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# Management of Varicose Veins Complicated with Chronic Venous Leg Ulcer: A Comparative Study

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## Abstract

**Background:** Varicose veins are twisted, swollen veins that typically affect the blood vessels in the lower extremities. Obesity and prolonged standing are the main causes of varicose vein disease. Inelastic bandages used in compression therapy are very successful to help venous leg ulcer healing. Stripping, which includes physically removing the vein, foam sclerotherapy, and thermal ablation with laser or radiofrequency are the most widely used methods for treating inefficient saphenous veins. Radiofrequency ablation (RFA), Sclerotherapy and phlebectomy are frequently combined with other operations and used to treat isolated tributary or perforator incompetence and recurrent varicose veins.

**Aim:** To identify the impact and influence of those different modalities on the incidence of healing of long-standing chronic venous leg ulceration, and the need for postprocedure elastic stockings to facilitate the ulcer healing or not.

**Subject and methods:** This was a prospective randomized controlled trial that was conducted on 60 patients with varicose veins complicated by chronic venous ulcers. The study was performed in the Department of Vascular Surgery, Al-Azhar University Hospitals. Patients were divided into 2 equal groups:- Group (1): included 30 patients treated by great saphenous vein stripping and complete clearance of the sapheno-femoral junction (SFJ), in addition to stab avulsion technique for below knee varicosities. Group (2): included also 30 patients treated with radiofrequency (RF) ablation technique.

**Results:** Regarding Venous Disability Score classification (VDS) distribution between the two studied groups, there is no significant difference between the two groups regarding classification.

Regarding postoperative visual analog scale (VAS), analgesic duration, return to normal activity, and return to work, there is a considerable difference between the two groups. The degree of ecchymosis varies significantly between the two groups. Postoperative venous clinical severity score (VCSS) in the RF group was considerably lower than in the surgical group.

**Conclusion:** The current experiment demonstrated the excellent efficacy of both surgery and RFA. Both led to improvement in the objective severity of venous illness and a notable reduction in the size of venous ulcers.

**Keywords:** Surgery, Varicose veins, Venous ulcers

## 1. Introduction

Varicose veins are twisted, swollen veins that are typically found in the lower limbs. They damage blood vessels, causing painful swelling and blood clots. Their prevalence rises with age and has an impact on a person's competence, productivity, and quality of life. Obesity and prolonged standing are the main causes of varicose vein disease.<sup>1</sup>

Obesity and prolonged standing are the main causes of varicose vein disease. In this overview, the causes, risk factors, consequences, and treatments of

varicose veins are discussed. Numerous types of therapies, including endovascular, surgical, and herbal ones, enhance quality of life and lessen the side effects of varicose veins.<sup>2</sup>

A significant contributor to morbidity and a decline in quality of life related to health are venous leg ulcers. Up to 5% of adults around the world are said to be affected by them, and some people experience a recurrent cycle of ulceration, healing, and recurrence. In the course of treating chronic venous disease, ineffective veins are removed or destroyed, and the reflux source is isolated from the

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rest of the vascular system. These operations result in a considerable reduction in symptoms and an increase in the quality of life for patients when compared to conservative therapies. Surgery and endovenous procedures are intended to prevent sequelae and lower the likelihood of superficial thrombophlebitis, much as compression and sclerotherapy.<sup>3</sup>

The aim of this work was the assess and evaluate the technical, and follow-up results of the standard surgical treatment of primary great saphenous vein (GSV) varicosities, especially those associated with reflux of the sapheno-femoral junction (SFJ), in comparison to the new endovenous, radiofrequency (RF) ablation technique. In addition, to identifying the impact and influence of those different modalities on the incidence of healing of long-standing chronic venous leg ulceration, and the need for post procedurals and ulcer healing to the use of elastic stocking or not.

## 2. Patients and methods

This was a prospective randomized controlled trial that was conducted on 60 patients presented with primary great saphenous vein (GSV) varicosities complicated with chronic long-standing venous leg ulceration. It was performed in the Department of Vascular Surgery, Al-Azhar University Hospitals. Patients included in the study were divided into 2 groups:

Group (1): included 30 patients and treated by short stripping of the great saphenous vein and complete clearance of the sapheno-femoral junction (SFJ), in addition to stab avulsion technique for below knee varicosities.

