

TitleRandomized Clinical Trial, Observational Study and Assessment
of Cost-Effectiveness of the Treatment of Varicose Veins (REACTIV Trial)AgencyNCCHTA, National Coordinating Centre for Health Technology Assessment
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Aim

To establish the cost effectiveness of surgery and sclerotherapy in treating varicose veins.

Conclusions and results

Of the randomized controlled trials (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 quality of life, 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 quality of life parameters.

Cost-effectiveness analysis based on the Group 3 trial showed that the surgery produced an estimated discounted benefit of 0.054 QALY over a 2-year period, with an additional discounted cost of 387.45 British pounds (GBP), giving an incremental cost effectiveness ratio (ICER) of GBP 7175 per QALY. Economic modeling suggested that surgery produced a still greater benefit when considered with a 10-year time horizon, with an ICER of GBP 1936 per QALY. Injection sclerotherapy produced an incremental benefit of approximately 0.044 QALY at a cost of GBP 155 when compared to conservative treatment, giving an ICER of GBP 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.

Recommendations

Standard surgical treatment of varicose veins by high ligation, stripping, and multiple phlebectomies is an effective and cost-effective treatment for varicose veins, with an ICER well below the threshold of about GBP 25 000 to GBP 35 000 per QALY normally considered appropriate for funding of treatments within the NHS. Injection sclerotherapy would also appear 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.

Methods

Randomized controlled trials have been done of 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 randomized trial. Additional data were collected via an observational study for those patients who had exclusion criteria or declined participation in the RCTs. Economic modeling was undertaken based upon the primary data collection and a literature review.

Further research/reviews required

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 quality of life. The study demonstrates the difficulty of large RCTs in this area. It is suggested that economic modeling combined with the collection of observational data may provide a useful approach in assessing the potential of new treatments for this condition.