

Ultrasound guided foam sclerotherapy: evaluation of complications and short-term effectiveness

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ABSTRACT

Objectives: To describe the complications following ultrasound guided foam sclerotherapy, and outcomes at 2 and 6 months following treatment.

Methods: Patients with primary or secondary varicose veins and treated with UGFS were followed up at 1 week and 2 months by Duplex Doppler Ultrasound to assess the effectiveness of the procedure and to document the complications.

Results: 117 patients, from the median age group of 47 years (ranging from 18–74 years) were treated; of which 79 were males and 38 were females. 91 of these were cases of primary varicose veins and 26 were of secondary or recurrent varicose veins (post-surgery recurrence in 24 and post-sclerotherapy recurrence in 2).

The complications noted in this study included severe pain at the time of injection (10), vasovagal syncope (1), focal perforator thrombosis (5), local skin ulceration (3), hyperpigmentation (3), ipsilateral inguinal lymphadenopathy (1) and an exacerbation of chicken pox vesicles in the injected leg 3 weeks after injection (1).

During the 2 month follow up 79 legs showed complete thrombosis and 20 had partial thrombosis. Pre-procedure CEAP grading ranged between 1 & 6 with a mean value of 4. Post-procedure CEAP grading ranged between 0 & 6 with a mean value of 3.3. This decrease in mean CEAP was found to be statistically significant ($p < 0.01$). 6 month follow up in 35 legs with complete thrombosis, showed good thrombosis in 31 legs and early recanalization in 4 legs.

Conclusion: UGFS is a simple, cost effective procedure, which leads to significant improvements in clinical symptoms and decreasing morbidity, associated with chronic venous disease.

Keywords: Varicose veins, Ultrasound, Duplex Doppler, Foam sclerotherapy, Sodium Tetra Decyl Sulphate (STDS), Saphenous veins

Abbreviations: STDS – Sodium Tetradecyl Sulphate 3%, USG – Ultrasonography, UGFS – Ultrasound guided Foam Sclerotherapy, DVT – Deep vein thrombosis, GSV – Great saphenous vein, SSV – Short saphenous vein, CEAP Score – clinical, etiological, anatomical and pathological score.

INTRODUCTION

Ultrasound guided foam sclerotherapy (UGFS) has played a significant role in the treatment of varicose veins, since its usage was reported in 1989 [1]. It is a minimally invasive method, which is cost-effective and significantly improves the quality of life. UGFS as a first line treatment for varicose veins has been reported in 2006 [2]. While endoluminal thermal and laser ablation is used in the treatment of truncal incompetence, sclerosant can be used for both truncal incompetence and varicosities involving the tributaries [2]. The earliest report at sclerotherapy was in

1680s with a large series of modern sclerotherapy being reported in 1939 by McCausland [3]. Foam sclerotherapy uses a foam sclerosant, i.e. sclerosant mixed with air or other physiological gases. Foam displaces blood from the vein and the contact between the foam and the endothelium causes vasospasm and occlusion. Sclerosant causes chemical damage to the endothelium, which initiates thrombogenesis. Progressively, the vein becomes a fibrotic cord [4]. According to Jia et al though foam sclerotherapy is not as effective as surgery, it is more effective than liquid sclerotherapy [5].

Sclerosants are classified into three categories

– Osmotic agents, detergents and irritant / corrosives. Hypertonic saline is an osmotic agent; polidocanol, sodium tetradecyl sulphate, sodium morrhuate, and ethanolamine oleate are detergent sclerosants. Irritant /corrosive agents include ethanol, phenol, polyiodinated iodine, chromated glycerine and glycerine / lidocaine / epinephrine [3].

Contraindications to sclerotherapy includes the history of allergy to the sclerosant, pregnancy, infection, deep vein thrombosis (DVT) and severe arterial disease[3].

The most common side effects of sclerotherapy are superficial thrombophlebitis and skin pigmentation. Other immediate complications include pain, vasovagal syncope and anaphylaxis. Persistent swelling, matting and staining, transient migraines scotomata, transient thrombus in common femoral vein / DVT, pulmonary embolism, nerve damage, arterial injection, hypertrichosis, sepsis, stroke and fatality are also mentioned [1].

CEAP classification (Table 1) is a simple and easy descriptive system in chronic venous disorders to base decisions for appropriate treatment. However, venous severity scoring and quality of life scores are essential to assess outcomes [6].