Group (2): included also 30 patients and treated with the newly performed, radiofrequency (RF) ablation technique.

### 2.1. Inclusion criteria

Patients were included in the current study if they had any of the following criteria: Age from 16 to 60 years old, patients with primary great saphenous vein varicosities due to SFJ incompetence complicated with active and/or recurrent chronic venous leg ulceration, patients presented with chronic long-standing venous leg ulcer that did not respond to conservative treatment and patients underwent weekly wound care and mechanical compression therapy for at least 30 days before being considered for operative treatment. The selection of the patients based on the Clinic Etiologic Anatomic and pathophysiology (CEAP) classification system, from

(C2–C4). This classification was considered as the internationally accepted standard for describing patients with venous diseases.

### 2.2. Exclusion criteria

Patients were excluded if they had any of the following criteria: Varicose veins in patients with competent SFJ, varicose veins due to leg perforator reflux, patients who presented with leg ulcer other than venous, patients with lesser saphenous vein varicosities, patients with haphazardly distributed varicosities that had no intimate relations to the axial vein, varicose ulcer associated with post phlebetic limb, patients with a previous history of deep vein thrombosis (DVT), patients with previous surgery or RF ablation of varicose veins, and/or those presented with recurrent varicosities, patients with superficial thrombophlebitis complicating varicose veins, patients with superficial thrombophlebitis complicating varicose veins complicated by telangiectasia or spider varicosities requiring compression sclerotherapy, patients with venous ulcers of less than one month duration, patients without at least wound care and compression once per week, patients with coexisting diseases or disabilities that would preclude surgical treatment, patients with a history of peripheral arterial.

#### All patients subjected to the following:

Each patient gave their informed permission.

Complete history taking, including personal, family, and past medical and surgical histories. a thorough physical examination The injured limb was examined locally to determine the clinical class (C) of the CEAP classification: Age and sex data were gathered and preserved, either unilaterally or bilaterally.

### 2.3. Pre-procedure assessment: color duplex ultrasound scan (CDUS) for all selected patients

Prior to standing with the leg not bearing weight, patients were assessed while supine, sitting, and developing a three-dimensional plan of the whole venous system in the leg. The presence of reflux, subjectively assessed by severity, lasting longer than 0.6 s, was a sign of incompetence. To analyse the entire lower limb, High-frequency linear array transducers with many frequencies were used. For patients with superficial veins, linear upper frequency transducers (5–10 MHz) were used, and the exam was made simpler by a thick layer of gel or a gel pad to keep the patient out of the dead zone of the transducer. For patients with deep veins, however, curvilinear lower-frequency transducers (4–7.5 MHz) were used. The duplex ultrasound

examination included a check of the SFJ, common femoral, femoral, and deep femoral veins in the groin. A thigh compression and quick release were used to induce reflux. The Valsalva manoeuvre was only used when there was no reflux during the compression/release test. The great saphenous vein (GSV), which runs the length of the saphenous canal, was then found and examined. The small saphenous vein (SSV) in the popliteal fossa was then scanned using a triangular fascia between the medial and lateral heads of the gastrocnemius muscle. Throughout the examination, compression distal to the section being examined was used to cause reflux.

#### 2.4. The surgical technique

Under general or spinal anesthesia, Access to the GSV was achieved through a small incision just below the knee. A 6-cm-long incision is done over the inguinal crease.

#### 2.5. The radiofrequency ablation (RF) technique

A 16 or 18 F needle under ultrasound guidance was used to puncture the refluxing vein at its most inept. Typically, access could only be made 15 cm away from the knee joint. The RF ablation catheter was then inserted under ultrasonographic guidance at least 2 cm distal to the sapheno-femoral junction. Once the catheter was in place, ultrasound guidance was used to inject a tumescent anaesthetic solution all the way around the vein. The tumescent anaesthetic solution contained epinephrine, bicarbonate, and lidocaine. Manual compression at the venous access point and catheter insertion at the end of the procedure were used to establish hemostasis. After the procedure, compression bandages and stockings were used to the treated leg for one to three days to reduce bruising and pain.

#### 2.6. Patients' follow-up

Patients were followed up immediately at the first postprocedure day then weekly in the first month, then every month for a maximum of six months. Most importantly, and following each procedure (surgical or RV), general instructions were discussed with the patients, that he followed to avoid recurrence.

