Endovenous laser obliteration for the treatment of primary varicose veins

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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 study examined two treatments, minimally invasive endovenous laser obliteration and the conventional stripping operation, for primary varicose veins. The two procedures were accurately described. Briefly, in the conventional stripping operation, a stripping of the insufficient great saphenous vein (GSV) was performed, followed by a local Muller phlebectomy if necessary. In endovenous laser obliteration, a laser procedure was performed using the multidiode endolaser system, introducing a laser fibre into the incompetent vein to produce a thrombotic occlusion and acute inflammation of the targeted vein.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised a cohort of patients with varicose disease caused by GSV insufficiency. Disease was defined according to the clinical, etiological, anatomical, and pathophysiological (CEAP) scoring system, and only primary CEAP clinical class C2-C4 varicose veins were included. Patients who had associated peripheral occlusive or inflammatory arterial disease were excluded, as were those with a known thrombotic or haemorrhagic tendency (also oral anticoagulation) and those with a history of irradiating low back pain. Also excluded were women who were pregnant or planning to become pregnant, and patients with a venous diameter greater than 20 mm and dilatation from the saphenofemoral junction with multiple insufficient side branches.

Setting
The setting was a hospital. The economic study was carried out in Belgium.

Dates to which data relate
The clinical and economic data were gathered from January 2002 to December 2003. The price year was 2002 for some costs.

Link between effectiveness and cost data
The costing was carried out prospectively on the same sample of patients as that used in the analysis of effectiveness.

Study sample
Power calculations were not performed. All eligible patients undergoing treatment for varicose veins over the study period were enrolled in the study. Of the 273 patients who met the inclusion criteria, only full-time working patients were included. This left 164 patients in the sample, of which 84 were in the stripping group and 80 in the laser group. In
the stripping group, the proportion of females was 73% (29 of 40) among those who received the unilateral procedure and 70% (30 of 42) among those who received the bilateral procedure. In the laser group, the proportion of females was 67% (26 of 42) among those who received the unilateral procedure and 65% (26 of 38) among those who received the bilateral procedure. In the stripping group, the average age was 43.3 (+/- 11.1) years for those who received the unilateral procedure and 39.3 (+/- 10.2) years for those who received the bilateral procedure. The average ages in the laser group were 37.6 (+/- 9.2) years (unilateral procedure) and 43.3 (+/- 12.7) years (bilateral procedure), respectively.

**Study design**
This was a prospective cohort study that was carried out at a single medical centre, the Department of Vascular Surgery, St. Andries Hospital, Tielt, Belgium. The same experienced surgeon performed all procedures. The first follow-up visit was after 1 week, while other follow-up contacts were at 4 weeks and at 9 months postoperatively. No patient was lost to the follow-up assessment. Blinding was not performed.

**Analysis of effectiveness**
All patients included in the initial study sample were accounted for in the analysis of effectiveness. The primary clinical end points used were:

- quality of life, which was estimated using the construction and validation of a quality of life questionnaire (CIVIQ);
- days of sick leave;
- days of non-steroidal anti-inflammatory drug (NSAID) use; and
- patient satisfaction (proportion of patients recommending the procedure to acquaintances).

Postoperative complications were also reported. At baseline, the study groups were comparable in their clinical and demographic factors.

**Effectiveness results**
In patients undergoing unilateral procedures, at 4 weeks, the CIVIQ score was 35.4 (+/- 12) in the stripping group and 23.7 (+/- 3.7) in the laser group, (p<0.001). The corresponding values in the sample of patients undergoing a bilateral procedure were 36.4 (+/- 10.8) in the stripping group and 28.6 (+/- 6.3) in the laser group, (p=0.002). These results suggest a lower morbidity in the laser group.

In patients undergoing unilateral procedures, the days of sick leave were 18.86 (+/- 14.5) in the stripping group and 4.1 (+/- 4.2) in the laser group, (p<0.001). The corresponding values in the sample of patients undergoing a bilateral procedure were 22.43 (+/- 13.8) in the stripping group and 8.64 (+/- 8.5) in the laser group, (p<0.001).

In patients undergoing unilateral procedures, the days of NSAID use were 5.5 (+/- 5.8) in the stripping group and 0.7 (+/- 1.2) in the laser group, (p<0.001). The corresponding values in the sample of patients undergoing a bilateral procedure were 6.1 (+/- 6.7) in the stripping group and 0.9 (+/- 1.3) in the laser group, (p<0.001).

In patients undergoing unilateral procedures, patient satisfaction was 84% in the stripping group and 96% in the laser group, (p=0.034). The corresponding values in the sample of patients undergoing a bilateral procedure were 77% (stripping group) and 92% (laser group), respectively, (p=0.004).

Complications were generally mild in both groups and did not require additional treatments.

