

ORIGINAL ARTICLE

FOAM SCLEROTHERAPY: AN EMERGING, MINIMALLY INVASIVE AND SAFE MODALITY OF TREATMENT FOR VARICOSE VEINS

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Background: Ultrasound guided foam sclerotherapy is an outdoor, office based and minimally invasive procedure for the treatment of varicose veins. This study was carried out to highlight the potential of foam sclerotherapy as a first line treatment for varicose vein.

Methods: This prospective observational study was conducted at CMH Rawalpindi, from 1 Aug 2017 to 30 Aug 2018. The demographic and outcome data of the patients, who underwent ultrasound guided foam sclerotherapy, were collected and analysed. **Results:** A total of 662 patients and 752 legs were treated with foam sclerotherapy. Four hundred and ten (61.93%) were males and 252 (38.06%) were females. Their ages ranged from 17 to 68 years with the mean age of 43.21 years. Six hundred and sixty-eight (88.82%) legs were having Great Saphenous Vein while 84 (11.17%) legs were having short saphenous vein disease. Maximum legs 256 (34.04%) had C3 disease. Single session of Foam sclerotherapy was enough in 511 (67.95%) legs, while 197 (26.19%) legs were treated with two and 44 (5.85%) legs were treated with three sessions of foam sclerotherapy. Percentages of main trunk occlusion were 98.01% at 1 month while 97.39% at 3 months follow up. Only 2 (0.30%) patients had Deep Venous Thrombosis while 3 (0.45%) patients had thrombophlebitis which required surgery.

Conclusion: Ultrasound Guided Foam sclerotherapy is an OPD based, innovative, minimally invasive and safe method of treatment for varicose veins. In the context of prevalence of varicose vein disease in our community, it relieves the Burden of operation theatre list and creates the theatre space for vascular surgeon for arterial Surgery.

Keywords: Ultrasound Guided Foam Sclerotherapy; UGFS; Varicose veins

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INTRODUCTION

Varicose vein disease is known to human being since advent of recorded history. Complications of varicose vein e.g. oedema and ulceration were described in Biblical time and use of compression dressing for complicated varicose vein can be traced back to Romans time. Hippocrates and Galen, forefathers of Medicine, described the varicose vein in fifth century BC.¹ Work of Brodie and Trendelenburg in 1850s and 1890s is recognized as a mile stone in understanding the modern pathophysiology of varicose vein and Trendelenburg is considered the father of varicose vein surgery.

Varicose vein management has multiple treatment option ranging from conservative to minimal invasive to open surgery depending upon the clinical severity of the disease.² Minimal invasive treatment of varicose veins includes Radiofrequency ablation³, Endovenous Laser therapy⁴, sub fascial perforator surgery⁵ and ultrasound guided foam sclerotherapy (UGFS)⁶. McPheeters and Dixon first time introduced

the Sclerotherapy as a modality of treatment for varicose in 1920 and it remained the treatment of choice for next two decades.⁷ Later on, it was abandoned due to very high recanalization rate. In late 90s Tessari rejuvenated foam sclerotherapy by introducing improvised method of foam creation.⁸ Sodium tetradecyl sulphate, polidocanol, 5% alcohol and hypertonic saline are most commonly used sclerosants for varicose vein treatment. According to NICE guidelines foam sclerotherapy is recommended as a second line treatment modality after Endovenous ablation.⁹ The objective of this study was to highlight the potential of foam sclerotherapy as a first line treatment for varicose vein.

MATERIAL AND METHODS

All the patients above 17 years of age of either gender undergoing UGFS for varicose veins in Combined Military Hospital Rawalpindi, between 1 Aug 2017 and 30 August 2018 were included in this study. After taking Hospital Ethical Committee approval, non-probability consecutive

sampling was used for data collection. The Patients with primary symptomatic/complicated varicose veins from C-2 to C-6 (CEAP Classification) as shown in figure 1, were included in the study after taking written and informed consent.

Patients with secondary varicose veins were excluded from the study. Detailed history was taken about nature of job, duration and nature of symptoms and previous treatment for varicose vein. Venous Doppler ultrasound was done by radiology department to rule out DVT and to establish the level of incompetence prior to booking of the patient for the procedure. All the cases were done office based in vascular surgery OPD. Sodium tetradecyl sulphate was used as sclerosant in every patient. Maximum dose of the foam was decided to be 20 ml per session. Foam was prepared in 1:4 (STD: Air), using Tessari Method.

