



2023

Section: General Surgery

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How to Cite This Article

Abdelhamid, Ahmed Mousa Hafez; Hammoda, Mohamed Ibrahim Abd El-Rahman; and Mohammed, Ahmed Mohammady Mohammed (2023) "Comparative Study of Outcome of Duplex Ultrasound Guided Catheter Directed Foam Sclerotherapy and Radiofrequency Ablation in the Management of Great Saphenous Varicose Veins," *Al-Azhar International Medical Journal*: Vol. 4: Iss. 7, Article 18.

DOI: <https://doi.org/10.58675/2682-339X.1906>

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Comparative Study of the Outcome of Duplex Ultrasound-Guided Catheter-directed Foam Sclerotherapy and Radiofrequency Ablation in the Management of Great Saphenous Varicose Veins

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Abstract

Background: Lower leg varicose veins were described as dilated subcutaneous veins more than 3 mm in diameter when assessed while standing.

Aim and objectives: To assess the effectiveness of radiofrequency (RF) ablation therapy with ultrasound-guided foam sclerotherapy (UGFS) for the treatment of primary, uncomplicated great saphenous vein varicosities.

Patients and methods: This prospective randomized study was performed between June and December 2022, in the vascular surgery department of the Al-Azhar University Hospitals (Al-Hussein and Sayed Galal).

The 40 patients were divided into two groups: Group (A): 20 patients with noncomplicated primary varicose veins and treated by radiofrequency ablation of GSV. Group (B): 20 patients with noncomplicated primary varicose veins and treated by ultrasound-guided direct catheter foam sclerotherapy of GSV.

Three to six months were spent on the experiment.

Result: There is no statistically significant difference between the two groups for the GSV recanalization rate, recurrence rate, reoperation rate, complication rate and type, patient satisfaction, venous clinical severity score, venous disability score, or venous-related quality of life score.

Conclusion: In terms of morphological obliteration and lowering clinical signs and symptoms in persons with GSV varicosity, foam sclerotherapy, particularly catheter-directed foam sclerotherapy, is just as successful as radiofrequency ablation. In impoverished countries where the cost and availability, and availability of RFA continue to be significant challenges in the government setup, it is a perfect and more economical alternative to RFA. It also provides almost the same advantages.

Keywords: Notably, Saphenous veins (radiofrequency), The great saphenous vein (GSV), The short saphenous vein (SSV), Ultrasound-guided foam sclerotherapy (UGFS)

1. Introduction

Varicose veins are subcutaneous veins that have dilated and are more than 3 mm in diameter when measured while standing. Varicosity may damage any superficial vein tributary of the lower limbs, including the principal axial superficial

veins, the Great Saphenous Vein, the Short Saphenous Vein, or any other superficial vein.¹

One of the most prevalent vascular issues that affects a big section of the population is varicose veins. From 20 to 70 years old, the condition affects 10–40% of the population.² According to the majority of research, women are more likely than males

Accepted 3 January 2023.
Available online 30 November 2023

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<https://doi.org/10.58675/2682-339X.1906>

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to have varicose veins, with a 3 : 1 female to male ratio.³

The indications for radiofrequency ablation (RFA) are identical to those for endovenous laser ablation (EVLA), with the exception that it is more challenging to treat veins larger than 12 mm in diameter with RFA. Even so, these veins can be successfully treated with enough tumescent anesthetic. Varicose veins between 4 and 8 mm and as large as 12 mm can be treated with a 5 F. (1.7 mm) and an 8 F. (2.7 mm) catheter, respectively. A brand-new catheter with a special size that can be utilised regardless of the vein's diameter was introduced by the manufacturer. Extreme caution must be used while treating convoluted and relatively small veins due to the size and hardness of the catheter in order to prevent perforation.⁴

RFA is a method that effectively eliminates truncal varicose veins using heat energy (radiofrequency waves). The disadvantages of this technique are its restricted availability and expensive treatment costs. For the treatment of large saphenous varicose veins, foam sclerotherapy, radiofrequency ablation, and endovenous laser therapy have all been shown to be at least as effective as surgery (2014).⁵

An example of interventional management is surgery. Other examples include hybrid techniques and injectable sclerotherapy. Injection sclerotherapy can be effective on its own in telangiectatic arteries and varicose veins with a diameter of less than 3 mm. By damaging the venous endothelium, sclerotherapy causes thrombosis and finally fibrosis.⁶

