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Original Research Article

An observational study to evaluate efficacy and safety of ultrasound guided foam sclerotherapy for treatment of varicose veins

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ABSTRACT

Background: There are various minimally invasive techniques for varicose veins. Tessari has invented simple method to create sclerosant foam that has become popular nowadays as treatment for varicose veins. Aim was to describe the efficacy and safety of ultrasound guided foam sclerotherapy for treating varicose veins.
Methods: The observational study was carried out in 50 patients between July 2020 to June 2021. Sclerosant foam was made by Tessari method using polidocanol was introduced under ultrasound guidance in to affected veins. After 3 days looked for any residual varicosities and complications. All patients were followed up at 3 days, 1 month, 3 month and 6 months after treatment.
Results: 37 patients were treated with 3.0% of polidocanol. Rest 13 patients (26.0%) were treated with 1.0% of polidocanol. Six (12.0%) and eight patients (16.0%) received three and four sessions of sclerotherapy respectively. After 1 month, 41 patients (82.0%) achieved complete occlusion, in 5 patients (10%) partial occlusion was seen. After 3 months, 47 patients (94%) achieved complete occlusion without any symptom and three patients (6.0%) had partial occlusion. At the end of 6 months 48 patients (96.0%) achieved complete occlusion without any symptoms. Four patients (8.0%) developed SVT blurred vision in 3 patients (6.0%) and pain with redness at injection site was observed in one patient (2.0%).
Conclusions: Ultrasound guided foam sclerotherapy is safe and effective in obliterating varicosities of lower limb including perforators using polidocanol sclerosant agent with less complication, low recurrences and good cosmetic outcome.

Keywords: Foam sclerotherapy, Polidocanol, Varicose vein

INTRODUCTION

Varicose veins are defined as dilated, tortuous, subcutaneous veins with diameter ≥3 mm measured in the upright position with demonstrable reflux. Affected population in the Western world is about 10-20% but in India it is 5%. Lower prevalence in India is because of majority of the patients do not go to the hospital unless there are complications such as pain, oedema, and ulceration. It does not threaten life but economic impact because of loss of productivity and work hours is enormous.[1]

Various trophic change in skin, ranging from pigmented dermatitis to lipodermatosclerosis, leg ulcers, symptoms attributable to venous dysfunction such as skin irritation, pain, feeling of swelling and itching heaviness induced by Chronic venous disorders. These disorders have important medical and economic consequences.

Any treatment for varicose veins should be minimally invasive with cosmetic improvement and should be usable for recurrent varicose veins so that it can be repeated as required.[2]

Surgery is the gold standard for the treatment of chronic venous insufficiency However, it is relatively invasive. The recurrence rate of varicose veins varied from 20% to 80% after 5 years of surgery.[2] However, at 5–10-year follow-up about a quarter of the patients are dissatisfied with treatment.[3]

Various minimally invasive techniques such as radio frequency ablation (RFA), endovenous laser therapy (EVLT) and transilluminated power phlebectomy (TIPP) are popular. They are effective and possibly superior alternatives to traditional saphenous vein stripping and stab avulsion of varicose veins.

Sclerosant foam made by Tessari technique has become popular nowadays. Ultrasound guided foam sclerotherapy avoids the need of hospitalization, general anaesthesia and long recovery times. Foams have many advantages over liquid sclerosants, like a large dose of foam can be used in a single session, have large surface area leading to greater efficacy, displaces blood and prevents dilution, and early inactivation of the sclerosants. Foams are visible on duplex ultrasound, and it is possible to manipulate the foam once it has been injected into the vessels.

Aim

Aim of the study was to evaluate the efficacy and safety of ultrasound guided foam sclerotherapy (UGFS) for treating varicose veins.

Objectives

Objectives of the study were to evaluate outcome of UGFS during 6 month follow up, and to study complication rate of UGFS.

METHODS

The observational study was carried out in the department of general surgery, SMIMER Hospital, Surat between July 2018 to June 2019 after approval from the institutional ethical committee and obtaining written and informed consents from the patients, 50 patients were included in the study based on the inclusion and the exclusion criteria.

Inclusion criteria

Patients with 18 year and above with lower limb varicose vein, and patients with varicose vein with varicose ulcer were included in the study.

Exclusion criteria

Patient with deep vein thrombosis, allergic to sclerosant agent, with local infection at the site of area of sclerotherapy, and pregnancy in the first trimester and after the 36th week of gestation were excluded.

