ULTRASOUND GUIDED FOAM SCLEROTHERAPY AS A PREFERRED TREATMENT OPTION FOR VARICOSE VEINS IN TERMS OF SAFETY, EFFICACY AND COST EFFECTIVENESS

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ABSTRACT

Objective: To assess the safety, efficacy and cost effectiveness of ultrasound-guided foam sclerotherapy in superficial venous reflux in Clinical, Etiological, Anatomical and Pathological (CEAP) classification grade 2-6 disease.
Study Design: Retrospective observational study.
Place and Duration of Study: Combined Military Hospital Rawalpindi, from Sep 2018 to Feb 2020.
Methodology: One thousand and sixty-seven patients (1312 legs) with varicose veins were treated by ultrasound-guided foam sclerotherapy using 3% sodium tetradecyl sulphate for truncal veins and 1% for smaller veins in 1:4 ratio with air. After 7 days, leg was assessed clinically and radiologically with Duplex ultrasound for occlusion of veins and complications. Second, third and fourth sclerotherapy sessions were performed for residual/recurrence/new varicosities. Compression bandage was used for at least 3 months after treatment.
Results: The overall eradication of superficial venous reflux and healing of ulcers, was seen in 92.1% (1208 legs). It was 83.5% (1095 legs) after 1st session of UGFS. Second, 3rd and 4th session of UGFS further increases this percentage of benefitted patients Deep vein thrombosis developed post procedure in 2 (0.18%) patients and pulmonary embolus in one patient. Three (0.28%) patients had transient visual disturbances within half an hour of treatment. Retreatment was required due to formation of new superficial venous reflux in 39 (2.9%) legs and recurrence in 93 (7.1%) legs.
Conclusion: Ultrasound guided foam sclerotherapy is a better option of treatment in varicose veins in terms of safety, efficacy and cost effectiveness.

Keywords: Cost effective, Safety, Superficial venous reflux, Ultrasound guided foam sclerotherapy.

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INTRODUCTION

Varicose veins are present in both men (5-15%) and women (3-29%) worldwide as a cause of superficial venous reflux[1], which can aggravate to venous insufficiency, venous hypertension and venous ulceration[2]. The traditional treatment is surgery (saphenofemoral/saphenopopliteal junction ligation, stripping of long saphenous vein in thigh and multiple stab avulsions in leg). Now a-days minimal invasive techniques like ultrasound guided foam sclerotherapy (UGFS), radio-frequency ablation (RFA) and endovenous laser ablation (EVLA) have proven to be better than surgery for treatment of superficial venous reflux[3-5].

Ultrasound-guided foam sclerotherapy (UGFS) is widely used in many countries to eradicate superficial venous reflux (SVR) and treat venous ulceration[6]. It improves symptoms, venous hemo-dynamics, and disease related quality of life[7]. UGFS is associated with high levels of patient satisfaction[8], and less morbidity and early return to work after treatment[9]. The results of all minimal invasive techniques for treatment of superficial venous reflux, are quite similar[3,4], but UGFS is better in terms of safety and cost-effectiveness[8,10]. In this study, we have treated 1067 patients (1312 legs) with UGFS and data analysis suggested UGFS as a preferred treatment option for eradication of superficial venous reflux in CEAP clinical grade 2-6 disease, in terms of safety, efficacy and cost effectiveness.

METHODOLOGY

This retrospective observational study was conducted at Combined Military Hospital Rawalpindi, from September 2018 to February 2020. Approval certificate (no. 74/05/20(20) from Ethics Committee/Combined Military Hospital Rawalpindi was obtained. A written informed consent was also obtained from all patients before treatment.

All patients reported with varicose veins (CEAP classification C2-6 disease) and with patent deep veins, during study period were included in study. The study sample was collected by non purposive consecutive technique. The sample size was not calculated as the study is retrospective and all patients were included in study.

