Ultrasound Guided Foam Sclerotherapy of Lower Limb Varicose Veins: Outcome and Patient Satisfaction

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ABSTRACT
Background: Varicose veins are defined as dilated, tortuous, and elongated superficial veins of the lower limbs with incompetent valves. Sclerotherapy could be a minimally invasive technique that uses an injection of a special chemical (sclerosant) into a varicosity to wreck and scar the inside lining of the vein. Resulting in blockage of the treated vein.

Objective: To explain the efficacy and safety of foam sclerotherapy within the treatment of varicose veins and to see patient's satisfaction after ultrasound-guided foam sclerotherapy.

Patients and Methods: This study was conducted at Sohag University hospitals to evaluate the efficacy, safety, and patient satisfaction following foam sclerotherapy for varicose veins. There was 60 cases with lower limb varicosities whose mean age was 33.72 years (range 20 – 52). Females represented 62% of cases, while the remaining cases were males.

Results: The cosmetic appearance showed a major improvement (p < 0.001) after our intervention. Pain sensation was significantly decreased after the intervention. Only 25% of cases reported that sensation after 1 week, of which percent decreased all the way down to 3, 3, and seven during the following visits respectively. Saphenofemoral reflux was present in 48% of cases before the intervention, and it decreased all the way down to 7, 3, 3, and seven of cases at the scheduled follow up visits respectively. Complications were reported by 28% of cases. Skin hyperpigmentation was the most common complication (22%), followed by visual disturbances (8%), and thrombophlebitis (7%).

Conclusion: Ultrasound-guided foam sclerotherapy seemed to be a safe and effective procedure for the treatment of chronic venous insufficiency within the selected group of patients.

Keywords: Radiofrequency ablation, Superficial venous reflux, Ultrasound guided foam sclerotherapy.

INTRODUCTION

Varicose veins are elongated, tortuous, and dilated lower-limb superficial veins with faulty valves. Varicose veins are described by the world Health Organization (WHO) as saccular dilatation of the veins, which are sometimes tortuous [1]. Varicose veins are divided into primary and secondary varicose veins according to their etiology. Secondary varicose veins nearly always occur as a result of a change within the deep venous system's operation, whether it's an outflow obstruction, pump failure, or a mixture of the two. Primary varicose veins are caused by a variety of things that are unknown [2].

Sclerotherapy may be a minimally invasive technique that uses an injection of a special chemical (sclerosant) into a venous blood vessel to break and scar the within lining of the vein, resulting in blockage of the treated venous blood vessel [3]. The results with foam sclerotherapy are excellent and this method of treatment offers a good alternative to surgery [4]. Ultrasound-guided foam sclerotherapy (UGFS) is effective for every kind of pathological venous dilatations from major truncal varicose veins to the smallest telangiectasias [5].

UGFS is widely employed in most countries to eradicate superficial venous reflux (SVR).
UGFS ends up in significant improvements in symptoms and venous hemodynamics and is additionally related to high levels of patient satisfaction [6].

Ultrasound is useful in guiding the injection of foamed sclerosants. Foam is extremely visible with ultrasound, allowing for a more accurate injection. It also enables immediate post-injection observation of vein compressibility as a predictor of treatment efficacy [1]. Foam sclerotherapy has potential benefits over other standard treatments for varicose veins like surgery and endovascular interventions. Surgery carries a risk of anesthesia and therefore the time of work off [2].

Most complications from sclerotherapy are minor and transient. They include hyperpigmentation, pain, and urticaria [7,8].

This study was done to explain the efficacy and safety of foam sclerotherapy within the treatment of varicose veins and to see patient's satisfaction after UGFS for varicose veins in terms of improvement in

appearance, beneficial effect on lifestyle and relief of symptoms.

PATIENTS AND METHODS

This prospective cohort study was done at the Radiology Department, Faculty of Medicine, Sohag University, and included 60 patients in a period of 2 years, from October 2018 to September 2020.

The study included patients with primary symptomatic varicosities due to great saphenous vein (GSV) reflux and/or lesser saphenous vein (LSV) reflux and/or incompetent perforators, patients with varicosities related to isolated refluxing accessory saphenous veins or tributaries, and patients with reticular vein and/or telangiectasia, and excluded patients with pregnancy, malignancy, coagulopathy, breastfeeding, recent or old deep venous thrombosis (DVT), peripheral arterial disease, known allergy to sclerosant material (Aethoxysclerol) and lack of mobility.

