A Prospective Randomized Study Comparing Polidocanol Foam Sclerotherapy with Surgical Treatment of Patients with Primary Chronic Venous Insufficiency and Ulcer

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Background: To compare polidocanol foam sclerotherapy with surgical treatment of patients with primary chronic venous insufficiency and active ulcer treated at a single vascular center.

Methods: Fifty-eight limbs of 56 patients with active ulcers were prospectively randomized to undergo either surgical treatment or foam sclerotherapy. Patients completed the Aberdeen Varicose Veins Questionnaire (AVVQ), the Venous Clinical Severity Score (VCSS), and Venous Disability Score (VDS). The follow-up was 502 ± 220 days.

Results: The ulcer healed in 100% and 91.3% of patients treated with surgery or foam sclerotherapy, respectively ($P > 0.05$). There were no significant differences in AVVQ, VCSS, and VDS between the 2 groups after the procedures ($P = 0.45$, 0.58, and 0.66, respectively; Mann−Whitney *U* test). Complications occurred in 14.2% and 13.0% in the surgical and foam sclerotherapy groups, respectively.

Conclusions: Surgical treatment and foam sclerotherapy achieved high rates of ulcer healing, without a statistically significant difference. Both treatments led to significant improvements in VCSS, VDS, AVVQ scores, demonstrating improvements in clinical outcomes and quality of life.

INTRODUCTION

Chronic venous ulceration is a condition that affects millions of people worldwide. It severely impairs health-related quality of life (HRQoL) and imposes a considerable burden on health care resources.[1−4]

Data from the Brazilian Social Security System revealed that chronic venous disease is ranked 14th for causes of temporary work absenteeism and 32nd for permanent disability and public financial assistance.[1]

Surgical treatment has been the main method of treating patients with lower limb venous disease associated with saphenous incompetence. Promising results have since been reported for alternative treatments, including endovascular radiofrequency or laser ablation. However, the use of these methods has been limited in many countries because of their cost.[5]

Foam sclerotherapy is an inexpensive and simple method that is easy to perform by experienced clinicians.[5] Numerous clinical series have used foam sclerotherapy to treat disorders of the great saphenous vein (GSV).[1,3−18] However, there are

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limited outcomes data for patients with Clinical-Etiology-Anatomy-Pathophysiology (CEAP) C5 (healed ulcer) and C6 (active ulcer) disease.[6,7]

Therefore, the aim of this study was to compare polidocanol foam sclerotherapy with surgical treatment of patients with primary chronic venous insufficiency and ulcer, with a particular focus on healing, complications, and QoL in the patients with venous disorders treated at the Clinics Hospital of São Paulo University Medical School (HC-FMUSP).

OBJECTIVE

The objective of the present study was to compare the effects of polidocanol foam sclerotherapy with surgical treatment of patients with primary chronic venous insufficiency and active ulcer. Study outcomes included the time taken for ulcers to heal, the incidence of complications, and improvements in QoL.

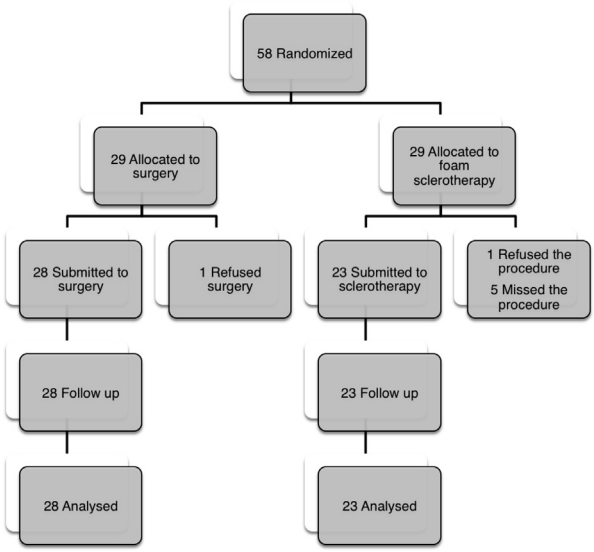

Fig. 1. Flow diagram of the progress through the phases of the trial.

METHODS

Patients and Methods

This was a prospective, open, randomized controlled study performed at the HC-FMUSP. The Local Ethics Committee for Research Affairs approved the study, and patients gave written informed consent for their inclusion in this study. The study was registered at Plataforma Brasil (number: 0158.0.015.000-0) and approved by Brazilian National Ethics Commitee (CEP) under the numer: 0170/09 before the firs patient was randomized.

Patients fulfilling the following criteria were eligible for the study: primary chronic venous insufficiency caused by reflux in superficial veins, GSV diameter of 0.7−1.4 cm as measured by duplex ultrasound, presence of an active ulcer (maximum 5-cm diameter), and an ankle-brachial index (ABI) of 0.9−1.3. Patients with any of the following were excluded: history of deep vein thrombosis, deep vein thrombosis or deep vein reflux in duplex assessment, arterial disease of the lower limbs (ABI <0.9 or >1.3), superficial thrombosis, diabetes, thrombophilia, pregnancy, or allergy to polidocanol.

Between August 2007 and February 2010, 58 consecutive limbs of 56 patients meeting the eligibility criteria were prospectively randomized (simple randomization) to undergo either surgical treatment (29 limbs) or foam sclerotherapy (29 limbs) as described in Figure 1. The intervention occurred within 30 days of the randomization.

All the patients had previously received elastic compression therapy with a 30-mm Hg above-knee elastic stocking for at least 6 months before enrolling in the present study. Most of the ulcers were recurrent.

Patients in both groups completed the Aberdeen Varicose Veins Questionnaire (AVVQ), except for the first question, because the patients experienced difficulty in drawing their veins. The Venous Clinical Severity Score (VCSS) and Venous Disability Score (VDS) were determined by a vascular surgeon. The ulcers were photographed and analyzed using image analysis software (Image Tool program).

Duplex ultrasound was performed in all the patients before undergoing treatment. Ultrasound was performed while the patients stood with their weight on the contralateral limb. The following venous segments were evaluated: femoral vein, popliteal vein, saphenofemoral and saphenopopliteal junctions, perforator veins, the entire length of the GSV, and the short saphenous veins. All veins were assessed for patency and compressibility. Reflux was induced by manually squeezing the calf and was defined as reverse flow persisting for >0.5 sec.

The mean ± standard deviation (SD) follow-up time was 502 ± 220 days.

Treatments

Surgery was performed under spinal anesthesia in a surgical room. It consisted of major saphenous stripping (saphenofemoral junction disconnection and stripping of the long saphenous vein to the ankle), phlebectomy of tributaries, and ligation of