All consecutive patients who presented to our clinic and willing to undergo UGFS were included in

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Received: 19 May 2020; revised received: 08 Jun 2020; accepted: 17 Jun 2020

study. One thousand and sixty-seven patients (1312 legs) with varicose veins disease (CEAP classification C2-6) were treated with UGFS (3% sodium tetradecyl sulphate for truncal veins and 1% for smaller veins in 1:4 ratio of STD and air) during the study period. The foam was made by mixing air and STD in two syringes connected through a 3-way connector and then pushing the fluid and air alternating through the connector to create a fine foam (suspension of air in STD solution). This foam was then injected into the diseased vein under ultrasound guidance and the movement of foam in the vein lumen was seen on the Ultrasound monitor. Compression bandage was applied post procedure and low molecular weight heparin was given subcutaneously for 5 days. 1st follow up was done after 7 days in OPD and leg was assessed clinically and with Duplex Ultrasound for occlusion of superficial veins and presence of any complication. Second, 3rd and 4th sessions were performed if required, for residual or new varicosities. Compression bandage was used for at least 3 months after the complete occlusion of veins and the follow up continued till Feb 2020.

RESULTS

A total of 1067 patients underwent UGFS for unilateral (n-822) and bilateral (n-245) for SVR in association with CEAP clinical grade 2-3 (n-802), 4 (n-201), or 5/6 (n-309) disease (table-I). The reflux in 1539 venous segments was treated as follows; (table-II) primary great saphenous vein (GSV) (n=741); recurrent GSV (n=268), primary small saphenous vein (SSV) (n=239), recurrent SSV (n=83); primary anterior accessory saphenous vein (AASV) (n-152); recurrent AASV (n 53) and vein of the popliteal fossa (n-3). Three hundred sixty seven (28%) legs had been previous operated. Nine hundred and seventeen (81%) truncal varicosities showed complete occlusion after first session (table= III). It was 72% (290) in recurrent varicose disease and 36 (69%) in perforator disease. A total of 136 (12%) underwent a further session of UGFS for truncal varicose veins, 32 (8%) recurrent varicose veins and 2 (3%) perforator disease. Third and fourth session were needed in another 2%, 1% and 0.5% respectively in truncal, recurrent varicose and perforator disease. The mean follow-up was 6 ± SD 2 months (range 1-18) months. Retreatment was required for development of new SVR in 39 (2.9%) patients previously not present clinically and radiologically on doppler ultrasound and recurrence (which remained occluded for 15 days after treatment) in 93 legs (7.1%). Eleven (0.8%) legs with C6 disease never had complete healing The follow up was at day 7 post procedure, then weekly for 1 month, monthly for 3 months and 3 - monthly for 11/2 year.

Two patients suffered post-UGFS deep vein thrombosis (0.18%) and one (0.09%) a pulmonary embolus within the first month of treatment. Three patients (0.28%) had transient visual disturbance within half an hour of treatment (table-III).

Table-I: Demographics of patients with varicose veins.

Parameters	n (%)
Gender	
Male	515 (48.26)
Female	552 (51.73)
Age	
Male	22-65 years (mean 36 ± SD 12)
Female	25-60 years (Mean 32 ± SD 14)
Limb Involved	
Right	381 (35.7)
Leftt	441 (41.3)
Bilateral	245 (22.96)
Previous DVT with recanalized veins	89 (8.34)

Table-II: Duplex findings.

Parameters	n
Pre-Treatment Duplex Findings	
Primary superficial venous reflux	1135
Recurrent superficial venous reflux	384
Deep venous reflux and deep venous reflux	20
Veins Involved on Duplex	
Great saphenous vein primary	741
Great saphenous vein recurrent	268
Small saphenous vein primary	239
Small saphenous vein recurrent	83
Anterior accessary saphenous veins primary	152
Anterior accessary saphenous veins recurrent	53

Table-III: Complications.