All patients were subjected to the full history taking and clinical examination, and they were informed about the ultrasound-guided foam sclerotherapy technique. They had pretreatment Doppler scanning to identify sites of superficial venous reflux and incompetent perforators and to exclude possible DVT or phlebitis, the long course of refluxing vein was marked by ultrasound guidance. They were treated by ultrasound-guided foam sclerotherapy: The target vein cannulated under ultrasound guidance with intravenous cannula or butterfly needle 18, 20, or 22G at multiple levels, foam generated using Tessari method (This method includes mixing one part of the commercially available sclerosant, aethoxysclerol l-3%, with four parts of air using two syringes and a three-way tap).

Great saphenous vein was treated with 3% aethoxysclerol. Accessory great saphenous and short saphenous veins were treated with 2% aethoxysclerol. Reticular veins and telangiectasia were treated by 1% aethoxysclerol. After cannulation, the limb was elevated prior to injection of foam then we manually compressed the saphenofemoral junction during injection into the GSV. The development of venospasm in the target vein and the detection that the vein was completely filled by foam that was used to judge satisfactory completion of the therapy session, then the patients were asked to actively dorsiflex and plantarflex the ankle to maintain deep venous blood flow after each injection.

Instructions given for patient immediately post-procedure:

To walk for at least half-hour. To have plenty of fluids. To maintain external compression for 4 days. The anti-inflammatory medication was prescribed. Early follow-up 1–3 days post-injection and long follow-up to 6 months (by clinical examination and Doppler study).

End-intervention questionnaire:

The patients were asked to grade the improvement that they would experience in terms of symptoms, cosmoses and lifestyle.

Table (1): Criteria for successful and unsuccessful treatment

	Post treatment successful criteria	**Post treatment unsuccessful criteria**
Doppler examination	• No reflux • Complete disappearance of treated vein or becoming fibrous cord or total occlusion (non-compressibility) of the treated venous segment.	• Reflux >1 second or unchanged. • Complete (or incomplete) patency and/or diameter unchanged.
Clinically	**No visible** varicose veins.	**No significant change** or **worsen** (i.e., varicose veins became larger and more visible).
symptoms	Confirmed **absent** or improved symptoms.	confirmed **No change** or worse symptoms

Ethical consideration:

An approval of the study was obtained from Sohag University Academic and Ethical Committee. Every patient signed an informed written consent for acceptance of sharing in this study.

Statistical analysis

The collected data were coded, processed and analyzed using the SPSS (Statistical Package for Social Sciences) version 22 for Windows® (IBM SPSS Inc, Chicago, IL, USA). Data were tested for normal distribution using the Shapiro Walk test.

Qualitative data were represented as frequencies and relative percentages.

Chi square test ($\chi 2$) to calculate difference between two or more groups of qualitative variables. Quantitative data were expressed as mean ± SD (Standard deviation). Independent samples t-test was used to compare between two independent groups of normally distributed variables (parametric data). P value < 0.05 was considered significant.

RESULTS

In this study, there were 60 patients included; 23 males (38%) and 37 females (62%). The average age in this study was 33.72 years ± Standard deviation (SD) 6.87, the youngest was 20 years and the oldest was 52 years. The right side was affected in 31 patients (52%) while the left side was affected in 29 patients (48%). The average duration of the disease was 6.03 years ± SD 3.04, the least duration of the disease was one year, and the maximum was 12 years.

Pre- and post-treatment assessment of bad cosmoses was done to the 60 patients. Compared to basal value, assessment of bad cosmesis showed statistically significant differences after one week, one month, 3 months and after 6 months after receiving treatment, so the treatment had an obvious effect on decreasing bad cosmesis (Table 2).

Table (2): Pre- and post-treatment assessment of bad cosmesis in the studied patients

Bad cosmesis	All patients (n= 60)	p
Basal	100% (60)	-
One week	58% (35)	< 0.001
One month	17% (10)	< 0.001
Three months	7% (4)	< 0.001
Six months	10% (6)	< 0.001

Pre- and post-treatment assessment of pain was done to 52 patients. Compared to basal value, there was a statistically significant differences after one week, one month, 3 months and 6 months after receiving the treatment, so the treatment had an obvious effect on decreasing the pain (Table 3).

Table (3): Pre- and post-treatment assessment of pain in the studied patients

Pain	All patients (n= 60)	p
Basal	87% (52)	-
One week	37% (22)	< 0.001
One month	3% (2)	< 0.001
Three months	3% (2)	< 0.001
Six months	7% (4)	< 0.001

The number of sessions done to the all patients in this study, the average volume of injected foam, the average concentration of aethoxysclerol, and the classification of patients according to Clinical-Etiological-Anatomical-Pathophysiological (CEAP) classification are shown in table 4.

