Results of Surgical Treatment Compared with Ultrasound-Guided Foam Sclerotherapy in Patients with Varicose Veins: A Prospective Randomised Study

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Varicose vein surgery;
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Polidocanol

Abstract Objectives: This study aims to compare venous clinical severity scores in patients with healed venous ulcers due to varicose veins of the lower limbs (the clinical, etiologic, anatomic, and pathophysiologic data (CEAP) classification: C5 EpAsPr) treated by saphenous stripping and phlebectomy or by ultrasound-guided foam sclerotherapy.

Method: Sixty patients were included: 29 underwent saphenous stripping and phlebectomy for varices in saphenous tributaries and 27 were treated by ultrasound-guided foam sclerotherapy; four cases were lost to follow-up. The main outcome measure was venous clinical severity scores (pain, oedema, inflammation, hyperpigmentation and lipodermatosclerosis). An ultrasound examination was carried out prior to treatment and 30, 60 and 180 days after the procedure to assess the relative efficacy of the methods in obliterating the saphenous trunk.

Results: The mean venous clinical severity scores measured before and after 180 days were as follows: Surgery group — pain: before 1.97 standard deviation (SD) 0.19, 180 days 0.72 SD 0.53; oedema: before 1.66 SD 0.48, 180 days 0.55 SD 0.63; inflammation: before 1.55 SD 0.63, 180 days 0.72 SD 0.45. Foam sclerotherapy group — pain: before 1.81 SD 0.40, 180 days 0.56 SD 0.51; oedema: before 1.70 SD 0.47, 180 days 0.48 SD 0.64; inflammation: before 1.67 SD 0.68, after 0.89 SD 0.32. All scores showed statistically significant reductions in both patient groups. The saphenous vein had been obliterated, 180 days after treatment, in 78% of the surgery group, compared with 90% in the foam sclerotherapy group.

Conclusions: Ultrasound-guided foam sclerotherapy is a safe and effective option for patients with chronic venous disorders.

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A new treatment for primary varicose veins should be minimally invasive and capable of being used on primary and recurrent varicose veins so that it can be repeated as required. There should be few significant complications and the treatment should have good efficacy in abolishing venous reflux in saphenous trunks, perforating veins and varices. Such a treatment should restore normal venous function and cure the clinical features of venous hypertension. The treatment should be accomplished at little cost and be capable of achieving both functional and cosmetic improvement with little time away from the patient’s usual occupation. Surgical treatment does not comply with this definition, since it is relatively invasive and necessitates time away from work.

Primary varicose veins are commonly treated by saphenous stripping combined with phlebectomy of saphenous tributaries and ligation of incompetent perforating veins. The rate of recurrence of varicose veins after 5 years has been reported to vary from 20% to 80%. The use of duplex ultrasound in the treatment of varicose veins allows alternative strategies to be used. Methods such as endovenous laser ablation, radiofrequency ablation and foam sclerotherapy have been increasingly used in these patients. Ultrasound-guided foam sclerotherapy has been considered particularly attractive because it avoids the need for general anaesthesia, hospital admission and long recovery times.

Few studies have been designed to compare conventional surgery and endovascular methods for the treatment of varicose veins. The present study aimed to compare the outcome of varicose vein surgery, including saphenous stripping and phlebectomies, with ultrasound-guided foam sclerotherapy. We were particularly interested in the clinical outcomes as well as ultrasound assessment results and have used clinical severity scores as the main outcome measure.

Method

Results of Surgical Treatment Compared with Ultrasound-Guided Foam Sclerotherapy

Patients attending the angiology and vascular surgery outpatient clinic of a public primary health-care unit in the municipality of Uberlândia, Brazil, between April and August 2006 were screened for inclusion in this study. A total of 60 patients were selected based on clinical history, physical examination and duplex ultrasound. The following inclusion criteria were taken into consideration: no previous clinical treatment of varicose veins; age between 18 and 70 years; and primary varicose veins classified as C5 EpAsPr (healed venous ulcers) according to the clinical, etiological, anatomic and pathophysiologic (CEAP) classification.

