

# Ultrasound-guided foam sclerotherapy for the treatment of varicose veins

S. G. Darke and S. J. A. Baker

Vascular Surgery Department, Royal Bournemouth Hospital, Castle Lane East, Bournemouth BH7 7DW, UK  
Correspondence to: Mr S. G. Darke (e-mail: sg.darke@btopenworld.com)

**Background:** The aim was to assess the early efficacy and complications of ultrasound-guided foam sclerotherapy (UGFS) in a cohort of patients with varicose veins.

**Methods:** Of 192 consecutive patients referred with varicose veins over 15 months, only 11 chose surgery; the rest underwent UGFS treatment. Polidocanol was foamed 1:3 with air. Under ultrasound control via butterfly or Seldinger cannulation, 1 per cent foam was injected into superficial veins and 3 per cent foam into saphenous trunks, up to a total volume of 14 ml. Outcome was defined as complete when occlusion of the saphenous trunk and/or over 85 per cent of the varicosities was achieved, and partial closure when less.

**Results:** In 163 legs, complete occlusion occurred after one intervention, a further 32 after a second, and one after a third (overall 91 per cent). Of the remainder, all other legs achieved partial occlusion after up to three interventions, apart from two legs with great saphenous vein (GSV) incompetence, which failed. All 23 legs with small saphenous veins had complete occlusion after one intervention compared with 64 of 97 legs with GSV incompetence ( $P < 0.010$ ). Occlusion rates were also higher when the GSV was cannulated directly: 56 of 70 versus 8 of 27 ( $P < 0.001$ ).

**Conclusions:** UGFS achieved early complete occlusion safely in over 90 per cent of legs with varicose veins.

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## Introduction

Although sclerotherapy treatment for varicose veins has been recognized for many years, enthusiasm for its use, in the UK at least, has been limited and varied. More recently, the introduction of vascular ultrasound has generated new interest because it facilitates the more accurate placement of injections, particularly into the saphenous trunk<sup>1-3</sup>. To complement this has been the emergence of a number of alternative endovenous techniques to obliterate these saphenous trunks.

Orbach<sup>4</sup> is credited as the first to enhance the effect of sclerosants in treating varicose veins by mixing them with air. However, the concept seems to have remained dormant until nearly 10 years ago, when foam was shown to be more effective than liquid sclerosant<sup>5-7</sup>, especially when combined with ultrasound guidance<sup>5,8-14</sup>.

Reports on this new technique have focused particularly on the saphenous systems<sup>8-14</sup> as opposed to the outcome of its use in the wider morphology of venous disease, including recurrent varicose veins.

This article reports early outcomes in a representative cohort of patients with varicose veins. This was a consecutive series of all patients referred to a single consultant vascular surgeon and treated under the UK National Health Service.

## Materials and methods

Ultrasound-guided foam sclerotherapy (UGFS) was offered to 192 consecutive patients referred to a single vascular surgeon for treatment of varicose veins over 15 months in whom intervention was considered appropriate. This was accepted in all but 11, who opted for surgery. The rest all had UGFS: 108 women and 73 men, with a median age of 52 years. Thirty-nine patients had bilateral veins, resulting in 220 legs for treatment.

## Morphological definitions

Primary varicose veins were defined as those presenting without previous surgical intervention. Those with a

history of previous liquid sclerotherapy were still regarded as primary. On the basis of clinical and continuous wave Doppler, and where indicated duplex ultrasound imaging, legs were classified as great saphenous veins (GSVs), small saphenous veins (SSVs) and other (non-saphenous), according to criteria described previously<sup>15</sup>.

Briefly, GSV and SSV varicose veins had evidence of reflux with continuous wave Doppler, subsequently confirmed at the time of the intervention on duplex ultrasound. At this stage, the maximum diameter of the trunk in the thigh or calf was measured with the patient supine.

