

Outcome Following Ultrasound Guided Foam Sclerotherapy Treatment for Varicose Veins in a Tertiary Care Centre

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DOI: <http://dx.doi.org/10.21276/ijcmsr.2018.3.4.19>

How to cite this article: Mayurika Singh, Anish Kola, Ila Katyayan, Soumitra Manwatkar. Outcome following ultrasound guided foam sclerotherapy treatment for varicose veins in a tertiary care centre. International Journal of Contemporary Medicine Surgery and Radiology. 2018;3(4):C82-C86.

A B S T R A C T

Introduction: Patients with varicose veins may present with dilated, elongated and tortuous superficial veins of the limbs with complaints of dull aching pain, heaviness, discomfort, and extremity fatigue. Patients with symptoms have difficulty in daily activities such as work, recreation. Such patients are subjected to sclerotherapy injection by ultrasound guided which is minimally invasive technique that allows patients to rapidly return to their baseline activity level. Objective: To evaluate the outcomes of the foam sclerotherapy (UGFS) treatment under ultrasound guidance for varicose vein.

Material and Methods: patients with varicose veins were selected and treated with sodium tetradecyl sulphate as sclerosant and followed up to 1-year. Total 185 legs in 148 patients, 111 unilateral limbs, and 74 bilateral limbs were treated by this method.

Results: Out of 185 legs saphenofemoral junction (SFJ) incompetence was found in 57 and sapheno-popliteal junction (SPJ) incompetence in 41, perforator's incompetence in 21, while combination of SFJ and perforators and SPJ and perforators in 19 and 14, respectively. Great saphenous vein varicosity was found in 87, short saphenous vein in 54 and others 44. Early outcome was 100% success rate. No recurrences were noted at 1-year follow-up. Early complications were: Superficial skin necrosis in 7 legs (3.78%), pain at injection sites in 27 legs (14.59%), superficial thrombophlebitis in injected vein in 23 legs (12.43%), and skin staining around injected veins in 16 legs (8.64%).

Conclusion: UGFS is a safe, comparatively easy, and beneficial for the patients with varicose veins and found to be associated with less complications like skin staining and pain.

Key words: Foam Sclerotherapy, Ultrasound Guided Foam Sclerotherapy Outcome, Ultrasound Guided Sclerotherapy, Varicose Veins

INTRODUCTION

UGS was described in 1989 as a treatment for the superficial axial system. Since then, the use of UGS has expanded to treatment of incompetent perforator branches and large venous tributaries. Sclerosants act to disrupt the venous endothelium, causing a periphlebitic reaction, which acts to obliterate the vein segment. Sclerosants mainly causes endothelial damage which reveals sub-endothelial collagen fibres and the intrinsic coagulation pathways are activated and cause inflammatory reactions that occur at the vessel wall and thrombus formation and maturation in the vessel lumen which results in fibrosis, and obliteration of the vessels.¹⁻⁵ various sclerosing agents include 3% sodium tetra decyl sulphate, ethoxy scleral, 5%ethanolamine oleate. The blood deactivates the action of the sclerosing agent, dose to adjusted to avoid adverse effects, which led to the development of UGFS (Ultrasound Guided Foam Sclerotherapy)

Foams have several benefits over liquid sclerosants, like

a large dose of foam can be used in a single session, have large surface area leading to greatest efficacy, displaces blood and prevents dilution, and inactivation of the sclerosants. Foams are visible on duplex ultrasound, and it is possible to manipulate the foam once it has been injected into the vessels.

The aim of the study was to compare the outcome of UGFS (minimally-invasive) over the surgical procedure with regards to complications following treatment in patients with varicose vein of the lower limb.

MATERIAL AND METHODS

The study was carried out in Swaroop Rani Nehru Hospital attached to M.L.N.Medical College Allahabad, after taking approval from the ethical committee and obtaining written and informed consents from the patients, between June 2017 and July 2018. The patients details were recorded for the new modality of treatment procedure. Every patient referred with

varicosity of the lower limb (varicose vein) were explained different modalities of treatments available at the hospital. The treatment modalities available were sclerotherapy and invasive surgical methods in the hospital. Other modern minimally invasive methods were not available in our hospital. After a full discussion of the available options to the patients and based on their requirements, ultrasound guided foam sclerotherapy (UGFS) seems to be selected by most of the patients, particularly those with strong cosmetic concern and army personnel. Patients included in the study were those having great saphenous vein (GSV), small saphenous vein (SSV), other recurrent veins with significant incompetent deep venous communication [Fig-1].

Clinical assessment

The full history and clinical examination of the patient was done who were undergoing UGFS treatment including palpation of peripheral pulses. Patients with, having deep vein thrombosis (DVT), deep venous insufficiency and A-V malformations, were excluded.

