Original article

Medium-term results of ultrasound-guided foam sclerotherapy for small saphenous varicose veins

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Background: The results of surgery for small saphenous varicose vein (SSV) varicosities may be suboptimal in terms of recurrence and complications. The role of minimally invasive alternatives remains incompletely defined. The aim was to review the medium-term outcomes of ultrasound-guided foam sclerotherapy (UGFS) for SSV.

Methods: Eighty-six patients (92 legs) undergoing UGFS for SSV were assessed before, and 1, 6 and 12 months after treatment. Outcome measures were occlusion of, and abolition of reflux in, the SSV (technical success), absence of visible varicose veins (clinical success) and improvement in disease-specific health-related quality of life (HRQL) following treatment (Aberdeen Varicose Vein Symptom Severity Score (AVSS)).

Results: The technical and clinical success rates at 12 months were 91 and 93 per cent respectively; only three patients required a second treatment. After treatment of isolated SSV varicosities there was a significant improvement in AVSS, from a median of 19·0 (interquartile range 13·4–26·8) before treatment to 10·2 (4·0–18·3) and 9·7 (3·5–19·1) at 6 and 12 months respectively. The only complication was a popliteal vein thrombosis that required anticoagulation.

Conclusion: UGFS was an effective treatment for SSV, with abolition of reflux and visible varicose veins, and improvement in HRQL for at least 12 months.

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Introduction

Approximately 20 per cent of patients presenting for treatment of varicose veins have small saphenous varicose vein (SSV) varicosities[1]. The surgical approach to such varicose veins remains controversial[2] and the outcomes are often suboptimal compared with great saphenous vein (GSV) surgery. The saphenopopliteal junction (SPJ) is subject to considerable anatomical variation, and surgery is often difficult, ineffective and associated with complications, including paraesthesia, and high recurrence rates[3–9].

Most studies examining the safety and efficacy of minimally invasive alternatives to surgery have focused on the GSV; their role in the treatment of SSV remains incompletely defined[10–14]. Endovenous laser ablation (EVLA)[10–13] and radiofrequency ablation (RFA)[14] are currently used to treat SSV with high success rates, but they are not suitable for all patients, often require additional phlebectomies or foam sclerotherapy, and can be associated with complications such as paraesthesia. The aim of the present study was to review the medium-term technical, clinical and patient-reported (symptomatic) outcomes following ultrasound-guided foam sclerotherapy (UGFS) for SSV.

Methods

Local Ethics Committee approval and written informed consent were obtained from each patient. Consecutive patients undergoing UGFS for symptomatic SSV between November 2004 and May 2007 were enrolled. All were National Health Service (NHS) patients referred to the Heart of England NHS Foundation Trust by general practitioners. They were assessed in a consultant-led

NHS outpatient clinic and had venous duplex imaging to determine sites of venous reflux. During the study, all patients presenting with SSV were offered UGFS or surgery; all chose UGFS.

Ultrasound-guided foam sclerotherapy

UGFS was performed on outpatients in a treatment room using the methods described previously[15]. The patient reclined in the prone position and the incompetent SSV was cannulated with a peripheral intravenous catheter (Optiva™; Medex Medical, Rossendale, UK) under direct ultrasound guidance. If the patient had GSV incompetence, the GSV was also cannulated under ultrasound guidance with the patient supine. One or two cannulas were usually employed in the SSV.

Sclerosant foam was prepared by Tessari's method using 0·5 ml 3 per cent sodium tetradecyl sulphate (Fibrovein®; STD Pharmaceuticals, Hereford, UK) and 2 ml air. Foam was injected in 2-ml aliquots, and its distribution and resulting venous spasm observed on duplex imaging. When all the trunk and tributary veins and the varices were in spasm, and fully occluded with foam, the cannulas were removed and compression was applied. The bandaging was left intact for 5–10 days, depending on the size of the veins, after which it was removed and a class II stocking worn alone for a further 3 weeks.

