



A STUDY OF FOAM SCLEROTHERAPY IN THE MANAGEMENT OF DIFFERENT SIZES OF VARICOSE VEINS

Surgery

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ABSTRACT

Aim: This study was done to assess the outcome among patients undergoing foam sclerotherapy in different sizes of Varicose veins.

Materials and method: The clinical trial included patients in an age group 18-60 years with uncomplicated varicose veins. The sclerosant used was 3% Polidocanol, 60 mg/2ml. Patients general vital charting (i.e pulse rate, blood pressure, temperature, all complications) were recorded.

Results: The study population consisted of 18.7% males and 81.3% females. Majority of the study population belonged to 30-45 years age group (52.0%). The chief complains reported were dilatation of vein in lower limb (27%), unsightly veins in lower limb (32.94%), Itching over dilated vein (22.35%), pigmentation around dilated veins (5.88%), Heaviness in legs (9.4%), and Ulcer over ankle (2.35%).

Most of the patients resumed work within 24 hours (45.3%) whereas 34.7% resumed work after 24-48 hours and 20.0% resumed work after 48 hours. The complication was reported among 5.33% cases only that included Superficial vein thrombophlebitis (SVT) among 5.33% cases. Complete disappearance of veins occurred in 80.0% cases. Recurrence was reported among 1.33% cases. Asymptomatic cases were 94.67% after 3 months and 6 months follow-up.

Conclusion: Sclerotherapy is an effective and safe treatment for lower limb varicose veins. The concentration of Polidocanol injected could be correlated significantly with improvement of symptoms and borderline correlation to the complication rate.

KEYWORDS

INTRODUCTION

Varicose veins are commonly encountered problem which has effect on the quality of life of an individual and has a considerable financial impact on the health care system. Varicose veins (VVs) are defined as tortuous, dilated, bulging, superficial veins typically having measurement of 4 mm or larger. The other patterns of venous pathology include reticular veins that have lesser tortuosity, flat veins having a diameter of 1-3 mm, and spider veins measuring less than or equal to 1 mm.[¹]

The incidence of Varicose veins among general population is around 40% with not much gender variation, though women more commonly experience the symptoms related to varicose vein compared to men.[¹] Risk factors include family history, pregnancy, prolonged standing, obesity, vascular malformations, old age, and hormone therapy. The Varicose veins occur more commonly among Caucasians and Whites in comparison to the Blacks or Asians.[¹]

The common symptoms reported among the patients with varicose veins' are aesthetic disfigurement, heaviness or tension, swelling of the limbs, restless legs, cramping, tingling, and itching. The prevalence of symptoms have a tendency to increase with age among both gender.[²] There is multifactorial pathogenesis of varicose veins with complete understanding though the disease is highly prevalent.[⁴]

Varicose veins of lower extremities are mainly caused by valvular insufficiency, weak vein wall and increased pressure of superficial vein.[⁵] Muscle pump plays a certain role in it. When muscle pump failure is caused by sedentary, neuromuscular degenerative diseases and obesity, it will aggravate venous stagnation and increase venous pressure.[^{6,7}]

Many treatment modalities are available for the varicose veins.[^{8,9}] These include compression stockings, sclerotherapy injection, open surgical procedures and minimal invasive surgeries.[¹⁰] Minimal invasive surgeries include laser and radiofrequency ablation (RFA) which have better clinical outcomes and patient satisfaction than the ligation surgery.[⁹] When these surgeries are done, after RFA along with necessary ligation of perforator and phlebectomy, and if there are significant amount of residual veins remaining, then adjunct sclerotherapy is an additional modality which helps in reducing the residual varicosities.[^{11,12}]

Foam sclerotherapy has led to the reduction in admission to hospital and the requirement for bed rest after treatment.[¹³] The simultaneous use of foam sclerotherapy with Endovenous Laser ablation (EVLA) has led to lesser need for re-operation and improve quality of life.[¹⁴⁻¹⁶] Sclerotherapy is associated with better outcome than surgery after one year of follow-up post-treatment.

