ORIGINAL ARTICLE

Clinical comparison of sodium tetradecyl sulfate 0.25% versus polidocanol 0.75% in sclerotherapy of lower extremity telangiectasia

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ABSTRACT

Background: Sclerotherapy is an effective therapeutic modality for the treatment of varicose and telangiectatic lower limb veins. The two most widely used sclerosing solutions worldwide are sodium tetradecyl sulfate (STS) and polidocanol (POL).

Objective: The aim of this work was to perform a clinical comparison of sodium tetradecyl sulfate 0.25% versus polidocanol 0.75% in sclerotherapy of lower extremity telangiectasia.

Patients And Method: The study was carried out on 21 patients; each patient was injected with STS in one limb and with POL in size matching telangiectatic veins in the other limb. Photographic records were obtained pre-treatment and one month after the first session and one and three months after the second session. Side effects of the treatment were assessed at each follow up visit. Patient satisfaction index and overall clinical improvement score were also calculated.

Results: Both STS and POL had a similar clinical improvement score. However, STS was more painful during the injection and caused more telangiectatic matting and skin necrosis while POL caused more pigmentation at the injection sites.

Conclusion: Both STS and POL are equally effective in treating lower limb telangiectasia, however STS is more painful during injection, carries more risk of skin necrosis and matting, and POL has more incidence of pigmentation.

KEYWORDS: sodium tetradecyl sulfate, polidocanol, sclerotherapy, telangiectasia

INTRODUCTION

Varicose veins are caused by poorly functioning valves within the veins and decreased elasticity of the vein wall which allows the blood to flow back to the superficial vessels causing them to enlarge and become varicosed.[1] Based on the CEAP classification for varicose veins developed by the subcommittee of the Society for Vascular Surgery (SVS) and the International Society for Cardiovacsular Surgery (ISCVS), lower limb telangiectasia is classified as Grade 1 varicose veins.[2]

Most patients with leg telangiectsias seek treatment for cosmetic reasons although up to 53% of patients with leg telangiectsias are reported to have associated symptoms.[3]

Sclerotherapy is a well-tolerated and highly efficacious treatment for varicose veins and telangiectatic leg veins. Sclerosing solutions act by inducing endothelial damage (endosclerosis), which eventually leads to endofibrosis of the treated vessels. Sclerosing solution can be placed into three broad categories based on their mechanisms for producing endothelial injury: detergent, osmotic, or chemical irritant solutions.[4]

Effective sclerotherapy occurs when the endothelial damage and associated vascular necrosis are sufficient to destroy the entire vessel wall. The ideal sclerosing solution should be painless on in-

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jection and free of adverse effects.[5]

The two widely used sclerosing solutions worldwide are Sodium Tetradecyl Sulfate (STS) and Polidocanol (POL).[4] Clinical studies comparing the efficacy of these two sclerosing materials are lacking in Egypt. Therefore, this study aimed at performing a clinical comparison of STS 0.25% versus POL 0.75% in sclerotherapy of lower extremity telangiectasia.

PATIENTS AND METHODS

This study was carried on 21 female patients, collected from the outpatient clinic of the Dermatology and Venereology Department, Tanta University Hospital. Ethical approval was sought and granted. They were of different skin phototypes and have superficial telangiectatic lower limb veins with a diameter that ranges from 0.5 to 1.5mm.

All the patients had disfiguring telangiectatic lower limb veins with no other enlarged larger vessels. None of them received previous treatment for varicose veins. Patients on anticoagulant therapy, currently pregnant or lactating females and those with systemic diseases or known allergy to the sclerosing materials were excluded from the study.

All the patients had complete history taking, thorough general examination and lower limb examination to assess the distribution of veins and exclude incompetent perforators. The sclerosants used were STS (Trombovar 3%) (Innotheria laboratories, France) diluted to reach a concentration of 0.25% by adding 0.5ml of STS to 5.5ml of distilled water, and POL (Aethoxysclerol 3%) (Kreussler Pharma, France) diluted to reach a concentration of 0.75% by adding one ml of Aethoxysclerol to three ml of distilled water.

