

# Catheter Foam Sclerotherapy of the Great Saphenous Vein, with Perisaphenous Tumescence Infiltration and Saphenous Irrigation

Attilio Cavezzi <sup>a,\*</sup>, Giovanni Mosti <sup>b</sup>, Fausto Campana <sup>c</sup>, Lorenzo Tessari <sup>d</sup>, Luca Bastiani <sup>e</sup>, Simone U. Urso <sup>f</sup>

<sup>a</sup> Eurocenter Venalinfa, San Benedetto del Tronto (AP), Italy

<sup>b</sup> Angiology Department, MD Barbantini Clinic, Lucca, Italy

<sup>c</sup> Private Hospital Villa Igea, Forlì, Italy

<sup>d</sup> "Gluco Bassi" Foundation, Trieste, Italy

<sup>e</sup> Institute of Clinical Physiology, Italian National Research Council and CNR, Pisa, Italy

<sup>f</sup> Private Hospital "Professor Nobili", Castiglione dei Pepoli (BO), Italy

## WHAT THIS PAPER ADDS

This paper adds information on a new, effective, and safe approach in varicose vein treatment, which is based on duplex guided foam sclerotherapy, with additional use of a catheter to release the foam, perivenous tumescence infiltration, and flushing of the vein before foam injection. The inclusion of these three technical additions to the usual foam sclerotherapy (mostly performed by direct injection or cannula) significantly improved clinical and duplex based outcomes up to 3 years after treatment.

**Objectives:** This was a prospective observational study to assess the short- to mid-term efficacy and safety of catheter foam sclerotherapy (CFS) of the great saphenous vein (GSV), including peri-saphenous tumescence infiltration (PST) and intra-saphenous saline irrigation (ISI), in combination with phlebectomy of the varicose tributaries.

**Methods:** Eighty-eight limbs in 82 patients (19 male, 63 female, mean age 55.7 years) affected by varices related to GSV incompetence were submitted to CFS of the refluxing GSV segment after PST and ISI, combined with phlebectomy of the varicose tributaries. Sodium tetradecylsulfate (STS) 3% + CO<sub>2</sub>/O<sub>2</sub> sclerosant foam (SF) (median 7 mL) was injected in the GSV trunk (median caliber 7.1 mm) by means of a 4F catheter. Clinical and colour duplex ultrasound (CDU) investigation was performed pre-operatively, and 40 days, 6, 12, and 36 months post-operatively. A visual analogue scale (VAS) was used to assess procedure related symptoms and venous symptoms before and 40 days after the treatment.

**Results:** Clinical recurrence (visible varices) at 40 days, 6 and 12 months was 0%, whereas at 36 months it was 4.7%; VAS pre-operative score of heaviness, pain, and cramps/paraesthesiae decreased from 6 (IQR 6–8) to 1 (IQR 0–3), from 3 (IQR 0–7) to 0 (IQR 0–1), and from 3 (IQR 0–7) to 0 (IQR 0–1) respectively at 40 days. The CDU based occlusion rate at 40 days, 6, 12, and 36 months was 100% (88/88), 100% (88/88), 94.3% (83/88), and 89.4% (76/85) respectively. Six of the nine patent saphenous veins (average diameter 1.4 mm) had antegrade flow (overall 96.5% reflux free GSVs). One superficial venous thrombosis was recorded without any further relevant complication.

**Conclusions:** GSV treatment by means of CFS and adjuvant PST + ISI, combined with phlebectomy of varicose tributaries, proved to be safe and effective in terms of clinical and duplex based outcomes at short/mid-term follow-up.

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## INTRODUCTION

Varicose veins (VVs) of the lower limbs and their complications represent a relevant socioeconomic burden, affecting more than 20% of general population.<sup>1</sup>

Different treatments have been proposed, including high ligation, stripping and phlebectomy, endovenous thermal ablation with radiofrequency or laser, and endovenous chemical ablation by means of foam sclerotherapy or

\* Corresponding author. Eurocenter Venalinfa, San Benedetto del Tronto (AP), Italy.

E-mail address: [info@cavezzi.it](mailto:info@cavezzi.it) (Attilio Cavezzi).

