

Outcome four years after transcatheter foam sclerotherapy of the greater saphenous vein

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Keywords

Foam sclerotherapy, endoluminal therapy, insufficiency of the deep veins, long-term results

Summary

The **aim** of the study was to evaluate the long-term results 4 years after a single-session, sonographically guided, transcatheter foam sclerotherapy. **Patients, methods:** We treated 20 patients with a total of 22 legs with varicoses of the greater saphenous vein (GSV, EpAsPr). Additional varicoses of the auxiliary veins of the GSV were sclerosed immediately afterwards. 20 legs or 91% in Hach stage III-IV, clinical stage C2-C5 and a mean GSV diameter of 9 mm (range: 7 to 13 mm) could be followed up 4 years later. **Results:** During the follow up period one leg showed clinical signs of recurrence and underwent surgery, two legs received a single additional sclerotherapy during the four years period. Examination four years after showed in 6 legs clinical signs of recurrence without notice of clinical symptoms by the patients. This gives a clinical recurrence rate of 40% (8 of 20 patients). Duplex sonography showed flow in the region of the saphenofemoral junction in a total of 13 legs (65% of the reexamined GSVs) with an average vessel diameter of 3.7 ± 1.6 mm (range 2 to 7 mm). Retreatments in 3 GSV of the 6 clinically relapsed GSV by a single injection of sclerosing foam showed an occlusion in 100% two weeks after. **Conclusion:** Transcatheter foam sclerotherapy of the GSV shows better clinical long-term results compared to known data of liquid sclerotherapy. Sonographically detected recurrency of the GSV could easily be retreated by a single session of foam sclerotherapy. Foam sclerotherapy is a promising and seriously to be taken option in the treatment of the insufficient GSV.

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Schlüsselwörter

Schaumsklerosierung, endoluminale Therapie, Stammveneninsuffizienz, Langzeitergebnisse

Zusammenfassung

Ziel der Studie war die Evaluation der Langzeitergebnisse einer einmaligen, ultraschallkontrollierten, kathetergestützten Schaumsklerosierung. **Patienten, Methoden:** Behandelt wurden 20 Patienten und 22 Beine mit einer insuffizienten Vena saphena magna (VSM). Zusätzliche Seitennastvarizen der VSM wurden unmittelbar danach sklerosiert. Nachuntersucht konnten 4 Jahre später 20 Beine oder 91% im Stadium III-IV nach Hach, klinisches Stadium C2-C5, mittlerer Durchmesser der VSM: 9 mm (min. 7 mm, max. 13 mm). **Ergebnisse:** Innerhalb der 4 Jahre Nachbeobachtungszeit wies ein Bein klinische Zeichen eines Rezidivs auf und wurde operiert, 2 Beine wurden erneut einmalig sklerosiert. In der Nachuntersuchung nach 4 Jahren zeigten 6 Beine klinische Zeichen eines Rezidivs ohne dass der Patient darauf aufmerksam wurde. Dies entspricht einer klinischen Rezidivrate von 40%. Duplexsonographisch zeigte sich ein Fluss in der Krossenregion bei 13 Beinen (65% der nachuntersuchten VSM) mit einem mittleren Gefäßdurchmesser von $3,7 \pm 1,6$ mm (2 bis 7 mm). Eine erneute einmalige Injektion von Verödungsschaum bei 3 VSM der 6 klinisch sichtbaren Rezidive zeigte eine 100% Verschlussrate 2 Wochen danach. **Schlussfolgerung:** Die kathetergestützte Schaumsklerosierung der VSM zeigt bessere Langzeitergebnisse verglichen mit den bekannten Ergebnissen der Flüssigsklerosierung. Sonographisch festgestellte Rezidive konnten durch eine einmalige Schaumsklerosierung wieder behandelt werden. Schaumsklerosierung ist eine vielversprechende und ernst zu nehmende Option bei der Behandlung der insuffizienten VSM.

