

FOAM SCLEROTHERAPY IN THE TREATMENT OF AXIAL VS COLLATERAL VARICOSITIES.

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Abstract.

Introduction:

Varicose veins are one of the most common distressing situations, affecting almost 30-50% of the adult population. Patients experience throbbing pain, heaviness of the limb, bleeding on trivial trauma, and even ulceration. There are many treatment modalities like compression stocking, radiofrequency ablation, sclerotherapy, and open surgical treatment. Among them, ultrasound-guided sclerotherapy has been a widely accepted procedure. It is simple, minimally invasive, and allows patients to return to their baseline activity level quickly. Foam sclerotherapy is the newest addition. Here air is mixed with the liquid sclerosant to create the "foam", which is injected into the vein under ultrasound guidance.

Aims and Objectives: To compare the effectiveness of foam sclerotherapy in treating axial and collateral varicosities.

Patients and Methods:

This study was conducted between August 2020 and July 2022 in Midnapore Medical College and Hospital. 100 patients having varicosity of the lower limb were divided into two groups of 50 patients each: patients having Axial varicosity and Collateral varicosity. Both the groups were treated with foam sclerotherapy and a serial ultrasound was obtained on the 2nd week, 1st month, 6th month, 12th month, and 24th month to see the effectiveness.

Result:

The p-value was statistically insignificant, which implied that there was no significant difference in the outcome of treatment of both axial and collateral varicosities by foam sclerotherapy.

Conclusion:

Foam sclerotherapy is equally effective in treating both axial as well as collateral varicosities.

Recommendation:

To increase the general safety of foam sclerotherapy injection of very viscous foam in the varicose veins should be considered. Also, the patient should not move, specifically their leg for several minutes, and also should not carry out the Valsalva maneuver.

Keywords: Foam sclerotherapy, Varicose veins, Axial varicosity, Collateral varicosity., Submitted: 2023-09-02 Accepted: 2023-09-14

1. INTRODUCTION.

Dilated tortuous elongated subcutaneous veins of 3 mm in diameter or larger are termed Varicose veins. They are often associated with intermittent blowouts, but are defined by the presence of reflux

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and may be straight and uniform tubes morphologically[1]. They are one of the common features of chronic venous insufficiency of the lower limb, having a prevalence of 30–50% in the adult population[1]. Varicose veins can be classified as trunk or axial varicosity, reticular or collateral varicosity, or telangiectasia. Most varicose veins are primary; only the minority are secondary to conditions such as deep vein thrombosis and occlusion, pelvic tumors, or arteriovenous fistulae[2]. Although varicose veins have traditionally been considered more common in women, few studies have found that the prevalence of trunk varices was more common in males than females[2]. The most commonly affected age group is 55 – 54 years (55.70%)[1]. Literature suggests that the vein wall is inherently weak in varicose veins, which leads to dilatation and separation of valve cusps so that they become incompetent[2]. Risk factors for varicose veins include increasing age and parity and occupations that require a lot of standing. Patients suffering from varicose veins, mostly have the complaint of the presence of dilated tortuous “worm-like” structure of the affected limb. Apart from that, they often complain of heaviness, dull aching pain, itching, bleeding on trivial trauma, change in the skin color and texture, swelling of the limb and even ulceration. Tourniquet tests and hand-held Doppler have now mostly been replaced by Duplex ultrasound scanning of the affected limb, as it can provide a confirmatory diagnosis on the presence and extent of reflux, deep venous obstruction, or thrombi, incompetent perforators, etc [1-4]. Many patients with asymptomatic varicose veins require only reassurance [1- 2]. Other treatment modalities include the use of Compression stockings, Endovascular ablation by laser or radiofrequency, Catheter-directed or USG-guided sclerotherapy, Endovascular glue, or Open surgical method namely Trendelenburg's operation (Saphenofemoral flush ligation and stripping off the saphenous vein). Surgery is a widely used method of treatment but often leaves scars and may result in damage to adjacent structures including nerves, lymphatics, major arteries, and veins[1,5-6]. Incidence of deep vein thrombosis and pulmonary embolism

are also not uncommon[7-8]. Ultrasound-guided foam sclerotherapy is one of the newest treatment modalities. The foam is produced by mixing a sclerosing agent with room air and is used to treat varicosities, particularly in advanced cases with skin lesions and ulcers[6,9]. This is a minimally invasive day-care procedure that allows the patients to return to their day-to-day activity quickly[10-12].

This study has aimed to compare the outcome of the treatment of Foam sclerotherapy, using Sodium tetradecyl sulphate as the sclerosant, in the treatment of axial and collateral varicosities.

