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The role of sclerotherapy in the management of varicose veins

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Abstract

Varicose veins are dilated branches of the great saphenous vein and small saphenous vein; the incidence of varicose veins varies from 10% to 30%. Risk factors of varicose veins include family history, age, and pregnancy; a possible risk factor is standing for a long period of time. High ligation and stripping is the traditional approach for varicose veins, yet a variety of alternative options have been used in recent decades, such as endovenous laser ablation (EVLA), endovenous radiofrequency ablation (RFA), foam sclerotherapy (FS), or TriVex Surgery has been the most often used treatment for varicose veins. Sclerotherapy refers to introduction of sclerosing solution into the varicose veins, which causes endothelial damage and subsequent fibrosis. Sclerotherapy is being practised extensively by dermatologists in the west. However, there are no Indian studies which specifically evaluate the role of sclerotherapy in the management of varicose veins and its skin complications. Hence, this study aims to evaluate the efficacy of sclerotherapy in managing varicose veins and its complications.

Keywords: EVLA, sclerotherapy, varicose veins, skin complications

Introduction

Varicose veins can be defined as: superficial veins of the lower limb, which have permanently lost its valvular efficiency and as a product of resultant venous hypertension in the standing position become dilated, tortuous, and thickened. About 17-50% of patients with varicose veins may have cutaneous findings^[1]. Varicose veins may cause significant morbidity including stasis dermatitis, ankle oedema, spontaneous bleeding, superficial thrombophlebitis, recurrent cellulitis, lipodermatosclerosis and ulceration of the ankle and foot. Varicose veins and its related complications are commonly seen in the dermatology clinics^[2, 3]. Patients with varicose veins present from asymptomatic to significant symptoms, including discomfort, aching, pain, itching or eczema, and deep vein thrombosis (DVT). The diagnosis of varicose veins is based on clinical manifestation and ultrasound. Duplex ultrasound is considered the gold standard for diagnosis of superficial venous incompetence^[4]. The various modalities to treat varicose veins include surgery (stripping, ambulatory phlebectomy, high ligation), sclerotherapy and endovenous occlusion by lasers or radiofrequency. The indications for any of the treatments of varicose veins include: (a) prevention of complications; (b) relief of symptoms; and (c) improvement of cosmetic appearance^[5, 6].

Sclerotherapy refers to the introduction of a sclerosing solution into the lumen of a vessel producing endothelial damage, which leads to thrombosis and subsequent fibrosis. It has been extensively used by dermatologists in the management of superficial varicose veins and other venous abnormalities^[5, 6]. However, it has not been widely practiced in India. The search for more effective means of prevention and treating varicose veins and its complications continues and this study aims at establishing the role and efficacy of sclerotherapy in managing varicose veins and its dermatological complications.

Aims & objectives

To study the safety and efficacy of sclerotherapy in the treatment of varicose veins and its dermatological complications.

Materials & methods

This is a prospective study involving 50 patients with varicose veins and its dermatological complications attending the dermatology out-patient department.

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The study was conducted over a period of 18 months. After thorough clinical, laboratory, and radiological evaluation, the patients were treated with sclerotherapy using Sodium Tetradecyl Sulphate of various concentrations depending on the vessel size. The patients were then followed up to look for disappearance of veins, healing of ulcers and eczema, and any complications.

Inclusion criteria: The inclusion criteria for the study was patients older than 18 years with varicose, reticular and/or telangiectatic leg veins and having skin manifestations of varicose veins like eczema, ulceration, lipodermatosclerosis, etc.

Exclusion criteria: The various exclusion criteria for the study were (a) deep venous thrombosis; (b) saphenofemoral junction/saphenopopliteal junction incompetence; (c) pregnancy; (d) myocardial decompensation; (e) hypercoagulable state; (f) dependency edema; (g) arterial disease; (h) diabetes mellitus; and (i) any other serious illness. The following investigations were carried out before the procedure: (a) Complete hemogram; (b) Random blood sugar; (c) Coagulation profile; (d) Urine-albumin, sugar and microscopy; and (e) Venous doppler of involved limb.

Results

The study included 50 patients with primary varicose veins and its complications. In the study out of 50 patients, maximum number of patients, 20 (40%) were in the 31-40 years age group followed by 16 (32%) patients in the 41-50 years age group, next followed by 51-60 years age group and the least being in 20-30 years age group with 8% of patients.

Table 1: Age distribution

Age group	No. of cases	Frequency %
21-30	4	8%
31-40	20	40%
41-50	16	32%
51-60	10	20%
Total	50	100%

Out of the 50 cases included in the study, 30 (60%) cases were male with only 20 (40%) female patients. In the present study, the commonest presentation was that of dilated and tortuous veins. The other symptoms were (a) pain in the affected limb - 38 patients (76%); (b) eczema - 40 patients (80%); (c) oedema - 15 patients (30%); (d) ulceration - 15 patients (30%); (e) lipodermatosclerosis - 10 cases (20%); and (f) telangiectasia and atrophie blanche - 2 cases (4%).