The protocol of injection was that published by Sadick, 2000,[6] all patients received two sessions of sclerotherapy (one month apart) in the form of STS 0.25% in a telangiectatic vein in the right lower limb and POL 0.75% for size matched leg veins on the left lower limb. Pain was evaluated during injection of both sclerosing materials (0=absent, 1=mild, 2=moderate, 3=severe).[7] The occurrence of erythema and/or localized urticarial reaction immediately after injection was also evaluated.

Each limb was assessed for improvement one month after the first treatment session, and one and three months after the second treatment session and an improvement score (0=<25%, 1=26%-50%, 2=51%-75%, 3=76%-100%) was done. Complications as skin hyperpigmentation (mild, moderate or severe), skin necrosis and telangiectatic matting were also assessed. Lesions were photographed at each injection and follow up visit after obtaining patient's consent.

Each patient was asked how satisfied she was after treatment on a scale from 0-100% and this was then categorized into 3 groups; (0=0%-25%, 1=26%-50%, 2=51%-75%, 3=76%-100%) as previously described.[4] An average was calculated for each sclerosant material.

STATISTICAL ANALYSIS

The data were collected, tabulated and statistically analyzed using SPSS soft ware statistical computer package version 16. For quantitative data, the mean and standard deviation were calculated. The difference between means was statistically analyzed using the Chi-square test. A p-value ≤ 0.05 was considered statistically significant.

RESULTS

In this study, during the first and second session of injection sclerotherapy, all patients experienced

burning pain during the injection of STS, while 15 out of 21 patients experienced burning pain during the injection of POL. The difference in pain experienced by the patients with STS and POL was statistically highly significant in the first and second sessions (P=0.003 and 0.001 respectively) (Table 1).

Immediately after the injection sclerotherapy, although erythema was observed in more patients after injection of STS (eighteen patients in the first session and sixteen patients in the second session) than after injection of POL (fifteen patients in both sessions), the difference was not statistically significant (P=0.26 and 0.71 respectively). Similarly, there was no statistically significant difference between occurrence of urticarial reaction with the use of both sclerosants in both sessions. Anaphylactic reaction or systemic allergic reactions were not observed during the injection of STS or POL in both sessions (Table 1).

In the current study, the average clinical improvement at time of the second session was 1.33±0.86 for STS injected side and 1.47±0.81 for POL injected side, the difference was not statistically significant (P=0.59). One month after the second session, the average clinical improvement score was 1.9±0.89 at STS injected side and 1.9±0.77 at POL injected side while after 3 months of the second session it was 2.09±0.57 and 2.14±0.77 respectively, (Fig. 1-4) (Table 2).

Skin hyperpigmentation was the most common complication after injection sclerotherapy with POL and STS (Fig. 4). Although, it was found to be more after injection of POL than after injection of STS the difference in the pigmentation was statistically non significant at all follow up visits (Table 3).

One month after of the second treatment session, a skin ulcer 2mm in diameter developed in one patient, (Fig. 5) and telangiectatic matting, (Fig. 6) in another patient at the injection site of STS but not with the use of POL (Table 3).

At the end of the follow up period, patient's satisfaction score was assessed for each sclerosing material with an average of 2.38 ± 086 for the injected sites with POL and an average of 2.33 ± 0.86 for the sites injected with STS. However, the difference was statistically non significant (P=0.85). On comparing the clinical improvement score with the patient's satisfaction score three months after the second session of injection, the difference was statistically non significant for both POL (P=0.30) and STS (P=0.35) (Table 4).

Table 1 Observation during the first and second sessions of injection sclerotherapy for patients with lower limb telangiectatic veins injected with POL versus STS

Items		Observations during 1st session			Observations during 2nd session		
		POL	STS	Chi-square *P*-value	POL	STS	Chi-square *P*-value
Pain	0=Absent	6	0	0.003*	5	0	0.001*
	1=Mild	9	5		9	3	
	2=Moderate	6	10		6	10	
	3=Severe	0	6		0	7	
Erythema		15	18	0.259	15	16	0.707
Urticaria		6	8	0.513	4	7	0.292
Anaphylaxis		0	0		0	0	