Ergebnisse vier Jahre nach kathetergestützter Schaumsklerosierung der Vena saphena magna

Mots clés

Sclérosation par mousse, sclérosation endoluminale, varice-souche, résultats à long terme

Résumé

L'objectif de cette étude était l'évaluation des résultats à long terme d'une unique sclérosation par mousse assistée par cathéter contrôlé par sonographie. **Patients, méthodes:** 20 patients ont été traitées et 22 jambes avec une veine saphène grande (VSG) insuffisante. Branche de côté supplémentaires de VSG est sclérosé directement ensuite. Après examen à 4 ans plus tard, 20 pieds, soit 91% de l'étape III-IV après de Hach, class clinique C2-C5, diamètre moyen de la VSG: 9 mm (min. 7, max 13 mm). **Résultats:** Au cours du temps d'après-observation pendant 4 ans de suivi du temps de la jambe a un signe clinique d'une rechute et a été opérée, 2 jambes ont été à nouveau sclérosant unique. 6 jambes ont montré signes cliniques d'une récurrence dans la visite de contrôle 4 ans plus tard sans que le patient est devenu attentif à cela.. Ceci correspond à un acompte de récurrence clinique de 40%. Un couler dans le secteur de la crosse de VSG a été prouvé par sonographie pour 13 jambes (32% du VSG après examiné) avec un diamètre en moyenne de mm $3,7 \pm 1,6$ (de 2 à 7 mm). Une nouvelle injection unique de mousse sclérosant à 3 VSG des 6 récurrences qui étaient cliniquement visibles en montrant une à 100% d'acompte de fermeture 2 semaines d'après. **Conclusion:** Le sclérosation par mousse assistée par cathéter de VSG montre de bons résultats de longue durée comparés avec la sclérosation liquide. Les récurrences constatées par sonographie pouvaient être traitées de nouveau par une sclérosation par mousse unique. Sclérosation par mousse est option qui prend une prometteuse et sérieuse au traitement du VSG insuffisant.

Results 4 ans après sclérosation par mousse assistée par cathéter de la veine saphène interne

There is a growing interest in foam sclerotherapy of the great saphenous vein with short term results (3, 5, 7, 12). Little is known about long-term results in transcatheter foam sclerotherapy (11). In a previous study we were looking at

the economic value of the method and the short term results (3). In this follow up study we evaluated the long term-effect of a single catheter aided foam sclerotherapy of the great saphenous vein (GSV) four years after.

Patients, methods

All patients who elected to undergo transcatheter foam sclerotherapy in the period of September 2003 to April 2004 rather than

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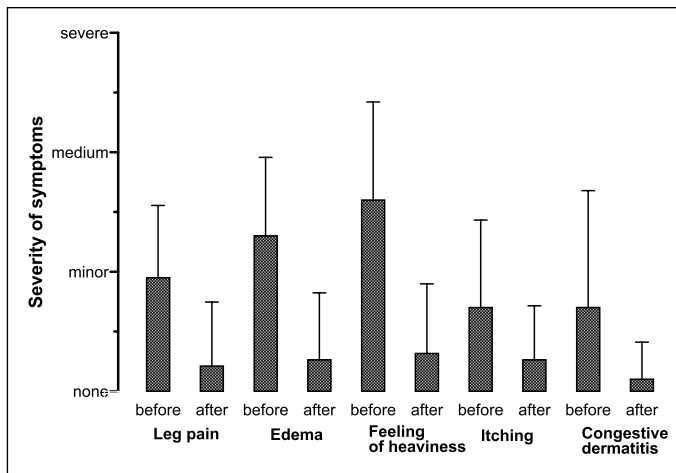


Fig. 1 Clinical symptoms before and four years after sclerotherapy, rated on a four-point scale

surgery were included in this study. A total of 20 patients (22 GSV) were treated (13 women, 7 men) with 22 insufficient GSV. Four years later one patient could not be examined due to a stroke happened a year ago, another patient moved house and the new address could not be tracked down. The other 18 patients (20 legs, 11 women and 7 men, age 54 ± 13.7 years) were examined by duplex sonography. The following data are based on the group of these 18 patients (20 GSV). Clinical severity was as follows:

- 2 legs were C2,
- 9 legs C3,
- 7 legs C4 and
- 2 legs C5.

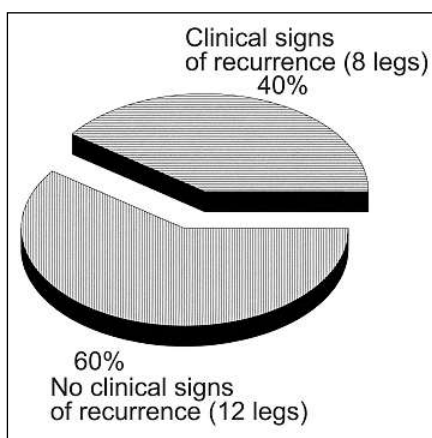


Fig. 2 Summarized clinical evident recurrence rate of treated GSV during the 4 years period and at final examination after 4 years

The sonographically measured mean diameter was 9 mm (range: 7–13 mm) 3 cm below the saphenofemoral junction with the patient reclining and head raised by approx. 30° . The diameter given is the average value of two measurements in a right angle. The calculated cross section area is based on the assumption of a circular cross section. Reflux was measured by duplex sonography on supine patients performing a Valsalva manoeuvre and lay over 4 s except one GSV with 1–4 s. No reflux is defined as <0.5 s. Patients with additional reflux in the small saphenous vein or in the deep venous system were excluded, as were patients with post-thrombotic changes. Clinical severity was distributed as follows:

- 2 legs were C2,
- 8 legs were C3,
- 8 legs were C4 and
- 2 legs were C5.