Table 2: Symptomatic classification

Symptoms	No. of Cases	Frequency %
Pain	38	76%
Eczema	40	80%
Oedema	15	30%
Ulceration	15	30%
Lipodermatosclerosis	10	20%
Telangiectasia & Atrophic Blanching	2	4%

Great saphenous vein was most commonly affected, in 94% of individuals. Most cases were primary varicose veins without any prior surgery.

Table 3: CEAP Classification

Classification	No. of Cases	Percentage
C1	5	10%
C2	12	24%
C3	13	26%
C4	15	30%
C5	5	10%
Total	50	100%

Varicose veins were most commonly of the C4 class (30%), followed by C 3 class (26%).

Table 4: Doppler findings

Doppler Finding	No. of Cases	Frequency
SFJ incompetence	8	16%
SPJ incompetence	4	8%
Only perforator incompetence	38	76%
Total	50	100%

Most patients had only perforator incompetence.

Table 5: Perforator location

Perforator Location	No. of Cases
Ankle	20
Calf	45
Thigh	7

Incompetent perforators were most commonly seen in the calf, in an overwhelming majority of cases (90%).

12 cases underwent SFL/ SPJ ligation prior to sclerotherapy, Out of 50, 12 cases underwent foam sclerotherapy. The remaining 48 underwent liquid sclerotherapy. Majority of cases (44%) underwent 2 sittings of sclerotherapy.

Best treatment response was seen in C1 and C2 class with 100% response. The response decreased with increasing class with poorest response seen in C5 (66%). Patients with recurrent varices had a 100% response rate. Out of twelve cases who underwent SFJ/SPJ ligation prior to sclerotherapy, 75% showed response.

Table 6: Complications following the procedure

Complications	No. of cases	Percentage
Local tenderness/ bruising	14	28%
Pigmentation	6	12%
Skin necrosis	3	6%
Thrombophlebitis	4	8%
Allergy	0	0
Matting	5	10%
Thromboembolism	0	0

The most commonly seen complication was local injection site tenderness seen in 28% of cases. There were no episodes of serious complications such as allergic reactions or foam embolism.

Discussion

1. Age incidence: The study included 50 patients with primary varicose veins and its complications. In the study out of 50 patients, maximum number of patients, 20 (40%) were in

the 31-40 years age group followed by 16 (32%) patients in the 41-50 years age group, next followed by 51-60 years age group and the least being in 20-30 years age group with 8% of patients. This correlates partially with the population based study by Dimikakos *et al.* [91] who found the highest incidence in the age group of 45-54. Most studies have found an increasing prevalence with age, and have identified age as an independent risk factor for varicose veins. The higher incidence in younger age group in our study might be explained by the fact that ours was a treatment based study and not an epidemiological one.

2. **Gender distribution:** Out of the 50 cases included in the study, 30 (60%) cases were male with only 20 (40%) female patients. However most other studies have found a female preponderance, with the exception of the one by Carpentier *et al.* [7] Several factors can explain this discrepancy. Most of these studies were carried out several decades ago; in the meantime, changes in lifestyle have occurred, leading to smaller differences in environmental factors that affect men and women. In addition, patients in our study were from a lower socioeconomic background for whom cosmesis was not a major concern.
3. **Side of the legs affected:** Both sides were almost equally affected in our study with 34% have left leg, and 30% having right leg involvement, with the remaining having bilateral involvement. The study by Carpentier *et al.* [7] echoes these findings, with no significant difference between right and left limbs.
4. **Mode of presentation:** Most patients (80%) gave a history of noticing eczematous lesions along with dilated tortuous veins on their limbs. The most common symptoms troubling the patient was pain in the lower limbs seen in 76 % of cases and itching seen in 60% of cases. These findings correlate well with the study by Chiesa *et al.* [8] aimed at correlating visible signs and symptoms with functional disease. They found that varicose veins and telangiectases were the most common objective signs in both men and women. Pain and limb discomfort were reported as a significant symptom for each of the six CEAP clinical categories in at least 50 percent of individuals. A study conducted by Fun on the etiology and symptomatology of varicose veins of lower limbs has shown patients having pain in 59%, pigmentation in 58%, edema in 53%, eczema in 29%, ulceration in 28%, bleeding in 21% and lipodermatosclerosis in 20%.
5. **Prior surgery:** 20% of cases in our study said they had been previously operated for varicose veins. The study by Van rij *et al.* [9] reported a recurrence rate of 23% after great saphenous vein surgery at three years duration. Further investigation into pattern and cause of recurrence was beyond the scope of our study.
6. **Vein affected:** The great saphenous vein was most commonly affected in our study seen in 94% of cases. Small saphenous vein was affected in 20% of cases. In the epidemiological study by Carpentier *et al.* [7], Great saphenous vein was found to be four to seven times more commonly involves than the small saphenous vein. Hence our study findings correlate well with theirs.
7. **CEAP classification:** The more common class of varicose veins seen in our study were C4 (30%), C2 (24%) and C3 (26%), which together accounted for 82% of all cases. These findings differ from those of Carpentier *et al.* [7] who found the higher prevalence in C1 (48.1%) and C2 (48.4%), which is echoed in other western studies. This discrepancy

