ORIGINAL ARTICLE

Evaluation of Foam Sclerotherapy as Minimally Invasive and First Line Treatment of Varicose Veins in Military Setup

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ABSTRACT

Objective: This case series was carried out to determine the efficacy of ultrasound guided foam sclerotherapy as first line and minimally invasive treatment of varicose veins.

Study Design: Prospective case series.

Place and Duration of Study: Department of Vascular Surgery, Combined Military Hospital, Malir from 1st January 2020 to 31st March 2021.

Materials and Methods: Total one hundred patients with varicosities mainly of great saphenous vein (GSV) were included after detailed history and examination. Ultrasound Doppler was done to rule out deep venous thrombosis (DVT) and any secondary reason for varicose vein. Patients were followed up after 3 days, 10 days, 1month and 3 months with a Doppler ultrasound.

Results: One hundred patients and 130 legs were studied. Age ranges from 30-60 years with mean of 39.75 years, 70 (70%) of the patients were males and 30 (30%) were females. 98 legs (75.38%) had varicosities of GSV, 10 legs (7.692%) with mixed great and small saphenous vein and 22 legs (16.92%) with isolated small saphenous vein. 25 patients (25%) developed pain at cannula site, 3 patients (3%) had bradycardia following procedure and 4 (4%) developed ulceration on skin at the site of cannulation. All patients were followed up for 3 months with a Doppler ultrasound and no recurrence was found post procedure. Average return period to normal function and work was 15 days. In terms of leg pain and physical functioning, patients who underwent intervention achieved health better in short term.

Conclusion: Ultrasound guided foam sclerotherapy is safe, least complicated, and efficacious management for varicose veins with minimal chance of technical failure. This being an outpatient procedure saves time and space for arterial casualties of a vascular surgeon.

Key Words: Deep Venous Thrombosis (DVT), Great Saphenous Vein (GSV), Small Saphenous Vein (SSV), Sodium Tetradecyl (STD), Ultrasound Guided Foam Sclerotherapy (UGFS).

Introduction

Varicose veins are tortuous, twisted, elongated superficial veins.^{1,2} The outnumbered group of varicose veins is primary; secondary varicose veins are mainly caused by conditions such as deep vein thrombosis, pregnancy and pelvic malignancies. Truncal varices are varicosities in the line of great or small saphenous vein or their major branches; however reticular veins are dilated tortuous

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Received: August 21, 2021; Revised: June 02, 2022 Accepted: June 10, 2022 subcutaneous veins not belonging to the main branches of the great or small saphenous vein. Telangiectasia are intradermal venules of <1 mm.³ Underlying cause include weak or damaged valves of vein and are diagnosed by clinical examination in addition to ultrasound venous Doppler for level of incompetent valve. Risk factors include obesity, lack of exercise and leg trauma. They are significantly associated with increasing age, weight, female sex; prolonged standing, family history, number of pregnancies and child birth.⁴

In history of surgeries performed for varicose veins preliminary method was ligation of the saphenofemoral junction, stripping up to knee level combined with phlebotomies and end up with the rapid rise of minimally invasive procedures, such as foam sclerotherapy, radiofrequency ablation, and endovenous laser therapy.⁵ Till now, gold standard treatment of varicose vein still is surgical ligation with stripping of the insufficient vein, however it may seldom be associated with substantial postoperative complications as bleeding, groin infections, thrombophlebitis and saphenous nerve damage.⁶ Sclerotherapy was introduced first time in 1920 and remained modality of treatment for next two decades, later due to high recanalization rates it was abandoned. Tessari rejuvenated this method in late 90's. Sodium tetradecyl sulphate (STD), polidocanol, 5% alcohol and hypertonic saline are generally used as sclerosant.⁷ To the best of author's knowledge the role of foam sclerotherapy in military setup was not extensively studied previously and thus no relevant literature was available. Hence there was a need to address this research gap which provided the rationale for this study.

Materials and Methods

After hospital ethics committee approval, a prospective study design of case series with consecutive sampling for data collection was made. It was carried out over sample size of one hundred patients; data was collected primarily by vascular surgery team from 1st January 2020 to 31st March 2021 at Combined Military Hospital, Karachi.

Inclusion parameters were age between 30-60 years and symptomatic primary varicose veins.

