Saphenion®-5 years sealing micro-foam for therapy of truncal varicose veins: Our experiences

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Zierau UT, Martell L, Lahl W. Saphenion®-5 years sealing micro-foam for therapy of truncal varicose veins: Our experiences. J Phlebol Lymphol.14(2):12-15.

5 years sealing micro-foam for truncal varicose veins: This sclerotherapy is a modification of the well-known method of micro-foam sclerotherapy of side branches, reticular and spider veins using aethoxysklerol micro-foam. The sclerosing component of the old process is expanded to include a sealing effect. This is done with the help of a highly concentrated sterile sugar solution. This was already used once in the 20s-60s of the last centuries for the treatment of truncal varicose veins and side branch varicose veins. **Key Words:** *Deep vein thrombosis; Inferior vena cava filters; Intestinal perforation*

INTRODUCTION

Saphenion®-5 years sealing micro-foam for varicose veins

The micro foam for the treatment of varicose veins has been known since 1938. He established himself in the 90s as a solid therapy of varicose veins and spider veins. The treatment management of the varicose disease was clearly facilitated and the therapy was gentle. Since 2010, the United States Food and Drug Administration (FDA) has approved micro foam therapy using aethoxyklerol foam for the treatment of varicose veins and has declared it the "gold standard" of spider vein and retinal vein therapy [1,2].

With the success of the vein glue since 2011, the idea was obvious to further develop the micro foam used since the mid-1990s. Sclerosing and sealing the truncal varicose vein simultaneously is one of the possible variations [3]. This variation is very suitable for the therapy of truncal varicose veins at all. However, clear definitions are necessary for the use of sealing micro-foam [4].

All that more so since current pathophysiological findings on the cause of varicose veins assume that incomplete rehabilitation of individual venous segments or venous valves or the so-called stage-adapted procedure are not sufficient for the therapy of varicose veins. Pathological changes at the cellular level and tissue structures, as well as chemical receptors (estrogen receptors!), initially cause the skin veins to expand. The mechanical component of reversing the flow of blood through venous valve defects is then a consequence of these cellular and tissue changes.

Saphenion® has been using micro-foam therapy for 16 years. We have introduced some changes in the injection technique and modified the micro foam. The almost over 8 years of successful work with the vein glue VenaSeal® "suggested the idea to give the micro-foam additionally a sealing effect" [5,6].

Through these technical improvements, the modifications of the micro-foam and the permanent use of the ultrasound bedside, therapy of side branches, and partially or completely defective truncal varicose veins (2-5 mm up to 4-5 mm in diameter) is possible. It is also recommended after diagnosis in all clinically possible cases. Even with cost aspects-especially with the self-payer-the sealing micro-foam is an excellent alternative since we no longer have to use only the expensive thermal catheter procedures or the more expensive vein glue for the treatment of insufficient truncal varicose vein sections.

HISTORICAL FACTS

Saphenion®-5 years sealing micro-foam for varicose veins

The beginning of the sclerotherapy were observations during a lues epidemic in 1911-before the First World War. Both the French dermatologist Jean Sicard, as well as the German Paul Linser discovered that arm veins at the injection of Salvarsan was sclerosed. This then led to the actual sclerotherapy on truncal veins and side branches. First, both doctors injected sublimate, then hypertonic saline. The successes of Paul Linser and Sicard brought surgical procedures in the background. Also, numerous, us surgeons left now the radical operative treatment (Figures 1 and 2).

Figure 1) *Salvarsan therapy during Lues epidemy in 1911-and the beginning of sclerotherapy*

Figure 2) *UT Zierau, Vascular Surgeon-Vein Care Center, Germany*

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Received: *February 03, 2021,* **Accepted:** *February 18, 2021,* **Published:** *February 25, 2021*

Ferdinand Sauerbruch, director of the surgery hospital Charitè-Berlin since end of 1927, has banned his surgeons at Charitè-hospital in 1928 all radical methods of varicose vein therapy! There the surgeons used sugar solution for sclerotherapy. He was followed by a lot of other colleagues in German hospitals (Figure 3).

Figure 3) *Ferdinand Sauerbruch, director of Charitè-Clinic of Surgery 1928-1949*

While radical surgery of varicose veins was once again defined as the method of the first choice in the FRG from 1949, in the GDR until the mid-1960s, sclerotherapy was preferred to radical stripping. This is also evidenced by the following quote from Sauerbruch's surgery theory, published by Bier/Braun/Kümmel, edition from 1958 (Barth publishing house, Leipzig, 1958) from volume VI-The operations on the extremities: Almost everywhere, the surgical treatment of varicose veins is completely or almost completely abandoned in favor of chemical sclerotherapy. It does more and more than surgical procedures have accomplished. There are several solutions for injecting varices for sclerotherapy [7-10].

