Title: Endovenous laser treatment (EVLT<sup>TM</sup>) for varicose veins – November 2003

**Agency:** Medical Services Advisory Committee (MSAC)

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http://www.msac.gov.au

Reference: MSAC Reference 1059. ISBN 0 642 82283 2. November 2003

#### Aim

The safety, effectiveness and cost-effectiveness of the treatment of varicose veins with endonvenous laser treatment (EVLT<sup>TM</sup>) was assessed by systematic literature review.

#### Conclusions and results

There were no studies available that compared the safety or effectiveness of endovenous laser treatment (EVLT<sup>TM</sup>) to conventional stripping and junction ligation for the treatment of varicose veins. Clinical outcomes from EVLT<sup>TM</sup> were indirectly compared to the stripping and/or junction ligation arm of randomized controlled trials. It would appear from the available case series evidence that EVLT<sup>TM</sup> is as safe as the current practice of stripping and/or junction ligation. Whether EVLT<sup>TM</sup> is as, or more effective, than the stripping and ligation procedure cannot be determined.

# Safety:

Self-limiting symptoms, eg pain, ecchymosis, induration and phlebitis, were common adverse events associated with EVLT<sup>TM</sup>. Serious adverse events, eg deep vein thrombosis and incorrect placement of the laser in vessels, were uncommon. Deep vein thrombosis occurred in one patient and required long-term administration of medication. Incorrect laser placement occurred in two patients, ie 0.3 per cent of total limbs treated in the full studies. This serious operator error resulted in no long-term harmful effects; however, the potential for significant damage was real. Paraesthesia, infection, bruising and haematoma were common adverse events associated with stripping of the saphenous vein. One study reported 30.3 per cent rate of limbs experienced paraesthesia after ankle to groin surgery at 1 year. Serious thrombotic adverse events were uncommon, with one pulmonary embolism and superficial venous thrombosis reported in three patients.

#### Effectiveness:

The main treatment outcome is the abolition of reflux, assessed in the saphenous vein alone after EVLT<sup>TM</sup>, but in the entire limb after stripping and junction ligation, and is therefore not comparable. Occlusion of saphenous veins and the abolishment of venous reflux was reported in 80 to 100 per cent of limbs after EVLT<sup>TM</sup>. The study with the longest follow-up period (24 months) reported occlusion of the greater saphenous vein in 93.4 per cent of limbs after EVLT<sup>TM</sup>. Reported rates of re-treatment are low (1.3 to 4.0 per cent) and rates for recanalisation are similarly low. Symptoms associated with varicose veins, eg pain and oedema, were reduced after EVLT<sup>TM</sup>. Reflux was abolished in 85.9 to 92.2 per cent of limbs after ankle to groin stripping; and in 57.1 to 100 per cent of limbs after groin to knee stripping. The study with the longest follow-up period (5 years) reported abolition of reflux in 85.9 per cent of limbs after groin to ankle stripping. Recurrent varicose veins in the absence of reflux were reported at rates of 12.5 to 33.3 per cent after stripping and junction ligation.

## Cost-effectiveness:

An analysis of the cost-effectiveness of this procedure was not possible due to a lack of high quality evidence on clinical effectiveness. The EVLT<sup>TM</sup> procedure does not treat tributary varicosities, and patients will require follow-up treatment for these. During the stripping procedure, tributary varicosities are ligated and avulsed. Therefore, a formal cost analysis would need to account for the whole procedure, including follow-up treatment of tributary vessels.

### Recommendations

On the strength of evidence pertaining to endovenous laser treatment (EVLT<sup>TM</sup>) for varicose veins public funding should not be supported for this procedure at this time.

### Methods

Medline, Embase, Current Contents, Cochrane Library, SSCI, ProceedingsFirst, AustHealth, Cinahl, Australian Medical Index, APAIS, internet databases and sites, and reference lists were searched from 1966-2003. Study selection followed a protocol and varied according to the research question being addressed. The evidence was assessed and classified using the dimensions of evidence defined by the National Health and Medical Research Council. Study quality was appraised using standard checklists.

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