

Original Research Article

A study to compare outcomes of Sodium tetra-decyl sulphate and Polidocanol in the treatment of varicosities due to incompetent tributaries of superficial vein of leg: a randomized controlled trial

Jitendra K. Kushwaha^{1*}, Akshay Anand¹, Abhinav A. Sonkar¹, Rajni Gupta²

¹Department of General Surgery, ²Department of Anaesthesiology, King George's Medical University, Uttar Pradesh, India

Received: 16 September 2018

Accepted: 29 September 2018

*Correspondence:

Dr. Jitendra k. Kushwaha,

E-mail: dr.jkkushwaha@gmail.com

Copyright: © the author(s), publisher and licensee Medip Academy. This is an open-access article distributed under the terms of the Creative Commons Attribution Non-Commercial License, which permits unrestricted non-commercial use, distribution, and reproduction in any medium, provided the original work is properly cited.

ABSTRACT

Background: Various options for treatment of varicosities of tributaries are mini-phlebectomy, hook phlebectomy, Trivex and sclerotherapy. Sodium tetra-decyl sulphate (STD) and polidocanol (POL) are most commonly used sclerosants. Adverse events caused by sclerosants are pain, thrombophlebitis, hyperpigmentation, allergy, anaphylactic shock, cutaneous necrosis, deep venous thrombosis, headache, visual disturbances and chest tightness. Foam sclerotherapy has been considered to be better than liquid sclerosant. In this study we have compared foam prepared by STD versus POL in the treatment of varicosities of tributaries of superficial vein of Leg.

Methods: Patients treated for SFJ or SPJ incompetency post their primary admission and management were attended and evaluated in outpatient department. Patients having varicosities were enrolled for study and treated in OPD by foam sclerotherapy. Patients were randomized to two groups - A or B. Patients were followed up for one month and various clinical outcomes were analyzed.

Results: In group A (STD) out of n=20 patients pain, hyperpigmentation and skin necrosis was present in n1=18 patients, n2=14 patients and in n3=2 patients respectively on the first post-operative day while in group B (POL) out of 24 patients it was present in n1=14, n2=8 and n3=1 patient respectively. Post sclerotherapy at one month follow up, in Group A pain and hyperpigmentation decreased to n1=08 and n2=04 patients respectively but skin necrosis was persisting in all n3=02 patients. In-group B pain and hyperpigmentation was present in patients each n1= n2=02 and skin necrosis was present in n3=01 patient.

Conclusions: Polidocanol is better than Sodium tetra-decyl sulphate for foam sclerotherapy in terms of better cosmetic outcomes.

Keywords: Foam sclerotherapy, Incompetent tributaries, Polidocanol, Sodium tetra-decyl sulphate, Varicose vein

INTRODUCTION

Varicose vein (VV) is defined as dilated, elongated, tortuous superficial vein of leg having reflux with a prevalence rate of 50-55% in females and 40-50% in males. Reflux may be due to incompetent valves at saphenofemoral junction (SFJ) or in the main trunk/axis

of great saphenous vein (GSV) or short saphenous vein (SSV) or due to incompetent perforators as well. Often bunches of varicosities are found on lateral or medial aspect of leg due to incompetent tributaries. Main trunk or main axis of incompetent superficial vein of leg is treated by endovenous thermal ablation, foam sclerotherapy, crossectomy and stripping of GSV.¹

Various treatment modalities for treatment of varicosities of tributaries are mini-phlebectomy, liquid sclerosant, foam sclerotherapy and Trivex. Various sclerosants used in VV treatment are sodium tetra-decyl sulphate (STD), polidocanol, ethanolamine oleate, sodium morhuate, hypertonic saline, phenol etc.

Out of these STD and polidocanol (POL) are safe and most commonly used.²⁻⁶ In this study we have compared early outcomes in patients having any one of these two sclerosants viz. STD and POL in the treatment of varicosities of tributaries of GSV and SSV.

METHODS

This study was carried at Department of General Surgery, King George's Medical University UP. Patients of chronic venous insufficiency (CVI) were diagnosed on the basis of Duplex Doppler USG in standing position. Patients were evaluated for SFJ, SPJ incompetency and perforators' incompetency and sites of varicosities.

Patients were classified on CEAP grading developed by American Venous Forum. Inclusion criteria were adult Patients (>15 year) with CVI, having varicosities on the leg.

Patients having clinical or radiological evidence of deep venous thrombosis, pregnancy, deranged coagulation profile, any other secondary varicose vein, congenital varicose vein and not giving consent were excluded for this study.

