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Duplex Ultrasound Outcomes Following Ultrasound-Guided Foam Sclerotherapy of Symptomatic Primary Great Saphenous Varicose Veins

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Abstract *Objectives:* To describe duplex ultrasound (DUS) outcomes 12 months following ultrasound-guided foam sclerotherapy (UGFS) of primary great saphenous varicose veins (GSVV).
Methods: A consecutive series of UK National Health Service patients underwent serial DUS examinations following UGFS with 3% sodium tetradecyl sulphate for symptomatic primary GSVV.
Results: 344 treated legs (CEAP $C_{2/3}$ 237, C_4 72, C_5 14, C_6 21) belonging to 278 patients (103 male) of median age 57 (range 21–89) years were enrolled between November 2004 and May 2007. The median volume of foam used was 10 (range 2–16) ml. Above-knee (AK) and below-knee (BK) GSV reflux was present in 333 (96.8%) and 308 (89.5%) legs respectively prior to treatment. AK and BK-GSV reflux was completely eradicated by a single session of UGFS in 323 (97.0%) and 294 (95.5%) legs respectively; and by two sessions of UGFS in 329 (98.8%) and 304 (98.7%) legs respectively. In those legs where GSV reflux had been eradicated, recanalisation occurred in 18/286 (6.3%) AK and 23/259 (8.9%) BK-GSV segments after 12 months follow-up.
Conclusions: A single session of UGFS can eradicate reflux in the AK and BK-GSV in over 95% of patients with symptomatic primary GSVV. Recanalisation at 12 months is superior to that reported after surgery and similar to that observed following other minimally invasive techniques.

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Introduction

Superficial venous surgery (SVS) comprising ligation of the saphenofemoral junction (SFJ), stripping of the above-knee (AK) great saphenous vein (GSV) to the knee, and multiple stab avulsions (MSA) appears to remain the preferred treatment for symptomatic GSV varicose veins (GSVV) among UK vascular surgeons.[1]

Although such surgery improves lower limb symptoms, venous haemodynamics and health-related quality of life (HRQL),[2–6] it is associated with a significant incidence of troubling and sometimes serious complications, morbidity, delayed return to work and normal activities, as well as medico-legal activity.[6–16]

Furthermore, previous studies of GSV stripping have reported a significant primary technical failure and recurrence rate.[3] Thus, despite best attempts to strip the GSV, post-operative duplex not infrequently reveals reflux in residual (remnant) GSV segments in the thigh and calf. Such residual disease is a well-recognised cause of clinically significant recurrent disease.[17,18]

Observational data suggest that the newer minimally invasive techniques, such as ultrasound-guided foam sclerotherapy (UGFS), offer significant advantages over surgery although durability, and specifically late recanalisation, remains incompletely defined.[11,19–22]

The aim of this study is to describe duplex ultrasound (DUS) outcomes 12 months following UGFS of primary GSVV.

Methods

Patients

Local medical ethics committee approval and written informed consent were obtained. Consecutive patients undergoing UGFS for symptomatic primary GSVV during the study period of November 2004 and May 2007 were enrolled in the study. All patients were NHS patients referred to the Heart of England NHS Foundation Trust by their general practitioners. All patients were assessed in a consultant-led NHS outpatient clinic by one of two consultant surgeons (DJA, AWB) prior to enrolment in the study. To be considered suitable patients had to have symptomatic venous disease (i.e. treatment was not offered for cosmetic indications), to have significant reflux ($>$ 0.5 s) in the GSV confirmed on DUS, and no previous history of GSV surgery on the same leg. Patients with absent pedal pulses or an ankle-brachial pressure index $<$ 0.9 were excluded, as were those with post-thrombotic deep venous disease.