Initial duplex ultrasound assessment

All patients with varicosity were initially subjected to duplex ultrasonography to examine superficial venous system and deep venous system in both standing and sitting position on the table. In standing position with their weight on the contra-lateral limb and the leg to be examined was kept slightly bent with the heel on the floor to relax the calf muscles. The veins and the venous segments were assessed were: the entire venous system of lower limb from the SF junction and sapheno-popliteal junction (SPJ), the whole length of the GSV, SSV, and competency of perforators were assessed. The diameter and reflux were assessed and were considered pathological when it exceeded 0.5 s.

Procedure

Cannulation and injection

Before initiating the treatment, in the standing posture veins were marked then cannulated under ultrasound guidance, depending on the size, depth, and tortuosity of the veins. For GSV, cannulation was done just below or above the level of

knee joint. For Other veins distal most accessible sites were used. The skin sensitivity of sclerosant was done before the use of drug.

Foam was made by connecting two 5 ml syringe to a tri-way and using 1 ml of sclerosant with 4 ml of air [Fig.2], leg was elevated about 45° and foam was introduced under ultrasound guidance in to the vein, where lower limb was elevated 40-50 degree angle. Maximum of 2 ml foam was injected per cannula. To increase the venous flow of the lower limb the patient was asked to plantar and dorsiflex the ankle. A maximum 15- 20 ml foam was used in a single session.

Bandaging and compression

After completing the foam injection, all cannulas were removed and crepe (elastic) bandage was applied to the limb [Fig. 4]. Too much pressure was avoided to prevent any vascular compromise to leg, after 3-5 days the compression bandage was removed and looked for any residual varicosities and complications. Patient was advised stocking or compression bandage while walking running and was advised limb elevation in night.

Follow-up

All patients were followed-up on a regular basis until one year. During follow up the complete examination was done and reviewed in the symptoms and varicosities any complications and any signs of DVT. Benefits of the treatment was assessed on the basis of improvement in signs and symptoms.

DATA ANALYSIS AND RESULTS

Total 185 legs in 148 patients (101 males and 47 females), 111 unilateral limbs, and 37 bilateral limbs were treated by this method for different types of lower limb varicosities [Table 1]. Out of 148 legs SFJ incompetence was found in 57 and SPJ incompetence in 41, perforator's incompetence in 27, while combination of SFJ and perforators and SPJ and perforators in 19 and 14 respectively [Table 2]. GSV varicosity was found in 87, short saphenous vein in 54 and others 44. 43 limbs had recurrent varicose veins previously treated by other modalities, and 142 limbs had primary

| Variables | Total no. patients | Male | Female | Total limbs | Bilateral limbs | Unilateral limbs |
|-----------|--------------------|------|--------|-------------|-----------------|------------------|
| Number | 148 | 106 | 42 | 185 | 37 | 111 |

Table-1: Patient demographics

| Incompetence | SFJ | SPJ | Perforator's | SFJ and perforator's | SPJ and perforator's | No |
|--------------|-----|-----|--------------|----------------------|----------------------|----|
| Number | 57 | 41 | 21 | 19 | 14 | 33 |

Table-2: Duplex findings

| Varicosities | GSV | SSV | Others | Primary | Recurrent | Uncomplicated | Complicated |
|--------------|-----|-----|--------|---------|-----------|---------------|-------------|
| Numbers | 87 | 54 | 44 | 142 | 43 | 120 | 65 |

GSV: Great saphenous vein; SSV: Small saphenous vein

Table-3: Location of varicosities

| Complications | Superficial skin necrosis | Pain at injection sites | Bruising | DVT | SVT | Superficial thrombophlebitis | Skin staining |
|---------------|---------------------------|-------------------------|-----------|-----|----------|------------------------------|---------------|
| Numbers(%) | 7(3.78%) | 27(14.59%) | 14(7.56%) | 0 | 9(4.86%) | 23(12.43%) | 16(8.64%) |

Table-4: Complications



Figure-1: Varicosity of great saphenous vein



Figure-4: Bandaging



Figure-2: Technique of foam preparation using two syringes and one triway

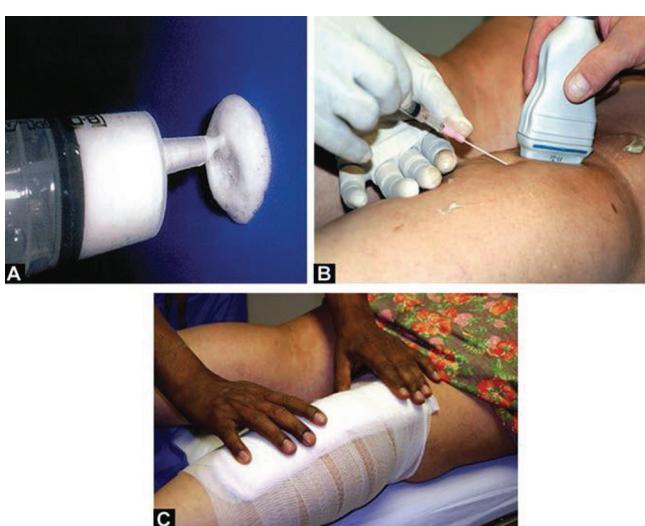


Figure-3: Procedures in foam sclerotherapy

varicose veins. 65 were treated for complicated varicose veins and 120 limbs for uncomplicated varicose veins Table 3. On first follow-up visit after 3–5 days, all varicosities treated with this method had disappeared. Early outcome was 100%.

