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76 Months Long Time Experience with the VenaSeal-System in Treatment of Truncal Varicose Veins.
A Follow-Up Study Conducted on 2091 Truncal Saphenous Veins in 1128 Cases

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Abstract

The paper is about long-time experiences in sealing truncal varicose veins: 76 month-follow up in treatment of 1128 cases and 2091 truncal varicose veins. Since 19 years by now, varicosis has been increasingly treated endovenously. At the start, the rather inconvenient VNUS® Closure plus-procedure and the more convenient linear laser procedure were used, and these were followed in 2006/2007 by the bipolar RFITT® catheter, the VNUS® Closure Fast system and the radial laser. Thus, in the course of the last few years, plenty of experience has been gathered with endoluminal therapy, quality criteria have been defined and standards for the different techniques have been developed. The present research paper sheds light on the advantages and disadvantages and presents the 76-months results of a single-center ambulatory clinical study with prospective design. We will report about our experiences and results of a prospective comparative study of VenaSeal®-Closure in the treatment of 2091 saphenous veins (1441 greater saphenous vein, 547 smaller saphenous veins, saphena akzessoria lateralis veins in 59 cases, saphena akzessoria medialis veins in 38, Giacomini veins in 2 and femoropopliteal veins in 4 cases). Treatment included also ulcera crures in 12 cases (Figure 1).

Keywords: Sealing truncal varicose veins, 76 months long time experiences in VenaSeal, non-tumescent non thermal sealing therapy, endovenous therapy varicose veins.

Introduction

In the base, all varicose veins should be treated actively. This we can find in nearly all guidelines worldwide. All the specialists know, that mobilization and compression alone cannot normalize the venous function of outflow venous blood from the leg. An insufficient varicose vein is working like a downpipe-the blood pressure at the lower leg is increased chronically. And so we get the typical chronique venose disease. Nearly 70% of all adults in Europe have clinical signs of this CVD.

Since 18 years by now, varicosis has been increasingly treated endovenously. Before this, the varicose veins were treated geradically with the “stripping”-method, a 110 years old radical surgery method. At the start, the rather inconvenient VNUS® Closure Plus procedure and the more convenient linear laser procedure were used, and these were followed in 2006/2007 by the bipolar RFITT® catheter, the VNUS® Closure Fast system and the radial laser. Thus, in the course of the last few years, plenty of experience has been gathered with endoluminal therapy, quality criteria have been defined and standards for the different techniques have been developed [1-16].

One very important technical development combined with the beginning of the endovenous therapy was the colour ultrasound

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Figure 1: Dr. Ulf Zierau and Assistant Claudia Reuter during live-op at the Madrid Endovenous Forum.

(duplex)-we can see the catheter inside the veins, the glue and we can control the tip of catheter, the work inside the vessel and the effects inside the body-without any radiation and without i.e., contrast agents. These is a very important fact, because working with an endovenous catheter without ultrasound isn't a fully noninvasive therapy because of using phlebography. Ratzek et al. have described exactly the sonographic appearances of common disorders of all tissues. They have worked about the high sensitivity of ultrasound in tissue diagnostics [17,18,19].

In addition, 15 years ago, far from the beaten tracks of radio wave and laser, the development of a fascinatingly simple, yet nevertheless highly effective method of sealing veins-the VenaSeal® closure technique-was initiated. After CE approval had been granted in the autumn of 2011, a number of vein centers in Germany and Europe started using the VenaSeal®-system. By now, 40 centers are working successfully with the new therapy system in Germany alone. Today there is an approval in all countries, also in USA since 2/2015 [1-3,8-11,20-22]. The author has applied VenaSeal for the first time in a great saphenous vein on 1st August 2012 [23-25]. (Figure 2)

