FOAM ECHOSCLEOTHERAPY OF THE SMALL SAPHENOUS VEIN

A PADBURY, MBBS, FRACGP
G L BENVENISTE, MBBS FRACS (Vasc.)

Lasers In Medicine
Kent Town, South Australia

Introduction

Incompetence of the small saphenous vein (SSV) accounts for approximately 20% of all varicose vein operations.1 The principle of treatment is similar to that for varicose veins arising in the great saphenous territory i.e. flush ligation of the incompetent superficial to deep connection and avulsion of the main trunk and any associated varices. However, due to variable anatomy and the need for anaesthesia in the prone position, saphenopopliteal ligation is technically demanding with a high rate of recurrence, in spite of pre-operative duplex marking.2 The morbidity following SSV surgery is also high with complications including paraesthesia (sural nerve damage), residual varicosities, wound infections, haemorrhage, swelling, deep vein thrombosis and death from pulmonary embolism.3

Exact figures are difficult to obtain due to a paucity of published figures but it is not surprising given these recurrence rates and potential complications that a recent review has highlighted varicose vein surgery as the commonest cause for litigation following vascular surgery.4

Sclerotherapy, although commonly used to treat perforator incompetence and isolated varices for many years has had a limited role in the ablation of great and small saphenous incompetence. Recently however ultrasound guided foam sclerotherapy of the great saphenous vein (GSV) has shown promising results5-8.

UGS was first mentioned in 1986 and first presented in 1989 at the UIP World Congress in Strassburg and it has subsequently been reported for treating saphenous junctions, truncal veins near saphenous junctions and perforating veins in a number of studies.9-13

In 1994 Schadeck11 reported that UGS caused an absolute revolution in the phlebologist’s therapeutic arsenal. Using

Methods: Consecutive patients presenting with isolated sapheno-popliteal junction reflux to a specialized phlebology service were treated with foam UGS and follow up data collected prospectively. Patients were reviewed at 2, 4 and 6 weeks and further sclerotherapy performed as required. At 6 months post procedure a final assessment was made of patient satisfaction. An independent observer documented the clinical and sonographic success of the procedure.

Results: A total of 14 patients and 15 limbs were treated. Primary success was achieved in all patients (SSV injected and obliterated). At 6 months, nine (60 %) had total occlusion, five (33 %) near total occlusion with a recurrent SSV present in one only. Minor varices were present in five (33 %) and skin discolouration in two (13 %). There was no evidence of sural nerve impairment, skin ulceration or deep vein thrombosis during the study period.

Conclusions: Foam UGS of the SSV is a feasible procedure with low morbidity, high (82%) sonographic success with excellent overall patient satisfaction. Randomized controlled studies are warranted to compare the efficacy and durability of this procedure with surgical intervention.
this method, treatment of underlying “invisible” varicose veins was possible which were responsible for clinically visible varicose changes.

In 2002 Sadoun et al.6 produced results of a review of the use of a sclerosing foam in treatment of varicose veins in over 600 patients, reporting an early to intermediate success rate of 80%. Cavezzi5 and his co-workers in Italy were among the early promoters and have completed two multicentre prospective clinical series. Patient satisfaction was high and complication rate low. In this study, the authors reported a serious complication rate of 8% which included two minor and localized DVT’s. Since the original study Cavezzi has not observed any DVTs and believes it was part of the “learning curve” with his technique. (Proceedings of the 8th Scientific Meeting of the Australasian College of Phlebology, Gold Coast, Qld, 2004).

A study by Myers et al10 on 100 echosclerotherapy procedures (78 great saphenous and 22 small saphenous) showed a 77% primary success rate and an 88% secondary success rate at one year. For surgery, there was a 71% primary success and an 87% secondary success at one year. However, success rates for the two techniques could not be compared since the indications for each were different.

The excellent immediate success rates and low complication rates that have been reported for foam echosclerotherapy in the above studies may lead one to question the role of surgery altogether. However, none of the reported series were randomised control trials and therefore conclusions regarding the role of UGS compared to surgery cannot be made with any certainty.

The aim of this paper is to present our experience with UGS of the small saphenous vein as a preliminary to setting up a randomised controlled trial.

**Methods**

**Patient selection and exclusion**

All patients presenting to a specialised Phlebology practice with significant varicose veins underwent venous duplex ultrasound scanning. Consecutive patients with isolated SSV incompetence were offered ultrasound-guided sclerotherapy. Patients with associated GSV or deep vein incompetence were excluded, as were those who had had previous surgery. Patient demographics, the severity of reflux, anatomical and sonographic features of the small saphenous system were documented prospectively. The procedure, risks and complications were explained and a consent form signed. Pre-treatment photographs were taken and the patients were asked to fill the Aberdeen Quality of Life questionnaire which has previously been adapted and validated for varicose vein patients.14

**Ultrasound Guided Sclerotherapy (UGS)**

All procedures were performed as a day case without sedation in the radiology department of a local hospital with trained ultrasonographers performing the imaging. A foamed solution was prepared, as originally described by Tessari, using two syringes and a three-way tap, with a ratio of 2 parts air: 1 part 3% sodium tetradecyl sulphate (Fibrovein®) (Australasian Medical and Scientific, Artamon NSW). Patients were positioned prone and the small saphenous vein visualised.

