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Treatment of Varicose Veins by Foam Sclerotherapy: Two Clinical Series

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ABSTRACT

Objective: To assess the efficacy and safety of sclerotherapy of varicose veins (VV) with sclerosing foam (SF) made using Tessari's method (three-way tap and two plastic syringes).

Design: Two multi-centre prospective clinical series were documented (CS1 and CS2). In CS1, which ran from March to December 2000, 177 patients (39 men, 138 women), mean age 56 years, were treated in three centres for VV related to incompetence of saphenous veins, recurrence, perforators or collaterals. Conventional or duplex-guided sclerotherapy was performed using SF made of purified sodium tetradecyl sulphate (PSTS) 0.2–3% (Fibro-vein, STD Pharmaceuticals, UK) and air. An average of 1.6 (SD 0.8) sessions per patient were performed and 2.9 (SD 1.0) ml of SF (i.e. 0.6 ml of PSTS) per session was employed. An elastic stocking providing 20–30 or 30–40 mmHg compression was worn by patients following treatment. All the patients were reviewed (clinical examination and colour duplex ultrasonography) at 1 month. Sixty-six patients had a further follow-up 45–370 days after treatment. The 17 patients in CS2, a multi-centre study, were treated in March and April 2001. An independent observer assessed patients with major VV (CEAP and VV type distribution similar to CS1) before and after the treatment, and also observed the treatment, which was carried out using the technique employed in CS1.

Results: In CS1 at 1 month follow-up there was: (A) obliteration of the vessel or antegrade flow in 161 (91%) patients, (B) minimal retrograde flow in the treated vein, without visible VV, in 15 (8.4%) cases and (C) persistence of vessel patency with retrograde flow and visible VV (failure) in 1 (0.6%) case. At 45–370 days (mean 138 days) follow-up results were: type A in 44 (67%) cases, type B in 17 (26%) cases and type C in 5 (8%) cases. The main complications were extension of sclerothrombus from superficial to deep veins (n = 2), allergy (n = 1), malaise (n = 1) and scotoma (n = 1). In CS2 at 30 days follow-up 100% of the treated venous segments had a type A outcome after an average of 1.4 sessions. No relevant complication occurred in this series.

Conclusions: Sclerotherapy of major VV by means of SF prepared by Tessari's method is a safe and effective form of treatment. Low doses and a low concentration of drug may be successfully employed. Further studies are needed to establish the long-term results and overall safety of this form of foam sclerotherapy.

Keywords: Sclerosing foam; Sclerotherapy; Ultrasound imaging; Varicose veins

Introduction

Sclerotherapy of varicose veins (VV) has advanced recently due to the introduction and development of sclerosing foam (SF). Orbach was the first to describe the use of a froth in sclerotherapy [1]. In 1995 new methods of transforming the sclerosing liquid into a foam were described by Cabrera et al. [2] and Monfreux [3]. In 1997 Henriet [4] reported his experience with Monfreux's technique (which transforms the sclerosing drug into a stable, large-bubble foam) for minor varicosities, while Cavezzi and Frullini [5] in 1999 reported their 13 month experience of duplex-guided

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sclerotherapy (DGS) with SF prepared by Monfreux's method. In 1998 Sadoun and Benigni [6] and in 1999 Garcia-Mingo [7] suggested new ways of manufacturing SF. In December 1999 Tessari [8] described a safe, easy method of producing a fairly stable and compact foam (made of micro-bubbles of detergent drug and air) using two plastic syringes and a three-way tap. Subsequently Frullini [9] and Gachet [10] suggested other ways to produce SF.

The foamy form of the detergent sclerosing drugs purified sodium tetradecyl sulphate (PSTS) and polidocanol (POL) has resulted in improvements in the efficacy of sclerotherapy. Foam sclerotherapy reduces the dose and concentration of injected drug [4,5]. DGS allows visualisation of the sclerosant and considerable control over which varices are treated. SF may be classified as froth, macro-mini-bubble foam and micro-bubble foam. The smaller the bubble size the greater the active surface of the drug. It is generally recognised that the sclerosing effect depends on the concentration of the drug within the vein, and not the concentration in the syringe. There is probably a 'minimum effective concentration' and the exposure time is a further important variable. Foam displaces blood from the vein, increasing the effective concentration of the sclerosant and exposure time of the vein to the drug allowing a lower concentration to be used [11].