Pre-treatment assessment

Patients were examined and the severity of venous disease according to the CEAP clinical classification was determined.[23] All patients had either visible varicosities (C_2 or C_3) or skin complications (C_4, C_5 or C_6). All patients underwent DUS at their initial outpatient clinic appointment to identify sites of superficial and deep venous reflux. All examinations were performed in a standard manner as previously described.[19]

UGFS treatment

The method of UGFS treatment has been described in detail previously and is therefore summarised here.[19] All treatments were performed as outpatient procedures in a treatment room, and each took less than 30 min. The incompetent truncal veins and superficial varices were marked on the skin using duplex imaging with the patient standing, and then cannulae were inserted into the truncal veins under direct ultrasonographic guidance with the patient supine. The leg was then elevated for injection of the sclerosant foam, prepared by a modified Tessari's method using two 2 ml syringes connected by a three-way tap and a 5 micron filter (B Braun Medical, Sheffield, UK), and comprising 0.5 ml of 3% sodium tetradecyl sulphate (STS) (Fibrovein®; STD Pharmaceuticals, Hereford, UK) and 2 ml of air.

With the leg still elevated a roll of Velband® (Johnson and Johnson Medical, Ascot, UK) was applied directly along the line of the previously marked saphenous trunk and superficial varices, and retained using Pehahaft® cohesive bandage (Hartmann, Heidenheim, Germany), and a thigh-length class II compression stocking (Credelast®; Credenhill, Ilkeston, UK) applied over the bandage. The bandaging was left intact for five to ten days, depending on the size of the veins, after which it was removed and the class II stocking worn alone for a further three weeks. All patients were provided with a 24 h "help-line" number to call at any time following treatment in case of any concerns.

Outcome measures and follow-up

The chosen outcome measure was complete occlusion of the vein and eradication of venous reflux in the GSV on DUS. 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 also asked whether they had had any complications following their treatment. Patients were specifically asked about visual disturbance, headache, and possible nerve problems in the treated leg.

Repeat DUS was performed at each follow-up visit as per the pre-treatment duplex. In addition, occlusion of the treated saphenous trunk was assessed by a lack of compressibility and the absence of any flow. Complete occlusion was defined as occlusion over the entire length of the GSV to the SFJ. Recanalisation was defined as the presence of flow in either an antegrade or retrograde direction in a previously occluded AK and/or below-knee (BK) GSV. Recanalisation was considered complete if over 50% of the length of vein had recanalised. Where recanalisation was found, the presence or absence of recurrent reflux was determined.

Patients with residual reflux or recanalisation at any follow-up appointment were offered further treatment by repeating foam sclerotherapy with 3% STS as outlined above.

At each follow-up appointment treated limbs were also examined to determine the presence of any visible trunk VV. The presence of reticular veins only was not recorded as clinical failure of treatment. The distribution (GSV, AASV, or SSV) of any residual or recurrent VV was recorded.

Results

Patients and treatments

The characteristics of the 278 patients (344 legs) undergoing UGFS for primary GSVV are shown in Table 1. One, two, three and four cannulae were used in 123, 202, 18, and 1 treatments respectively. The median volume of 3% STS foam used at each treatment was 10 (range 2—16) ml. Ten patients (12 legs) were taking warfarin (INR 2.5 to 3.5).

Three patients complained of visual disturbance shortly after their injections which consisted of blurring of vision and in all cases lasted for less than 10 min. There was no deep vein thrombosis in this group of patients detected either clinically or on follow-up DUS. There were no reported cases of pulmonary embolism. There were no other complications.

Eradication of AK-GSV reflux

Complete eradication of reflux in the AK-GSV was achieved in 323/333 (97.0%) legs after one, and in a further 6/333 (1.8%) legs after two treatment sessions (course of primary treatment) (Fig. 1). In four legs (1.2%) complete eradication of reflux in the AK-GSV was not achieved by one treatment session but these patients, despite residual reflux in the AK-GSV, were content with the clinical result and declined further treatment sessions.

Eradication of BK-GSV reflux

Complete eradication of reflux in the BK-GSV was achieved in 294/308 (95.5%) legs after one, and in a further 10/308 (3.2%) legs after two treatment sessions (course of primary treatment) (Fig. 2). In four legs (1.3%), complete eradication of reflux in the BK-GSV was not achieved by one treatment session but these patients, despite residual reflux in the BK-GSV, were content with the clinical result and declined further treatment sessions.

