Randomized comparative study to compare between conventional surgical ligation and stripping of great saphenous vein and radiofrequency ablation in the treatment of venous ulcers

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Background
This comparative study compared the outcomes of radiofrequency ablation (RFA) of the great saphenous vein versus conventional surgery in healing of venous ulcers.

Aim
This study aimed to analyze the benefits of RFA of the great saphenous vein versus conventional surgery in the healing of venous ulcers.

Patients and methods
This is a prospective comparative study involving 40 patients, carried out in the Vascular Surgery Department at Ain Shams University Hospitals and Ahmed Maher Hospital in Cairo with follow-up at 2, 4, and 6 months. Here, we present the early follow-up outcomes of both treatment modalities and more follow-up time will be needed to confirm the results of this study.
This study included 40 patients, 20 patients for conventional surgery (group A) and 20 patients for conventional RFA (group B) suffering from primary varicose veins with venous ulcers. The mean age was 29.15 years for group A and 28.45 years for group B; of these, 28 (70%) patients were males.

Results
There was no statistical difference between great saphenous vein (GSV) stripping and RFA in terms of age. Both treatment modalities are equally effective according to improvement and decrease in linical, etiological, anatomical and pathophysiological classification (CEAP) clinical class and venous clinical severity scores. RFA required less time in the operation room in comparison with stripping. Also, RFA needed a stay of a few hours in the hospital, while almost all patients who underwent stripping were discharged the next day.

Conclusion
The present study confirmed that both surgery and RFA are highly effective. Both resulted in a significant decrease in venous ulcer size and improvement in the objective severity of venous disease (venous clinical severity scores and venous disability score). RFA is less time consuming than stripping in terms of operation time and hospital stay. Successful treatment of venous ulcer results in significant improvements of quality-of-life. RFA causes less postprocedure pain than surgery and allows early return to work and normal activities.

Keywords:
CEAP classification, healing of venous ulcers, radiofrequency ablation of GSV, stripping and ligation of GSV

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Introduction

Chronic venous disease is the most common venous disorder. It is caused by venous hypertension due to either reflux, outflow obstruction or both [1].

The treatment of varicose veins decreased patients complains and periods of sickleaves away from work. Visible varicose veins occur in up to 40% of men and 32% of women. The frequency of more severe chronic venous signs such as eczema, pigmentation, lipodermatosclerosis, or venous ulceration reaches a prevalence of about 3% in men and women [2,3].

Varicose vein without skin changes can be found in about 20% of the general population [2].

The diagnosis of primary varicose veins depends on patient history and physical examination; currently, duplex scanning is the method of choice for the diagnosis of venous reflux. It combines the

assessment of anatomic structure and the function evaluation of blood flow to enable quantification of reflux duration in specific superficial and deep vein segments. In addition, it is a non-invasive and repeatable method of imaging [4].

Venous ulcers, also known as stasis ulcers, are the most common etiology of lower extremity ulceration. Venous ulcers are often recurrent. Open ulcers can persist from weeks to many years [5]. Although the overall prevalence is relatively low, the refractory nature of these ulcers increases the risk of morbidity and mortality, and has a significant impact on patient quality-of-life (QoL) [6].

The primary risk factors for venous ulcer development are older age, obesity, previous leg injuries, deep venous thrombosis, and phlebitis. On physical examination, venous ulcers are generally irregular, shallow, and located over bony prominences [7].

Treatment of primary varicose veins includes many choices such as conservative measures including leg elevation to reduce edema, venotonic drugs, and elastic stocking. Sclerotherapy includes either traditional injection or foam sclerotherapy and stripping of saphenous veins. Endovenous measures include radiofrequency and laser ablation [8].

During the past decade, minimally invasive techniques, including ultrasound-guided foam sclerotherapy and endovenous laser ablation (EVLA), have gained popularity in the treatment of varicose veins, and have largely replaced surgery [9].

Patient and methods

This study was revised and approved by the members of the Medical Ethical Committee at Ain Shams University.