Other veins were predominantly isolated anterior thigh veins or posterior thigh veins, which were found to arise independently and in the presence of a normal GSV. Anterior thigh veins or posterior thigh veins co-existing with GSV incompetence were classified as GSV. Recurrent varicose veins were defined as those developing after previous surgical intervention to that system and classified according to criteria previously described<sup>16</sup>. Persistent or reconstituted GSV trunks were at least 3 mm in diameter and in continuity with the superficial varicosities and usually with the femoral vein in the groin. SSV recurrence was defined as reconnection with the popliteal vein, with or without a recurrent or persistent incompetent SSV trunk. Recurrent other veins were defined as those occurring through independent perforators without recurrence in either saphenous system. Where incompetence occurred in a second previously unoperated saphenous system (such as the SSV after previous GSV surgery), this was regarded as primary<sup>16</sup>. A detailed classification of the veins treated with UGFS is shown in *Table 1*. Most were treated for symptomatic, uncomplicated varicose veins, but seven legs were ulcerated and three were treated primarily for bleeding from superficial veins.

## Intervention

Patients were treated in a Day Surgery Unit at 30-min intervals, usually six to eight in one session. Superficial

varices were cannulated at up to three different sites with 23 gauge butterfly cannulas, usually with the legs dependent. After insertion they were flushed with saline to confirm intraluminal placement and to prevent thrombosis within the cannula. The saphenous trunks were cannulated with a Seldinger catheter (Leader Cath arterial 20G 8 cm; Vygon Ecquen, France) under ultrasound guidance (SonoSite Titan<sup>®</sup> 5 MHz Probe, SonoSite, Bothell, Washington, USA) and similarly flushed. Occasionally, a butterfly was also used for an obviously superficial and palpable GSV trunk.

Polidocanol (Sclerovein<sup>®</sup>; Resinag AG, Zug, Switzerland) foamed in a ratio of 1:3 with air was mixed using a three-way tap and a 5- and 2-ml syringe with not less than 20 passages using the Tessari technique<sup>17</sup>. Generally speaking, this was injected using either 1 per cent for superficial veins or 3 per cent for saphenous trunks, according to the standard protocol (See *Table 2*). Each injection was limited to 2 ml aliquots to a total volume not exceeding 14 ml. The saphenous trunk was usually treated first, with the patient supine and the leg flat initially. Ultrasound imaging was used to track foam within the vein, and when it reached the saphenofemoral junction, the leg was elevated to limit further cephalad progress and facilitate filling of the distal component of the varicose system. Elevation also had the effect of emptying the superficial varices. More recently, the degree of spasm seen in the saphenous trunks was noticed, since it is very variable. In some patients where attempted Seldinger catheterization had failed or was not attempted being too deep or otherwise inaccessible, saphenous trunks were filled via the adjacent butterflies placed in the superficial varicosities.

The superficial varicosities were then injected with 1 per cent polidocanol foam. Ultrasound guidance was used to milk the foam to fill any remaining segments. Sealing of superficial varicosities was checked by leaving the butterfly cannula open after the foam injection. Throughout the procedure the patients were asked to perform intermittent foot flexion to maintain deep venous flow.

**Table 1** Morphology of varicose veins treated by ultrasound-guided foam sclerotherapy (220 legs)

Morphology	No. of legs	Men:Women	Median (range) age (years)	Ulcer	Median trunk diameter (range) (mm)
Primary GSV*	97	30:67	55 (21–84)	6	5.5 (3.8–10.5)
Primary SSV*	23	5:18	53.5 (33–86)	1	5.5 (4.4–10.2)
Primary other†	38	4:34	41 (19–73)	0	
Recurrent GSV	18	7:11	57 (34–75)	0	4.5 (3.2–7.5)
Recurrent SSV	5	2:3	63 (56–80)	0	5.0
Recurrent other	39	5:34	58 (25–75)	0	

\*Four legs had both GSV and SSV, regarded as separate interventions. †Anterior thigh vein, 26; Posterior thigh vein, seven; Thigh/Calf perforators arise locally. GSV, great saphenous vein; SSV, small saphenous vein.