** P is significant at < 0.05, POL = Polidocanol, STS = Sodium tetradecyl sulfate.*

DISCUSSION

In this study, we compared clinically STS and POL in treatment of lower limb telangiectasia. It was observed that patients experienced burning pain during injection of STS more than during injection of POL in both sessions. This was in agreement with previous studies.[8-11] The fact that

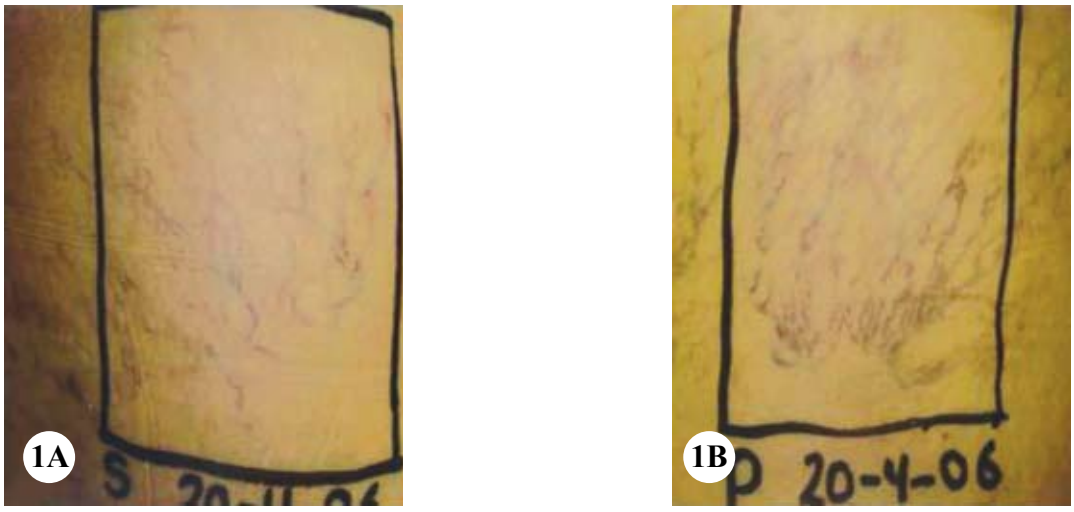

Fig. 1 A female patient with lower limb telangiectasia before treatment with STS (A) and POL (B).

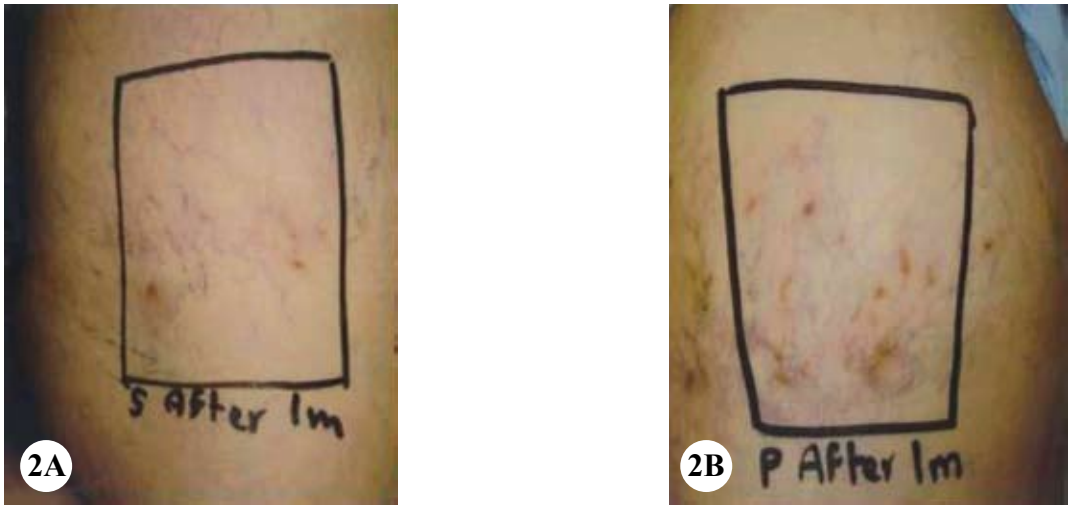

Fig. 2 The same patient one month after the first session (at time of second session) of sclerotherapy with STS (A) and POL (B).

