

**EFFICACY OF FOAM SCLEROTHERAPY IN MANAGEMENT OF SYMPTOMATIC VARICOSE VEINS OF LOWER EXTREMITIES- A PROSPECTIVE OBSERVATIONAL STUDY**

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**ABSTRACT**

**Background:** The prevalent issue of varicose veins in the lower extremities necessitates exploring effective and efficient treatment methods. This study aims to evaluate the efficacy of foam sclerotherapy, focusing on improvements in the venous clinical severity score and the swift return to work post-treatment. Through this research, we intend to ascertain whether foam sclerotherapy can serve as a cost-effective, safe, and satisfactory alternative to traditional treatments.

**Methodology:** A universal sampling method was implemented to select the sample size for the study. The study cohort consisted of 31 patients who visited the outpatient department and met the established inclusion criteria. These patients underwent comprehensive history evaluation and physical examinations. Subsequent to the preliminary evaluations, the patients were subjected to necessary hematological and biochemical analyses along with appropriate radiological investigations, including USG venous Doppler studies, dictated by clinical suspicions. All participants underwent USG-guided foam sclerotherapy and their progress was monitored based on predefined outcomes.

**Results:** The study predominantly involved males aged between 30 and 60 years. A significant enhancement in patient satisfaction was documented, with notable reductions in ulcer size in 3 out of the 31 patients who initially presented with ulcers. Moreover, the therapy ensured a 100% reduction in reported pain and swelling, with no hospital stays extending beyond one day. Remarkably, 28 out of the 32 patients managed to resume their work within a span of less than 7 days, showcasing no side effects from the treatment.

**Conclusion:** The data gleaned from the study underscore the considerable patient satisfaction derived from foam sclerotherapy, especially concerning alleviation in pain, swelling, and enhanced ulcer healing.

Furthermore, patients reported a significant reduction in lower limb pigmentation following the therapy. Not only is foam sclerotherapy cost-effective and safe, but it also facilitates a quicker return to work coupled with shorter hospital stays, establishing itself as a potent alternative in managing symptomatic varicose veins.

**Keywords:** Foam Sclerotherapy, Varicose Veins, Venous Clinical Severity Score, Ulcer Healing, Outpatient Department.

## **INTRODUCTION**

Varicose veins, prominently observed in the lower extremities, are a prevalent vascular condition characterized by the enlargement and twisting of superficial veins due to venous insufficiency. This medical condition affects a significant portion of the adult population worldwide, raising substantial concerns pertaining to public health and quality of life. The continual advancements in medical science have fostered the development of diverse treatment modalities to manage this pervasive condition effectively. One such emerging treatment is foam sclerotherapy, a minimally invasive procedure that has garnered attention for its efficacy in the management of symptomatic varicose veins. This prospective observational study meticulously explores the efficacy of foam sclerotherapy in managing symptomatic varicose veins of the lower extremities.

The pathogenesis of varicose veins involves the malfunctioning of the venous valves, leading to venous hypertension and subsequent dilatation of the veins, which affects the lower limbs predominantly[1]. The symptomatic presentation often includes leg pain, swelling, and notable skin changes, including pigmentation and ulcers[2]. Notwithstanding, the condition also exerts a significant psychosocial impact, as it frequently affects individuals' self-esteem and quality of life due to the cosmetic disfigurement it entails[3].

Foam sclerotherapy, an innovative treatment modality, has emerged as a potent alternative to surgical interventions, offering benefits such as shorter hospital stays and quicker return to daily activities[4]. This procedure involves the injection of a sclerosing agent in the form of

foam directly into the affected veins, causing their closure and subsequent absorption by the body. This minimally invasive approach, thus, targets the root cause of the condition, mitigating symptoms and improving the overall clinical severity score[5].

The venous clinical severity score (VCSS) is a robust tool frequently utilized in research and clinical settings to assess the severity of varicose veins and to monitor the patient's progress post-treatment[6]. The efficacy of foam sclerotherapy can thus be quantitatively evaluated using the VCSS, presenting a reliable means to gauge the treatment's success in improving patients' symptoms and quality of life over time.

