Original Research Paper

Volume - 12 | Issue - 11 | November - 2022 | PRINT ISSN No. 2249 - 555X | DOI : 10.36106/ijar

Radiology

OUTCOME OF ULTRASOUND GUIDED FOAM SCLEROTHERAPY IN THE TREATMENT OF VARICOSE VEINS

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ABSTRACT Varicose veins are one associated aspect of evolution that humans could have happily lived without. It's almost certainly the price we pay for the two-legged erect posture. Though we have achieved cure for various diseases, till now no reliable cure has been found for venous insufficiency.The gold standard for treating chronic venous insufficiency has been surgery. The surgeon dealing with varicose veins has always had to strike a balance between an aesthetically pleasing outcome and a low rate of recurrence and complications. Sclerotherapy, which was first used over 150 years ago, is still the most efficient method for permanently removing pathologically swollen as well as cosmetically unpleasant but otherwise normal veins.Foam sclerotherapy, in which the sclerosant is mixed with air or physiological gases, is more effective than direct injection of sclerosants, because the agent's contact with the endothelium is prolonged by the air in the foam. The use of foam sclerotherapy for big veins has reduced recurrence rates. Large-scale researches have demonstrated the safety of foam sclerotherapy. Foam sclerotherapy has a recurrence rate that is comparable to surgery. The efficacy of foam sclerotherapy has been variable as per different studies across different institutions.

KEYWORDS : Varicose veins, Foam sclerotherapy, Sclerosant, VCSS

INTRODUCTION

Varicose veins are one associated aspect of evolution that humans could have happily lived without. It's almost certainly the price we pay for the two-legged erect posture. Delicate valves that evolved through thousands of years of ambulation on four legs are unable to bear the increased gravitational pressure in two-legged upright posture. In the text, varicose veins are described by the author as "torturous and solid, with many knots, as if blown up by air" but also recommended that they be left alone and not treated. Though we have achieved cure for various diseases, till now no reliable cure has been found for venous insufficiency.

The gold standard for treating chronic venous insufficiency has been surgery. The surgeon dealing with varicose veins has always had to strike a balance between an aesthetically pleasing outcome and a low rate of recurrence and complications. The treatment of superficial venous reflux and varicose veins is fast developing due to an increase in well-informed patients who pressurize the treating surgeon for cosmetically acceptable results, as well as the proliferation of minimally invasive procedures.

Sclerotherapy is the injection of a chemical irritant into the vein to create chemical thrombophlebitis. American physician H. I. Biegeleisen (1) coined the terminology in the 1940s. Sclerotherapy, which was first used over 150 years ago (2), is still the most efficient method for permanently removing pathologically swollen as well as cosmetically unpleasant but otherwise normal veins.

Foam sclerotherapy, in which the sclerosant is mixed with air or physiological gases, is more effective than direct injection of sclerosants (3), because the agent's contact with the endothelium is prolonged by the air in the foam. As a result, maximum sclerosant effect can be achieved with lower concentrations and quantities. The action of the foamed substance is felt in the microcirculation, which is inaccessible to other methods.

The use of foam sclerotherapy for big veins has reduced recurrence rates (1). Large-scale researches have demonstrated the safety of foam sclerotherapy. Foam sclerotherapy has a recurrence rate that is comparable to surgery. The efficacy of foam sclerotherapy has been variable as per different studies across different institutions. So, we decided to conduct a study on Ultrasound (USG) Guided Foam Sclerotherapy of varicose veins in the lower limbs, its efficacy, and complications at our institution.

Our endpoints included patient satisfaction and objective evaluation of the outcome of the procedure.

AIMS AND OBJECTIVES:

1. To evaluate patients of varicose veins by Doppler USG.
2. To assess the outcome and effectiveness of USG Guided Foam Sclerotherapy with measures including
   - technical success
   - clinical status
   - patient satisfaction
3. To report major and minor complications following USG Guided Foam Sclerotherapy.

