

## ORIGINAL RESEARCH

## Treatment of Recurrent Symptomatic Saphenous Trunk Reflux with Catheter Directed Foam Sclerotherapy and Tumescent Anaesthesia

Luis Leiva Hernando<sup>\*</sup>, Agustín Arroyo Bielsa, Juan Carlos Fletes Lacayo

Vithas Nuestra Señora de America Hospital. Madrid. Spain

**Objective:** The aim was to assess short and midterm efficacy and safety of catheter directed foam sclerotherapy (CDFS) with tumescent anaesthesia in patients with recurrent symptomatic saphenous reflux.

**Methods:** This was a prospective observational study (February 2018 to February 2019) including 21 consecutive patients referred with recurrent symptomatic varicose veins. Standing duplex ultrasound (DUS) with saphenous vein diameter measurement 3 cm from the terminal valve was performed pre-operatively. All the patients were operated on under local anaesthesia. By ultrasound guided puncture a hydrophilic 0.035" guidewire and 5F Berenstein catheter were inserted through a 5F introducer sheath. Peri-saphenous tumescent anaesthesia (PSTA) was performed under ultrasound guidance. Sclerosant foam was prepared with sodium tetradecyl sulphate 3% or polidocanol 3% using the Tessari method. Concomitant phlebectomies were performed in 52%. Clinical evaluation and DUS were performed pre- and post-operatively at one week, six months, and 12 months.

**Results:** There were 11 men and 10 women (median age 52 years; interquartile range [IQR] 43 – 61). The great saphenous vein was treated in 18 patients. The median vein diameter was 6.8 mm (IQR 4.7 – 8.9). Previous procedures were Cure conservatrice et Hemodynamique de l'Insuffisance Veineuse en Ambulatoire (CHIVA), mechanochemical ablation, thermal ablation, and cyanoacrylate closure. The distribution of the clinical class (Clinical Etiology Anatomy Pathophysiology [CEAP] classification) was 16 C2, three C3, and two C4 limbs. Immediate technical success was 100%. There were no complications in the early post-operative period. The median follow up was eight months (IQR 5 – 10). The occlusion rate demonstrated by DUS was 100% (21/21) at one week, 100% (21/21) at six months, and 86% (18/21) at 12 months. The median post-procedural vein diameter at one week, six months, and 12 months was 4.8 mm (IQR 3.9 – 6), 4.3 mm (IQR 3.5 – 5.5), and 4 mm (IQR 3 – 4.9), respectively.

**Conclusion:** Combination CDFS with PSTA achieves good short and medium term venous occlusion rates, associated with few complications in patients with recurrent symptomatic saphenous reflux.

© 2022 The Author(s). Published by Elsevier Ltd on behalf of European Society for Vascular Surgery. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

Article history: Received 17 March 2021, Revised 25 November 2021, Accepted 14 January 2022,

### INTRODUCTION

The varicose vein recurrence rate is variable and remains a complex and costly problem despite improvements in pre-operative investigation and surgical techniques. Duplex ultrasound (DUS) recurrence does not necessarily mean clinical recurrence. The most frequent source of recurrent reflux is incompetence of the saphenofemoral junction (SFJ) resulting from several aetiologies: neovascularisation (most frequent), technical failure or tactical error, disease progression, and uncertain causes.<sup>1</sup>

Ultrasound guided sclerotherapy with liquid agent was described for the first time by Schadeck in 1986.<sup>2</sup> The

introduction of foam showed benefits compared with the liquid form by minimising dilution, increasing surface area, and prolonging sclerosant-endothelium contact time, thus enhancing the therapeutic action with a major reduction in the total volume used. Ultrasound guided foam sclerotherapy (UGFS) has advantages compared with surgery and endovenous ablation: less time consuming, easily repeatable, less pain, fast recovery, and relatively inexpensive.<sup>3</sup> Although UGFS is the endovenous technique with the highest recanalisation rates in primary varicose vein treatment,<sup>4–6</sup> it may be an option in recurrent symptomatic patients with several technical details modified.

