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Recalcitrant Venous Leg Ulcers May Heal by Outpatient Treatment of Venous Disease Even in the Presence of Concomitant Arterial Occlusive Disease

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WHAT THIS PAPER ADDS

In patients with mixed ulcers and moderate arterial impairment, arterial revascularization is very often the first treatment step, and compression therapy is considered to be contraindicated. This paper shows that treating just the venous incompetence by foam sclerotherapy to the superficial refluxing veins, and by applying compression therapy with a reduced compression pressure not higher than 40 mmHg, may aid ulcer healing. As clear therapeutic recommendations for the frequent problem of mixed leg ulcers are missing, this approach could aid clinical practice.

Objective/Background: Peripheral arterial occlusive disease (PAOD) is reported in about 15–20% of patients with venous leg ulcers (VLU). In such cases arterial recanalization is often recommended, and compression therapy is considered a contraindication when the ankle brachial pressure index (ABPI) is < 0.8. The aim of this study was to compare the outcome of patients with recalcitrant VLU, both without any arterial impairment ("pure venous recalcitrant leg ulcer" [pvRLU]) and with associated PAOD ("mixed arterial and venous recalcitrant leg ulcer" [mavRLU]), by treating only the venous disease.

Methods: The records of 180 outpatients with recalcitrant ulcers treated between January 2011 and July 2014 were reviewed retrospectively. In total, 109 were affected by pvRLU and 71 by mavRLU, with moderate PAOD defined by an ABPI between 0.5 and 0.8. In addition to the same local wound dressing, the patients received ultrasound guided foam sclerotherapy of the refluxing superficial veins and a modified inelastic compression with a pressure $\leq$ 40 mmHg. No patient was referred for arterial revascularization. The patients were followed until ulcer healing.

Results: Patients with pvRLU and mavRLU showed comparable demographic characteristics. Twenty-five patients were lost to follow up and the outcomes were analyzed in 93 patients with pVLU (85.4%) and in 62 patients with mavRLU (87.4%). The maximum time to complete healing was 48 weeks in the pvRLU group and 52 weeks in the mavRLU group ($p = .009$), The median healing time was 23 (pvRLU) versus 25.5 weeks (mavRLU) ($p = .030$). Deep venous incompetence ($p < .001$), ulcer surface area ($p < .001$), arterial disease ($p = .002$), and ulcer duration ($p < .010$) were risk factors for prolonged healing.

Conclusion: Treatment of recalcitrant leg ulcers by treating venous incompetence by foam sclerotherapy and modified compression is successful, even if underlying moderate PAOD is not actively treated.

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INTRODUCTION

In about 15–20% of patients with venous leg ulcers (VLU) co-existing peripheral arterial occlusive disease (PAOD) is reported.[1,2] In such cases arterial revascularization is often recommended as the first therapeutic step.[3–5] Compression therapy (CT) to improve the impaired venous hemodynamics is often considered a contraindication when the ankle brachial pressure index (ABPI) is < 0.8,[6] or permitted only if applied with reduced pressure.[1,6,7]

The aim of this study was to compare the clinical outcomes of patients with recalcitrant VLU, both "pure venous recalcitrant leg ulcer" (pvRLU) and those associated with

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moderate PAOD ("mixed arterial and venous recalcitrant leg ulcer" [mavRLU] with an ABPI 0.5—0.8), simply by treating the venous disease and ignoring the arterial component.

PATIENTS AND METHODS

This was a retrospective analysis carried out in accordance with the Declaration of Helsinki.

Patients

Of a total of 298 outpatients treated for leg ulcers between January 2011 and July 2014, the records of 180 ulcers (43 men, 137 women; mean age 74 ± 11.5 years [range 31—92 years]), defined as recalcitrant by the absence of any sign of healing after 6 months treatment, were reviewed retrospectively.

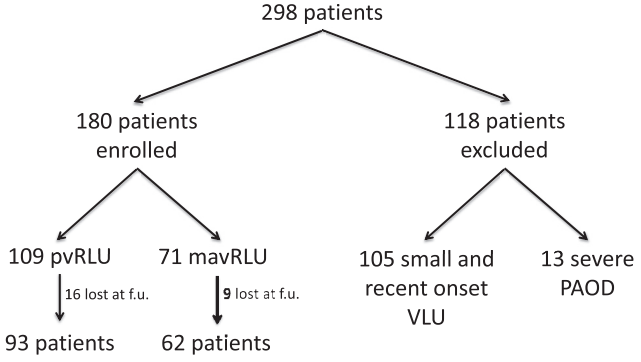
In total, 109 patients (60.6%) had pvRLU (30 men, 79 women; mean age 72.4 ± 13.8 years [range 31—90 years]) and 71 (39.4%) had concomitant moderate PAOD defined by a reduction of ABPI to 0.5—0.8 (22 men, 49 women; mean age 75.8 ± 9.8 years [range 43—92 years]). The patients were followed until ulcer healing.