In the past 10 years, the use of ultrasound-guided foam sclerotherapy (UGFS) to treat varicose veins has grown significantly. The costs are low, anesthesia is not necessary, foam sclerotherapy is efficient, and the safety profile is acceptable. The theory behind the treatment is that sclerosant drugs cause persistent vasospasm and vessel obliteration, which irreversibly harm the endothelium by disrupting cell membranes. As a result of its direct instillation of sclerosant drugs as 'microfoam' with air, this treatment for axial reflux in the great or small saphenous vein has gained popularity (GSV and SSV).⁷

This study compares the effectiveness of radiofrequency (RF) ablation therapy and UGFS for treating primary, uncomplicated great saphenous vein varicosities. This can be done by assessing each procedure's technical merits, recurrence frequency, and complication rates. The absence or ablation of GSV was the primary outcome. Along with the health-related quality of life score, the secondary objectives include the presence of varicose veins (VV) throughout follow-up, the frequency of reoperations, changes in response to interventions using

the venous clinical severity score (VCSS), and more (HRQOLS).

2. Patients and methods

This prospective Randomized Controlled Clinical Trial (RCT) was performed in the vascular surgery department of Al-Azhar University Hospitals (Al-Hussein and Sayed Galal Hospitals) between June and December 2022.

The study composed of 40 patients that divided into two equal groups.

Group (A): 20 patients with noncomplicated primary varicose veins and treated by radiofrequency ablation of GSV.

Group (B): 20 patients with noncomplicated primary varicose veins and treated by ultrasound-guided direct catheter foam sclerotherapy of GSV.

2.1. Inclusion criteria

Noncomplicated Primary varicose veins, age between 18 and 50 years of age, sex, no predilection between males and females, symptomatic patients belonging to (CEAP) classification (C2–C5), incompetent saphino-femoral junction (SFJ), vein diameter at the GSV greater than or equal to 5 mm and less than or equal to 10 mm and Reflux in GSV greater than 0.5 s and intact deep vein system.

2.2. Exclusion criteria

Patients with previous Deep Venous Thrombosis (DVT), patients with congenital venous anomalies, patients with chronic lower limb ischemia, patients with abnormal coagulation profile, patients with active pulmonary or pleural disease, pregnant ladies, allergic to sclerosing or anesthetic agent, patients refuse to provide a written consent for treatment and tortuous GSV rendering the vein unsuitable for endovenous treatment.

2.3. Patient evaluation

After taking a written consent, patients were subjected to the following: Clinical evaluation and duplex Ultrasound for varicose veins.

2.4. Clinical evaluation was carried out for all patients according to the following scheme

2.4.1. Detailed history

Age, sex, and whether or not there is discomfort, soreness, burning, aching, throbbing, heavy legs,

cramping, muscle exhaustion, pruritus, nocturnal cramps, and ‘restless legs’ are present.

2.4.2. Detailed general examinations

Local examination of the lower limb to detect: affected GSV or SSV or both, distribution of affected veins, ineffective perforators, shape (spider, serpentine, or saccular), truncal or extra truncal varicosities, and impacted.

Duplex Ultrasound for varicose veins to detect: mapping of the lower leg's superficial venous system and examination and assessment of the arterial system.

Exclude any venous anomalies of the L.L., exclude accessory GSV, and map it if it is present. Deep venous system patency, sapheno-femoral or sapheno-popliteal reflux and their degrees, presence and quantity of perforators.

Pre procedure Assessment: total blood count, liver and kidney function tests, all patients' Doppler/duplex scans, and blood sugar monitoring.

2.5. Procedures: ultrasound-guided foam sclerotherapy (UGFS) protocol

2.5.1. Anesthesia

Local.

2.5.2. Positioning

In supine position.

2.5.3. Sterilization

Bovine iodine sterilization of the afflicted limb followed by application of sterilized cloths.

2.6. Technique

During therapy for the GSV, patients are positioned supine, with the optimal puncture location being 5–10 cm below the knee. To prevent local spasms, 1–2 ml of mepivacain, Carbocain 1%, were infused at the puncture site (Figs. 1–4).

2.7. Radiofrequency ablation protocol (RFA)

2.7.1. Anesthesia

Local.

2.7.2. Positioning

In supine position.

2.7.3. Sterilization

Sterilization of the affected limb with bovidon iodine then putting of sterilized towels.

2.8. Technique

Figs. 5 and 6.