Subjects and Methods:

Patients: Prospective study was conducted in 31 patients with varicose veins at Gauhati Medical College and Hospital, Guwahati. Diagnosis of varicose veins was made on the basis of clinical history and duplex USG. Stable patients were selected between the age groups of 18 to 65 years of both genders having varicose veins without deep venous thrombosis or having large varicosities re requiring multiple sessions of foam sclerotherapy and who would rather benefit from one session of surgery.

USG Guided Foam Sclerotherapy: Patient should be recumbent during the procedure (4), for comfort and to promote venous emptying. The skin where the injection is to be given is wiped with surgical spirit to remove oil, dirt and then with betadine for antisepsis. Butterfly cannula, of size according to the venous diameter, was the inserted under USG guidance. Once the cannula was secured with micropore, the leg was elevated (to empty the veins) for injection of the foam. Correct placement of the cannula within the vein can be directly visualized by USG. It can also be seen by the non-pulsating venous blood back flushing into the cannula. All cannulae were then flushed with normal saline to ensure that they were not dislodged during the changes in leg. Foaming is done by 'Tessari' method, in which a 5 ml syringe is filled with room air, another syringe is filled with 1 ml of the diluted sclerosant (sodium tetradecyl sulphate)(5) and the two syringes are connected to a 3 way stop cock.(6) Foaming is done by to and fro movement of both the syringes. Concentration of the sclerosant was calculated according to the diameter of the varicose veins.With the limb in elevated position, the veins are emptied and the diameter is decreased. Foam is then injected, 2ml at a time, and its distribution and resultant venous spasm observed by DUS. At least 30 seconds was left between injecting each portion of foam. After each injection patients

were asked to dorsi- and plantar-flex their ankle several times to clear any foam that might have entered the deep venous system. When all the trunk and tributary veins and the varices were in spasm, and filled with foam, the cannulae were removed and compression was applied with the leg still elevated using elasto-crepe bandage. The bandaging was left intact for five to ten days, depending on the size of the veins, after which it was removed and the class II stocking worn alone for a further three weeks. After the procedure patients were required to walk for around 10 minutes and then it was suggested that they walk for at least five minutes during every waking hour while the bandages were in situ. Patients were immediately assessed with USG for any inadvertent passage of foam into the deep veins. They are then observed for about half an hour for any immediate post procedure complications.

Data Analysis: Technical outcome was assessed according to the criteria recommended by 2nd European Consensus Meeting on Foam Sclerotherapy(7) and comprises of Full Success in whichDuplex ultrasound shows no saphenous reflux, no visible varices or incompressibility of the treated vein segment, Partial Success- Duplex ultrasound shows saphenous reflux <1 s, smaller visible varices or partial incompressibility and partial occlusion of the treated vein segment and diameter reduction, No Success-Duplex ultrasound shows saphenous reflux >1 s and unchanged or worsened varices.In addition to these, another category was added, namely Recanalization, defined as the presence of flow in either an antegrade or retrograde direction in a previously occluded vein.(8)

Clinical outcome was assessed in terms of change in Venous Clinical Severity Score(VCSS) (9) from the baseline at the end of study period, i.e., at 12 months. Follow up was done at 7 days for assessing the fibrosis of the vessels, reduction in diameter of the lumen and local or systemic complications (if any). Procedure was repeated at an interval of 2 weeks depending upon the response which was judged on the basis of USG. DUS was repeated at the end of 1st, 6th and 12th months. In case it was seen that there was absence of the expected response on USG, patients were offered a further session of sclerotherapy. At the end of 12 months, the revised VCSS was again assessed. We assessed patient satisfaction on the basis of the clinical outcome, absence of complications and return to daily activities following procedure.

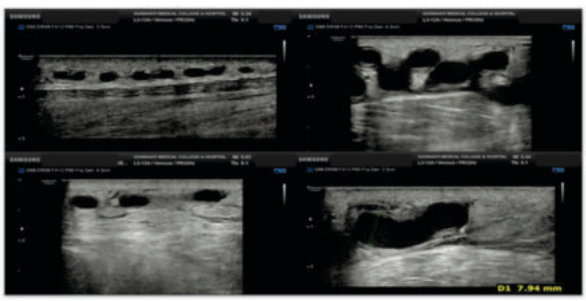


Figure 1: Few cases of varicose veins

Fig 2: Venous puncture: Needle is inserted under USG guidance.