Table (4): Number of sessions, volume and concentration of injection and CEAP classification of the studied patients

All patients (n= 60)					
	Mean ± SD	Med	Mini	Maxi	IQR
Number of sessions	1.67 ± 0.752	1.50	1.00	3.00	1.00, 2.00
Volume of injected foam (ml)	11.33 ± 4.011	10.00	5.00	22.00	9.00, 14.00
Concentration of Aethoxy-sclerol	0.02 ± 0.006	0.02	0.01	0.03	0.02, 0.03
CEAP	1	12% (7)			
	2	70% (42)			
	3	12% (7)			
	4	2% (1)			
	5	2% (1)			
	6	3% (2)			

Med: median, Min: minimum, Max: maximum

Pre- and post-treatment assessment of long saphenous vein reflux was done to 29 patients. Compared to basal value, there was a statistically significant differences after one week, one month, 3 months and after 6 months, so the treatment had an obvious effect on decreasing the long saphenous vein reflux (Table 5).

Table (5): Pre- and post-treatment assessment of long saphenous vein reflux in the studied patients

Long saphenous vein reflux	All patients (n= 60)	P
Basal	48% (29)	-
One week	10% (6)	< 0.001
One month	3% (2)	< 0.001
Three months	3% (2)	< 0.001
Six months	7% (4)	< 0.001

Pre- and post-treatment assessment of **short saphenous vein reflux** was done to 8 patients. Compared to basal value, there was a statistically significant differences after one week, one month, 3 months and after 6 months, so the treatment had an obvious effect on decreasing the short saphenous vein reflux (Table 6).

Table (6): Pre- and post-treatment assessment of short saphenous vein reflux in the studied patients

Short saphenous vein reflux	All patients (n= 60)	p
Basal	13% (8)	-
One week	0% (0)	**0.008**
One month	0% (0)	**0.008**
Three months	0% (0)	**0.008**
Six months	0% (0)	**0.008**

Pre- and post-treatment assessment of posterior accessory saphenous vein (PASV) reflux was done to 8 patients. Compared to basal value, there was a statistically significant differences after one week, one month, 3 months and after 6 months, so the treatment had an obvious effect on PASV reflux (Table 6).

Table (7): Pre- and post-treatment assessment of PASV reflux in the studied patients

APSV reflux	All patients (n= 60)	p
Basal	13% (8)	-
One week	3% (2)	**0.021**
One month	0% (0)	**<0.001**
Three months	0% (0)	**<0.001**
Six months	0% (0)	**<0.001**

Pre- and post-treatment assessment of telangiectasia was done to 9 patients. Compared to basal value, there was a statistically significant differences one month, 3 months and after 6 months, so the treatment had an obvious effect on telangiectasia (Table 8).

Table (8): Pre- and post-treatment assessment of telangiectasia in the studied patients

Telangiectasia	All patients (n= 60)	p
Basal	15% (9)	-
One week	8% (5)	0.424
One month	0% (0)	**0.004**
Three months	0% (0)	**0.004**
Six months	0% (0)	**0.004**

Pre- and post-treatment assessment of venous ulcer was done to 3 patients. Compared to basal value, there wasn't any statistically significant differences after one week, one month, 3 months or 6 months on the venous ulcer after receiving treatment due to the small number of patients affected (Table 9).

Table (9): Pre- and post-treatment assessment of venous ulcer in the studied patients

Venous ulcer	All patients (n= 60)	p
Basal	5% (3)	-
One week	5% (3)	1.000
One month	5% (3)	1.000
Three months	0% (0)	0.250
Six months	0% (0)	0.250

Pre- and post-treatment assessment of incompetent perforators was done to the 60 patients. Compared to basal value, there was a statistically significant differences after one week, one month, 3 months and 6 months on the incompetent perforators after receiving treatment, so the treatment had an obvious effect on decreasing the incompetent perforators (Table 10).

Table (10): Pre- and post-treatment assessment of incompetent perforators in the studied patients

Incompetent perforators		All patients (n= 60)	P
Basal	0	58% (35)	-
	1	17% (10)	
	2	20% (12)	
	3	5% (3)	
One week	0	97% (58)	< 0.001
	1	3% (2)	
One month	0	97% (58)	< 0.001
	1	3% (2)	
Three months	0	97% (58)	< 0.001
	1	3% (2)	
Six months	0	97% (58)	< 0.001
	1	3% (2)	

Post-treatment complications were assessed in this study and there were 17 patients who had complications (Table 11).