#### 2.7. Statistical analysis

Utilizing SPSS 22.0 for Windows, all information were assembled, organized, and measurably analysed (SPSS Inc., Chicago, IL, USA). Utilizing the

Shapiro Walk test, the circulation of the information was inspected for ordinairness. Frequencies and relative rates were utilized to portray subjective information. The contrast between the subjective factors was determined utilizing the  $\chi^2$  test and Fisher definite, as displayed. For parametric and non-parametric information, individually, the mean and SD (standard deviation) were utilized to communicate quantitative information. For parametric and non-parametric factors, separately, the Autonomous T test and the Mann–Whitney test were utilized to ascertain the contrast between quantitative factors in the two gatherings. Each factual correlation utilized a two-followed importance test. A level of P-esteem 0.05 means a tremendous contrast,  $P < 0.001$  indicates an exceptionally huge distinction and  $P > 0.05$  signifies no distinction by any stretch of the imagination.

### 3. Results

This table shows that there is no significant difference between the two groups regarding age, sex, and BMI (Table 1).

There is no significant difference between the two groups regarding CEAP classification (Table 2).

There is no significant difference between the two groups regarding VDS classification (Table 3).

This table shows that there is no significant difference between the two groups regarding tumor size and site (Table 4).

This table shows that there is a significant difference between the two groups regarding post-operative VAS, analgesic duration, return to normal activity, and return to work (Table 5).

There is no significant difference between the two groups regarding histopathology findings (Table 6).

This table shows that there is no significant difference between the two groups regarding recurrence (Table 7).

This table shows that postoperative VCSS was significantly lower among RF group compared to surgical group. However, preoperative VCSS score was comparable in both groups. Moreover,

Table 1. Comparison of demographic data between the two studied groups.

	Surgical (N = 30)	RF (N = 30)	t	P
Age (years)	38.8 ± 9.74	39.27 ± 8.53	0.199	0.843
Mean ± SD				
BMI (kg/m <sup>2</sup> )	27.41 ± 3.62	28.13 ± 3.75	0.757	0.452
Mean ± SD				
Sex				
Male	12 (40%)	10 (33.3%)	0.287	0.592
Female	18 (60%)	20 (66.7%)		

Table 2. CEAP classification distribution between the two studied groups.

	Surgical (N = 30)	RF (N = 30)	$\chi^2$	P
C2	22 (73.3%)	25 (83.3%)	1.19	0.551
C3	6 (20%)	3 (10%)		
C4	2 (6.7%)	2 (6.7%)		

Table 3. Venous Disability Score classification (VDS) distribution between the two studied groups.

	Surgical (N = 30)	RF (N = 30)	$\chi^2$	P
0	3 (10%)	2 (6.7%)	1.82	0.403
1	22 (73.3%)	26 (86.7%)		
2	5 (16.7%)	2 (6.7%)		

postoperative QoL was lower among RF group compared to surgical group but without statistically significant difference (Table 8).

There is no significant difference between the two groups regarding postoperative CEAP classification (Table 9).

There is no significant difference between the two groups regarding postoperative VDS classification (Table 10).

#### 4. Discussion

Chronic venous disease (CVD) is a common health problem that affects approximately one-quarter of the adult population.<sup>4</sup>

Radiofrequency ablation (RFA) has many advantages over the conventional surgery as it can be safely performed in an office-based setting under

Table 4. Operative data between both groups.

	Surgical (N = 30)	RF (N = 30)	Test	P
Operative time (min) Mean $\pm$ SD	35.81 $\pm$ 5.76	48.13 $\pm$ 8.37	6.64	<0.001
Theatre time (min) Mean $\pm$ SD	44.71 $\pm$ 5.21	60.88 $\pm$ 9.14	8.42	<0.001
Hospital stay (day) Mean $\pm$ SD	30.92 $\pm$ 9.83	14.79 $\pm$ 8.41	6.83	<0.001

Table 5. Clinical characteristics between both groups.