As we delve further into the prospect of foam sclerotherapy as a potential mainstay treatment for symptomatic varicose veins, it becomes imperative to analyze various aspects including its efficacy in reducing pain, minimizing pigmentation, and facilitating ulcer healing. Furthermore, the rapid resumption of daily activities post-treatment stands as a testament to its less invasive nature, fostering a quicker recovery process compared to traditional surgical interventions[7].

Considering the economic aspect, foam sclerotherapy presents as a cost-effective alternative to surgery, minimizing hospital stay duration and facilitating quicker return to work[8]. Additionally, it demonstrates a favourable safety profile, with a considerably lower incidence of complications compared to other treatment modalities, thus signifying its potential as a preferable treatment option for symptomatic varicose veins in the foreseeable future.

In the present study, we envisage filling the existing gaps in literature pertaining to the efficacy of foam sclerotherapy in the management of symptomatic varicose veins of the lower extremities. Through a prospective observational lens, the study seeks to furnish concrete data and insights, contributing significantly to the burgeoning body of research in this domain.

In conclusion, as we stand on the cusp of a paradigm shift in the management of symptomatic varicose veins, foam sclerotherapy emerges as a promising candidate, potentially revolutionizing the treatment landscape. Through meticulous investigation and data analysis,

this study aims to corroborate the efficacy of foam sclerotherapy, thus paving the path for its widespread acceptance and implementation in clinical practice.

The forthcoming research promises not only to substantiate the efficacy of foam sclerotherapy but also to spotlight its significant role in enhancing patients' quality of life, fostering quicker recovery, and reducing the economic burden associated with the management of symptomatic varicose veins.

## **AIMS&OBJECTIVES**

### **Aim:**

To conduct a prospective observational study evaluating the overall effectiveness of foam sclerotherapy in managing symptomatic varicose veins.

### **Objectives:**

#### **Primary:**

To assess the enhancement in the venous clinical severity score following foam sclerotherapy treatment.

#### **Secondary:**

To analyze the duration required for patients to resume work post-foam sclerotherapy procedure.

## **Materials and Methods**

### ***Study Setting:***

- **Location:** Department of general surgery, Sahyadri Narayana Multispeciality Hospital, Shimoga.
- **Duration:** 18 months.
- **Design:** Prospective Observational Study.

### ***Population and Sampling:***

- **Target Population:** All patients consulting at the general surgery and vascular department OPD.

- **Sample Size:** A universal sampling method determined the sample size, encompassing all patients with varicose veins visiting the hospital, with a minimum inclusion of thirty individuals (n=30).
- **AgeRange:** 20-80 years, including both genders.

***Inclusion Criteria:***

- Recurrent varicose veins.
- Residual perforator incompetence.
- Patients unwilling to undergo open surgery.
- Clinically diagnosed perforator incompetence.

***Exclusion Criteria:***

- Previous history of Deep Vein Thrombosis (DVT).
- Documented allergy to sclerosing agents.
- History of vasculopathy or peripheral vascular disease (PVD).
- Truncal and junctional incompetence.

***Parameters Studied:***

The following parameters were closely monitored to gauge improvements post foam sclerotherapy in patients with varicose veins in the lower extremity:

1. Age
2. Gender
3. Pain levels
4. Varicose veins status
5. Skin pigmentation
6. Ulcer presence
7. Inflammatory responses
8. Induration levels
9. Venous oedema

10. Venous clinical severity scores (at admission and follow-up)

11. Return to work post-treatment

***Methodology:***

31 patients within the age bracket of 20-70, exhibiting symptoms such as dilated veins, pain, skin pigmentation, swelling, or venous ulcers, were enlisted for the study. Diagnosis relied on clinical examinations and doppler studies. Post Institutional Research and Ethical committee approval, and with informed consent from participants, the study commenced at Sahyadri Narayana Multispeciality Hospital. The follow-up spanned 18 months, during which the efficacy of foam sclerotherapy was assessed based on parameters like pain reduction, pigmentation improvement, oedema alleviation, and ulcer healing. The study utilized Setrol (60 mg/2ml) injections administered through ultrasound-guided foam sclerotherapy under regional block in the OT, ensuring a one-day hospital stay and systematic follow-ups at specified intervals over a year.