Table 1 Patient and disease characteristics.

Parameter	278 patients (344 legs)
Age in years — median (range)	57 (21—89)
Sex	
M	103 (37.1)
F	175 (62.9)
CEAP clinical grade	
C_2	213 (61.9)
C_3	24 (7.0)
C_4	72 (20.9)
C_5	14 (4.1)
C_6	21 (6.1)
Etiology	
Primary (E_p)	344 (100)
Secondary (E_s)	0 (0)
Anatomical patterns of venous reflux	
Superficial and deep (A_{sd})	10 (2.9)
Superficial only (A_s)	334 (97.1)
Primary GSV above and below-knee	297 (86.3)
Primary GSV above-knee only	36 (10.5)
Primary GSV below-knee only	11 (3.2)
Pathophysiological classification	
Reflux (P_r)	344 (100)
Obstruction (P_o)	0 (0)

Recanalisation of the AK-GSV

In the 329 legs in which the primary course of UGFS achieved complete eradication of the reflux in the AK-GSV, recanalisation was observed in 7/295 (2.4%) legs at 6 months and 18/286 (6.3%) legs at 12 months (Fig. 1). 34 legs were not seen at 6 months; 43 at 12 months.

At 6 months this AK-GSV recanalisation was partial ($< 50\%$) without reflux in one leg and partial with reflux in six legs. Of these seven legs, four underwent one session of repeat UGFS which resulted in successful complete eradication of AK-GSV reflux, and three patients were content with the clinical result and declined further treatment.

At 12 months this AK-GSV recanalisation was partial without reflux in two legs, partial with reflux in 13 legs, and complete ($> 50\%$) with reflux in three legs. Of these 18 legs, eight underwent one session of repeat UGFS which resulted in successful complete eradication of AK-GSV reflux, and ten were content with the clinical result and declined further treatment.

Recanalisation of the BK-GSV

In the 304 legs in whom the primary course of UGFS achieved complete eradication of the reflux in the BK-GSV, recanalisation was observed in 4/272 (1.5%) legs at 6 months and 23/259 (8.9%) legs at 12 months (Fig. 2). 32 legs were not seen at 6 months; 45 at 12 months.

At 6 months this BK-GSV recanalisation was complete with reflux in all four legs. Of these four legs, three underwent one session of repeat UGFS which resulted in successful complete eradication of BK-GSV reflux, and one patient was content with the clinical result and declined further treatment.

At 12 months this BK-GSV recanalisation was partial without reflux in one leg, partial with reflux in seven legs, and complete with reflux in 15 legs. Of these 23 legs, 12 underwent one session of repeat UGFS which resulted in successful complete eradication of BK-GSV reflux, and for the remaining 11 legs the patient was content with the clinical result and declined further treatment.

Clinical success

There were no visible VV in 304 legs (88.4%) after one treatment, and in 316 legs (91.9%) after two treatment sessions (course of primary treatment) to eradicate GSV reflux. Six legs had residual GSV reflux in association with residual VV after one session, but were happy with the results and did not want further treatment. In 22 legs, there were still some residual visible VV after successful eradication of GSV reflux with just one session of treatment. For six of these legs, no further treatment was requested by the patient; and a single session of foam injections directly into the visible varicosities successfully