Postprocedural assessment: Follow-up: Clinical assessment: Each patient's visit included the collection of a standard set of data. Clinically and sonographically on days 7, 30, and 90. Clinical assessment utilising the VCSS and the VDS, taking into account the need for compression therapy, the ability to carry out daily activities, the existence of discomfort, residual varicosity, edoema, pigmentation, and induration. Complications and symptoms. Duplex assessment: After 1 m week, 1 month, 3 months, 6 months and following treatment for the presence of recurrent varicose veins.



(A)

(B)

Fig. 1. (A) Duplex guided puncture of GSV by 18 G needle then (B) insertion of Sheath 6F after introducing of guide wire.

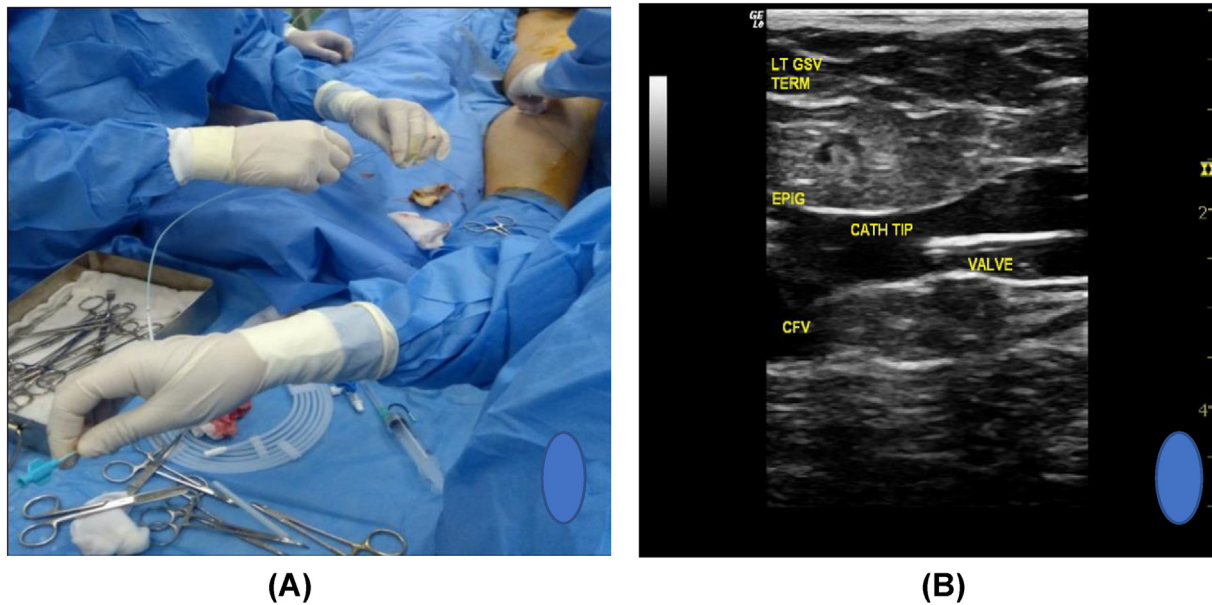


Fig. 2. (A) Catheter insertion Via Sheath (B)Tip of the catheter distal to sapheno-femoral junction (2–3 cm).

3. Results

There is no statistically significant difference between both groups as regard the sex (Table 1).

There is no statistically significant difference between both groups as regard the site and the side of lesion (Table 2).

There is no statistically significant difference between both groups as regard the success rate (Table 3).

There is no statistically significant difference between both groups as regard the recurrence rate (Table 4).

There is no statistically significant difference between both groups as regard the reoperation rate (Table 5).

There is no statistically significant difference between both groups as regard the complication rate and type (Table 6).