Inclusion criteria were patients of both sexes and any ages affected by VLU, with or without moderate PAOD, at an inflammatory stage defined as ulcer bed partially or totally covered by necrotic slough with or without clinical signs of local infection; ulcer size up to 100 cm^2; ulcer duration > 6 months; no signs of healing.

Exclusion criteria were: small ulcers; ulcer surface > 100 cm^2; ulcer duration < 6 months; type 1 diabetes mellitus; patients on immunosuppressive therapy; active cancer; life expectancy < 6 months; severe PAOD (ABPI < 0.5).

Based on the above criteria 105 patients were excluded as they were affected either by small pvRLU or had an ulcer duration < 6 months. Thirteen patients were excluded because of severe PAOD requiring arterial revascularization (Table 1).

Table 1. Patient selection for retrospective review.



Note. pvRLU = pure venous recalcitrant leg ulcers; mavRLU = mixed arterial and venous recalcitrant leg ulcers; f.u. = follow up; VLU = venous leg ulcers; PAOD = peripheral arterial occlusive disease.

Vascular assessment

On enrollment the patients were examined by color duplex ultrasound (Esaote MyLab 60 with a multi-frequency linear probe [7.5—12 MHz]; Esaote s.p.a., Genoa, Italy) standing to investigate the superficial and deep veins, and supine to investigate the arterial system of the legs. Reflux in deep veins, saphenous veins, and tributaries was elicited by manual calf compression/release and the Valsalva maneuver. Reflux time > 0.5 s for superficial veins and > 1 s for the deep veins was considered pathological. Venous occlusion/obstruction was diagnosed by ultrasound compression.

Ankle pressures were measured in every patient, using a 8 MHz continuous wave Doppler probe. ABPI was calculated by dividing the ankle pressure by the brachial systolic blood pressure. PAOD was classified into three categories: mild (ABPI > 0.80); moderate (0.5 < ABPI ≤ 0.80); severe (i.e., critical limb ischemia, ABPI ≤ 0.5).[7]

Therapeutic procedures

Ulcer cleansing and dressings. At dressing change the ulcer was cleansed with a saline solution. The same non-adherent, absorbent dressing (polyurethane foam) was applied to all ulcers.

In patients with clinically infected ulcers (defined as blocked healing, redness of peri-wound skin, increasing fluid exudate and/or pain, change in granulation tissue appearance, or malodour) Cadexomer powder (Smith & Nephew, Hull, UK) containing 0.9% iodine was added until the clinical signs of infection disappeared.[8,9] No patient received systemic antibiotic treatment.

Compression therapy. All patients were treated by CT using inelastic materials applying the bandages from the base of the toes to the knee in a spiral fashion.

In the patients with pvRLU the compression device consisted of a short stretch bandage (Rosidal K; Lohmann & Rauscher, Rengsdorf, Germany) applied with full stretch on top of a sub-bandage padding layer made up of cotton padding and a multi-layer cohesive short stretch bandage (Cellona and Mollelast Haft [both Lohmann & Rauscher]).

In patients with mavRLU, Cellona and Mollelast Haft were applied with reduced stretch ("modified compression"), and Rosidal K was not used.

Compression pressure. Compression pressure (CP) was measured using a Picopress device (MicrolabItalia, Padua, Italy) which has been proved to provide accurate, linear, and reproducible pressure values.[10] CP was measured in the first 4 weeks of treatment, both after application and before removal of the bandage. The probe was applied at the B1 point (the transition from gastrocnemius tendon to gastrocnemius muscle on the medial aspect of the leg) as recommended by a consensus document.[11] CP was set to > 60 mmHg at application in patients with pvRLU and at around 40 mmHg in patients with mavRLU. Bandage removal and dressing changes were planned once a week. Patients were asked to return for additional visits in the event of unusual pain, excess exudate, or any unwanted effect.