1.1. OBJECTIVE.

To compare the efficacy of Foam sclerotherapy in the treatment of Axial and Collateral varicosities.

2. PATIENTS AND METHODOLOGY.

2.1. Study design.

The study was an Institution prospective comparative interventional study, which was conducted in the Department of General Surgery, Midnapore Medical College and Hospital.

The study sample was selected based on patients attending the general surgery OPD of Midnapore Medical College and Hospital. Subjects who fulfilled the inclusion and exclusion criteria were given a predesigned Informed Consent Form and a valid, legal consent was taken from them. They were also explained in detail about their disease and the treatment modality being used. The sample size was 100 and a total study period of 24 months was taken into consideration, i.e., from August 2020 to July 2022. At the initial stage, 610 patients were examined for eligibility, however, 510 patients were excluded from this study due to not being eligible. Then they were divided into two groups: patients having varicosity of the axial system and patients having varicosity of the collateral system. Both groups had the same number of patients. Following this, a detailed history was taken of each, and every subject, and a thorough clinical examination was done, and the findings were noted down.

After this, the patients underwent ultrasound-guided foam sclerotherapy. During the post-operative period, they were closely monitored to look for any complications. They were discharged on postoperative day 3 and were followed up with serial ultrasound after 2 weeks, on the 1st month, 6th month, 12th month, and 24th month to see the outcome. In this study, we included pain, stiffness of the limb, itching, and visible or residual varicosity among the post-operative complications. To assess pain, the visual analog scale was used. Residual varicosity was assessed by whether the varicosity persisted clinically (by inspection) or radiologically.

All data was captured in a predesigned Case Data Sheet and analysis of the data was done using the Grand chart or the Master chart to conclude.

2.2. Study Parameters.

All of the study tools, starting from History to the Application of foam sclerotherapy and follow-up – were important in the study. They all need a brief and special mention.

2.3. History Taking.

A careful, thorough, and detailed history was taken regarding the socio-demographic profile of every patient, mentioning – Name, Age, Sex, Occupation, Religion, Residence, Socioeconomic scale (based on Modified B.G Prasad Scale), Chief complaint, History of present illness – with a special emphasis on straining factors like prolonged standing, history of any vascular disorder, trauma, History of similar episodes in the past, Family history, Personal history including bowel and bladder habits, history of any allergy, addiction to any substance, sleep and appetite history etc.

2.4. Clinical Examination.

This included a General survey, a brief assessment of all systems, and a local examination. In the general survey, any venous prominence of any other part of the body was noted. The local examination included Inspection, Palpation, Percussion, and Auscultation of the venous system

of the affected limb. During Inspection, the type and location of the varicosity, and any swelling or ulceration or skin changes were noted. Palpation was used to confirm the fascial defect at the level of perforators. Various tests were also performed to confirm the diagnosis, namely Brodie Trendelenburg test, Multiple tourniquet test, Perthe's and Modified Perthe's test, Schwartz test, Pratt's test, Morrissey's cough impulse test, and Fegan's test. The percussion was done to confirm the presence of an incompetent or absent valve in between the tapping and palpating fingers. To rule out any arterio-venous fistula, Auscultation was done. Examination of regional lymph nodes as well as the other limb was also done. Tests to rule out Deep venous thrombosis were also done.

2.5. Biochemical Examination.

Routine hematological examinations were performed.

2.6. Radiological Examination.

Every patient underwent an Ultrasonographic color Doppler study of the bilateral lower limb arterio-venous system: first to confirm the diagnosis before the procedure, and then, after 2 weeks of sclerotherapy, on the 1st month, 6th month, 12th month, and 24th month after the treatment with foam sclerotherapy, to see the outcome.

2.7. Sample Size.

A total number of 100 patients having dilated and tortuous veins of the lower limb were taken into the study.

2.8. Inclusion Criteria.

- Patients having lower limb varicosities either involving the axial or the collateral system
- Patients agreeing to follow-up

2.9. Exclusion Criteria.

- Pediatric age group patients
- Pregnant patients
- Patients diagnosed with deep venous thrombosis

- Patients having Arterial or Diabetic ulcers in the lower limb
- Immunocompromised patients or patients with other comorbidities like uncontrolled diabetes, hypertension, chronic kidney disease, or coagulation disorder
- Patients allergic to Sodium tetradecyl sulphate (sclerosant used)
- Patients not giving consent

2.10. Study Tools.

Rubber Tourniquet, Non-elastic plastic tape, Paper, Pen, Liquid Hand wash, Sterile disposable gloves, Calculator, Computer.