Every patient referred with varicosity of the lower limb was explained different modalities of treatments (sclerotherapy and invasive surgical methods). After a full discussion of the available options to the patients and based on their requirements, ultrasound guided foam sclerotherapy selected by most of the patients. After history and clinical examination of the patients' routine investigations and duplex scan for varicose veins were done.

Mapping and drawing the venous network on skin was done to choose the site(s) of injection; and to decide the section to be sclerosed. The skin sensitivity of sclerosant was done before the use of drug. Foam was made by connecting two 5 ml syringe to a three way and using 1 ml of 1% or 3% polidocanol sclerosant with 4 ml of air, leg was elevated about 45° and foam was introduced under ultrasound guidance in to the vein. Maximum of 2 ml foam was injected per cannula. To increase the venous flow of the lower limb the patient was asked to plantar and dorsiflex the ankle. Maximum 15-20 ml foam was used in a single session. After completing the foam injection, all cannulas were removed and Bandage and grade 2 medical stockings were applied to the limb for 24 hours. Too much pressure was avoided to prevent any vascular compromise to leg. Patient was advised stocking or compression bandage while walking, running and was advised limb elevation in night. After 3 days the compression bandage was removed and looked for any residual varicosities and complications. All patients were followed up at 3 days, 1 month, 3 month and 6 months after treatment. During follow up the complete examination was done and reviewed in the terms of symptoms, varicosities, presence of any complications and signs of deep vein thrombosis. Repeated duplex scan was performed at each follow-up visit. Occlusion of the treated vein was assessed by a lack of compressibility and the absence of any flow.

Statistical data was analysed by statistical package for the social sciences (SPSS) version 20 software.

RESULTS

In the present study, total 50 patients of varicose vein were treated with ultrasonography guided foam sclerotherapy. Out of 50 patients, majority cases of varicose vein were in the age group of 41 to 50 years (42.0%) followed by 31 to 40 years (28.0%). Mean age of patients was 41.3±9.97 year (Table 1).

Table 1: Age wise distribution of patients.

Age group (year)	Frequency	Percentage (%)
21 to 30	7	14.0
31 to 40	14	28.0
41 to 50	21	42.0
51 to 60	8	16.0
Total	50	100.0
Mean±SD	41.3±9.97	

Total 56.0% patients were male and 44.0% patients were female with male to female ratio was 1.27:1 (Table 2).

No any patients had associated morbidity such as diabetes, peripheral arterial diseases and other illness.

Table 2: Gender wise distribution of patients.

Gender	Frequency	Percentage (%)
Male	28	56.0
Female	22	44.0
Total	50	100.0

Majority of patients had complaints of pain (28, 56.0%), followed by itching (17, 34.0%), dilated veins (13, 26.0%), heaviness (9, 18.0%) and swelling (6, 12.0%). One patient had venous ulcer of 2×2 cm on medial side of left leg. It was managed by normal saline dressings. All patients required oral analgesics. In half of the patients 25 in number (50.0%), right lower limb was treated and in 20 patients (40.0%), left lower limb was treated. Bilateral varicose vein was treated in only 5 patients (Table 3).

Table 3: Distribution of varicose patients based on the type of presenting complaints.

Symptom	Frequency	Percentage (%)
Pain	28	56.0
Itching	17	34.0
Dilated vein	13	26.0
Heaviness	9	18.0
Swelling	6	12.0
Ulcer	1	2.0

*Multiple symptoms were observed in patients

Incompetent perforators were observed below knee (17, 34.0%), calf (16, 32.0%) and above ankle (2, 4.0%). Multiple incompetent perforators were seen in 4 patients (8.0%). Nine patients had multiple thread veins. Multiple superficial varicosities along with great saphenous vein were observed in two patients (Table 4).

Table 4: Incompetence observed on colour Doppler.

Color Doppler study	Frequency	Percentage (%)
Below knee incompetent perforator	17	34.0
Calf incompetent perforator	16	32.0
Ankle incompetent perforator	2	4.0
Multiple incompetent perforators	4	8.0
Multiple thread veins	9	18.0
Multiple superficial varicosities along GSV	2	4.0

Total 37 patients were treated with 3.0% of polidocanol. Rest 13 patients (26.0%) were treated with 1.0% of polidocanol. Six (12.0%) and eight patients (16.0%) received three and four sessions of sclerotherapy respectively (Table 5).

Table 5: Concentration of polidocanol, duration and number of sessions required for the procedure.