Table (11): Post-treatment complications in the studied patients

	All patients (n= 60)
Complications	28% (17)
Skin Hyperpigmentation	22% (13)
Thrombophlebitis	7% (4)
DVT	0% (0)
Visual disturbance	8% (5)
Stroke	0% (0)
Migraine	0% (0)
Skin necrosis	0% (0)

CASE PRESENTATION

Female patient 35 years old, had right visible varicosities and pain for 3 years, its CEAP classification was C2 Ep As Pr, her Doppler findings showed evidence of refluxing posterior accessory saphenous vein with related subcutaneous varicosities. Two incompetent perforators are also seen. Her treatment was UGFS that was done for refluxing vein and two incompetent perforators, through 2 sessions. The volume of injected foam (ml) was 15 ml and the concentration of aethoxysklerol was 2%. Her post-treatment assessment showed complete disappearance of treated vein and incompetent perforators. Nearly no visible varicosities could be detected. The patient

satisfaction was excellent and there were no complications.

Figure (1): the stated case shows (A) visible subcutaneous varicosities at the posterior aspect of leg and thigh. (B) After one session of UGFS. (C) After two sessions of UGFS, total disappearance of varicosities.

DISCUSSION

Chronic venous insufficiency could be a quite common medical problem. Surgical therapy remains the first treatment option at all stages of the disease above clinical state C1. Surgery has never been required for telangiectasias. There's a large armamentarium of therapeutic options in additional advanced clinical states of venous insufficiency [9].

The selection of the best approach depends on many factors: stage of the venous lesion in keeping with the CEAP classification, location of this lesion, cost of the treatment, complaints, concomitant diseases, and obesity, willingness to resume work, prejudice against some methods of treatment or their complications, etc. [10]. **Rasmussen et al.** [11] in their investigation comparing UGFS, radiofrequency ablation (RFA), endovenous laser ablation (EVLA), and surgery reported the highest recurrence of reflux in treated GSVs 1 year after foam sclerotherapy. These authors however recognized this method as the least traumatic, the most affordable, and straightforward to repeat. The treatment itself is comparatively easy to perform, effortless, and may be conducted in an outpatient clinic [12].

This study conducted at Sohag University Hospitals was planning to evaluate the efficacy, safety, and patient satisfaction following foam sclerotherapy for varicose veins. We included a complete of 60 cases with lower limb varicosities whose mean age was 33.72 years (range, 20 – 52). Another study handling the identical perspective included a complete of 52 cases with GSV incompetence and with or without concomitant varicose veins were treated with US-guided foam sclerotherapy. The mean age was 54 (from 30 to 65) years [13].

Within the current study, females represented 62% of cases, while the remaining cases were males. Another study also reported female predominance. Authors included 46 (88.5%) females and 6 (11.5%) male patients [13]. This was further confirmed by another study, which reported that 82% of the included cases were females [14]. Conversely, another study reported high predominance of males, as they represented 74% of the study cases [15].

Regarding CEAP classification, class 2 was the most common class encountered (42 cases – 70%), followed by class 1 and three (12% for each), class 6 (3%), whereas class 4 and 5 were present in 2% of cases for each. In another study, CEAP classification was as follows; class 2 (9.52%), class 3 (36.51%), class 4 (46.03%), and class 5 (7.94%) [16].

The cosmetic appearance showed a significant improvement after our intervention. All cases reported bad cosmoses before the intervention, which decreased down to 58, 17, 7, and 10% at 1-week, 1-, 3-, 6-month follow-up visits respectively. Although there was a

small rise at the 6-month visit, it was also significantly better than the basal value.

In the current study, most symptoms showed a significant improvement compared to the baseline values during the scheduled follow-up visits. Moreover, edema showed significant improvement 1 month after intervention, and that improvement was also noticed through the following visits. Unlike the other complaints, it did not show significant change after 1 week. This could be explained by the occurrence of post-procedural inflammation and tissue response, which may delay the resolution of the preexisting edema.

In another study, the majority of patients (96%) reported an improvement in symptoms. In a semi-quantitative fashion, 33 (66%) patients reported > 50% improvement, while 15 (30%) patients reported < 50% amelioration. Only two patients felt that the procedure provided no benefit [17].

