Safety And Feasibility of Outpatient Treatment of Varicose Veins With Foam Sclerotherapy: A Prospective Study

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Abstract : Varicose veins of lower limbs instead of conducting blood upwards, back to heart, conduct blood downward in reversed fashion, back to foot. The management depends on the severity and whether the deep system is involved or superficial system is involved. The authors have treated 100 patients of varicose veins using foam sclerotherapy with good results and without any significant complications.

Keywords: Varicose veins, Foam sclerotherapy, OPD treatment

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I. Introduction

Varicose veins are dilated, elongated and tortuous veins which occur in several locations of body.¹ It is estimated that at least 10% of the world's population has varicose vein in the lower extremities.² The pathophysiology of varicose vein is probably related to defective connective tissue and smooth muscle in the vein wall leading to secondary incompetence of the valves rather than to a primary defect in the valves, which occurs in a small subgroup of patients.³ Varicose veins are managed according to severity of disease. For the management of small varices, sclerotherapy is a safe OPD procedure and thus no need for admission. In the present study the authors have used foam sclerotherapy on OPD basis in patients of varicose veins.

II. Methods

The study was conducted in 100 patients of varicose veins presenting to the outpatient department of our institute. A careful history regarding various symptoms of the disease and especially about any history of allergic reaction was taken. A thorough clinical examination with routine laboratory investigation was performed in all the patients. Patients were classified as per CEAP classification. Doppler examination was done to rule out saphenofemoral and saphenopopliteal incompetence. Patients having varices, clinically having C1 and C2 or residual varicose veins (after operation for varicose veins) were included in the study. The patients who had deep venous thrombosis or having saphenofemoral and/or saphenopopliteal incompetence were not taken for the study. The sclerosant used was Sodium Tetradecyl Sulphate which is available in the market as 2ml or 3ml ampoules of 3% concentration. Foam was prepared by Lorenzo Tessari, s Tourbillon technique. Two plastic disposable syringes were connected by a three way stopcock. The foam was prepared by mixing the liquid sclerosant with 4 or 5 parts of air, through 20 passes between the two syringes with hub at a 30 degree rotation. The prominent veins were marked with the patients in standing position and needle of the syringe containing foam was inserted in the vein after taking full aseptic precautions. The syringe was secured with tapes. Then the patient was asked to lie down and elevate the leg and the foam was injected in the vein. After injection, crepe bandage was applied and the patient was allowed to walk for few minutes so that the sclerosant got dispersed properly. Once the procedure was complete the patient was advised to be on regular follow up at 2 weeks, 6 weeks and 3 months. During this period the patients were clinically evaluated. At the end of the study, the data was collected, tabulated and analysed using Cochrane Q test and conclusions were drawn.

III. Results

This prospective study was conducted on 100 patients of varicose veins belonging to clinically C1 and C2 groups and residual varices after surgery, presenting to our institute. Mean age of patients in our study was 29.36 years and there were 46 males and 54 females. In our study, 43.5% males were sportsmen and 64.8% females were house-wives. Other occupations of patients were farmer, policemen, teacher and barber. Dilated or

prominent veins was the presenting symptom in 93 patients (93%). Out of 100 patients, pain in leg was present in 93 patients (93%). Thirty one patients (31%) were having residual varices after surgery. Duration of symptoms in our study varied from 3 months to 24 months. Maximum number of patients (83%) were having history of symptoms for the last twelve months. Forty patients (40%) presented with C1 severity while sixty patients (60%) had C2 severity. After foam sclerotherapy, patients were assessed clinically at two weeks, six weeks and three months. The observations made on follow-up were as depicted in table I.

Table I – observations in follow up period			
Follow up	2 weeks	6 weeks	3 months
Symptomatic relief	13	50	80
Pain	86	37	13
Reduction in size of varices	10	57	83
Pigmentation	76	46	13

Out of 20 patients who were not relieved symptomatically, 17 patients were having persisting veins while three patients was having pain at injection site. Seventeen patients who did not have disappearance of veins at three months, they were given second sitting of sclerotherapy and they improved symptomatically after this. Ulcer formation was seen in 10 patients (10%) at the site of injection possibly due to extravasation of foam. In eight patients ulcer healed in one month with antiseptic dressings while other two patients took three months for ulcer healing. No patient showed any evidence of deep vein thrombosis, visual disturbances, pulmonary embolism, migraine, dizziness, transient ischemic attack and epileptic fits in the present study.

