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# Treatment of Varicose and Telangiectatic Leg Veins: Double-Blind Prospective Comparative Trial Between Aethoxyskerol and Sotradecol

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**BACKGROUND.** One hundred twenty-nine patients were treated with either polidocanol (POL) or sodium tetradecyl sulfate (STS) to compare the efficacy and adverse sequelae of each agent.

**OBJECTIVE.** To determine the safety and efficacy of two sclerosing solutions.

**METHODS.** Each patient's leg veins that did not have incompetence from the saphenofemoral junction (SFJ) were divided into three categories by size (<1 mm, 1–3 mm, 3–6 mm). Each leg was randomly treated with either 0.25%, 0.5%, or 1.5% of STS or 0.5%, 1.0%, or 3% of POL respective of size. An inde-

pendent, three-panel, blindly randomized photographic examination was obtained pretreatment and at 4 and 16 weeks. Patient satisfaction index and overall clinical improvement assessment were also obtained.

**RESULTS.** 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 POL group.

**CONCLUSION.** Both STS and POL are safe and effective sclerosing solutions for varicose and telangiectatic leg veins.

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**SCLEROTHERAPY REFERS** to the introduction of a foreign substance into the lumen of a vessel causing thrombosis and subsequent fibrosis. The mechanism of action for sclerosing solutions is that of producing endothelial damage (endosclerosis) that ends in endofibrosis. The extent of damage to the blood vessel wall determines the effectiveness of the solution. For sclerotherapy to be effective without recanalization of the thrombotic vessel, the endothelial damage and resulting vascular necrosis must be extensive enough to destroy the entire blood vessel wall.<sup>1</sup> The ideal sclerosing solution should be painless to inject, free of all adverse effects, and specific for damaged (varicose) veins. This article evaluates the safety and efficacy of two detergent sclerosing solutions, sodium tetradecyl sulfate (STS) and polidocanol (POL).

## Sodium Tetradecyl Sulfate

Sodium tetradecyl sulfate is a synthetic, surface-active substance first described by Reiner<sup>2</sup> in 1946 (Figure 1). It is composed of sodium 1-isobutyl-4-ethyloctyl sulfate plus benzoyl alcohol 2% (as an anesthetic agent)

and phosphate buffered to pH 7.6. It is a long-chain fatty acid salt of an alkali metal with the properties of soap. The solution is clear, nonviscous, has a low surface tension, and is readily miscible with blood, leading to a uniform distribution after injection.<sup>2</sup> It primarily acts on the endothelium of the vein because, when diluted with blood, the molecules attach to the surface of red blood cells, causing hemolysis. The recommended maximal dosage suggested by the British manufacturer in a treatment session is 4 ml of a 3% solution [S.T.D. injection product data sheet (1977), S.T.D. Pharmaceuticals Products Ltd., Hereford, England]. The recommended maximum dosage by U.S. and Canadian manufacturers is 10 ml of a 3% solution with intervals between treatments of 5–7 days [Tromboject product information (rev. 10/87) from Omega, Montreal, Canada].

It is available as a 1% or 3% solution that can be diluted with sterile water or normal saline to achieve an appropriate therapeutic concentration. It is also available with the same pH and preservative as Fibro-Vein (STD Pharmaceutical Products Ltd., Hereford, England) in 5 ml multiuse vials as 0.2%, 0.5%, 1%, and 3%. Concentrations of 0.1–0.3% are commonly used for the treatment of telangiectatic veins 0.2–1.0 mm in diameter; 0.5–1% for treatment of uncomplicated varicose veins 2–4 mm in diameter; and 1.5–3% for the treatment of larger varicose veins.

STS became widely used in the 1950s after its introduction in 1946 and many articles have been written describing its safety and efficacy.<sup>3–6</sup>

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**Table 2.** Disappearance of Varicosities<sup>a</sup>

Vein <1 mm		Vein 1–3 mm		Vein 3–6 mm		All	
STS (N = 32)	POL (N = 26)	STS (N = 28)	POL (N = 27)	STS (N = 27)	POL (N = 27)	STS (N = 69)	POL (N = 60)
4.4 ± 0.6	4.6 ± 0.4	4.6 ± 0.8	4.4 ± 0.6	4.5 ± 0.4	4.7 ± 0.4	4.5 ± 0.7	4.5 ± 0.5
P = .055		P = .832		P = .581		P = .117	

Disappearance scale (1–5): 1 = worse than before treatment, 2 = no change, 3 = minor disappearance, 4 = moderate disappearance, 5 = complete disappearance. P = treatment with STS compared to POL; two-way ANOVA.

as to the agent being injected. Veins less than 1 mm in diameter were randomized to be treated with either POL 0.5% or STS 0.25%, veins 1–3 mm in diameter with POL 1% or STS 0.5%, and veins 3–6 mm in diameter to POL 3% or STS 1.5%.

Photographs were taken and questionnaires were administered before treatment and at 1, 4, and 16 weeks after treatment. Three vascular surgeons blinded to treatment and study center evaluated pre- and posttreatment photographs to determine overall disappearance on a scale of 1–5: 1 = worse than before treatment, 2 = no change, 3 = minor disappearance, 4 = moderate disappearance, 5 = complete disappearance.

## Results

An analysis of the individual study center and/or treating physician was not performed in this study. To do so would have limited the statistical significance required to properly compare the two sclerosing solutions in the three sizes of veins.

POL and STS were equally effective in causing the disappearance of veins in all size categories (Table 2). Pain, inflammation, hyperpigmentation, ecchymosis, and vein thrombosis were similar with both agents. However, POL caused less localized urticaria and skin necrosis than STS (Table 3).

## Discussion

Sclerotherapy is a popular and effective treatment for varicose and telangiectatic leg veins when treatment is performed in a logical stepwise fashion. This article details the largest comparative clinical study to date on

the two most popularly used sclerosing solutions available worldwide. STS has been used in the United States and worldwide since the 1950s. It has never been formally investigated under an FDA-required protocol, but its use in millions of patients yearly for the past 50 years attests to its safety and efficacy. POL, another detergent class of sclerosing solutions has been used worldwide since the mid 1960s. It is also used extensively, with millions of treatments being given each year in a safe and effective manner.

We believe that this study as well as the Australian clinical trial<sup>11</sup> and many studies from around the world<sup>6,8,10,13–18</sup> prove that POL is at least as safe and effective as STS for the treatment of varicose and telangiectatic leg veins.

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**Table 3.** Summary of Adverse Events by Treatment Group

Adverse event	STS	POL	Total
Ecchymosis	64 (70%)	48 (58%)	112 (64%)
Hyperpigmentation	58 (64%)	44 (53%)	102 (59%)
Vein thrombosis	42 (46%)	35 (42%)	77 (44%)
Local urticaria	33 (36%)	19 (23%)	52 (30%)
Telangiectatic matting	10 (11%)	6 (7%)	16 (9.2%)
Skin necrosis	6 (6.6%)	0 (0%)	6 (3.5%)
Allergic reaction	0 (0%)	1 (1%)	1 (0.6%)

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