A new option for endovascular treatment of leg ulcers caused by venous insufficiency with fluoroscopically guided sclerotherapy

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Abstract

Introduction: *Ulcers of lower legs are the most bothersome complication of chronic venous insufficiency (CVI).*
Aim: *To assess the effectiveness of endovascular fluoroscopically guided sclerotherapy for the treatment of venous ulcers.*
Material and methods: *Thirty-eight limbs in 35 patients with crural venous ulcers were treated with guided sclerotherapy under the control of fluoroscopy. Patients with non-healing ulcers in the course of chronic venous insufficiency, with and without features of past deep vein thrombosis, were qualified for the study. Doppler ultrasound and dynamic venography with mapping of venous flow were performed. Ambulatory venous pressure measurements, leg circumference and varicography were performed just before and following the procedure.*
Results: *In 84% of cases, ulcers were treated successfully and healed. Patients with post-thrombotic syndrome (n = 17) healed in 13 (76.5%) cases, whereas patients without post-thrombotic syndrome (n = 21) healed in 19 (90.5%) cases. The mean time of healing of an ulcer for all patients was 83 days (in the first group it was 121 days and in the second group 67 days). Recurrence of an ulcer was observed in 10 limbs: 6 cases in the first group and 4 cases in the second group. Occurrence of deep vein thrombosis associated with the procedure was not observed. Temporary complications were reported but none giving a serious clinical outcome.*
Conclusions: *Endovascular fluoroscopically guided sclerotherapy can be an alternative method of treatment of venous ulcers, especially in situations when surgical procedures or other options of treatment are impossible.*

Key words: *venous ulcer, endovascular treatment, sclerotherapy.*

Introduction

Ulcers of the lower legs are a serious complication of chronic venous insufficiency (CVI). They develop as a consequence of chronic hypertension in the venous system provoked by venous reflux and/or obstruction of deep veins. Pain, edema, and a necessity of permanent nursing care of the wound limit the quality of patients' lives, which constitutes a socioeconomic problem. Venous ulcers occur in about 0.3% of the adult population in Western Europe [1–4]. The ulcer treatment takes a long time and healed wounds often recur. Only 50% of ulcers can be healed after 4 months [5] 20% remain open

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after 2 years, and 8% remain open after 5 years [6]. The recurrence of an ulcer, a year after total healing, occurs in about 6–15% of cases [7–9]. Despite extensive knowledge on etiopathogenesis, results of treatment are still unsatisfactory.

Aim

The objective was to assess the effectiveness of endovascular fluoroscopically guided sclerotherapy for the treatment of venous ulcers.

Material and methods

Study group

Thirty-eight limbs in 35 patients with venous ulcers of the legs, including 23 men aged 34–77 years (mean age: 62 years), were treated with an endovascular procedure. The mean ulcer duration before the procedure was 28 months (for the post-thrombotic syndrome (PTS) group, 41 months; no PTS, 20 months).

The study included only patients who failed standard compression therapy and were not eligible for surgery, due to either unrelated medical factors or their unwillingness to undergo an operation.

Inclusion criteria were: patients with lasting wounds in the course of CVI due to insufficiency of the main trunk of superficial veins (stage III and IV insufficiency according to Hach) and perforating veins in class C6 according to the CEAP (Clinical-Etiology-Anatomy-Pathophysiology Classification System for Chronic Venous Disorders) classification.

Exclusion criteria were: obstruction of either the deep veins or main superficial veins – great saphenous vein (GSV) or short saphenous vein (SSV), thrombophlebitis, patients following stripping procedures, allergy to contrast medium.

Patients were divided into two groups. Group one consisted of 17 limbs with PTS as defined by prior history of deep vein thrombosis or venographic findings indicative of PTS. Group two included 21 limbs with ulcers due to CVI and no history of thrombosis or signs of thrombotic changes in the veins (no PTS).

In all patients measurements of the ulcer area, Doppler ultrasound, descending dynamic venography, ambulatory venous pressure measurement, leg circumference and varicography were performed before the procedure.

Post-procedure follow-up included Doppler ultrasound examination, venography, ambulatory venous pressure measurement and leg circumference.

Clinical success was defined as total healing of an ulcer after the procedure. Recurrence was defined as return of an ulcer following a technically successful procedure and complete healing of the ulcer.

Follow-up protocol: a follow-up study was conducted 7–10 days after treatment. Further checks were carried out after 1, 3, 6, 12, 18 and 24 months, then after 2, 3, 4 and 5 years following treatment. Physical examination and ultrasonography were performed in order to confirm the closure of the insufficient veins. In cases with uncertain diagnostics ascending venography was performed.