Sclerosing agents act by damaging the endothelial lining and subendothelial collagen fibers that are exposed, which leads to the initiation of the coagulation cascade and eventually resulting in thrombosis of the vessel.[¹⁸] The sclerotherapy initially began as the liquid sclerotherapy, that gradually evolved into the foam sclerotherapy. European consensus meeting on sclerotherapy has given the conclusion that foam sclerotherapy is better than the liquid sclerotherapy.[^{19,20}]

Foam sclerotherapy is preferred method due to less side effects and good contact of the drug with the vessel wall. As per vein size, appropriate foam volume has to be matched. Using excessive foam volume might lead to the migration of foam to the deep veins that can result in the deep vein thrombosis. Foam sclerotherapy is also known to have some of the side effects such as thrombotic complications, visual disturbances, neurological complications, dry cough and other rare occurring side effects.[²⁰]

Singh et al. show that foam sclerotherapy has less side effects and good contact with the blood vessel wall, so it is the first choice for treatment.[²¹] Oliveira et al. show that foam sclerotherapy reduces the use of anesthesia and shortens the time of hospitalization and bed rest after treatment.[¹³] At present, there are a number of randomized controlled studies.[²²⁻²⁶] The results show that polidocanol in the treatment of varicose veins of the lower extremities can significantly relieve symptoms and improve the appearance of legs, eliminate venous reflux and reduce vein diameter, and the operation method is simple and quick, the postoperative recovery is fast, and the adverse events are mild and short-lived. However, there are differences in the research scheme and curative effect of each clinical trial, which leads to uneven results.[⁷]

There is limited literature in the Indian scenario regarding the use of foam sclerotherapy for treatment of Varicose veins. This study was done to assess the outcome among patients undergoing foam sclerotherapy in different sizes of Varicose veins.

MATERIAL & METHODS

This prospective randomized clinical study was conducted after clearance from Board of Studies and Ethical committee at, Dr. Sushila Tiwari Government Hospital, Haldwani, Nainital.

Sample Size

The sample size was calculated from the study by Nagesh T Subbarao study on Sclerotherapy in the management of varicose veins. The power of the study was taken to be 80% and Confidence Interval (C.I.) of 95%. The study population has been calculated by using G-power software which estimated the sample size to be 75 patients.

Study population

The study subjects were chosen as per the inclusion and exclusion criteria and colour doppler studies of lower limb for ruling out deep vein thrombosis (DVT). The study included patients in an age group 18-60 years with uncomplicated varicose vein, Residual perforators, Recurrent perforators and Great saphenous vein (GSV) incompetence with truncal varicosities which were willing and consented to be part of the study. The study excluded subjects with colour doppler findings suggestive of DVT, documented allergy to sclerosant and vasculopathy coexisting with diabetes, and sapheno-femoral junction incompetence.

Study procedure

After approval from the Institutional Ethical committee all patients were selected as per inclusion and exclusion criteria. A detailed history, complete physical examination and routine & appropriate investigations were done for all patients.

Patients reporting to surgery OPD were selected as per the criteria. Informed consent was taken from all the subjects prior to the procedure. Patient's treatment and follow up were done on OPD basis. The Sclerosant used was 3% Polidocanol, 60 mg/2ml. Patients general vital charting (i.e pulse rate, blood pressure, temperature, and all complications) were recorded.

After injecting the foam, the limb was kept in the elevated position and wrapped with a 12-cm wide elastic bandage from below upwards, that are kept in place for about 3 days, and patients are advised to wear elastic compression stockings for 2 weeks after that. After finishing the procedure, the patients are given instructions of walking and allowed for resuming their normal routines.

Patients were called after 7 days. If complete closure of target veins was not achieved then additional sessions were done. Additional sessions, with one or more punctures, were conducted, as necessary (on a case-by-case basis), at 7-day intervals.

Statistical analysis

The data was entered into the Microsoft excel and the statistical analysis was performed by statistical software SPSS version 21.0. The Quantitative (Numerical variables) were present in the form of mean and Standard deviation (SD) and the Qualitative (Categorical variables) were present in the form of frequency and percentage.

The repeated measures ANOVA test was used for comparing the mean values between different time intervals whereas chi-square test was applied for comparing the frequency. The p-value was considered to be significant when less than 0.05.

RESULTS

The study population consisted of 14 (18.7%) males and 61 (81.3%) females. Of study population, 5 (6.7%) belonged to 16-29 years, 39 (52.0%) belonged to 30-45 years, 11 (14.7%) belonged to 46-60 years and 8 (10.7%) belonged to above 60 years. The mean age of the study population was 43.49 ± 10.07 (16-69) years. The type of vein affected was Medium in 35 (46.67%) and Small in 40 (53.33%) cases.