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cyanoacrylate embolisation. All these treatments result in some degree of clinical and/or duplex ultrasound based recurrence in the treated limb in the mid- to long term, which has been estimated to be about 30% at 5 years by some authors.<sup>2,3</sup>

The literature data show an overall inferiority of ultrasound guided foam sclerotherapy (UGFS) in terms of the venous occlusion rate compared with other endovenous techniques, such as laser and radiofrequency, or surgery.<sup>4,5</sup>

UGFS has been proved effective and safe in the treatment of saphenous veins, tributaries, perforators, recurrences, venous malformations, and venous ulcers,<sup>6,7</sup> but data on UGFS studies show an increased recanalisation rate for larger saphenous diameters.<sup>8–10</sup> In the presence of larger veins a larger volume of blood in the target veins negatively impacts any sclerosant activity by deactivating liquid and foamed sclerosant drugs both in vitro and in vivo, even after a few seconds.<sup>11–14</sup>

The introduction of a catheter as the means of sclerosant foam (SF) delivery has been proposed in order to have a more even SF distribution to possibly improve the results.<sup>15–17</sup> More interestingly, the positioning of a catheter in a vein allows use of ultrasound guided peri-saphenous infiltration of the tumescent solution (PST) to reduce the vein caliber, and hence blood content, prior to SF delivery.<sup>18–20</sup> Similarly in 2009 intrasaphenous irrigation (ISI) with saline solution was proposed to flush the blood out of the vein, in order to complement PST and possibly achieve a nearly blood free great saphenous vein (GSV) segment before SF is injected through the catheter.<sup>19</sup>

The aim of this study was to assess whether a modified method of foam sclerotherapy, based on catheter foam sclerotherapy (CFS) with the inclusion of PST and ISI, in combination with hook phlebectomy of the varicose tributaries, could achieve better outcomes in GSV treatment than UGFS literature data.<sup>3,4,7–9</sup>

## PATIENTS AND METHODS

### Patients

Patients with symptomatic VVs and GSV incompetence were enrolled in the study on an intention to treat basis.

Inclusion criteria were primary VVs related to valvular incompetence of the GSV (reflux > 0.5 s) and of the terminal valve (TV) of the saphenofemoral junction (SFJ). Exclusion criteria were pregnancy, acute deep or superficial vein thrombosis, severe peripheral arterial occlusive disease (e.g., basal ankle–brachial index below 0.5), symptomatic patent foramen ovale (PFO), cardiac or renal failure, immobility, active cancer, relevant thrombophilia (e.g., deficit of AT III, protein C, and protein S), allergy to sodium tetradecylsulfate (STS).

Patients were fully informed on the interventional procedures and gave their informed consent to the treatment and the study protocol. The study complied with the ethical principles of the Helsinki Declaration for Medical Research involving human subjects. According to the Italian regulations, ethics committee approval is not required in cases of

an observational study performing clinically established interventional procedures.

### Clinical and duplex ultrasound evaluation

The clinical assessment included (1) CEAP (Clinical, Etiological, Anatomical, and Pathophysiological) staging of the limb to be treated; (2) pre- and post-operative (40 days after intervention) patient reported “venous” symptoms, pain, heaviness sensation, cramps; (3) peri-procedural symptoms (pain, paraesthesiae, swelling sensation) related to the applied technique 3 and 7 days after procedure; (4) the absence/presence of visible VVs in the treated area. A visual analogue scale (VAS) assessment was used to evaluate the symptoms as to above.

Patients underwent clinical and colour duplex ultrasound (CDU) investigation (Vivid 7, GE, Amersham, UK; linear probe 7.5–13 MHz) in the standing position, following previously published Union Internationale de Phlébologie (UIP) recommendations,<sup>21</sup> with measurement of GSV caliber 15 cm below the TV of the SFJ; measurement was not performed at the site of a focal dilatation, but just above or below. All patients were investigated with CDU at 40 days, 6 months, 12 months, and at 36 months.

### Interventional procedure

All patients were operated on in an outpatient setting with local anaesthesia (buffered mepivacaine 0.125%, without adrenaline), which was injected at the catheter entrance point and along the phlebectomy sites. The GSV trunk was cannulated at its distal refluxing site (mostly just below or above the knee) under ultrasound guidance in a semi-recumbent limb position, whereas the rest of the procedure was performed in the Trendelenburg position. Transcutaneous GSV cannulation was performed with an 18G or a 21G needle.

A hydrophilic 45 cm long j-shaped guidewire was then inserted to allow insertion of a 6F introducer and a sheath, to provide with Hemostop, and an external tube with a three way valve (to perform blood aspiration and washing). A 4F closed-tip PVC catheter, with two side holes in close proximity to the tip (Cathfoam kit, Techlamed, Florence, Italy), was advanced through the sheath inside the GSV trunk. The tip of the catheter was positioned about 5 cm below the TV of the SFJ.

The 70 cm catheter has a 1.3 mm (4F) outer diameter and an inner lumen where a removable metal wire is contained. An included plastic adaptor was used to connect the distal part of the catheter to the syringe.

Once the catheter was positioned inside the targeted GSV segment, PST was performed under ultrasound guidance, strictly within the saphenous compartment in order to maximise the squeezing action of the refluxing segment of GSV (Fig. 1A). Tumescent solution was composed of 5 mL of 1% mepivacaine with adrenaline, 5 mL of sodium bicarbonate 10 mEq/10 mL, and 250 mL of saline solution. The volume of tumescence solution used was sufficient to fully collapse the GSV trunk for the whole targeted length.

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