***Data Collection:***

Data aggregation involved a structured questionnaire where patients' histories and physical examination findings were meticulously recorded. Necessary blood and radiological tests were performed, and data were catalogued into Microsoft Excel for comprehensive analysis.

***Statistical Analysis:***

Utilizing SPSS v16 on Windows 10, the data was analyzed, with demographic data presented as frequencies and percentages, and continuous variables as mean  $\pm$  SD. The student t-test evaluated the mean score differences for independent variables, considering a p-value  $<0.05$  as statistically significant. Graphic representations of the data were created using MS Excel and Word, offering insights through bar and pie charts.

**RESULTS**

A total of 31 patients fulfilling inclusion criteria are included in present study after obtaining the informed consent aged between 20 to 80 years. Patients were assessed using venous

severity scores scale and charted with respect to outcomes.

**TABLE NO:3 AGE DISTRIBUTION:**

Age	Frequency and percentage (%)
31-35	7(22.6%)
36-40	15(48.4%)
41-45	3(9.7%)
>45	6(19.4%)

Above table shows age wise distribution of the study group. Out of 31 patients evaluated 15 patients (48.4%) were <40 years. 3 patients (9.7%) were <45 years. 6 patients (19.4%) were >45 years.

**TABLE NO:4 GENDER DISTRIBUTION**

Gender	Frequency and percentage (%)
Male	23(74.2%)
Female	8(25.8%)

The above table shows gender wise distribution of study group. 23 patients (74.2%) were male and remaining 8 patients (25.8%) were female which indicates that males are predominantly affected in the study.

**TABLE NO:5 PAIN DISTRIBUTION IN STUDY GROUP.**

Pain scores	Frequency At admission with %	At 1 month	At 3 months	At 6 months
None	0	26(83.9%)	30(96.8%)	31(100%)
occasional	7(22.6%)	3(9.6%)	1(3.2%)	0
Daily pain (not restricting)	19(61.3%)	2(6.5%)	0	0
Daily pain (restricting)	5(16.1%)	0	0	0

The above table shows distribution of pain in the study group. At admission

7 patients (22.6%) had occasional pain, 19 patients (61.3%) had daily pain (not restricting daily activity) and 5 patients (16.1%) had daily pain (restricting daily activity). At 1 month follow up majority of patients i.e., 26 patients (83.9%) had no pain, 3 (9.6%) had only occasional pain and 2 patients had pain which restricted their daily activity. At 3 month follow up 30 patients (96.8%) had no pain and 1 patient had occasional pain.

**TABLE NO:6 VENOUSEDEMA DISTRIBUTION IN STUDY GROUP**

Varicose oedema	Frequency and (%) at admission	At 1 month	At 3 months	At 6 months
None	23 (74.2%)	28 (90.3%)	31 (100%)	31 (100%)
Above ankle but below knee	8 (25.8%)	3 (9.7%)	0	0

The above table shows distribution of venous oedema in the study group. 23 patients (74.2%) out of 31 patients had no oedema at admission. 8 patients (25.8%) had oedema below knee but above ankle. At 1 month follow up venous oedema significantly reduced to 3 patients (9.7%). At 3 months no patients were found to have venous oedema.

