

Comparison of Efficacy of Foam Sclerotherapy with and without Ultrasound Guided for the Treatment of Varicose Veins

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ABSTRACT

Objective: To compare the efficacy of foam sclerotherapy with and without ultrasound guided (Palpatory method) in the treatment of great saphenous and tributary varicose vein.

Place & Duration of Study: This Randomized controlled trial was conducted at Vascular surgery department, CMH Lahore during June to December 2023.

Methodology: Patients were enrolled and randomly divided in two equal groups. In group A, foam sclerotherapy was performed under ultrasound guidance. In group B, foam sclerotherapy was performed without ultrasound guidance. Duration of procedure was noted. Total number of sessions to achieve complete thrombosis of great saphenous vein, number of pricks required to achieve a successful cannulation, Post-procedure bruises, deep venous thrombosis and extravasation of foam were examined. All the data was recorded in proforma. Data was entered into SPSS version 25.

Results: The mean age of patients was 42.72 ± 14.01 years in group I (ultrasound guided procedure) and 43.69 ± 13.19 years in group II (conventional treatment for varicose veins). In group I, all were males (100%) while in group II, there were 31 (96.9%) males and 1 (3.1%) was female. In group I, the mean time for procedure was 6.47 ± 1.22 minutes and in group II, mean time for procedure was 7.59 ± 1.36 minutes ($p < 0.05$).

Conclusion: Ultrasound guided method is more appropriate and as better outcomes than conventional treatment. Now in future, we will use ultrasound guided treatment of varicose veins.

Keywords: efficacy, foam sclerotherapy, ultrasound guided, Palpatory method, great saphenous vein, tributary varicose vein

INTRODUCTION

The varicose veins are the swollen, coiled blood vessels which are located in the subcutaneous tissues of the limbs particularly the legs where they maybe observed readily. It is a problematic state when they are present in large numbers. (1) Varicose veins is a chronic disease related to venous system and affecting the lower limbs. It is dilation of about 3 to 4 mm in diameter of the subcutaneous veins. Different types of this disease are reticular, telangiectasia and trunk veins. It may produce shooting, sore, aching pains, throbbing pains, night cramps, and sheer leg fatigue. (2, 3) Diagnosis of Varicose veins include detailed history and clinical examination with the help of diagnostic tests to assess the severity of venous conditions and inefficiencies are duplex Doppler test, duplex ultrasound imaging, thermography, phlebodynamometry, angiography or capillaroscopy. (4, 5)

The majority of the patients can be managed by a proper explanation and calming down and by a number of therapies, which are developing rapidly during the mentioned time span. (6) Sclerotherapy is the direct chemical destruction of a varicose vein via injecting into the vein a liquid or foam sclerosant. Intradermal subcutaneous and or transfascial (perforator) veins of the lower limbs are treated by this method as well as epi, supra and subfascial vessels with venous malformation affecting the lower limbs. (7, 8) It leads to the destruction of the endothelial lining of the vein; and possibly, other areas of the wall of the vein where the sclerosant is activated but deactivated by the components of blood and circulating cells. After a successful sclerotherapy, the varicose vein is in the long run turned into a chain of tissue connection, a process being sclerosis. (9) Injection sclerotherapy (liquid or foam) is a commonly used technique for the management of varicose veins with a view of converting it into fibrotic cord. However, there is a lack of sufficient literature concerning its efficacy and safety among individuals with a more severe form of the illness. (10)

Foam sclerotherapy is one of the ways through which varicose veins and spider veins can be removed through a minimal invasive procedure. This regards employing a foam sclerosant inside a blood vessel in a way that the lining of the vein is damaged and scarred. (11) The foam solution leads to vocational

contraction of the vein of interest and a larger quantity of the chemical compound can be administered without using a large measure of sodium tetradecyl sulphate solution. (12) There is a recirculation of the blood through healthier veins thus experiencing a comparatively normal blood flow. (13) Aim of this study was to compare the efficacy of foam sclerotherapy with and without ultrasound guided (Palpatory method) in the treatment of great saphenous and tributary varicose vein. This would aid the surgeons to perform foam sclerotherapy even without the ultrasound guidance as both methods are equally effective. This would also help the general surgeons to manage the varicose veins independently without the color Doppler Ultrasonography.

