

Ultrasound guided foam sclerotherapy in Varicose veins – Is it necessary?

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Abstract: Varicose veins affect up to 25% of women and 15% of men in the western world³ and incidence is apparently low in India.⁴ Male preponderance was observed with male to female ratio 14:1 in Indian scenario.⁵ Sclerotherapy involves the injection of a sclerosing agent directly into the superficial veins. The most commonly used is sodium tetradecyl sulphate. The direct contact with detergent causes cellular death and initiates an inflammatory response, aiming to result in thrombosis, fibrosis and obliteration (sclerosis). Blood deactivates the action of the sclerosing agent and the doses administered need to be limited to avoid adverse effects, causing a trade-off between poor efficacy and safety.¹¹ In this study outcomes of non usg guided injection sclerotherapy were studied and analyzed among patients coming to RIMS, Ranchi which is a tertiary care centre in Jharkhand. A total of 50 cases who underwent non usg guided foam sclerotherapy were studied out of which, all had obliteration of Varicose Veins. The secondary outcomes were symptomatic improvement, ulcer healing, recurrence, and adverse events. Adverse effects were pain (86%), pruritis (32%), swelling (14%), thrombophlebitis (16%) and skin ulceration (2%). Complete obliteration was achieved after one injection in all cases. Thrombosis and neurologic events were not seen. Hence, Foam Sclerotherapy, even non USG guided, appears to be a safe and effective outpatient therapy for the treatment of Varicose Veins and hence can be used even in set-ups lacking the facility of USG.

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I. Introduction

Varicose veins are common and are present in at least 10% of the general population.¹ The findings of varicose veins may include dilated and tortuous veins, telangiectasias, and fine reticular varicosities. Risk factors for varicose veins include obesity, female sex, inactivity, and family history.² Chronic venous insufficiency (CVI) is a common and under-recognized problem, affecting greater than 20% of the general population.³ Varicose veins (VVs), the most common manifestation of CVI, affect up to 25% of women and 15% of men in the western world³ and incidence is apparently low in India.⁴ Male preponderance was observed with male to female ratio 14:1 in Indian scenario.⁵ While Varicose Veins have traditionally been regarded as simply a cosmetic problem, more commonly they produce symptoms of heaviness, fatigue, pain, swelling, restlessness, burning, and itching.^{6,7} Varicose Veins are associated with a number of complications including spontaneous varix rupture with hemorrhage, superficial thrombophlebitis, deep vein thrombosis (DVT), and venous ulceration.⁷ Venous ulcerations are particularly troublesome for the patients since many may take more than 9 months to heal, with 66% lasting more than 5 years.⁶

Traditional treatment modalities for varicose veins include conservative measures using external compression therapy and, if unsuccessful, surgical ligation and stripping of varicose veins and incompetent deep perforating veins. While surgical treatment of varicose veins has proven effective, it has fallen out of favor due to high cost, time away from work, and procedural complications of wound infection, hematoma, and nerve paresis.⁸ More recently, percutaneous interventional therapies including endovenous laser therapy (EVLT), radiofrequency ablation (RFA) followed by microphlebectomy, and chemical sclerotherapy using foam have become available for outpatient treatment of varicose veins.⁷ A valuable treatment for primary varicose veins should be minimally invasive and capable of being used on primary and recurrent varicose veins so that it can be repeated as required. There should be few significant complications and the treatment should have good efficacy in abolishing venous reflux in saphenous trunks, perforating veins and varices.⁹ The treatment should be accomplished at little cost and be capable of achieving both functional and cosmetic improvement with little time away from the patient's usual occupation.¹⁰ Sclerotherapy is the original non-endothelial, non-tumescent technique and has been performed for over 100 years. It involves the injection of a sclerosing agent directly into the superficial veins.¹¹ Despite the availability of endovenous foam sclerotherapy (EFS) for the obliteration of varicose veins since 1944 and widespread use within the US, there is no commercial foam product available, and the use of this procedure in the US is not FDA-approved.¹² Moreover, few studies in the US have systematically evaluated the efficacy of this procedure in a large series of patients.¹³

The procedure commences with the patient standing and the sites of venous cannulation are selected. With the patient supine, the major venous trunks and superficial varicosities to be treated are then all cannulated. Once all injection sites are cannulated the foam can be prepared. The most widely used method is that of Tessari, which utilises two syringes connected using a three-way tap. A 1:3 or 1:4 ratio mixture of sclerosant and air is drawn into one syringe, and is then oscillated vigorously between the two syringes about 10 or 20 times. The foam produced in this way is stable for about 2 minutes so it should be injected as soon as it has been made.¹¹ Elastic bandages are wrapped around the leg after injection and worn continuously for 3 to 5 days to produce apposition of the inflamed vein walls and prevent thrombus formation. After the bandages are removed, elastic compression stockings should be worn for a minimum of 2 weeks. Complications from sclerotherapy include allergic reaction, local hyperpigmentation, thrombophlebitis, DVT, and possible skin necrosis.¹⁴ This study aims to see the effects of non usg guided injection sclerotherapy, though usg colour Doppler were performed earlier, before the procedure.