This randomized comparative study was carried out in the Vascular Surgery Department at Ain Shams University Hospitals and Ahmed Maher Hospital in Cairo with follow-up at 2, 4, and 6 months. Nevertheless, we are presenting the early follow-up results and we need more follow-up time to confirm the results. The study protocol was approved by the Ain Shams University Ethical Committee. The study included 40 patients (20 patients for radiofrequency ablation (RFA) and 20 patients for conventional surgery) suffering from primary varicose veins with venous ulcers. The inclusion criteria were all male and female patients between 15 and 55 years old who were willing to participate and provide an informed consent; they all had incompetent saphenofemoral junction confirmed by duplex ultrasound and venous ulcers [linical,etiological, anatomical and pathophysiological classification (CEAP) class 6], and all of them had intact pedal pulse. Exclusion criteria were patients with secondary varicose veins, unhealed ulcers for more than one year, patients with general debilitating disease (i.e. diabetes mellitus, chronic kidney disease) or refusal to participate in the study. Also, we excluded patients with a history of vasculitis or neuropathy.

Patients who fulfilled inclusion criteria were selected and underwent baseline preoperative duplex scanning for both lower limbs to evaluate the patency of both superficial and deep venous systems and exclude the presence of DVT.

Patients were randomized using the random number generator method into two groups:

(1) Group A was subjected to saphenofemoral junction ligation and stripping of the great saphenous vein.
(2) Group B was subjected to radiofrequency endovenous ablation of great saphenous vein (GSV).

Radiofrequency endovenous ablation of GSV

RFA was performed with local tumescent anesthesia with or without sedation in a sterile operation theater under the supervision of experienced surgeons to avoid any complications. Venous access was gained by a puncture under ultrasound guidance. Most commonly, the diseased GSV was accessed at the knee level because of ease of access (i.e. large diameter and linear course) and the smaller risk of nerve injury. After entry into the varicose vein was established, a guide wire was passed through the hollow needle into the vein. After the guide wire was in place, the needle was removed, and a 7 F sheath was introduced over the guide wire. Subsequently, the RFA catheter could be introduced after removing the guide wire. The most pivotal step in the RFA procedure is positioning the echodense tip of the catheter 2 cm distal to the saphenofemoral junction under longitudinal ultrasound visualization, after which tumescent anesthesia was injected into the perivenous fascia under duplex guiding, followed by segmental application of RFA.

Saphenofemoral junction ligation and stripping of the great saphenous vein

The surgical procedure was carried out through a 4–6 cm incision in the groin crease just medial to the femoral pulsation, with ligation of the GSV and division of all tributaries. The GSV was then removed using a stripper to just below the knee.

All patients were followed up at 2, 4, and 6 months using the CEAP classification, Venous clinical severity scoring (VCSS) for chronic venous disease and the venous disability score to classify stages of venous disease, evaluate the severity of venous disease and its effects on work and QoL, and provide a standardized evaluation of treatment effectiveness. Wound care and debridement of infected ulcers were performed for all patients using occlusive silver, collagenase, and hyaluronic containing dressings and hydrogels. Graduated elastic stocks were used to provide graded compression with a compression pressure of 30–40 mmHg at the ankle.

Statistical analysis

Data were collected, revised, coded, and entered into the Statistical Package for Social Science (IBM SPSS) version 20 (Statistical analysis was done using IBM SPSS statistics for windows, Version 23.0. Armonk, NY: IBM Corp.) and the following tests were performed:

Qualitative data were presented as number and percentages, while quantitative data were presented as mean, SD, and ranges.

The comparison between two groups with qualitative data was performed using the χ^2 test.

The comparison between two independent groups with quantitative data and parametric distribution was performed using an independent t-test.

Results

A total of 40 procedures were performed; 28 (70%) patients were males and 12 (30%) were females, and no statistical difference was found between the two groups (Fig. 1).