Another study reported that there was a significant improvement in the Aberdeen Varicose Vein Symptom Severity Score as it decreased from 18.9 down to 9.7 after long-term follow up [18]. In another study, improvements in symptoms and quality of life were 100% [15]. In terms of expectations, one study showed exceeded 25% while unmet in 10% [19]. Regarding patient satisfaction, it was subjectively categorized in a previous study as 'excellent, 'good', 'average' and 'poor'. 14 (28%) patients considered foam sclerotherapy to be an excellent treatment, while 27 (54%) decided it was good, and nine (18%) patients subjectively confirmed the procedure to be average. No patient thought that it was a poor intervention [17]. Furthermore, other authors reported that assessment of patients' satisfaction demonstrated that 94.4% reported satisfaction with the treatment outcomes, 88.9% stated that they would undergo the procedure again if necessary, and 77.8% said that they would recommend the treatment to a friend [20].

As regard venous reflux in the short saphenous vein in our study, it was present in 13% of cases before the intervention, and it was not detected in any of the included cases after the intervention. Furthermore, large saphenous reflux was present in 48% of cases before the intervention, and its incidence decreased down to 10% after 1 week. The following visits also showed a significant decrease down to 3, 3, and 7% respectively. Furthermore, saphenofemoral reflux was present in 48% of cases before the intervention, and it decreased down to 7, 3, 3, and 7% of cases at the scheduled follow-up visits respectively. On the other hand, although saphenopopliteal reflux disappeared after the intervention, that improvement was statistically insignificant.

As regard venous ulcer improvement, it didn't show a major change within the current study. Nevertheless, it had been present in 5% of cases before the intervention, while it absolutely was absent after 3 months. In another study, the assessment of the patients presenting venous ulcers as the main complaint (10 cases) demonstrated that upon the primary follow-up, 7 were completely healed, 2 presented improvement although healing wasn't complete, and 1 healed but presented recurrence. Thus, the venous ulcers reepithelialization rate was 70%, with 30% presenting recurrence or improvement without complete reepithelialization [20]. **O'Hare and Earnshaw** [21] reported 91.2% rate of healing in 24 weeks, **Kulkarni et al.** [22] 71.1% in 24 weeks, and **Campos et al.** [23] 91.3% after one year.

Incompetent perforators showed a major decrease after intervention. It had been absent in 97% after the intervention. Although reticular vein did show any significant improvement after intervention, the prevalence of telangiectasia decreased significantly from 15% before intervention, all the way down to 0% after 1 month.

In a previous study, treatment was more likely to be effective for great saphenous compared to small saphenous veins [14]. Others have reported better outcomes for small compared to large diameter veins [24,25] although satisfactory results for giant veins have also been reported [3, 26]. In another study, Doppler examination follow up showed complete occlusion of the treated vein following 79% of procedures (n = 100). Partial occlusion of the treated vein was evident following 14% of procedures (n = 18) and a patent treated vein was seen after 6% of procedures (n = 8) [16].

In another study, 177 patients with varicose veins, who were recruited from 3 different practices in Italy, were accustomed assess the efficacy and safety of ultrasound-guided foam sclerotherapy. Complete obliteration of the treated vein was detected in 161 (91%) patients at 1 month. This percentage was diminished to 67% between 66 patients who had another follow-up visit at 138 (mean) days [27].

Rabe et al. [28] reported occlusion of great saphenous vein 3 months after sclerotherapy in 70% of cases, whereas **Bountouroglou et al.** [29] noted success in 87%. Both authors used 3% foamy polidocanol for sclerotherapy. Consistent with **Gonzalez-Zeh et al.** [30] **and Figueiredo et al.** [31], patent great saphenous vein 6 months after foam sclerotherapy was detected in 11.3% and 22% respectively.

When it involves complications encountered in our study, it had been reported by 28% of cases. Skin hyperpigmentation was the most common complication (13 cases – 22%), followed by visual disturbances (5 cases – 8%), and thrombophlebitis (4 cases – 7%).

Regarding complications in other studies, six (11.5%) patients felt moderate pain at the location of injection as it was administered every week and a month after sclerotherapy thrombophlebitis of a part of the treated vein or its tributaries were present in 11

(21%) cases. During follow-up, hyperpigmentation, disappear with time, was detected on the skin of the thigh or calf in 9 (17%) cases. Serious complications like DVT, embolism (PE), dyspnea, anaphylaxis, or neurological abnormalities (vision disorders, vertigo, and loss of consciousness, stroke, or transient ischemic attacks) weren't recorded [13].

Limitations of the study: First of all, it's a single-center study. Besides, it included a comparatively small sample size. Additionally, it's not a comparative study. These considerations should be kept in consideration in performing future studies.

CONCLUSION

Ultrasound-guided foam sclerotherapy appeared to be a safe and effective procedure for the treatment of chronic venous insufficiency in the selected group of patients. The complications were simple and most of the patients reported good satisfaction with the therapy outcomes.

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