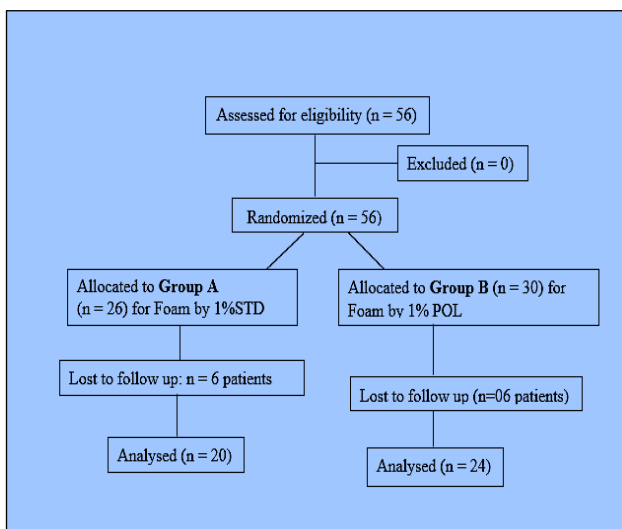


Figure 1: Consort diagram.

Patients having incompetent SFJ /SPJ who were admitted were followed in OPD post treatment and discharge.

Patients having incompetent SFJ was treated by Endovenous Laser ablation (1470 nm, Biolitec) or Ligation and cutting of all three tributaries (crosssectomy)

and SFJ ligation and stripping of GSV up to knee followed by treatment of tributaries varicosities in OPD after one week.



Figure 2: Varicosities on Leg.

Incompetent SPJ was treated by SPJ ligation only. In OPD visit, superficial varicosities of tributaries were treated after one week by foam sclerotherapy. These patients having varicosities were randomly allocated to either in Group A (1% STD) or Group B (1% POL) by opening the sequentially numbered opaque sealed envelope Figure 1.



Figure 3: Foam in 20 ml Luer Lock Syringe.

Three percent sclerosants (Inj Setrol having 3% STD for Group A or Inj Asklerol having 3% polidocanol for Group B) were easily available and these were diluted to 1.0% (2ml 3 % sclerosant in a ampoule was diluted by adding 4 ml Normal Saline).

Maximum 2 ampoules (120mg) were used in a single sitting. Foam was prepared by having 1% sclerosant in one 20 ml Luer Lock syringe and 4 times room air in

another syringe. Both syringes were connected to tri-way stopcock and by 20-22 times to and fro motion of both syringes foam was prepared.^{7,8}

Foam was administered inside clinically visible varicosities [Figure 2,3 and 4]. First in standing position varicosities were marked by ink marker. Then in supine position scalp vein set (no 24Fr or 26Fr) was introduced inside varicosities and blood flow in the tube was checked.



Figure 4: Passing Foam inside Varicosities.

If varicosities disappeared in supine position, then vein viewer was used. Through the scalp vein set 2ml foam was passed slowly at low pressure in single punctured site. Immediately elastic crepe bandage was applied for 5-7 days.



Figure 5: Skin necrosis at ankle after sclerotherapy.

Post therapy patients were evaluated immediately for various outcomes like allergy, visual disturbances, headache and anaphylactic shock. Other outcomes like pain, hyperpigmentation, skin necrosis Figure 5, DVT,

embolism was documented on first day and after 4 weeks of sclerotherapy.

RESULTS

In this study total 56 patients were enrolled having varicosities of tributaries; n=26 patients in Group A and n=30 Patients in Group B. Result of n=6 patients in each group could not be evaluated due to loss of follow up. Finally results of n=20 patients in Group A and n=24 patients in Group B were evaluated.

In Group A, out of 20 patients, 17 patients were treated for SFJ incompetency and 03 patients for SPJ incompetency with SFJ incompetency. These patients having superficial varicosities were treated by 1% STD foam sclerotherapy in OPD Table 1.

In Group B, 23 patients had only SFJ incompetency and one had both SFJ and SPJ incompetency. These n=24 patients were having below knee superficial varicosities and treated by 1% POL Sclerotherapy on outpatient basis.

All Patients were evaluated on the day, at first day post foam sclerotherapy and after 4 weeks after sclerotherapy. Patients developing skin necrosis in follow up were managed by skin grafting later.

In group A (STD) out of 20 patients' pain, hyperpigmentation and skin necrosis was present in n1=18 patients, n2=14 patients and in n3=02 patients respectively on the first post-operative day while in group B (POL) out of 24 patients it was in n1=14, n2=08 and n3=01 patient respectively.

Table 1: Demographic profiles of patients.

Factors	Group A (n=20) STD	Group B (n=24) POL
Male	17	18
Female	03	02
Age	16-47 yrs	17-55 yrs
SFJ incompetent	20	23
SPJ incompetent with SPJ incompetent	03	01
Perforators incompetent	04	03
Based on CEAP classification		
C2	6	6
C3	4	4
C4	5	7
C5	5	6
C6	0	1

Post sclerotherapy after 4 weeks, in Group A pain and hyperpigmentation were present in n1=08 and n2=04 patients respectively but skin necrosis was persisting in all n3=2 patients.