Analysis of the different methods of making SF has revealed the advantages and disadvantages of each technique. Cabrera et al.'s method of preparing foam is under development for possible furture commercialisation; the details of this method have never been published though the results of treatment look promising [12,13].

Tessari introduced a method to produce a fairly stable SF by means of a three-way tap and two plastic, disposable syringes, which results in a dense foam (Figs 1, 2). The authors have prepared PSTS foam using this method for the last 2 years and in our hands it has given very promising results, avoiding a few of the disadvantages of alternative techniques. The limited durability of this kind of foam (significant coalescence starts after the first 2–3 min) is resolved by reforming the foam using the residual sclerosant.

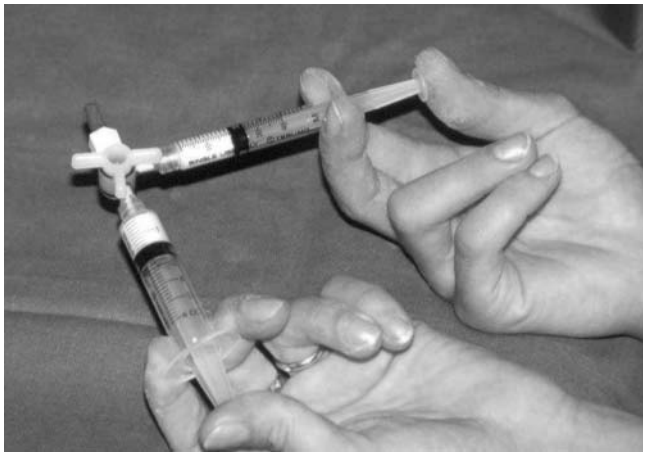

Fig. 1. Foam formation by means of Tessari's method (three-way tap and two disposable syringes).

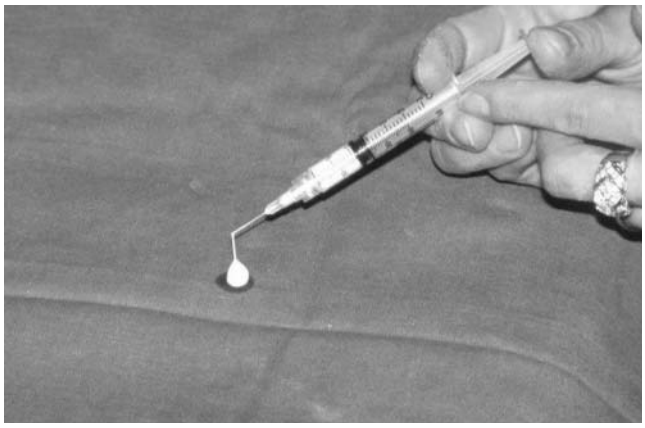

Fig. 2. The resulting sclerosing foam.

The main features of this method were established in a pilot study [14–16] which investigated how best to produce and maintain SF. This pilot study analysed a number of variables in the method of foam production, as well its basic safety and efficacy.

Subsequently, the authors have completed two multicentre clinical studies, which are reported here, in order to evaluate the immediate, short-term and medium-term outcomes after sclerotherapy of truncal VV with SF formed with PSTS according to Tessari's method. The clinical appearance of the limbs and the haemodynamic results were assessed by means of physical examination and colour-flow fuplex imaging (CFDI). We also assessed the local and systemic complications of treatment.

