

Catheter-directed foam sclerotherapy treatment of saphenous vein incompetence

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Summary

Background: The aim of this study is to report the short-term results of catheter-directed foam sclerotherapy (CDFS) in the treatment of axial saphenous vein incompetence.

Patients and methods: Data of all patients undergoing CDFS for symptomatic primary incompetence of the great or small saphenous vein were prospectively collected. Treatment results in terms of occlusion rate and patients' grade of satisfaction were analysed. All successfully treated patients underwent clinical and duplex follow-up examinations one year postoperatively.

Results: Between September 2006 and September 2010, 357 limbs (337 patients) were treated with CDFS at our institution. Based on the CEAP classification, 64 were allocated to clinical class C3, 128 to class C4, 102 to class C5 and 63 to class C6. Of the 188 patients who completed the one year follow up examination, 67% had a complete and 14% a near complete obliteration of the treated vessel. An ulcer-healing rate of 54% was detected. 92% of the patients were satisfied with the results of treatment. We registered six cases of thrombophlebitis and two cases of venous thromboembolism, all requiring treatment.

Conclusions: The short-term results of CDFS in patients with axial vein incompetence are acceptable in terms of occlusion and complications rates.

Key words: Foam, sclerotherapy, saphenous vein incompetence, catheter directed

Zusammenfassung

Katheter-gesteuerte Schaumsklerotherapie in der Behandlung der Vena saphena-Insuffizienz

Hintergrund: Ziel der Untersuchung ist es, über die kurzfristigen Ergebnisse der Katheter-gesteuerten Schaumsklerotherapie (KDSS) in der Behandlung der Stamminsuffizienz der Vena saphena magna (VSM) und parva (VSP) zu berichten. **Patienten und Methoden:** Alle Daten von Patienten, die wegen einer primären symptomatischen Stamminsuffizienz der VSM/VSP behandelt werden sollten, wurden prospektiv registriert. Verschluss- sowie Zufriedenheitsrate wurden analysiert. Eine klinische und duplex-sonographische Nachuntersuchung wurde bei allen Patienten mit primär erfolgreicher Behandlung durchgeführt.

Ergebnisse: Zwischen September 2006 und September 2010 wurden 357 Beine (bei 337 Patienten) mit KDSS behandelt. 64 Extremitäten wurden der klinischen Klasse C3 nach der CEAP Klasseneinteilung zugeordnet, 128 der Klasse C4, 102 der Klasse C5 und 63 der Klasse C6.

Bei den 188 Patienten, die nach einem Jahr follow up nachuntersucht wurden, hatten 67% eine komplette und 14% eine partielle Obliteration der behandelten Vene.

54% der venösen Ulzera waren geheilt. Die Zufriedenheitsrate lag bei 92%. Insgesamt wurden sechs Fälle von symptomatischer Thrombophlebitis und zwei Fälle von tiefer Beinvenenthrombose registriert.

Schlussfolgerungen: Die kurzfristigen Ergebnisse der KGSS in der Behandlung der Stamminsuffizienz der VSM /VSP sind zufriedenstellend im Bezug auf Okklusion- und Komplikationsrate.

Introduction

The use of ultrasound guided foam sclerotherapy to treat varicose veins has rapidly increased during the last decade. Foam sclerotherapy is cheap, does not require anaesthesia, is effective and has an acceptable safety profile [8, 18]. The treatment rationale is that sclerosant agents damage the endothelium irreversibly by disrupting cell membranes resulting in sustained vasospasm and vessel obliteration [15].

The direct instillation of sclerosant agents as “microfoam” with carbon dioxide or air made it become an attractive treatment for axial reflux in the great or small saphenous vein (GSV and SSV) [2, 5, 14, 15]. A large number of reports have documented the potential advantages of this technique for treating incompetent axial veins [2, 3, 5, 11, 14, 15, 21, 24]. Publications have focused on foam preparation techniques and the necessary amount of sclerosant agent.

