The EASI Study
Efficacy and Safety of Aethoxysklerol®, Sotradecol® and Isotonic Saline for the Sclerotherapy of Telangiectasias and Reticular Varicose Veins

The EASI study compared the efficacy and safety of polidocanol (POL, German trade name Aethoxysklerol®) with sodium tetradecyl sulphate (STS, Sotradecol®) and isotonic saline (placebo) for the treatment of telangiectasias and reticular varicose veins with sclerotherapy. The FDA-approved, double-blind, randomized, prospective, controlled multicenter trial was designed to obtain marketing authorization in the USA for POL under the trade name Asclera™.

Treatment method

160 patients with telangiectasias and 156 patients with reticular varicose veins were included in 19 German practices and hospitals. They received placebo or treatment with POL or STS according to the regulations of the German and US marketing authorizations, respectively.

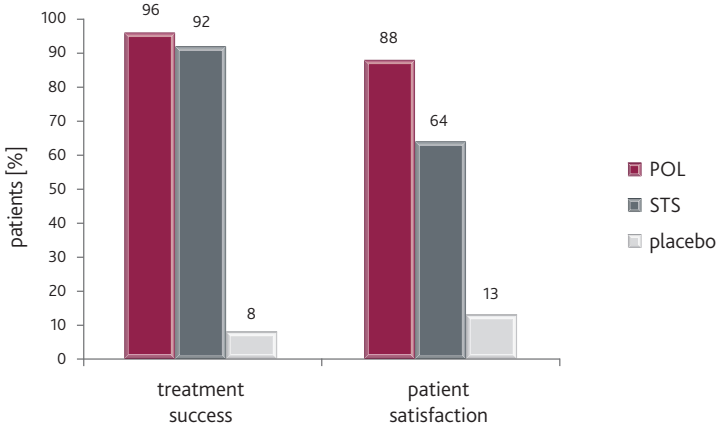
Type of varicose vein	POL	STS	Saline (placebo)	Max. dose per session
Telangiectasias	0,5% (n = 82)	1% (n = 51)	0,9% (n = 27)	4,8 ml
Reticular varicose veins	1% (n = 76)	1% (n = 54)	0,9% (n = 26)	2,4 ml

The concentration of STS used during this study was requested by the FDA. In daily practice, however, it may be common to dilute the drug.
Three treatment sessions per patient were allowed depending on the treatment success.

Efficacy and safety criteria

Three and 6 months after the last injection, the efficacy and safety as well as patient satisfaction were evaluated. The primary efficacy criterion was the improvement of the veins assessed by means of photographs taken with a newly established digital imaging system. The treated area was rated by the investigator and blinded medical experts according to a 5-grade scale. Treatment success was defined as grade 4 (good improvement) or 5 (complete treatment success).

Results: The EASI study clearly shows the high efficacy of Aethoxysklerol®



The mean score of improvement 3 months after the last treatment was significantly higher ($p < 0.0001$) with POL (4.52) and STS (4.47) than with placebo (2.19).
The treatment was successful in a slightly higher percentage of patients with POL (96%) than with STS (92%).
The mean percentage of patients who were "satisfied" or "very satisfied" with their treatment after 3 months was significantly higher ($p < 0.0001$) with POL (88%) than with STS (64%) or placebo (13%).
Results after 3 and 6 months were comparable.
Treatment with POL was safe and, apart from transitory symptoms at the injection site, well tolerated.

Conclusion

- **The treatment success rate of Aethoxysklerol® 0.5% and 1% in the treatment of small varicose veins was 96%, which was a little, but not significantly, higher than that of STS (92%)**
- **Aethoxysklerol® showed fewer side effects and was better accepted by patients than STS**

In summary, the EASI study demonstrates that Aethoxysklerol® is highly effective in the treatment of telangiectasias and reticular varicose veins while showing an excellent safety profile.