IV. Discussion

Chronic venous disorder remains a common problem worldwide. Varicose veins are dilated and tortuous veins which permits reverse flow through its faulty valves.⁴ The patient with symptomatic varicose veins commonly reports heaviness, discomfort, and extremity fatigue. In earlier stages, the pain is characteristically dull, does not usually occur during recumbency or early in the morning, and is exacerbated in the afternoon, especially after periods of prolonged standing. Varicose veins are managed according to severity of disease either conservatively using elastic compression stockings and injection sclerotherapy for mild form of disease or by surgical intervention for severe form of disease. Now a days, minimally invasive procedures like RFA (Radiofrequency ablation) and EVLA (Endovenous laser ablation) are becoming more popular for the management of varicose veins in comparison to the surgery. For the management of small varices where the main long and short saphenous and their major tributaries are competent, sclerotherapy is a better treatment modality. For the last few years, there has been a revival of foam sclerotherapy. It was first described in 1939 by S.McAusland.⁵ Foam holds several advantages over traditional liquid sclerotherapy. Foam, displaces the blood allowing direct contact of the sclerosant with the endothelium. As a result, the efficacy of the sclerosant is increased hence a lower concentration can be given to treat varicose veins. In addition, a given volume of liquid can be used to produce four or five times its volume in foam, depending on the foaming method. This allows the use of a smaller total dose of sclerosant to achieve the desired effect.

The present study was done to evaluate the efficacy and safety of foam sclerotherapy in 100 patients of C2 grade with residual veins C1 and and varices after surgery varicose Mean age of patients in our study was 29.36 years. The various presenting complaints of varicose veins patients reported in literature are cosmetic reasons, tiredness and aching sensation particularly at the end of day, night cramps, heaviness in legs, ankle swelling, DVT, ulcer and eczema of legs etc. depending on the stage of disease.^{6,7} In almost all the studies including the present study, dilated and prominent veins was the commonest presenting symptom while other symptoms were present in variable percentage in different studies depending on the stage of disease.⁸⁻¹⁰ In the present study, maximum number of patients (83%) were having history of symptoms with duration of twelve months. The reason for maximum number of patients presenting within 12 months of complaints is the awareness among the patients and we included the patients with C1 and C2 grades of severity in our study.

Sclerotherapy is the targeted chemical ablation of varicose veins by injection of a lquid or foamed sclerosing drug. Different sclerosing solutions have been used to treat varicose veins in recent decades, depending on national regulations, national traditions, and the size of the veins to be treated. We used Sodium Tetradecyl Sulphate (STS). Sodium Tetra Decyl Sulphate is chemically a soap foam which when injected into the empty vein will result into an inflammatory reaction in the vein wall which in favourable circumstances will cause occlusion of the lumen of the vein and convert it into a fibrous cord incapable of recanalisation. After foam sclerotherapy, patients were assessed clinically at two weeks, six weeks and three months.

A well placed injection of sclerosant into the vein should not cause immediate pain but may be followed by a slight stinging sensation. A real pain after injection of sclerosant indicates intra-arterial injection.

In present study, only 13% of patients were complaining of pain at three months. Jia et al reported the median rate of pain at site of injection in 25.6% of patients.¹¹

In the present study, 80% of patients were relieved symptomatically and 83% of patients showed complete disappearance of varices after three months of foam sclerotherapy. Hamel-desnos et al, Belcaro et al and Martimbeau reported the complete disappearance of varices in 84.4%, 92.2% and 81% of patients respectively in their studies.¹²⁻¹⁴

Sclerotherapy is commonly followed by pigmentation overlying the knotty cord of occluded vein and this takes months to clear. For this reason sclerotherapy is often slow to give good cosmetic results and it is wise to caution the patients upon this. In the present study, 76% of patients were having pigmentation on follow-up at two weeks while pigmentation was present in only 13% at three months of follow up. Bountouroglou et al and Wright et al reported the incidence of pigmentation as 17.2% and 55.1% in their respective studies.^{13,14} This complication can be prevented by being perfect in the procedure during injection because this pigmentation occurs when the sclerosing agent had extravasated at the site of injections. So a proper technique is needed to avoid this complication. Seventeen patients (17%) were having recurrence at three month follow-up as they did not get any relief following sclerotherapy while ulcer formation occurred in only ten patients (10%). No patient showed any evidence of deep vein thrombosis. In our study none of the patients had anaphylactic shock or pulmonary embolism. Studies by Issacs, Schaedeck and Zummo have recurrences in 14.5%, 15.5% and 9.4% cases respectively.¹⁵ Present study had recurrence in 17% of patients.

Conclusions V.

Limitations of our study are the relatively small number of patients (100) and a short follow-up period (3 months). Long term follow-up is essential to see the effect of treatment of varicose veins as late recurrence is well described. It is less time consuming, is cost effective and patient is made mobile immediately after treatment. We found that Foam sclerotherapy is also an effective and safe procedure when performed without duplex guidance in small veins.

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