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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.

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