Patients were excluded if they reported a history of deep vein thrombosis, thrombophilia, allergy to polidocanol, bronchial asthma, post-thrombotic syndrome, severe systemic disease, immobility or confinement to bed, pregnancy, peripheral arterial insufficiency (ankle–brachial index <0.8), lower limb oedema, diabetic foot (peripheral neuropathy or ulceration) or presence of a patent foramen ovale on echocardiography.

All the selected patients were provided with detailed information related to conventional surgery and ultrasound-guided foam sclerotherapy. Patients who agreed to participate in the study and who gave informed written consent were randomly allocated to one of the treatment groups, according to the following randomisation process: a total of 60 slips of paper were deposited in a sealed box; half the number of the slips were identified as conventional surgical treatment of varicose veins, and the other half as ultrasound-guided foam sclerotherapy. For each patient included in the study, one slip of paper was drawn, and the corresponding treatment was initiated 48 h later.

The primary outcome measure assessed in this study was the venous clinical severity scores prior to treatment and 30, 60 and 180 days after the procedure. These scores were assigned by the authors after clinical examination at each follow-up appointment. The frequency of treatment complications and duplex ultrasound findings at 180 days were recorded as further measures of efficacy and safety.

This study protocol was approved by the Ethics Committee of the Universidade Federal de São Paulo.

Conventional surgery

The surgical approaches employed were saphenofemoral or saphenopopliteal ligation combined with saphenous stripping and phlebectomy for varicose saphenous tributaries and ligation of incompetent perforating veins. All surgical treatments were carried out under regional anaesthesia in one session. The treated limbs were bandaged immediately following surgery using inelastic bandages (Linopress, Famara, Boituva, SP, Brazil). After 2 days, the bandages were replaced by below-knee graduated elastic compression stockings (Comfortline, Venosan, Abreu e Lima, Brazil), with a compression of 30–40 mmHg for 3 months.

Ultrasound-guided foam sclerotherapy

Injections were made with the patients standing; soon after the injection, patients were placed in Trendelenburg’s position, and the great or small saphenous vein was identified on ultrasound imaging 15–20 cm from the saphenofemoral or saphenopopliteal junction. Injections of foam were made into the saphenous trunk using a 20-gauge × 1.88” needle. The accessory veins were cannulated using 25-gauge butterfly needles, and the incompetent perforating veins were injected using 22-gauge 1.25” needles. Tessari’s method was used to produce foam. The foam was made from polidocanol (Aethoxysklerol®, Kreussler Pharma, Wiesbaden, Germany) and room air at a 1:4 ratio. Volumes and concentrations are shown in Table 1.

Foam was injected as a bolus and its progress along the saphenous vein monitored using ultrasound imaging. A maximum of 10 ml of foam was injected per session;
sessions were repeated up to 3 times, as required, at 30-day intervals. Soon after completion of all injections, the lower limb was elevated, and the foam was observed to almost reach the saphenofemoral or saphenopopliteal junction. In cases where the foam was identified in deep veins, patients were asked to perform ankle dorsiflexions to promote clearance of foam from these veins. Manual compression of the saphenofemoral junction (SFJ) or short saphenous vein (SSV) was performed using the ultrasound transducer for 10–15 min.

After 15 min of compression of the SFJ or SSV, the limb was bandaged using a 12 cm-wide inelastic bandage (Linthpress, Famara, Boituva, SP, Brazil) for 3–5 days. Subsequently, 30–40 mmHg below-knee elastic stockings (Comfortline, Venosan, Abreu e Lima, Brazil) were used for 3 months.

Treatment assessment

Clinical assessment of the two treatment approaches was based on venous clinical severity scores, taking into consideration the presence of pain, oedema, inflammation, hyperpigmentation and lipodermatosclerosis10 prior to the procedure (first assessment) and 30, 60 and 180 days after the treatment. Duplex ultrasound was also performed at 180 days to assess treatment effectiveness.