2.11. Statistical Analysis.

A total of 100 patients having lower limb varicose veins were taken into the study. They were divided into two groups: varicosity involving the Axial system and varicosity involving the Collateral system. Each group had 50 patients. Every patient underwent a detailed history and clinical evaluation, hematological, biochemical, and radiological examination. All of them were followed up for 2 years with full data and reports. Data were entered and analyzed with the help of MS Excel EPI info (TM) 7.2.2.2. EPI INFO is a trademark of the Centers for disease control and Prevention (CDC). To find out the effectiveness of the treatment in managing both axial and collateral varicosities, the Chi square test was used on a 2 x 2 table. A p-value of < 0.05 was considered to be statistically significant.

2.12. Ethical approval.

This study was conducted only after getting ethical approval from the Institutional Ethical Committee, by the Helsinki Declaration of 1975, as revised in 1983. Patients' identity was not disclosed throughout the study.

2.13. Sample size calculation.

Taking the Prevalence of Varicose veins (p): 40% [16] Reliability coefficient (Z): 1.96

Confidence limit: 95%

Margin of error (d): 5%

Population size (N): 150

q (= 1 - p): 60

For calculating sample size of a proportion or prevalence - $n = (N \times X) / (X + N - 1)$

where, $X = (Z^2 \times p \times q) / d^2$ So, $X = (1.96^2 \times 40 \times 60) / 25$

= 368

Hence, $n = (150 \times 368) / (368 + 150 - 1)$

= 107

There were 3 dropouts and 4 patients didn't turn up for follow up. Hence the final sample size was 100.

3. RESULTS.

There was an overall female preponderance (61%). Among the patients suffering from axial varicosity, 66% were females and 34% were males. Whereas, in collateral varicosity patients, 56% were females and 44% were males (Table 1).

Patients having lower limb varicosity mostly belonged to the age group of 40-60 years (56%), i.e., post-reproductive working population. There was not much alteration in this percentage whether the subjects had axial varicosity (52%) or collateral varicosity (60%). In geriatric age group. Axial varicosity was more predominant (26%) (Table 2).

Among the male population (39%), 46% were farmers and 44% were labourers. And among female population (61%), 74% were housewives. This implied that any occupation that needs prolonged standing was associated with varicosity of the lower limb (Table 3 and 4).

During the post-operative period, 37% of the patients developed complications, which included pain, stiffness, itching and residual varicosity. Pain was one of the most common symptoms that occurred even in the patients who had successful treatment by foam (Table 5 and 6). Distribution of the study subjects as per the complications they

Table 1: Distribution of the study subjects as per Gender (n = 100)

Table 1		Varicosity		Row Total
		Axial	Collateral	
Sex distribution	Males	17	22	39
	Females	33	28	61
	Column Total	50	50	100 (n)

Table 2: Distribution of the study subjects as per the Age groups (n = 100)

Table 2		Varicosity		Row Total
		Axial	Collateral	
Age distribution	< 20 yrs.	0	0	0
	20 - 40 yrs.	11	13	24
	40 - 60 yrs.	26	30	56
	> 60 yrs.	13	7	20
	Column Total	50	50	100 (n)

Table 3: Distribution of the Male subjects as per their Occupation (n = 39)

Table 3		Varicosity	
		Axial	Collateral
Occupation of Malesubjects	Farmer	11	7
	Labour	5	12
	Others	1	3
	Column Total	17	22

Table 4: Distribution of the Female subjects as per their Occupation (n = 61)

Table 4		Varicosity	
		Axial	Collateral
Occupation of Female subjects	Housewife	24	21
	Farmer	5	2
	Other	4	5
	Column Total	33	28

Table 5: Distribution of the study subjects as per the development of complications (n = 100)

Table 5		Varicosity		Row Total
		Axial	Collateral	
Complications	Occurred	21	16	37
	Didn't occur	29	34	63
	Column Total	50	50	100 (n)

Table 6: Distribution of the study subjects as per the complications they encountered (n = 37).

Table 6		Varicosity	
		Axial	Collateral
Types of complications	Pain	7	6
	Stiffness	1	0
	Itching	2	2
	Visible Varicosity	11	8
Column Total		21	16

The outcome of treatment following foam sclerotherapy in both axial varicosity and collateral varicosity was similar and comparable. Post procedure, 78% of the patients with axial varicosity and 84% of the patients with collateral varicosity showed significant improvement in symptoms and reduction in visible varicosity. Only 22% of patients having axial varicosity and 16% having collateral varicosity had residual disease, even after the 24th month ultrasound report (Table 7).

Plotting these results in a 2 x 2 contingency table and applying the Chi-square test, the result was 0.5848. The degree of freedom was 1. Hence, the p-value was 0.444439. The value was not significant at $p < 0.05$. This indicated that the null hypothesis could not be rejected, i.e., there was no significant difference in the outcome of treatment of axial and collateral varicosity by foam sclerotherapy.