**TABLE NO:7 PIGMENTATION DISTRIBUTION IN STUDY GROUP**

Pigmentation	Frequency and (%) at admission	At 1 month	At 3 months	At 6 months
None	26 (83.9%)	27 (87.1%)	28 (90.3%)	28 (90.3%)
Limited to perimalleolar region	1 (3.2%)	3 (9.7%)	3 (9.8%)	3 (9.8%)
Diffuse over lower third of calf	4 (12.9%)	1 (3.2%)	0	0



The above table shows the distribution of pigmentation. 26 patients (83.9%) out of 31 had no pigmentation at admission. 1 patient (3.2%) had pigmentation in perimalleolar region and 4 patients (12.9%) had diffuse pigmentation over lower third of calf. At 1 month of follow up pigmentation reduced and 27 (87.1%) had no pigmentation, limited to peri malleolar area in 3 patients (9.7%) and 1 patient (3.2%) had pigmentation diffusely over lower third of calf. At 3 months 28 patients (90.3%) had no pigmentation, 3 patients (9.7%) had only pigmentation limited to perimalleolar region. At 1 year only 3 patients (9.7%) had pigmentation limited to perimalleolar area.

**TABLE NO:8 VARICOSE VEIN DISTRIBUTION**

Varicose veins	Frequency and (%) at admission	At 1 month	At 3 months
None	0	31(100%)	31(100%)
Few/scattered	8(25.8%)	0	0
Confined to calf	23(74.2%)	0	0

The above table shows distribution of varicose veins in the study group. 23 patients (74.2%) had varicose veins confined to calf. 8 patients (25.8%) had few /scattered varicose veins. At follow up at 1 month, none of the patients had varicose veins. (100%).

**TABLE NO:9 INFLAMMATION IN THE STUDY GROUP**

Inflammation	Frequency and (%) at admission	At 1 month	At 3 months
None	28(90.3%)	29(93.5%)	31(100%)
Diffuse over lower third of calf	3(9.7%)	2(6.5%)	0

The above table shows distribution of inflammation in study group. 28 patients (90.3%) had no inflammation at admission. 3 patients (9.7%) had inflammation diffusely over lower third of the calf. At 1 month follow up 29 (93.5%) had no inflammation. At 3 months, none (100%) of patients had inflammation.

**TABLENO:10INDURATIONINSTUDYGROUP**

INDURATION	Frequency and % at admission	At 1 month	At 3 months	At 6 months	1 year
None	28(90.3%)	29 (93.5%)	31	31	31
Limited to perimalleolar area	3(9.7%)	2(6.5%)	0	0	0

The above table shows distribution of induration in study group. 27 patients(87.1%) had no induration at admission. 4 patients (12.9%) had induration limited to perimalleolar region at admission. At 1 month induration was found in only 2 patients (6.4%). At 3 months none of the patients had induration on followup.

**TABLENO11ACTIVEULCERNUMBERINSTUDYGROUP**

Active ulcer number	At admission	At 1 month	At 3 months	At 6 months
None	28(90.3%)	28	29	31
1	1(3.2%)	1	1	0
2	1(3.2%)	1	1	0
>3	1(3.2%)	1	0	0

The above table shows distribution of ulcer number in study group. 28 patients(90.3%) had no active ulcer at admission. 3 patients (3.2%) had active ulcer which reduced substantially to 2 patients with ulcer at 3 months and at end of 6 months none of patients had any ulcer.

**TABLENO:12ACTIVEULCERSIZE.**

Active ulcer size	Frequency and (%) at admission	At 1 month	At 3 months	At 6 months	At 1 year
None	28(90.3%)	29 (93.6%)	31(100%)	31(100%)	31(100%)

<2cm	1(3.2%)	2(6.4%)	0	0	0
2-6cm	2(6.5%)	0	0	0	0

The above table shows Ulcer size distribution of study group. 28 patients (90.3%) had no ulcer at admission. 1 patient (3.2%) had ulcer size of <2cm and 2 patients (6.5%) had ulcer size between 2-6cm. At 1 month patient of ulcer size 2-6cm reduced to <2cm in 2 patients. At 3 months all the ulcers healed and none were found to have ulcers.