might be explained by the fact that in our study was conducted in a developing country, where cosmesis was not as important a concern to our patients. Hence patients presented more commonly when more disabling symptoms including pain developed, which are more commonly seen in higher CEAP classes.

8. **Perforator location:** On Doppler, incompetent perforators were most commonly seen in the calf in 90% of cases. They were seen in the ankle in 40% of cases, and the thigh in 14% of cases. This correlates well with the radiological study on Indian patients by Irodi *et al.* [10] They found incompetent calf perforators in 77% of cases, incompetent thigh perforators in 9% of cases, and ankle perforators in 19% of cases.
9. **Treatment modality:** Twelve cases with either saphenopopliteal or saphenofemoral incompetence underwent ligation before undergoing sclerotherapy. Out of the total of 50, 12 cases with major truncal varices underwent foam sclerotherapy with liquid sclerotherapy. The remaining 38 cases underwent liquid sclerotherapy alone.
10. **Treatment response:** In this study 50 cases of superficial varicose veins were treated with compression sclerotherapy. Treatment response was judged on the following parameters relief of symptoms (pain, fatigue, tiredness). Disappearance of varices, reduction of edema, decrease in eczema, pigmentation. The response is based on the clinical findings of basic signs of varicose veins. A good response was seen in relief of pain, itching and disappearance of varices, edema. Pain improved in 78% of cases, while visible varices reduces in 85% of cases. Itching showed the maximum response in 86% of cases. Edema was reduced in 70% of cases. A less favorable response as seem with respect to pigmentation which improved in 52% of cases. Skin changes such as lipdermatosclersosis showed the poorest response with improvement in only 33% of cases. Thus symptoms of recent onset showed better response as compared to more chronic symptoms. According to study conducted by Labas P *et al.* [11] 78% of patients showed improvement in pain, 83% showed disappearance of varices, 72% showed reduction of edema, 80% showed improvement in eczema, 94% showed healed ulcers. Hence the results of our study correlate well with the above study. Another study by Weiss *et al.* showed an improvement in pain symptoms in 85% of cases after compression sclerotherapy [12]. A study conducted by Kahle *et al.* has shown 76.8% improvement in the disappearance of varicose veins. [16] Cabrera *et al.* have reported complete healing of venous ulcers in 83% of patients [17]. In our study, greatest response was seen in C1 and C2 classes, which showed a 100% response rate. C3 class showed an 85% response rate. C4 showed 73% response, while C5 showed the poorest response rate at 60%. This is in accordance with the above findings which showed a poorer response of lipodermatosclerosis to sclerotherapy. Recurrent varices after surgery showed an excellent result in our study with a 100% response rate. Patients who underwent SFP/SPJ ligation prior to sclerotherapy showed a 75% response rate. Bountouroglou *et al.* [13] in their study comparing ligation with sclerotherapy versus surgical treatment alone found no significant difference in terms of outcomes between the two groups. They however concluded that ligation with sclerotherapy was less expensive with a more rapid recovery. The Cochrane review by Tisi *et al.* [14]

reviewed seventeen articles covering all aspects of sclerotherapy. They concluded that the available evidence supported the current position of sclerotherapy in clinical practice, which is mainly in the treatment of early varicose veins and recurrent varices. Our findings are parallel with this Cochrane review.

- 11. Complications:** The most common complication was injection site tenderness and bruising seen in 28 % of cases, which resolved in all cases over a few weeks. The next most common complication was local pigmentation seen in 12% of cases, and matting seen in 10% of cases. Local skin necrosis due to extravasation was seen in 4 cases, and thrombophlebitis seen in 8% of cases. Serious complications including deep vein thrombosis, foam embolism and allergic reactions were not seen in any cases. The study by Labas P *et al.* has showed results with 12% showing pigmentation, 7% showing local necrosis, deep vein thrombosis in 0.01% of patients [11]. Pain is common after sclerotherapy, indicating vessel wall damage or occasionally extravasation. Rates of local tenderness in studies range from 15 to 25% [10]. Ulcers may occur when the sclerosing agent extravasates from the vein into the subcutaneous tissue. The reported incidence is 1 to 5 percent of patients treated. In our study, injection site ulceration was seen in the earlier cases of the study due to the learning curve of the technique of sclerotherapy. The incidence of ulceration reduced in the latter part of the study. All ulcers resolved with conservative treatment within four weeks.