**Clinical conclusions**
The effectiveness analysis showed that the laser procedure led to better outcomes and significantly shorter duration of sick leave in comparison with conventional stripping.
Measure of benefits used in the economic analysis
The health outcomes were left disaggregated and no summary benefit measure was used in the economic analysis. In effect, a cost-consequences analysis was carried out.

Direct costs
The analysis of the costs was carried out from a societal perspective. It included the direct medical costs of the vein stripper, laser fibre, catheter, generator, surgeon and anaesthesiologist's fees, basic instrumentation, duplex, surgeon visits, day stay in the hospital and compression stockings. The unit costs and the resource quantities were presented separately. Resource use was estimated from the patterns of resource consumption actually observed in the sample of patients involved in the effectiveness analysis. The sources of the costs were not explicitly stated, although the costs might have been derived from a previous cost analysis. The unit cost for the laser equipment was estimated by dividing the purchase price by the expected number of patients to be treated with the device. Discounting was not relevant as the costs were incurred during a short time. The price year was not explicitly stated.

Statistical analysis of costs
Statistical analyses of the costs were not performed.

Indirect Costs
Productivity costs due to the treatments were included in the analysis, which was appropriate given that a societal perspective was adopted. Days of sick leave were derived from the sample of patients included in the effectiveness analysis. The cost of a lost working day came from the average gross wage level in Belgium in 2002. The unit costs and the resource quantities were presented separately. Discounting was not relevant and was not performed.

Currency
Euros (EUR).

Sensitivity analysis
Sensitivity analyses were not carried out.

Estimated benefits used in the economic analysis
Please see the ‘Effectiveness Results’ section.

Cost results
For unilateral procedures, the total direct medical costs per patient were EUR 716.44 in the stripping group and EUR 852.89 in the laser group.

The total indirect costs per patient were EUR 1,942.51 in the stripping group and EUR 424.15 in the laser group.

The total societal costs per patient were EUR 2,658.95 in the stripping group and EUR 1,277.04 in the laser group.

For bilateral procedures, the total direct medical costs per patient were EUR 1,009.86 in the stripping group and EUR 1,145.95 in the laser group.

The total indirect costs per patient were EUR 2,310.04 in the stripping group and EUR 889.54 in the laser group.

The total societal costs per patient were EUR 3,319.9 in the stripping group and EUR 2,035.49 in the laser group.
Synthesis of costs and benefits
A synthesis of the costs and benefits was not relevant as a cost-consequences analysis was performed.

Authors' conclusions
Endovenous laser ablation led to reduced postoperative pain, shorter sick leave, faster return to usual occupational activities, and lower societal costs than the conventional stripping operation for the treatment of primary varicose veins.

CRD COMMENTARY - Selection of comparators
The rationale for the selection of the comparators was clear in that the conventional treatment was compared with a new approach for the treatment of primary varicose veins. A full description of the two procedures was provided. You should decide whether they are valid comparators in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness data were derived from a prospective cohort study that enrolled consecutive patients. The use of a randomised trial would have been more appropriate, but the prospective nature of the study and the baseline comparability of the study groups represent two strong features of the analysis. Moreover, no patient was lost to follow-up and details of the sample selection procedure were reported. The authors stated that the instrument used to assess the primary clinical outcome (i.e. quality of life) was valid, reliable and stable. However, some potential drawbacks of the study need to be highlighted. First, the evidence came from a single institution, which might not be representative of the patient population and treatment patterns in other medical centres. Second, the size of the sample was not justified by means of statistical calculations. Third, blinding was not performed and this might have led to some assessment bias, especially in the patients' subjective evaluation of postoperative pain. These issues should be considered when judging the internal validity of the analysis.

Validity of estimate of measure of benefit
No summary benefit measure was used as a cost-consequences analysis was performed.

Validity of estimate of costs
The analysis of the costs was consistent with the authors' stated perspective. The adoption of a societal perspective and the consequent inclusion of indirect costs was a key characteristic of the analysis. Extensive information on the economic aspects of the study was provided. A detailed breakdown of the cost items was given, together with all details relating to patterns of resource consumption and unit costs. Although the sources of the costs were not stated clearly and the price year was reported only for productivity costs, the reporting of the economic data was, in general, satisfactory. Statistical analyses of the costs were not performed and the impact of using alternative economic data was not investigated.

Other issues
The authors did not make extensive comparisons of their findings with those from other studies. They also did not address the issue of the generalisability of the study results to other settings. Sensitivity analyses were not performed, which further reduces the external validity of the study. The study referred to employed patients with primary varicose veins and this was reflected in the authors' conclusions. The fact that all patients were employed enhanced the influence of indirect costs in the analysis.

Implications of the study
The study results support the use of endovenous laser obliteration for the treatment of primary varicose veins. The authors pointed out that the fact that the treatment can be performed under local anaesthesia as an outpatient procedure could have major implications for treatment costs.

Source of funding
None stated.
Bibliographic details

Other publications of related interest
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Subject indexing assigned by CRD

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