Duplex and clinical assessment before treatment

All patients had preoperative duplex imaging in a standard manner as described previously[15]. Venous flow was induced with a manual calf squeeze and reflux was defined as reverse flow longer than 0·5 s. The clinical, (a)etiological, anatomical, pathophysiological (CEAP) clinical grade was determined on the day of treatment[16]. All patients had visible varicosities in association with SSV reflux.

Outcome measures and follow-up

The chosen outcome measures were complete occlusion of, and abolition of reflux in, the SSV on venous duplex imaging (defined as technical success), the complete absence of any visible varicose veins (defined as clinical success), and self-reported improvement in disease-specific health-related quality of life (HRQL) as measured by the Aberdeen Varicose Vein Symptom Severity Score (AVSS), defined as symptomatic success[17–20].

All the patients were seen at 1, 6 and 12 months after treatment in a dedicated research clinic. At the first visit the patients were asked whether they had had any complications after treatment. Patients were specifically asked about visual disturbance, headache, and possible sensory problems in the treated leg.

All legs had repeat venous duplex examination at each follow-up visit using the same protocol. In addition, occlusion of the treated saphenous trunk was determined by a lack of compressibility and the absence of any flow on duplex imaging. Complete occlusion was defined as occlusion over the entire length of the treated SSV up to the first junction with a deep vein, usually the popliteal vein, but sometimes a gastrocnemius vein. Recanalization was defined as the presence of flow in either an antegrade or retrograde direction in a previously occluded segment. Treated legs were also examined to determine the presence of any visible trunk varicosities. The presence of reticular veins alone was not recorded as a clinical failure of treatment. The distribution of any residual or recurrent varicose veins was recorded. Patients with residual or recurrent veins were offered further treatment. One per cent polidocanol liquid (Sclerovein®; Resinag, Zurich, Switzerland), or 0·5 per cent or 1 per cent sodium tetradecyl sulphate foam, was injected directly into the varicosities; if saphenous truncal reflux was present, foam sclerotherapy was repeated with 3 per cent sodium tetradecyl sulphate as outlined above.

The AVSS questionnaire was posted to patients 1 week before treatment and before each follow-up visit. No reminders were sent. Patients who had undergone recent UGFS treatment of the other leg and those who did not bring the completed questionnaire to their first treatment session were excluded from the HRQL part of the study. The AVSS comprises 13 questions and provides a final score between 0 and 100; a higher score denotes more symptoms and so a poorer disease-specific HRQL.

Statistical analysis

Non-parametric methods within SPSS® version 17.0 (SPSS, Chicago, Illinois, USA) were used.

Results

A total of 92 legs (86 patients) had UGFS for SSV (*Table 1*). Sixty legs had UGFS for isolated SSV; the remaining 32 also had sclerotherapy for coexisting varicose GSVs at the same treatment session. In the 60 legs that had treatment for SSV varicosities alone, a single cannula was used in 58 legs and two in the other two. The median volume of foam used was 6 (range 2–8) ml. In the 32 legs that had simultaneous treatment for GSV incompetence, a median of 2 (range 2–4) cannulas were used and 10 (range 6–16) ml of foam. All treatments took less than 30 min.

Table 1 Demographic data and full CEAP classification in 86 patients having foam sclerotherapy for small saphenous varicose veins

	n
No. of patients	86
No. of legs	92
Age (years)*	57 (47–66)
Sex	
M	28 (33)
F	58 (67)
CEAP clinical grade	
C2	62 (67)
C3	10 (11)
C4	14 (15)
C5	6 (7)
(A)etiology	
Primary (E_P)	92 (100)
Secondary (E_S)	0 (0)
Anatomical patterns of venous reflux	
Deep (A_D)	0 (0)
Superficial only (A_S)	92 (100)
Primary SSV alone	47 (51)
Recurrent SSV alone	13 (14)
Primary SSV and primary GSV	22 (24)
Primary SSV and recurrent GSV	9 (10)
Recurrent SSV and primary GSV	1 (1)
Pathophysiological classification	
Reflux (P_R)	92 (100)
Obstruction (P_O)	0 (0)

Values in parentheses are percentages unless otherwise indicated; *values are median (interquartile range). CEAP, clinical, (a)etiological, anatomical, pathophysiological; SSV, small saphenous vein; GSV, great saphenous vein.