**Table 2** Guideline protocols for injection of polidocanol foam

Morphology	Cannulation	Strength (%)	Volume (ml)	Comments
GSV trunks	Seldinger	3	2–8	Elevate leg when foam reaches groin Watch for spasm
SSV trunks	Seldinger	1 or 3	2–4	Watch for foam entering popliteal vein
Superficial varicosities	Butterfly 1–3 ports	1	2–6 per port	If possible to point of sealing from 'bleed back'
Thigh veins	Butterfly 1–3 ports	1	2–8 per port	Large volumes may be required
Recurrent superficial varicosities	Butterfly 1–5 ports	1	2–4*	Caution over foam destination

\*This amount was exceeded in early experience and subsequently modified in light of embolic events. GSV, great saphenous vein; SSV, small saphenous vein.

Self-adhesive elastic bandages were applied over cotton wool pads at the site of the injected varicosities. An antithromboembolism stocking was then put on over the top. Patients were allowed to drive home if they wished and return to work the next day unless they had a particularly heavy job, when 2 or 3 days off work was advised.

After 5 days, the bandaging was removed by the patient and the antithromboembolism stocking worn during the day for a further 2 weeks. Patients were warned to expect tender lumpiness and discolouration at the site of the injections. Where large varicosities had been injected, patients were seen to aspirate clot under local anaesthetic 2 to 4 weeks later.

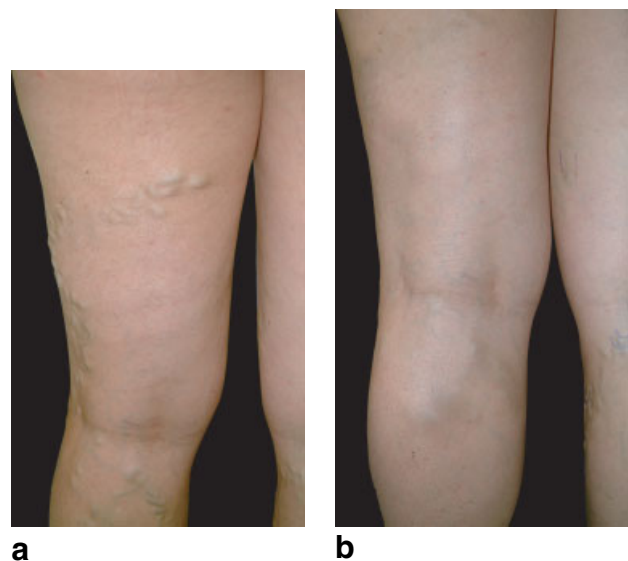
**Outcome measures**

Patients were reviewed within 6 weeks of treatment. They were assessed clinically for the occlusion of superficial varicosities by palpation and ultrasound imaging. On this basis, categories of outcome were graded as follows: complete occlusion was closure of relevant saphenous and/or at least 85 per cent of varicosities; partial occlusion was less than the above but with patients satisfied (for example, GSV still open but varicosities all closed, or less than 85 per cent varicosity closure); failed occlusion was any outcome less than the above.

Patients underwent further foam treatment as necessary, usually about 6 weeks later. In this respect, patient preference did play some part in as much that some were already been satisfied with what had been achieved. As a consequence, some patients who had a partial occlusion might have achieved a complete occlusion with further intervention.

**Results**

Overall, complete occlusion occurred in 163 legs after one intervention with a further 33 after a second intervention, and one after a third (overall 91 per cent). (Fig. 1)



**Fig. 1** Leg of a 39-year-old woman (a) before and (b) 1 month after treatment of posterior thigh vein with 6 ml of 1 per cent polidocanol foam. This shows a good early cosmetic outcome with closure of the vein on ultrasound

Of the remaining legs, all achieved partial occlusion after up to three interventions apart from three. Two of these had GSV incompetence, which failed to close in spite of three interventions. One of these patients was on warfarin anticoagulation. Finally, one patient with widespread recurrent varicose veins decided to defer further intervention after one treatment that resulted in partial occlusion.

