A systematic review and meta-analysis of randomised controlled trials comparing endovenous ablation and surgical intervention in patients with varicose vein

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CRD summary
Primary failure and recurrence in endovenous laser ablation and radiofrequency ablation were non-significantly different compared with surgery. Patients treated with endovenous techniques had lower haematoma, less wound infection, less pain and quicker return to normal activities. The review had some limitations but overall the authors’ conclusions are likely to be reliable.

Authors’ objectives
To compare the clinical effectiveness of minimally invasive endovenous procedures and surgery in patients with varicose veins.

Searching
MEDLINE and Scopus databases were searched from 2000 to August 2011 for relevant studies published in English. Search terms were reported. Reference lists of previous reviews and all eligible papers were scanned.

Study selection
Randomised controlled trials (RCTs) that compared the outcomes of minimally invasive endovenous procedures (endovenous laser ablation, radiofrequency ablation, ultrasound-guided foam sclerotherapy) and surgery or between minimally invasive endovenous procedures themselves in patients with great saphenous vein reflux were eligible. Included studies had to report at least one outcome of interest.

The primary outcome was failure to completely abolish reflux in the axial vein. The secondary outcomes were clinical recurrences, postoperative complications, postoperative pain measured by visual analogue scale, time return to normal activities or work and quality of life measured by the Aberdeen varicose vein severity score. Secondary outcomes were measured at the end of study except complications and pain. Different types of surgery were used in the included trials. The mean age of participants ranged from 33 to 55 years. Most included patients were within CEAP C2 category (classification of venous disease that involves simple varicose veins only). Local, regional and general anaesthesia were used for the procedures. Most patients wore compression stockings for a minimum of one week to a maximum of three months, where reported.

Two reviewers performed the study selection independently. Any disagreements were resolved by consultation with a third reviewer.

Assessment of study quality
Studies were assessed for quality using the Cochrane risk of bias tool.

Two reviewers independently evaluated study quality. Any disagreements were reviewed and arbitrated by a third reviewer.

Data extraction
Data were extracted to calculate relative risk (RR) for dichotomous outcomes or mean difference (MD) for continuous outcomes and their associated 95% confidence intervals (CIs). Mean and standard deviations were estimated from median and range where necessary.

Two reviewers performed the data extraction. Any disagreements were resolved by consensus and checked by a third reviewer. Study authors were contacted for missing information.

Methods of synthesis
Pooled relative risks and weighted mean differences (WMDs) and their 95% CIs were calculated using a DerSimonian
and Laird random-effects model where heterogeneity was present; otherwise a fixed-effect inverse-variance model was used. Heterogeneity was assessed using $I^2$ and Q test. $I^2$ of 25% or more was considered sufficiently heterogeneous to indicate use of a random-effects model. Heterogeneity was explored by fitting co-variables in a meta-regression. If the co-variable reduced the $I^2$, a subgroup or sensitivity analysis of that co-variable was performed. Publication bias was assessed by the Egger test and funnel plot.

Results of the review
Twenty-eight RCTs (16 to 500 patients per study) were included in the review. Most trials randomised limbs rather than individuals. Follow-up ranged from one week to five years. In the quality assessment 83% of studies reported intention-to-treat analysis, 78% reported allocation concealment and absence of selective outcome reporting and 43% reported blinding for the quality assessment. Only seven trials scored "yes" for random sequence generation. There was no evidence of publication bias for all comparisons of primary failure except for endovenous laser ablation versus surgery.

Primary failure: There were no statistically significant differences in failure rate of endovenous laser ablation and radiofrequency ablation compared with surgery. Ultrasound-guided foam sclerotherapy showed twofold higher risk of failure compared to surgery (RR 2.4, 95% CI 1.6 to 3.6; $I^2$=22.7%). Comparison of radiofrequency ablation and endovenous laser ablation produced similar results.

Clinical recurrence: No significant difference results were found for the rate of clinical recurrence in endovenous laser ablation and radiofrequency ablation versus surgery.

Venous clinical severity score: There was no statistically significant difference between endovenous laser ablation and surgery for venous clinical severity score.

Postoperative complications: One or more of the endovenous techniques had advantages over surgery in lowering wound infections (RR 0.3, 95% CI 0.1 to 0.8; $I^2$=0% for endovenous laser ablation) and haematoma (RR 0.5, 95% CI 0.3 to 0.8; $I^2$=9.9% for endovenous laser ablation and RR 0.4, 95% CI 0.1 to 0.8; $I^2$=64.2% for radiofrequency ablation). No significant differences were found for paraesthesia and ecchymosis but there was a higher risk of superficial thrombophlebitis for radiofrequency ablation technique compared to surgery (RR 2.3, 95% CI 1.1 to 5.0; $I^2$=8.2%).

Postoperative pain, return to normal activity or work and quality of life: Endovenous techniques were associated with reduced first recorded postoperative pain (MD -0.6, 95% CI -1.1 to -0.2; $I^2$=31.7% for endovenous laser ablation and MD -1.6, 95% CI -2.1 to -1.1; $I^2$=0% for radiofrequency ablation) and faster return to normal activities or work (MD -4.9 days, 95% CI -7.1 to -2.7; $I^2$=86.9% for radiofrequency ablation) compared with surgery. There was no statistically significant difference between endovenous laser ablation and surgery for quality of life.

Further subgroup and sensitivity analyses were reported.

Authors' conclusions
The primary failure and recurrence in endovenous laser ablation and radiofrequency ablation were non-significantly different compared with surgery. Patients treated with endovenous techniques had lower incidence of haematoma, less wound infection, less pain and quicker return to normal activities.

CRD commentary
The review addressed a clear question and was supported by appropriate inclusion criteria. The search covered relevant databases. Relevant studies may have been missed because unpublished studies and studies in languages other than English were not searched. Attempts were made to minimise reviewer errors and bias in the review process. Appropriate criteria were used to assess the study quality. Appropriate method was used to pool study data. Statistical heterogeneity was assessed and explored using subgroup and sensitivity analyses.

The authors acknowledged the limitations of this review, including inability to adjust for correlated data (randomisation by limbs meant that different interventions were applied to the same patients), poor methodological quality of some studies and shortage of data on long-term outcomes. The large number of outcomes assessed meant that some statistically significant results could have arisen by chance. Despite these limitations, the authors' conclusions reflect the evidence presented and appear likely to be reliable.
Implications of the review for practice and research

**Practice:** The authors did not state any implications for practice.

**Research:** The authors stated that more studies with long-term follow-up were needed.

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