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Comparative Study of Ultrasound Guided Foam Sclerotherapy and Surgical Management for the Treatment of Varicose Veins

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Authors' contributions

This work was carried out in collaboration between all authors. Author PS designed the study and wrote the protocol. Author AM wrote the first draft of the manuscript. Author RR managed the literature search. All authors read and approved the final manuscript.

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Case Study

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ABSTRACT

Objective: Varicose veins of the lower limb are being treated with a number of modalities, mostly by surgical methods. Present study was conducted to compare foam sclerotherapy with surgical treatment of varicose veins.
Materials and Methods: The study was conducted in Deen Dayal Upadhyay Hospital, Delhi on total of 60 patients randomized into two groups of 30 patients each. Both the groups were comparable in terms of preprocedural clinical parameters. After the completion of the study the patients were followed for mean period of more than one year by clinical examination and Doppler study.
Results: The symptomatic and clinical outcomes achieved in both the groups were similar. Foam sclerotherapy was easily administered, well tolerated, safe procedure which was done without risks of anaesthesia and surgery; moreover no hospitalization was needed. Patients returned to their activities the very next day.

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Conclusion: Ultrasound guided foam sclerotherapy was found to be effective and durable method of treatment of varicose veins and the associated complications. As alternative to subfascial endoscopic perforator surgery along with stripping, foam sclerotherapy may lead to fewer skin and wound healing complications. It also results in no loss of daily activities because of hospitalization, a factor of great importance in our patient group.

Keywords: Foam sclerotherapy; polidocanol; varicosity; sclerotherapy.

1. INTRODUCTION

Venous disorders of lower limbs are frequently encountered problem, affecting 10-20% population in the western world and a slightly lower incidence in the developing world. Majority of these disorders are due to the varicose veins of the lower limbs and their associated complications. Women have been reported to be affected slightly more frequently than men [1].

Foam sclerotherapy [2] is a modification of conventional technique of sclerotherapy where bubbles of sclerosant are produced using either air or carbon dioxide and then injected into the affected vein under sonographic guidance. Foam sclerotherapy needs lesser quantity of sclerosant as compared to conventional sclerotherapy and is claimed to be better than conventional sclerotherapy.

2. MATERIALS AND METHODS

This study was conducted by Department of Radiodiagnosis in collaboration with Department of Surgery, Deen Dayal Upadhyay Hospital, Delhi as a randomized controlled trial with a total of 60 patients divided into 2 groups of 30 patients in each group and allocated as follows :

1) Surgical treatment group – Control group
2) Foam Sclerotherapy group – Treatment group

2.1 Inclusion Criteria

Clinically symptomatic patients, males and females in any age group belonging to C.E.A.P Class -2 to 6 (Table 1) have been included in the study.

2.2 Exclusion Criteria

- History of deep vein thrombosis
- C.E.A.P Class – 0 to Class -1
- Severe systemic disease/infection
- Local procedure site infection
- Advanced peripheral arterial occlusive disease stage – 3 and 4
- Pregnancy at first trimester and after 36 weeks.

2.3 C.E.A.P (Clinical. Etiology. Anatomy. Pathophysiology) Classification

The C.E.A.P Classification [3] is a recent scoring system that stratifies venous disease based on clinical presentation, etiology, anatomy and pathophysiology. This classification scheme is useful in helping the physicians coherently and thoughtfully assessing a limb afflicted with venous insufficiency and then arrive at an appropriate treatment plan.

Table 1. C.E.A.P Classification (Class 0 – 6)

Class 0	**No visible or palpable sign of venous disease**
Class 1	Superficial spider veins (reticular veins) only
Class 2	Simple varicose veins only
Class 3	Ankle edema of venous origin
Class 4	Skin changes ascribed to venous disease (e.g pigmentation, venous eczema, lipodermatosclerosis)
Class 5	Healed venous ulcer
Class 6	An open venous ulcer

After C.E.A.P classification attention was focused on the patient's symptoms and a severity score was calculated based on various parameters (Table 2). Once the clinical examination was over, the patient was subjected to Doppler Venous evaluation and assigned to one group for treatment. Finally as part of the clinical examination the patient's ability to carry out their usual activities of day to day life was evaluated and disability score of 0 to 3 was obtained (Table 3).