The major chief complaints among the subjects with varicose veins were dilatation of vein in lower limb (27%), followed by unsightly veins in lower limb among 32.94%, Itching over dilated vein (22.35%), pigmentation around dilated veins among 5.88%, Heaviness in legs (9.4%), and Ulcer over ankle (2.35%).

Majority subjects had to undergo two sessions (60.0%) whereas 24.0% required one session and 16.0% required three sessions. The amount of foam used was 2 ml among 21 (28.0%), 4 ml among 31 (41.3%) and 6 ml among 23 (30.7%) subjects.

Most of the patients resumed work within 24 hours (45.3%) whereas 34.7% resumed work after 24-48 hours and 20.0% after 48 hours respectively.

The complication was reported among 4 (5.33%) cases only that included Superficial vein thrombophlebitis (SVT) among 5.33% cases. Complete disappearance of veins occurred in 60 (80.0%) cases. Recurrence was reported among 1 (1.33%) cases. Asymptomatic cases were 94.67% after 3 months and 6 months follow-up.

DISCUSSION

In-detail planning is required for the successful treatment of lower limb varicose veins with sclerotherapy. In general, sclerotherapy is conducted with respect to the order of the reflux points, beginning from medium caliber varicose veins to small calibre veins.^[28] Therefore, adequate clinical and anatomic assessments must be performed before treatment.^[29]

Along with clinical assessment, vascular ultrasound has important role in assessing the venous reflux of lower extremities. It is a low-cost, non-invasive examination that is well tolerated by patients. It helps in the direct visualization, localizing and quantifying the venous reflux with sensitivity and specificity of 95.0% and 100.0% respectively.^[30]

Age and gender distribution

In our study, the study population consisted of 18.7% males and 81.3% females which were in similarity to the findings by *Rana et al.*^[31] 92.5% were male and 7.5% were female patients. This was contrasted to the findings by *Maurya et al.*^[21] with 91 males and 32 females.

In a study 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.^[32] In another study, the prevalence was 10% among men and 29% among women aged 15 and over; it rose with age in each sex.^[33] Majority of males (74.7%) were found in another Indian study.^[34]

In current study, majority of the subjects belonged to 30-45 years age group (52.0%), followed by 46-60 years (14.7%) and above 60 years (10.7%). The mean age of the study population was 43.49 ± 10.07 (16-69) years.

Symptoms

The symptoms of varicose veins in the lower extremities range from mild symptoms such as fatigue, heaviness, itching, to severe diseases such as edema, skin fat sclerosis and ulcers, which seriously affect people's quality of life. Some studies have shown that varicose veins have a substantial effect on the function and psychology of patients.^[35]

In our study, major chief complaint among the subjects with varicose veins was Dilatation of vein in lower limb (27%), followed by unsightly veins in lower limb among 32.94%, Itching over dilated vein (22.35%), pigmentation around dilated veins among 5.88% Heaviness in legs (9.4%), and Ulcer over ankle (2.35%).

Resolution

Our study reported the complete disappearance of veins among 80.0% cases. This was quite similar to the findings by *de Oleivira*^[22] reported the rate of reflux elimination at 90 days was 87%, which is comparable to rates described in the literature.^[36] *Seayam et al.* in their study found that the successful rate of occlusion was 80.3%. *Smith*^[29] found that 82% cases reported no recanalization and there was complete obliteration at follow-up.

In current study, asymptomatic cases were 94.67% after 3 months and 6 months follow-up. Recurrences associated with ultrasound guided foam sclerotherapy (UGFS) treatment varies from 4.9% to 40%^[37-41] Our study reported the recurrence rate of 9.3% but in contrast, *Maurya et al.*^[21] reported that there were no recurrences.

Seayam et al.^[22] stated that no recanalization at the short spectrum follow-up of 12 weeks while *Bradbury et al.*^[43] had 8.7% recanalization rate with a duration of follow-up of 28 months. While *Gibson and Gunderson*^[44] using 2% Pol. showed 23% limbs showed complete occlusion of the GSV trunks. *Darvall et al.*^[44] show complete occlusion in the range from 93 to 98% of treated legs, and recanalization occurred in 9-12% cases with 12-month follow-up. *Figueiredo et al.*^[46] using 3% polidocanol showed 78% of cases show complete occlusion.