The absence of a standard delivery technique makes foam sclerotherapy difficult to compare with other endovascular ablation techniques such as endovenous laser therapy (ELT) and radiofrequency ablation (RFA) [14]. In a previous report, we presented a technique intended to optimise and standardise foam sclerotherapy of the GSV and SSV in patients with axial reflux [12]. In this extended analysis further follow-up data including safety and efficacy of the method, are reported.

Patients and methods

All patients undergoing CDFS due to incompetence of the GSV and/or the SSV in a 4-year period were prospectively registered in an appropriate ad hoc database. All patients gave informed consent and approval was obtained from our local Ethics committee. The study and the examination protocols have been previously described [12]. Clinical data were collected in a standardized manner at the first visit as well as at every follow up control. Accordingly, all patients were investigated using duplex ultrasound (US) imaging to assess the extent of superficial and deep venous incompetence in an accredited vascular laboratory. CDFS was taken in consideration as a treatment option in patients with advanced disease, i.e. venous insufficiency associated with eczema, recurring thrombophlebitis, skin discoloration, active or previously healed leg ulcer. The aim of the treatment was primarily to eliminate axial venous reflux rather than to eliminate varicosities. A short term control consisting of a clinical as well as an US examination 4 week postoperatively was conducted in the first 81 patients of the study cohort. Information regarding the remaining patients was collected by telephone interviews and a review of clinical records from the emergency departments of the region and from general practitioners.

All successfully treated patients were invited to a one-year clinical and duplex follow-up examination. In particular, we focused our attention on the skin status, registering the presence of excema, new ulcerations or the healing of previous ulcers. Furthermore, the degree of satisfaction (0 not satisfied, 1 satisfied, 2 very satisfied) based on overall improvement of symptoms was recorded.

We defined the treatment as successful when the axial vein appeared to be completely occluded at the US exami-

nation. Partial success was defined as the obliteration of at least 70 % of the vessels lumen.

In case of symptomatic recurrence a further CDFS was undertaken.

Technical aspects

Duplex ultrasonography was conducted using a high resolution transducer (10 MHz, Logiq 9, General Electric, Milwaukee, USA) on an adjustable examination couch, which could be tilted to 45 degrees in order to unmask incompetence of the deep as well as the superficial venous system.

The cut-off value for reflux in the superficial and deep calf veins was set at 500 msec as suggested by Labropoulos et al. [13].

During treatment the patient in the tilted position supported their weight with the contralateral leg to facilitate puncture of the vein. Patients lay supine during treatment of the GSV with the preferred puncture site normally 3–5 cm below the knee. When lying prone for treatment of the SSV, this was punctured 1–2 cm below the sapheno-popliteal junction.

A small amount of local anaesthetic (1–2 ml mepivacain, Carbocain 1 %*, Astra Zeneca, Södertälje, Sweden) was infiltrated at the puncture-site to avoid local spasm. The vein was punctured under ultrasound guidance with an 18G standard vascular access needle. A guide wire (Angiodyn SFC 150–035, B.Braun, Melsungen, Germany) was inserted into the dilated vessel by the Seldinger technique and advanced under US guidance to the sapheno-femoral/popliteal junction. After a small cutaneous stab incision a 5Fr. introducer sheath (RCFW-5.0–38-45 William Cook Europe, Bjaeverskov, Denmark) was advanced over the guide wire. The patient was tipped back to a horizontal position and the leg was elevated 30 degrees using a wedge-pillow. The introducer

tip was placed up to 1 to 2 cm distal to the sapheno-femoral/popliteal junction. Sclerosant foam was prepared in a liquid/air ratio of 1:4 using 2 ml of 3 % polidocanol (Aethoxysklerol®, Kreussler, Wiesbaden, Germany) in order to produce 10 ml of foam. In our experience this ratio combined with cooling of the sclerosant in ice rendered an acceptable viscosity. The GSV or the sapheno-popliteal junction were manually compressed proximal to the introducer tip for treatment of the GSV or the SSV respectively. The introducer was loaded with foam (usually 2 ml). When the foam reached the introducer-tip the sheath was slowly withdrawn, while injecting 8–10 ml of sclerosing foam in the GSV and 4–8 ml in the SSV.