3. FOAM SCLEROTHERAPY

The patient selected to undergo sclerotherapy was specifically checked for any history suggestive of allergic disorder. Patients were admitted and an informed consent was taken.

Table 2. Severity scoring

Atribute	Absent	Mild	Moderate	Severe
Pain	None	Occasional	Daily	Limit activity
Varicose veins	None	Few, scattered	Multiple (GSV)	Extensive (GSV, SSV)
Venous edema	None	Evening, Ankle	Afternoon, Leg	Morning, Leg
Pigmentation	None	Limited area	Wide (lower one-third)	Wider (above one-third)
Inflammation	None	Cellulitis	Cellulitis	Cellulitis
Induration	None	Focal (<5 cm)	< Lower one-third	Entire lower one-third
Number of active ulcers	0	1	2	3
Duration of active ulcers	None	<3 months	3-12 months	> 1 Year
Size of active ulcers	None	<2 cm	2-6 cm	> 6 cm
Compression	Not used	Intermittent	Most days	Continually

(GSV: Great Saphenous vein, SSV: Short Saphenous vein)

Doppler imaging was done with the patient standing or in the markedly trunk elevated position. This was to ensure the veins are filled, and also to ensure that gravity will return blood through any incompetent vein. Imaging was obtained with a 7.5 MHz linear probe. Both superficial and deep venous system were assessed. Varicose veins were assessed to see how they were being filled. They were usually filled by reverse flow in an incompetent superficial vein but could be filled directly from incompetent perforators. The veins to be sclerosed were marked with skin marking pen (Fig. 1).

The vein was cannulated under Doppler ultrasound guidance (Fig. 2). Depending upon the vein size the suitable amount of polidocanol 3% was taken into a 10 ml syringe and air was taken into another syringe four times the volume of polidocanol (Fig. 3). Both these were connected to 3-way connector. Now by backward and forwards movement of the syringes, foam was prepared (Fig. 4). This procedure turned the liquid into foam that had the consistency of shaving foam. Once ready, the third end of the connector was attached to the venous cannula. The foam was pushed into the vein under ultrasound guidance and directed into the affected veins manually and also using the sonographic probe (Figs. 5, 7). Once the foam was at the junction of the deep and superficial veins, (either behind the knee or in the groin) the probe was used to compress the vein gently. This would stop the foam going into the deep veins. The compression was applied over the entire extremity. Once all this was completed (took approximately 15-20 min), some padding and a bandage was applied to help compress the vein. The foam irritates and causes inflammation to the lining of the vein and in response the vein collapses. A light compression stocking was applied over the top of the bandage. This was an important part of the treatment as the stocking act as clamp to close the vein together whilst the sclerosant is still working. The patients were immediately asked to ambulate. The patients were regularly followed both clinically and with Doppler study for period of one year (Fig. 6).

Table 3. Disability scoring

Score	Definition
0	Asymptomatic
1	Symptomatic, but able to carry out usual activities (patient's activities before the onset of disability due to venous disease) without compressive therapy
2	Able to carry out usual activities only with compression and/or limb elevation
3	Unable to carry out usual activities even with compression and/or limb elevation

4. SURGICAL TREATMENT

The patient enrolled to undergo surgical treatment Subfascial Endoscopic Perforator Surgery (SEPS) with Trendulburg's operation was admitted and requested to sign informed consent. In operating room, the patient was placed supine and a tourniquet was placed above the knee. An Esmarch band was placed tightly around the lower extremity to empty the

blood from the surgical site. An incision of size 1 cm was made 10 cm below the tibial prominence and 5 cm medial to the anterior border of the tibia. The glistening fascia was identified and incised. The subfascial space was made by finger and peanut dissection and a 10 mm trocar was inserted. Carbon dioxide insufflation was started through the trocar, maintaining a pressure of 30 mm Hg to keep the subfascial space expanded. A second incision was made inferior and posterior to the first, allowing insertion of 5 mm trocar. The perforating veins were identified traversing the subfascial space and ligated. The lateral perforators were taken care by incising the intermuscular septum and mobilizing the medial head of the soleus. The incisions were closed in two layers and a pressure dressing was applied before the tourniquet was released.