Table 2 Clinical improvement scores for patients with lower limb telangiectatic veins treated with sclerotherapy with POL versus STS

Improvement score		1 month after the 1st session		1 month after 2nd session		3 month after 2nd session	
		POL	STS	POL	STS	POL	STS
0= (0-25%)		4	3	1	2	0	1
1= (26-50%)		7	6	4	3	2	2
2 = (51-75%)		9	11	12	11	14	12
3= (76-100%)		1	1	4	5	5	6
Average	Mean ± SD	1.33 ± 0.856	1.476 ± 0.813	1.905 ± 0.768	1.905 ± 0.889	2.142 ± 0.573	2.095 ± 0.768
	P-value	0.589		1.000		0.823	

POL= Polidocanol, STS = Sodium tetradecyl sulfate.

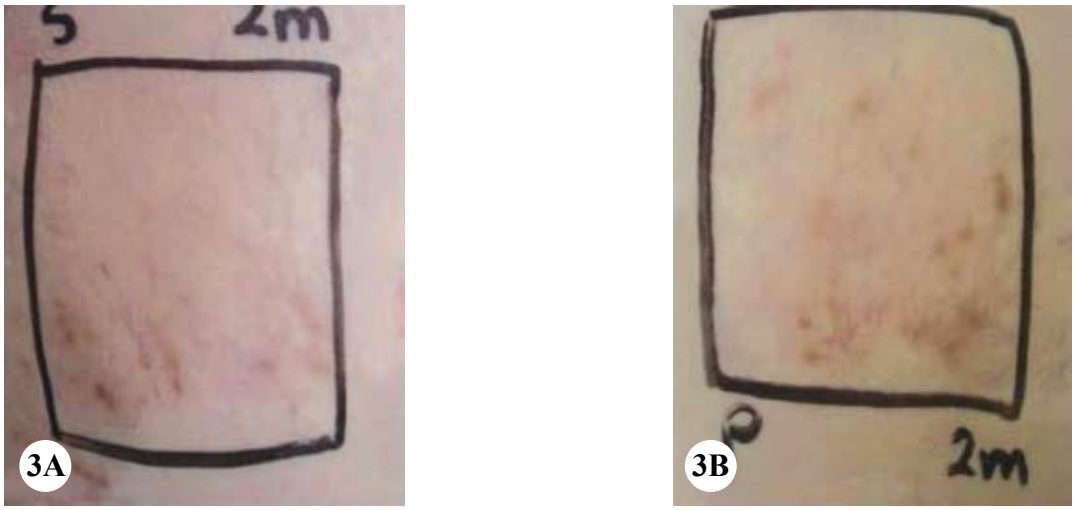

Fig. 3 The same patient one month after the second session of sclerotherapy with STS (A) and POL (B).