In 1997, Parsi<sup>7</sup> published a technical modification adding the use of angiographic catheters in order to release the foam in a more homogeneous way and cause spasm in the vein wall during the pull back procedure. This modification is called catheter directed foam sclerotherapy (CDFS) and ensures contact between the foam and the endothelium. In 2005, Thibault<sup>8</sup> reported his experience combining foam

<sup>\*</sup> Corresponding author. Vithas Nuestra Señora de America Hospital, C/ Arturo Soria 103–105, 28043, Madrid, Spain.

E-mail address: [dr.leiva@clinicamedivas.net](mailto:dr.leiva@clinicamedivas.net) (Luis Leiva Hernando).

2666-688X/© 2022 The Author(s). Published by Elsevier Ltd on behalf of European Society for Vascular Surgery. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>).

<https://doi.org/10.1016/j.ejvsf.2022.01.008>

sclerotherapy and peri-venous tumescent anaesthesia in order to minimise the vein diameter and ensure the best possible contact between sclerosant and venous wall.

UGFS may be considered the primary treatment in patients with recurrent reflux with a IIa recommendation and B level of evidence recommendation in the 2015 European Society for Vascular Surgery (ESVS) Guidelines.<sup>3</sup>

The aim was to assess the short and midterm efficacy and safety of CDFS with tumescent anaesthesia in patients with recurrent symptomatic saphenous trunk reflux.

## MATERIALS AND METHODS

This was a prospective observational study from February 2018 to February 2019 including 21 consecutive patients referred with recurrent symptomatic varicose veins due to saphenous insufficiency.

Inclusion criteria were patients with recurrent symptomatic saphenous incompetence (reflux > 0.5 seconds). Exclusion criteria were pregnancy, acute deep or superficial vein thrombosis, severe peripheral arterial occlusive disease (ankle brachial index < 0.5), symptomatic patent foramen ovale (PFO), cardiac or renal failure, immobility, active cancer, thrombophilia (e.g., deficit of AT III, protein C, and protein S), allergy to sodium tetradecyl sulphate (STS) or polidocanol.

All patients were fully informed of the interventional procedures and gave their informed consent to the treatment.

Standing DUS with measurement of great saphenous diameter three cm from the terminal valve was performed pre-operatively.

All the patients underwent surgery in an operating room under local anaesthesia (mepivacaine 1% without adrenaline) injected at the puncture point and along the phlebectomy sites. The saphenous trunks were cannulated under ultrasound guidance at the most distal refluxing site.

A hydrophilic 0.035" guidewire and a 5F Berenstein catheter were inserted through a 5F introducer sheath. Once the catheter was placed at the most proximal area of the saphenous trunk, peri-saphenous tumescent anaesthesia (PSTA) was performed under ultrasound guidance until the puncture site was reached. Tumescent solution was composed of 10 mL of 1% mepivacaine, 10 mL of sodium bicarbonate 10 mEq/10 mL, and 500 mL of saline. The volume of tumescent solution used was sufficient to make the whole length of the vein collapse.

Sclerosant foam (SF) was prepared with STS 3% or polidocanol 3% using the Tessari method (one part of sclerosant liquid and four parts of air). Once PSTA had been completed, the catheter was pulled back continuously at approximately 2cm/s while injecting foam. The volume injected foam depended on the length of the vein to be treated.

Post-operative compression consisted of a multilayer low elasticity adhesive bandage for 48 hours followed by a medical compression stocking class II (22 – 29 mmHg pressure at the ankle) for 45 days during daytime only. Prophylactic low molecular weight heparin was prescribed for 10 days after surgery.