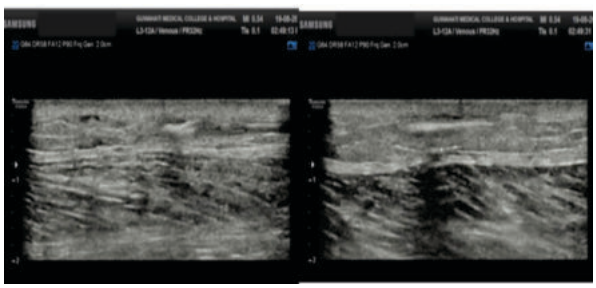


Fig 3: Progression of foam in the vein

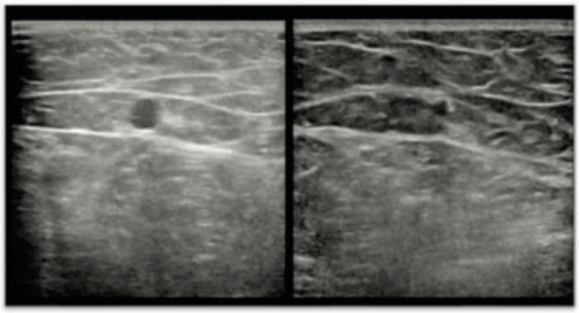


Fig 3: Vasospam following foam injection

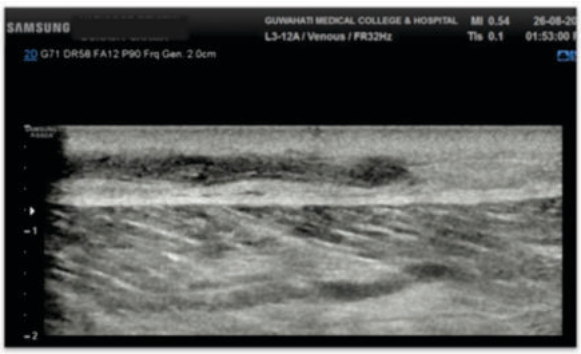


Fig 4: Follow up at 1 month showing sclerothombus formation.

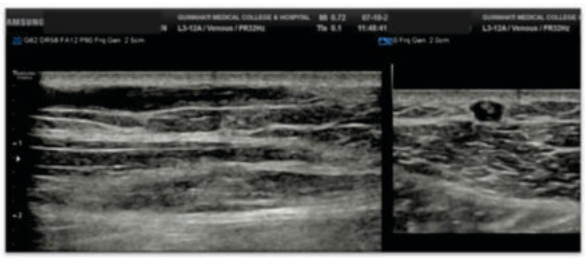


Fig 5: Partial obliteration of vein at 6 months.

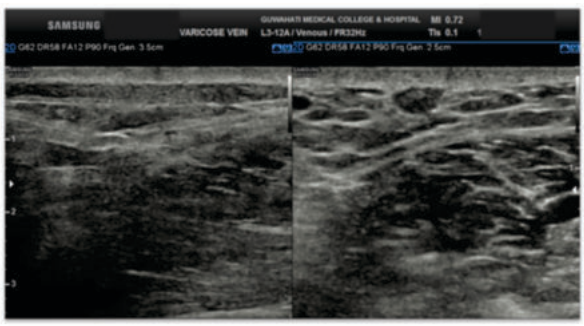


Fig 6: Complete obliteration of vein at 12 months.