**Complications**

One ulcer occurred in the thigh, at the site of the trunk cannulation. This patient was on warfarin therapy and the foam was seen on ultrasound to leak from the GSV puncture site and extravasate after removal of the cannula. The ulcer healed fully within a few weeks.

Two patients experienced transient visual disturbance for about 5 min and one had chest discomfort for a similar interval. These three patients were being treated for recurrent varicose veins arising from multiple perforators and had all received 1 per cent polidocanol into superficial varicosities totalling 14, 10 and 6 ml, respectively. One further patient experienced visual disturbance, which seemed more likely to have been migrainous as has been described<sup>18</sup>. She had received a total of 10 ml divided between the GSV trunk and superficial varicosities.

Phlebitis and pigmentation were common, especially soon after treatment (*Fig. 2*). This was difficult to quantify and was not recorded but is obviously an important cosmetic consideration in the longer term. Four legs were lost to follow-up.



**Fig. 2** Leg of a 54-year-old woman 1 month after treatment of incompetent great saphenous vein with 6 ml of 3 per cent polidocanol foam, and calf varicosities with 6 ml of 1 per cent polidocanol foam. This reaction is common in large veins and usually resolves. Clot aspiration may speed recovery

### Primary GSV

The practice of filling the saphenous trunks with foam indirectly via butterfly cannulation of adjacent varicosities has already been mentioned. In 27 of 97 legs, the GSV trunks were filled in this way via adjacent varicosities. In 13, this was because attempted direct Seldinger cannulation of the trunk had failed for technical reasons. In the remaining 14, the size or depth of the GSV made it potentially difficult. The trunk was nonetheless filled by these means, as confirmed on ultrasound imaging. Eight of these 27 trunks were found to be completely occluded at first follow-up. Seven of those that remained open subsequently underwent a further injection, this time directly into the GSV trunk, after which closure was secured. Of the rest, either further injections also failed or the patients were satisfied with the outcome and an expectant policy was followed (*Table 3*). In contrast, 56 of 70 trunks injected directly via a Seldinger placement were completely occluded. The difference in outcome between the two methods was statistically significant ( $\chi^2$  test,  $P < 0.001$ ).

### Primary SSVs versus GSVs

Of 23 legs with SSV incompetence, 10 had direct injections into the distal incompetent dilated SSV trunk. Half received 1 per cent polidocanol and half 3 per cent; this distinction was empirical and based on trunk size. In the remainder, injections were confined to adjacent varicosities. As has been previously reported, this is because, unlike the GSVs, these legs exhibited focal saphenopopliteal reflux and the distal trunks were small and competent<sup>19</sup>. In all these legs, satisfactory closure occurred to the saphenopopliteal junction and in the incompetent trunk where relevant. There was a better outcome in the SSVs than the GSVs overall (*Table 3*). All the patients with SSV incompetence were occluded after one injection, whereas only 64 of 97 patients with GSV incompetence

**Table 3** Early outcome of ultrasound-guided foam sclerotherapy

Morphology	No. of limbs treated	Complete after one intervention	Complete after two interventions	Complete after three interventions	Partial after one intervention	Partial after two interventions	Partial after three interventions	Fail after three interventions	Lost to follow-up
Primary GSV	97	64	19	1	5	3	2	2	1
Primary SSV	23	22							1
Primary other	38	33	2		2				1
Recurrent GSV	18	10	5		1	1	1		
Recurrent SSV	5	5							
Recurrent other	39	28	7		3				1

GSV, great saphenous vein; SSV, small saphenous vein.

were occluded ( $\chi^2$  test,  $P < 0.010$ ), despite the use of lower volumes of foam (median 3 ml *versus* 6 ml).