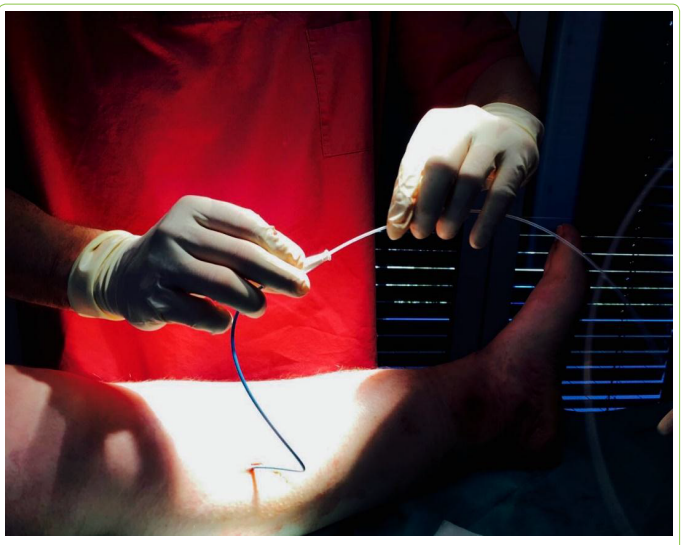

Figure 2: VenaSeal-Closure technique.

Materials and Methods

Based on the manufacturer's application instructions, sealing with the VenaSeal-system was started 1-3 cm from the sapheno femoral junction, and a spot of glue was applied at intervals of 2-3 cm, depending on the diameter and the flow/pressure of the vein. Thick branch-offs of auxiliary side branches were additionally treated with a single-shot glue. The maximal diameter of truncal veins was 2-3 cm, also venous aneurysms, ectatic veins and perforators were treated. The follow-up observation period in our study was up to 76 months.

The great saphenous vein was treated in 1441 cases, in 547 cases the small saphenous veins were treated and in 97 cases the trunk of an inguinal accessories vein was treated. Two Giacomini veins and four femoro popliteal veins also were treated.

VenaSeal® interventions were performed under light sedation with Dormicum or local anesthesia for venous access accompanied by music therapy, 109 patients didn't get any anesthesia. One patient performed pain acupuncture on herself on point G4. All patients are given a follow-up examination by duplex sonography in the scope of a prospective study (our own quality management) on the 1st /14-30th/70-90th. day as well as after 6 and 12 months. After this we controlled every following year. Nearly all duplex sonography examinations post intervention were done by another colleague, not by the vascular surgeon treated the truncal veins. (Figure 3)

Results

During the time period from 1st August 2012 to 30th November 2018 (76 months), VenaSeal® was applied to

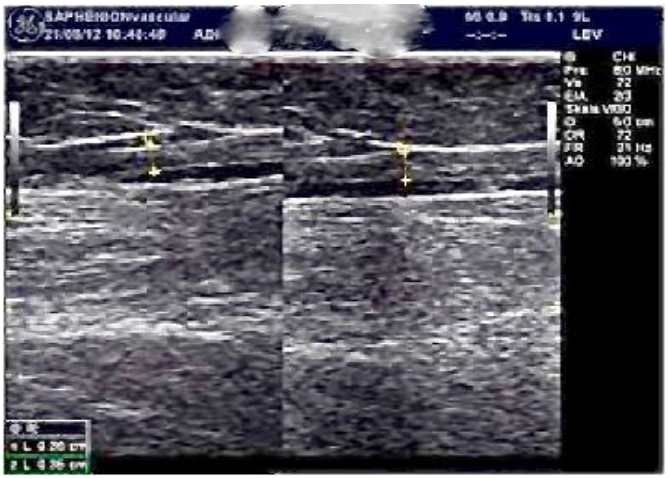

Figure 3: Typical ultrasound of GSV after sealing.

achieve closure of the vein in 2091 truncal varicose veins. In 339 patients one saphenous vein was treated; in 643 patients two saphenous veins were treated; in 119 patients 3 saphenous veins were treated. In 24 cases 4 truncal veins, and in two cases 5 veins, in one case 6 truncal veins were treated simultaneously.

Grade 2-3 saphenous varicosis of the GSV according to Hach, and in the case of the SSV grade 2 saphenous varicosis acc. to Hach, was the inclusion criteria. In accessories veins we treated the inguinal trunk in length between 12-25 cm.