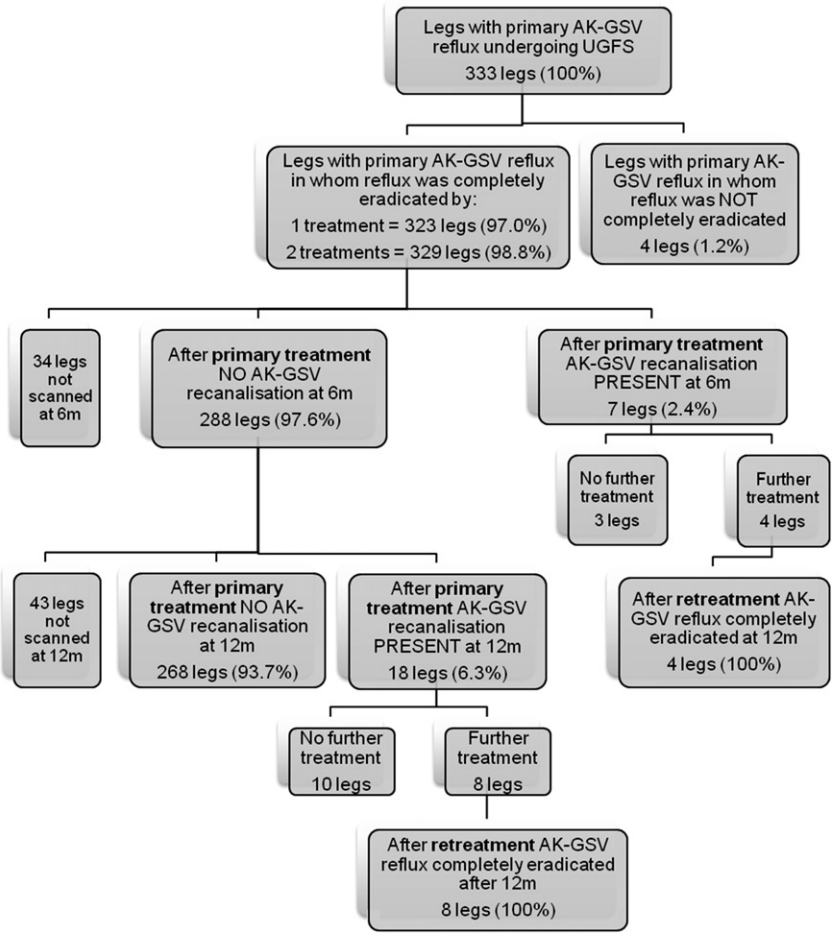

Figure 1 Eradication of reflux and recanalisation in the above-knee great saphenous vein (AK-GSV).

treated the residual VV in the remaining 16 legs, giving a total of 332 legs (96.5%) with no visible VV after a maximum of two treatment sessions.

By 12 months, 273/311 (87.8%) still had no visible VV after their primary course of treatment (33 were lost to follow-up or had residual untreated VV). Six legs had recurrent VV in association with recanalisation at 6 months, and 19 had recurrent VV in association with recanalisation at 12 months. Fifteen of these 25 had further successful UGFS treatment resulting in both eradication of the reflux and disappearance of their recurrent VV; the remainder were happy with the clinical results. Ten legs had a few recurrent VV at 12 months but no recanalisation or reflux and only two of these wanted further treatment; three had VV secondary to new reflux in the SSV.

Discussion

VV represent a chronic, frequently relapsing, condition that develops secondary to valvular failure. It is, therefore, unrealistic to expect the complete and permanent eradication of superficial reflux in all patients following a single treatment whether that be surgical, UGFS, or another minimally invasive alternative. This paradigm shift in the treatment of VV from a single event to a process has lead to a re-evaluation of outcome measures and reporting standards.[24,25]

Although still considered by many surgeons as the "gold standard",[1] it is widely recognised that residual and recurrent GSV reflux are common after surgery for primary GSVV.[17] For example, MacKenzie and colleagues reviewed 66 patients two years after SFJ ligation and attempted GSV stripping in the thigh and found that 62% had AK and 69% had BK truncal reflux.[3]

Van Rij and colleagues prospectively followed-up 92 patients (127 limbs) after GSV surgery.[18] At two weeks after surgery, of 100 SFJ ligations only one had clearly failed, with DUS demonstration of an intact SFJ. Clinical recurrence in all limbs was progressive, present in 13.7% (17/124) at three months, 31.6% (36/114) at one year, and 51.7% (60/116) limbs after three years. Of 100 SFJ that were adequately ligated, 23 demonstrated recurrent reflux at three years, with most of the recurrences present by one year.