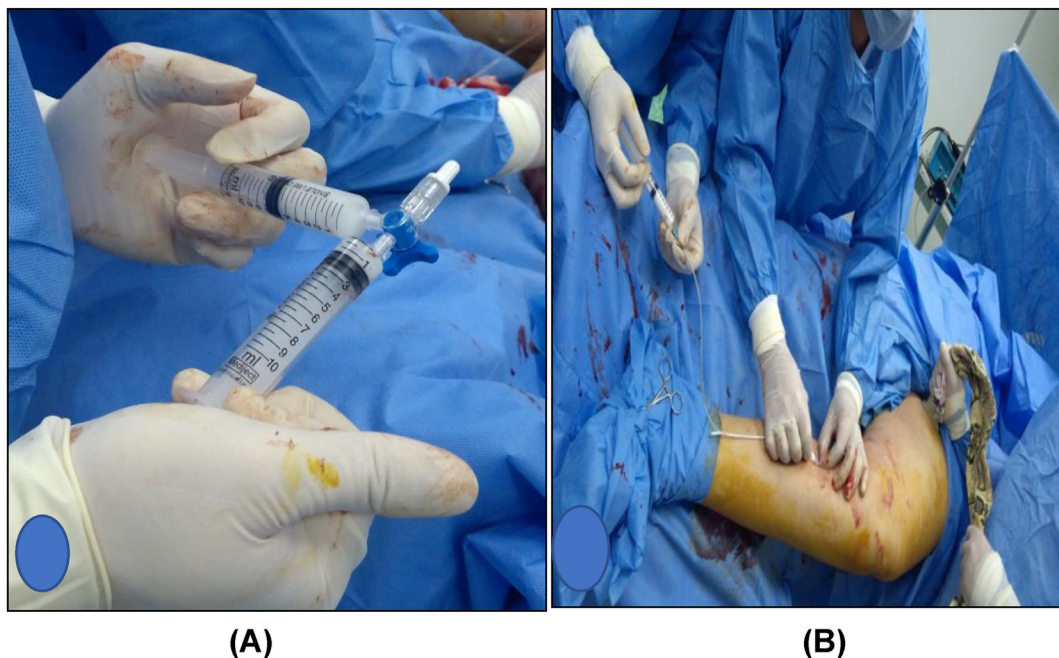


Fig. 3. (A) Foam preparation by the tessari technique with ratio (1 : 4) (B) Foam injection via catheter with compression on SFJ.



Fig. 4. Bandage compression (Al-Azhar University Hospital).



Fig. 5. (A) Duplex guided puncture of GSV with 18 G needle (B) insertion of Sheath 7 F after introducing of guide wire.

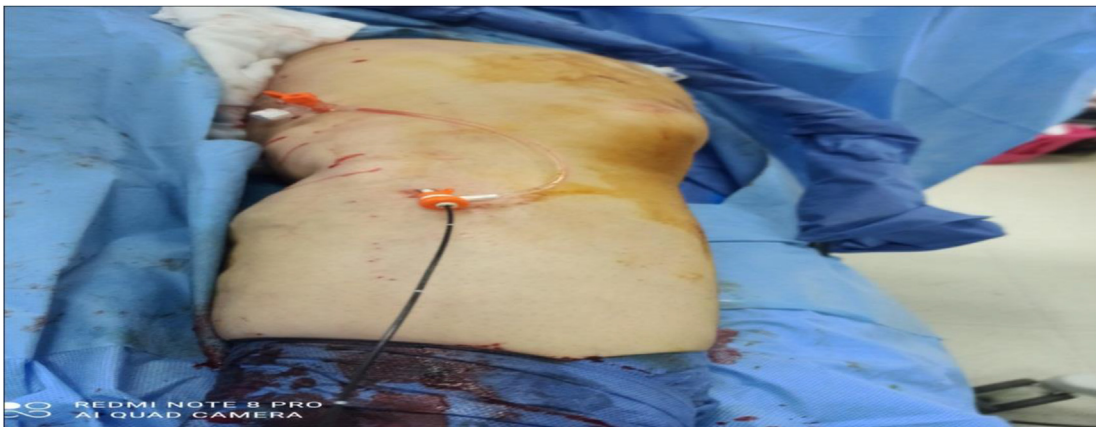


Fig. 6. Catheter inclusion by means of Sheath then segmental removal strategy of the Conclusion Quick framework, every 7 cm fragment of vein was dealt with freely briefly span. The underlying treatment portion 2–2.5 cm distal to the SFJ requires two 20 s cycles to guarantee effective removal. For every 20 s cycle, the temperature should arrive at 120 °C in something like 5 s on the off chance that this temperature was not accomplished inside the expressed time period, the section should go through an additional 20 s treatment cycle.

Table 1. The sex of the studied population.

	UGFS N = 20	RF N = 20	Test of significance	
	N (%)	N (%)	χ^2	P value
Sex				
Male	9 (45%)	11 (55%)	0.960	0.327
Female	6 (30%)	14 (70%)		

Table 2. The site of lesion of the studied population.