Endovascular transcatheter foam sclerotherapy (EVS) was performed as described in detail by Wildenhues and previously by us (3, 11). We punctured the GSV below knee and applied a total of 10ml of foam (except in one leg with a narrow GSV due to vasospasm, here we applied 4 ml). Foam was produced by use of a double syringe system consisting of a female/female connector (Braun Melsungen) and two 10 ml syringes with a mix of 1 part 3% Polidocanol (Aethoxysclerol®, Kreussler Pharma) to 4 parts air. Right after the foam was produced, 4 ml of it was applied through the catheter

(RF*X1750G M, Terumo) as a bolus close to the saphenofemoral junction while the GSV was compressed by the ultrasound head proximal to the catheter end. The other 6 ml of foam were continuously applied while withdrawing the catheter. After the procedure the patients received low-dose heparin treatment with fractionated heparin (Innohep®, Leo Pharma) for six days. One week later all patients were examined by ultrasound to confirm total occlusion of the GSV and 4 years later the GSV was again examined by ultrasound 3 cm below the GSV junction. In addition, the clinical symptoms of the patients were documented on a 4-point scale before treatment and at the four-year follow-up.

Results

Clinical recurrence of varicosis

In the 4 years period

Two patients reported the recurrence of a feeling of heaviness in the legs with edema at the ankle. There were clinical signs of a recurrence of GSV varicosis. Both patients were successfully retreated by a single injection of 3% polidocanol foam with an indwelling cannula (7). In one of these two patients the GSV recanalized again and thereafter the patient decided to undergo surgery.

Another patient suffered from a newly appeared incompetence of the V. saphena accessoria anterior. This was successfully treated by foam sclerotherapy.

All of the other 15 patients (17 legs or 85%) did not experience any clinical symptoms during the 4 year follow up time.

After four years

None of the 17 patients (equivalent to 19 treated GSV, one patient was operated) reported the recurrence of a feeling of heaviness in the legs with oedema at the ankle (Fig. 1, Fig. 2). There were clinical signs of a recurrence of GSV varicosis in six legs (30%) detected by visible side branches, mainly at the lower leg. One of these patients received already additional

foam sclerotherapy of the GSV during the 4 years period.

This sums up in a total clinical recurrence rate of 40% (8 GSV) if the recurrence rate during the 4 years period is taken into account.

Colour duplex sonography

One week after sclerotherapy

All GSVs showed complete obliteration from the catheter insertion site to the junction of the inferior superficial epigastric vein, which regularly flushed the sapheno-femoral junction.

Four years after sclerotherapy

We found flow 3 cm below the sapheno-femoral junction in 13 GSV (65%) (Fig. 3, Fig. 4). Six these legs (30%) showed visible side branches, 9 GSV (45%) showed a reflux (8 GSV >4 s and 1 GSV 1.5 s) during Valsalva maneuver. These GSV showed a mean vessel diameter of 4 mm. Compared to the original diameter of a 9 mm this is a 56% reduction of the diameter or 79% of the cross-section, based on the assumption of a circular vessel. Four patients (20%) showed no reflux during Valsalva maneuver. These GSV showed a mean diameter of 2 mm. This corresponds a 77% reduction of diameter (original 11 mm) and 94% in cross-section area. The cross-section area at follow up in patients with reflux was $57 \pm 43\text{mm}^2$ compared to $10 \pm 17\text{mm}^2$ in patients without reflux.

In all 13 patients the mean reduction in cross-section area was 87% compared to the original value. One patient (5% of GSV) underwent surgery due to a relapse before the 4 years period ended. No recurrence of a vessel was detected in six legs (30%).