Patients and Methods

Two multi-centre prospective clinical series were recorded (CS1 and CS2). The studies were performed in three different centres (private offices or clinics) by the authors and only truncal VV were included for the treatment (not minor varicosities). In the second study (CS2) an external independent oberver (S.R., an expert in varicose vein surgery) assessed the protocol. The first clinical series (CS1) was carried out between March and December 2000; 177 patients (39 men, 138 women), mean age 55 years, were treated for their VV in one limb. Only truncal varicosities were included and no reticular veins or telangiectases were treated. Exclusion criteria were: known allergy to PSTS, deep venous thrombosis within the previous year, immobility, severe general diseases (cardiac or renal failure, etc.), pregnancy, puerperium or thrombophilic state.

All patients underwent clinical examination and CFDI evaluation prior to treatment in order to record an anatomical and haemodynamic map of the veins to be treated. The diameter of the long saphenous vein (LSV), anterior accessory saphenous vein (AASV) and short saphenous vein (SSV) was measured 3 cm below the junction. Table 1 summarises vein type and diameter as well as the CEAP clinical class.

Table 1. Clinical series 1: Vein and CEAP distribution, mean values and standard deviation of the diameter of the different kinds of veins

Vein					CEAP		
	n	%	Diameter		C	*n*	%
			Mean	SD			
Coll	70	40%	5.1	1.6	2	115	65%
Rec	14	8%	7.6	2.3	3	26	15%
Aasv	8	5%	7.1	2.5	4	28	16%
Lsv	37	21%	7.5	2.7	5	7	4%
Ssv	31	18%	6.6	1.7	6	1	1%
Perf	17	10%	7.0	1.8			
Total	177		6.3	2.2	Total	177	

PSTS, purified sodium tetradecylsulphate; Coll, collaterals; Rec, groin or popliteal recurrence; Lsv, long saphenous vein; Ssv, short saphenous vein; Aasv, accessory anterior saphenous vein.

PSTS (Fibro-vein, STD Pharmaceuticals, UK) was used for all treatment. The concentration of PSTS was determined according to the type and extent of VV. Each author decided on the correct strength to use according to his experience. This resulted in a wide range of concentrations (from 0.2% for collaterals to 3% for larger veins), which are reported in Table 2. In the majority of cases 1% PSTS was used for saphenous veins and recurrences. SF was formed by mixing 1 part of PSTS and 4 or 5 parts of air, through 20 passages between two disposable syringes and a three-way tap (stop-cock) which had 30° rotation of the hub, in order to narrow the aperture through which the foam passed. The method of foam formation was standardised amongst the authors, according to the features reported in the pilot study [16]. Before CS1 and CS2 were embarked upon, Dr Di Stefano and Dr Minnocci from Pisa University were asked to examine PSTS foam produced by the Tessari method by electron microscopy. These observations confirmed the bubble size of PSTS foam produced by this method to be less than 100 μm. Finally the three authors had a pre-study meeting in order to standardise the method of foam formation.

Duplex-guided sclerotherapy (DGS) was the preferred method of treating saphenous stems or recurrences. Conventional sclerotherapy was performed for collaterals. All the patients were treated in the supine position, and vein canulation was performed under transverse or longitudinal duplex scanning (DGS). Conventional sclerotherapy was used to treat clinically apparent varices. The injections were made through a 'close needle' technique; no catheter or butterfly was used. The foam was left free to fill the veins in CS1, while in CS2 sometimes foam was moved using the duplex probe to the site at which it was required, e.g. towards the saphenous junction. Immediate spasm is usually seen following injection of foam and this was assessed by CFDI and it was divided in 'type I' (with more than 80% reduction of the calibre), or 'type II' (0–79%).

Compression was used in all patients. Cotton or rubber pads were applied to the skin at the injection site to increase the local pressure. A stocking was then applied to the limb over the pads. The strength of compression used was either 20–30 or 30–40 mm Hg.

The end-point of each session was the spasm of the segment which had been treated. The final goal of the whole treatment was the obliteration of the vein with disappearance of reflux. An average of 1.6 (SD 0.8) sessions per patient were performed. The quantity of SF per session varied according to the treatment plan, averaging 2.9 ml (SD 1) of SF per session (see Table 2 for details). This SF dose corresponds to an average of 0.6 ml of PSTS per session.