Then an incision was made over the upper thigh 5 cm below and lateral to the pubic tubercle centered over sapheno-femoral junction and extending laterally. Tissues dissected and the great saphenous vein and its feeding tributaries were identified, ligated and cut. The vein was than stripped above downwards from groin to just below knee. The incision sites were then sutured and compression bandage applied.

Gentle ambulation was encouraged. The dressing was changed after 48 hours and compression was applied. The patient was than discharged with advice to use compression, and alternate days dressing change. If the patient did not notice any difficulty he was instructed to report to the outpatient department 7-10 days after surgery. The sutures were removed at this visit and patient was advised to continue the use of the compression for 6 weeks. The patients were regularly followed both clinically and with Doppler study for period of one year.

5. RESULTS

The mean age group in Surgery group and Foam sclerotherapy group was 38.4 years and 39.7 years respectively. The male: female ratio in both groups was 5:1. 7 patients in the Surgery group and 12 patients in the Foam sclerotherapy group were found to have active ulcers. In both the groups, patients had single ulcer present for a variable duration. Venous ulcer are difficult to treat and there is significant chance that they will reoccur after healing.

The procedure related time was 60-100 min and 15-45 min respectively for the Surgery group and Foam sclerotherapy group (Table 4). 26 patients reported troublesome pain after Surgery requiring analgesia; 21 of them needed it for 2 days only and 5 of them for 5 days. Bruising along the stripped vein was noted in the 7 patients in the Surgery group. Tingling was noted in 5 patients in the Foam sclerotherapy group. No hematoma, deep vein thrombosis and nerve injury (neuralgia) was noted in either of the groups. The mean hospital stay time for the patients was 47 hours and 9 hours respectively in the Surgery group and Foam sclerotherapy group. The patients in the Surgery group were able to resume their work after 7-10 days whereas those in the Foam sclerotherapy group resumed their work the very next day. Ulcer healing rate was faster in the Foam sclerotherapy group as compared to the surgery group. Mean time to ulcer healing in our study was 178 days in the Surgery group and 123 days in the Foam sclerotherapy group. No ulcer recurrence was noted in our study in both the groups till the end of follow-up

One patient in the Surgery group had accessory Great saphenous vein which showed varicosity and pathological reflux. It was managed by foam sclerotherapy at 20 months on patient's request. Recanalization and pathological reflux was noted in 4 patients of Foam sclerotherapy group. All these patients were subjected to a second session of sclerotherapy. Till the time of completion of the study, no new recurrence of the ulcers/ recanalization of the veins were noted. The symptomatic and clinical outcomes achieved in both the groups were similar (Table 5).

6. DISCUSSION

History of foam sclerotherapy dates back to Egmont James Orbach [4] who proposed use of foam in 1944, generated by simple process of shaking a sclerosant solution in a syringe with air. Various techniques of foam preparation have been described since 1944. These range from aspirating (Fluckiger, Gachet and Sigg), stirring (Caberra and Garcia-Olmendo), or pumping (Tessari, Frullini and Grigg) to the use of special devices (Mayer and Brucke) and pressurized systems (Garcia-Mingo) [2]. Foam prepared immediately before injection is now called extemporary foam. Later on interest in sclerotherapy faded until 1993 when Juian Cabrera started using microfoam preparation of sodium tetra decyl sulfate and polidocanol for sclerotherapy. It representated a revolution in

treatment of venous diseases. In 1997, Monfreux described foam produced in a glass syringe. In December 1999, Tessari [5] described a new method for producing a stable and compact foam by means of two plastic syringes and a three-way stop cock. Tessari method is now most popular because of its simplicity, low cost and production of high quality foam.

6.1 Tessari and Double Syringe System (Dss) Technique

This technique was proposed in 1999. Sclerosing foam is generated with two disposable plastic syringes. One syringe contains the liquid sclerosing solution, and other contains air. The outlets of syringes are connected with a three-way-tap or two-way-connector. Pumping the contents of both the syringes backwards and forwards (approximately 20 times for the original Tessari technique, also known as Tourbillion technique) or 5 times with additional pressure and 7 times without additional pressure for the DSS technique. The liquid to air ratio varies from 1:4 (one plus three) to 1:5 (one plus four) for the original Tessari technique. The DSS version is defined for 3% polidocanol solution, two latex free 10 ml syringes (one with rubber plunger) and a fixed liquid to air ratio of 1:5. Tessari technique gives small bubbled foam, which is rather fluid if low concentration or viscous if high concentration of sclerosant is used. The DSS procedure gives small bubbled viscous foam.