Venography

Ascending dynamic venography was performed using Rabinov and Paulin's method with Hach's modification [10, 11]. In the assessment of valve competence, the criteria given by Hach were accepted [12]. Descending venography was performed using Hach' method [11]. A contrast medium (30 ml) was administered after applying the Valsalva maneuver and setting the tilt table to an angle of 45°.

Measurement of venous pressure

Direct measurement of venous pressure was performed during venography using a cannula fitted with a manometer of an angiopathy diagnostic tester [13]. The basis for diagnosis was the observation and recording of vein pressure alterations in a patient during and after a series of knee bending exercises. Using parameters of venous pressure and refilling time it is possible to indicate insufficiency, while the use of a pneumatic cuff allows one to differentiate between superficial and deep venous insufficiency. By performing these measurements before and after treatment, one can first predict, then evaluate the effect of medical intervention.

Venous system schemes

Duplex ultrasound mapping is essential for understanding venous pathology and should lead to more specific treatment with improved outcomes [14, 15]. A scheme of the superficial and deep venous system, as well as insufficient perforators, with indication of the direction of blood flow, was created (Figure 1). This scheme formed the basis for analysis of pathology of the venous circulation, and the planned procedure.

Sclerotherapy

The trunk of the GSV, SSV or a vein connected with a perforator was punctured using the Seldinger method. The trunk of the GSV was either punctured, descending, in the femoropopliteal segment, or ascending in the ankle area. In obese patients or those with edema the vein was localized with ultrasound guidance. The patient was in a supine or lateral recovery position depending on the puncture site or anatomic conditions. The puncture site was anesthetized with 2–5 ml of 2% Polocaine (Polfa, Poland). A catheter (Venflon Pro; Becton Dickinson, Poland) was used for the puncture. Then varicography was performed under the control of fluoroscopy: 5–10 ml of contrast medium (Visipaque; GE Healthcare, Ireland) were administered for the anatomical visualization of the veins. Before the procedure Papaverine (Polfa, Poland) was administered to weaken the spasm reaction of the vein during manipulation. After introduction of the guide wire (Emerald; Cordis USA or Guide wire Terumo Deutschland GmbH), as far as possible peripherally, the cannula was removed and the hole of the puncture was dilated using a 5 Fr Dilator (Cordis, USA), or in the case of considerable skin callosity, punctured again. A 5 Fr Introducer (Cordis, USA) and 4 Fr therapeutic catheter (vertebral or TC-BNK, Cook Medical, USA or Bern; Boston Scientific, USA) were used.

In the case of GSV puncture in the proximal segment the catheter was introduced in a distal direction and placed in the initial segment of a perforator, starting as far away from the puncture site as possible. Contrast medium was administered to analyze the vein's width, length, and possible branches. After correction of the position of the catheter end, sclerotherapy was performed (Photos 1–3). The vascular bed was first filled with contrast medium, and then sclerosant in foam form (0.5–5 ml – 0.5–2% of lauromacrogol, Kreussler-Pharma, Germany) was administered under fluoroscopic control. The foam was prepared using Tessari's method (1 : 4 ratio of sclerosant to air) [16]. The rate of administration was adjusted based on displacement of the contrast medium. The sclerosant pushes out the contrast medium, and thus the border between them was well visible. This enabled precise application of the therapeutic agent and stopping of injection when the medium had filled the vessel or when it reached the origin of the deep vein system. This method of administration protected against accidental flow of obliterating agent into the deep veins. Secondly the catheter was withdrawn under fluoroscopic control, the next portion of contrast was administered and other insufficient perforators and varicose branching were found and closed using sclerotherapy. The procedure was finished with sclerotherapy of the GSV, totally or excluding the insufficient part of the GSV. After occlusion of all insufficient perforators and the trunk of the GSV in the proximal segment, the catheter was withdrawn.