Early complications were: Superficial skin necrosis in 7 legs at one or two injection sites (3.78%). Pain at injection sites in 27 legs (14.59%), superficial thrombophlebitis in injected vein in 23 of the 185 legs (12.43%), bruising was noted in 14 legs (7.56%), and skin staining around injected veins were found in 16 legs (8.64%). Only 9 of the 185 legs developed superficial vein thrombosis (4.86%), which was treated with NSAIDS, rest, limb elevation and stockings Table 4. For all these complications, no treatment was required, and they disappeared without any specific treatment. At the end of 6 months and 1-year, no complications and recurrences were found.

DISCUSSION

When results of the study was compared with other conventional methods such as saphenous vein stripping, UGFS is found to be associated with lesser pain, very much-tolerable and safe, and no DVT, or any allergic reaction, infection, headache, and blurring of vision. Bruising was noted in 14 legs (7.56%) in this study which was less than other methods like saphenous vein stripping (SVS). The incidence of bruising with SVS was found to be 25–30% reported in different other studies.^{6,7} With UGFS treatment bruising and pigmentation was found to be 26– 30% in various studies^{8,9,12}. After RFA, it is about 13–27%^{7,13} and after EVLA, it is 11–15%.^{14,15}

According to Kalodiki et al.¹⁶ and Shadid et al.¹⁷ surgery is associated with the lesser incidence of pigmentation (5% and 1.1% respectively) in comparison to UGFS (15% and 5.6%, respectively). Improvements in symptoms and quality of life were 100% in our study which was found to be similar to other studies.¹⁸ In terms of expectations, one study shows that exceeded in 25% while unmet in 10%.¹⁹

Recurrences associated with UGFS treatment varies from 4.9% to 40%^{8,20–23} but there were no recurrences seen in our study. Treatment failures associated with UGFS treatment was 2%⁸ and 57%,¹² but there were no failure in our study conducted in SRN Hospital. Anaphylaxis is an established complication of liquid sclerotherapy, but can occur with foam also. No cases of anaphylaxis was recorded in our study like

other studies.⁹ Bradbury et al.³ reported allergy to the foam in 0.1% of patients in their study.

DVT and thromboembolism after UGFS is a very rare complication and reported in <1% of the patients.^{3,8,9,27,28} No incidence of DVT was noted in this study and also according to Brunken et al.¹⁰ and Hamahata et al.,²⁴ Figueiredo et al.¹² reported the occurrence of DVT in 9% of their patients. Later on it was found that using foam volume more than 10 ml in single limb resulted in 3-fold chances of DVT²⁵ and increased production of endothelin-1 is associated with high chances of DVT.³¹ Scurr et al.,²⁶ Brzoza et al.,³⁰ and Guex et al.,²⁹ each of them reported single case of allergic reactions in their studies.

After this study, Breu et al.³² and Hamel-Desnos et al.³³ uses maximum 10 ml of foam without any incident of DVT. Superficial thrombophlebitis incidence reported in different studies was found to be <15%.^{8,10}

Different maneuvers have been described to improve the efficacy and safety of foam sclerotherapy by decreasing the amount of foam entering into the deep venous system and systemic circulation, like leg elevation before foam injection, blocking of SFJ and SPJ before injection.³⁴ One study shows 39% incidence.³⁵ In our study, it's incidence was about 12.43%. Other systemic complications associated with UGFS were photopsia, transient blurring of vision, transient ischemic attack, headache, chest tightness, and dry cough has been reported in <1% of the patients.^{3,8,9} No such complications noted in our study.

The drawback of the study was that there is no comparison and randomization between two groups. Only surgeons in our unit of general surgery of swaroop rani nehru hospital used UGFS as preferred treatment while others unit surgeons used conventional methods of treatment such as SVS, SFJ ligation, SPJ ligation, and perforator ligation. All patients in this study were referred from surgeons of our hospital through a common referral pool. Therefore, there was some clinical or surgeon selection bias.

Another limitation of our study was the size of UGFS cohorts, although this was unlikely to have resulted in any systematic bias. Assessment of complications and outcomes were objective and decided by the therapist. The observer bias could have been improved by subjective assessment of complications and outcome in the follow up, by using a validated questionnaire method and scoring system.

CONCLUSION

In comparison to the conventional invasive method UGFS seems to be associated with less complications and decrease recurrences with good cosmetic out come and cost effective and also safe to the patient. UGFS can be used in all varicosity of the lower limb including the perforators.

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Source of Support: Nil; **Conflict of Interest:** None

Submitted: 20-09-2018; **Accepted:** 29-10-2018; **Published online:** 02-12-2018