RESULTS:

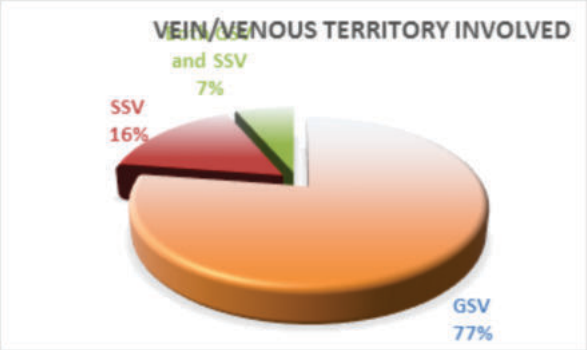
Patient data was collected. Of the total 31 of cases included in the study, the age of the patients ranged from 21 to 62 years. The majority of the patients were in the age group of 41-45 years (25.8 %) and majority were males (58.07 %). It was seen that housewives (25.8 %) and farmers (22.6 %) constituted the majority of our study cases.

Table1. Distribution of patients according to presenting symptoms.

Symptom	No. of limbs	Percentage
Pain	25	80.64
Heaviness	23	74.19
Swelling	8	25.8
Varicose vein	25	80.64
Ulcer	3	9.68
Itching	7	22.59
Dermatitis	3	9.68

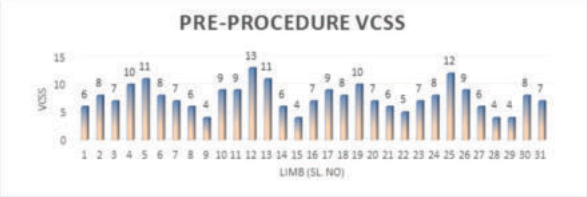
Pain (80.6 %), heaviness (23%) and swelling (8%) were the major presenting symptoms of the patients in our study.

Table2. Distribution Of Cases According To Vein/venous Territory Involved



There was more involvement of the great saphenous vein territory in our study comprising 77% of the cases while small saphenous vein territory comprised of only 16% of cases. In 7 % cases there were involvement of both GSV and SSV territory.

Table3. Bar diagram showing VCSS in patients before commencement of treatment.



The minimum VCSS in our study at baseline was 4 and the maximum VCSS was 13. The mean pre procedure VCSS was 7.61 with a standard deviation of 2.30.

Table 4. Pre-procedure Vein Diameter

Vein diameter in mm	No. of patients	Percentage
4 to 6	12	38.7
6 to 8	13	41.93
8 to 10	3	9.68
10 to 12	3	9.68
Total	31	100

In our study, the mean pre procedure diameter of the treated varicose veins was 6.85 mm with a standard deviation of 1.98. The minimum diameter was 4.5 mm while the maximum diameter was 12 mm.

Table 5: Complication Following Procedure

Complication	No. of cases	Percentage
Bruising	13	41.9
Pain	14	45.1
Pigmentation	5	16.1
Thrombophlebitis	11	35.4
Transient scotoma	1	3.2
Pulmonary Embolism	0	0
DVT	0	0

The major post procedure complications in our study were brushing and pain in 13 and 14 cases respectively. There was thrombophlebitis in 11 cases and pigmentation in 5 cases. One cases had transient scotoma. There was no incidence of pulmonary embolism or DVT in our study.

Table 6: Technical Outcome

Time of follow up	Full success	Partial success	No success	Recanalization
1 month	21	7	3	0
6 month	26	4	1	0
9-12 month	28	0	0	3

Full success was registered in 21 cases at the end of 1 month which increased to 26 and 28 cases at the end of 6 and 12 months respectively. There were 7 cases with partial success at the end of 1 month which decreased to 4 cases at 6 months and zero cases at 12 months. The no of cases with no success was 3 in the first month which decreased to 1 case at 6 months and zero cases at 12 months. There were 3 previously successful cases, which showed recanalization at 12 months.

Table 7: Time To Return To Work

Time to return to work	No of patients	Percentage
24-48hrs	19	61.29 %
48-72 hrs	10	32.25%
>72 hrs	2	6.45 %

We found in our study that 61.29% patients could return to their daily activities within 1-2 days. 32.2 % could return within 2-3 days and 6.4% patients needed more than 72 hours.