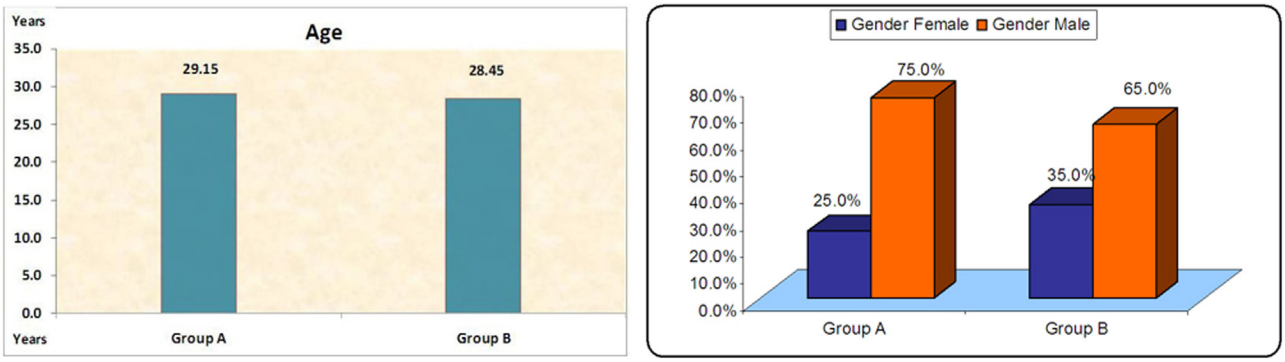
The mean age was 29.15 for group A and 28.45 for group B (P=0.717), and there was no statistical difference between both groups according to age (Table 1).

At 2 months postoperatively, complete healing of venous ulcers was found in four (20%) patients in group and became CEAP class 5 compared with three (15%) patients in group B (Table 2).

At 4 months postoperatively, complete healing of venous ulcers was observed in nine (45%) patients in group A compared with seven (35%) patients in group B.

At 6 months postoperatively, complete healing of venous ulcers was observed in 15 (75%) patients in group A compared with 16 (80%) patients in group B.

Figure 1



Distribution of baseline characteristics for each of the two treatment groups (age and sex).

Table 1 Distribution of baseline characteristics for each of the two treatment groups (age)

	Group A: CS N=20	Group B: RFA N=20	Test value	P	Significance
Age					
Mean±SD	29.15±6.62	28.45±5.46	0.365•	0.717	NS
Range	19–45	21–42			

CS, conventional surgery; RFA, radiofrequency ablation. •Significant study.

There was a significant reduction in venous ulcer size in both groups after treatment, and there was no significant difference between the two groups; RFA and GSV stripping were comparably effective in treating venous ulcers as all cases showed a decrease in CEAP clinical class (Table 3) and VCSS (Table 4) at 2, 4, and 6 months of follow-up in both groups.

The operation time in group A was longer (range: 40–70 min) than that in group B (range: 35–50 min) (Tables 5 and 6, Fig. 2).

The frequency of infection events was low and not significantly different between the two treatment groups (P=0.147). Two patients were seen earlier than 2 months after treatment with complaints of groin infection after GSV stripping; there was no wound infection after RFA (Table 7). The early postoperative differences in pain scores were as follows: patients who underwent RFA reported less pain than those in the surgery group from day 1 (P=0·002) (Table 8). It was found that there was a highly significant difference in the length of hospital stay between the two groups (P=0.001), with less time with the RFA group in comparison with Stripping (Table 9). No significant postoperative complication was recorded for both groups (Figs 3–5).

Table 2 Distribution of baseline characteristics for each of the two treatment groups (sex)

	Group A: CS [*n* (%)] *N*=20	Group B: RFA [*n* (%)] *N*=20	Test value	*P*	Significance
Sex					
Female	5 (25.0)	7 (35.0)	0.476*	0.490	NS
Male	15 (75.0)	13 (65.0)			

CS, conventional surgery; RFA, radiofrequency ablation. *Significant study.