In the step 1 (as shown in picture 1) the patient was exposed in standing position for examination with application of tourniquet at proximal one third of thigh. In step 2 (as shown in Picture 2) marking of the main trunk and varicosities was done. In step 3 (as shown in Picture 3) ultrasound guided cannulation of main trunk and varicosities was done using 20 Fr Butterfly needles in lying position. After successful cannulation, the tourniquet was released. In step 4 (as shown in Picture 4) leg was raised at 45 degrees to facilitate the emptying of veins followed by injection of foam in the cannulated sites. In step 5 (Figure-5) Multi layered compression bandage was applied in the elevated position of the leg. Every patient was given 5000 I.U. of Heparin I/V at the end of the procedure and made to walk for 20 minutes. All the patients were given oral antibiotics, analgesics for 5 days and advice to have injection clexane sub cutaneous in prophylactic dose according to their body weight for 2 days at home. Multi layered compression bandage was replaced by TED stocking after 2 days by the patient at home as per advice.

Follow up was done at 5 days to review the complications like DVT and Thrombophlebitis. For the assessment of truncal occlusion and need of further session the patient used to be followed up at one- and 3-months post sclerotherapy. Documentation was done for successful truncal occlusion, need of further session of UGFS, DVT and Thrombophlebitis requiring surgical management.

EAP classification	
Clinical classification	
C0	No visible or palpable signs of disease
C1	Telangiectasias or reticular veins
C2	Varicose veins
C3	Edema
C4a	Pigmentation or eczema
C4b	Lipodermatosclerosis or atrophic blanche
C5	Healed venous ulcer
C6	Active venous ulcer
S	Symptomatic, including ache, pain, tightness, skin irritation, heaviness, muscle cramps, and other complaints attributable to venous dysfunction
A	Asymptomatic
Etiologic classification	
Ec	Congenital
Ep	Primary
Es	Secondary (post-thrombotic)
En	No venous cause identified
Anatomic classification	
As	Superficial veins
Ap	Perforator veins
Ad	Deep veins
An	No venous location identified
Pathophysiologic	
Pr	Reflux
Po	Obstruction
Pr, o	Reflux and obstruction
Pn	No venous pathophysiology identifiable

Figure-1: CEAP classification



Step-1: Exposure & Examination of the patient in standing position.



Step-2: Marking of main trunk and most prominent varicosities.



Step-3: Ultrasound guided cannulation of veins.



Step-4: Elevation of leg & foam injection.



Step-5: Multi-layered compression bandage.

Demographics studied were age, gender and hospital registration number entered in pre designed *Proforma*. All the data was recorded on the *Proforma* by the researcher. Data analysis regarding truncal occlusion of Great saphenous vein was done by specific tests on SPSS version 20.0. Quantitative data, like age was calculated in terms of mean by using descriptive statistics. Frequency and percentages were calculated for qualitative variables.

RESULTS

A total of 662 patients and 752 legs were treated with foam sclerotherapy in this period. Out of which 410 (61.93%) were males and 252 (38.06%) were females. Their ages ranged from 17 to 68 years with the mean age of 43.21 years. Majority were military personnel while others were military dependents and civilians. 572 (86.40%) patients had unilateral while 90 (13.59%) had bilateral disease as shown in Table-1. Out of total 752 treated legs 668 (88.82%) were having Great Saphenous Vein disease while 84 (11.17%) legs were having short saphenous vein disease. Distribution of percentage according to clinical stage of the disease at the time of presentation is shown in figure-1. Number of UGFS sessions required to treat a leg is presented in figure-2, which shows that 511 (67.95%) legs were treated with single session of Foam sclerotherapy, while 197 (26.19%) legs were treated with 2 sessions and 44 (5.85%) legs were treated with 3 sessions of foam sclerotherapy. Percentages of main trunk occlusion and lost to follow up patients are shown in table 2 and 3. Only 2 (0.30%) patients had Deep Venous Thrombosis while 3 (0.45%) patients had thrombophlebitis which required surgery.

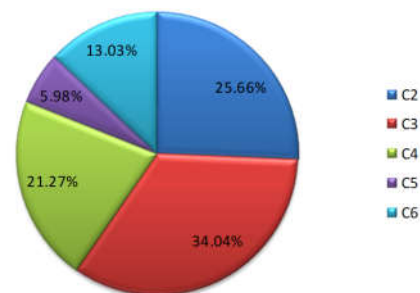


Figure-1: Clinical stage of disease at the time of presentation

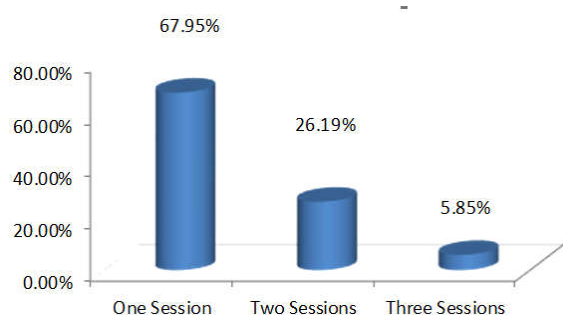


Figure-2: Number of sessions of UGFS for truncal occlusion in percentage of legs

Table-1: Demographic characteristics

Total No. of Patient	662
Total No. of Legs Treated	752
Male	410 (61.93%)
Female	252 (38.06%)
Mean Age	43.21 years
Unilateral Disease	572 (86.40%)
Bilateral Disease	90 (13.59%)