The patients in our study were more males (M:F = 5:1), which is in sharp contrast to the ratio mentioned in most of the western literature, where more females were suffering from this disease [6-8]. 25 patients in the surgery group (83% approx.) and 26 patients in the foam sclerotherapy group (84% approx.) were younger than 50 years; in comparison to most of the patients in western world in their late 50s and early 60s [7,8]. This might well be accounted for by the fact that most of the patients suffering from the disease in our study group belonged to low socio-economic status; they were forced into work to earn their livelihood early in their life. As more males are involved in heavy labor, the fact may explain predominantly younger and male patients suffering from the disease.

Complications immediately after the surgery and at first follow up were minor and in accordance to the one's reported in the literature. 26 patients reported troublesome pain after surgery requiring analgesia; 21 of them needed it for 2 days only and 5 of them for 5 days. 7 patients had bruising along the stripped vein. No other complication was noted after the surgery. At first follow up complication rate of 3-10% was noted, similar to those reported in the published series [6,9,10]. In our study complications in the foam Sclerotherapy Group were tolerable and transient like discomfort in walking, tenderness etc and did not require any active intervention, which are again comparable to the published series [2,11].

Table 4. Comparison of foam sclerotherapy (FS) treatment with subfascial endoscopic perforator surgery (SEPS) treatment

	SEPS	FS
Active ulcers	7	12
Procedure time	60-100 min	15-45 min
Troublesome pain requiring analgesia after procedure	26 pts	0
Bruising along stripped vein	7 pts	0
Tingling	0	5 pts
Mean hospital stay time	47 hrs	9 hrs
Mean time to ulcer healing	178 days	123 days
Time to resume work after procedure	7-10 days	Next day
Recanalization requiring second session of procedure	0	4 pts
Hematoma / Deep venous thrombosis / Nerve injury	0	0
Ulcer recurrence at I year follow up	0	0

Table 5. Comparison of venous severity scoring before and after foam sclerotherapy (FS) and subfascial endoscopic perforator surgery (SEPS) treatment

Venous severity score	SEPS		FS	
	Pretreatment	Posttreatment	Pretreatment	Posttreatment
Total	242	40	263	41
Mean	8.67	1.33	8.77	1.67
Percentage change	84% decrease		81% decrease	

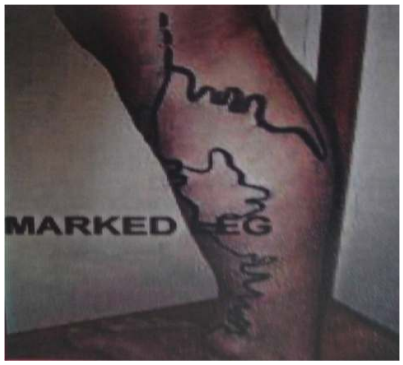

Fig. 1. Image showing skin marking for varicose veins

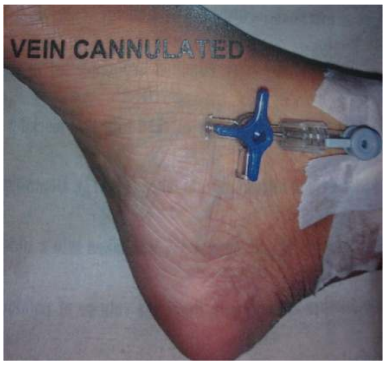

Fig. 2. Image showing cannulated vein for foam sclerotherapy

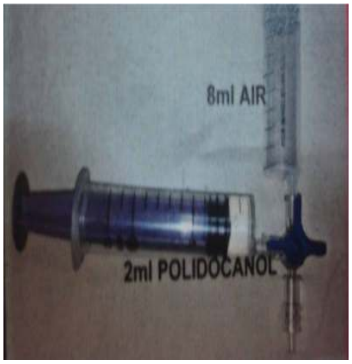

Fig. 3. Image showing three way connection between 2 ml polidocanol and 8 ml air before foam preparation