	Surgical (N = 30)	RF (N = 30)	Test	P
Pain score VAS Mean $\pm$ SD	4.62 $\pm$ 0.956	2.11 $\pm$ 0.937	6.64	<0.001
Analgesic duration (day) Mean $\pm$ SD	7.41 $\pm$ 2.86	2.05 $\pm$ 1.55	8.42	<0.001
Return normal activity (day) Mean $\pm$ SD	8.9 $\pm$ 2.71	4.35 $\pm$ 1.28	6.83	<0.001
Return to work (day) Mean $\pm$ SD	14.33 $\pm$ 1.85	6.95 $\pm$ 1.72	10	<0.001

Table 6. Adjunctive procedure distribution between the two studied groups.

	Surgical (N = 30)	RF (N = 30)	$\chi^2$	P
None	4 (13.3%)	21 (70%)	20	<0.001
Perforator interruption	6 (20%)	0	6.67	0.010
Foam sclerotherapy	2 (6.7%)	8 (26.7%)	4.3	0.038
Phlebectomy	20 (66.7%)	2 (6.7%)	23	<0.001

Table 7. Comparison of recurrence between both groups.

	Surgical (N = 30)	RF (N = 30)	$\chi^2$	P
Recurrence	3 (10%)	1 (3.3%)	1.07	0.302
None	27 (90%)	29 (96.7%)		

Table 8. Success and follow-up clinical evaluation between both groups.

	Surgical (N = 30)	RF (N = 30)	Test	P
<b>VCSS</b>				
Preoperative Mean $\pm$ SD	6.71 $\pm$ 2.44	6.85 $\pm$ 2.31	0.228	0.820
Postoperative Mean $\pm$ SD	3.15 $\pm$ 1.09	2.41 $\pm$ 0.837	2.95	0.005
<b>QoL</b>				
Preoperative Mean $\pm$ SD	6.76 $\pm$ 5.33	6.94 $\pm$ 4.74	MU 238	P 0.891
Postoperative Mean $\pm$ SD	3.89 $\pm$ 2.24	3.52 $\pm$ 1.75	MU 492	P 0.487

Table 9. Postoperative CEAP classification distribution between the two studied groups.

	Surgical (N = 30)	RF (N = 30)	$\chi^2$	P
C2	26 (86.7%)	29 (96.7%)	1.96	0.161
C3	4 (13.3%)	1 (3.3%)		

Table 10. Postoperative Venous Disability Score classification (VDS) distribution between the two studied groups.

	Surgical (N = 30)	RF (N = 30)	$\chi^2$	P
0	6 (20%)	10 (33.3%)	2.21	0.331
1	23 (76.7%)	20 (66.7%)		
2	1 (3.3%)	0		

local anesthesia with less postoperative pain, faster return to full activity,<sup>5</sup> and excellent success rates.<sup>6</sup> RFA, however, has shown to have higher rates of primary failure and superficial thrombophlebitis than surgery,<sup>5,7</sup> and it may develop serious complications such as skin burns especially during the learning curve of the surgeon's experience.<sup>8</sup>

This prospective, randomised, controlled study was carried out at the Al-Azhar University Hospitals' Vascular Surgery Department.

This study involved 60 individuals who had chronic long-standing venous leg ulcers in addition to main great saphenous vein (GSV) varicosities. The surgical group ( $n = 30$ ) and the RF group ( $n = 30$ ) were each given a group of all patients. Regarding age, sex, BMI, and comorbidities, there were no discernible differences between the RF and surgical groups according to the demographic information of the study's participants. Additionally, we discovered no discernible difference between the two groups in terms of CEAP categorization and VDS classification.

In agreement with the current study Mohamed *et al.*,<sup>9</sup> compared the advantages of great saphenous vein RFA to traditional surgery in the treatment of venous ulcers. This study included 40 patients with primary varicose veins and venous ulcers, 20 for conventional surgery (group A) and 20 with conventional RFA (group B). According to the study, there was no discernible difference between the two groups in terms of venous clinical severity scores, age, sex, CEAP categorization, or any other factor. Regarding the operative data between both groups, it was found that the surgical treatment takes significantly shorter operative time and theatre time in comparison to RF treatment, but surgical treatment was associated with significantly longer hospital stay.

In constancy with our results Mohamed *et al.*,<sup>9</sup> revealed that the conventional surgery has significantly longer operative time than RFA treatment. But in contrast to our results, they revealed that surgical treatment takes significantly longer operative time and theatre time in comparison to RF treatment, the disagreement may be due to the difference in inclusion criteria and the incidence of operative complications.