**TABLE NO:13 ACTIVE ULCER DURATION AT ADMISSION**

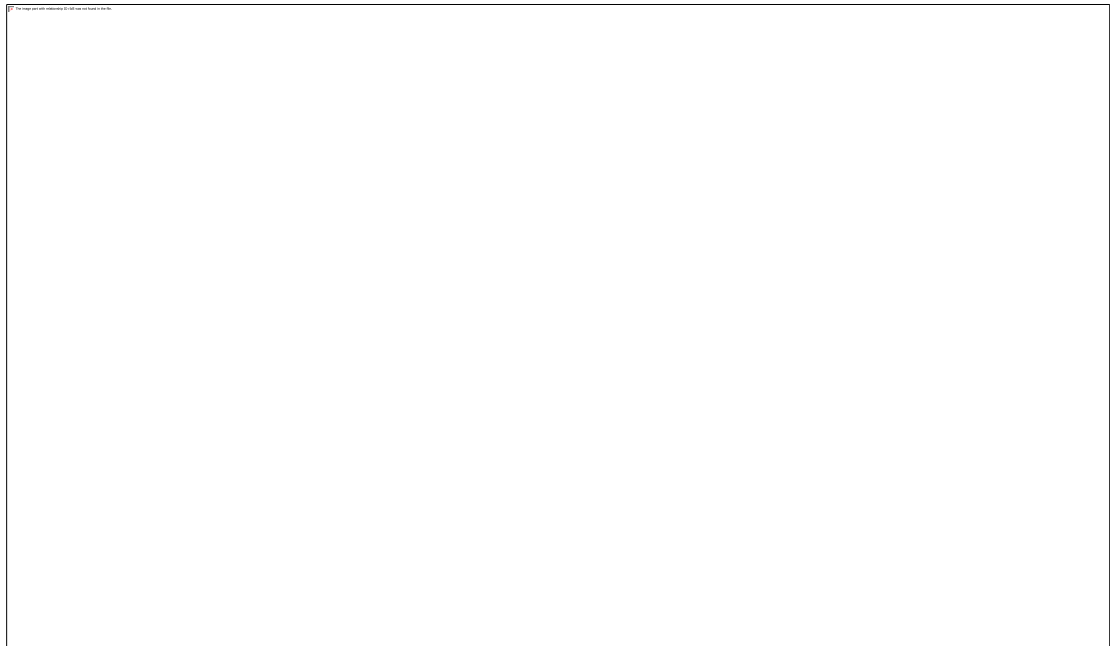
Active ulcer duration	At admission
None	28(90.3%)
<3 months	1(3.2%)
3 months -1 year	2(6.5%)

The above table shows active ulcer duration in study group. 28 patients (90.3%) had no ulcer at admission. 1 patient (3.2%) had ulcer with duration of <3 months and 2 patients (6.5%) had ulcer duration between 3 months to 1 year.

**TABLE NO :14 USE OF COMPRESSION THERAPY-STOCKINGS AT ADMISSION**

		Frequency	Percent
<b>USE OF COMPRESSION STOCKINGS</b>	Not Used	25	80.7
	Intermittent use	1	3.2
	Use on most days	5	16.1
	Total	31	100.0

The above table shows distribution of use of stockings in the study group at admission. 25 patients (80.7%) had not used compression therapy. 1 patient (3.2%) had used intermittently and 5 patients (16.1%) had used compression therapy most of the days.



**Figure 1: Distribution of Return to work in study group**

The above table shows patients returning to work after foam sclerotherapy. 20 patients (64.5%) returned to work in 4 days .6 patients (19.4%) in 7 days and 3 patients (9.7%) returned to work in 14 days.

**TABLE NO: 16 VENOUS CLINICAL SEVERITY SCORE AT ASDMISSION AND AT FOLLOW UP**

	Mean	SD	95%CI	Tvalue	Pvalue
Totalscoresat admission	5.61	4.28	3.967-6.227	9.212	<0.0001
Totalscoresat 1month	0.52	1.338			
Totalscoresat admission	5.61	4.28	3.99-6.90	7.65	<0.0001
Totalscoresat 2months	0.16	0.37			
Totalscoresat admission	5.61	4.28	3.99-6.90	7.65	<0.0001
Totalscoresat 3months	0.16	0.37			
Totalscoresat admission	5.61	4.28	3.99-6.90	7.65	<0.0001
Totalscoresat 6months	0.16	0.37			
Totalscoresat admission	5.61	4.28	3.99-6.90	7.65	<0.0001
Totalscoresat 1year	0.16	0.37			

The above table shows the comparing scores at follow up in study group. The mean total score at admission was 5.61 $\pm$  4.28 and the mean total score on follow up at 1 year was 0.16 $\pm$ 0.37. The difference in the mean at the time of admission and after foam sclerotherapy was statistically significant ( $p=0.001$ ).

