International Surgery Journal
Madhu BS et al. Int Surg J. 2017 Feb;4(2):751-756
http://www.ijsurgery.com
pISSN 2349-3305 | eISSN 2349-2902

DOI: http://dx.doi.org/10.18203/2349-2902.isj20170227

Original Research Article

Efficacy and safety of ultrasound guided foam sclerotherapy with sodium tetradecyl sulphate for residual and minor varicosities

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Received: 03 December 2016
Accepted: 31 December 2016

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ABSTRACT

Background: Ultrasound-guided foam sclerotherapy (UGFS) is becoming an accepted standard of treatment varicose veins. It is a relatively safe, effective inexpensive method in limited, small varicose veins.
This study aims to assess the safety and efficacy of UGFS using sodium tetradecyl sulphate (setrol) in patients presenting with minor varicosities and residual varicosities of lower limb.
Methods: 78 patients with minor varicosities or residual varicosities post-surgery who presented between January2015 and June2016 at KR hospital attached to Mysore Medical College and Research Institute, Mysuru, underwent ultrasound-guided foam sclerotherapy with 0.5ml (at a single session) setrol prepared as a foam by Tessari technique. The efficacy criterion was the disappearance of the varicosities and improvement in symptoms and signs: 1 week, and 1, 3, 6 and 12 months after the treatment. Complications of sclerotherapy were reported during follow-up.
Results: Decrease or withdrawal of complaints was reported in 96% of cases (74 patients). Disappearance or decrease of varicose veins was observed in all patients (100%). Phlebitis and pigmentation as a complication was noted in 5 (7%) and 9 (11.5%) cases respectively. Major complications, such as deep vein thrombosis, pulmonary embolism, dyspnoea, anaphylaxis, or neurological abnormalities, were not reported.
Conclusions: Ultrasound-guided foam sclerotherapy for minor varicosities and residual varicosities with sodium tetra decyl sulphate is a safe and satisfactory method of treatment of minor and residual varicosities.

Keywords: Foam sclerotherapy, Sodium tetradecyl sulphate, Ultrasound-guided, Varicose veins

INTRODUCTION

Ultrasound guided foam sclerotherapy (UGFS) involves the injection of a sclerosant directly into the superficial veins. Foam sclerotherapy is the application of a sclerosing agent in the form of foam under ultrasound guidance into a varicose vein, leading on to reduction or occlusion of the vessel diameter.[1,2]

The most commonly used (and the only sclerosant recognized for treatment in the United Kingdom) is the sodium tetradecyl sulphate although others are available on a named patient basis. Sclerosing agent destroys the lipid membrane of the endothelial cells causing them to shed, leading to thrombosis, fibrosis and obliteration (sclerosis).

Orbach was the first person who documented usage of foam in sclerotherapy by air block technique in 1944.[3] Cabrera et al. later in 1997, reported microfoam technique under ultrasound guidance.[4] Tessari later popularised his method of foam sclerotherapy in 2000. He used two Leur-lock syringes connected by a three-way tap.[5]

In recent years many minimally invasive methods of treatments of varicose veins, such as sclerotherapy, thermoablation (radiofrequency, laser, steam ablation) and intravascular glue have been introduced. The least invasive, among mentioned ways of treatment is the foam sclerotherapy.

Ultrasound-guided foam sclerotherapy is a relatively inexpensive procedure, minimally invasive and can also be repeated many times in the case of recurrence of varicose veins.[6]

The present study is aimed at describing the results of ultrasound-guided foam sclerotherapy in the treatment of minor and residual varicosities of lower limbs.

METHODS

78 patients with minor varicosities or residual varicosities post-surgery who presented between January 2015 and June 2016 at KR hospital attached to Mysore Medical College and Research Institute, Mysuru, India underwent ultrasound-guided foam sclerotherapy with Sodium tetradecyl sulphate (0.5ml at each site to a maximum of 2ml per session) prepared as a foam by Tessari method.

1% and 3% sodium tetradecyl sulphate (setrol) has been approved to be used as a sclerosant for the treatment of varicose veins. All patients were informed about the method of treatment. They were also informed about the details of the procedure, its indications and contraindications, as well as possible complications and gave their informed consent for the procedure.

Thorough medical history was obtained and then relevant physical examination was done.

Inclusion criteria

- Perforators incompetence below knee along GSV.
- Recurrent Varicosities after surgery.
- Age 18-60 years.
- CEAP classification- C2-C4a, Ep, As with/without Ap, Pr.