Table 2: Results showing outcomes in both Groups.

Complications	On first post sclerotherapy day			After 4 weeks of follow up		
	Group A (n=20) STD	Group B (n=24) POL	p-Value	Group A (n=20) STD	Group B (n=24) POL	p-Value
Pain	18	14	0.012	08	02	0.010
Hyperpigmentation	14	08	0.011	04	02	0.249
Allergy	00	00	-	00	00	-
Skin necrosis	02	01	0.249	02	01	0.249
Thromboembolism	00	00	-	00	00	-
Anaphylactic shock	00	00	-	00	00	-
Visual disturbance	00	00		00	00	

In-group B pain and hyperpigmentation were present in n1=02 patients only and skin necrosis was persisting in that patient (Figure 4). DVT, allergy, visual disturbances, headache and chest tightness were absent in both groups.

DISCUSSION

Common adverse events after sclerotherapy are hyperpigmentation, which occurs due to migration of melanin in skin and deposition of hemosiderin due to extravasation of RBC along the course of vein and is found in 10-30%. It usually resolves in 6-12 month. Post sclerotherapy neovascularization (telangiectasia) occurs in 15-20% patients in area of sclerotherapy. Nerve injury i.e. saphenous nerve or sural nerve injury, adjacent to varicose vein occurs, which normally resolves in 3-6 months.

Superficial thrombophlebitis occurs in 4-7.5% characterized by erythema, tenderness and thrombosed vein. Cutaneous necrosis occurs in 0.23% due to extravasation or due to vasospasm or it may be due to leaking of sclerosant agent into capillary or artery. Other adverse events are transient ischemic attack, visual disturbances (1.4-14%), DVT (0.1%-6%) and cardiac toxicity.⁹

In a study for treatment of VV by sclerosant, Subbarao et al. found that 70-80% of patients showed symptomatic improvement along with disappearance of veins and healing of eczema and ulcers. Most of the complications were minor, which resolved over a period of few weeks.¹⁰

There is evidence that 3% polidocanol foam is no more effective than 1% polidocanol foam. The optimum ratio of gas to liquid is 4:1, although a range of ratios is reported in the published work.

There is a wide variation in the volume used as well as the method by which it is injected. The use of carbon dioxide foam reduces the systemic complications, particularly visual disturbance, as compared with air foams.¹¹ We used room air for foam sclerotherapy 1% in all patients. In a study of total 100 women patients with telangiectasias and small varicose veins of less than 4

mm were randomized for foam or liquid sclerotherapy and authors concluded that complete disappearance was determined in 84% of patients in the foam form group and in 72% in the liquid form group.

Although polidocanol in foam form's success rate was higher than the liquid form of polidocanol to clear the vessels, this result did not reach statistical significance (p=0.148).¹²

VDs following sclerotherapy for varicose veins are rare and all reported events were transient. Bubble embolism or any kind of embolism seems unlikely to be the only underlying mechanism.¹³ In a systemic review of 500 patients, no persistent visual disorders disturbances (VD) were reported.

VD has been reported to occur with polidocanol and sodium tetra-decyl sulphate in different concentrations (0.25–3%). Various forms of foam preparation including various ways of foam production and the liquid –air ratio (1 or 2 parts of liquid mixed with 3, 4 or 5 parts of air) were reported in association with the occurrence of VD. We did not find any patient having VD in either of the group. Rare complication like alopecia areata and anaphylactic shock following STD has been reported in literature post sclerotherapy.^{14,15}

In a study reporting glycerin as a sclerosant, it was shown comparable to STD in discomfort of injection but demonstrated a significant decrease in bruising, swelling, and post procedural hyperpigmentation. Glycerin also demonstrated a better, more rapid clearance of treated telangiectasia.¹⁶

In a comparative study by Goldman et al of POL versus STD as sclerosant for patients having competent SFJ and varicose vein divided into three categories on basis of size (<1 mm, 1-3 mm, 3-6 mm). Each leg was randomly treated with 0.25%, 0.5%, or 1.5% of STS or 0.5%, 1.0%, or 3% of Polidocanol respective of size. In this study an independent, three-panel, blindly randomized photographic examination was obtained pretreatment and at 4 and 16 weeks. All patients had an average of 70% improvement and were 70-72% satisfied in all vein

categories treated with either solution. There was no significant difference in adverse effects between each group except for a decrease in ulcerations and swelling in the polidocanol group.¹⁷

In another double blinded comparative study twenty subjects were treated with either polidocanol (POL) or sodium tetra-decyl sulfate (STD) to compare the efficacy and adverse sequelae of each agent. An average 83% improvement was noted for all vein sizes in all subjects with both POL and STD after a single treatment.