Local and systemic complications were recorded for each patient. All the patients were reviewed by clinical examination and CFDI 1 months following completion of treatment. In addition 66 of the 177 patients had a follow-up of 45–370 days (mean value 138 days). Each author remained responsible for treatment and follow-up of his own patients.

The second clinical series (CS2) was completed in March and April 2001. The methodology was identical to that of CS1, except that an independent observer (IO), external to the group of doctors treating the patients, assessed the efficacy of treatment. Seventeen patients (16 women, 1 man; average age 53 years) were treated (one limb per patient) for their truncal VV. All the patients were evaluated before and after the treatment by the IO, by means of clinical examination and CFDI evaluation. CEAP and VV distribution was similar to that of CS1, and is reported in Table 3. All treatments were performed in the presence of the IO. An average of 1.4 sessions per limb were performed and an average of 3.2 ml of SF per session was used (i.e. 0.63 ml of PSTS). The maximum permissible concentration of PSTS was

Table 2. Clinical series 1: PSTS concentration and doses according to the type of vein. Foam was made of 1 part of PSTS and 4 or 5 parts of air

PSTS concentration							
	Rec	Coll	Perf	Aasv	Ssv	Lsv	Total
0.2–0.5%	1	46	2	3	2	7	61
0.6–1%	4	19	9	4	16	12	64
>1%	9	5	6	1	13	18	52
Total	14	70	17	8	31	37	177

PSTS foam doses							
	Rec	Coll	Perf	Aasv	Ssv	Lsv	Total
⩽2 ml	4	22	3	0	9	7	45
2.5–3 ml	6	39	9	4	16	20	94
>3 ml	4	9	5	4	6	10	38
Total	14	70	17	8	31	37	177

Abbreviations as in Table 1.

Table 3. Clinical series 2: Vein and CEAP distribution, mean values and standard deviation of the diameter of the different kinds of veins

Vein					CEAP		
	n	%	Diameter			*n*	%
			Mean	SD			
Rec	1	6%	7.0	0.0	2	7	41%
Coll	5	29%	6.2	2.4	3	5	29%
Aasv	3	18%	6.5	3.5	4	3	18%
Ssv	2	12%	5.5	0.7	5	2	12%
Lsv	6	35%	7.6	2.2			
Total	17		6.7	2.2	Total	17	

Abbreviations as in Table 1.

fixed at 1%, except for those LSV's having a diameter over 8 mm (see Table 4 for the related details). SF was formed by mixing one part of sclerosant with 4 parts of air and the maximum allowed dose of SF was 4 ml. The method of limb compression was the same as in CS1. Conventional sclerotherapy or DGS were administered according to the vein type, as in CS1. Injections were performed with the limb slightly raised (20 cm above the couch level), in order to decrease vein diameter, thus improving foam filling of the VV. The elevated limb was maintained in this position for about 5 min after the last injection, in order to allow the SF to be absorbed from the superficial veins. In this study the authors used duplex imaging following injection of foam by DGS or conventional sclerotherapy, in order to monitor foam movement and the early result. The resulting venous spasm was evaluated as type I or II and any complication was noted. All 17 patients were reviewed by the IO 30 days after completion of the treatment (end-point as in CS1). The patients were interviewed by the IO concerning their own judgement of the efficacy and acceptability of the treatment.

In both series the outcome of the treatment was classified according to the following criteria:

(A) Good, with obliteration of the vein or antegrade flow within the treated vessel. Duplex imaging in these cases revealed a sclerothrombus occupying the whole treated venous segment or part of it (partially occlusive thrombus). No reflux was present.

(B) Moderate, with minimal retrograde flow within the treated vessel, which was without visible varices. Duplex showed partial sclerothrombosis of the vein (partial compressibility).

(C) Failure, due to the persistence of vessel patency as a whole or of a segment, with retrograde flow within and visble VV.

Data are reported as the mean and standard deviation. Statistical analysis of contingency tables was performed using the chi-square test in order to assess significance of the findings.

