Ultrasound-guided foam sclerotherapy combined with sapheno-femoral ligation compared to surgical treatment of varicose veins: early results of a randomised controlled trial

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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
The study examined two treatments for varicose veins, sapheno-femoral ligation, great saphenous stripping and multiple avulsions (SFL-SS-MA) versus sapheno-femoral ligation and ultrasound-guided foam sclerotherapy to the saphenous vein (SFL-USFS). Details of the procedures were provided.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients with primary symptomatic varicosities involving the long saphenous vein system, who had not undergone previous treatment for varicose veins, and who were suitable for day-case surgery. The exclusion criteria included patients with primary varicosities involving both the long and short saphenous veins, patients with previous surgery for varicose veins, and patients previously treated with sclerotherapy for varicosities. Further exclusion criteria were deep vein thrombosis, risk factors for deep vein thrombosis (apart from varicose veins), coagulopathy, peripheral vascular disease, known allergy to local anaesthetic or sclerosing agents, previous iatrogenic allergic reaction, malignancy, or pregnancy.

Setting
The setting was an outpatient clinic. The economic study was carried out in the UK.

Dates to which data relate
The effectiveness and resource use data were gathered from July 2004 to February 2004. The price year was not reported.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
The authors stated that power calculations were not performed as this represented their first experience with this...
technique. A sample of 60 patients gave consent to participate in the study. Each group comprised 30 patients. The median age was 43 years (range: 21 to 72) in the foam sclerotherapy group and 43 years (range: 20 to 76) in the surgical group. The proportion of women was 47% in the foam sclerotherapy group and 60% in the surgical group. It was not stated whether some patients refused to participate or were excluded for any reason from the study. In patients with bilateral varicose veins, only the most affected limb was considered.

**Study design**
This was a prospective, randomised clinical trial that was carried out at a single institution, the outpatient clinic of Ealing Hospital in the UK. Randomisation was based on sealed envelopes. The patients were evaluated at 3 weeks and 3 months after the operation. Two patients in the surgical group did not undergo the intervention (one patient did not want to have the operation, while another patient moved to a different area). Thus, 2 patients were not considered in the surgical group. At the end of the follow-up period, there were 28 patients in the foam sclerotherapy group and 23 patients in the surgical group. Blinding was not performed.

**Analysis of effectiveness**
The clinical analysis was carried out on all patients who received the interventions. The outcome measures used in the analysis of effectiveness were:

- time until return to work or to normal activity;
- quality of life, estimated using the Aberdeen Vein Questionnaire;
- the duration of treatment; and
- postoperative complications.

The patients were comparable at baseline in terms of their age, gender, and disease characteristics.

**Effectiveness results**
All procedures were completed as intended and no procedure was abandoned due to technical difficulty.

The median time until return to work or back to normal activity was 2 days (range: 0 to 6) in the foam sclerotherapy group and 8 days (range: 5 to 20) in the surgical group, (p<0.001).

Median quality of life decreased from 15.4 to 9.3 (i.e. 43%) in the foam sclerotherapy group and from 26.1 to 14.1 (i.e. 40%) in the surgical group, (p<0.001).

The median duration of treatment was 45 minutes (range: 45 to 60) in the foam sclerotherapy group and 85 minutes (range: 70 to 95) in the surgical group, (p<0.001).

In the postoperative period, few complications arose in either group. No major complications were observed. Four patients (13.3%) in the foam group needed a second session of sclerotherapy for full obliteration of the great saphenous vein system. In the stripping group, 2 patients (7%) needed a further sclerotherapy session for full obliteration of their residual veins. Five patients (17%) in the foam group had developed resolving skin pigmentation and three (10%) had had an episode of self-limited superficial thrombophlebitis. In the surgical group, 2 patients (9%) complained of symptoms suggesting saphenous nerve injury, and one (4%) developed a skin ulcer following liquid injection sclerotherapy for her residual varicose veins.