The sublimate solution originally specified by Linser is abandoned because of its toxic side effects. Nowadays the most common are:

1. Hypertonic 10%-30% saline

2. Concentrated 50%-60% sugar solution

3. Unsaturated solution of fatty acid salts. The saline solutions work very safely but have the disadvantage that they cause unpleasant painful tissue necrosis that takes a long time to heal. We haven't seen these two disadvantages, tissue necrosis and relapse when using the fatty acid salt solution in many hundreds of applications.

RESULTS

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After 5 years of therapy on truncal varicose veins, the sealing micro-foam shows a similar success rate as the laser or radical surgical stripping with significantly fewer side effects in the period mentioned and the indications mentioned. The course of therapy is much gentle on the tissue and can be mobilized immediately. And the neurological complications and injuries of lymphatic tracts, especially on the lower leg, known for radical surgery and thermal procedures, are eliminated [11].

Since December 2006 we have performed 17,578 micro-foam therapies. In the last 60 months (1/2016-1/2021), Saphenion® chose sealing micro-foam in 5889 cases for the treatment of truncal varicose veins [12-18].

Truncal varicose veins were treated in 933 cases. Specifically, this affected the small saphenous vein in 335 cases, the great saphenous vein in 240 patients, and in 358 accessory saphenous veins. The mean age of the patients was 54 years (15-93 years).

The therapy of an incomplete truncal varicose vein is almost 100% successful over a period of 5 years. The small saphenous vein (SSV) is occluded in 89.2% (299 veins). The great saphenous vein (GSV) was occluded in 87.1% of the cases (209 veins) over the same period. The accessory saphenous veins were occluded in 92.7% (332 veins). This corresponds to a total occlusion rate of 92.25% for all treated veins (Figure 4).

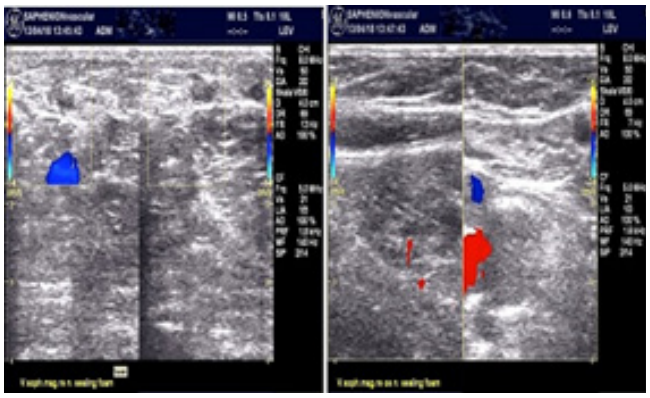

Figure 4) *Ultrasound after sealing micro-foam therapy of GSV*

EXPERIENCES

Saphenion®-5 years sealing micro-foam for varicose veins

In addition to the improved closure effectiveness, we also see much less frequently the ugly post-therapeutic brown lines and spots, so-called hyperpigmentation. Ecchymoses (bleeding under the skin) have become rare (<8%). We have seen phlebitis in 32 cases (3%, 4%).

A partial deep vein thrombosis of lower leg veins was seen in 3 cases. This has led us to perform a single thrombosis prophylaxis Intra op for all micro-foam therapies of truncal varicose veins [19].

In one case, multiple puncture ulcers were found, however. Here was experimented outside with ointments and sprays, so that the cause of the ulcer is not fixed. In no case have any of our patients been reported to have any sensory or post–treatment sensation of numbness [20-25].

Essentially, in addition to the visible small puncture hematomas, it was primarily extrinsic pressure and tenderness over the treated vein that was reported. Muscular catlike symptoms also appeared. This is similar to the symptoms after VenaSeal®-glue therapy. There were no other side effects (allergies) or complications (embolism).

Thus, the Sealing Micro-foam therapy is a very good, effective, and inexpensive alternative and supplement to the thermal catheter procedures often used in truncal varicose veins, f. e. laser, radio wave, superheated steam, or the non-thermal ClariVein® or vein glue VenaSeal®. Micro foam therapy is also interesting for use in cosmetically demanding patients and older patients.

Taking into account the current knowledge on the causes of varicose veins (cell wall remodeling and destruction, connective tissue alteration, excess hormone receptors), the Sealing Micro foam is an excellent alternative therapy for a cause-adapted extension of the therapy indications (Figure 5).