On the 1st day 2091 veins were checked (2076 veins were closed initially=99.28%) in the scope of follow-up, and up to the 30th day, partial recanalization was found in 41 veins, and complete recanalization was found in 9 veins. This corresponds to a closure rate of 97.61%.

Over a time period of 3 months up to 4 months after the treatment, we were able to follow up 1599 saphenous veins (76.5% of all veins that had been treated), and here we found 43 partials and 15 complete recanalization's. The closure rate is thus 97.23%.

1380 saphenous veins (68.2%) were followed up over a 6-8 months' time period and 50 partial and 28 complete recanalization's were found, resulting in an effectiveness of 96.23%.

No further recanalization's were found after 76 months. In the follow-up period of 5 years after therapy we controlled 1236 truncal varicose veins (59,1%) up to now. All 12 leg ulcers were healed until to 12 weeks after intervention.

2091 truncal varicose veins having been sealed with VenaSeal®, the results achieved over the entire time period of 76 months are equivalent to a closure rate of 96.23%.

The pain score (range 1-10) for subjectively felt pain on the 1st day post-sealing was between 1.6 and 3.4 (2.1)-in RFITT between 3.8 and 4.1.

In 167 treated veins (7.9%), we observed a postoperative unspecific inflammatory skin reaction after approx. 10-14 days in the VenaSeal group; with appropriate antiphlogistic treatment with ibuprofen and cooling dressings, this subsided within 3-5 days.

In all other cases subjected to follow-up examinations, no complications of any kind, no paresthesia's or hypoesthesia's, no permanent skin reactions, no phlebitis or thrombosis or infections were observed. Only in 11 cases we were seen a lymphatic fistula at the peripheral punition.

In particular, even subcutaneously situated saphenous veins could be glued without any significant skin reaction (reddening, swelling). We also clearly prefer VenaSeal® in treatment of SSV and now also in GSV due to the large number of neurological sensations in connection with treatment by Laser and Radiofrequency [23,24] (Figure 4).

Nearly all patients were greatly surprised at the fully ambulatory intraoperative procedure and the brief and pleasant postoperative convalescence phase. All patients were able to leave the office between 30 and 120 minutes after the intervention.

In the case of VenaSeal, we have up to now refrained from applying compression therapy in over 90% of all cases. We prefer to use compression stockings only in cases, the diameter of the treated vein its over 1.5 cm or in treatment of venous aneurysm or ectatic varicose veins.

Discussion

In the last 19 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.

Thus, the colleagues who work with endovenous procedures meanwhile have reliable criteria for a high-quality therapy [1-4,10,12,16,20-22,24,25].

The VenaSeal®-closure procedure is the newest technical development in the series of endovenous therapeutic procedures. Although it is a catheter-based procedure in terms of the basic principle of the therapeutic approach, it differs fundamentally with regard to the closure technique.

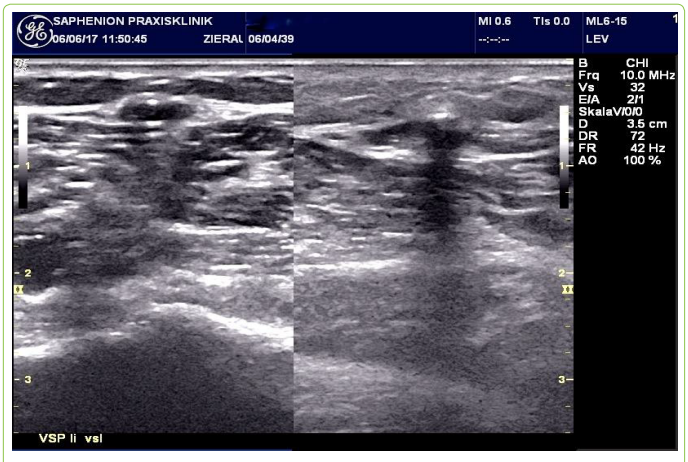

Figure 4: Sealing SSV is first choice.