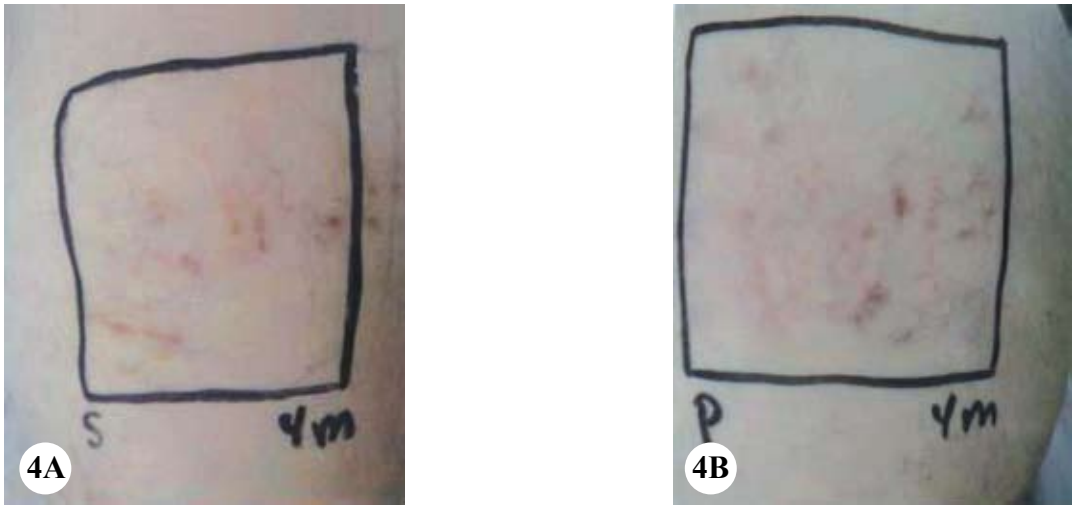

Fig. 4 The same patient three months after the second session of sclerotherapy with STS (A) with clinical improvement score= 3 and POL (B) with clinical improvement score=3 and hyperpigmentation.

Table 3 Complications of injection sclerotherapy with POL versus STS for patients with lower limb telangiectatic veins

Post-sclerotherapy complications		1 month after the 1st session			1 month after 2nd session			3 month after 2nd session		
		POL	STS	Chi-square *P*-value	POL	STS	Chi-square *P*-value	POL	STS	Chi-square *P*-value
Hyper pigmentation	No	1	5	0.211	2	6	0.186	4	7	0.360
	Mild	6	6		5	6		8	9	
	Moderate	10	9		9	8		7	5	
	Severe	4	1		5	1		2	0	
Skin necrosis		0	0		0	1		0	0	
Telangiectatic matting		0	0		0	1		0	1	

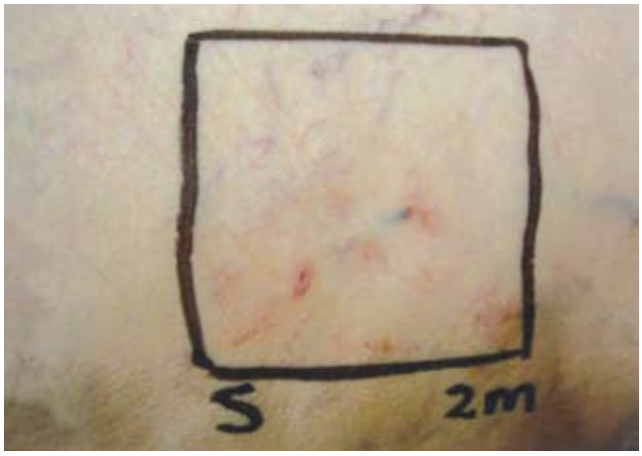

Fig. 5 A patient with lower limb telangiectasia after sclerotherapy with STS showing small skin ulceration.

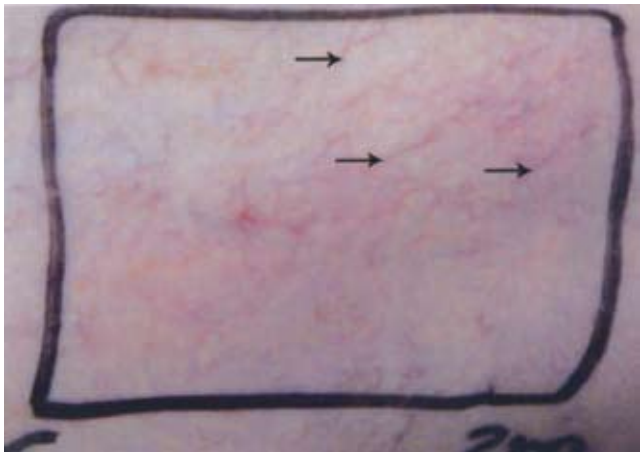

Fig. 6 A patient with lower limb telangiectasia after sclerotherapy with STS showing telangiectatic matting.

Table 4 The averages of patient's satisfaction compared with clinical improvement score in patients with lower limb telangiectasia three months after the second session of injection sclerotherapy with POL versus STS

Sclerosing material		STS	POL
Satisfaction	Mean	2.38	2.33
	± SD	0.86	0.86
Improvement score	Mean	2.14	2.09
	± SD	0.57	0.77
P-value		0.29	0.35

POL= Polidocanol, STS = Sodium tetradecyl sulfate.