Results

Results of CS1 (the first clinical series) are detailed in Table 5. In summary, CS1 outcomes at 1 month follow-up when all 177 patients were assessed were of type A in 91% of cases. This fell to 67% of cases at the second follow-up where 66 patients were reviewed. These results show a 99% positive outcome as a whole (obliteration of the treated vessels and/or VV disappearance) at 30 days and 92% cumulative positive results at the second follow-up. Post-treatment spasm was of type I in 161 cases and of type II in 16. When examining the mid-term (second follow-up for 66 patients) outcomes, a type A result was documented in 71% of those cases with type I spasm but only 29% positive (type A) results in type II spasm.

Significant general and local complications were: 8 limited thrombophlebitis, 2 segmental extensions of the sclerothrombus from SSV to deep vein (one of the two was due to a technical mistake), 1 transient lymphoedema, 1 malaise, 1 scotoma, 1 small skin necrosis and 1 allergy.

The results of the second series (CS2) were similar to the first. The main outcomes and the patients' assessments of their own treatment are summarised in Table 6.

Table 5. Clinical series 1: outcomes at 30 days and at second follow-up

Results	30 days		Second follow-up	
A	161	91%	44	67%
B	15	8.4%	17	26%
C	1	0.6%	5	8%

Table 4. Clinical series 2: PSTS foam concentration and doses according to the type of vein. Foam was made of one part of PSTS and 4 parts of air

PSTS concentration							
	Rec	Coll	Perf	Aasv	Ssv	Lsv	Total
0.2–0.5%	0	3	0	2	0	2	7
0.6–1%	1	1	0	1	1	2	6
>1%	0	1	0	0	1	2	4
Total	1	5	0	3	2	6	17

PSTS foam doses							
	Rec	Coll	Perf	Aasv	Ssv	Lsv	Total
⩽2 ml	0	1	0	0	1	0	2
2.5–3 ml	1	2	0	0	1	4	8
>3 ml	1	2	0	3	0	1	7
Total	2	5	0	3	2	5	17

Abbreviations as in Table 1.

Table 6. Clinical series 2: Spasm occurrence and outcomes at 30 days

Results and spasm		
Spasm type I	17	100%
Result type A	17	100%

One hundred per cent of the patients had a type I spasm, and a positive result (type A, with disappearance of reflux and VV disappearance) was achieved in 100% of the cases at 30 days follow-up. No relevant complications occurred. Table 6 also summarises the details of the short-term outcomes according to the CFDI findings. Patients' overall satisfaction was very high, both in terms of symptom relief and in terms of cosmetic appearance of the limb.

In CS1 there was no significant relationship between vein type, vein diameter, CEAP class and outcome after 30 days follow-up.

Table 7 shows that the larger- diameter veins (i.e. diameter over 7 mm) negatively influenced the outcome at the second follow-up in comparison with results at 30 days ($p = 0.076$). Moreover, limbs with complicated VV, such as CEAP C3–C6, had a slightly worse result at the second follow-up compared with limbs with CEAP C2.

Discussion

Sclerotherapy is influenced by several variables and it is still considered a controversial modality of VV treatment, probably with a higher recurrence rate than surgery. An international consensus conference [17] has shown a wide range of different practices in sclerotherapy, demonstrating a lack of uniformity in performing this treatment. A number of differences between the techniques of the three authors of this paper emerged during the collection of the first clinical series. During CS2 the treatments were standardised as far as possible. A few technical details were improved following CS1, such as the introduction of the elevation and immobilisation of the treated limb, reflecting our increased understanding of the new technique. Foam sclerotherapy represents an advance of VV treatment and our initial experience highlights the efficacy of SF prepared by Tessari's method using PSTS.

Two factors may explain the good results reported here with foam sclerotherapy. Firstly the SF displaces blood contained within the vein, with very little drug dilution in the blood, for at least the first few minutes. Secondly the active surface of the drug is greatly increased by preparation of the foam.