The introducer was then removed and the GSV or SSV compressed in order to prevent the foam from passing uncontrollably into the deep venous system. Treatment results were verified with US. The patient was then mobilized immediately and required to walk for five minutes and advised to wear long compression stockings during the first postoperative week. Knee length compression stockings were adopted from week two to week eight.

Results

Between September 2006 and September 2010 337 patients (357 limbs) were treated with CDFS at our vascular centre. Demographic data and severity of venous disease are shown in Table I. Of the 357 limbs, 21 were treated owing to recurrence after previous surgical treatment for non axial varicose veins (n = 10) or previous CDFS (n = 11). 22 patients had clinical signs and symptoms of previous deep vein thrombosis, and, additionally, 12 cases had primary deep vein incompetence based on ultrasound examination. Eleven patients were on oral anticoagulants at the time of treatment.

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Primary technical success was achieved in 354 of 357 limbs. In three patients puncture of the GSV was technically impossible following repeated unsuccessful punctures and subsequent vasospasm. In twelve patients very tortuous axial veins required the use of angled angiographic catheters and glide-wires. No patient developed chest discomfort, dry cough, dizziness, migraine, nausea or visual disturbances at the time of treatment. The GSV was treated with a median of 8,7 ml foam while the treatment of the SSV required a median of 7,6 ml sclerosant. Six patients required low molecular weight heparin due to painful treatment-related thrombophlebitis a week after the procedure. In Table II the results of treatment 1 year postoperatively are summarized. 92% of the treated patients were either satisfied or very satisfied with the result of treatment.

Eleven patients were treated for their venous disease whilst on long term oral anticoagulation with cumarin, seven for atrial fibrillation and four due to previous deep vein thrombosis. Eight of the 11 patients had occluded saphenous trunks one week after treatment despite ongoing ordinary anticoagulation. Clinical improvement was sustained in these patients at 1 year follow up.

Of the 63 patients treated in class C6, 47 underwent the 1-year follow-up examination. 35 of those were found to have healed ulcers. In the remaining cases, four had combined venous and arterial disease.

Three patients developed a new ulcer in association with venous reflux due to recanalisation of the GSV at 1 year. One patient with a chronic ulcer in spite of treatment was later found to have a squamous cell carcinoma of the skin.

We registered two cases of treatment-related thromboembolism. A 62 year old female patient with a

Table I: Descriptive data of severity classification according to CEAP on 357 limbs (337 patients) treated for axial reflux. US= ultrasound, PTS= post thrombotic syndrome, DVI= deep vein incompetence, HT= hormonal treatment

	Number of patients (total 337)
Age (median and range)	59 (18–95)
Sex (M/F)	139/198
Ongoing HT	8
US signs of PTS	22
US signs of DVI	11
Treated vessel (tot. 357)	
Great saphenous vein	308
C-score	
Class 3	58
Class 4	116
Class 5	85
Class 6	49
Small saphenous vein	49
C-score	
Class 3	6
Class 4	12
Class 5	17
Class 6	14

Table II: Duplex follow-up data at one year on 188 limbs (188 patients)

Location	Success/ occluded	Partial success/ partly occluded	No success/ recanalized and reflux
GSV (n=169)	69%	14%	18%
SSV (n=19)	58%	16%	26%

previous history of DVT and ongoing oestrogen replacement therapy was treated successfully but suffered pulmonary embolism verified by CT-angiography nine days later. No DVT was detected by duplex US. The patient was treated with intravenous unfractionated heparin followed by cumarin and made an uneventful recovery. A 59-year-old male patient with painful thrombophlebitis was managed initially with non-steroidal anti-inflammatory drugs and low molecular weight heparin (enoxaparin). In this case as well, US could not detect any sign of DVT. However, a CT-scan revealed ilio-femoral thrombosis and the patient underwent locoregional thrombolysis, which unmasked a tight stenosis of the left

common iliac vein requiring endovascular treatment as well as oral anticoagulation. The patient recovered well and is presently free of venous incompetence-related symptoms.