One patient developed a symptomatic popliteal vein thrombosis that was detected 4 days after treatment and remained localized to the area of the SPJ. After 6 months of warfarin this patient had mild (new) popliteal vein incompetence; the SSV remained occluded, there were no visible varicosities and the patient was asymptomatic. There were no other complications or adverse side-effects and, in particular, no visual/neurological symptoms, or symptoms of nerve injury in the treated leg.

Technical success

At 1, 6 and 12 months, the technical success rates (complete SSV occlusion without reflux) were 100, 91 and 91 per cent (84 of 92 legs), respectively. At 6 months, seven patients had a partially recanalized SSV with reflux, and one patient had reflux at the SPJ into a tributary while the SSV remained occluded. Of these eight technical failures, six had some associated visible varicosities (clinical failure) but only three patients requested further treatment. None of the 14 patients who had UGFS for recurrent SSV following previous surgery experienced a technical failure up to 12 months.

Clinical success

At 1 month, four legs (4 per cent) had some visible varicose veins. The SSV was occluded without reflux in all of these patients. Two patients wanted and underwent tidy-up injections of these tributaries and reticular veins at this stage. At 6 months, nine legs (10 per cent) had some visible varicose veins and in six this was due to recanalization of the main SSV or a tributary. In the remaining three legs, the varicosities were due to new GSV incompetence. Six of these legs had further UGFS at between 6 and 12 months. At 12 months, six legs (7 per cent) had visible varicose veins (clinical success rate 93 per cent). Three were associated with SSV recanalization that was present at 6 months; there were two further SSV recanalizations, and one patient had varicose veins in association with an incompetent below-knee perforating vein.

Symptomatic success

HRQL scores were presented for all patients and then separately for those who had unilateral SSV UGFS alone to ensure that the improvement seen was not due to concomitant GSV treatment (*Table 2*). Fifty-five (64 per cent) of 86 patients completed the questionnaire before attendance for treatment and were therefore included. Improvement in AVSS was seen as early as 1 month after treatment, but the symptom score had halved by 6 months and this was sustained at 12 months.

Missing data

All 86 patients attended 1-month follow-up. Three did not attend follow-up at 6 months, but when seen at 1 and 12 months they had complete technical and clinical success and so were assumed to have had successful treatment at 6 months. Two patients did not attend follow-up at 12 months, but when seen at 6 months and subsequently at 2 years they had complete technical and clinical success, so were assumed to have had treatment success at 12 months. A further two patients did not attend 12-month follow-up, but when seen at 6 months they had recanalization of the SSV and recurrent visible varicose veins for which they did not want any additional treatment. These were included as treatment failures in the 12-month analysis so as not to underestimate the recurrence rate at 12 months.

Table 2 Improvement in Aberdeen Varicose Vein Symptom Severity Score after treatment

	All patients			SSV only treated		
	n	AVSS score	*P**	*n*	AVSS score	*P**
Before treatment	55	22·1 (14·3–29·4)		34	19·0 (13·4–26·8)	
After treatment						
1 month	49	17·6 (9·5–28·4)	0·081	30	14·3 (7·1–28·5)	0·217
6 months	47	11·0 (5·3–15·1)	< 0·001	30	10·2 (4·0–18·3)	< 0·001
12 months	41	10·8 (4·0–16·8)	< 0·001	23	9·7 (3·5–19·1)	< 0·001

Values are median (interquartile range). SSV, small saphenous vein; AVSS, Aberdeen Varicose Vein Symptom Severity Score. **Versus* before treatment (Wilcoxon signed rank test). Each post-treatment time point is compared with the pretreatment values.

Discussion

The main finding of this study was that UGFS is a safe, quick, technically (91 per cent) and clinically (93 per cent) effective treatment for SSV for up to 12 months. A single treatment was sufficient in 89 of 92 legs. Treatment was associated with a significant improvement in disease-specific HRQL. The only complication was a short, occlusive popliteal vein thrombosis that resolved following 6 months of warfarin. This patient had no identifiable risk factors for thrombosis and it is unclear why it occurred. In particular there were no instances of transient visual disturbance or other central neurology, or features of nerve injury in the treated leg.