Complications

Phlebitis which was a sequelae of excessive inflammatory reaction of the sclerosing foam had-occurred in 2% of legs (two different patients), while Frulliniani Cavezzi^[47] and Rabee et al.^[48] reported only 1% phlebitis. In our study, the complication was reported among 5.33% cases only that included Superficial vein thrombophlebitis among 5.33% cases. Superficial thrombophlebitis incidence reported in different studies was found to be <15%.^[37,49,50] Our study resembled the findings by *Maurya et al.*^[21] which reported incidence of about 14.18%(<15%) whereas one of the study reported a high incidence of 39.0%.^[46]

Our study findings were comparable to *Rana et al.*^[31] who reported that pain was the commonest complication (85%) followed by pruritis (40%), swelling (17.5%), superficial thrombophlebitis (15%) and skin ulceration (2.5%). Complications such as Deep vein thrombosis (DVT) and neurological complications were not seen.

The fact that there were no major complications, such as pulmonary embolism, in our sample is in line with other findings in the medical literature by *de Oliveira*^[13] and *Ji et al.*^[36] *de Oliveira*^[13] reported that the pigmentation rate was 13% and phlebitis requiring drainage in 2 cases (6%). In one case, there was partial propagation of the thrombus from the GSV into the deep vein system, although it affected less than 50% of the femoral vein lumen, with spontaneous regression and no need for treatment.

Karmacharya et al.^[20] found that 88.23% patients were without immediate complication and 76.47% patients were free from short term complication. Most common complication noted was painful thrombosed veins among 9 patients (17.64%). In the study done by *Li et al.*^[7] varicose veins treated by sclerotherapy alone had higher incidence of painful thrombosed veins (14.9%) compared to foam sclerotherapy as adjunct to surgery (1.1%). Another study showed this as second most common complication occurring in about one-fifth of the cases treated with UGFS.^[51] In a review article by *Guex et al.* on complications of sclerotherapy, this occurred in more than 10% of the patients.^[28]

The research has shown that in comparison to the classic liquid sclerotherapy, foam sclerotherapy was found to have effectiveness of about 4 times as the contact time is more with the venous wall, more surface area of the venous wall.

CONCLUSION

Sclerotherapy is an effective and safe treatment for lowerlimb varicose veins. The concentration of Polidocanol injected could be correlated significantly with the improvement of symptoms and borderline correlation to the complication rate.

Table 1: Demographic characteristics of the study population

		N	%
Gender	Male	14	18.7%
	Female	61	81.3%
Age	16-29 years	5	6.7%
	30-45 years	39	52.0%
	46-60 years	23	30.7%
	Above 60 years	8	10.7%
	Mean±SD	43.49±10.07 (16-69) years	
Type of vein	Medium	35	46.67%
	Small	40	53.33%

Table 2: Chief complaints associated among patients with varicose veins

	N	%
Unsihty veins in lower limb	28	32.94%
Dilated veins in lower limb	23	27%
Heaviness in legs	8	9.4%
Itching over dilated vein	19	22.35%
Pigmentation around dilated veins	5	5.88%
Ulcer over ankle	2	2.35%

Table 3: Number of sessions required of foam sclerotherapy required among study population

required among study population			
		N	%
Number of sessions required	One	18	24.0%
	Two	45	60.0%
	Three	12	16.0%

Amount of foam used (ml)	2	21	28.0%
	4	31	41.3%
	6	23	30.7%

Table 4: Time to return to work/ routine activity among study population

Time to return to work/ routine activity	N	%
< 24 hours	34	45.3%
24-48 hours	26	34.7%
> 48 hours	15	20.0%

Table 5: Complications reported among study population

Complications	N	%
None	71	94.67%
Superficial vein thrombophlebitis	4	5.33%

Table 6: Complete disappearance of veins and Recurrence among study population

		Frequency	Percent
Complete disappearance of veins	No	15	20.0%
	Yes	60	80.0%
Recurrence	No	74	98.67%
	Yes	1	1.33%

Table 7: Follow-up after 1 month, 3 months and 6 months among study population

		Frequency	Percent
Follow-up after 1 month	No	33	44%
	Sclerosed vein	38	50.67%
	SVT managed	4	5.33%
3 month follow up	Asymptomatic	71	94.67%
	Follow-up	4	5.33%
6 month follow up	Asymptomatic	71	94.67%
	Follow-up	4	5.33%

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