Exclusion criteria

- GSV diameter <4mm and >10mm
- Non willing patients
- Peripheral arterial disease, H/o DVT, Superficial thrombophlebitis
- Chronic renal/liver diseases, pregnancy, coagulopathy, known malignancies uncontrolled diabetes mellitus

Foam production

Foam was produced using two syringes connected using a three way tap. One syringe was filled with 2 ml of 3% sodium tetradecyl sulphate (Setrol) and the second one with 8 ml of air. A 1:4 ratio mixture of sclerosant and air is drawn into one syringe, and then oscillated vigorously between the two syringes about 10-20 times. The foam produced in this way being stable for about 2 minutes, should be injected as soon as it has been made.

The procedure commences with the patient in standing position, the sites of venous cannulation are marked using ultrasound (with a 5-9 MHz linear transducer).Blood flow was elicited with manual compression and release below the transducer. Perforators were considered to be incompetent if the reflux was for >0.5 seconds. Then, with the patient in supine position, the marked sites were all cannulated under ultrasound guidance with 18guaze cannula. Once all injection sites were cannulated, foam was prepared by Tessari method. Leg was then elevated to empty the veins of blood, and 0.5ml of setrol was injected at each site, totalling to around 2ml (i.e. less than 10-12 ml of foam) at one setting. The progression of foam within the cannulated vein was visualised and massaged with the ultrasound probe. No further foam was injected at a site when the foam was visualised at the site of junctional incompetence (Figures 1 and 2). Elastic compression (class II compression stockings – from 20 to 30 mmHg) was then applied. Elastic compression stockings were advised to be worn during the first 48 h (day and night). Then, the patients were advised to wear stockings during the ambulatory period of the day for 2-3 months.

The efficacy criteria were as follows:

- Absence of reflux in the treated vein and
- Withdrawal or decrease of complaints during follow-up.

Patients were followed up 1 week, and 1, 3, 6 and 12 months after the treatment. Patient was examined for any complications related to sclerotherapy during the follow-up period.

The clinical assessment was divided into three grades:

- 2: normalization: lack of visible varicose veins
- 1: improvement: smaller visible varicose veins
- 0: lack of improvement or clinically progressive (as per CEAP classification).

The ultrasound assessment was also divided into 3 grades:

- 2: Full success: Absence of reflux
- 2a: Completely obliterated vein
- 2b: Completely occluded (incompressible) vein
- 2c: Presence of an un-obliterated vein, with decreased diameter (compared to the initial assessment) and no reflux
- 1: Partial success: reflux < 1 s or partial incompressibility or partial obliteration of vein with decrease of its diameter

- 0: failure of treatment: reflux for >1 s or without any changes compared to the pre-treatment time; total or partial persistence of vein diameter and/or without its change compared to the pre-treatment state.

RESULTS

78 patients with minor varicosities or residual varicosities post-surgery who presented between January2015 and June2016 at KR hospital attached to Mysore Medical College and Research Institute, Mysuru, India underwent ultrasound-guided foam sclerotherapy.

Total number of males were 49 (62.8%) and females were 29 (37.2%). Mean age was 48 (from 18 to 60) years.

Complaints of chronic venous insufficiency were reported to be subsided in 96% of cases (74 patients). Disappearance or decrease in size of varicose veins was present in all patients (100%). Full success (grade 2) of ultrasound was achieved in 57 (73%) cases, and 16 (21%) patients presented a partial desired effect (grade 1), 1 year after the treatment. Persistence of reflux for more than 1s in the treated vein was seen in 5 cases (6%).

One-week follow-up

At the first week of follow up, patients were re-examined to rule-out deep vein thrombosis (DVT) and to check for the desired occlusion of the vein. Ultrasound examination revealed no signs of DVT. Additionally all patients had the vein occluded to the desired extent.

1 month after treatment

After one month of the procedure, patients were examined for thrombophlebitis. Occlusion of the treated vessel was also evaluated.

3, 6 and 12 months after sclerotherapy

Physical examination and ultrasound of the treated vein was performed. The clinical outcome and vessel occlusion were assessed according to the consensus on foam sclerotherapy from the 2nd European meeting in Tegernsee.[7]

All (100%) patients reported improvement during the first 3 months of follow-up during which compression stockings were used regularly. Only 3 (4%) persons discontinued the usage of compression stockings despite the symptoms. Inspite of changing the compression grading to class one, these patients did not abide to the doctor's advice. Most persons (75, 96%) noticed improvement and the decrease or withdrawal of complaints.

Table 2 shows the results of ultrasound examination 3 and 6 months and 1 year after the treatment. A 1-year follow-up visit revealed grade 2 in 57 cases (73%) and grade 1 in 16 cases (21%). Failure in US was recorded in 5 (6%) patients. Figure 3, AC present the correctly occluded GSV without any signs of blood flow respectively after 3, 6 and 12 months.

Table 1: Results of ultrasound examination at 3, 6 and 12 months of follow-up.