OBJECTIVES

The aim of this retrospective study was to evaluate the immediate complications, the short term efficacy of the procedure at 2 months, and the improvement in CEAP scores.

MATERIALS AND METHODS

A retrospective analysis of the records was made. 117 patients who underwent UGFS in the Department of Radiodiagnosis between October 2009 and December 2013 were analysed.

All patients were symptomatic (CEAP 2-6) with primary or secondary varicose veins referred for UGFS. They had undergone a pre-procedure Doppler evaluation for the assessment of deep vein thrombosis (DVT), Sapheno femoral junction & Sapheno-popliteal junction incompetence and perforator incompetence. Pre-UGFS CEAP score was also documented. All patients were above 18 years of age. Pregnant or lactat-

ing patients, children, patients with deep vein thrombosis, history of allergy to sclerosant, infection and severe peripheral vascular disease were excluded.

PROCEDURE

UGFS was done in the Department of Radiodiagnostic, with the patient in supine position. Based on the involvement of the GSV or SSV system, the vein to be injected was marked after USG screening. Pulse and oxygen saturation of the patient was monitored during the procedure by a pulse oximeter. The vein was viewed in the longitudinal plane and a 23G needle or intravenous cannula was positioned within the lumen. Foam sclerosant was injected under visualisation and followed up to the Saphenofemoral (SFJ) or saphenopopliteal junction (SPJ) as applicable. After elevation of the lower limb to about 45 degrees, compression of the SFJ or SPJ was done up to about 5 minutes following the injection. Compression bandage was applied from the foot up to the thigh following the procedure. Large perforators adjacent the injection site were also occluded by finger compression.

The sclerosant used was Sodium TetraDecyl Sulphate 3% (STDS) as a foam, mixing it with air by Tessari method [3]. The ratio of foam:air during the period of study was 1:4.

All patients were issued post-procedure instructions regarding being ambulant and were kept under observation for about 2 hours following the procedure, and sent home the same day. They were instructed to wear compression bandage continuously for 2 weeks. Follow up Doppler was done after 1 week to assess complications and to document the extent of venous thrombosis. Further follow up Doppler was done at 2, 6, 12 months, and yearly after that.

Efficacy was defined as a complete thrombosis of the great and small saphenous veins or its tributaries. Non-compressible superficial veins with or without visible intraluminal thrombus and no colour uptake was termed thrombosed.

Complete thrombosis indicated that the dilated superficial veins and the GSV / SSV up to the junction were thrombosed.

It was considered partial thrombosis, when either the GSV / SSV was not thrombosed up to the SFJ or few of the superficial veins in the system were partially thrombosed or patent. Lack of thrombosis of the GSV / SSV and the superficial veins was considered as no thrombosis.

ETHICS

All the procedures followed were in accordance with the ethical standards of this institution.

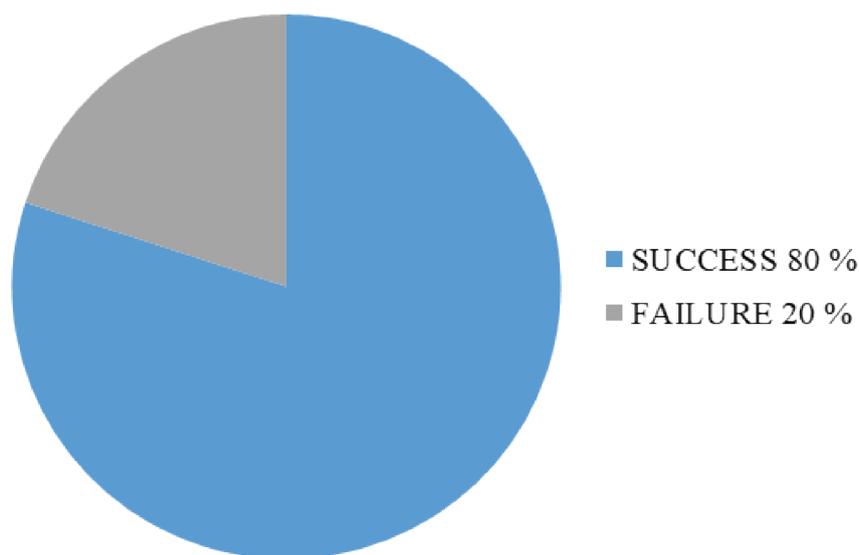
RESULTS

Records of UGFS done in 117 limbs, 79 of whom were men and 38 of whom were women were analysed. They ranged in age from 18 to 74 years (median age was 47 years). 91 (77%) were primary and 26 (23%) secondary or recurrent varicose veins. The CEAP scores of the patients prior to UGFS were as follows:

