

OHTAC Recommendation

Endovascular Laser Treatment for Varicose Veins

*Presented to the Ontario Health Technology
Advisory Committee in November 2009*

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OHTAC Ontario
Health Technology
Advisory Committee

Issue Background

The Ontario Health Technology Advisory Committee (OHTAC) met on November 27, 2009 to review the safety, effectiveness and cost-effectiveness of endovascular laser therapy (ELT) for the treatment of primary varicose veins based on an evidence-based review by the Medical Advisory Secretariat (MAS).

Clinical Indication

Varicose veins (VV) are twisted or elongated veins caused by poorly functioning valves and decreased elasticity in the vein wall resulting in reflux (reversed venous blood flow). The symptoms of venous reflux can include: aching leg pain, leg swelling, throbbing, night cramps, restless legs, leg fatigue and heaviness or itching and burning. Left untreated, venous reflux can lead to various complications such as varices rupture with hemorrhage and superficial thrombophlebitis. Pronounced venous reflux can also result in chronic venous insufficiency (CVI), a pathological condition of the skin and subcutaneous skin caused by prolonged stasis of venous blood flow. The clinical signs of CVI include a spectrum of conditions: edema, hyperpigmentation, eczema, lipodermatosclerosis and ulcers. Chronic venous disease is associated with a reduced quality of life (QOL) particularly in relation to pain, physical function, and mobility.

VV of lower limbs is common and exhibits a familial predisposition. It's also estimated to be the seventh most common reason for referral to a physician in the US. The prevalence worldwide ranges from 5% to 15% among men and 3% to 29% among women, while the annual incidence (estimated from the Framingham Study) is reported to be 2.6% among women and 1.9% among men with little variation among the age ranges (40-89 years) studied.

Approximately 1% of the adult population has a leg ulcer of venous origin at any one time and 4% are at risk of developing a leg ulcer. Episodes of leg ulcers are lengthy lasting for several years in some cases and, despite the effectiveness of compression and multilayer bandaging, recurrence is high. Recent trials involving superficial vein surgery, however, have shown significantly reduced recurrence after healing.

The Technology

ELT is an image-guided, minimally invasive treatment alternative to surgical stripping of superficial venous reflux. It does not require an operating room or general anesthesia and can be performed in an outpatient setting by a variety of medical specialties including surgeons (vascular or general), interventional radiologists, and phlebologists. Rather than surgically removing the vein, ELT works by destroying, cauterizing or ablating the refluxing vein segment using heat energy delivered through a laser fibre.

Prior to ELT, color-flow Doppler ultrasonography is used to confirm and map all areas of venous reflux to devise a safe and effective treatment plan. The ELT procedure itself involves the introduction of a guidewire into the target vein under ultrasound guidance, followed by the insertion of an introducer sheath through which an optical fibre carrying the laser energy (810 nm to 1320 nm wavelengths have been used) is advanced. A tumescent anesthetic solution is injected into the soft tissue surrounding the target vein along its entire length serving to anesthetise the vein and insulate adjacent nerves, skin, and other structures from heat damage. Once satisfactory positioning is confirmed with ultrasound, the laser is activated and both the laser fibre and the sheath are pulled back along the length of the target vessel. At the end of the procedure, homeostasis is achieved by applying pressure to the entry point.

Adequate and proper compression stockings and bandages are applied after the procedure to reduce the risk of venous thromboembolism and to reduce postoperative bruising and tenderness. Patients are encouraged to walk immediately after the procedure. Follow-up protocols vary, with most patients returning 1 to 3 weeks later for an initial follow-up visit and often a second follow-up visit over the subsequent 1 to 3 months to evaluate clinical and technical results. If required, sclerotherapy may be performed during the ELT procedure or at any follow-up visits.

Regulatory Status

Endovascular lasers for varicose veins treatment were approved by Health Canada as class 3 devices in 2002. Saskatchewan has offered the treatment as an insured service in since 2007 and is the only province to do so. Although not an insured service in Ontario, ELT for venous reflux has been provided since 2002 in private clinics by surgeons (vascular and general) and interventional radiologists.

Evidence

The MAS evidence-based review of ELT for VV was performed as an update to the 2007 health technology review by the Australian Medical Services Advisory Committee (MSAC) to support public financing decisions. The MAS evidence search on ELT for VV identified 14 systematic reviews, 29 cohort studies on safety and effectiveness, four cost studies and 12 randomized controlled trials involving ELT; six comparing endovascular laser with surgical ligation and vein stripping.

Since 2007 alone, 22 cohort studies have been published involving 10,883 patients undergoing ELT of the great saphenous vein (GSV). Imaging defined treatment effectiveness, mean vein closure rates, were reported to be greater than 90% (range 93% to 99%) at short term follow-up. Longer than one year follow-up was reported in five studies with life table analysis performed in four but with limited follow-up to three and four years. The overall pooled major adverse event rate (including deep vein thrombosis, pulmonary embolism, skin burns or nerve damage) was 0.63% (69/10,883).

The overall level of evidence of randomized trials comparing ELT with surgical ligation and vein stripping (n= 6) was graded as moderate to high. In the trials, recovery after treatment (median number of days to return to work) was significantly shorter after ELT (4 days after ELT versus 17 days after surgery; $p = .005$). Major adverse events occurring after surgery were not significantly higher than those after ELT (0.4%; n = 1). Treatment effectiveness as measured by imaging defined vein absence or closure, symptom relief or quality of life were similar in the two treatment groups and both treatments resulted in significant improvements in these outcomes. Recurrence was low after both treatments at follow-up but neovascularization (growth of new vessels), a key predictor of long-term recurrence, was significantly more common (18% vs. 1%; $p = .001$) after surgery. Although patient satisfaction was reported to be high (>80%) with both treatments, patient preferences evaluated through recruitment process, physician reports and consumer groups were strongly in favour of ELT. For patients with VV, minimal complications, quick recovery, and dependability of outpatient scheduling were key considerations.