POL is less painful than STS could be explained by noting the anesthetic character of POL to the extent that it was originally used as an anesthetic material.[12,13]

In the current study, some patients developed local urticarial reaction immediately after injection at the injection sites of both sclerosants. This correlated with the finding of Goldman, 2002[14] and Rao et al., 2005.[4] The local urticarial reaction might be as a result of sclerosant-mediated inflammation with subsequent release of histamine and other inflammatory cytokines mediators.[15] Goldman 1987[16] and Leibaschoff et al., 1994[17] found that severe urticarial reaction could be treated with systemic H1 antihistaminic and topical twice daily-application of a medium-potency topical steroid cream. However, in the current study, the reaction was mild and required no medical treatment.

Anaphylactic or systemic allergic reaction didn't occur during injection in both sclerosants. Rao et al., 2005,[4] Leibaschoff et al., 1994[17] and Guex, 1993[18] found that allergic reactions are much rare to occur with the use of POL than with the use of STS. They believe that the decrease in antigenicity of POL is secondary to the absence of a benzene nucleus and a paramine group, and the presence of a lone free alcohol group. So, patients who are even allergic to STS or iodine have no allergic manifestations to injections of POL.[8,17] However, Goldman 2002[14] stated that the incidence of systemic allergic reaction with the use POL is higher than that of STS.

Concerning the average clinical improvement score, it was found that there was no statistically significant difference between both sclerosing solutions used. This was similar to the findings of previous studies.[5,14,15,19,20,21,22] They concluded that

both POL and STS were nearly equally effective in abolishing veins in lower limbs. On the other hand, in their recent comparative study between POL and STS, Rabe et al.,[23] concluded that POL is highly effective than STS and deserves the adjunct 'gold standard'.

In the current work, skin hyperpigmentation was the most common complication after sclerotherapy. Although POL caused more pigmentation at the injection site than STS, the difference was statistically not significant. In contrast to our results, Rao et al., 2005[4] and Goldman 2002[14] found that the incidence of post-sclerotherapy hyperpigmentation was higher with the use of STS than with the use of POL. These contradictory results could be due to the different concentrations of POL used for sclerotherapy. They used a less concentration of POL (0.5%) than that used in our study (0.75%). Goldman et al., 1987[20] and Goldman, 1991[24] supposed that utilizing the lowest effective concentration of sclerosing solution may decrease the incidence of pigmentation.

A skin ulcer was detected after the second session at the injection site of STS only. This matches the results of Conrad et al., 1995,[9] Collini 2000[10] and Goldman 2002.[14] However, an equal incidence of post-sclerotherapy skin necrosis was reported with both STS and POL by Rao et al., 2005.[4] Sclerosing solutions vary in the degree of cellular necrosis they produce. It was found that a significant cutaneous necrosis can occur with all agents except POL that appears experimentally to be the least toxic to subcutaneous tissue. However, in sufficient concentration it will cause cutaneous necrosis.[25] The highest incidence of skin necrosis was observed with hypertonic saline followed by STS followed by Polyiodide iodine then POL.[26]

In this work, one patient developed telangiectatic matting at the injection site of STS. Goldman 2002[14] detected a higher incidence of telangiectatic matting at injection sites after utilization of STS than after the use of POL. However, an equal incidence of telangiectatic matting was reported by Rao et al., 2005[4] after the use of both sclerosant. The incidence of matting was discovered to be proportional to the degree of inflammation and thrombus formation induced by the sclerosants. The quantity and strength of solution should be limited to the amount that will not produce excessive endothelial damage.[27]

In the present work, there was no statistically significant difference between patient's satisfaction towards both sclerosing solutions. This was similar to the finding conducted by Rao et al., 2005.[4] On reviewing literature, there was either a comment on patient's satisfaction score or clinical improvement score. Thus it was interesting to conduct a comparison between them in the present study. No statistically significant difference was found between patient's satisfaction and the average clinical improvement score.

To conclude: both STS and POL are nearly equally effective in treating lower limb telangiectasia. However, STS in addition of being more expensive, it is more painful and carries more risk of skin necrosis and matting than POL. Although POL causes more hyperpigmentation at the injection sites, this could be avoided by using lower concentrations.

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