Table/Fig 1: Distribution in the patients according to CEAP clinical grade

CEAP GRADE	DESCRIPTION	DISTRIBUTION
C0	No visible or palpable signs of venous insufficiency	7 (5%)
C1	Telangiectasis and/or reticular varicosities	10 (8%)
C2	Varicose veins	28 (24%)
C3	Varicose veins with edema	25 (21%)
C4	Venous eczema, pigmentation, lipodermatosclerosis, atrophie blanche	23 (19%)
C5	Healed varicose ulcers	14 (12%)
C6	Active venous ulceration	10 (8%)

Table/Fig 2. Percentage distribution of the sample according to the outcome at 2 months following UGFS



*Success is defined as a complete occlusion
 +Failure is defined as partial/no occlusion

Table/Fig 3 Comparison of CEAP before UGFS and after UGFS (2 months follow-up)

	PRE CEAP	POST CEAP
Mean	4.3	3.3
Median	4.0	3.0
Standard Deviation	1.2	1.4
Minimum	1.0	0.0
Maximum	6.0	6.0

*Wilcoxon signed Rank test =8.8, p<0.01

Table/Fig 4. Percentage distribution of the sample according to post procedural complication at 1 week

Follow up at 1 week complication	Count (out of 114)	Percentage
No complications	89	78
Pain at injection site	10	9
Perforator thrombosis	5	4
Pigmentation	3	2
Edema	3	2
Ulcer	3	2
Vasovagal syncope	1	1
Inguinal lymphadenopathy	1	1

DISCUSSION

UGFS was performed in 117 patients who were referred from the Department of General Surgery for the treatment of lower limb varicose veins. Prior to the procedure, all patients were examined clinically to evaluate the severity of the venous disease using CEAP scoring system and Duplex Doppler to determine the site of reflux and the involvement of great saphenous or short saphenous system, or both.

The patients were followed up at an interval of 1 week initially to look for the procedure related complications, and later at 2 months to assess the efficacy of the procedure.

The patients included in this study were in the age group ranging from 18 to 74 years.

Of the sample patients, 91 (77%) had primary varicosity, 26 (23%) had secondary / recurrence of varicose veins. Studies have shown that primary and secondary varicosities can be effectively closed with UGFS, with high levels of patient

satisfaction [7, 8]. In our study also, there were high levels of success in patients with primary and secondary varicosities.

Out of the 99 patients (18 defaulters at 2 months follow up), 79 (80%) patients were found to have a successful outcome following UGFS. Success of UGFS was defined as a 2 month Duplex Doppler showed complete occlusion / thrombosis of the superficial veins. 20 patients (20%) with partial occlusion at 2 months follow up were considered to have a failed outcome. 6 month follow up in 35 legs with complete thrombosis, showed good thrombosis in 31 legs and early recanalization in 4 legs.

Figueiredo et al, reported that GSV treated with UGFS showed a success rate of 80% [9]. This is similar to the result obtained in our study.

Prior to the procedure, the severity of the venous disease was assessed using the CEAP scoring system. Out of the 117 sample patients, 18 patients were defaulters at 2 months follow up. Out of the 99 patients, 89 (90%) showed an improvement

in the CEAP classification and the rest (10%) remained static. The mean CEAP score before the procedure was 4.3 and after the procedure at 2 months follow up was 3.3. This difference in mean CEAP following UGFS at 2 months follow up was found to be statistically significant.

A study by Gamal et al showed an improvement in CEAP classification in 80% of the patients at one year follow up, following UGFS [10]. This improvement is similar to our study.

Procedure related complications were assessed immediately after the procedure and after 1 week following UGFS; 3 patients showed discoloration at the injection site, 10 complained of pain at the injection site, 3 were found to have edema, 5 had perforator thrombosis, 3 developed injection site ulceration, 1 developed inguinal lymphadenopathy and 1 had vasovagal syncope. A patient had exacerbation of chicken pox vesicles in the injected leg 3 weeks after injection.