	UGFS N = 20	RF N = 20	Test of significance	
	N (%)	N (%)	χ^2	P value
site of lesion				
Unilateral	16 (80%)	14 (70%)	0.533	0.465
Bilateral	4 (20%)	6 (30%)		
side of lesion				
left	10 (50%)	9 (45%)	0.10	0.919
Right	6 (20%)	5 (25%)		

Table 3. The success rate in the studied population.

	UGFS N = 20	RF N = 20	Test of significance	
	N (%)	N (%)	χ^2	P value
Success				
Yes	18 (90%)	17 (85%)	0.229	0.633
No	2 (10%)	3 (15%)		

Table 4. The recurrence rate in the studied population.

	UGFS N = 20	RF N = 20	Test of significance	
	N (%)	N (%)	χ^2	P value
Recurrence				
Yes	3 (15%)	4 (20%)	0.173	0.677
No	17 (85%)	16 (80%)		

Table 5. The reoperation rate in the studied population.

	UGFS N = 20	RF N = 20	Test of significance	
	N (%)	N (%)	χ^2	P value
Reoperation				
Yes	2 (10%)	3 (15%)	0.229	0.633
No	18 (90%)	17 (85%)		

Table 6. The complications rate in the studied population.

	UGFS	RF	Test of significance	
	N = 20	N = 20	χ^2	P value
Complication				
Yes	3 (15%)	4 (20%)	0.173	0.677
No	17 (85%)	16 (80%)		
Complication type				
Thrombophlebitis	3 (15%)	3 (15%)	4.000	0.406
DVT	1 (5%)	0		
Allergy	1 (5%)	0		
Hyperpigmentation	0	1 (5%)		
Venous ulceration	0	1 (5%)		

Table 7. The patient satisfaction in the studied population.

	UGFS N = 20	RF N = 20	Test of significance	
	N (%)	N (%)	χ^2	P value
Patient Satisfaction				
Yes	15 (75%)	14 (70%)	0.125	0.723
No	5 (25%)	6 (30%)		

There is no statistically significant difference between both groups as regard the patient satisfaction (Table 7).

There is no statistically significant difference between both groups as regard the Venous Clinical Severity Score (Table 8).

There statistically significant positive correlation between impaired Venous-related quality of life Score and worse VCSS and VDS at baseline, 1 week, 1, and 3 months follow-up (Table 9).

4. Discussion

About 40% of people will experience varicose veins at some point in their lifespan.

Due to its increasing prevalence, healthcare costs are currently on the rise. Historically, the gold standard of care for varicose veins was conventional open surgery, which involves a high ligation, stripping of the great saphenous vein (GSV), and numerous stab avulsions. Numerous nonsurgical therapy approaches have been examined over the past 20 years. Current first-line treatment procedures including endovenous laser removal and radiofrequency removal (RFA) are very powerful yet can cause heat-related outcomes such persevering inconvenience, neuralgia, and cutaneous consume Daylan and Islamoglu.⁸

This planned Randomized Controlled Clinical Preliminary (RCT) was led on 40 patients, separated in two gatherings; Gathering (A): 20 patients with non-confounded essential varicose veins will be treated by radiofrequency removal of GSV. Bunch (B): 20 patients with nonmuddled essential varicose veins will be treated by ultrasound directed direct catheter froth sclerotherapy of GSV. The length of the review went from 3 to 6 months.

Table 8. The venous clinical severity score of the studied population.

	UGFS		RF		Test of significance	
	N = 20	N = 20	N = 20	N = 20	t	P value
At baseline	Mean	SD	Mean	SD		
After 1 week	17.15	2.81	17.80	3.00	-0.706	0.484
After 1 month	14.90	3.60	15.65	4.31	-0.598	0.554
After 3 months	13.30	5.60	13.55	5.78	-0.139	0.89
	10.50	6.06	11.05	6.63	-0.274	0.786

Table 9. Correlation between venous-related quality of life score and venous clinical severity and venous disability score.

	Venous-related quality of life Score							
	Baseline		1 week		1 month		3 months	
	r	P value	r	P value	r	P value	r	P value
VCSS	0.954	<0.0001	0.981	<0.0001	0.994	<0.0001	0.997	<0.0001
VDS	0.661	<0.0001	0.661	<0.0001	0.875	<0.0001	0.844	<0.0001

Regarding age, sex, and BMI, there is not a quantifiably enormous difference between the two social occasions. Our disclosures were supported by Mishra and colleagues' study, which reported having 30 members (26 patients) in the UGFS bundle and 31 limbs (31 patients) in the RFA pack.