Table 3 Comparison between group A and group B according to the CEAP classification

	Group A (*N*=20) [*n* (%)]	Group B (*N*=20) [*n* (%)]	Test value*	*P*	Significance
Preoperative CEAP class					
CEAP 6	20 (100.0)	20 (100.0)	0.152	0.623	NS
After 2 months					
CEAP 6	16 (80.0)	17 (85.0)	0.173	0.677	NS
CEAP 5	4 (20.0)	3 (15.0)			
After 4 months					
CEAP 6	11 (55.0)	13 (65.0)	0.131	0.937	NS
CEAP 5	9 (45.0)	7 (35.0)			
After 6 months					
CEAP 6	5 (25.0)	4 (20.0)	0.770	0.680	NS
CEAP 5	15 (75.0)	16 (80.0)			

CEAP, linical, etiological, anatomical and pathophysiological classification. *Significant study.

Table 4 Comparison between group A and group B according to VCSS

Group A (*N*=20) [*n* (%)]		Group B (*N*=20) [*n* (%)]		*P*	Significance
VCSS (0–30)		VCSS (0–30)			
Preoperative					
24	13 (65.0)	23	15 (75.0)	0.236	NS
21	7 (35.0)	20	5 (25.0)		
After 2 months					
18	13 (65.0)	17	16 (80.0)	0.268	NS
14	7 (35.0)	13	4 (20.0)		
After 4 months					
16	11 (55.0)	14	13 (65.0)	0.442	NS
10	7 (35.0)	10	5 (25.0)		
7	2 (10.0)	7	2 (10.0)		
After 6 months					
12	9 (45.0)	13	11 (55.0)	0.344	NS
10	5 (25.0)	9	2 (10.0)		
6	6 (30.0)	6	7 (35.0)		

VCSS, venous clinical severity scores.

Table 5 Difference between the two treatment modalities according to the operation time

	Group A *N*=20	Group B *N*=20	Test value•	*P*	Significance
Operation time (min)					
Mean±SD	58.25±7.48	43.00±5.48	7.355	0.001	HS
Range	40–70	35–50			

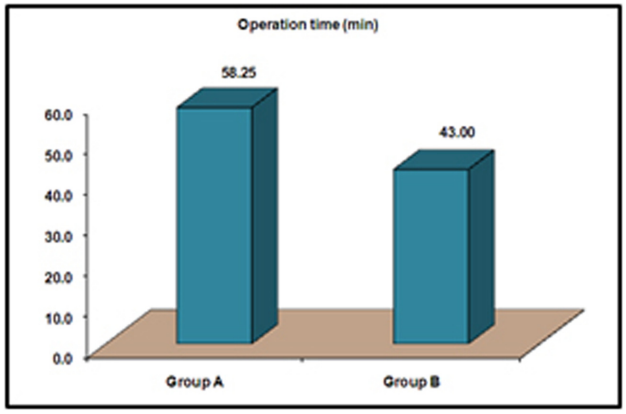
HS, highly significance. •Significant study.

Table 6 Difference between the two treatment modalities according to time to resume work

	Group A *N*=20	Group B *N*=20	Test value•	*P*	Significance
Return to work (days)					
Mean±SD	12.00±0.79	6.85±0.75	21.141	0.001	HS
Range	11–13	6–8			

HS, highly significance. •Significant study.

Figure 2



Difference between the two treatment modalities according to operation time and infection.

Discussion

In the last decade, RFA, EVLA, and MOCA (Mechanochemical Endovenous Ablation) have been optimized.

These minimally invasive interventions are increasingly being used as an alternative to surgery for treating saphenous veins [10].

The RFA technique, always performed under duplex guidance, appeared to be a very effective treatment, with high success rates at short-term follow-up [8].

Minimally invasive methods for ablation of the GSV have gained increasing popularity in the treatment of varicose veins. RFA, EVLA, and MOCA have previously been compared with each other or with conventional surgery in randomized trials with short-term and medium-term follow-up. The present study demonstrated no difference in RFA and stripping in ablation of the GSV.