4. DISCUSSION.

This study aimed to compare the efficacy of foam sclerotherapy in the treatment of axial and collateral varicosities. Also, to correlate between different epidemiological factors affecting the disease process. After analysis of the data using proper statistical tools, graphs, and tables, it was found that varicosity was more common in females (61%) than males (39%). Also, the disease process mainly affects the age group of 40 – 60 years (56%). Occupations that indulge the subjects into prolonged standing as a part of their day-to-day activity, act as a predisposing factor for developing varicosity of the inferior extremity. Thus, we have found that, among the male

subjects, 46% were farmers and 44% were labourers. And among female subjects, 74% were housewives. 37% of the study population had developed postoperative complications, that included pain, stiffness, itching, and residual varicosity. While comparing the effectiveness of treatment by foam, it was seen that both groups had significant improvement in the outcome. 78% of the subjects having axial varicosity and 84% of the subjects having collateral varicosity had achieved complete relief from the symptoms as well as from the varicosity. Only in a few cases, (22% in axial and 16% in collateral) post-operatively the residual varicosity persisted. The Chi-square test result was 0.5848. From this, the p-value obtained was 0.444439, which was statistically not significant at $p < 0.05$. Thus, we have failed to reject the null hypothesis. This implied that the outcome of foam sclerotherapy while treating axial and collateral varicosity, was similar and comparable.

Sclerotherapy refers to the method of varicose veins interventional treatment, where a chemical substance is introduced into the lumen of a vein to cause endothelial necrosis and subsequent fibrosis. Apart from reducing the size of the vein to a small fibrous cord, effective sclerotherapy also eliminates the pathophysiological reflux associated with varicose veins. It can be effective for all types of pathological venous dilatations from major truncal varicose veins to the finest telangiectasis [12]. Foam sclerotherapy has several advantages from liquid form; a smaller quantity of sclerosing agent is to be injected, no dilution with blood and it ensures a homogenous effect along the injected vein, provided the diameter remains reasonable [12].

Table 7: Distribution of the study subjects as per the final outcome after treatment (n= 100)

Table 7		2yrs. following foam sclerotherapy		Row total
		Improved	Not improved	
Varicosity	axial	39	11	50
	Collateral	42	8	50
	Column total	81	19	100 (n)

Of late, there have been many publications on detailed reviews of the outcomes of ultrasound-guided foam sclerotherapy. Rasmussen et al., [10] have done a randomized control trial involving 500 patients with GSV reflux. They were randomized to endovenous laser ablation (980 and 1470 nm, bare fiber), radiofrequency ablation, ultrasound-guided foam sclerotherapy, or surgical stripping using tumescent local anesthesia with light sedation. The patients were examined with duplex imaging before surgery and after 3 days, 1 month, and 1 year. They found out that all the treatments were efficacious. The technical failure rate was highest after foam sclerotherapy, but both radiofrequency ablation and foam were associated with faster recovery and less postoperative pain than endovenous laser ablation and stripping. Cabrera et al. [13] have published a clinical series of 500 legs treated by foam sclerotherapy. There it had been reported that after three or more years 81% of the treated great saphenous trunks remained occluded and 97% of superficial varices had disappeared. This required one session of sclerotherapy in 86% of patients, two in 11%, and three sessions in 3% of patients. No DVT or pulmonary embolism was encountered in this series. Subsequently, several authors have published clinical series based on this technique including Frullini and Cavezzi [9] who reported a series of 453 patients, and Barrett et al. [14] who reported a series of 100 limbs. Cavezzi et al. [15] have subsequently published a detailed analysis of the efficacy of foam sclerotherapy in 194 patients, reporting a good outcome in 93% of patients.

5. CONCLUSION.

From this study, we can conclude that Foam sclerotherapy is equally effective in the treatment of axial as well as collateral varicosity and can be used as an alternative to surgical stripping of veins.

6. LIMITATIONS.

The limitations of this study include a small sample population who were included in this study. The findings of this study cannot be generalized for a larger sample population. Furthermore, the lack of a comparison group also poses a limitation for this study's findings.

7. RECOMMENDATION.

To increase the general safety of foam sclerotherapy injection of very viscous foam in the varicose veins should be considered. Also, the patient should not move, specifically their leg for several minutes, and also should not carry out the Valsalva maneuver.

8. ACKNOWLEDGEMENT.

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9. LIST OF ABBREVIATIONS.

USG- Ultrasonography
 OPD- Outpatient Department
 CDC- Centers of disease control

10. Source of Funding

The study was not funded.

11. Conflict of interest.

The authors report no conflicts of interest in this work.

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