The median clinical, etiologic, anatomic, pathophysiologic class (used to classify clinical stage) and the median venous clinical severity score (used to assess disease severity) improved in both groups, but the difference between the groups did not achieve statistical significance.
Clinical conclusions
The effectiveness analysis showed that foam sclerotherapy for the treatment of varicose veins was a safe procedure and resulted in both a shorter treatment time and a more rapid recovery in comparison with the surgical approach.

Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was performed.

Direct costs
The perspective adopted in the study was not stated. The cost categories considered were:

- surgeon, assistant, anaesthetist, nursing, anaesthetic, anaesthetic assistant, consumables, and sterile supplies during the operation;
- theatre recovery, ward time, and ultrasound in the postoperative period; and
- capital and overheads.

The unit costs were reported, but the resource quantities were not. Resource use was estimated using the sample of patients included in the effectiveness analysis. The source of the costs was not explicitly reported. Discounting was not relevant as the costs were incurred during a short time. The price year was not reported.

Statistical analysis of costs
Statistical analyses of the costs were not performed.

Indirect Costs
The indirect costs were not included.

Currency
UK pounds sterling (£).

Sensitivity analysis
Sensitivity analyses were not carried out.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total costs per procedure were 1,120.64 in the surgical group and 672.97 in the foam sclerotherapy group.

Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant as a cost-consequences analysis was carried out.

Authors' conclusions
Compared with the conventional surgical approach, foam sclerotherapy was associated with a reduced operation time,
earlier return to work or normal activities, and lower costs in patients with varicose veins.

**CRD COMMENTARY - Selection of comparators**
The authors justified their choice of the comparators, which were appropriate for the study question. You should decide whether they are valid comparators in your own setting.

**Validity of estimate of measure of effectiveness**
The effectiveness evidence came from a clinical trial, which was appropriate for the study question. The method of randomisation was described and should have reduced the impact of selection bias. Limited information on the approach used to select the sample of participating patients was reported, and it was not stated whether some patients refused to participate or were excluded for any reasons from the initial study sample. The study groups were well balanced at baseline, not only in demographics but also in terms of the clinical aspects, and this enhances the robustness of the comparison. However, the trial was open-label, thus assessment bias might have affected the results of the study. Further, the sample size was not justified; the small group of patients included might explain the lack of statistically significant differences found between the groups in all outcome measures. Statistical analyses were carried out to test for the significance of differences between the groups. The length of follow-up was appropriate although short. The analysis of the clinical study appears to have been based on treatment completers only, although this was not explicitly stated. The evidence came from a single centre, thus caution is required when extrapolating the results of the analysis to other settings. These issues might limit the internal validity of the analysis.

**Validity of estimate of measure of benefit**
No summary benefit measure was used in the analysis because a cost-consequences analysis was conducted. Please refer to the comments in the 'Validity of estimate of measure of effectiveness' field (above).

**Validity of estimate of costs**
The authors did not explicitly state the perspective adopted in the study. A breakdown of the cost items was provided and extensive information on unit costs was reported. However, the quantities of resources used were not given, which limits the possibility of replicating the analysis in other setting. The source of the costs was not stated. The costs were treated deterministically and the cost estimates were specific to the study setting. The price year was not reported, which will make reflation exercises in other time periods difficult. The authors noted that their cost analysis did not consider potential socio-economic benefits, such as the earlier return to professional activities, which might reduce the indirect costs.

**Other issues**
The authors reported the results from several studies that assessed the efficacy and safety of foam sclerotherapy in patients with varicose veins. The current study appears to confirm the previous findings. The issue of the generalisability of the study results to other settings was not explicitly addressed and sensitivity analyses were not performed, which reduces the external validity of the analysis. The study referred to patients with varicose veins and this was reflected in the authors' conclusions.

**Implications of the study**
The study results suggested that the use of foam sclerotherapy for the treatment of varicose veins has several short-term advantages over the conventional surgical procedure. However, long-term studies should be performed to corroborate the findings of the current study.

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