## DISCUSSION

The venous insufficiency of lower limb has substantial effects on patient's health-related quality of life and results in health status comparable to other chronic conditions such as diabetes mellitus and cardiovascular diseases.

Open surgery is to date the gold standard in the treatment of lower limb varicose veins. This, however, entails the use of general or regional anaesthesia and necessitates a groin incision for surgical dissection of the SFJ. The use of doppler ultrasound in the treatment of varicose veins allows alternative strategies to be used.

Foam sclerotherapy was an established method of causing venous occlusion by the injection of sclerosing into the affected veins. Direct contact of sclerosant with the venous endothelium initiates endothelial and contiguous mural injury. A local, wall-adherent thrombus then forms, and subsequent sclerosis transforms the treated vein into a fibrous cord. An ideal treatment should relieve all physical symptoms, significantly improve the appearance of the leg, be complication-free, allow a fast (immediate) return to normal activities, be inexpensive, and be widely available and applicable to affected patients.

The present study aimed to assess the efficacy of foam Sclerotherapy in overall management of symptomatic varicose veins.

A total of 31 patients fulfilling inclusion criteria are included in present study after obtaining the informed consent aged between 20 to 80 years. Similar to present study, Kharl RAK et al., to assess the outcome of patients undergoing ultrasound-guided foam sclerotherapy. Their ages ranged from 17 to 68 years with the mean age of 43.21 years. Six hundred and sixty-eight (88.82%) legs were having Great Saphenous Vein while 84 (11.17%) legs were having short saphenous vein disease. Maximum legs 256 (34.04%) had C3 disease.<sup>9</sup>

The venous clinical severity scoring was assessed among all the patients, at the initiation of the treatment and at 1<sup>st</sup> yr of treatment follow-up. The scoring system involved different variables and the scoring was 0 for minimum and 3 as maximum score showing the highest severity. At the initial period of treatment, the

pain score was maximum among 5 patients (16.1%), varicose veins was confined to calf or thigh in 23 patients (74.2%), Venous oedema was seen above ankle but below knee in 8 patients (25.8%), pigmentation as diffuse over lower third of calf in 4 patients (12.9%), inflammation as diffuse over lower third of calf in 3 patients (9.7%), indurations in peri malleolar area in 3 patients (9.7%), active ulcer duration of more than 3 months was seen in 2 patients (6.5%), the active ulcer size was seen to be 2-6cm in 2 patients (6.5%) and use of compression stockings was used on most of days in 5 patients (16.1%). On assessment of the mean total score at admission, it was found to be  $5.61 \pm 4.28$ . On follow up of patients at the 1<sup>st</sup> year, the mean score was found to be  $0.16 \pm 0.37$ , with no venous clinical severity symptoms. In study by Yilmaz S et al., followed up clinically and with colour Doppler ultrasound at 1, 6, and 12 months. ELA was technically successful in all cases, although another venous puncture was necessary in 29 legs. Concomitant USGFS was also technically successful in all cases, but one to three additional sclerotherapy sessions were performed in 203 legs with persistent varicosities. During the follow-up, recanalization of the laser-ablated refluxing veins occurred in 16 legs (1.7%) and was treated with repeat ELA or USGFS.<sup>10</sup> In study by Gafar AT et al., documented similar to present study that Twenty-five (50%) patients reported deformity, 30 (60%) patients reported pain, 30 (60%) patients reported heaviness, and 35 (70%) patients reported oedema. Pain at injection sites was reported in 32 (64 percent) of patients, itching in four (8 percent), ecchymosis in 18 (36 percent), and superficial thrombophlebitis in eight (16 percent). In the treatment of primary varicose veins, foam sclerotherapy is safe, effective, and less difficult.<sup>11</sup>