Patients with secondary varicose vein, active or previous history of deep venous thrombosis, peripheral vascular disease, infection, active ulcer, thrombophlebitis, pulmonary embolism, pregnancy, patent foramen ovale and allergy to sclerosant were excluded from study.

A comprehensive history was recorded about job type, duration, any history of DVT, aggravating or relieving factors affecting symptoms and any prior treatment for varicose vein. Venous Doppler ultrasound was advised to exclude DVT and establish the level of incompetence prior to booking for procedure. All cases were evaluated according to Clinical, Etiological, Anatomical and Pathophysiological (CEAP) Classification with C3 and below selected for foam sclerotherapy. All cases were carried out in minor operation theater of vascular surgery OPD. Sodium tetradecyl sulphate (STD) was used as sclerosant in every patient with maximum dose of 4ml. Foam was mixed in 1:4 (STD: air) ratio using modified Tessari method by adding 1ml of liquid sclerosant and 4ml air in 5cc syringe.(8) Ultrasound guided marking of main trunk and varices along with cannulation were done using 20G Butterfly needles in slight reverse trendelenberg position with subsequent injection of foam in the cannulated sites. Multilayered compression bandage was applied while keeping leg elevated at 45 degree. Each of the patients was given intravenous 5000 I.U. of Heparin at the end of the procedure followed by walking for few minutes. Compression bandage was replaced by leg compression stockings on third day and continued for 2 weeks. Re-checkup was carried out after 10 days to evaluate complications like DVT, thrombophlebitis and pain. Patients were advised to resume duty with light work for 5-7 days post procedure. Follow-up was done at 1 month and 3 months for assessment of failure of treatment and extent of re-cannulation if present. Documentation was done following results of ultrasound Doppler for successful occlusion of varicose veins, any need of further session of UGFS, DVT or thrombophlebitis requiring medical intervention.

This is a non-parametric study in which SPSS was used for data analysis and P value was not required since it's a case series.

Results

Patients examined in this study were exclusively military personals and their families. 100 consecutive patient and 130 legs were randomized. 70 (70%) were males and 30 (30%) were females with age ranging from 30-60 years and mean age of 39.75 years. The percentage distribution of patients with respect to clinical stage of the disease at the time of presentation is shown in (Figure 1). Varicose veins in region of GSV (75.38%), SSV (16.92%) and mixed type (7.692%) were noted. Individuals with bilateral and recurrent disease were also included to be treated simultaneously in single session (Table I). The number of legs with satisfactory occlusion of varicose veins recorded after one month of first session of foam sclerotherapy was 107 (82.30%), whereas 23 legs (17.69%) required second session of foam sclerotherapy for complete occlusion (Figure 2). Reason for failure or partial occlusion was either noncompliance to preventive measures prescribed or prolonged standing. All patients were followed up for 3 months with a Doppler ultrasound and no recurrence was found post procedure. 25 patients (25%) complained of pain over the insertion site of cannula on first 10-day follow-up, which was

completely settled by consecutive follow-up visits. 3 patients (3%) had bradycardia during the procedure and 4 patients (4%) developed wound at cannulation site after procedure which was managed conservatively (Figure 3).

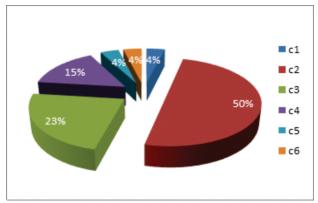
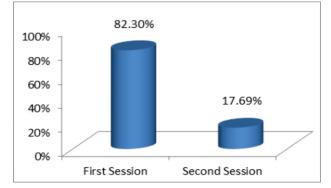


Fig. 1: Clinical Stages at the time of Presentation



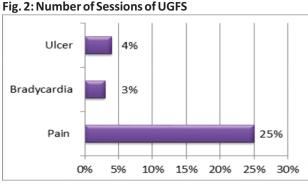


Fig. 3: Incidence of Complications

Table I: Demographic Characteristics of Patients

Number of patients	100
Number of legs	130
Mean age	39.75 years
Male	70 (70%)
Female	30 (30%)
Isolated varicose veins of GSV	88 (67.69%)
Bilateral varicose veins	19 (14.61%)
Isolated SSV varicose	13 (10%)
Mixed varicose veins	10 (7.69%)

