower complication profile, and were out from work for a shorter period of time. Longer follow-up periods are needed to assess the results reached at short-term follow-up periods.

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Conflicts of interest

There are no conflicts of interest.

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