

The Hemorrhoid Foam Study

Efficacy and Safety of Aethoxysklerol® Foam for Sclerotherapy of First Grade Hemorrhoidal Disease

In Germany, sclerotherapy with liquid polidocanol (POL) is the treatment of choice for first grade hemorrhoidal disease. For varicose veins, foam sclerotherapy is more efficacious than liquid and, therefore, it was assumed that foam may also be successful in the treatment of hemorrhoids. This Good Clinical Practice (GCP) compliant, single-blind, randomized, prospective, controlled multicenter study was designed to compare the efficacy and safety of liquid POL (German trade name: Aethoxysklerol®) with POL foam in the treatment of hemorrhoidal disease.

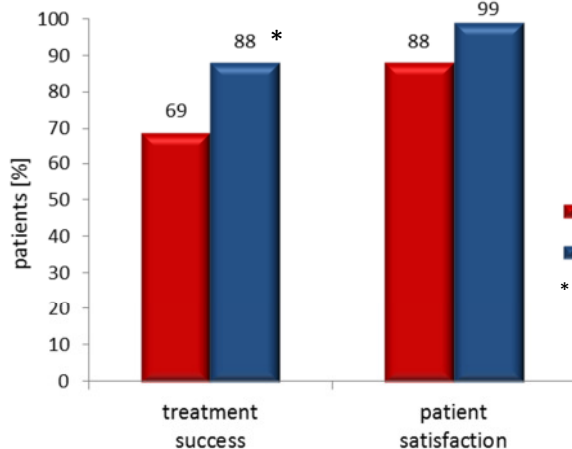
Treatment method

In this study 130 patients suffering from bleeding first grade hemorrhoidal disease were included. 64 patients were treated with liquid Aethoxysklerol® 3% (2 ml per session = 60 mg POL) and 66 patients with POL 3% foam (6 ml per session = 32 mg POL). Standardized foam was prepared using the EasyFoam® Kit. Injections were given according to Blanchard on a bi-weekly schedule until patients were free of bleeding. Four treatment sessions per patient were allowed depending on the treatment success. As foam and liquid can easily be distinguished by their appearance during application, it was not possible to blind the investigators and only the patients were blinded.

Efficacy and safety criteria

The primary efficacy criterion was the cessation of bleeding after the first sclerotherapy session. Bleeding was assessed by the patients, who recorded each episode of bleeding for at least 3 months. Secondary efficacy variables were patient satisfaction and safety.

Results: The hemorrhoid foam study shows the excellent efficacy of Aethoxysklerol® 3% foam



After a single sclerotherapy session, the success rate of 88% in the foam group was significantly higher than that of 69% in the liquid group ($p = 0.01$). After the second sclerotherapy session, 98% of the patients had been treated successfully with the foam and 92% with the liquid. 99% of the patients were satisfied or very satisfied with their treatment in the foam group compared to 88% in the liquid group. The number of required sessions for treatment success and the total amount of injected POL were significantly reduced in the foam group.

No serious adverse events occurred during the study. Sclerotherapy with both liquid and foamed POL was safe and well tolerated and there was no difference in safety between the two groups.

Conclusion

- Treatment success of first grade hemorrhoidal disease after a single sclerotherapy session was significantly higher with foamed Aethoxysklerol® 3% (88%) than with the liquid form (69%)
- Foam sclerotherapy allows significant reduction of both the number of treatment sessions and the total amount of injected active substance
- Liquid sclerotherapy remains a reliable treatment option for hemorrhoidal disease with a 92% success rate after the second session
- Patient satisfaction was very high (88% with the liquid and 99% with the foam)
- The study confirms the good safety profile of liquid and foamed Aethoxysklerol®

In summary, the results of this study show that foam sclerotherapy with POL is a new, highly effective and safe non-surgical method in the treatment of hemorrhoidal disease.