As clinical effectiveness of the two treatments was similar, a cost-analysis was performed to compare the differences in resources and costs between the two procedures. A budget impact analysis was also performed to evaluate potential costs of introducing ELT as an Ontario a health service. The average case cost (based on direct hospital costs and medical resources) for surgical vein stripping was estimated to be \$1,799. The estimated average case cost for ELT, which included device related costs, physician fees and hospital costs, was an average case cost for ELT of \$2,025 (hospital costs same as surgery) or \$1,602 (hospital costs 40% less than surgery).

A 5-year projection model was constructed to estimate annual volumes and costs based on historical patterns of surgical vein stripping for VV in the province. In 2007/2008, 3,481 surgical vein stripping procedures (28% of which were for repeat surgical procedures) were performed in Ontario. The annual volume of ELT procedures currently performed in the province through 20 private clinics was estimated to be approximately 840 cases. If ELT were to be publicly reimbursed, it would capture approximately 35% of the vein stripping surgeries in the first year, increasing to 55% in subsequent years. The cost to the province to meet needs for vein stripping surgery would be approximately \$5.9 million. Reimbursed ELT would cost between \$7.1M and \$8.2M, depending upon the real hospital costs.

The conclusions on the comparative outcomes between ELT and surgery are summarized in the table below.

Table 1: Outcome comparisons of ELT vs. surgery for varicose veins

Outcome Comparators	
Post procedural pain, minor complications	ELT < Surgery
Recovery	ELT < Surgery
Major adverse events	ELT < Surgery
Effectiveness - Imaging vein occlusion/ absence	ELT ~ Surgery
Effectiveness -Vein symptom improvement	ELT ~ Surgery
Effectiveness - Quality Of Life	ELT ~ Surgery
Recurrence	ELT ~ Surgery
Patient satisfaction	ELT ~ Surgery
Patient preference	ELT > Surgery
Procedure costs	ELT ~ < Surgery
Budget impact	ELT > Surgery

ELT; Endovascular laser therapy

The results of the evidence-based review on ELT for varices are summarized below:

Patient Outcomes – *ELT versus Surgery*

- ELT has been shown to result in faster recovery than surgery, which is attributable to a reduction in pain, fewer minor complications, and the use of local anesthesia with immediate ambulation.
- ELT is as effective as surgery in the short term as assessed by imaging anatomic outcomes, symptomatic relief, and health related quality of life outcomes.
- Recurrence rate after treatment is similar between the two modalities, but neovascularization, a key predictor of long-term recurrence, is significantly higher with surgery.
- Patient satisfaction is equally high after both treatments, but patient preference is much more heavily weighted toward ELT. Surgeons performing ELT are satisfied with treatment outcomes and offer ELT as an alternative to surgery.

Clinical or Technical Advantages – *ELT over Surgery*





- An endovascular approach can more easily and more precisely treat multilevel disease and difficult to treat areas.
- ELT is an effective and a less invasive treatment for the elderly with venous reflux and those with venous leg ulcers.

System Outcomes – *ELT replacing Surgery*

- ELT may offer system advantages in that the treatment can be offered by several medical specialties in outpatient settings
- As ELT does not require an operating theater or general anesthesia and decants patients from the OR, it could result in: fewer pre-surgical investigations, less demand on anesthetists' time, shorter hospital stays, decreased wait times for VV treatment, and more reliable outpatient scheduling.
- Depending on the reimbursement mechanism for the service, however, it may also result in closure of outpatient clinics with an increasingly centralization of procedures in selected hospitals with large capital budgets resulting in larger and longer waiting lists.
- Procedure costs may be similar for the two treatments, but budget impact may be greater with insurance of ELT because of the transfer of the cases from the private market to the public payer system.

Decision Determinants

Based on the evidence reported in the MAS Endovascular Laser Therapy for Varicose Veins review and the deliberations of OHTAC on November 27, 2009 pertaining to this evidence, OHTAC made the following ratings with respect to the decision determinants criteria:

Endovascular Laser Therapy for Varicose Veins		
Overall clinical benefit		High
Consistency with expected societal and ethical values		Moderate
Value for money		Moderate with uncertainty
Feasibility of adoption into the health system		Moderate with uncertainty

For additional information on the decision determinants criteria, please refer to the OHTAC website at http://www.health.gov.on.ca/english/providers/program/ohtac/decision_frame.html .

OHTAC Recommendations

In considering the above ratings, OHTAC took into account the:

- 1) high burden of venous disease, need, and moderate evidence of effectiveness and safety;
- 2) consistency with expected societal and ethical values;
- 3) moderate uncertainty of cost-effectiveness due to similarities of treatment costs and effects and limited economic studies; and
- 4) moderate uncertainty of feasibility of adoption into the health system.

Therefore, OHTAC made the following recommendations:

1. Endovascular laser ablation should be considered a safe and effective treatment for patients with primary varicose vein reflux based on moderate quality evidence.
2. Patients with varicose veins should have a full duplex ultrasound investigation of the superficial and deep venous system and be counseled about the full range of treatment options available.
3. Endovascular laser therapy should be offered as a treatment alternative to surgical ligation and vein stripping based on moderate quality evidence for patients who have:
 - a. primary symptomatic varicose veins with ultrasound documented vein reflux,
 - b. failed a prior course of conservative medical management, and
 - c. signs of chronic venous insufficiency (including eczema, pigmentation, lipodermatosclerosis or ulceration) or symptoms interfering with activities daily living.