Accordingly to the study done by Guex et al, UGFS for the treatment of CVD is associated

with a low rate of major complications [11]. Other studies have also shown major complications like stroke, anaphylaxis and pulmonary embolism to be very rare [12-15]. In our study also, there were no major complications like stroke, anaphylaxis and pulmonary embolism.

Thomas et al, detected skin staining in (28%), pain in (14%), DVT in (1%), skin blistering in (1%), an allergic reaction in (1%) [8].

LIMITATIONS

1. Clinical grading using the recent tools (Revised Venous Clinical Severity Score - VCSS) were not done prior to and after the procedure to better assess the improvement in the quality of life. However, CEAP grading as documented was used.
2. Since this was a retrospective study, patients in whom the recorded data of follow up was unclear were excluded.
3. Patient compliance, regarding wearing of the compression bandage, was also not documented.

REFERENCES

1. P Chapman-Smith, A Browne. Prospective five-year study of ultrasound guided foam sclerotherapy in the treatment of great saphenous vein reflux. *Phlebology* 2009;24:183-188.
2. T.Beckitt, A.Elstone, S.Ashley. Air versus Physiological Gas for Ultrasound Guided Foam Sclerotherapy Treatment of Varicose Veins. *Eur J VascEndovascSurg*(2011) 42, 115 -119
3. Robert L., Worthington K. Injection Sclerotherapy. *SeminInterventRadiol.* 2005 September; 22(3): 209–217.
4. Sandro Ceratti, Fabricio Macedo Okano, Alexandra B. Goes Pontes, Antonio Luiz Pontes. Ultrasound-guided foam sclerotherapy in the treatment of chronic insufficiency. *Radiol Bras* 2011 May/Jun; 44(3): 167 – 171
5. Michel Perrin, Bo Eklof. Randomized controlled trials in the treatment of varicose veins. *Phlebolympology* 2012: 19(2): 91-99
6. K.A. Myers, D.Jolley, A.Clough, J.Kirwan. Revision of the CEAP classification for chronic venous disorders: Consensus statement. From the American Venous Forum Outcome of Ultrasound-guided Sclerotherapy for varicose veins: Medium term results assessed by ultrasound surveillance. *Eur J VascEndovasc-Surg* 33. 116 – 121 (2007)
7. Chapman HT. *Varicose Veins, Their Nature, Consequence and Treatment.* London: Churchill. 1864.
8. Asser A. Gouda,¹ Saad R. Gebaly,² Ultrasonic guided foam sclerotherapy for varicose vein. *Egyptian Journal of Surgery* 2013 , 32(1),12-19
9. Figueiredo M, Araujo S, Barros Jr N, Miranda Jr F. Results of Surgical Treatment Compared with Ultrasound-Guided Foam Sclerotherapy in Patients with Varicose Veins: A Prospective Randomised Study. *Eur J VascEndovasc Surg.*2009;38:758-63.
10. WM G, AS M. Color Duplex Ultrasound-Guided Foam Sclerotherapy: An Approach in the Management of Patients with Superficial Varicosities of Lower Extremity. *Journal of Vascular Medicine & Surgery.* 2016;04(03):263
11. Guex JJ, Allaert FA, Gillet JL, et al. Immediate and midterm complications of sclerotherapy: report of a prospective multicenter registry of 12,173 sclerotherapy sessions. *Dermatol Surg.* 2005;31:123–8.
12. Forlee M, Grouden M, Moore D, Shanik G. Stroke after varicose vein foam injection sclerotherapy. *Journal of Vascular Surgery.* 2006;43(1):162-164.
13. Bergan J, Pascarella L, Mekenas L. Venous disorders: treatment with sclerosant foam. *J Cardiovasc Surg.* 2006;47:9-18.
14. Cabrera J, Redondo P, Becerra A, Garrido C, Cabrera Jr J, Garcia-Olmedo MA, et al. Ultrasound-guided injection of polidocanol microfoam in the management of venous leg ulcers. *Arch Dermatol.* 2004;140:667-73.
15. Coleridge-Smith P. Chronic venous disease treated by ultrasound guided foam sclerotherapy. *Eur J VascEndovasc Surg.* 2006;32:577-83