Clinical evaluation and DUS were performed pre- and post-operatively. "Complete occlusion" was defined as total incompressibility of the great saphenous vein (GSV) trunk and absence of colour Doppler flow over more than 80% of the length of the treated segment. "Partial recanalisation" was defined as partial compressibility of the treated segment and or an occlusion <80% of the intended length treated. A fully recanalised vein was diagnosed in the presence of a completely compressible lumen over more than 20% of the treated segment. Recanalised vein segments were tested for the presence of antegrade flow only, or reflux.

A descriptive statistical analysis was made using median as measure of central tendency, interquartile range (IQR) as measure of spread and absolute and relative (percentage %) values.

## RESULTS

The sample consisted of 11 male and 10 females (median age 52 years; IQR 43 – 61). No patients were excluded from the study as they all met the inclusion criteria.

The great saphenous vein was treated in 18 patients and the small saphenous vein in three patients. The median vein diameter was 6.8 mm (IQR 4.7 – 8.9). The previous procedures were CHIVA (76%,  $n = 16$ ), mechanochemical ablation (14%,  $n = 3$ ), radiofrequency thermal ablation (5%,  $n = 1$ ), and cyanoacrylate closure (5%,  $n = 1$ ).

The distribution of the clinical class (Clinical Etiology Anatomy Pathophysiology [CEAP] classification) was 16 C2, three C3, and two C4 limbs.

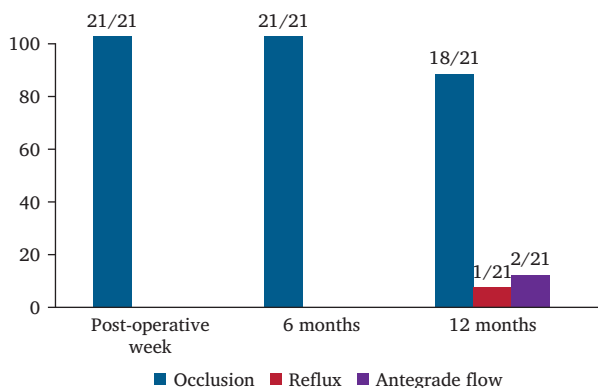
Immediate technical success was 100%. The median volume of SF per procedure was 9 mL (IQR 7 – 10) and the median length of the targeted vein was 30 cm (IQR 20 – 45). Concomitant phlebectomies were performed in 52% ( $n = 11$ ). There were no complications in the early post-operative period. Patients did not report any neurological, pulmonary, or cardiac symptoms intra-operatively, or in the following hours or days; no deep vein thrombosis was detected at clinical or DUS follow up. No skin pigmentations were observed at the site of the treated veins. No complementary procedures were necessary during follow up.

All the patients reported improvement of the symptoms (heaviness, swelling, cramps) discussed before the procedure. Only one patient reported a feeling of tightness in the first post-operative week without clinical findings of superficial vein thrombosis that was resolved with non-steroidal anti-inflammatory drugs.

The median follow up was eight months (IQR 5 – 10).

The treated saphenous trunk occlusion rate, demonstrated by DUS, was 100% (21/21) at one week and six months (21/21), and 86% (18/21) at 12 months. Two of the three patients with recanalised veins presented with antegrade flow and without symptoms, so the "reflux free" ratio was 95% (20/21) at 12 month follow up (Fig. 1).

The median post-procedural vein diameter at one week, six months, and 12 months was 4.8 mm (IQR 3.9 – 6), 4.3 mm (IQR 3.5 – 5.5), and 4 mm (IQR 3 – 4.9), respectively (Fig. 2).