While the glue likewise gives rise to a certain temperature (approx. 45-50°C), the procedure is not a thermal one. Side effects as those known to occur in connection with laser and radio wave therapy ultimately play no significant role here. The necessary reliable closure is achieved by means of a non-tumescent non thermal cyanoacrylate superglue, the basic chemical formula of which has been known since several decades, and which is being used in neuroradiology in the treatment of vascular malformations since 1981. We also worked with this glue since 1988 in vascular surgery at the Charitè-hospital.

We do not need anesthesia's anymore and can in most cases do without postoperative compression therapy. Elastic stockings should nevertheless by all means be recommended after the treatment of thicker saphenous varicose veins measuring > 1.2 cm, and they become compulsory where we intend to apply gluing therapy in larger lumens measuring 1.5 cm and more, ectatic veins, junction aneurysms and also perforator veins.

The significantly reduced side effects and a well - nigh negligible pain score are also clear advantages in comparison with laser and radio wave therapy. No paresthesia's, no hypoesthesia's, no phlebitis, extremely rare occurrence of skin pigmentations is only a few of the important advantages of the VenaSeal®-procedure.

In the final analysis, the new procedure has to meet solely the hard criterion of efficacy, namely the permanence of an effective vein closure. And as far as this aspect is concerned, both the first results of the eSCOPE study [11] and the results of single-center studies, and also currently of the VeClose study [21] are very good. The closure rate is similarly high as that achieved with radio waves, namely between 93-100% when all results are summarized.

Thus, the VenaSeal®-procedure appears to be on the same level with, or even superior to the high-frequency radio wave system [10,12]. In the time periods between 12 and 36 months covered by follow-up examinations up to now, both procedures have proven quite clearly superior (99.6%) [10-12,20,22,24] to laser therapy in terms of effectiveness.

The results of first comparative studies show that the VenaSeal® -glue is clearly superior with regard to postoperative side effects though. Both the pain score and the rate of side effects are very low in comparison [24]. Particularly pain as well as the neurological side effects no longer play any significant role at all. These are the main problem associated with laser and radio wave therapy though [8-11,16,21-25]. (Figure 5)

By now, VenaSeal® has undeniably become at SAPHENION the therapy of first choice for the treatment of the SSV. Here, we meanwhile consider the well - known risk of neurological side effects and complications associated with application of the laser and radio frequency techniques as being too high [6,10-12,16,20-22,24,25].

In the light of the 17 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®, all insufficient saphenous veins should as far as possible always be treated in one session.

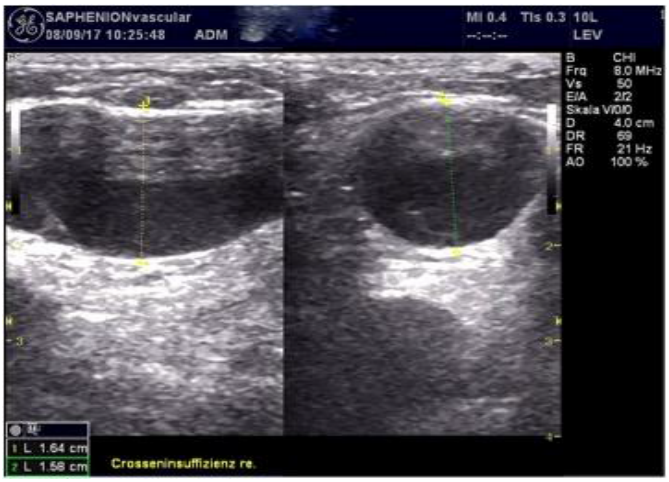

Figure 5: Sealing ectatic and aneurysmatic parts of truncal veins is also possible-ultrasound from SFJ-aneurysm.

Independently of this and including all experiences with modifications of the sealing technique we at SAPHENION® meanwhile regard VenaSeal®-closure as treatment of first choice in the range of catheter-supported therapeutic procedures for GSV and SSV or VSAA-varicosis and we see this method as a very good method.

Conflict of Interest

There are no conflicts of interest; the present research paper was not sponsored.

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