The effectiveness of GSV surgery is also limited by the reluctance, based on fear of damaging the saphenous nerve, to strip the BK-GSV; a common cause of residual and recurrent disease. Furthermore, redo surgery for residual or recurrent reflux is usually difficult, often morbid and frequently associated with sub-optimal patient outcomes.[26]

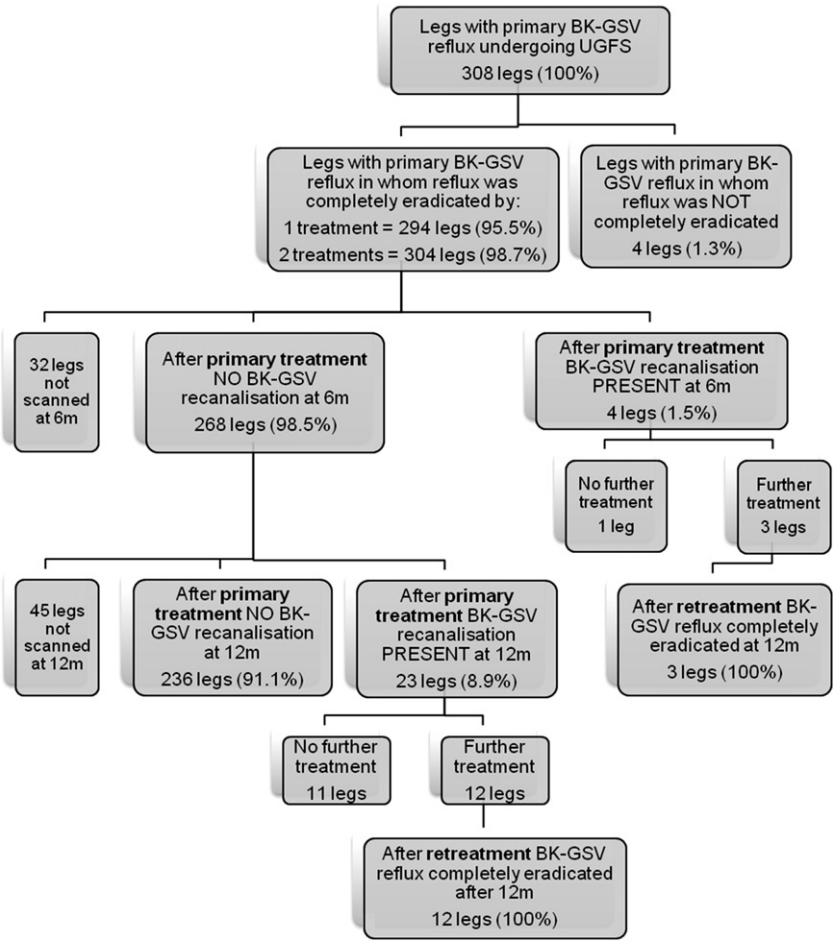

Figure 2 Eradication of reflux and recanalisation in the below-knee great saphenous vein (BK-GSV).

By contrast, as clearly demonstrated here, patients can be offered a primary course of UGFS treatments until all AK and BK-GSV reflux has been eradicated. In most cases this requires only one treatment session using a modest volume of foam and is associated with a very low incidence of side-effects and complications, and rapid return to work and other activities.[19] Furthermore, as also shown here, if recurrent reflux develops as result of recanalisation that disease can be very simply and effectively treated, usually by a further single injection of foam.

One issue with UGFS is that the technique itself is far from standardised and many variations on the basic theme exist.[27,28] We have honed our technique over almost 10 years and it continues to develop and we think improve. For example, present data on eradication of GSV reflux appear materially superior to those reported in a multi-centre prospective trial of Varisolve ® 1% polidocanol microfoam (Provensis, BTG, London, UK).[29]

In conclusion, the present paper adds further evidence that UGFS is a safe and clinically and cost-effective treatment for primary GSVV. A primary course of UGFS, comprising one and infrequently two treatment sessions, leads to complete eradication of GSV reflux in virtually 100% of cases. Recanalisation at 12 months is superior to that reported after surgery and similar to that observed following other minimally invasive techniques.

Conflict of interest

None.

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