Efficacy of Foam Sclerotherapy for Treatment of Varicose Vein of Lower Limb

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Abstract: Varicose veins are defined by combination of permanently elongated and dilated vein/s whose path has become tortuous, inducing pathological circulation. After taking approval from local ethical committee and willful inform consent, foam sclerotherapy was offered to 50 patients, with 23 patients showed varicosity of both legs and 27 patients with varicosity of one leg. Our study showed obliteration of diameter of dilated vein achieved in 95.5% of patients, however some of them require additional one or two session of therapy. It is cost effective and with less complication than surgical procedure in the management of varicose veins.

Keywords: Varicose veins, Foam, sclerotherapy, lower limb.

INTRODUCTION

Chronic venous disease (CVD) of the legs is a common medical disorder and ranges in severity from minor asymptomatic incompetence of the venous valves to chronic leg ulceration. Varicose veins are defined by combination of permanently elongated and dilated vein/s whose path has become tortuous, inducing pathological circulation [1-3]. Several epidemiological studies of Chronic Venous Disease in various countries have been performed over the past several decades [4, 5]. The prevalence of varicose veins varies from 25% to 33% of females and from 10% to 20% of males in Western countries [4, 6, 7]. The reported variation in these data can be partially explained by the use of different definitions for varicose veins and venous disease, the inclusion of different age groups. There are no studies that indicate the epidemiology of chronic venous disease in India. Incidence of varicose vein in women is far higher than presumed in India, given the fact that a large number of rural populations do not report themselves for asymptomatic veins. It is estimated that venous leg ulceration, the end stage of Chronic Venous Insufficiency, affects 1% of the population at some point in their lives [8]. It is assumed that approximately 50% of venous leg ulcers are the result of varicosity of superficial venous system [9]. However, it is nearly impossible to predict which patient with varicose veins will eventually develop a venous leg ulcer. Important risk factor for varicose veins includes older age, female, family history, deep vein thrombosis [4, 6, 10]. Varicose veins can also occur in children and adolescents [11]. Prevalence of varicose veins increases with age in both sex [11,12].

Chronic venous disease of lower limb can affect both superficial and deep venous system, and patients may present with wide range of clinical conditions like telangiectasia, reticular veins, varicose vein, chronic venous insufficiency and chronic venous ulcer

Objectives

The aim of this study is to investigate efficacy of foam sclerotherapy for treatment of varicose vein of lower limb.

MATERIALS AND METHODS

Study area-Department of general surgery, Nalanda Medical College and Hospital, Patna, during the period December 2009 to September 2011.

Study population- Patients admitted in department of general surgery with varicose vein of lower limb

Sample design- simple random sample

Study design-randomised study.

Inclusion criteria

• Patients of any age attending surgical out-patient department with varicosity of one or both legs.
• Patients and family given willful consent to be included in trial and undergo foam sclerotherapy for treatment of varicose vein of lower limb.
• Failure of conservative management with compression therapy.
• Patients with advanced disease.
• Recurrent disease(after surgery)
Exclusion criteria
- Unwilling patients.
- Patients who are hypersensitive to sclerosants.
- Obliteration of deep venous system (e.g., following extensive previous deep venous thrombosis with no recanalization of deep veins).
- Arterio-Venous fistula of lower limb.
- Pregnancy
- Tumour in pelvis pressing on iliac veins.
- Saphenovarix or only saphenofemoral incompetence

Parameters to be studied
Primary outcome
Obliteration of varicose vein. Outcome will be defined as complete, when occlusion of saphenous trunk and/or over 80 percent of varicosities is achieved, and partial when less.

Secondary outcome
To assess clinical improvement of symptoms of chronic venous insufficiency, such as pain, swelling, ulceration

Tools
- 10 cc syringes
- 3-way cannula
- Sclerosant (injection 3% sodium tetradecylsulphate)
- Sterile Cotton ball
- i.v cannula (25G)
- 6" crepe bandage

Methodology
After taking approval from local ethical committee and willful inform consent, foam sclerotherapy was offered to 50 patients, with 23 patients showed varicosity of both legs and 27 patients with varicosity of one leg. 28 patients were of primary varicosity of great saphenous vein, 9 of primary varicosity of short saphenous vein, and 4 of incompetent perforators while 5 patients of recurrent varicosity of great saphenous vein, 2 of recurrent varicosity of short saphenous vein and 2 of recurrent incompetent perforators. All of them were presented with pain, while 26 patients presented with swelling and 13 patients with venous ulcer.