METHODOLOGY

This Randomized controlled trial was conducted at Vascular surgery department, CMH Lahore during June to December 2023. The sample size of 64 was calculated by using the W.H.O. sample size calculator after setting confidence level at 95%, margin of error at 7% and Percentage of efficacy of foam sclerotherapy as 92% (14) by using following formula:

$$n = \frac{z_{1-\alpha/2}^2 P(1-P)}{d^2}$$

All the patients with primary varicose veins of either gender, who are above 18 years of age BMI < 27 kg/m² were enrolled in the study. Patient with arterial vascular diseases, already received interventions before current presentation, diagnosed with deep venous thrombosis were excluded from the sample.

The patients who fulfilled the above stated selection criteria were enrolled in the study by applying Non-probability, consecutive sampling technique. Patients were enrolled from OPD. Informed consent was taken after explaining them the pros and cons of research project. Basic demographics including name, age, gender, BMI, duration of veins, site of veins, occupation, standing hours, working hours, life style, socioeconomic status, etc. were noted. Then patients were randomly divided in two equal

groups by using random number table. Random number table was generated in Microsoft excel and list was saved for future use. In group A, foam sclerotherapy was performed under ultrasound guidance. In group B, foam sclerotherapy was performed without ultrasound guidance. Duration of procedure was noted. Total number of sessions to achieve complete thrombosis of great saphenous vein, number of pricks required to achieve a successful cannulation, Post-procedure bruises, deep venous thrombosis and extravasation of foam were examined. All the data was recorded in proforma.

Statistical Analysis: Data was entered into SPSS version 25. Quantitative variables were presented as mean and standard derivation and were compared in both groups by using independent samples t-test. Qualitative data was presented in terms of frequency and percentage and group comparison was done using chi square test. P-value ≤0.05 was regarded as significant.

RESULTS

In this study, total 4 patients were enrolled and underwent treatment for varicose veins. Patients were equally randomized to two groups having mean age of 42.72 ± 14.01 years in group I (ultrasound guided procedure) and 43.69 ± 13.19 years in group II (conventional treatment for varicose veins). In group I, all were males (100%) while in group II, there were 31 (96.9%) males and 1 (3.1%) was female. In group I, the mean BMI of patients was 25.30 ± 2.30 kg/m² and in group II was 25.66 ± 1.12 kg/m². In group I, great saphenous vein was involved in 20 (62.5%) cases, short saphenous vein in 3 (9.4%) cases and both systems were involved in 9 (28.1%) cases. In group II, great saphenous vein was involved in 27 (84.4%) cases, short saphenous vein in 0 (0%) cases and both systems were involved in 5 (15.6%) cases. In group I, clinical severity level C2-C5 was observed in 24 (75.0%) cases, from C6-C9 in 4 (12.5%) cases and from C10-C13 in 4 (12.5%) cases. In group II, clinical severity level C2-C5 was observed in 32 (100%) cases, while severity level C6-C13 was absent in all cases in group II. Table 1

Table 1: Baseline Features of Patients Enrolled (n = 64)

	Ultrasound guided	Conventional treatment
N	32	32
Age (in years)	42.72 ± 14.01	43.69 ± 13.19
Gender		
Male	32 (100%)	31 (96.9%)
Female	0 (0%)	1 (3.1%)
BMI (kg/m ²)	25.30 ± 2.30	25.66 ± 1.12
System involved		
Both	9 (28.1%)	5 (15.6%)
Great Saphenous Vein	20 (62.5%)	27 (84.4%)
Short Saphenous Vein	3 (9.4%)	0 (0%)
Clinical severity		
C2-C5	24 (75.0%)	32 (100%)
C6-C9	4 (12.5%)	0 (0%)
C10-C13	4 (12.5%)	0 (0%)

In group I, the mean time for procedure was 6.47 ± 1.22 minutes and in group II, mean time for procedure was 7.59 ± 1.36 minutes. Group I showed significantly less time for procedure (p<0.05). In both groups, prick was done in first attempt. In group I, out of 32 patients, 10 (31.3%) patients required another session for resolution of varicose veins. While in group II, out of 32 patients, 8 (25.0%) patients required second session. Although both groups did not show significance (p>0.05). Bruising was noted in ultrasound guided cases (56.3%) than group II while deep venous thrombosis was more common in group II i.e. 0% vs. 46.9%, p<0.05). Contrast extravasation was noted in 1 (3.1%) case in group I. No lost to follow-up was reported. Complete occlusion in great saphenous vein was noted in 18 (56.3%) cases in both groups (p>0.05). Table 2

Table 2: Comparison of Both Groups for Outcome (n = 64)