## Discussion

This study addressed the efficacy of UGFS in achieving the immediate technical objective of varicose vein occlusion. This was attainable in most patients with safety not only in GSVs but in SSVs and recurrent varicose veins as well. Similarly, Cabrera *et al.*<sup>8</sup> reported successful saphenous trunk closure up to 3 years after a single treatment in 81 per cent and a further 11 per cent with a second treatment. Superficial varices disappeared in 96.5 per cent, although some patients had further treatments. These results are in keeping with the experience of other authors<sup>9-14</sup>, some of whom also emphasized the need for subsequent supplementary injections to maintain closure<sup>12</sup>.

The results reported here are very early, although it is clearly of fundamental importance that initial efficacy is demonstrable. It remains uncertain whether these early results will translate into similarly satisfactory longer-term outcomes, even if further injections are necessary.

As yet, no comparative trial of surgery against UGFS has been published. This would be of considerable interest, particularly the relative incidence of recurrence. There are theoretical reasons why the recurrence rate might be lower with UGFS than with surgery. Neovascularization in the groin region is a major factor in recurrence<sup>16</sup>. Some suggest that this arises in response to the angiogenic stimulus inherent to the surgical procedure<sup>20,21</sup>. Another explanation is that it is the ablation of normal groin tributaries that might provoke neovascularization, and to retain them might avoid it<sup>22</sup>. Either way, endovenous interventions would, at least theoretically, avoid either of these stimuli.

Another important area for comparison with surgery is cosmetic outcome. Initial anecdotal experience suggests that it takes longer with UGFS to reach a satisfactory appearance, and persistent skin staining and to a lesser extent nodularity can be of concern even when an aggressive policy of aspiration after sclerotherapy has been employed. However, others with longer follow-up report that, although this may last a year, it rarely persists<sup>11</sup>.

In many other respects, differences between the two forms of treatment are self-evident in terms of cost, convenience, time off work, and the avoidance of an anaesthetic and surgical intervention. It is these aspects that may attract a number of patients who otherwise might not seek intervention. Another advantage is that it offers treatment for patients who are on the borderline for surgery on the basis of fitness or age. There are also those in whom

the technical prospects of a surgical intervention may be daunting. Re-exploration of the saphenofemoral junction might be one example. Finally, there is the management of SSV incompetence where objective assessment shows the results of conventional surgery to be disappointing<sup>23</sup>.

Cannulation of the GSV under ultrasound guidance was a new skill that took time to acquire. During the learning period, there were occasions when cannulation was either not attempted or failed. It was apparent that the trunk could nonetheless be filled via adjacent superficial varices; however, initial results suggested that this way was less effective than direct injection. Although the two groups of patients were not randomized, it seems likely that direct cannulation is better.

Overall the procedure appears to be safe, as has been reported by others<sup>8-14,24</sup>. There were three episodes that may have resulted from embolism of foam. Interestingly, all these patients were being treated for recurrent veins and in retrospect may have been given inappropriately large amounts of foam. Most of the foam almost certainly rapidly spilled into the deep system via multiple perforator connections<sup>16</sup>. Although when treating a single system, such as primary GSV, moving the foam around by milking and leg elevation is effective, it may not be appropriate in recurrent varicose veins. It is essential to monitor where the foam is tracking with ultrasound imaging; since becoming aware of this, there have been no further embolic problems in 150 legs treated. Even when this does occur, symptoms seem to be transient without any lasting consequence<sup>24</sup>.

Another area of concern is the possibility of deep vein thrombosis due to diffusion of foam into the deep system. Patients were not screened routinely, but no such events apparently occurred. Such a complication would seem to be rare, as has been the experience of others<sup>8-14,24</sup>.

The technique and protocol of this study was used in the light of considerable experience gained from others (see Acknowledgements), from the literature and from personal practice. Clearly, there is no evidence that this is the optimal technique; there could be a wide variety of regimens in terms of sclerosant, concentration, volume and mode of administration<sup>25</sup>. Using this protocol, however, it is reasonable to conclude that UGFS in the short term is safe and effective in treating a fully representative spectrum of patients with varicose veins.

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