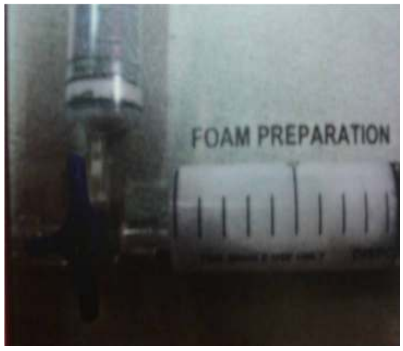

Fig. 4. Image showing shaving foam like consistency of foam sclerosant after mixing of polidocanol with air

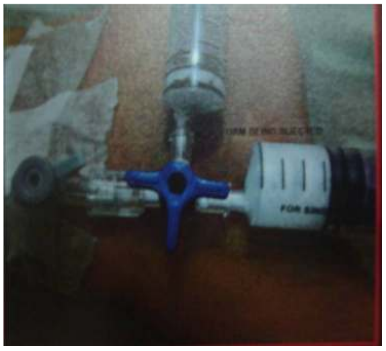

Fig. 5. Image showing injection of foam sclerosant

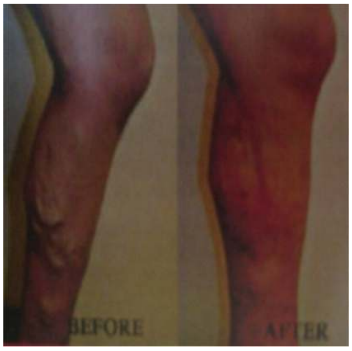

Fig. 6. Image showing site of varicose vein before and after treatment with foam sclerotherapy

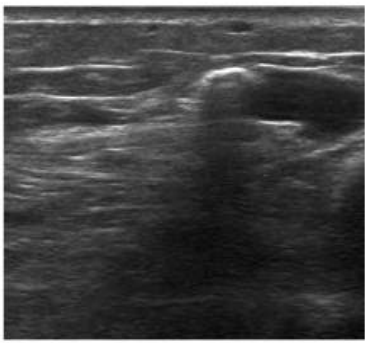

Fig. 7. Image showing echogenic foam sclerosant within great saphenous vein

29 of our patients in the Surgery group were able to resume their work after 10 days. All patients resumed work next day in the Foam Sclerotherapy group. Ulcer healing rate was faster in the Foam sclerotherapy group as compared to the surgery group. No ulcer recurrence was noted in our study in both the groups till the end of follow-up. 4 patients (13.3%) in the Foam Sclerotherapy group needed second session of sclerotherapy for pathological reflux between 7-15 months follow up.

There are few limitations in our study. First of all, only 60 patients have been enrolled for the study. Secondly, these patients have been followed only for short period. Lastly, many new treatment methods are available now like radiofrequency ablation and Laser treatment of varicose veins. In our study, foam sclerotherapy has only been compared with surgical treatment of varicose vein.

7. CONCLUSION

Foam sclerotherapy has come up as safe and reliable method of the treatment of the varicose veins [12,13,14]. This does not require any other set up to be established, except for a Doppler, as the facility of the Duplex ultrasound is available in all the major hospitals. The cost of the treatment is also very economical and can be done in an outpatient without any anesthesia.

Foam sclerotherapy appears to be promising, safe and cost effective alternative approach to venous ulcer. The therapy was highly satisfying to the patients in terms of its ease of administration, no hospital stay, no risk of anaesthesia, low cost, no interference of daily activity, immediate return to work, and outcomes very similar to those after surgery. The main drawback that may be put against this form of therapy is the need to undertake multiple sessions of therapy in few selected patients.

In summary, Foam sclerotherapy of superficial and perforating veins is a well tolerated and effective outpatient procedure. Major advantage include a great increase in action of the sclerosant agents in this novel pharmaceutical form, selective effect on endothelium, visibility on ultrasound examination, predictability of outcome, high success rate and low frequency of recurrence.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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