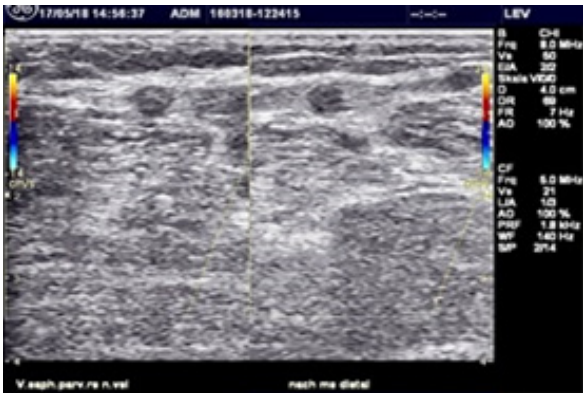

Figure 5) *Sealing foam SSV*

DISCUSSION

Saphenion®-5 years sealing micro foam for varicose veins

In the last 22 years, the necessary quality criteria for endovascular interventions on veins with varicose changes were largely laid down, and several comparative studies on functional efficiency of radical stripping surgery on the one hand and endovenous treatments on the other hand, were furthermore conducted. By now, it has emerged as an undeniable fact that endovenous interventions do not only exhibit a merely cosmetic advantage as was hitherto assumed. They also have clinical advantages and quite significantly reduce side effects and complications such as still occur regularly today as in the past in connection with the conventional surgical technique. This is not new knowledge. Also, the surgeons of the "Golden Twenties" didn`t love the radical surgery!

But today we have the ultrasound and all colleagues who work with endovenous procedures meanwhile have reliable criteria for a high-quality therapy. We do not need anesthesia anymore. Elastic stockings should be for 10-14 days. Working and sports is possible one day after treatment.

The significantly reduced side effects and a well-nigh negligible pain score are also clear advantages in comparison with laser and radio wave therapy. In the final analysis, the new sealing procedure has to meet solely the hard criterion of efficacy, namely the permanence of an effective vein closure in our defined cases.

Likewise, the foam therapy is found in the guidelines of the German Society for Phlebology. The European Vascular Surgeon's Guidelines see the use of second-choice therapy in the field of truncal varicose veins in micro foam therapy-before radical surgical stripping. With the success of the vein glue, the idea was close to developing the Sealing Micro-foam.

In addition to improving permanent vein occlusion, the rate of side effects is also reduced. Neurological abnormalities were also not reported. In one case, we saw multiple puncture ulcerations after therapy-however, treatment was given abroad with various ointment dressings.

In addition to visible small puncture hematomas, our patients report primarily extrinsic pressure and tenderness over the treated vein. Muscular catlike symptoms also appeared (this is similar to the symptoms after VenaSeal®-superglue).

Other side effects did not occur in any case. Thus, endovenous sealing foam therapy is a very good, effective, effective and inexpensive alternative to the also frequently used catheter methods laser, radio wave, superheated steam, Clarivein, and vein glue.

Thus, the Sealing procedures appears to be on the same level with, or even superior to the laser system. In the time periods between 12 and 36 months covered by follow-up examinations up to now, both procedures have proven quite clearly superior (100% incomplete truncal veins, 95% small saphenous vein) to laser therapy in terms of effectiveness. So, Sealing Micro-foam has the nearly same closure rate then radiofrequency over 3 years in treatment of SSV and incomplete truncal varicose veins.

By now, Sealing Micro-foam has undeniably become at SAPHENION® the therapy of the first choice for the treatment of the SSV to a vein diameter to 0.45 cm. Here, we meanwhile consider the well-known risk of neurological side effects and complications associated with the application of the laser and radio frequency techniques as being too high.

CONCLUSION

In the light of the 20 years of experience, we have gathered by now, we recommend that every vein center that applies endovenous treatment should have at least 2 alternative treatment procedures at its disposal. For us, this means that in practical work with VenaSeal®, with Sealing Microfoam and Radiofrequency all insufficient saphenous veins should as far as possible always be treated.

Independently of this and including all experiences with modifications of the sealing technique we at SAPHENION® meanwhile regard the not tumescent, not thermal sealing therapy as treatment of the first choice in the range of catheter-supported therapeutic procedures in truncal varicose veins SSV or VSAA-varicosis.

And we see this method as a very good method also in ultrasound-guided treatment of great saphenous veins GSV, recurrent veins, side branches of truncal veins and greater perforator veins.

Last Comment: Therapies with saline solutions and pre coagulated blood are not carried out for technical reasons.

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AUTHOR`S CONFLICT OF INTERESTS

There is no conflict of interest!

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