Cost-effectiveness of treatments for varicose veins

What problem was this research addressing?
Ultrasound-guided foam sclerotherapy (UGFS) and thermal ablation techniques such as endovenous laser ablation (EVLA) have become widely used alternatives to surgery for the treatment of varicose veins. UGFS involves injecting a foam substance into the vein so that walls become sticky and the vein closes off, whilst EVLA uses the heat energy of a laser to close the vein. Despite the widespread use of these techniques, uncertainty remains regarding their clinical and cost-effectiveness compared with conventional surgery. The CLA SS (Comparison of LAser, Surgery and foam Sclerotherapy) trial compares the outcomes and costs of these three commonly used treatments for primary varicose veins.

What this research adds
The CLA SS trial is the largest pragmatic UK based multicentre trial to have compared surgery, UGFS and EVLA, and the results should be generalisable across the NHS. The present analysis relies on the CLA SS trial cost and outcome data reported at 6 months follow-up, extrapolated to 5 years using a Markov model incorporating available data on short to medium-term clinical recurrence rates for the alternative treatment modalities. The CLA SS study follow-up will be ultimately extended to 5 years, which will allow for the collection of much needed long-term outcome data. Once complete, the 5-year follow-up of CLA SS participants will provide a means for validating and updating the model based estimates of cost-effectiveness.

Methods
A cost-utility analysis was conducted using individual participant cost and outcome (utility) data collected alongside the CLA SS trial to 6 months post treatment. Cost-utility analysis is a methodology for comparing treatments in terms of their costs and the quality adjusted life years (QALYs) that they generate. Identifying cost-effective treatments allows for efficient spending within the health care budget.

Total NHS costs were estimated for each participant based on resource use data collected on case report forms and participant questionnaires. Utility scores were derived from participant responses to the generic EQ-5D questionnaire at baseline, 6 weeks and 6 months. Utility scores represent the desirability of the different health states defined by the EQ-5D on a scale where 0 represents death and 1 denotes full health. Quality adjusted life-years (QALYs) were calculated for individual patients from baseline to 6 months based on these scores, assuming a linear change in utility between time points. Regression methods were used to estimate the effects of the alternative treatments on costs to the NHS, QALYs to 6 months, and utility scores at 6 months. A Markov decision model was developed to extrapolate the trial cost-effectiveness data over a 5-year time horizon. For the first 6-month cycle, the model was populated using the estimated mean cost and utility data obtained from the trial analysis. Beyond 6 months, monthly probabilities of clinical recurrence, derived from the best currently available source, were incorporated in the model.

Key Findings
- For patients with primary varicose veins in whom all three of the investigated treatment options offer a clinically viable option, our results suggest that EVLA performed under local anaesthetic has the highest probability of being cost-effective.
- In the interests of cost-effectiveness, EVLA should be performed where possible in a clinic treatment room setting, and the levels of nursing support required should be considered carefully.
- There is currently a paucity of long-term randomised data on quality-of-life, recurrence rates and costs associated with the alternative treatment options included in this study. The ongoing extended follow-up of CLA SS participants will ultimately provide data on these outcomes to 5 years post randomisation.
Data used in health economic models are subject to some degree of uncertainty. To characterise this uncertainty, each model input was assigned a distribution appropriate to the nature of the variable, and the model was analysed probabilistically. The probability of each treatment option being cost-effective was assessed at increasing values of willingness-to-pay per QALY gained. A ceiling willingness to pay ratio of £20,000–£30,000 per QALY is generally applied by the National Institute for Health and Care Excellence (NICE) to inform judgements on cost-effectiveness.

**Policy relevance of research findings**

The resources available to health care are scarce and choices amongst competing claims on limited resources have to be made.

For patients with primary varicose veins, the CLASS trial has shown that EVLA when performed under local anaesthetic has the highest probability of being cost-effective at accepted willingness-to-pay thresholds per QALY gained. This finding is driven by a number of factors: 1) greater estimated QALY and utility gains at 6 months versus foam sclerotherapy and, to a lesser extent, surgery; 2) its significantly lower cost at 6 months compared with surgery; and 3) its slightly lower estimated clinical recurrence rate compared with foam sclerotherapy and surgery.

Further analysis suggests that the cost-effectiveness of EVLA can be enhanced by delivery in a clinic treatment room rather than in theatre, with one to two nurses (in addition to the surgeon) performing the procedure. Our findings suggest that, for patients with primary varicose veins in whom all three of the investigated treatments offer a clinically viable option, EVLA performed under local anaesthetic has the highest probability of being cost-effective. Where possible, EVLA should be performed in a clinic treatment room and the nurse staffing profile should be carefully considered.

**Research Highlights**

- Results suggest that in a population where all three treatment options are viable, EVLA performed under local anaesthetic has the highest probability of being cost-effective at accepted values of willingness to pay per QALY gained.
- Based on the model based probabilistic analysis, at ceiling willingness-to-pay ratio of £20,000, EVLA has approximately a 79% chance of being cost-effective by 5 years.
- Results were generally robust to uncertainty surrounding various model parameter inputs and assumptions. However, uncertainty remains regarding the long-term effectiveness of the alternative treatment modalities.

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For further information see the full paper: Tassie, E, Scotland, G, Brittenden, J, Cotton, SC, Elders, A, Campbell, MK, Campbell, B, Gough, M, Burr, JM, Ramsay, CR. Cost-effectiveness of ultrasound guided foam sclerotherapy and endovenous laser ablation (UGFS), endovenous laser ablation (EVLA), and surgery as treatments for primary varicose veins: results based on the CLASS trial. *British Journal of Surgery* 2014; 101: 1532-1540.

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**References**


