

## Press release of Kreussler

Focus on (foam) sclerotherapy of hemorrhoidal disease

First international expert meeting at Kreussler's headquarter in Wiesbaden

Sclerotherapy with liquid Aethoxysklerol has been used successfully for the treatment of hemorrhoidal disease since 1966. Whereas foam sclerotherapy has been proved as an effective treatment option for varicose veins for years, it was as late as 2006 when first studies in the treatment of hemorrhoidal disease with foam were started in Italy and Germany. However, the Italian method using a flexible endoscope turned out to be too complex and cost-intensive. The method using a proctoscope that has been developed by Dr. Moser from Germany, was picked up in Italy only in 2015 and then further evaluated in several clinical studies. The latter Italian activity caused a real boom in sclerotherapy.

For this reason Kreussler Pharma, as the world's leading manufacturer of sclerosants, has initiated this first meeting focusing on hemorrhoidal disease with key opinion leaders from Germany, Italy, and Poland. The aim of the meeting was to find a consensus on the most important issues in the field of sclerotherapy. On the 18<sup>th</sup> of January 2020, in the conference rooms of Kreussler, the experts discussed and summarized essential diagnostic measures and the best sclerotherapy techniques. In the afternoon, the experts introduced their experiences with foam sclerotherapy and pointed out that higher grade hemorrhoidal disease may also be treated successfully with foam. This was considered by all participants to be a highly interesting approach.

At the end of the eventful day, all experts were united in their enthusiasm for sclerotherapy and felt sure that the results of this meeting will substantially contribute to optimize sclerotherapy. The recommendations gathered during the meeting will be made available by Kreussler in printed and electronic form.

### Proctology in the footsteps of phlebology

The causes of hemorrhoidal disease and varicosis are multifactorial, however, in the etiology of both diseases a congenital weakness of connective tissue plays an important role. Therefore, it is not surprising that a new clinical study shows that half of the patients suffering from chronic venous insufficiency are also affected by hemorrhoidal disease (1). Sclerotherapy with Aethoxysklerol is a good treatment option for both diseases. Regarding hemorrhoidal disease, sclerotherapy is especially used for the treatment of grade 1 and 2, often in combination with rubber band ligation. For the treatment of spider veins sclerotherapy is still the method of choice and for larger varicose veins foam sclerotherapy is a good alternative to surgical and thermal methods.

Foam sclerotherapy has proven to be more efficacious than liquid polidocanol solution, therefore, it was reasonable to ask if foam sclerotherapy could also be more efficacious in the treatment of hemorrhoidal disease.

### The development of foam sclerotherapy for hemorrhoidal disease

Foam sclerotherapy for varicose veins has continued to develop successfully since the end of the 90s. In contrast, the first reports on foam sclerotherapy of hemorrhoidal disease appeared as late as 2006. The Italian experts used a flexible endoscope, which allowed the injection of foam from retrograde into the hemorrhoidal nodes. Despite good results, this method could not convince the international medical community because it

was too complex and cost-intensive.

In the same year, Dr. Moser from Germany had the idea to perform foam sclerotherapy using a proctoscope. After the first encouraging results, he performed a clinical study together with the German Colorectal Center in Mannheim to examine the efficacy and safety of foam in comparison to liquid polidocanol (2). The treatment success after a single injection with Aethoxysklerol 3% foam was significantly higher (88%) than with liquid (69%). After the second treatment session, the success rate was 98% with foam compared to 92% with liquid. Dr. Moser could further show that the recurrence rate after six years was significantly reduced with foam (46%) compared to liquid (67%) and that foam is also efficacious in the treatment of grade 2.

In Germany, there was a high interest in this new method, however, many experts continued to use liquid polidocanol which remained a reliable treatment option.

It was only in 2015 that the Italian experts returned to foam sclerotherapy for the treatment of hemorrhoidal disease. This time, Prof. Dodi and Dr. Lobascio followed the method with proctoscope and were quickly convinced of its advantages. Particularly worth mentioning are Prof. Trompetto and Dr. Gallo, who started several foam studies in the treatment of grade 1 to 3. Initial findings indicate that foam sclerotherapy might also be a good treatment option for grade 3 hemorrhoidal disease. The presentation of the first study results on international congresses and meetings caused a sclerotherapy boom not only in Italy but also in other countries like Poland, Portugal, Spain and China. Currently, several clinical studies in the treatment of grade 2 and 3 are ongoing - their results are awaited with great interest.

### **The first expert meeting - a milestone for Kreussler**

The current boom in sclerotherapy has brought with it the idea to organize a meeting with renowned experts to exchange experiences on foam sclerotherapy for hemorrhoidal disease, but also to find a transnational agreement on the necessary diagnostic measures and performance of sclerotherapy.

The scientific meeting took place in January this year in the newly constructed conference rooms of Kreussler's headquarter in Wiesbaden. The German participants were Prof. H. J. Krammer and Prof. A. Herold from the German Colorectal Center in Mannheim, Dr. G. Kolbert from the German Colorectal Center in Hannover, and Dr. K.-H. Moser from Cologne. From Italy joined Dr. R. Perinotti, Dr. G. Gallo, and Prof. Dr. M. Trompetto and from Poland Dr. A. K. Skowroński.

During the one day meeting the experts focused in particular on the essential diagnostic measures and the most appropriate injection techniques for sclerotherapy and agreed on recommendations and basic procedures in the field of sclerotherapy of hemorrhoidal disease. In the afternoon the experts presented their studies and results with foam sclerotherapy and agreed on two main techniques. On the one hand, the technique according to Dr. Moser that involves the injection of foam into the tissue right above the hemorrhoidal node. And on the other hand, the Italian and Polish technique that involves the tangential injection of foam directly into the hemorrhoidal node. Despite good results, a final assessment of foam sclerotherapy in the treatment of grade 3 could not be made without further study results.

Thanks to the great engagement and outstanding know-how of the experts the meeting was an important milestone for Kreussler in the field of foam sclerotherapy for hemorrhoidal disease. The summarized recommendations and tips of the experts will be made available by Kreussler on request.

„A good sclerotherapy technique is the prerequisite for an optimal outcome in the treatment of hemorrhoidal disease. That is why we have taken this important step to set a future benchmark for the standardization of sclerotherapy“, summed up Dr. Petra Gliem, head of medical marketing at Kreussler. Further international expert meetings are planned in the near future.

#### Literature

(1) Godeberge P et al. Hemorrhoidal disease and chronic venous insufficiency: concomitance or coincidence, results of the CHORUS study (chronic venous and hemorrhoidal diseases evaluation and scientific research). 2019. Gastroent Hepatol Epub ahead of print.

(2) Moser K-H et al. Efficacy and safety of sclerotherapy with Polidocanol foam in comparison with fluid sclerosant in the treatment of first-grade haemorrhoidal disease: A randomised, controlled, single-blind, multicentre trial. 2013. Int J Colorectal Dis 28(10):1439-47.