

The **ESAF** Study

Efficacy and Safety of Great Saphenous Vein Sclerotherapy Using Standardized **Aethoxysklerol®** Foam

The ESAF study was the first Good Clinical Practice (GCP) compliant, randomized, prospective, controlled multicenter clinical trial in Germany to evaluate the efficacy and safety of foam sclerotherapy of the great saphenous vein (GSV) compared with liquid sclerotherapy.

Treatment method

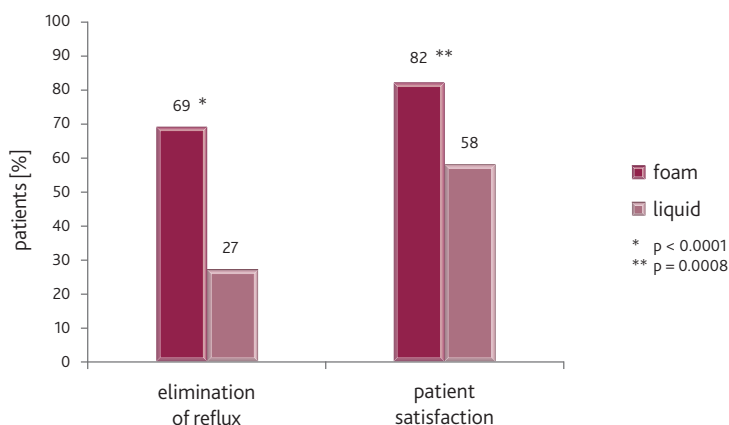
106 patients were treated in 11 study centers with polidocanol 3% (POL, German trade name Aethoxysklerol®) either as foam or liquid under standardized treatment conditions. Eligible patients had an incompetent GSV with a reflux of > 1 s and a diameter of less than 12 mm, measured 3 cm below the sapheno-femoral junction (SFJ).

Standardized microfoam was prepared with the EasyFoam® Kit. Foam or liquid Aethoxysklerol® was injected into the GSV under ultrasound guidance at least 10 cm below the SFJ. Only one injection with a maximum dose of 5 ml foam or 4 ml liquid was allowed per session. Further treatment was possible 2 and 4 weeks following the first.

Efficacy and safety criteria

The primary efficacy criterion was the elimination of reflux (from > 1 s to < 0.5 s) measured 3 cm below the SFJ at 3 months after the last injection. The most important secondary criteria were patient satisfaction and safety of the treatment.

Results: The ESAF study proves the efficacy and safety of foam sclerotherapy



The ESAF study clearly shows that reflux was eliminated effectively with POL foam in significantly more patients (69%) in comparison with liquid sclerosant (27%). In addition, significantly more patients were satisfied (voted "improved") with foam (82%) compared to liquid (58%) sclerotherapy. The number of incidents was comparable in both treatment groups and included mainly mild transitory reactions close to the injection site. No serious adverse drug reactions were observed.

Conclusion

- **Successful treatment of the GSV was significantly higher with Aethoxysklerol® foam (69%) compared with its liquid form (27%)**
Five out of 11 study centers even had a success rate of 100% with foam. In those centers, higher mean volumes had been injected into GSVs with a smaller mean diameter. In this study only one injection of the GSV was allowed per session. Superior results can be reached in daily practice if GSVs, tributaries and accessory veins are treated in one session.
- **Treatment success was achieved with small volumes of foam in an average of only 1.3 sessions**
- **Patient satisfaction was significantly higher after foam sclerotherapy**
- **Sclerotherapy with foam is as safe as liquid sclerotherapy**

In summary, foam sclerotherapy with Aethoxysklerol® is a highly effective and safe method for the treatment of incompetent great saphenous veins.