Discussion

Varicose veins are one of the most prevalent disorder of the vascular system among adults with 20-25% occurrence of visible varicosities in women and 10-15% in men.⁹ Delay in treatment can subsequently result into a number of complications, including venous ulceration and thrombosis.¹⁰ The prone areas for development of varicose veins in saphenous tributaries suggest that there are susceptible sites where changes in wall, hemodynamic pressure and orthostatic posture can initiate reflux. Reflux of GSV calf tributaries are more common where majority of the limbs belong to classes C1 and C2 of the CEAP classification.¹¹ In our military setup, soldiers face long orthostatic postures which results in early development and increased prevalence of varicose as compared to others. Combined Military hospital is a tertiary care referral center for vascular surgery which provides management for peripheral arterial diseases, vascular access surgery for hemodialysis, civilian and military vascular trauma, lymphatic, and venous diseases, in addition to it, heavy turnover of trauma cases requiring surgical and vascular attention and low availability of operation theaters; UGFS serves as safest, less time consuming, outpatient department based and definitive treatment option.

Many studies were conducted to compare the long term outcome of UGFS with great saphenous vein stripping, in one study N. Shadid¹² concluded from randomized control trial of 230 patients treated by UGFS and 200 by GSV stripping, 2-year probability of recurrence was similar in the UGFS and surgery groups: 11.3% (24 of 213) and 9% (16 of 177). They concluded at 2-year follow-up, UGFS was not inferior to surgery and is a potential cost-effective approach which supports our aim of using foam sclerotherapy as first line method. The use of sodium tetradecyl sulphate in this study was primarily because of its superiority over other sclerosant in terms of better elimination of venous reflux, improved cosmetic appearance, minimum post procedure pain and fewer failure rates. Efficacy rates of foam sclerotherapy over alternatives measures well with the values published in most studies. Studies that compared foam to conventional sclerotherapy found negligible difference in failure rate or recurrence in varicosities. Similarly recanalization rate was also not different between the two treatments.^{13,14}

A recent analysis by Darval et al¹⁵ concluded advantages of minimally invasive UGFS over conventional surgery with respect to decrease in morbidity and faster recovery times. Assessment was done by analyzing the result of questionnaire sent to patients of both groups after 4 weeks of procedure. Individuals who had surgery were more likely to have substantial bruising and pain. Those who underwent UGFS, 43.2% returned to work within a day compared with none who had surgery. Patients who had UGFS were more likely to resume driving within 4 days with less association of pain, analgesia requirements and time off-work. Number of sessions required for 82.30% of the patients for optimum elimination of varicosities in present study was single, which did not cross the mean volume of 4ml of STD required for foam formation in 1:4 ratio. The protocol allowed an extra session if the GSV was found to be patent during the first month which resulted in a smaller number of failure rates in the long run, that can be due to larger volume of foam used than the mean of 4ml per leg. At a consensus meeting in Europe it was recommended not to use volumes of foam above 10ml per session.¹⁶

Stücker et al¹⁷ in his study appreciated the effectiveness of foam sclerotherapy over liquid. It is important to select the correct concentration and the correct foam volume and offers possibility of using lower sclerosant concentrations than with liquids. Jia et al¹⁸ did a systematic review to assess safety and effectiveness of foam sclerotherapy over sixty-nine studies which concluded that rate of critical adverse events, including pulmonary embolism, deep vein thrombosis and visual disturbance were less than 2 per cent. The median rate of headache, thrombophlebitis was less than 5% and pain at the site of injection measured 25.6%. individuals treated with UGFS experienced minimum post-operative pain, it also influences recovery, less time off work and early return to normal work confirming previous observations.^{19,20}

Conclusion

Ultrasound guided foam sclerotherapy serves as a minimally invasive and less time-consuming method for treatment of varicose vein. Due to high prevalence in our military setup this modality of treatment shares workspace of vascular surgeon with promising results and minimal technical failure rate.

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CONFLICT OF INTEREST

Authors declared no conflicts of Interest. **GRANT SUPPORT AND FINANCIAL DISCLOSURE** Authors have declared no specific grant for this research from any funding agency in public, commercial or nonprofit sector. Dermatologic Surgery. 2010. DOI:10.1111/j.1524-4725.2009.01406.

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DATA SHARING STATMENT

The data that support the findings of this study are available from the corresponding author upon request.

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