Cost-effectiveness analysis of surgery versus conservative treatment for uncomplicated varicose veins in a randomized clinical 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 use of surgery for the treatment of uncomplicated varicose veins.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
The study population comprised patients with uncomplicated varicose veins and evidence of saphenofemoral or saphenopopliteal reflux. Patients with recurrent varicose veins were excluded. The supplementary paper (Michaels et al. 2006, see 'Other Publications of Related Interest' for bibliographic details) may include further details of the study population.

Setting
The setting was secondary care. The economic study was conducted in the UK.

Dates to which data relate
The dates over which the effectiveness and resource use data were collected were not reported (see Michaels et al. 2006), although both were collected at the same time. The unit costs and prices related to the years 2002 to 2003.

Source of effectiveness data
The effectiveness data were 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 study.

Study sample
A total of 246 patients were included in the study. These were randomly allocated to the study groups, 124 to the surgery group and 122 to the conservative group. Details about the selection process were not reported. The authors stated that full details of the effectiveness study were reported in an accompanying paper (Michaels et al. 2006).

Study design
The authors designed a randomised trial at two participating centres (Sheffield and Exeter hospitals). The patients were followed for 24 months. Five patients were randomised to the surgery group that received conservative treatment before being re-treated with surgery. Forty-two patients were randomised to conservative treatment and finally had surgery. Further details may be available in the authors’ accompanying paper (Michaels et al. 2006).

**Analysis of effectiveness**

The patients were analysed on an intention to treat basis. The primary health outcome described in the current report was the Short Form (SF)-6D, a single patient preference-based measure of health. Values were obtained from patients at 1, 6, 12 and 24 months. Missing data were imputed on the basis of straight line interpolation. The current report did not compare the patients in the two patient groups.

**Effectiveness results**

The total area under the SF-6D scores curve for 0 to 12 months was 0.696 (standard deviation, SD=0.099) for conservative treatment and 0.724 (SD=0.091) for surgery. The difference was -0.028 (95% confidence interval, CI: -0.059 to 0.002).

The total area under the SF-6D scores curve for 0 to 24 months was 1.420 (SD=0.205) for conservative treatment and 1.503 (SD=0.168) for surgery. The difference (-0.083, 95% CI: -0.162 to -0.005) was statistically significant, (p<0.05).

**Clinical conclusions**

The authors concluded that for patients with varicose veins and evidence of saphenofemoral or saphenopopliteal reflux, surgical treatment offers a modest health benefit over conservative treatment.

**Measure of benefits used in the economic analysis**

The summary measure of benefit used was the number of quality-adjusted life-years (QALYs) gained. These were measured using the SF-6D in the baseline analysis. The health outcomes were discounted for the 12- to 24-month period of follow-up at a rate of 3.5%.

**Direct costs**

The authors adopted the perspective of the NHS for the economic analysis. Resource use data were collected on hospital admission, surgical treatment, outpatient visits, other NHS visits (such as accident and emergency visits, general practitioner visits), compression hosiery and treatment for complications. The unit costs related to the price year 2002/03 and were taken from national sources where possible (Personal and Social Services Research Unit database, NHS reference costs). The authors reported that, where national costs were unavailable, local costs from the two participating hospitals’ finance departments were used. Resource use was reported separately from the costs. The costs were discounted for the 12- to 24-month period of follow-up at a rate of 3.5%.

**Statistical analysis of costs**

Arithmetic means and standard t-test based CIs were used to compare mean costs.

**Indirect Costs**

The indirect costs were not relevant to the perspective of the study.

**Currency**

UK pounds sterling (£).
Sensitivity analysis
The authors used bootstrapping (including only patients with complete cost and effectiveness data) to test the robustness of the results to changes from the base-case, particularly with respect to national rather than local costs and using the EuroQoL (EQ)-5D as the summary measure of health outcome. Responses to the EQ-5D were converted into utility scores using the York Measurement and Valuation of Health project. In addition, the authors used cost-effectiveness acceptability curves to gain an understanding of the uncertainty surrounding the estimate of incremental cost-effectiveness.