Concentration	Frequency	Percentage (%)
3.0%	37	74.0
1.0%	13	26.0
No. of sessions		
1	16	32.0
2	20	40.0
3	6	12.0
4	8	16.0

On first follow-up visit after 3 days, all varicose veins were better sclerosed than previous condition. After 1 month, 41 patients (82.0%) achieved complete occlusion and in 5 patients (10%) partial occlusion was seen. Cord like structure was felt in 3 patients (6%) and were given oral tablet amoxycillin. Residual perforator was seen in one patient (2%) and was treated with 1% polidocanol. After 3 months, 47 patients (94%) achieved complete occlusion without any symptom and three patients (6.0%) had partial occlusion. At the end of 6 months 48 patients (96.0%) achieved complete occlusion without any symptoms. Two patients who had partial occlusion at 6 months were followed up at 12 months and partial occlusion was found in them (Table 6).

Table 6: Condition of varicose vein during 6 month follow up.

Condition of vein during	Frequency	Percentage (%)
3 days		
Better sclerosed vein	50	100.0
1 month		
Complete occlusion	41	82.0
Partial occlusion	5	10.0
Cord like structure	3	6.0
Residual perforator (failure)	1	2.0
3 months		
Complete occlusion	47	94.0
Partial occlusion	3	6.0
6 months		
Complete occlusion	48	96.0
Partial occlusion	2	4.0

Total 42 patients developed no complications after foam sclerotherapy. Four patients (8.0%) developed SVT which was treated with oral tablet amoxicillin, blurred vision in 3 patients (6.0%) was transient and managed conservatively and pain with redness at injection site was observed in one

patient (2.0%). All patients were given oral analgesic (Table 7).

Table 7: Distribution of patients according to complication.

Complication	Frequency	Percentage (%)
SVT	4	8.0
Blurred vision	3	6.0
Redness and pain	1	2.0
None	42	84.0
Total	50	100.0

DISCUSSION

In our study majority cases of varicose vein were in the age group of 41 to 50 years (42.0%) followed by 31 to 40 years (28.0%). Mean age of patients was 41.3±9.97 year. Total 56.0% patients were male and 44.0% patients were female with male to female ratio was 1.27:1.

Mishra et al conducted cross sectional study among 60 cases of varicose vein at D. Y. Patil Medical College Hospital and Research Centre, Pune, to seek a better knowledge about the epidemiology of the varicose vein and reported similar patient characteristics.[4] In their study, 70% of patients were males and 30% patients were females. Maximum patients were in age group of 45–54 years (21.7%). Madhu et al evaluated efficacy of ultrasound guided foam sclerotherapy with 0.5 ml sclerosant prepared as a foam by Tessari technique among 78 varicose vein patients at Mysore Medical College and Research Institute, Mysore.[5] Mean age was 48 years with 1.68:1 male to female ratio.

In the present study, majority of patients had complaint of pain (56.0%) followed by itching (34.0%), dilated veins (26.0%), heaviness (18.0%) and swelling (12.0%). One patient had venous ulcer of 2×2 cm on medial side of left leg.

Dwivedi observed similar pattern of complaints in his dissertation.[6] The chief complaint was pain (45.0%) followed by dilated vein (40.0%), ulcer (30.0%; healed-22.5%, active – 7.5%), swelling (15.0%), stasis dermatitis (15.0%), heaviness (7.5%), and recurrence (7.5%).[6]

In the present study, right lower limb was treated in half of the patients (50.0%), and left lower limb was treated in 40.0% cases. Both lower limbs were involved in 10.0% cases. This is in consonance with various studies with higher proportion of unilateral as compared to bilateral lower limb involvement in varicose vein. Mishra et al showed similar findings as 90.0% of patients had varicosities in one limb and only 10.0% cases had bilateral involvement.[4] Singh et al treated 185 limbs in 148 patients with foamed sclerosant.[7] Total 60.0% unilateral limbs and 40.0% bilateral limbs were treated by them.

In the present study, incompetent perforators were observed most commonly below knee (34.0%), calf (32.0%) and above ankle (4.0%). Multiple incompetent perforators were seen in 8.0% patients. Nine patients had multiple thread veins. Multiple superficial varicosities along with great saphenous vein were observed in 4.0% patients.