	Ultrasound guided	Conventional treatment	p-value
Time of procedure (min)	6.47 ± 1.22	7.59 ± 1.36	0.001
Number of pricks			
1 st	32 (100%)	32 (100%)	>0.999
Second session	10 (31.3%)	8 (25.0%)	0.578
Bruising	18 (56.3%)	0 (0%)	0.000
Deep venous thrombosis	0 (0%)	15 (46.9%)	0.000
Contrast extravasation	1 (3.1%)	0 (0%)	0.313
Lost to follow-up	0 (0%)	0 (0%)	>0.999
Great saphenous vein occlusion			
Complete	18 (56.3%)	18 (56.3%)	>0.999
Partial	14 (43.8%)	14 (43.8%)	

DISCUSSION

Varicose diseases of the lower extremities refer to diseases that affecting the great saphenous vein and the main trunk and branches of the small saphenous vein and etc, which can be common clinical diseases with an incidence that may be as high as 25%. (15, 16) In previous clinical treatment experience regarding varicose veins, the traditional treatment is mainly surgical treatment, including high ligation and stripping of the great saphenous. The risks of the surgical treatment of fistula, wound contamination, bleeding, slow recovery, and tendency for the fistula to reoccur (17, 18). While in the recent years, due to the advancement in tools such as sclerosing agents and endoluminal radiofrequency closure, clinical work shifted towards minimally invasive therapy which has less impact and facilitates quick recovery, higher effectiveness, and low complication rates. Nonetheless, there are few prior reports describing the combination of US-guided foam sclerotherapy together with EL-RFA treatment in patients with varicose veins. (19-21)

Thus the study by Verma et al., showed that on average the procedure time for cardiac operations was 103. The average operating time in MA group was 2 min and in foam group was 29 min and statistically significant (p < 0. 001). Obesity comorbidity complications in both groups were essentially the same. mean hospital stay was 31 hours in surgery and 2 (p <0. 001) in foam group. It is evident from the tabulation that both the groups depict 100 percentage obliteration on colour duplex at 1month post treatment with 0% pathological reflux. The mean time to resume normal activities was 9. 4. 88 ± 0. 98 days in surgery and 1 (p <0. 001) days in foam group. Average daily dosage of the analgesic was 4. 46 days in surgery and 0 conservatory days Majority of the patients (77%) had surgery on Monday to Friday while the remaining 23% had surgery on Saturday and Sunday. 46 in foam group. (22) Elmadany et al. , concluded that as per the aesthetic point of view, maximum improvements were registered (p < 0. 001) after the interventions. According to the findings of the researcher, ultrasound guided foam sclerotherapy appeared to be safe and effective for the treatment of chronic venous insufficiency in the chosen sample of patients. (23) The two also applied Ultrasound guided foam sclerotherapy applying the two needle method applying sodium tetradecyl sulphate. However, the studies showed that using this method veins were closed completely with a single injection of the sclerosant at 1 month follow up in 89 percent. 5% legs. One of the legs (5,3%) was injected one more time and 5. Of the 100 respondents, 3% who required the leg said that they had to be given two injections. (24)

Kakkos et al, in a trial utilised the Tessari method in the generation of foam and utilised 3% sodium tetradecyl sulphate in generating the foam up to a level of 6 ml per session in the ultrasound control. This reasoning gave them the notion that A, SC single sclerotherapy session was sufficient in 26 (58 %) legs. In 87 percent of all legs, complete elimination of not only varicose veins but all reflux points was observed. More sclerotherapy sessions [median 2 (1–2)] were done in legs with IRSFJ/GSV or AGSV (n=16) for complete varicose vein elimination than in legs with other primary reflux sites [median 1 (1–2), p = 0. 12]. They stated

that ultrasound-guided foam sclerotherapy in most patients seems to be as safe as other treatments and has a good immediate outcome in recurrent varicose veins. (25) In our study, the patients in both groups had equal distribution of great saphenous vein occlusion and complete obliteration observed in 18 (56. 3%) cases: $p > 0$.

Bruising was seen in 56. 3 percent in US guided cases than group II and deep venous thrombosis was seen in group II i. e. 0percent vs 46 percent. 9%, $p < 0. 05$). The absence of other complications, including but not limited to deep venous thrombosis or pulmonary embolism, in the sample corresponds to other studies in the medical literature. (26) Health-related quality of life improves after superficial venous surgery for varicose veins, but the effect of ultrasound-guided foam sclerotherapy on Health-related quality of life is unknown. So further trial should be done regarding this issue.

CONCLUSION

Ultrasound guided method is more appropriate and as better outcomes than conventional treatment. Now in future, we will use ultrasound guided treatment of varicose veins. Still further trials are warranted in order to confirm the above findings with larger sample size and prolonged follow-up.

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