**Figure 1.** Colour duplex ultrasound post-operative outcomes at one week, six months, and 12 months.

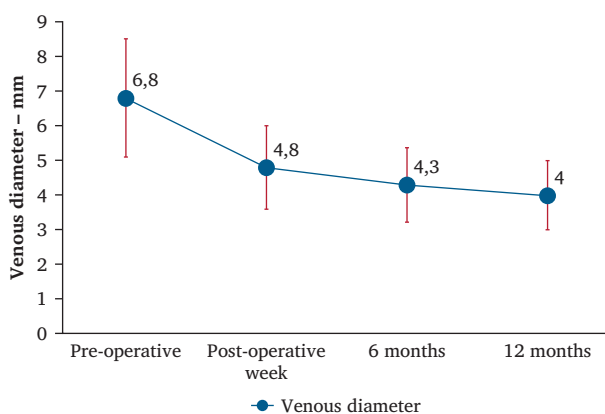
## DISCUSSION

The DUS results of the present study show that CDFS for venous truncal incompetence combined with PSTA and additional phlebectomies of the varicose tributaries is a safe and effective technique increasing the probability of success in terms of vein occlusion at midterm follow up for the treatment of recurrent varicose veins, although it is also the case that this combination (CDFS with PSTA) makes the procedure more complex than UGFS.

A 100% occlusion rate was obtained at six month and 86% at 12 month follow up without complications. For the treatment of primary varicose veins, this procedure has already demonstrated many advantages over UGFS, such as high occlusion rates at short, medium, and long term follow up with a lower risk of major complications.<sup>9</sup>

An overall absence of procedure related symptoms and signs was recorded, which may correlate with the mini-invasiveness of the procedure and with the good efficacy of compression.

Dos Santos et al.<sup>10</sup> reported a full success rate of 75% at 12 month follow up, but 12 patients of the CDFS with tumescence group received re-treatment sessions. The



**Figure 2.** Comparison of median post-procedural vein diameter at one week, six months, and 12 months was 4.8 mm (interquartile range [IQR] 3.9 – 6), 4.3 mm (IQR 3.5 – 5.5) and 4 mm (IQR 3 – 4.9), respectively.

present results are slightly better with no patients requiring re-treatment sessions.

A series of 88 limbs with primary GSV reflux managed by CDFS after perivenous tumescent anaesthesia was reported by Cavezii et al.<sup>11</sup> The occlusion rates based on colour duplex ultrasound were 100% at 40 days or six months, 94.3% at 12 months, and 89.4% at 36 months. These slightly better results, compared with the present study, may be due to the application of intrasaphenous saline irrigation in order to flush the blood out of the vein and to achieve a nearly blood free GSV segment. At the 36 month follow up six of the nine recanalised veins presented antegrade flow and none of them refluxed. The overall DUS showed no reflux in 82 of the 85 GSVs available for the 36 months follow up, which accounts for 96.5% “reflux free” (occluded plus competent veins) GSVs. These results are very similar to those obtained in the study after 12 months (“reflux free ratio 95.2%).

The difference in results compared with other similar publications may be for two reasons: (1) systematic application of echo guided perivenous tumescent anaesthesia that minimises the vein diameter ensuring a better contact between endothelium and sclerosant; (2) controlled and more homogeneous foam release as has been proven by other authors with occlusion rates ranging from 67% – 93% in patients with primary venous reflux.<sup>12–16</sup> Moreover, the catheter itself induces vasospasm furthering the vein diameter reduction resulting from the application of tumescence.

The weak points of the study are the limited number of patients and the lack of a control group, which does not facilitate comparison with other techniques (e.g., thermal ablation or cyanoacrylate sealing); hence, the comparison only refers to literature data.

## Conclusions

This prospective observational study demonstrates that the combination of catheter directed foam sclerotherapy with peri-saphenous tumescent anaesthesia achieves good short and medium term venous occlusion rates, associated with a low risk of complications in patients presenting recurrent symptomatic saphenous reflux.

Larger randomised controlled studies with longer follow up are needed to further validate this therapeutic modality.

## FUNDING

None.

## CONFLICT OF INTEREST

None.