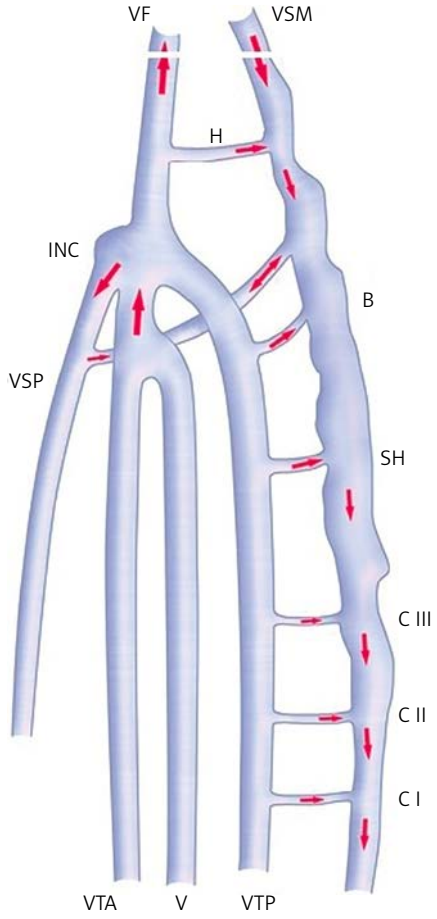

Figure 1. Mapping the venous system based on venography and ultrasound

VF – Femoral vein, VTA – anterior tibial vein, VTP – tibialis posterior vein, SH – Shermann perforator, C – Cockett perforator, H – Hunter perforator, B – Boyd perforator, INC – internal confluens, VSM – vena saphena magna, VSP – vena saphena parva.

The ulceration was treated with dressing material, the limb was slightly raised and a short stretch bandage was applied starting from the foot. The patient was mobilized after a few hours (4–8 h). Graduated compression therapy was recommended until the ulcer had healed. For a period of 7 days after the procedure a preventative dose of low molecular weight

Photo 1. Venography before the procedure. Insufficient great saphenous vein. Insufficient Hunter's perforator

Photo 2. Delivery of sclerosant with the catheter introduced through the great saphenous vein. Arrow – catheter introduced to perforator

heparin (Clexane, Sanofi-Aventis, France) was administered in a dose dependent on the patient's weight.

Results

In 38 limbs 62 endovascular procedures were performed – 22 limbs were treated once, 8 limbs twice, and 8 limbs three times. Re-do procedures were performed in cases where ulcers did not heal and Doppler ultrasound showed incomplete occlusion of insufficient perforators or the GSV.

Ulcer treatment outcome

Clinical success was achieved in 32 out of 38 cases (Table I). Recurrence of ulcers occurred in a period from 7 months to 5 years following treatment (PTS: mean 1.8 years; no PTS: 2.8 years).

In analysis of the causes of recurrence, Doppler ultrasound examination was used. New insufficient superficial and perforating veins developed in all ten patients.

In 3 patients (all from the no-PTS group) the development of insufficiency of the SSV vein was found. Recurrence of deep vein thrombosis was found in 2 patients (from the PTS group), and perforators recanalization was noted in 2 patients.

Pressure measurements

The refilling time measured in seconds up to 90% of the initial value of pressure was analyzed, before and following treatment. Results with use of the leg cuff and without are shown in Figure 2.

Calf circumference

This was performed 2 cm above the ankle. After the procedure the circumference of the calf decreased by 6.3% on average: 6.6% in the PTS group and 5.9% in the no-PTS group.

Complications

Deep vein thrombosis associated with the procedure there was not found. Complications observed: 1) local edema (n = 8); 2) local skin inflammation present up to 4 weeks after the procedure (n = 12); 3) local hyperpigmentation (n = 14); 4) disruption of the vein and limited hematoma in the area of manipulation (n = 2); 5) increase of temperature over 38°C up to 24 h after the procedure (n = 10); 6) hematoma in the puncture site (n = 11).

Discussion

Ulcers of venous origin are a complex state depending on many pathological processes which lead to venous hypertension. If reflux takes place in at least two venous systems, then skin lesions or ulcers will occur in 2/3 of patients [17, 18]. Since multi-segment reflux is the most frequent cause of an ulcer, its total removal is crucial for the success of treatment [19].

Ulcers often present difficult circumstances for surgery, sometimes prohibiting an operation. The described method of fluoroscopically guided sclerotherapy is part of research for a new minimally invasive treatment for cases in which operative and conservative treatment appear to be inefficient or contraindicated, as well as for situations when the patient's consent cannot be obtained for a surgical procedure or other options of treatment.

The endovascular method, approaching via a superficial system, allows us to reach with a catheter refluxing insufficient venous segments then selectively and carefully occlude them from the circulation. One of the advantages of endovascular methods, over surgical procedures, is that there is a possibility of reaching insufficient perforators in hardened tissues or those affected by a lesion near the ulcer and those with extensive ulcers. It has been shown that complete deactivation of insufficient perforants is very important in effective treatment of recalcitrant venous ulcers [20].

