

Randomised clinical trial, observational study and assessment of cost-effectiveness of the treatment of varicose veins (REACTIV trial)

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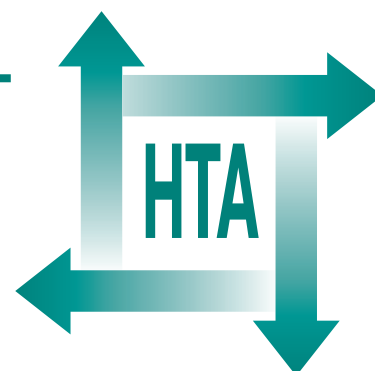
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Executive summary

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Executive summary

Objective

The objective of this study was to establish the cost-effectiveness of surgery and sclerotherapy for the treatment of varicose veins.

Design

Randomised controlled trials (RCTs) were carried out for conservative treatment, sclerotherapy and surgery for varicose veins, supplemented by observational data collection in those patients who had exclusion criteria or declined participation in the RCTs. An economic analysis was carried out alongside the randomised trial. Economic modelling was undertaken based on the primary data collection and a literature review (database searches undertaken in April 2000 and updated in March 2001).

Setting

Primary data collection was from two centres, recruiting from sequential referrals of patients with varicose veins to vascular surgeons at a large district general hospital in Exeter and a teaching hospital in Sheffield over a 2-year period from January 1999. Cost-effectiveness analysis and economic modelling were carried out using an NHS perspective.

Participants

A total of 1009 patients were recruited, with 34 being randomised in Group 1 (minor varicose veins with no reflux, randomised between conservative treatment and sclerotherapy), 77 in Group 2 (moderate varicose veins with reflux, randomised between surgery and sclerotherapy) and 246 in Group 3 (severe varicose veins with reflux, randomised between conservative treatment and surgery). The remaining 652 patients formed the observational part of the study.

Main outcome measures

The cost-effectiveness analysis was based on NHS treatment costs for the 2002–3 financial year, and

utilities based on the Short Form 6D (SF-6D) preference-based health measure. For the clinical trial, the outcome measures were health-related quality of life (HRQoL) [Short Form with 36 Items (SF-36), EuroQol quality of life questionnaire (EQ-5D), visual analogue scale (VAS) and standard gamble], symptomatic relief, anatomical extent (for which a new classification was developed and validated), patient satisfaction and the incidence of complications.

Results

Of the RCTs, only the Group 3 trial was large enough to provide clear results. This showed that surgical treatment produced better results than conservative treatment in terms of HRQoL, symptomatic relief, anatomical extent and patient satisfaction. The observational study showed no significant differences in outcomes from the RCTs, with no major complications from sclerotherapy and a complication rate of 1.7% following surgery. Clinical outcomes of surgery and sclerotherapy showed significant improvement in the extent of varicose veins, symptomatic and HRQoL parameters.

Cost-effectiveness analysis based on the Group 3 trial showed that the surgery produced an estimated discounted benefit of 0.054 quality-adjusted life-year (QALY) over a 2-year period, with an additional discounted cost of £387.45, giving an incremental cost-effectiveness ratio (ICER) of £7175 per QALY. Economic modelling suggested that surgery produced a still greater benefit when considered with a 10-year time horizon, with an ICER of £1936 per QALY. Injection sclerotherapy produced an incremental benefit of approximately 0.044 QALY at a cost of £155 when compared with conservative treatment, giving an ICER of £3500 per QALY. When surgery was compared with sclerotherapy, surgery produced greater benefit with a lower ICER (showing extended dominance). These findings were robust over a range of univariate and multivariate sensitivity analyses, covering different assumptions, and estimates of probabilities, costs and outcomes.

Conclusions

Standard surgical treatment of varicose veins by saphenofemoral ligation, stripping and multiple phlebectomies is a clinically effective and cost-effective treatment for varicose veins, with an ICER well below the threshold normally considered appropriate for the funding of treatments within the NHS. Injection sclerotherapy also appears to be cost-effective, but produces less overall benefit, with a higher ICER than surgery for patients with superficial venous reflux. In minor varicose veins without reflux, sclerotherapy is likely to provide a small average benefit with acceptable cost-effectiveness.

Recommendations for further research

One of the key issues in calculating cost-effectiveness is the difficulty in evaluating the potential utility benefit of successful treatment in

this condition. Research is needed into the methodology for producing accurate and acceptable utility evaluations for conditions with relatively minor effect on HRQoL. The study demonstrates the difficulty of large RCTs in this area. It is suggested that economic modelling combined with the collection of observational data may provide a useful approach to the assessment of the potential of new treatments for this condition. In future studies, it is important that a validated and standardised method of classification is used to allow comparisons of the extent of varicose veins, the effects of treatment and progression of the disease.

Publication

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NHS R&D HTA Programme

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Reviews in *Health Technology Assessment* are termed 'systematic' when the account of the search, appraisal and synthesis methods (to minimise biases and random errors) would, in theory, permit the replication of the review by others.

The research reported in this monograph was commissioned by the HTA Programme as project number 95/05/06. The contractual start date was in October 1998. The draft report began editorial review in June 2004 and was accepted for publication in May 2005. As the funder, by devising a commissioning brief, the HTA Programme specified the research question and study design. The authors have been wholly responsible for all data collection, analysis and interpretation, and for writing up their work. The HTA editors and publisher have tried to ensure the accuracy of the authors' report and would like to thank the referees for their constructive comments on the draft document. However, they do not accept liability for damages or losses arising from material published in this report.

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