Patients' satisfaction

A survey at the follow-up examination four years after the therapy revealed that all except one patient would repeat the procedure. No worsening was seen in 17 legs (85%) during the four years period. The side

Fig. 3 Sonographically detected recurrence rate after 4 years (except one patient who received surgery, reflux: >0.5 s, small recanalization – mean cross-section area was reduced by 87%)

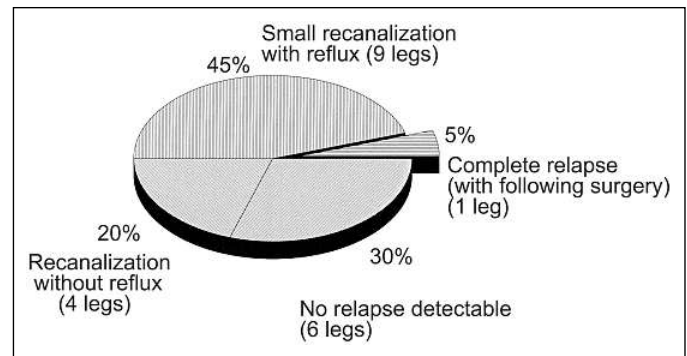
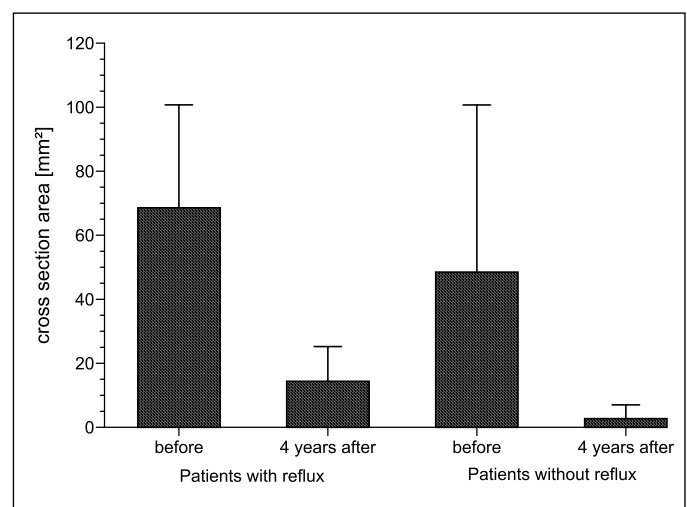


Fig. 4 Calculated cross section area with standard deviation before sclerotherapy and at follow up 4 years later in patients with reflux and without reflux.



branches detected in six patients (6 legs) during clinical examination at the end of the 4 years period did not be recognized by the patients as remarkable deterioration. Only three of these patients accepted resclerosing of the recurrent veins, the other three patients decided rather to wait until further worsening.

Side effects

Except minor side effects (four patients with bruising at the injection side, seven with sensitivity to pressure along the GSV, hyperpigmentation only seen at side branches). All these side effects completely disappeared. No major side effect was seen.

Discussion

Therapeutic options of sclerotherapy was markedly improved by introduction of the combination of sonography and the use of foam technique (4, 10). We can now effectively treat the saphenous veins without the use of anesthetics (7). The use of the catheter improves the positioning close to the saphenofemoral junction even in adipose patients, and the total length of the GSV from the distal puncture site to the saphenofemoral junction can be accessed and treated via the catheter in just one session (2, 3, 5, 8, 11). Only little is known of long term results (11).

With a 100% initial occlusion rate at seven days after a single treatment the success rate is higher compared with liquid sclerotherapy. In addition, the method

proved to be well tolerated with only minor side effects. The marked patient satisfaction with this method is best explained by the good tolerability, which is outwardly visible in the speed with which the patients were able to return to work and the nearly complete absence of pain.

The long term results gives us an additional therapeutic option with a good promising: only one patient underwent surgery and only two patients needed a single additional sclerotherapy during the 4 years period. This result is superior to the recently reported results by a single injection method (6)

During the 4 years period one patient suffered from noticeable relapse, even after a second sclerotherapy of the GSV. This patient decided to undergo surgery. The other 17 patients (19 legs) noticed no signs of relapse, even if the GSV partially recanalized. The reduction in diameter, with a consequently marked reduction in cross-section, reduced the retrograde flow so much, that a deterioration was not observed by the patients. Some patients with recanalization of the GSV with very small diameter showed even no reflux at all. In addition, the recanalization of the GSV is less visible compared to the easily detectable side branches close to the groin or in the medial thigh after surgery. The easily and successful performed retreatment with a single injection of foam in three patients shows a simple and promising way how to deal with recurrent veins.

According the last consensus meeting no heparin prophylaxis is needed, except in

high risk patients for deep venous thrombosis (1). It cannot be excluded that heparin therapy may worsen the outcome. Further studies without heparin prophylaxis will show, whether this may improve the outcome (9).

Conclusion

Foam sclerotherapy is a promising and seriously to be taken option in the treatment of the GSV. Future multicenter studies with an increased number of patients are needed to verify these preliminary results

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