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

Cost results
The average costs per patient derived from the reference case were 267.52 (SD=350.91) for the conservative group and 705.45 (SD=276.95) for the surgery group.

The results of the bootstrap showed that the mean discounted cost over 24 months was 344.53 (SD=357.47) for conservative treatment and 733.10 (SD=134.99) for surgical treatment.

The difference in means was 388.57 (95% CI: -281.99 to 505.52; p<0.050)

Synthesis of costs and benefits
In the base-case, the incremental cost-effectiveness ratio was 4,682 per QALY (95% CI: 2,039 to 20,830).

When the EQ-5D was used to calculate the QALYs, the cost-effectiveness ratio was 3,299 per QALY.

When using NHS reference costs for the cost of surgical treatment, the cost-effectiveness ratio ranged from 2,566 per QALY (lower quartile) to 12,580 (upper quartile).

Sensitivity analyses indicated that the base-case results were not sensitive to the use of mean NHS reference costs rather than local costs, or to the use of the EQ-5D to estimate outcomes.

Assuming a maximum willingness-to-pay of 20,000 (30,000) per QALY and using SF-6D outcomes, the cost-effectiveness acceptability curve indicated a 70% (76%) probability that the cost per QALY for surgical treatment falls below 20,000 (30,000).

Authors’ conclusions
"For patients with varicose veins and evidence of saphenofemoral or saphenopopliteal reflux, surgical treatment offers a modest health benefit for a relatively little additional NHS (National Health Service) cost with respect to conservative treatment."

CRD COMMENTARY - Selection of comparators
The authors compared conservative and surgical treatment for varicose veins. They clearly stated that there was a parent study that provided further information and gave full bibliographic details enabling the reader to access this information. A brief background was reported and although details of conservative treatment were not provided this seems the natural comparator. Specific conservative treatment may differ between settings, thus the generalisability of the results may be limited.

Validity of estimate of measure of effectiveness
The authors designed a randomised trial. Although specific details were not provided in the current report,
randomisation helps to reduce the possibility of systematic differences between the two patient groups and so improves the validity of the results obtained. Readers would need to consult the primary study to ascertain whether the patient groups were comparable at analysis. As the authors reported, the losses to follow-up might have reduced the differences between the trial groups, biasing the results against the surgery group, since some dissatisfied patients receiving conservative treatment finally underwent surgery. The authors carried out appropriate statistical analyses and gave a detailed report of their results and conclusions.

Validity of estimate of measure of benefit
QALYs were used as the summary measure of health benefit. They were estimated using both the SF-6D and the EuroQoL method of estimation. This makes it easy to compare the results with other health-related technologies.

Validity of estimate of costs
The costs were estimated from the perspective of the UK NHS and the unit costs relevant to this perspective were included in the analysis. The authors gave clear reports of the sources of the costs and used national costs where possible. A sensitivity analysis explored the impact of using national costs for the instances where local costs had been used. The unit costs and resources used were reported separately, thereby allowing greater generalisability of the analysis, and full details of discounting were provided. The price year was reported, which will aid any future reflation exercises. The results showed statistically significant differences, thus, if there were small omissions in the analysis, these may not have affected the principle conclusions drawn. Statistical comparisons of both resources used and costs were conducted by means of bootstrapping.

Other issues
The authors provided a clear and concise account of their study. The issue of generalisability was considered from several perspectives, with the authors initially incorporating sensitivity analyses to improve the generalisability to other settings and populations. The authors then discussed how the methodology may have led to an underestimation of the costs for some sub-groups of populations so enabling other authors to anticipate results in their own setting. The relatively short time horizon was identified as a possible limitation of the study, although the authors argued that increasing the follow-up period may well have improved the incremental cost-effectiveness ratio. The results were clear and do not appear to have been presented selectively. The conclusions were an accurate reflection of the results and related well to the scope of the study. The interpretation of the results and conclusions might have been improved by a comparison of the current results with those from other studies.

Implications of the study
The authors did not make any recommendations for policy or practice following their study and did not suggest any required further work.

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None stated.

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Other publications of related interest


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