Mishra et al reported incompetent mid-thigh perforators in 36.7% patients, incompetent knee perforators in 68.3% patients, incompetent mid-calf perforators in 63.3% patients, incompetent ankle perforators in 61.6% patients.[4] Singh et al found saphenofemoral junction incompetence in 30.8% and saphenopopliteal incompetence in 22.1%, perforator incompetence in 11.4%, while combination of saphenofemoral junction with perforator incompetence and saphenopopliteal junction with perforator incompetence in 10.3% and 7.6% respectively.[7] Great saphenous vein varicosity was found in 47.0%, short saphenous vein varicosity in 29.2%. In the study of Dwivedi, great saphenous vein incompetence in 41.0%, saphenopopliteal junction incompetence in 2.4% was noted. None of patient had short saphenous vein incompetence.[6]

In the present study, 3.0% polidocanol was used in 74.0% patients and 1.0% polidocanol was used in rest of the patients (26.0%). Dwivedi used 3.0% of polidocanol injection (60 mg/2 ml) and all cases received foam sclerosant made by modified Tessari technique.[6] The choice of sclerosant appears to be based on its minimum concentration, complication profile, patient's allergy profile, pain tolerance and previous treatment response. It depends on the type, size and site of the veins to be injected, the doctor personal knowledge and experience.[8]

In the present study, all varicose veins were better sclerosed than previous condition at 3 days follow up. After 1 month, 82.0%patients achieved complete occlusion and partial occlusion in 10.0% patients. Cord like structure was felt in 3 patients (6%) and were given oral tablet amoxicillin. Residual perforator was seen in one patient which was treated with 1% polidocanol. After 3 months, 94.0% patients achieved complete occlusion without any symptom and 6.0% patients had partial occlusion. At the end of 6 months, 96.0% patients achieved complete occlusion without any symptom.

In the study of Gamal et al, total occlusion of great saphenous vein (GSV) was achieved in 92%, 96% and 98% of patients at 1 month, 6 months and 12 months respectively.[9] Partial re-canalisation without reflux was observed in 2%, 2% and 6% of patients at 1 month, 6 months and 12 months respectively. Partial re-canalisation with reflux was observed in 2%, 0% and 4% of patients at 1 month, 6 months and 12 months. Recurrence rate was 6% of patients at 1 year.

Madhu et al revealed full success with no reflux in 73% and partial success with reflux less than 1s in 21% cases.[5]

Failure was recorded in 6% patients. In the Tessari group, they found immediate success in 93.3% cases. In the study done by O'Hare et al the target vein occlusion rate was 93% by duplex scan at 2 weeks follow up and 74% by duplex scan at 6 month follow up.[10]

Thomasset et al reported that, with 3 months of follow up 79% of cases showed complete occlusion, 14% showed partial occlusion and the rest 6% showed complete patency.[11] Jia et al reviewed 69 studies and concluded that the median rate of target vein occlusion was 87% (range 60-98).[12] In another study done by Cabrera et al, 81% target vein remained occluded after 3 years or more.[13] Dwivedi revealed 93% full success and 7% had partial success.[6]

In the present study, 84% patients had no complication after foam sclerotherapy. Most common complication was superficial venous thrombophlebitis (8.0%) followed by blurred vision (6.0%) and pain with redness at injection site (2.0%). Complications were tolerable and transient and did not need any active intervention. No skin necrosis, wound infection, sclerosant induced ulcer, or neurasthenia was reported in our study because of constant guidance, use of cannula and dilute solution of sclerosant.

Singh et al, Gamal et al, and Madhu et al reported higher incidence of complications than the present study.[5,7,9] In the study of Singh et al, most common complication was superficial skin necrosis (3.8%) followed by, pain at injection sites (14.6%), superficial thrombophlebitis in injected vein (12.4%), and skin staining around injected veins (8.6%).[7] There was no recurrence at 1-year follow up.

In the study of Gamal WM et al, most common complication was pain at injection site (12.0%), hyperpigmentation (10.0%), thrombophlebitis (10.0%), telangiectasia matting (8.0%), headache (6.0%), DVT (2.0%) and pulmonary embolism (2.0%).[9]

Madhu et al observed pain at the injection site in 11.5% patients, thrombophlebitis in 21.0% cases.[5] Hyperpigmentation was seen in 17% cases which was reduced to 3.0%, with persisting hyperpigmentation on the calf.