Table-2: Follow-up visit at one month

Total No. of Legs treated	Assessed Legs	Lost to Follow Up	Main Trunk Occlusion in Assessed Legs
752	707 (94.02%)	45 (5.98%)	693 (98.01%)

Table-3: Follow-up visit at three months

Total No. of Legs Treated	Assessed Legs	Lost to Follow Up	Main Trunk Occlusion in Assessed Legs
752	690 (91.76%)	62 (8.24%)	672 (97.39%)

DISCUSSION

Varicose vein disease is one of the highly prevalent diseases amongst the Pakistani population. Search of the local data reveals (36.4%) men and (33.0%) women are suffering from this disease.¹⁰ The maximum prevalence is of C3 (36.7%), followed by C2 (15.8%) clinical stage, indicating symptomatic disease which need more than conservative strategy to avoid further progression and disfiguring complications. Long waiting list time for varicose surgery signifies the unmet workload over surgical services to manage this disease. Our hospital is a tertiary care referral centre for vascular surgery which provides management for peripheral arterial diseases, vascular access surgery for haemodialysis, carotid surgery for CVA/TIA patients, civilian & military vascular trauma, lymphatic and venous diseases. Considering the available operation theatre space and prevalence of varicose vein disease in the conjunction of other vascular diseases, it is literally impossible to manage all C3 varicose veins in Operation Theatre with surgery and indoor post operatively. So, we adopted UGFS as primary modality to treat varicose veins in our centre, as it is

OPD based, minimally invasive, safe and cost-effective method of treating primary and recurrent varicose veins.

Shadid N *et al*¹¹ published an RCT of UGFS versus surgery for incompetent great saphenous vein in which 230 patients were treated by UGFS and 200 underwent stripping of GSV. The 2-year recurrence rate was similar in the UGFS and surgery groups: 11.3% (24 of 213) and 9% (16 of 177) respectively. They concluded that at 2-year follow-up, UGFS was not inferior to surgery in terms of venous reflux and it has potential to be a cost-effective modality for venous diseases as well. Results of this study are comparable to our study.

Darvall KA *et al*¹² published patient reported outcomes after 5–8 years of UGFS for varicose veins in 2014. A total of 391 limbs in 285 patients were included in the study and followed up for 71 months following first UGFS treatment. Results were quite encouraging as only 15.3% legs required re treatment after 5 years. Pre-treatment expectations were met in 93.8% of patients. Overall, 82% patients were fully satisfied with their treatment while only 3.3% were dissatisfied. Moreover, 91% patients would recommend this treatment to others as well. These results endorse our rationale to adopt UGFS as primary modality for treatment of varicose veins.

A study published in British journal of surgery in 2009¹³ discussed the medium-term results of UGFS in the treatment of short saphenous veins. 86 patients (92 legs) underwent UGFS for Short Saphenous Vein. They were assessed at 1, 6 and 12 months after treatment for technical success, i.e., No Reflux and clinical success, i.e., absence of visible varicose veins. Their technical and clinical success at 12 months period was 91 and 93% respectively; only 3 patients had to undergo second treatment. Though this study was specific for short saphenous vein but we can generalize the results for long saphenous and recurrent varicose veins as well, as it is evident from our study.

Darvall KA¹⁴ conducted another study to compare the recovery after UGFS versus conventional surgery in terms of morbidity, use of painkillers, time to return to driving and work. They sent questionnaire to the patients after 4 weeks of treatment and analysed their impression. Patients with surgery had more significant pain and bruising as compared to UGFS group. 43.2% patients joined their work within 24 hours after UGFS as compared to none in surgery group. Moreover, patients having UGFS were driving after 4 days. These results further augment our reason to choose UGFS as primary modality for treatment of varicose veins in our centre.

CONCLUSION

Ultrasound guided Foam sclerotherapy is an OPD based, innovative, minimally invasive and safe method of treatment for varicose veins. In the context of prevalence of varicose vein disease in our community, it relieves the Burdon of operation theatre list and creates the theatre space for vascular surgeon for arterial surgery. However, to assess the 5 years successful truncal occlusion rate of this methodology, studies encompassing long term follow up are suggested.

Conflict of Interest: This study has no conflict of interest to declare by any author.

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AUTHORS' CONTRIBUTION

RAKK: Conception of main theme, study design and write-up. NIK: Overall supervision, analysis and interpretation of data. HKP: Critical revision of important intellectual content. KA: Data analysis and graphic presentation. FH, SS, ZA, MN, MB, AS: Data collection and review.

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