By contrast, the literature indicates that outcomes after surgery for SSV are often suboptimal, with high rates of recurrence and a significant complication rate[2–9]. Popliteal fossa anatomy is highly variable and, despite preoperative duplex marking, surgery is often technically inadequate, with an intact SPJ being reported in 24–47 per cent of patients at 6 weeks[3,5,8]. In one recent prospective multicentre observational study paraesthesia was present in 27 per cent of legs at 6 weeks, and in the majority this persisted after 12 months[3]. Two studies reported visible recurrent varicose veins in 26 and 30 per cent of patients at 1 and 5 years respectively[3,6].

More recently EVLA and RFA have been used for SSV in an attempt to reduce morbidity and allow faster return to normal activities. Early occlusion rates following EVLA to the SSV range from 91 to 100 per cent[11–13,21], and the limited data available suggest that this is sustained to 6 months (95–100 per cent)[10–12,21], and even to 3 years (92–100 per cent)[13,21]. Two studies reported an absence of visible varicose veins in 71 and 82 per cent of patients at 6 weeks after EVLA[11,12]; early paraesthesia rates ranged from 0 to 11 per cent[10–12,21], but all resolved by 6-month follow-up.

Most studies of RFA have concentrated on GSV treatment. Merchant and colleagues[14] treated 52 SSV with RFA; however, they combined duplex and clinical outcomes for both GSVs and SSV[14]. They found paraesthesia in 9 per cent of legs in which the SSV had been treated at 1 week, and in 10 per cent at 6 months.

Three other groups have examined UGFS outcomes for SSV. Darke and Baker[22] reported an occlusion rate of 100 per cent at 6 weeks in 27 legs, but did not look at longer-term results. Half of their patients only had direct injections into varicosities as the distal SSV trunks were small and competent. Smith[23] found SSV occlusion in 83 per cent of legs followed for longer than 6 months, but unfortunately those attending follow-up represented fewer than 60 per cent of the treated cohort. In contrast with these reports and the present study, Myers and colleagues[24] noted a worse outcome after UGFS of the SSV than the GSV – only 36 per cent occlusion at 3 years. Some of these patients were treated with liquid sclerosant only, some had tributary rather than truncal injections, and various types and concentrations of sclerosant were used[24]. Paraesthesia is not a documented complication of UGFS, and the reported rate of deep vein thrombosis is similar (0–5 per cent) with all modes of SSV treatment.

Theivacumar and co-workers[12] measured disease-specific HRQL following EVLA for SSV, and found a median improvement of 10 in AVSS score at 3 months. This was similar to that found after surgery or EVLA of the GSV[20,25,26], and to the median improvement of 11 at 6 months found in the present study.

The occlusion rates after UGFS in the present study are better than those after conventional surgery; paraesthesia rates are also lower. The results of this study are similar to those found after EVLA or RFA, although the medium- to long-term recanalization rate is probably higher after UGFS. However, subsequent UGFS is no more technically difficult than the initial procedure and is usually effective. In addition, anatomical failure does not necessarily result in clinical recurrence.

EVLA and RFA replace only the stripping component of venous surgery. In addition, the remaining tributary

varicosities have to be treated by either sclerotherapy or phlebectomy, thereby increasing treatment time and costs[14,26–28]. EVLA and RFA also require a relatively straight segment of SSV at least 10 cm long immediately distal to the SPJ, and the absence of severe varicosities arising within 5 cm of the SPJ[12]. Indeed, only 70 per cent of consecutive patients with SSV incompetence were suitable for EVLA in one study[12]. UGFS has no such requirements; the only limiting factor is the experience of the operator. Indeed, in the present study, no patient was declined UGFS for symptomatic SSV incompetence.

Fourteen patients were treated for recurrent SSV, and none had developed a recurrence by 12 months. UGFS would be particularly suitable for recurrent SSV where the anatomical requirements for EVLA or RFA may not be met, and surgery is more technically demanding and associated with higher complication rates[29].

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