Photo 3. Venography 2 years after the procedure. Obstructed perforators and obstructed great saphenous vein

Table I. Results of endovascular treatment of ulcers

Group	Number of limbs	Number of limbs with initial ulcer healing, n (%)	Mean healing time, days (range)	Recurrence of ulcers, n (%)
All patients	38	32 (84.2)	83 (11–161)	10 (26.3)
Without post-thrombotic syndrome	21	19 (90.5)	67	4 (19)
With post-thrombotic syndrome	17	13 (76.5)	121	6 (35.3)

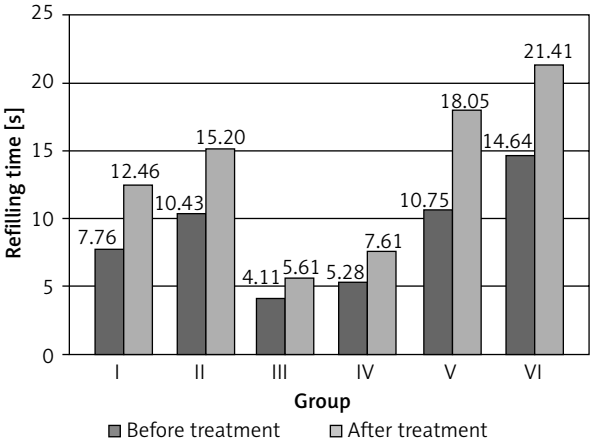

Figure 2. Results of refilling time (RT) I – all (without the cuff); II – all (with the cuff); III – PTS patients (without the cuff); IV – PTS patients (with the cuff); V – group without PTS (without the cuff); VI – group without PTS (with the cuff)

Moreover, controlled administration of contrast medium through a therapeutic catheter enables active control and modification of the performed procedure, which is not possible in a surgical method or with conventional sclerotherapy. Precise administration of the sclerosant agent into the selected venous segment, after its previous filling with contrast, enables full control of the administration site and the dislocation of the agent. It also allows aspiration of the administered sclerosant medium, which prevents migration to the deep veins and the occurrence of further complications.

The recurrence of ulcers after a Linton's operation has been diagnosed in 55% of cases, including 100% of patients with PTS [21]. Following minimally invasive methods, recurrence is observed in 27.1% of cases [22]. In a study by Gloviczki, after subfascial endoscopic surgery the percentage of healing after 1 year was 88% and the mean time of healing was 54 days. The incidence of recurrence was 16% after 1 year and 28% after 2 years. Complications around the wound occurred in 6% of cases [23]. In our study similar results were obtained: healing was achieved in 84% of cases, and among the cured patients recurrence was observed in 26%, mostly in patients with PTS. The procedure was well tolerated by the patients; diagnosed complications were temporary, did not constitute a serious clinical problem, and the sites where the catheter was used were not visible.

Results appear to be dependent on whether patients had PTS. In refilling time analysis, an improvement was seen to a large extent in patients without PTS, and only a slight improvement in patients with PTS was noted. This also corresponds with surgery results – better improvement is obtained in patients with primary insufficiency of valves than in patients with PTS [24, 25]. Patients with a 3-6 CEAP classification were treated with a similar technique. Based on observations made during a 1 year follow-up, 67% of patients experienced complete occlusion of veins, whereas in 14% of patients, short fragments of veins became partially recanalization. Complete healing of leg ulcers in 54% of patients was achieved [26]. The novel endovenous procedure of steam ablation has been available for a few years. The steam when injected disperses over a distance of at least 2 cm. This may give the possibility for treatment of short perforator veins and short segments of meandering veins. When we compare steam ablation to classic surgery procedures, they are similar taking into account recurrence rate, complication rate and venous severity score. But we do not have results of this method in the treatment of venous leg ulcers [27, 28].

A diagnostic strategy is still under discussion. In order to achieve clinical success it is probably necessary to carry out precise anatomical/physiopathological diagnostics [26]. Duplex ultrasound examination remains the preferred tool as it is non-invasive. However, venography, which provides comprehensive and detailed images of the venous circulation, still presents better results, especially in the most severe cases (CEAP 5–6 class), and in patients previously treated with invasive methods [29, 30]. Venography has crucial importance for planning the course of the procedure and selection of access sites to affected vessels. In order to achieve success, a knowledge of the anatomy, reflux, and flow direction is required. Current modern non-ionic contrast media are safe, and we did not observe any complications connected with venography.

One disadvantage of this method is that, if all treated veins do not occlude, a re-do procedure is necessary; the number of re-do procedures should decrease along with improved operator experience.

Conclusions

Endovascular fluoroscopically guided sclerotherapy can be an alternative method of treatment

of venous ulcers, especially in situations when surgical procedures or other options of treatment are impossible.

Conflict of interest

The authors declare no conflict of interest.

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