Follow-up visits (months)	Grade 0 (reflux >1s or unchanged)	Grade 1 (reflux <1s)	Grade 2 (no reflux)
3	3 (4%)	5 (6%)	70 (90%)
6	5 (6%)	13 (17%)	60 (77%)
12	5 (6%)	16 (21%)	57 (73%)

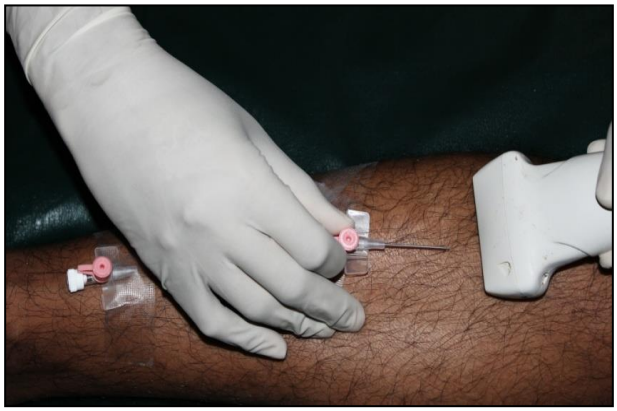

Figure 1: Cannulation of collapsed varicose vein under ultrasound guidance.

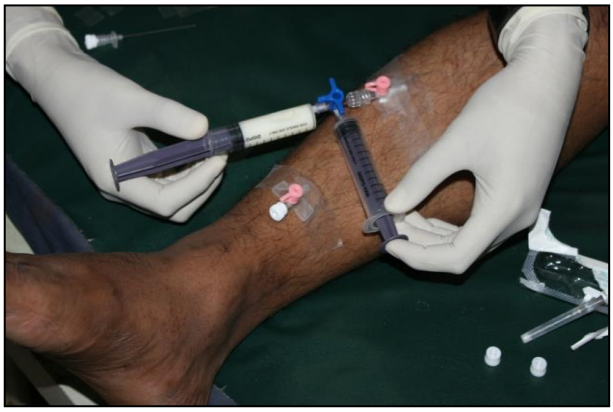

Figure 2: Tessari method of foam sclerotherapy.

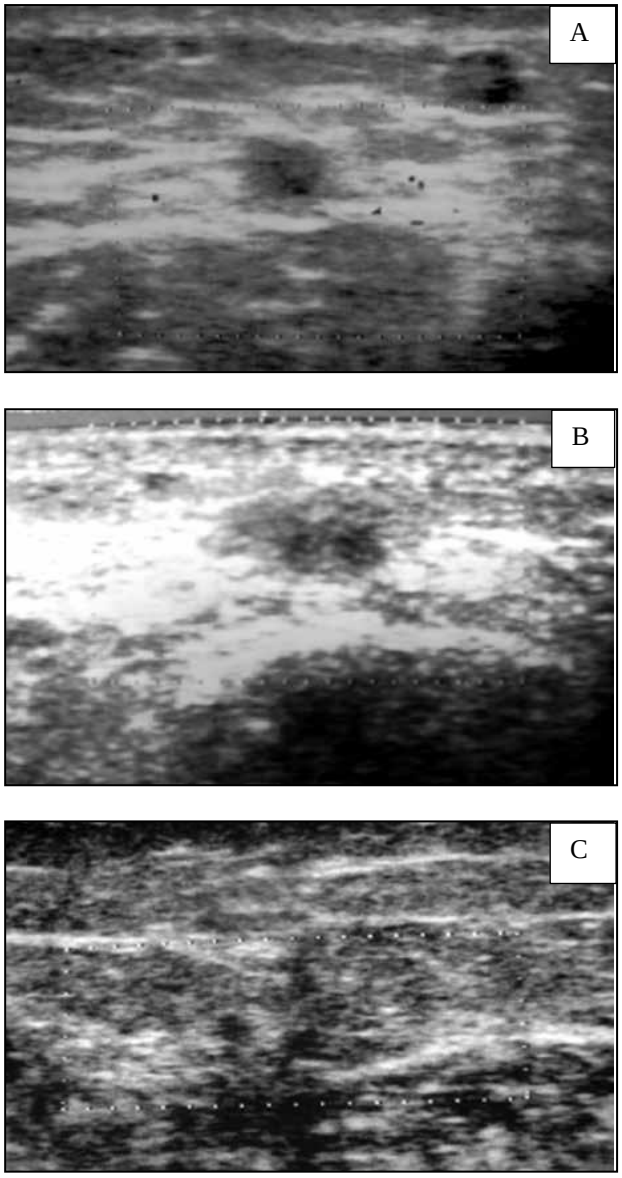

Figure 3: Ultrasound photos of the treated vein at; A) 3 months of follow-up; B) 6 months of follow-up; C) 12 months of follow-up.