Most of introductions were made by men, with a mean time of 42.19 years (M: F proportion of 4.1 : 1). In both review gatherings, standard attributes were equivalent. As per the consequences of the ongoing examination, there is no genuinely huge contrast between the two gatherings with regards to the area and side of the sore. Our discoveries were confirmed by a concentrate by El shemy and colleagues,⁹ which showed that 51 treated appendages in 39 patients were partitioned into three gatherings: radio-frequency removal (RFA bunch), ultrasound directed froth sclerotherapy (UGFS bunch), and endovenous laser removal (EVLA bunch). The EVLA bunch comprised of 18 legs in 13 patients and the RFA gathering of 16 legs in 13 patients. The RFA bunch comprised of 17 legs in 13 patients. Whether the sore was one-sided or respective, there was no measurably massive contrast between the three gatherings under study. Patients in the RFA bunch were for the most part one-sided.

Our outcomes showed that there is no measurably huge distinction between the two gatherings as respect the incredible saphenous vein C-scores. There is no measurably tremendous distinction between the two gatherings as respect the research center examinations.

Our outcomes were in accordance with investigation of El shemy and colleagues,⁹ as they uncovered that there was nontremendous contrast in conveyance of CEAP arrangement between the three concentrated on gatherings. Greater part of cases were in C4 class. This shows that patients look for clinical guidance in late phases of the sickness.

In the concentrate in our grasp, there is no genuinely huge contrast between the two gatherings as respect the achievement rate. There is no genuinely huge distinction between the two gatherings as respect the repeat rate. There is no genuinely huge distinction between the two gatherings as respect the reoperation rate, recanalization of the GSV and the progressions in C of the CEAP-grouping.

Our results were supported by study of El shemy and colleagues,⁹ as they reported that Valve closure time was nonsignificant among the three studied groups. There was nonsignificant difference that required reoperations or complementary procedures; except in 4 cases in UGFS group, in whom required an additional session of UGFS for complete obliteration of GSV. Mean survival from failure in EVLA and RFA was 24 ± 0 months, while in UGFS was 19.5 ± 2.9 months.

Also, Abd Al-Rahman and colleagues,¹⁰ reported that segmental radiofrequency ablation actually provides high ablation rates in conjunction with a very moderate side effect profile. The advantages of RFA are far greater than its associated risks. The technique was extremely easy to apply, very reliable both in terms of patient's satisfaction and the clinical results. However, in their study of 58 patients (91 legs), Whiteley and colleagues¹¹ found that neovascularization, the most common reason for recurrence, occurred in three patients (2%) despite the fact that the origin of each case's recurrence could not be determined. All three of these patients had previously undergone traditional surgical procedures before enrolling in their study for RFA. Therefore, it is extremely unlikely that it was a result of RFA, especially in light of the low incidence of neovascularization in the remaining cohort and the previously released data demonstrating that primary varicose veins did not neovascularize after RFA, as shown by Kianifard and colleagues.¹²

The current study's findings showed that there is no clinically significant difference between the two groups' venous-related quality of life Scores.

These outcomes suggest that the two methodologies were compelling in lessening torment and improving patients' personal satisfaction. Our discoveries support Rai and colleagues study's¹³ discoveries, which they stated uncovered the mean (SC) scores of the SF-36 construction at check and surveyed time centres concerning Prosperity Related Individual fulfilment. The HRQOL scores created after some time at the time centres. There were no measurably huge contrasts between the 2 gatherings whenever focuses following the analyzed treatment. El shemy and colleagues studies found that the 11 UGFS group took significantly longer to

get back to work than the EVLA and RFA groups, which both showed no changes. After the three treatments, all patients showed improvement in VAS, with EVLA and RFA groups showing significantly greater improvement than UGFS group within the first week and one month postoperatively than preoperatively. Our findings demonstrated a statistically significant positive link between the poorer VCSS and VDS at baseline, 1 week, 1, and 3 months follow-up and the impaired Venous-Related Quality of Life Score.

4.1. Conclusion

Catheter-directed froth sclerotherapy is similarly successful as radio recurrence removal in treating clinical signs and side effects and morphological annihilation in patients with GSV varicosity. It is an ideal and more affordable option in contrast to RFA, especially for poor countries, and it offers benefits that are essentially the same.

Disclosure

The authors have no financial interest to declare in relation to the content of this article.

Sources of funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

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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