Parameters	n (%)
Eradication of reflux (overall)	92.1% (1208 legs)
Eradication of reflux (overall) (after 1st session of UGFS)	83.5% (1095 legs)
Eradication of primary truncal veins reflux (after 1st session of UGFS)	81% (917 legs)
Eradication of recurrent reflux (after 1st session of UGFS)	72% (290 legs)
Retreatment with UGFS	
Newly formed varices on doppler Ultrasonography	2.9% (39 legs)
Recurrence after treatment	7.1% (93 legs)
Complications	
Deep vein thrombosis	0.18%
Pulmonary embolism	0.09%
Visual disturbance	0.28%

In terms of cost effectiveness, cost of one session of USFG is almost 70% less than standard surgery for

varicose veins. Even those patients who needed two sessions, the cost was still less than the standard surgery. Furthermore, the patients were not exposed to any kind of anesthesia and they went home same day after the session so that saved hospital expenses in addition to the cost of surgery, thus making UGFS more cost effective than other procedures. RFA and EVLA need UGFS for infra genicular reflux eradication which enhance the total cost of treatment.

DISCUSSION

Primary and secondary varicose veins result in superficial and deep venous insufficiency, venous hypertension and chronic venous ulceration if not treated in time[2]. Traditional treatment of superficial venous reflex is surgery which is now not the treatment of choice in most of the developed world. New minimal invasive techniques (RFA, EVLA and UGFS) are now preferable option for treatment[4].

UGFS was thought to be beneficial only for recurrent and residual varicose veins before the varisolve european phase III trial. After that trial it was preferred for treatment of truncal varicose veins over surgery because of its many advantages[11]. The number of patients treated with UGFS for varicose veins increased rapidly[12]. In our study we treated 1067 patients with UGFS in sessions with 1:4 STD and air. The follow up done is comparable with the follow up reported in the literature (at 7-10 days interval till one month and then monthly for 3 months and 3-monthly for 18 months[13].

The venous thromboembolism complication rate can be compared well with that reported after surgery, RFA, and EVLT[14]. All symptomatic DVT/PE occurred within 1 month. Three patients experienced self-limiting transient visual disturbance but that had been reported in liquid sclerotherapy independent of air bubbles as a result of vasospasm. This supports the thought that the risks of micro-embolism leading to clinically significant adverse outcomes are negligible[15]. Thrombophlebitis, redness and pain developed after UGFS especially in veins near skin due to retension of foam within the superficial venous system[16]. Using dilute (0.5-1%) STS foam usually achieves occlusion without causing perivenous inflammation. It provides relief of symptoms and reduces skin pigmentation which may develop in up to a third of patients. We informed our patients that this pigmentation may fade slowly over weeks and it was found not to be permanent[9].

The UGFS techniques interpretation vary considerably in literature[17]. Using low concentration of sclerosant to minimize foam volumes[18], and use of multiple cannulae to deliver "fresh" foam to each segment of vein. The foam is deactivated immediately while coming in contact with blood and vein wall. The doppler ultrasound is stressed to be done to ensure veins are in spasm and full of foam, followed by good compression application.

Retreatment rate after UGFS was required in recurrent (7.1%) and in newly formed varices especially below knee (2.9%). This can be compared favorably with those reported after surgery, RFA, and EVLT[19]. Redo UGFS is simple and easier than redo surgery, RFA, or EVLT[20]. Treating perforating veins by UGFS also require UGFS of above knee great saphenous vein, even if it is competent[21].

Catheter induced foam sclerotherapy is a relatively new version of UGFS and being practiced in some countries with good results[22]. UGFS has now replaced all other treatment options in our routine practice due to its simplicity of the procedure with minimal complications rate, easy regular follow up for recurrence/ new varices/residual varices and availability of our team on tele phone. In our setup only 2 patients opted for surgery while another two asked for RFA. UGFS has become a versatile complete treatment even in one session due to its safety and cost effectiveness. The only disadvantage of UGFS is the availability of doppler USG machine and adequate clinical skill of the surgeon. On the other hand patients undergoing RFA or EVLA may spend additional money for the procedures required below knee since these methods mainly focus on the saphenous vein in thigh and proximal leg only. Further, EVLA require additional safety equipment and capable operation theatre.

CONCLUSION

UGFS is the preferred option of treatment for superficial venous reflux disease in terms of safety, efficacy and being inexpensive. The low recurrence rate and formation of new reflux on doppler ultrasound, can be treated in a simple and highly effective way.

CONFLICT OF INTEREST

This study has no conflict of interest to be declared by any author.

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