Complications

Mild pain at the site of injection as it was administered was experienced by 9 (11.5%) patients. A week and a month after sclerotherapy, thrombophlebitis of part of the treated vein or its tributaries was present in 16 (21%) cases. Evacuation of the thrombus was accomplished by a small incision, 4 weeks after the procedure.

Hyperpigmentation, was seen in 13 (17%) cases. After 1 year pigmentation was hardly visible in 11 (15%) cases and 2 patients had persisting hyperpigmentation on the calf (2.56%).

Patients who developed complications over the calf did not use compression stockings as advised.

Major complications such as deep vein thrombosis, pulmonary embolism, hypersensitivity reactions or any neurological symptoms (blurring of vision, vertigo, loss of consciousness, stroke or transient ischemic attacks) were not reported.

DISCUSSION

The cochrane review, has compared the results of sclerotherapy and surgery, and showed that sclerotherapy was very much superior to surgery in one year span of time.[8]

The main objective of the present study is to assess the efficacy of sclerotherapy as a treatment alternative in patients with varicose veins. More importantly, this method is safe, rapid and is less expensive than surgery and other treatment options for varicose veins, constituting an important and valuable option for patients.

A Brazilian study evaluated the treatment of varices with ultrasound-guided microfoam sclerotherapy and shown that 84% of cases resulted in complete occlusion and partial recanalization.[9] O'Hare JL et al, demonstrated total occlusion of 74% and partial occlusion of 10%, six months after ultrasound guided foam sclerotherapy.[10]

The choice of a better treatment option depends on various factors: stage of the venous disease as per CEAP classification, site of the lesion, complaints, comorbid diseases and obesity, resumption to work, cost of the treatment, prejudice against some methods of treatment or their complications, etc.

Rasmussen et al. from Denmark showed that stripping of GSV is as expensive as endovenous laser ablation (EVLA). The time for daily activities and to resume work was the longest after surgery when compared to EVLA, radiofrequency ablation (RFA) and ultrasound guided foam sclerotherapy (UGFS). Ultrasound- guided foam sclerotherapy was the cheapest and the most convenient method of treatment of varicose veins. These authors however recognized this method as the least traumatic, the cheapest and easy to repeat.[11]

The importance of compression therapy after foam sclerotherapy was also recognized in the second European meeting on foam sclerotherapy in Tegernsee in 2006.[7]

Coleridge Smith P, in 2006 also reported that Ultrasound guided foam sclerotherapy as a relatively easy to perform procedure, to be effortless and that it can be performed as outpatient basis. They also suggested longer initial compression, lasting for more than 2 weeks.[12]

The site of insertion of the intravenous cannula, volume of foam and its production and the concentration of the sclerosant used were in accordance with the Consensus from the 2nd meeting on foam sclerotherapy.[7]

Follow-up examinations were done to assess the efficacy of the treatment and for appropriate management in case of any complications. Patients were thus followed up at 1 week, and 1, 3, 6 and 12 months after the treatment. Similar follow-up has also been suggested by several other authors.[12-15]

An ultrasound examination was done a week after therapy showed optimum obliteration of the treated vein in all the cases and also showed no signs of DVT. Thus re-sclerotherapy was not required. The reported results after 1 week of the procedure are similar to those documented by others.[2,16]

Rabe et al. documented occlusion of GSV 3 months after treatment in 70% of cases, whereas Bountouroglou et al. noted similar results in 87%.[17,18] According to Gonzalez-Zeh et al. and Figueiredo et al., patent GSV 6 months after sclerotherapy was observed in 11.3% and 22% respectively.[19,20] In several studies, the success rate of occlusion of the GSV, at 1 year after sclerotherapy, ranges from 77.4% to 88%. [2,14,20]

The most frequent complication after sclerotherapy was thrombophlebitis in this study. It was present in 16 (21%) cases. Many other researchers have documented phlebitis in 2% to 10% of patients.[12,16,21] Inadequate compression could be one main cause of increased incidence of thrombophlebitis in these patients.

Some also documented that more concentrated sclerosants might increase the chance of phlebitis.[22] In the present study, the hyperpigmentation was documented in 13 patients (17%) at 1 month after the procedure. It faded with time and at 1 year after the procedure, it was seen in 11 patients (14%).

CONCLUSION

Ultrasound-guided foam sclerotherapy with sodium tetradecyl sulphate can thus be regarded as a safe, effective and more importantly a satisfactory procedure for management of small, residual and recurrent varicose veins owing to its ease of understanding and implementation, simple procedure which can be visualised under ultrasound, cost effective out-patient procedure and satisfactory results.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the institutional ethics committee

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Cite this article as: Madhu BS, Kumar SHB, Reddy NKM, Kalabhairav S, Reddy AV. Efficacy and safety of ultrasound guided foam sclerotherapy with sodium tetradecyl sulphate for residual and minor varicosities. Int Surg J 2017;4:751-6.