In the present study, the mean age was 29 years, ranging from 19 to 45 years, which is relatively younger compared with the mean age of 45 years for the patients of the Pronk and Monets [10] study. Pronk carried out a study on 130 patients and had documented older mean age, which was 50 years in the surgical group and 49 years in the endovenous ablation group [10]. This might be due to variations in the population and average life span difference.

On of randomization, according to age, there was no statistical difference between group A GSV stripping and group B RFA.

There was a significant reduction in venous ulcer size in both groups after treatment, and there was no significant difference between the two groups; RFA and GSV stripping were comparably effective in treating venous ulcers as all cases showed a decrease in CEAP clinical class and VCSS at 2, 4, and 6 months of follow-up in both groups. Similar results were found in a study by Choi *et al.* [11], which also utilized RFA; the CEAP clinical stage improved and the VCSS score also improved.

In terms of the operation time estimated in the stripping group in comparison with RFA, the mean were operative times were 58 and 43 min, which is highly significant.

According to hospital stay, RFA was performed under local tumescent anesthesia as a day case and in the stripping group, almost all patients were discharged the next day.

In group A and group B, pain was reported on a scale from 0 to 10 (up to a score of 7 in group A and up to 4 in group B, which is highly significant).

Table 7 Difference between the two treatment modalities according to infection

	Group A [*n* (%)] *N*=20	Group B [*n* (%)] *N*=20	Test value•	*P*	Significance
Infection					
No	18 (90.0)	20 (100.0)	2.105*	0.147	NS
Yes	2 (10.0)	0			

*Significant study.

Table 8 Difference between the two treatment modalities according to pain

	Group A *N*=20	Group B *N*=20	Test value	*P*	Significance
Pain					
Mean±SD	5.20±1.06	2.10±1.29	8.301•	0.002	HS
Range	2–6	1–4			

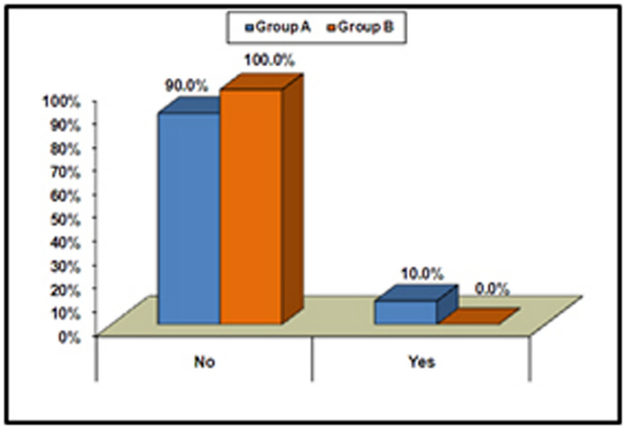
HS, highly significance. •Significant study.

Table 9 Difference between the two treatments modalities according to length of hospital stay (hours)

	Group A *N*=20	Group B *N*=20	Test value	*P*	Significance
Hospital stay					
Mean±SD	18.35±2.72	4.60±0.91	21.436•	<0.001	HS
Range	14–23	3–6			

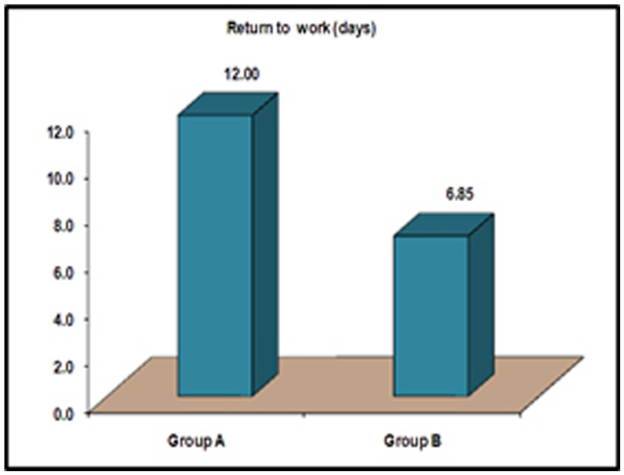
HS, highly significance. •Significant study.