Also, in agreement with our results Mohamed *et al.*,<sup>10</sup> reported that the surgical treatment takes significantly shorter operative time and theatre time in comparison to RF treatment, but surgical treatment was associated with significantly longer hospital stay.

In agreement with our findings, Sincos *et al.*<sup>11</sup> discovered that surgical surgery was connected to a considerably longer hospital stay when compared to

RF treatment. In terms of postoperative VAS, analgesic duration, return to normal activity, and return to work, the current study showed a significant difference between the two groups, with RFA treatment being preferable. According to studies by Mohamed *et al.*, which are in line with our own, standard surgery has a significantly longer recovery time than RFA treatment. RFA therapy was associated with lower postoperative pain as indicated by the VAS when compared to surgery. Mohamed *et al.*<sup>10</sup> observed similar results to ours, concluding that RFA therapy was superior to the control group in terms of postoperative VAS, analgesic duration, return to regular activities, and return to work. Additionally, Singh *et al.*,<sup>12</sup> discovered that the RFA group had significantly lower average pain scores, average oral analgesic intake, ambulation times, and return to regular activities (all  $P < 0.001$ ) than the control group.

According to Sincos *et al.*,<sup>11</sup>  $P < 0.001$ , the radio-frequency group also had significantly less absenteeism from activities. We found that the distribution of adjunctive operations varied significantly between the two study groups, with the need for supplementary treatments being more common in the RFA therapy group. There was a significant difference between the two groups in terms of the need for an adjunctive procedure, with RFA treatment being preferable in both situations, according to Mohamed *et al.*<sup>10</sup>'s research, which is consistent with our findings. When the frequency of postoperative complications was compared between the groups that were studied, it was found that surgery was associated with a higher frequency of ecchymosis but that other effects were equal. Mohamed *et al.* findings were in line with ours in that they discovered no statistically significant variation in the incidence of infection between the groups under study. In accordance with our findings, Mohamed *et al.*<sup>10</sup> also reported that there was no significant difference between patients in the two groups in terms of postoperative complications following the two procedures, with the exception of ecchymosis, which affected 15 (36.6%) patients receiving surgical treatment and only 4 (9.8%) patients receiving RFA, and postoperative paraesthesia, which affected 10 (24.4%) patients receiving surgical treatment and only 3 (7.3%) patients receiving RFA. Additionally, Singh *et al.*,<sup>12</sup> did not discover a statistically significant difference between the study groups' postoperative problems. Sincos *et al.* also found that clinical outcomes were comparable between the two therapy groups. The investigation found that there was no appreciable difference in recurrence between the two groups. Mohamed *et al.*<sup>10</sup> expressed

that there was no measurably tremendous contrast between the analysed gatherings with connection to repeat at 1, 6, and a year postoperatively, which is reliable with our discoveries. Moreover, we found that postoperative CEAP and VDS orders did not altogether contrast between the two gatherings. Both RFA and GSV stripping were similarly viable in regarding venous ulcers as all cases showed a decrease in CEAP clinical class and VCSS at 2, 4, and a half year of follow-up in the two gatherings, which is predictable with our discoveries. Mohamed *et al.*<sup>9</sup>'s discoveries that there was a huge decrease in venous ulcer size in the two gatherings after treatment, and there was no tremendous distinction between the two gatherings, were likewise upheld by our discoveries. The achievement rate per appendage ( $P = 0.540$ ), VCSS ( $P = 0.636$ ), AVVQ ( $P = 0.163$ ), and clinical outcomes were comparable in the two treatment gatherings, as per Sincos *et al.*

#### 4.1. Conclusion

The current experiment demonstrated the excellent efficacy of both surgery and RFA. Both led to improvements in the objective severity of venous illness and a notable reduction in the size of venous ulcers. RFA modality resulted in better outcome in terms of hospital stay, postoperative VAS, analgesic duration, return to normal activity, return to work, need for adjunctive procedure, the incidence of Ecchymosis complication, and VCSS, however, the operative time is longer. Our findings need to be confirmed by more comparative studies with larger sample sizes and longer follow-up in order to pinpoint the risk factors for adverse outcomes.

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#### Authorship

All authors have a substantial contribution to the article.

#### Conflicts of interest

The authors declared that there were NO conflicts of Interest.

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