Table8: Comparison Of Vcss Pre And Post 12 Months Of Procedure

Parameters	Pre-Procedure VCSS	Post-Procedure VCSS (at 12 months)
Mean	7.61290323	2.0323
SD	2.3096	1.663

Using the above data of mean and standard deviation, Paired 't' test was performed. P value was found to be < 0.001. P value <0.05 is statistically significant and indicates that null hypothesis formed initially was wrong.

Hence, we can concluded that USG guided foam sclerotherapy is an effective treatment modality for treatment of lower limb varicose veins as per data of present study.

DISCUSSION

In the study it was found that the group the youngest case was 25yrs old while the eldest was 61 yrs. old with a mean of 42.9 years with a standard deviation of 9.3 years. Maximum patients were of the age group 41-45 years. 58.07 % of cases which presented to us with varicose veins were male while 41.9% were female.

Almost all of the patients have jobs requiring prolonged standing. Pain, heaviness and swelling were the major presenting symptoms of the patients in our study. There was more involvement of the great saphenous vein territory in our study comprising 77% of the cases while small saphenous vein territory comprised of only 16% of cases. In 7 % cases there were involvement of both GSV and SSV territory.

The diameters of the target veins were recorded before procedure. The mean pre procedure diameter of the treated varicose veins was 6.85 mm with a standard deviation of 1.98. The minimum diameter was 4.5 mm while the maximum diameter was 12 mm. In our study, 21 cases needed only one session of sclerotherapy, 7 cases needed a further second session and 3 cases needed a third session of sclerotherapy.

The major post procedure complications in our study were bruising and pain in 13 and 14 cases respectively. There was thrombophlebitis in 11 cases and pigmentation in 5 cases. One cases had transient scotoma. There was no incidence of pulmonary embolism or DVT in our study. There was no incidence of death in our study.

Full success was registered in 21 out of 31 cases at the end of 1 month which increased to 26 and 28 cases at the end of 6 and 12 months respectively. There were 7 cases with partial success at the end of 1 month which decreased to 4 cases at 6 months and zero cases at 12 months. The no of cases with no success was 3 in the first month which decreased to 1 case at 6 months and zero cases at 12 months. There were 3 previously successful cases, which showed recanalization at 12 months. These 3 cases were offered another session of sclerotherapy which will be followed up later.

Foam sclerotherapy is done as an out-patient procedure, involving half to 1 hour of observation after the procedure with no hospital admission. We found in our study that 61.29% patients could return to their daily activities within 1-2 days. 32.2 % could return within 2-3 days and 6.4% patients needed more than 72 hours. The severity of the disease and clinical improvement was assessed with the Venous Clinical Severity Score. The minimum VCSS in our study at baseline was 4 and the maximum VCSS was 13. The mean pre procedure VCSS was 7.61 with a standard deviation of 2.30. The mean VCSS decreased to 2.03 at the end of 12 months. This decrease was found to be statistically significant.

CONCLUSION

This study addressed the outcome of UGFS in the treatment of varicose

veins of lower limbs. As seen in our study and in numerous similar other studies around the world, foam sclerotherapy has proven to be a safe and effective treatment for varicose veins. This is a very easy and short procedure and does not need a big setup except from a USG machine and because duplex ultrasonography is accessible in all large hospitals, the cost of the therapy becomes relatively affordable. UGFS can be performed as an outpatient procedure under local anaesthetic, which saves a lot of money and time in the hospital. In terms of immediate post-procedure complications, improvements in severity scores, recurrence and overall clinical and radiological results, all of the therapy's outcomes are equivalent to other modalities of treatment, specifically surgical care.

The patients were quite pleased with the therapy because of its simplicity of administration, lack of hospitalisation, lack of anaesthetic risk, low cost, lack of interruption with daily activities, prompt return to work, and outcomes that were remarkably comparable to those following surgery. The procedure was well tolerated both locally and systemically, with no serious problems and a high level of patient acceptance. However, it must be stressed that a greater number of patients must be studied with a longer follow-up period before a clear conclusion and view can be reached that this type of therapy may be the gold standard treatment in the future.

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