

## The **ESA**-China Study Efficacy and Safety of **Aethoxysklerol**® for Sclerotherapy of Varicose Veins in Chinese Patients

The Good Clinical Practice (GCP) compliant, double-blind, randomized, prospective, controlled multicenter ESA study was designed to show that sclerotherapy with polidocanol (POL, German trade name Aethoxysklerol®) is an efficacious and safe treatment for varicose veins in the Han Chinese population and to obtain marketing authorization for POL in China.

### **Treatment method**

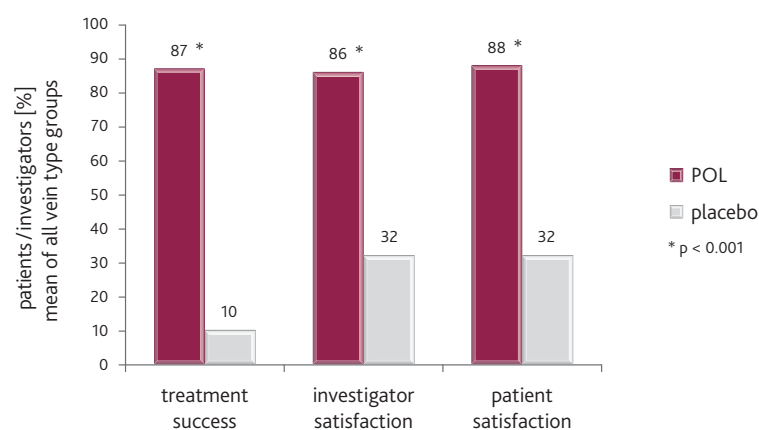
In this study 214 patients received treatment with liquid Aethoxysklerol® and 71 patients received placebo. A maximum of 3 treatment sessions were possible depending on the treatment success.

Group	Type of varicose vein	Treatment
Group A	Telangiectasias of < 1 mm	POL 0.5% (n = 72) or placebo
Group B	Reticular veins and/or small-sized varicose veins of 1-5 mm	POL 1% (n = 70) or placebo
Group C	Medium-sized and/or large non-saphenous subcutaneous varicose veins of > 5 mm and with reflux of > 0.5 s	POL 3% (n = 72) or placebo

### **Efficacy and safety criteria**

The primary efficacy criterion was the outcome of the treatment at 3 months after the last sclerotherapy session. In group A and B, efficacy of treatment was assessed by means of photographs taken with the digital imaging system established in the EASI study. The treated area was rated by the investigator according to a 5-grade scale. Treatment success was defined as grade 4 (good improvement) or 5 (complete treatment success). For group C, efficacy was evaluated by duplex examination and treatment success was defined as occlusion of the vein and/or absence of reflux > 0.5 s. Secondary efficacy variables were investigator and patient satisfaction as well as safety of POL.

### **Results: The ESA-China study confirms the excellent efficacy of Aethoxysklerol® in Chinese patients**



Three months after the last treatment, the success rate was significantly higher with POL than with placebo throughout all vein type groups (mean of group A: 87%, group B: 86% and group C: 89%). Additionally, both the percentages of investigators and patients who voted "satisfied" or "very satisfied" with the treatment outcome were significantly higher with POL (86% and 88%, respectively) than with placebo.

The study clearly showed that sclerotherapy with Aethoxysklerol® was safe and well tolerated in Chinese patients apart from mild transitory reactions at the injection site.

### **Conclusion**

- The treatment success rate in small, medium-sized and large non-saphenous varicose veins was significantly higher with 0.5%, 1% and 3% Aethoxysklerol® (87%) than with placebo (10%)
- Liquid sclerotherapy remains a reliable treatment option for medium-sized and large varicose veins (89% treatment success)
- Investigator and patient satisfaction was very high (86% and 88%) after sclerotherapy with POL
- Aethoxysklerol® was well tolerated in Chinese patients

In summary, the multicenter ESA study confirms in the Han Chinese ethnic group the findings from previous studies: Aethoxysklerol® is highly effective and safe in the treatment of varicose vein patients.