An assessment was carried out 8 ± 2 days after the procedure (data not shown), aiming to detect deep vein thrombosis11 in the following veins: femoral, popliteal, posterior and anterior tibial, fibular, soleal, lateral and gastrocnemius. Two post-treatment assessments were carried out, approximately 30 and 60 days after the procedure, to assess the need for a new foam injection session in the foam sclerotherapy group and the presence of residual varicose veins in the conventional surgery group.

Finally, 6 months or 180 days after surgery or after the last foam sclerotherapy session, a new evaluation was carried out to assess the effectiveness of the procedures. In the surgery group, failure was defined as presence of reflux or residual varicose veins in any of the segments assessed. In the foam sclerotherapy group, success was assigned to one of the four grades12: (1) total occlusion; (2) partial recanalisation without reflux; (3) partial recanalisation with reflux; and (4) total recanalisation (Fig. 1). The procedure was considered to be successful in cases presenting total occlusion or partial recanalisation without reflux; the two remaining categories were considered to reflect treatment failure.

Statistical analysis

The non-parametric Mann–Whitney test was used for significance testing to compare between group differences before and after treatment (at 180 days) for each venous clinical severity score (pain, oedema, inflammation, pigmentation and lipodermatosclerosis). Significance was considered to have been reached when \( p < 0.05 \).

Results

Of the 60 patients selected, 29 were submitted to conventional surgery (52%) and 27 to ultrasound-guided foam sclerotherapy (48%). Three patients were lost to follow-up in the foam sclerotherapy group and one in the surgery group. The mean age of patients was 49 years (range: 29–72 years) in the surgery group and 53 years (range: 25–76 years) in the foam sclerotherapy group. Women formed the majority in both the groups: 79% of the surgery and 85% of the sclerotherapy group.

A total of 56 foam sclerotherapy sessions were carried out as follows: three patients underwent one session, 19 underwent two sessions and five patients were treated during three sclerotherapy sessions. The average number of sessions per patient was 2.1.

The venous clinical severity scores obtained before and after treatment are shown in Table 2. Comparisons between the surgery and sclerotherapy groups revealed improvements, with a statistical significance for pain, oedema and inflammation \( (p < 0.005) \).

Duplex ultrasound, carried out 180 days after the treatment, showed that ultrasound-guided foam sclerotherapy was successful in 78% of the patients (21 of the 27 patients treated), whereas conventional surgery had a success rate of 90% (26 of the 29 patients treated), with a non-significant difference between the two methods in terms of effectiveness.

No serious adverse events were associated with any of the treatments employed. The most frequent complications recorded are shown in Table 3.

Discussion

In many countries, varicose vein surgery remains the most common treatment, and saphenous vein stripping operations the method most commonly used.13 The potential complications and long-term outcome of
varicose vein surgery are well established, so any new treatment should provide an equivalent or better outcome than surgery.

New treatment methods should be compared to surgery in order to assess their credibility and safety. The importance of randomised clinical trials for clinical decision making has been widely recognised. Our study aimed at comparing conventional saphenous stripping with a more recent method, namely ultrasound-guided foam sclerotherapy, in a small group of patients with varicose vein disorders classified as C5 EpAsPr.

A number of reports have been published concerning the use of clinical scores for comparing the efficacy of different treatment methods. In 2003, an article validated clinical scores as the best way to assess results of the surgical treatment of primary varicose veins; the authors observed a linear relationship between treatment efficacy and the CEAP classification. Later, in 2006, the same scoring system was used in the comparison of post-treatment results in patients submitted to ultrasound-guided foam sclerotherapy with those submitted to surgery. The authors found improved clinical scores in both the groups, similarly to those observed in our study.

Duplex ultrasound has been frequently used in the assessment of foam sclerotherapy. Establishment of duplex ultrasound criteria to determine treatment efficacy is therefore extremely important. In our study, foam sclerotherapy was considered to be successful when total occlusion or partial recanalisation without reflux was achieved, a criterion already adopted in other studies.