The incidence of telangiectatic matting has been reported to be 15 to 24 percent of patients and usually resolves within 3 to 12 months. Sodium tetradecyl sulphate has been associated with a lower incidence of telangiectatic matting. The incidence of hyperpigmentation after sclerotherapy has reported as upto 30%. However most of these studies bring performed in western populations with a fairer skin would have a higher incidence as compared with that reported in our study. According to a study by Leach and Goldman, bruising was seen in 54% of patients, pain in 15% of patients [18]. Another study by Goldman has shown ecchymosis in 70%, hyperpigmentation in 64%, vein thrombosis in 46%, local urticaria in 36%, telangiectatic matting in 11% and skin necrosis in 6% of patients [2].

Most of the complications in our study are minor and gradually resolved. Other rare complications reported in the literature include anaphylaxis, extensive tissue necrosis and pulmonary embolism. However, the treating physician should be aware of the early signs of anaphylaxis and should have emergency equipment available.

The incidence of severe complications such as deep vein thrombosis, foam embolism and anaphylaxis in studies has been reported in less than 1% of cases. These were not seen in our study.

- 5. Patient satisfaction:** All patients were interviewed after the procedure regarding their satisfaction with sclerotherapy. 92% of cases reported that they were satisfied with the technique of sclerotherapy. The 8% of cases who weren't satisfied in our procedure all had experienced some complication of sclerotherapy which could have influenced their opinion. In a similar study by Tan *et al.* [15] 96% of patients had expressed their satisfaction with the procedure. The most common reasons for the high patient satisfaction with sclerotherapy include its cost efficacy, simplicity of the

technique, and the ease of it being an outpatient procedure. The etiology of varicose veins is multi-factorial and all treatments presently available including, surgery and sclerotherapy are palliative and not etiological. Varicose veins with its dermatological complications are commonly seen in the dermatology OPD (out patient department). Surgical procedures like ligation and stripping are the preferred modalities of treatment. Sclerotherapy is a valuable method of treatment for varicose veins of the lower limb and is one of the frequently used procedures by Dermatologists in the west. However, on extensive review of literature, there are no Indian studies which have specifically evaluated the role of sclerotherapy in the management of varicose veins and its complications.

Sclerotherapy is the injection of a chemical solution (sclerosant) into a vein, damaging the endothelial lining and causing vessel occlusion and the development of fibrous tissue. The objective of sclerotherapy is not only to produce complete endothelial damage and subsequent fibrosis of the entire vein wall without recanalization, but also to locate the points of abnormal flow from the deep to the superficial veins and must be permanently obliterated by the injection of a sclerosant. With this, the secondary incompetent but not permanently damaged valves can regain their normal functions. The most important aspect of treatment is to diminish local venous hypertension by interrupting the leaking points via perforating veins into the superficial network. The migration of the sclerosing solution in isolated segments (digital compression) of injected superficial vein can reliably close the perforator complex of perforators. Localization of incompetent perforating veins by this technique could yield a perfect result in 90 out of 100 patients. The incompetent perforators are almost always found near the skin changes and in typical places in the legs [1, 3, 4, 5].

Sclerosing solutions are classified into three groups, based on the mechanism of action; detergent agents, osmotic agents and chemical irritants. The various sclerosants include STS, polidocanol, hypertonic saline, sodium morrhuate, etc. STS, a detergent sclerosant was used in our study. It causes destruction of endothelium by altering the surface tension around the endothelial cells by a process known as protein theft mechanism [2, 4, 6, 10].

Conclusion

Sclerotherapy is a simple, safe, and effective procedure for the treatment of varicose veins of the lower limb. The procedure is particularly effective for early smaller varicosities, which may help in preventing the development of skin changes and also for residual varicosities after surgery. This being an out-patient procedure, it reduces the cost and morbidity associated with surgical treatment. When the procedure is done with adequate precautions, there are relatively very few complications which are usually minor. Any treatment failures could be most often due to inappropriate technique rather than shortcoming of the procedure. However, further larger Indian studies can be taken up for the evaluation of this technique and also newer advances like ultrasound guided foam sclerotherapy can be incorporated in our practice, which further enhances the efficacy and safety of the procedure. Hence we recommend more and more of our fellow dermatologists to take up this procedure, which can be an efficient tool to manage patients with varicose veins and its related complications.

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