Figure 3



Difference between the two treatment modalities according to operation time and infection.

Figure 4



Difference between the two treatment modalities according to time to resume work.

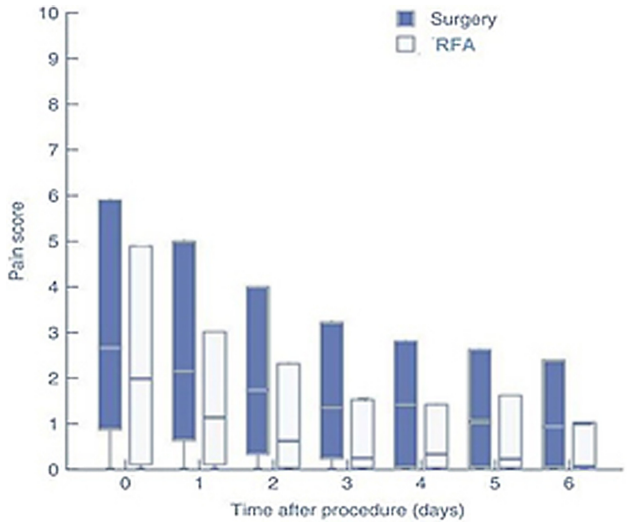
Infection occurred in two patients in group A; this was not found in group B and this was not highly significant.

Deep vein thrombosis and superficial vein thrombosis were not found to occur in both groups.

Considering the postoperative complications that we found in other studies, in 2012, Siribumrungwong *et al.* [12] reported that patients treated with surgical ligation of saphenofemoral junction (SFJ) had higher rates of hematoma compared with those who were treated with endovenous ablation. Postoperative pain was also less severe in RFA than in surgical intervention. It was reported that wound infection is less in the endovenous ablation group by 60% compared with the incidence of infection in patients who underwent surgical ligation of SFJ and stripping. Similar to our study, this study also reported that RFA had a lower incidence of hematoma formation and pain on day 0 to day 7 following procedures.It is anticipated that the long-term results of the minimally invasive interventions will motivate surgeons to switch to minimally invasive procedures.

Return to normal activities after surgery is of great importance to patients. They usually seek to know the

Figure 5



Difference between the two treatment modalities according to pain.

time frame within which they can resume their usual daily activities as before the surgical intervention. Kalteis and Sadek [13] documented that patients who underwent endovenous ablation needed less time to return to daily activities than those who underwent surgical ligation of the saphenofemoral junction and stripping of GSV. However, Pronk and Moneta [10] reported different results in their study. They found that there was no significant difference between the surgical intervention and endovenous ablation groups.

In our study, there was a significant difference between the two groups in the time needed to return to normal activity. In surgery groups, the mean time was 12.00 ±0.79 days and in the RFA group, the mean time was 6.85±0.75 days. Moreover, it was found that patients who underwent conventional surgery needed more convalescence time than those who underwent RFA.

Similar to our results, Gloviczki and colleagues reported that patients of the endovenous ablation group returned back to their normal lifestyle earlier than patients of the conventional surgery group. What has been clearly shown is that successful treatment of venous insufficiency and venous ulcer results in significant QoL improvements.

Conclusion

The present trial confirmed that both surgery and RFA are highly effective. Both resulted in a significant decrease in venous ulcer size and improvements in the objective severity of venous disease.

RFA is less time consuming than stripping in terms of operation time. In terms of hospital stay, RFA was performed under local tumescent anesthesia as a day case, while for the stripping group, almost all patients were discharged the next day.

It has been shown clearly that successful treatment of venous ulcer results in significant QoL improvements. RFA has been demonstrated to result in less postprocedure pain than surgery and allows early return to work and normal activities.

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Nil.

Conflicts of interest
There are no conflicts of interest.

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