Some studies have assessed the efficacy of foam sclerotherapy for the treatment of primary varicose veins. In 2006, an article comparing surgical treatment and foam sclerotherapy demonstrated that the conventional method was superior to foam sclerotherapy in terms of occlusion and elimination of reflux (86% vs. 63%), while foam sclerotherapy proved to be superior to liquid sclerotherapy (90% vs. 76%). Another clinical trial showed that foam sclerotherapy combined with SFJ ligation presented lower cost, shorter operating time and faster recovery when compared with surgical treatment.

Our study is original in that it compared 180-day results of the conventional method (saphenectomy) with ultrasound-guided foam sclerotherapy in a homogeneous sample: all patients had been diagnosed as C5 EpAsPr. Previously published randomised studies have included patients at different disease stages, varying from C2 to C6 in the CEAP classification, thus making comparison of results more difficult in view of the various clinical manifestations that may be present. One of these trials compared surgery and foam sclerotherapy and showed an 89% saphenous obliteration rate in the surgery group compared with 78% in the foam sclerotherapy patients; in another trial, saphenous reflux was abolished in 85% of surgery patients and 84% of foam sclerotherapy patients 12 months after treatment. The use of a non-homogeneous sample may lead to false conclusions, because patients with a milder form of varicose disease cannot be compared in terms of clinical recovery with those affected more severely. A recent meta-analysis has concluded that data are still insufficient to prescribe one or the other treatment as the best option.

Results obtained in our study were similar to those published in clinical series, with 90% success for the surgical treatment, compared with 78% for the ultrasound-guided foam sclerotherapy. The great saphenous vein was the most commonly treated vessel: 27 in the surgery group and 25 in the foam sclerotherapy group, with 96% vs. 80% of success, respectively.

### Table 2

<table>
<thead>
<tr>
<th>Group/score</th>
<th>Pre-treatment mean (SD)</th>
<th>30 days mean (SD)</th>
<th>60 days mean (SD)</th>
<th>180 days mean (SD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgery</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>1.97 (0.19)</td>
<td>0.93 (0.53)</td>
<td>0.79 (0.49)</td>
<td>0.72 (0.53)</td>
</tr>
<tr>
<td>Oedema</td>
<td>1.66 (0.48)</td>
<td>0.69 (0.60)</td>
<td>0.59 (0.63)</td>
<td>0.55 (0.63)</td>
</tr>
<tr>
<td>Inflammation</td>
<td>1.55 (0.63)</td>
<td>0.76 (0.44)</td>
<td>0.72 (0.45)</td>
<td>0.72 (0.45)</td>
</tr>
<tr>
<td>Ultrasound-guided foam sclerotherapy</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain</td>
<td>1.81 (0.40)</td>
<td>0.89 (0.51)</td>
<td>0.59 (0.50)</td>
<td>0.56 (0.51)</td>
</tr>
<tr>
<td>Oedema</td>
<td>1.70 (0.47)</td>
<td>0.70 (0.54)</td>
<td>0.56 (0.64)</td>
<td>0.48 (0.64)</td>
</tr>
<tr>
<td>Inflammation</td>
<td>1.67 (0.68)</td>
<td>0.89 (0.32)</td>
<td>0.89 (0.32)</td>
<td>0.89 (0.32)</td>
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SD = standard deviation. $p < 0.005$ for all scores when comparing pre-treatment and 180-day results.