II. Material And Methods

This cross sectional descriptive study was carried out on patients of Department of CTVS at Rajendra Institute of Medical Sciences, Ranchi from December 2018 to May 2019. A total 50 patients were included in this study.

Study Design: Cross sectional descriptive study

Study Location: This was a tertiary care teaching hospital based study done in Department of CTVS, at Rajendra Institute of Medical Sciences, Ranchi, Jharkhand.

Study Duration: December 2018 to May 2019.

Sample size: 50 patients.

Data Collection – A pretested semi structured questionnaire was used to collect the relevant data and other observations. Patient satisfaction after completion of the procedure was asked at the time of discharge. A Likert score scale was used to rate his satisfaction regarding the treatment received was taken with a maximum score of five, starting from one.

Data analysis – Data thus collected was entered on excel template using MS Excel and analysis was done using SPSS version 22.0. Measure of central tendency like mean, mode etc and appropriate statistical tests like Chi square, ANOVA, Logistic Regression analysis were done to interpret the results.

Inclusion criteria:

Willing Patients of Varicose veins with perforator incompetence having-

1. Below knee perforator incompetence
2. Competent Saphenofemoral and saphenopopliteal junction

Exclusion criteria:

1. Patients with SFJ and SPJ Incompetence.
2. Patients with associated DVT.
3. Above knee Perforator Incompetence.
4. Varicose veins with ulcer.

Procedure methodology

As the patients came with varicose veins to the OPD, they were explained about the study and if they were willing to be part of the study, a well-designed questionnaire was used to collect the details of the patients which included name, registration number, socio-demographic characteristics such as age, gender, nationality, religion and occupation. Complaint with duration was asked and detailed history and general examination was done with routine investigations and Colour Doppler of lower limbs were done to know the cause of varicosity. After the procedure, patients were prescribed Tab Daflon 1g OD and called for follow up after 3 weeks and their phone numbers were also taken. Patients were encouraged to report any complications following the procedure while being enquired from the department on phone.

III. Result

The sample size of the study was 50, out of which 47 (94%) were male and 3(6%) were female patients. Thus majority of cases were males with male:female ratio of 47:3.

Primary effect – Obliteration of varicosity occurred in all patients.



Picture showing varicose veins before and after the injection of foam sclerotherapy

Secondary effects -

1. Symptomatic improvement – Symptoms such as heaviness of limb, itching etc were relieved in all cases of varicose veins post injection of foam.
2. Recurrence – Recurrence was seen in 2(4%) of the cases.
3. Adverse events-
 - (a) Pain - 86% of patients had pain post injection sclerotherapy which was the most common side effect seen.
 - (b) Pruritis – It was noticed in 32% of the cases.
 - (c) Swelling - 14% of the patients had swelling after injection sclerotherapy
 - (d) Thrombophlebitis – Superficial thrombophlebitis was noted among 16% of patients which eventually subsided after conservative management.
 - (e) Skin ulceration – This complication was seen in one patient (2%) whose ulcer however healed subsequently.

IV. Discussion

This hospital based study showed the incidence of the disease about sixteen times higher in males than their female counterpart. The male:female ratio was 47:3 which is much higher than the western world. In a study done among north Indian population, 46.7% of females and 27.8% of males were found to be having varicose veins whereas 49.3% of females and 18.9% of males were having venous symptoms.¹⁵ In another study, the prevalence was 10% among men and 29% among women aged 15 and over; it rose with age in each sex.¹⁶ The incidence among females in another series was much low 7.14% as compared to the western counterpart⁵ similar to our study. Majority of males 127(74.7%) were found in another Indian study,¹⁷ similar to our result.

This study shows the effectiveness of non usg guided foam sclerotherapy in cases of varicose veins due to perforator incompetence. All patients had complete obliteration of varicosity in single injection. In a study 99% of patients achieved complete (65%) or near complete(34%) obliteration of their varicose veins after the initial injection.¹⁸ In our study, pain was the commonest complication (86%) followed by pruritis (32%), swelling (14%), superficial thrombophlebitis (16%) and skin ulceration (2%). Complications such as Deep vein thrombosis (DVT) and neurological complications were not seen. These results are comparable to those achieved with surgical or other interventional endovascular procedures¹⁹⁻²⁴, however foam was injected under usg guidance in earlier studies. We used USG Colour Doppler before the procedure and not during the procedure, making it useful for treatment even in periphery, where USG may not be available always.

Our study has limitations too. Sample size was small and thus results cannot be generalized on the basis of this study. A larger sample size is required to generalize the findings. Further, this study was not a randomized trial but included a consecutive cohort of patients in a closed practice who underwent foam sclerotherapy at department of cardiothoracic and vascular surgery, Rajendra Institute of Medical Sciences , Ranchi during a defined period of time. Still, as we performed the injection sclerotherapy procedure with great precision and correct technique even without using USG guidance during the procedure, we did not see major complications like DVT or neurological deficits, making it a safe procedure.

V. Conclusion

Foam Sclerotherapy, even without USG guidance done with appropriate technique, appears to be a safe and effective outpatient therapy for the treatment of Varicose Veins and hence can be used routinely, though USG Colour Doppler is required beforehand. Hence, the procedure is useful in setups where facility of USG is not available, making it feasible in paripheries also.

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