An initial volume of 1.5mls of foam was injected directly into the small saphenous vein using a 25 gauge 1.5 inch needle. Further injections were carried out until the predetermined end-point was achieved i.e. persistent venoconstriction and sonographic obliteration denoted by incompressibility of the entire short saphenous lumen.

**Post treatment Care**

Following the procedure, patients were fitted with class 2 graduated compression stockings with a waist belt applied and asked to walk for half an hour. The patients were instructed to leave the stocking on for 72 hours continuously. Thereafter for the next 4 days the stocking was worn for 24 hours a day (can take off to shower daily) and then daily during the second week. Patients were advised to take non-prescription analgesia as required and to return if they experienced unresolved pain or problems.

**Follow-Up and Analysis**

Patients were then seen at 2, 4 and 6 weeks, where simple sclerotherapy of calf varices was undertaken if required (at this stage all patients had a clinically successful outcome therefore no repeat UGS was required). At 6 months post treatment an independent observer assessed clinical improvement and complications. At this examination particular attention was paid to the presence of residual varices, staining due to the sclerotherapy and the status of the sural nerve.

The patients also underwent follow-up duplex scanning to assess saphenous vein obliteration and patency of the deep system. Technical outcome was classified as either complete occlusion (CO), near complete occlusion (NCO), defined as less than a 5 cm segment of reflux flow in treated vein, or recanalization, defined as greater than a 5 cm segment of reflux flow in the treated vein15.

A post treatment Aberdeen varicose vein QoL questionnaire was filled in and further photographs of the affected leg were taken.
Results

UGS with foam was performed on a consecutive series of 14 patients (15 limbs) with isolated small saphenous incompetence as diagnosed by duplex ultrasound. One patient had bilateral SSV incompetence treated on separate occasions. There was 1 man and 13 women with a median age of 50 (range 26 – 68). The mean number of injections per patient was 2.5 (range of 1-4) while the mean foam volume injected was 3.75 mls (range 1.5 – 6 mls). The procedure was well tolerated with 23% requiring mild analgesia post- procedure with the remaining 77% experiencing no discomfort. There were no cases of anaphylaxis and all patients were able to resume normal activities the following day.

Clinical assessment: At six months, of the fifteen limbs examined, five (33%) had minor residual varices, while two (13%) had a minor degree of post-sclerotherapy pigmentation. None of the patients had any clinical evidence of sural nerve impairment or clinical suspicion of deep venous thrombosis (DVT).

Sonographic assessment: Of the fifteen limbs, duplex examination at 6 months revealed nine with total occlusion (60%), five (33%) with near total occlusion and 1 with a residual patent incompetent SSV. The one patient with recanalization of the SSV had a 9mm diameter vein pre-treatment. No patient had any evidence of DVT.

Aberdeen varicose vein QoL questionnaire: This is based on the well established SF 36 Health Survey Questionnaire that is widely used in the UK and consists of 13 questions relating to the symptoms and concerns of patients with varicose veins. Answers to questions are weighted and then summed. A patient with no symptoms has a score of zero while a score of 100 indicates almost total incapacity. Statistical analysis takes into account not only the magnitude of change but also the sign (i.e. whether the change is positive or negative.)

Patient satisfaction as gauged by the Aberdeen varicose vein QoL questionnaire demonstrated an excellent response with all patients recording a positive improvement. The mean difference was -10 with a range of -4 to -23. This difference was highly significant (p<0.05 N=15) using the Sign test.

At the six month clinical and sonographic assessment, there was a discussion of the outcome with each patient. For the patient with complete recanalization, a repeat procedure was recommended. For the five patients with near total occlusion, it was recommended that a repeat procedure be carried out if clinically indicated (ie presence of symptoms or clinical varices arising from the segment). Otherwise, it was recommended that the patient be reviewed by the Phlebologist at a later date if the patient was having symptoms or veins were recurring. Similarly, this advice was given to the nine patients with total occlusion at six months.

Discussion

The clinical and sonographic results achieved in our study with no significant complications are comparable to other studies and certainly supports the value of this technique.

However, unlike other reported studies, the post sclerotherapy clinical and sonographic assessment was carried out by a surgeon (G.B.) independent of the phlebologist (A.P.).

While confirming the results of others, our study demonstrates objective patient satisfaction with the procedure.

