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A STUDY ON FACTORS ASSOCIATED WITH OUTCOMES AND COMPLICATIONS IN ULTRASOUND GUIDED FOAM SCLEROTHERAPY OF VARICOSE VEINS.

General Surgery

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ABSTRACT

OBJECTIVES: In recent years ultrasound guided foam sclerotherapy (UGFS) has become an increasingly popular treatment for varicose veins. Although many published series detail the results of UGFS, little is known about the factors which are associated with outcomes and complications. The aim of this study was to identify these factors.

DESIGN: A review of a prospectively collected database of UGFS which commenced in July 2020.

METHODS: A successful outcome was defined as complete occlusion of the target vein on duplex scanning at follow-up. Four factors were assessed to determine whether they were associated with outcomes and complications. These factors were compliance with post procedure compression hosiery, single or multiple sites of injection, concentration of sclerosant, and volume of sclerosant used.

RESULTS: Between July 2020 and Jan 2021, a total of 16 patients (11 men, 5 women) attended follow-up visits and had a post-procedure duplex scan. Targets for UGFS included the great saphenous vein , small saphenous vein and anterior accessory great saphenous vein. The remainder of procedures involved other veins or more than a single target vein. The median timing of follow-up was 3 months with duplex scans revealing complete occlusion of the target vein in 68.75% of patients. The only factor associated with a successful outcome was compliance with post-procedure compression hosiery ($p < 0.05$). The most frequently encountered complications following UGFS were skin staining (28%), superficial thrombophlebitis (18%) and pain (14%).

KEYWORDS

ultrasound guided, foam sclerotherapy, varicose vein.

INTRODUCTION:

Ultrasound guided foam sclerotherapy (UGFS) is a popular treatment option for varicose veins. Orbach is credited as the first to introduce foam sclerotherapy to treat varicose veins. In 1950 he described froth produced by vigorously shaking a syringe containing air and sclerosant to treat varicose veins.2 However, the concept of foam sclerotherapy remained relatively dormant until the mid-1990s, when numerous attempts to refine the technique were reported.3 e5 It was not until 2000 when Tessari described a method of preparing foam using two disposable syringes and a three-way tap that this procedure became popular.5

Although a number of studies have reported the results of UGFS, data on factors associated with outcomes and complications is relatively sparse. Several studies have suggested that outcome following UGFS is influenced by vein diameter, with superior outcomes observed when smaller veins are treated.6,7

Nature of the sclerosant injected (foam vs. liquid), the dilution and volume of sclerosant and vein diameter were all significantly associated with rates of venous occlusion. In a separate study Myers et al. describe significant associations between rates of deep vein thrombosis (DVT) following ultrasound guided sclerotherapy and vein diameter and the concentration and volume of sclerosant injected. Liquid sclerosant was also used in the early phase oft his study. 9 Morrison et al. have suggested that the volume of foam injected during UGFS is inversely related to complications following the procedure. However, average volumes of foam used in this study were notably high (27 ml air-based foam,25mlCO2 based foam).10 The indications for UGFS should become clearer as further information on prognostic factors is elucidated. The aim of this study was therefore to further define factors associated with outcomes and complications following UGFS.

METHODS:

A prospectively gathered computerised database of all patients undergoing UGFS was established in July 2020. In January 2021 this database was analysed and patients who had attended follow-up during this period were included in this study.

INDICATIONS AND TECHNIQUE:

All patients presenting with symptomatic varicose veins CEAP clinical stages 2e6, with truncal vein reflux diagnosed on duplex ultrasonography were considered suitable for UGFS. All treated great saphenous and short saphenous veins had terminal valve incompetence.

UGFS was performed. Immediately prior to undergoing sclerotherapy target veins were marked using a portable duplex scan. Target veins were cannulated under duplex guidance with an I/V cannula (18e21 gauge) or butterfly needle (21e25 gauge), depending on the size, depth and tortuosity of the vein.

The great saphenous vein was cannulated immediately above or just below the knee. Care was taken to cannulate the varicosities away from perforating veins. Once cannulated, patients were laid in a supine position with treated leg elevated.

Foam was generated using the Tessari method,5 mixing one part sclerosant, sodium tetradecyl sulphate (STS) 0.5e3% with four parts air using two syringes and a three-way tap. Great saphenous veins were treated with 3% STS. Accessory great saphenous and short saphenous veins were treated with 1% STS. A concentration of 0.5% STS was reserved for smaller veins. The average volume of STS injected was 12 ml (range 5 e15 ml). Following injection patients were asked to plantar- and dorsiflex the ankle to encourage proximal migration of foam along the target vein and speed neutralisation of any foam reaching the deep venous system. Foam pads were then applied over the treated vein. A class II thigh length graduated compression stocking with waist extension was applied over the foam pads. Following the procedure foam pads were worn for one week and stockings were worn for 6 weeks.