### Table 3

<table>
<thead>
<tr>
<th>Group/Complications</th>
<th>Patients affected, n (%)</th>
</tr>
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<tbody>
<tr>
<td>Surgery (n = 29)</td>
<td></td>
</tr>
<tr>
<td>Infection</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Haematoma</td>
<td>2 (7)</td>
</tr>
<tr>
<td>Lymphedema</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Suture dehiscence</td>
<td>11 (38)</td>
</tr>
<tr>
<td>Neurologic, objective</td>
<td>1 (3)</td>
</tr>
<tr>
<td>Neurologic, subjective</td>
<td>6 (21)</td>
</tr>
<tr>
<td>Lymphoedema</td>
<td>2 (7)</td>
</tr>
<tr>
<td>Ultrasound-guided foam sclerotherapy (n = 27)</td>
<td></td>
</tr>
<tr>
<td>Respiratory</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Local haematoma</td>
<td>3 (5)</td>
</tr>
<tr>
<td>Scotomas</td>
<td>1 (2)</td>
</tr>
<tr>
<td>Post-foam extravasation</td>
<td>5 (9)</td>
</tr>
<tr>
<td>Thrombus with drainage</td>
<td>5 (9)</td>
</tr>
<tr>
<td>Thrombus without drainage</td>
<td>15 (27)</td>
</tr>
</tbody>
</table>
Compression bandaging and stockings were used after surgery and after sclerotherapy, in accordance with the latest European consensus on foam sclerotherapy. Before inclusion in the present study, none of the patients had been submitted to clinical treatment with compression stockings; after treatment, elastic stockings were used for 3 months only. Since the use of elastic stockings was identical in both treatment groups and was discontinued 3 months before the 180-day evaluation, the improvement observed in our patients probably did not result from compression only.

In the duplex ultrasound assessment of patients treated surgically, eight limbs had residual varicose veins at the 6-month assessment. Ultrasound-guided foam sclerotherapy usually prevents this problem since it can easily be repeated should residual varices be found during follow-up. There is no need for general anaesthesia or hospital treatment, which greatly facilitates the use of this treatment.

Complications are inherent to any invasive technique and may occur following both surgical treatment and ultrasound-guided foam sclerotherapy. The complications observed in our patients treated surgically were similar to those reported in the published literature, but no severe complication occurred in the two groups. Suture dehiscence affected almost half of our patients in the surgery group, a finding that can be explained by the strictness adopted in the present analysis for the assessment of complications, especially those related with the healing of incisions.

A previous study has identified post-sclerotherapy thrombophlebitis and consequent hyperpigmentation as the most frequent complication associated with foam sclerotherapy. In an earlier publication, 20 cases of chemical thrombophlebitis were diagnosed, of which 15 required aspiration drainage; the remaining five cases improved spontaneously in 30 days, forming a fibrous cord. Hyperpigmentation, however frequent, is of little importance because patients with thrombophlebitis were already affected by cutaneous and subcutaneous disorders such as hyperpigmentation and lipodermatosclerosis.

Regarding the risk of thrombembolism, previous studies have shown that the foam reaches the right ventricle easily, with no significant complication. In our study, foam was always found in the deep venous system; however, due to the small amount injected and to the high flow of the deep venous system, no complication occurred.

In Brazil, an increased interest in ultrasound-guided foam sclerotherapy can be observed in response to the advantages offered by this method, since it may be carried out on an outpatient basis and there is a substantial reduction in time away from work. These factors have influenced the medical community as well as patients who now seek minimally invasive treatment for their varicose veins.

The results obtained with our patients suggest that both treatments (surgery and ultrasound-guided foam sclerotherapy) have similar efficacy in patients with varicose veins. In the Brazilian public health-care system, patients have to wait a long time to receive surgical treatment, whereas ultrasound-guided foam sclerotherapy represents a treatment option that can be carried out safely in outpatient clinics and at significantly lower costs.

The main limitations of the present study refer to the small number of patients assessed and the short period of follow-up. On the other hand, the fact that we were working with a homogeneous sample (all patients classified as C5 EAPs) allowed discussing the management of this specific type of patient. Further studies involving homogeneous samples should be carried out with the aim of defining a more accurate classification profile.

**Conclusion**

Our study in patients with healed venous ulcers suggests that ultrasound-guided foam sclerotherapy is effective in obliterating saphenous trunks. The technique has the advantage of reaching areas that are more difficult to treat surgically, especially regions of the limb affected by lipodermatosclerosis, where incisions tend to heal slowly.

**Conflict of Interest/Funding**

None.

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