DGS with SF is technically easier since SF is highly echogenic on ultrasound imaging. SF is easily managed and extravasation of SF is less harmful than pure liquid extravasation. We recorded a high spasm and sclerosing effect in the treated veins, and rapid achievement of the end-points. We have used very low doses of the sclerosing drug at a low concentration and these have been sufficient to achieve the final positive results.

Our experience of this method of treatment during the last 5 years [18–20] suggests some negative aspects of SF. Extra time is required for the patient to lie supine following the last injection. Deep vein thrombosis may be provoked more easily with SF, due to technical mistakes such as injections given too near deep veins or an excessive amount of SF injected and chemical and physical proprieties of foam. Neurological symptoms have been reported by the present authors and by others using SF. These require further study and necessitate careful management of SF with limitation of the total injected volume of sclerosant. Sclero-resistance as well recurrence and recanalisation in the treated vessels still persist. Sclerotherapy and surgery may be complementary treatments adequate to manage superficial venous insufficiency of the lower limbs. However, a few major differences between the two methods surely exist.

Sclerotherapy may result in a higher recurrence rate due to recanalisation of the treated veins in the long term. This may be more of problem with large size saphenous trunks. Our results show that at longer follow-up rather more signs of recurrence are seen, in keeping with other reports on this subject. SF achieves the same or better results as liquid sclerotherapy, using much lower doses and concentrations of drug [21–23]. Complications and side effects compare favourably with other reports on this subject.

Duplex assessment of sclerotherapy outcomes has opened a window on the evolution of the treated vein during follow-up [24,25]. Recanalisation of saphenous stems following treatment does not always mean the re-appearance of VV or of symptoms. This may be because tributaries often remain sclerosed, perhaps preventing saphenous reflux. Re-entry of saphenous retrograde flow

Table 7. Clinical series 1: Analysis of type A results as to the main vein variables

Results type 'A' as to CEAP				Results type 'A' as to diameter				Results type 'A' as to vein			
CEAP	30 days	FU	%	Diameter (mm)	30 days	FU	%	Vein	30 days	FU	%
2	34	27	79%	<5	10	9	90%	Coll, Perf	30	24	80%
3–6	23	17	74%	5–7	33	25	76%	Lsv, Ssv, Aasv	27	20	74%
				>7	14	10	71%				

Coll, collaterals; Perf, perforators; Lsv, long saphenous vein; Ssv, short saphenous vein; Aasv, accessory anterior saphenous vein; FU, follow-up.

into deep veins may occur directly along saphenous stems, without passing through tributaries. Fibrotic vein walls resist turbulence better, thus varicose degeneration of the treated veins is prevented. Sclerotherapy usually reduces the diameter and haemodynamic load in treated vessels, reducing venous compliance.

The absence of a life-long cure for varicose disease of the lower limbs necessitates re-treatment when varices recur. Part of the philosophy of the sclerotherapy approach is that retreatment is an integral part of this method. Foam sclerotherapy using Tessari's method incurs little expense for consumable items; the material for a single session, drug included, costs as little as 10–12 euros.

Foam sclerotherapy is undergoing further improvements and a reappraisal of general sclerotherapy managment is probably necessary. SF could possibly replace liquid sclerosants for larger veins, increasing the efficacy of DGS. Larger quantities of SF could be employed than we have recorded above [26], possibly achieving better results. In our most recent experience we have injected larger quantities of SF (up to 6 ml). This strategy may reduce the number of sessions required to complete the treatment of all veins whilst still maintaining safety. Our experience suggests that in SSV treatment less than 3 ml of SF per session should be used. Other types of foam may require different technical procedures, but no data are available at the moment to allow recommendations to be made.

The treatment of reticular varices and spider veins using SF requires great caution as SF seems too powerful even at low concentrations.

Larger groups of patients with extended follow-up are necessary for a better elucidation of the proprieties of Tessari's method in foam sclerotherapy. Our first experiences have demonstrated that sclerotherapy of major VV by means of PSTS SF formed according to this method is a safe and very effective form of treatment. The ease and cheapness of this method should ensure its widespread use, though some technical aspects of the treatment mean that the outcome may be operator dependent.

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