Discussion

This clinical series shows that CDFS has acceptable results in the treatment of incompetent GSV and SSV. The complication rate was low (see Table III). Events such as visual disturbance, migraine or chest problems which have been previously described as following foam sclerotherapy [2, 14, 21] could not be detected. This freedom of early adverse effects of foam therapy with our technique is

promising, but may also be attributed to the limited amount of foam injected in our patients. In this series only two serious thromboembolic complications were encountered and this is consistent with previous clinical series concerning foam sclerotherapy [2, 6]. Follow-up at one year showed recanalisation of saphenous trunks in about 19% of duplex controlled treated limbs. This is comparable to other reports [1, 9, 20, 22]. However, it is important to clarify that treatment at our institution is principally aimed at improving venous haemodynamics in order to prevent future ulcers. In patients with active ulcers wound healing was rapid and age by itself did not influence treatment results.

One of the aspects, which have been most often investigated regarding the sclerotherapy of incompetent superficial veins is the application technique. Furthermore, the distribution of foam depends on multiple factors such as the degree of vasospasm, injection-pressure, position of the leg, amount of foam.

The technique we have developed could have several potential advantages. The delivering catheter itself induces venospasm resulting in a high concentration of foam as well as an optimal contact to the vein wall. Regarding the foam itself, Cavezzi [6] had already reported that the characteristics of home-made foam greatly influence the choice of the gas component, the liquid-to-gas ratio and the type of syringes. Larger needles are preferred for injection of foam while long catheters seem to be a valid alternative especially when combined with tumescence to minimise the saphenous diameter.

The distribution of foam achieved by direct puncture technique is unpredictable [10, 16]. Direct puncture sclerotherapy may allow larger amounts of the foam to pass into the deep veins [18]. This “spill-over” of foam occurs mainly via perforators of the thigh to the deep venous system and can potentially be reduced using catheter-directed delivery into defined vessel-segments and a low injection pressure under withdrawal of the catheter [7]. However, this aspect needs further investigation.

The total rate of ulcer healings was 54% at 1 year, and is low if compared with other experiences [17, 18, 20]. This can be explained by our decision not to mention those patients that still have ulcers healing later after successful treatment.

Foam-sclerotherapy is often referred to as ultrasound-guided and -controlled. This implies accuracy and safety. In most studies ultrasound is used to aid the puncture of the GSV and then to compress the saphenofemoral junction to prevent foam migration. However, the ultrasound transducer is also used to guide the foam using external massage pressure or “milking”-techniques [1, 2, 5, 9, 23]. In our experience using ultrasound for these purposes is technically difficult. Careful delivery of foam to the intended site of action using a sheath along the length of the axial vein is technically easier and more reliable. The immediate success rate and the degree of reflux at one-year follow-up of catheter-directed foam sclerotherapy compares well with the results of ELT or RFA treatment [14, 24]. However, the fact that the procedure does not cause ecchymosis and does not

require anaesthesia speaks in favour of catheter-directed foam sclerotherapy [7]. Furthermore, in patients with recurrent varicose veins foam sclerotherapy has also shown positive haemodynamic results reflecting significant improvement of the venous function [4, 26, 27].

This study has limitations since only half the original patients treated attended the one-year follow-up. We did not record haemodynamic data before and after the treatment to assess the efficacy of our treatment on venous function. We are therefore unable to comment on whether CDFS can be used to improve venous function in order to prevent further worsening and complications.

The short and incomplete length of follow up does not allow any sort of recommendation. However, we believe that the high degree of patients’ acceptance as well as the positive early results should be taken into consideration. In conclusion, the use of this catheter based technique facilitates foam sclerotherapy with a high primary- and acceptable short-term occlusion rates, and low numbers of complications.

Further studies are required to evaluate how the migration of foam into the common femoral vein can be diminished and whether the techniques used in this study of leg elevation and manual compression provide any advantage.

Conflicts of interest

There are no conflicts of interest existing.

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Table III: Immediate complications (337 pat.)

Location	Thrombophlebitis	Deep vein thrombosis
GSV (n = 308)	1.9%	0.6%
SSV (n = 49)	–	–

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