The increasing need to justify expenditure of the health dollar has meant that treatment outcomes must be shown to provide improved patient outcome. To this end the short form 36 (SF 36) health survey questionnaire was developed. Its validity and internal consistency has been subjected to stringent statistical analysis and is now in widespread use in the National Health Service of the UK.

The Aberdeen Varicose Vein Questionnaire designed in 1993, is a disease-specific questionnaire that measure health related quality of life (HRQOL) in patients with varicose veins. It consists of 13 questions relating to problems associated with varicose veins and has been shown to be a reliable way of measuring outcome of varicose vein treatment.

In this study, a highly significant improvement in HRQOL was seen, mean pre treatment 14.8 compared to 4.7 post treatment. In comparison, figures reported by Smith et al in assessing the benefits to a group of 137 patients undergoing varicose vein surgery, were 18.8 pre surgery and 14.08 post surgery.

Although these results are encouraging a randomised control trial is warranted in order to properly compare UGS with surgery.

References

6. Sadoun S, Benigni JP. Prospective study of sclerosing foam in the treatment of


12. Thibault PK. 5 year follow-up of greater saphenous vein incompetence treated by ultrasound guided sclerotherapy. ANZ J Phleb 2003;1:5-8


<table>
<thead>
<tr>
<th>Pt Name</th>
<th>Age</th>
<th>Sex</th>
<th>Leg</th>
<th>Clinical Varices</th>
<th>Pigmentation</th>
<th>Sural Nerve</th>
<th>Sonographic Result</th>
<th>QOL Scores Pre</th>
<th>QOL Scores Post</th>
</tr>
</thead>
<tbody>
<tr>
<td>YD</td>
<td>56</td>
<td>F</td>
<td>L</td>
<td>Minor</td>
<td>Min</td>
<td>-</td>
<td>NCO</td>
<td>9.660</td>
<td>3.669</td>
</tr>
<tr>
<td>JC</td>
<td>57</td>
<td>F</td>
<td>L</td>
<td>Flares</td>
<td>-</td>
<td>-</td>
<td>NCO</td>
<td>28.23</td>
<td>4.969</td>
</tr>
<tr>
<td>EZ</td>
<td>52</td>
<td>F</td>
<td>L</td>
<td>-</td>
<td>-</td>
<td>CO</td>
<td>10.3</td>
<td>4.688</td>
<td></td>
</tr>
<tr>
<td>CT</td>
<td>52</td>
<td>F</td>
<td>R</td>
<td>-</td>
<td>Min</td>
<td>-</td>
<td>CO</td>
<td>3.9</td>
<td>5.081</td>
</tr>
<tr>
<td>PS</td>
<td>54</td>
<td>F</td>
<td>L</td>
<td>Minor</td>
<td>-</td>
<td>-</td>
<td>CO</td>
<td>11.137</td>
<td>5.778</td>
</tr>
<tr>
<td>GR</td>
<td>40</td>
<td>F</td>
<td>R</td>
<td>Minor</td>
<td>-</td>
<td>-</td>
<td>NCO</td>
<td>20.6</td>
<td>0</td>
</tr>
<tr>
<td>AW</td>
<td>51</td>
<td>F</td>
<td>R</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>CO</td>
<td>12.9</td>
<td>9.132</td>
</tr>
<tr>
<td>JB</td>
<td>25</td>
<td>F</td>
<td>L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>CO</td>
<td>10.29</td>
<td>3.326</td>
</tr>
<tr>
<td>LB</td>
<td>59</td>
<td>F</td>
<td>R</td>
<td>Minor</td>
<td>-</td>
<td>-</td>
<td>NCO</td>
<td>18.2</td>
<td>0.581</td>
</tr>
<tr>
<td>CS</td>
<td>40</td>
<td>F</td>
<td>R</td>
<td>Minor</td>
<td>-</td>
<td>-</td>
<td>OPEN</td>
<td>28.765</td>
<td>13.142</td>
</tr>
<tr>
<td>SP</td>
<td>48</td>
<td>F</td>
<td>L</td>
<td>Minor</td>
<td>-</td>
<td>-</td>
<td>CO</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>NT</td>
<td>37</td>
<td>F</td>
<td>R</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>CO</td>
<td>21.05</td>
<td>17.257</td>
</tr>
<tr>
<td>DD</td>
<td>67</td>
<td>F</td>
<td>L</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>CO</td>
<td>14.912</td>
<td>2.270</td>
</tr>
<tr>
<td>JL</td>
<td>52</td>
<td>F</td>
<td>R</td>
<td>-</td>
<td>-</td>
<td>-</td>
<td>NCO</td>
<td>6.704</td>
<td>0.344</td>
</tr>
</tbody>
</table>

Table 1. Results at 6 month Review