Jiaet al showed pain (16.0%) and pigmentation (20.0%) were the two most important complications in foam group.[12] Thomasset et al showed skin discolouration in 30% patients, superficial thrombophlebitis in 16%, and allergy to the foam sclerosant in 2.5%.[11] Smith et al reported thrombophlebitis (5.0%), and calf vein thrombosis (1.2%).[14]

Myers et al also observed higher incidence of deep vein thrombosis (3.2%).[15] Bruising was noted in (6.0%) in this study which was less than other studies with ultrasonography guided foam sclerotherapy treatment (26–30%).[12,16]

Van den Bos reported 31% recurrence rate after 2 years.[17] Recurrences associated with ultrasonography guided foam sclerotherapy treatment varies from 4.9% to 40% but there were no recurrences seen in our study.[16,18-20] Following surgery, recurrence rates after 2-5 years vary between 20 and 50%.[21,22]

Deep vein thrombosis and thromboembolism after foam sclerotherapy is a very rare complication and reported in <1% of the patients.[12,15,16,23,24] No incidence of deep vein thrombosis was noted in the present study. It was found that using foam volume more than 10 ml in single limb resulted in 3-fold chances of deep vein thrombosis and increased production of endothelin-1 is associated with high chances of deep vein thrombosis.[25] Breu et al and Hamel-Desnos et al used maximum 10 ml of foam without any incident of DVT.[26,27] Incidence of superficial thrombophlebitis reported in different studies was found to be <15%.[16,28]

No case of anaphylaxis was recorded in our study. Bradbury et al reported allergy to the foam in 0.1% of patients.[20] Scurr et al, Brzoza et al and Guex et al reported single case of allergic reactions in their studies.[23,29,30]

Other systemic complications associated with ultrasound guided foam sclerotherapy were photopsia, transient ischemic attack, headache, chest tightness, and dry cough has been reported in <1% of the patients.[12,16,23] No such complications were noted in our study.

Cotton et al stated that both ultrasonography guided foam sclerotherapy and endovenous laser ablation resulted in a significantly quicker recovery compared with surgery for 13 of the 15 behaviours assessed.[31] Ultrasonography guided foam sclerotherapy was superior to endovenous laser ablation in terms of return to full-time work (hazard ratio 1.43, 95 % CI (1.11 to 1.85), looking after children (1.45, 1.04 to 2.02) and walks of short (1.48, 1.19 to 1.84) and longer (1.32, 1.05 to 1.66) duration.

Brittenden et al conducted multicenter trial comparing foam sclerotherapy or laser treatment with surgery for the treatment of primary varicose veins, quality-of-life measures at 6 months did not differ substantially between groups.[32] However, patients treated with foam had moderately worse outcomes on a measure of disease-specific quality of life than did those who underwent surgery.

Figueiredo et al showed the obliteration rate of 78% in foam sclerotherapy group and 90% in surgery group after 6 month of follow up.[33] A recent meta-analysis reported the outcome of 13 studies of surgery and 10 studies of USGF with an average follow-up of 32.2 months.[17] The estimated pooled success rates were 77% (69-84%) for USGF and 78% (70-84%) for surgery. It was concluded that foam sclerotherapy was as effective as surgery.[9] However, Brittenden et al documented that the frequency of completely successful ablation of great saphenous veins

was significantly higher among participants who were randomly assigned to surgery (84.4%) or laser treatment (83.0%) than among those assigned to foam treatment (54.6%, p<0.001 for both comparisons).[32]

The incidence of bruising with saphneous venous stripping was found to be 25–30% reported in different other studies.[34,36] After radiofrequency ablation, it is about 13–27% and after endovenous laser ablation, it is 11–15%.[34-37] According to Kalodiki et al and Shadid et al surgery is associated with the lesser incidence of pigmentation (5% and 1.1% respectively) in comparison to ultrasonography guided foam sclerotherapy (15% and 5.6%, respectively).[38,39] This would be decreased as per the learning curve. Brittenden et al also documented that there were no significant differences between groups in the number of serious adverse events.[32] The frequency of any procedural complications was lower in the laser group (1.0%) than in the foam group (6.2%) or the surgery group (7.1%) (p<0.001 for both comparisons). At 6 weeks and 6 months, the frequency of overall complications predominantly lumpiness and skin staining were greatest in the foam group

Limitations

Limitations of this study include the fact that it is based on patients recruited from a single setting. our sample size may not be adequate to determine potential confounders.

CONCLUSION

Ultrasound guided foam sclerotherapy is safe and effective in obliterating varicosities of lower limb veins including perforators using polidocanol as sclerosant agent. It has less complication and low recurrences with good cosmetic outcome.

Study recommends ultrasound guided foam sclerotherapy to be first line of treatment for multiple small varicosities, isolated perforator, remnant varicosities. It is also treatment of choice for recurrent varicosities. It should be offered to patients as an alternate treatment of choice for large varicosities.

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