Khari RAK et al., documented that single session of Foam sclerotherapy was enough in 511 (67.95%) legs, while 197 (26.19%) legs were treated with two and 44 (5.85%) legs were treated with three sessions of foam sclerotherapy. Percentages of main trunk occlusion were 98.01% at 1 month while 97.39% at 3 months follow up. Only 2 (0.30%) patients had Deep Venous Thrombosis while 3 (0.45%) patients had thrombophlebitis which required surgery.<sup>9</sup>

In study by Darvall et al., documented Recanalization at 12 months is superior to that reported after surgery and similar to that observed following other minimally invasive techniques.<sup>12</sup> In study by Kumicki J et al., among 96 percent of subjects,

symptoms of chronic venous insufficiency were reduced or eliminated (50 patients). All patients experienced the disappearance or reduction of varicose veins (100 percent).

According to Tegernsee's consensus, full success of ultrasonography was obtained in 38 (73 percent) instances after 12 months, while 11 (21 percent) patients showed a partial desired result. In three (6%) cases, reflux lasted longer than one second in the treated great saphenous vein.<sup>13</sup>

Present study documented no adverse effects with the treatment procedure with better safety for the patients. Major complication documented in 1.4% of the treated legs and included skin necrosis and calf vein thrombosis in study by Yilmaz Set al.,<sup>10</sup> and main trunk occlusion were 98.01% at 1 month while 97.39% at 3 months follow up. Only 2 (0.30%) patients had Deep Venous Thrombosis while 3 (0.45%) patients had thrombophlebitis which required surgery in study by Kharl RAK et al.<sup>9</sup> In addition to present study, Satoshi W et al., concluded in their study that TLFS combined with EVLA may be an easy, safe, and effective procedure with acceptable complications vs. EVLA alone and reduces additional second stage interventions.<sup>14</sup>

Maurya AK et al., documented early complications included: superficial skin necrosis in 4 legs (2.70%), pain at injection sites in 21 legs (14.18%), superficial thrombophlebitis in injected veins in 21 legs (14.18%), bruising in 18 legs (12.16%), superficial vein thrombosis in 10 legs (6.75%), and skin staining around injected veins in 13 legs (8.78 percent).<sup>15</sup> Early effects included: superficial skin necrosis in 7 legs (3.78%), discomfort at injection sites in 27 legs (14.59%), superficial thrombophlebitis in the injected vein in 23 legs (12.43%), and skin discolorations surrounding injected veins in 16 legs (8.64 percent). In conclusion, UGFS is a safe, simple, and useful procedure for individuals with varicose veins.<sup>16</sup>

Similar to present study, Kumicki J et al., concluded that during a one-year study, ultrasound-guided foam sclerotherapy of incompetent great saphenous veins and varicosities was proven to be an effective and safe therapeutic approach.<sup>13</sup> The safety and clinical effectiveness of UGFS were excellent for all clinical, aetiological, anatomical, and pathological elements classes of GSV reflux. In conclusion, the popularity of this outpatient approach among patients may be attributed to the convenience of treatment, cheaper cost, absence of downtime, and removal of venous indications and symptoms.

## **CONCLUSION**

The current study unequivocally highlights the pronounced efficacy of foam sclerotherapy in alleviating symptomatic manifestations such as pain and venous oedema, as well as in reducing pigmentation in the lower limbs attributed to varicose veins. Remarkably, this treatment modality not only accelerates the healing process of venous ulcers but also enables patients to resume their occupational responsibilities more rapidly, coupled with reduced hospitalization durations. Furthermore, the absence of complications within our study cohort underscores the safety and simplicity of foam sclerotherapy, positioning it as a cost-effective intervention that facilitates substantial improvements in symptom management and ulcer healing.

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