## REFERENCES

- 1 Brake M, Lim CS, Shepherd AC, Shalhoub J, Davies AH. Pathogenesis and etiology of recurrent varicose veins. *J Vasc Surg* 2013;57:860–8.
- 2 Schadeck M. Doppler et échotomographie dans la sclérose des veines saphènes [Doppler and ultrasonic diagnosis in sclerosis of the saphenous veins]. *Phlebologie* 1986;39:697–716.

- 3 Wittens C, Davies AH, Bækgaard N, Broholm R, Cavezzi A, Chastanet S, et al. Editor's choice — management of chronic venous disease: clinical practice guidelines of the European Society for Vascular Surgery (ESVS). *Eur J Vasc Endovasc Surg* 2015;**49**:678–737.
- 4 Rasmussen LH, Lawaetz M, Bjoern L, Vennits B, Blemings A, Eklof B. Randomized clinical trial comparing endovenous laser ablation, radiofrequency ablation, foam sclerotherapy and surgical stripping for great saphenous varicose veins. *Br J Surg* 2011;**98**:1079–87.
- 5 Myers KA, Jolley D, Clough A, Kirwan J. Outcome of ultrasound-guided sclerotherapy for varicose veins: medium-term results assessed by ultrasound surveillance. *Eur J Vasc Endovasc Surg* 2007;**33**:116–21.
- 6 Hamann SAS, Giang J, De Maeseneer MGR, Nijsten TEC, van den Bos RR. Editor's Choice — five year results of great saphenous vein treatment: a meta-analysis. *Eur J Vasc Endovasc Surg* 2017;**54**:760–70.
- 7 Parsi K. Extended long line echosclerotherapy. *Sclerother Soc Aust Newsbullet* 1997;**1**:10–2.
- 8 Thibault P. Internal compression (peri-venous) following ultrasound guided sclerotherapy to the great and small saphenous veins. *Aust NZ J Phlebol* 2005;**9**:29–32.
- 9 Lim SY, Tan JX, D'Cruz RT, Syn N, Chong TT, Tang TY. Catheter-directed foam sclerotherapy, an alternative to ultrasound-guided foam sclerotherapy for varicose vein treatment: a systematic review and meta-analysis. *Phlebology* 2020;**35**:369–83.
- 10 Dos Santos JB, Júnior WC, Porta RM, Puggina J, da Silva DF, Puech-Leão P, et al. Catheter-directed foam sclerotherapy with tumescence of the great saphenous vein versus ultrasound-guided foam sclerotherapy: a randomized controlled trial. *Phlebology* 2020;**35**:84–91.
- 11 Cavezzi A, Mosti G, Campana F, Tessari L, Bastiani L, Urso SU. Catheter foam sclerotherapy of the great saphenous vein, with perisaphenous tumescence infiltration and saphenous irrigation. *Eur J Vasc Endovasc Surg* 2017;**54**:629–35.
- 12 Brodersen JP, Geismar U. Catheter-assisted vein sclerotherapy: a new approach for sclerotherapy of the greater saphenous vein with a double-lumen balloon catheter. *Dermatol Surg* 2007;**33**:469–75.
- 13 Liu XP, Guo W, Jia X, Du X, Xiong J, Yin T, et al. [Catheter-directed foam sclerotherapy of incompetent saphenous reflux: early results]. *Zhonghua Wai Ke Za Zhi* 2009;**47**:1873–5.
- 14 Tan VK, Abidin SZ, Tan SG. Medium-term results of ultrasonography-guided, catheter-assisted foam sclerotherapy of the long saphenous vein for treatment of varicose veins. *Singapore Med J* 2012;**53**:91–4.
- 15 Williamsson C, Danielsson P, Smith L. Catheter-directed foam sclerotherapy for insufficiency of the great saphenous vein: occlusion rates and patient satisfaction after one year. *Phlebology* 2013;**28**:80–5.
- 16 Ascitto G, Lindblad B. Catheter-directed foam sclerotherapy treatment of saphenous vein incompetence. *Vasa* 2012;**41**:120–4.