Subjects were satisfied with treatment, regardless of the sclerosant agent used or the vein size treated. There was no statistically significant difference in adverse effects between each group to deduce the superiority of either of the sclerosant agent.¹⁸

CONCLUSION

Pain and hyperpigmentation at site of varicosities is statistically more in STD group whereas skin necrosis is caused by both but is more in STD group compared to POL group. Polidocanol is better than Sodium tetra-decyl sulphate for foam sclerotherapy in terms of better cosmetic outcomes.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

1. Callam MJ. Epidemiology of varicose veins. Br J Surg. 1994 81(2):167-73.
2. Burleva EP, Tiurin SA, Smirnov OA, Faskhiev RR. Comparative 3-year results of phlebectomy and thermal ablation for lower limb varicose veins. Angiol Sosud Khir. 2018;24(2):82-91.
3. Puggioni A, Kalra M, Carmo M, Mozes G, Gloviczki P. Endovenous laser therapy and radiofrequency ablation of the great saphenous vein: analysis of early efficacy and complications. J Vasc Surg. 2005;42(3):488-93.
4. Lam YL, Lawson JA, Toonder IM, Shadid NH. Eight-year follow-up of a randomized clinical trial comparing ultrasound-guided foam sclerotherapy with surgical stripping of the Great saphenous vein. Br J Surg. 2018;105(6):692-8.
5. Zolotukhin IA, Seliverstov EI, Zakharova EA, Kirienko AI. Short-term results of isolated phlebectomy with preservation of incompetent great saphenous vein (ASVAL procedure) in primary varicose veins disease. Phlebol. 2017;32(9):601-60.
6. Pittaluga P, Chastanet S, Locret T, Barbe R. The effect of isolated phlebectomy on reflux and diameter of the great saphenous vein: a prospective study. Eur J Vasc Endovasc Surg. 2010;40(1):122-8.
7. Bunke N, Brown K, Bergan J. Foam sclerotherapy: techniques and uses. Perspect Vasc Surg Endovasc Ther. 2009;21(2):91-3.
8. Bergan J, Pascarella L, Mekenas L. Venous disorders: treatment with sclerosant foam. J Cardiovasc Surg (Torino). 2006;47(1):9-18.
9. Yiannakopoulou E. Safety Concerns for sclerotherapy of telangiectases, reticular and varicose veins. Pharmacol. 2016;98:62-9.
10. Subbarao NT, Aradhya SS, Veerabhadrapa NH. Sclerotherapy in the management of varicose veins and its dermatological complications. Indian J Dermatol Venereol Leprol. 2013;79(3):383-8.
11. Smith CP. Sclerotherapy and foam sclerotherapy for varicose veins. Phlebology. 2009;24(6):260-9.
12. Uncu H. Sclerotherapy: a study comparing polidocanol in foam and liquid form. Phlebol. 2010;25(1):44-9.
13. Willenberg T, Smith PC, Shepherd A, Davies AH. Visual disturbance following sclerotherapy for varicose veins, reticular veins and telangiectasias: a systematic literature review. Phlebol. 2013;28(3):123-3.
14. Whiteley MS, Smith VC. Exacerbation of alopecia areata: A possible complication of sodium tetradecyl sulphate foam sclerotherapy treatment for varicose veins. SAGE open medical case reports. 2017;5:2050313X17712643.
15. Chang YY, Lu PH, Yang CH. Anaphylactic shock after injection of foamed sodium tetradecyl sulfate. Dermatol Surg. 2017;43(6):887-8.
16. Leach BC, Goldman MP. Comparative trial between sodium tetradecyl sulfate and glycerin in the treatment of telangiectatic leg veins. Dermatol Surg. 2003;29(6):612-4.
17. Goldman MP. Treatment of varicose and telangiectatic leg veins: double-blind prospective comparative trial between aethoxyskerol and sotradecol. Dermatol Surg. 2002;28(1):52-5.
18. Rao J, Wildemore JK, Goldman MP. Double-blind prospective comparative trial between foamed and liquid polidocanol and sodium tetradecyl sulfate in the treatment of varicose and telangiectatic leg veins. Dermatol Surg. 2005;31(6):631-5.

Cite this article as: Kushwaha JK, Anand A, Sonkar AA, Gupta R. A study to compare outcomes of Sodium tetra-decyl sulphate and Polidocanol in the treatment of varicosities due to incompetent tributaries of superficial vein of leg: a randomized controlled trial. Int Surg J 2018;5:3515-9.