After detail history and clinical examination, each patient was evaluated by Duplex ultrasound examination of deep and superficial venous systems, all major truncal branches of venous system including the presence of incompetent perforating veins and patency of deep venous system. Diameter of veins at thigh and calf was measured at initial and subsequent examination at the time of foam sclerotherapy. Patients were treated in a Day care surgery unit as outdoor patient basis. Patients with bilateral disease only one leg treated at one time and other leg treated at least four weeks later.

Superficial dilated veins were cannulated with 25 gauge intravenous cannulas.

Depending on the size and length of vein to be occluded, sclerosant (sodium tetradecyl sulphate 3% percent) was taken in 10ml syringe and connected to 3-way stopcock which in turn connected with another syringe with 4 times amount of air. By repeated to and fro motion of solution and air into syringes minimum of 20 times, dense white foam was prepared (Tessari method)[13]. Each injection was limited to 2 ml aliquots to a total volume not exceeding 15 ml. The saphenous trunk was usually treated first, with the patient supine and the leg elevated 30degree. Elevation also had the effect of emptying the superficial varicose vein. Cannula removed after the foam injection.

Self-adhesive elastic bandages were applied over cotton wool pads at the site of the injected varicosities. An anti-thromboembolism stocking was then put on over the top.

Patients were allowed to go home and return to work on next day unless they had a particularly heavy job, when 2 or 3 days off work was advised. After 5 days, the bandaging was removed by the patient and the anti-thromboembolism stocking worn during the day for a further 4 weeks. Patients were warned to expect tender lumpiness and discoloration at the site of the injections.

Data were entered in MS excel spread sheet and analysed by standard statistical method. Categorical variables are expressed as Number of patients and percentage of patients and compared across the 2 groups using one sample t test for Independence of Attributes. An alpha level of 5% has been taken, i.e. if any p value is less than 0.05 it has been considered as significant.

RESULTS
Our study showed obliteration of diameter of dilated vein achieved in 95.5% of patients, however some of them require additional one or two session of therapy. Improvement of chronic leg symptoms like pain, swelling and ulceration were 88.6%, 96.2% and 92.3% respectively. No major side effects were noted in any of patients during or at the end of the one year of follow-up.

So from this study foam sclerotherapy showed an effective, safe form of treatment modality of primary as well as recurrent varicosity great and short saphenous vein. It is also effective for the treatment of incompetent perforators.

DISCUSSION
Since the introduction of the ultrasound technique in the early 1980s as a diagnostic device in
venous insufficiency, ultrasound-guided foam sclerotherapy has been used in the treatment of saphenous veins. Initially foam sclerotherapy was performed using liquid sclerosants. This therapy appeared to be efficient, safe, and inexpensive and exhibited no major side-effects.

This study addressed the efficacy of foam sclerotherapy in achieving the immediate technical objective of varicose vein occlusion as well as symptomatic relief of pain, swelling and ulceration. This was attainable in most patients with safety not only in great saphenous veins but in short saphanous veins and recurrent varicose veins as well.

**CONCLUSION**

Foam sclerotherapy is a minimally invasive procedure. It is cost effective and with less complication than surgical procedure in the management of varicose veins. Improvement of chronic leg symptoms of varicose vein after treatment with foam sclerotherapy is either comparable or more efficacious than surgical treatment. Recurrence rate of this procedure is also less and easily manageable. The results underline the efficacy of this technique not only for legs with great saphenous venous system involvement but also for those with other superficial venous system involvements.

The results shown here are still early with a small sample size, still, they are sufficient to say that foam sclerotherapy is a promising alternative for the management of varicose veins. We expect that Foam Sclerotherapy will play an important role in the treatment of varicose veins, possibly greater than that of surgical intervention. More Studies to compare these results with that of surgery in varicose veins are needed to be done, as foam sclerotherapy may really prove to be an excellent alternative to surgery with its comparable efficacy and better safety and cost profiles.

**REFERENCES**