Outpatient follow- up appointments were made for all patients following UGFS. Data were collected regarding superficial thrombophlebitis, pain, skin staining, visual disturbance, headache, neurological problems, skin ulceration and any other complications that were encountered. In addition, the questionnaire included assessment of compliance, defined as wearing foam pads for one week and compression stockings for 6 weeks following the procedure.

ANALYSIS:

A successful outcome was defined as complete occlusion of the target vein on duplex analysis at follow-up. Four variables were assessed to determine whether they were associated with outcomes and complications. These variables were compliance with post- procedure compression hosiery, previous, single or multiple sites of injection, concentration of sclerosant, and volume of sclerosant used.

Categorical variables were correlated with outcome and complications using the chi-squared test. Continuous variables were compared with outcome and complications using binary regression analysis. Statistical analysis was performed using the SPSS.

A p value of <0.05 was considered significant.

RESULTS:

Between July 2020 and Jan 2021, 20 patients underwent UGFS. Of these 16 patients (11 male, 5 female), who underwent a total of 16 UGFS sessions, attended follow-up appointments. The median age of patients undergoing foam sclerotherapy was 55 years. Targets for sclerotherapy included the great saphenous vein (n = 9), small saphenous vein (n= 4) and accessory great saphenous vein (n = 1). The remainder of procedures involved other veins or more than a single target vein (n = 2).

The median timing of follow-up was 3 months following treatment. Duplex scans at follow-up revealed complete occlusion of the target vein following 68.75% of procedures (n = 11). Partial occlusion of the target vein was evident following 18.8% of procedures (n = 3) and a patent target vein was seen after 12.5% of procedures (n = 2).

Four variables were analysed to determine whether they were associated with outcome and complications. Of the variables analysed compliance with post-procedure compression hosiery was the only factor associated with a successful outcome ($p < 0.05$).

TABLE 1

Post procedural compliance with compression hosiery.	Number of patients
Yes	11
No	5
Total	16

TABLE 2

Occlusion of target vein	Number of patients
Complete	11
Partial	3
No occlusion	2
Total	16

Table 3

Post procedural compliance with compression hosiery.	Complete occlusion of target vein	Not complete occlusion of target vein	Total
Yes	10 (7.56) [0.79]	1 (3.44) [1.73]	11
No	1 (3.44) [1.73]	4 (1.56) [3.8]	5
Total	11	5	16

The chi-square statistic is 8.045. The p-value is .004563. Significant at p < 0.05.

The chi-square statistic with Yates correction is 5.083. The p-value is .024162. Significant at p < 0.05.

DISCUSSION :

Since the new found interest in UGFS in mid 1990s, many reports have emerged detailing outcomes of the procedure. A systematic review conducted by Jia et al. based on 69 studies of UGFS concluded a median rate of target vein occlusion of 87% (range 60e98.2).11 In this series 79% of target veins were completely occluded on duplex scans at follow-up. In addition, another 14% of the target veins were partially occluded. These results therefore compare favourably with other published series. UGFS is not free of complications. However, large multicenter studies have demonstrated a low rate of significant complications.Stroke, anaphylaxis6 and pulmonary embolism have been described, but are extremely rare. In this series 18% of patients developed superficial thrombophlebitis, which is higher than reported in the literature. The majority of these patients were in the early phase of the study when truncal varicosities of >10 mm were treated. Rates of skin staining (28%) and pain (14%) compared favourably with the published literature. One patient developed a DVT (1%), one patient developed skin blistering (1%) and another had an allergic reaction (1%). The DVT described in this series was below-knee and occurred following treatment of the great saphenous vein and a varix with 15 ml 3% STS.

Skin blistering was experienced by one patient and was related to the tape applied.

This was therefore thought to be due to tape traction or an allergic reaction.

Concentration of the sclerosant and its effect on outcome is widely debated in the literature. Most studies have used 1e3% STS or polidocanol to produce foam. A small randomised study, involving twenty patients, has suggested that sodium tetradecyl sulphate and polidocanol have similar efficacy, tolerability and patient satisfaction. Although some randomised control studies have reported superior efficacy with higher concentrations of sclerosant, others have questioned the importance of sclerosant concentration. A meeting of European experts in 2006, failed to reach a consensus regarding foam concentration, however, did suggest that the volume of foam is also important and that not more than 10 ml of foam produced by Tessari's technique they should be injected in a single session.

Compliance with post-procedure compression hosiery was the only factor associated with a favourable outcome following UGFS in this study. With the exception of female gender, this series failed to identify any major factor associated with complications following UGFS. Complications in this study were assessed using a questionnaire and it does seem probable that female patients are more likely to report cosmetic complications, for example skin staining.

CONCLUSION :

UGFS offers an alternative to surgical treatment for varicose veins and our clinical series confirms that it is effective and safe. Compliance with post-procedure compression hosiery is the single most important factor associated with a favourable outcome following ultrasound guided foam sclerotherapy. It is therefore of absolute importance that patients are given clear instructions regarding compression hosiery and the importance of adhering to these is emphasised.

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