NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of endovenous laser treatment of the long saphenous vein

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid non-comprehensive review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in July 2003.

Procedure names

- Endovenous laser venous treatment.
- Endovenous ablation.

Specialty society

Vascular Surgical Society of Great Britain and Ireland.

Description

Varicose veins are a sign of underlying venous insufficiency and affect 20–30% of adults. Long saphenous vein insufficiency is the most common form of venous insufficiency in people presenting with symptoms.

People with venous insufficiency may have symptoms of fatigue, heaviness, aching, throbbing, itching and cramps in the legs. Chronic venous insufficiency can lead to skin discolouration, inflammatory dermatitis, cutaneous infarction and ulceration in some patients.

Current treatment and alternatives

Surgical stripping of the long saphenous vein is the most common treatment option for varicose veins.

Surgery has been associated with complications such as paraesthesia (numbness caused by nerve damage), haematoma, infection and scarring.

The development of minimally invasive procedures for the treatment of varicose veins has primarily been led by the desire to reduce operative trauma and bruising associated with standard surgical techniques.

What the procedure involves:

Under ultrasound guidance and local anaesthesia, a catheter is placed into the larger saphenous vein. A laser fibre is passed through the catheter and positioned below the saphenofemoral junction.

An anaesthetic agent is injected and the fibre is slowly withdrawn while laser energy from a diode laser is applied in short pulses (once per second).

This procedure is then repeated along the entire length of the vein until the long saphenous vein is closed from saphenofemoral junction to the point of access. A 30 cm vein can be treated in around 90 seconds.

If the vein is small the laser energy may be adjusted to a different energy level after the laser fibre has been withdrawn below the saphenofemoral junction.

Efficacy:

The evidence on efficacy was based on five case-series studies. In these studies mean follow up ranged from 1 to 17 months. Long saphenous vein closure rates were between 95 and 100%, with one study reporting a closure rate of 93.4% in patients followed up for 2 years (113/121 veins).

Opinion varied among Specialist Advisors as to the efficacy of the procedure. One Advisor felt that efficacy had not been established. A second stated that short-term results were favourable but that medium and long-term results were still unknown, while a third advisor commented that durability of the procedure had been established, at least in the medium term.

Safety:

The most common complications associated with the procedure were pain and bruising. In a case-series report on 423 patients using a 810 nm diode laser, 90% of patients reported feeling tightness along the limb and 24% of patients experienced bruising, this resolving within 1 month after treatment. Phlebitis was also reported in a minority of patients.

Specialist Advisors listed potential complications of endovenous laser as: sensory loss; skin burns and perforation of deep veins. One Advisor stated that endovenous laser had fewer complications than standard surgical treatment, while one Advisor believed that the complication rate was still unknown.

Literature review

The medical literature was searched to identify studies and reviews relevant to endovenous laser treatment of varicose veins. Searches were conducted via the following databases, covering the period from their from commencement to February 2003: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and Science Citation Index. Trial registries and the Internet were also searched. No language restriction was applied to the searches.

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts, the full paper was retrieved.

Table 1 Inclusion and exclusion criteria

Characteristic	Criteria
Publication type	Clinical studies included. Emphasis was placed on identifying good quality comparative studies. Articles were excluded where no clinical outcomes were reported; or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty in appraising methodology.
Patient	Patients with varicose veins.
Intervention/test	Endovenous laser treatment.
Outcome	Articles were retrieved if the abstract contained information relevant to safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

Studies included in the overview

This overview is based on five case series studies [1-5]

A list of related publications not included in the summary tables is listed in Appendix A .

Table 2 Summary of key efficacy and safety findings on endovenous laser from case-series data

Study details	Type of laser	Key efficacy findings	Key safety findings	Comments
Min et al (2003) [1] Study design: uncontrolled USA 423 patients (499 limbs) • 353 women (83%) • 71 men (17%) Mean age: 42 years (range 23–77 years) Follow up: 17 months (range 1–39 months)	Diode laser 810 was delivered at 14 W	**GSV closure** Months — Ratio closed (limbs) 1 month 490/499 (98%) 3 months 444/447 (99.3%) 6 months 390/396 (98.5%) 9 months 351/359 (97.8%) 12 months 310/318 (97.5%) 24 months 113/121 (93.4%) After 1 month 9 limbs had repeat procedure. 8/9 were successfully closed with the second treatment. 40 patients have been followed up for 3 years – no new recurrences have been reported. All recurrences were noted before 9 months, authors suggest that they were not true recurrences but rather inadequate initial treatments. Pain: pain resolved in all limbs (6 months) Patient Satisfaction: 99.8% stated that they would recommend procedure.	**Complications** 24% limbs (or patients?) developed bruising outside the puncture site (resolved before 1-month follow up) 90% of patients felt tightness (lasting 3–10 days) 5% of patients developed superficial phlebitis of varicose tributaries. Authors note that there have been no skin burns, paraesthesias, cases of deep vein thrombosis or other minor or major complications.	Consecutive-enrolment of patients. States consecutive but notes in the text that patients were given a choice. 504 GSV were treated. Five limbs were lost to follow-up (no reasons given). Exclusion criteria clearly stated. Clinical evaluation was undertaken by the same physician who performed all endovenous laser procedures. Reports on limbs rather than patients. Unclear whether some patients are those included in later papers.
Min et al (2001) [2] Study design: uncontrolled USA 84 patients (90 GSV) Inclusion: Incompetence of SFJ caused by GSV Mean follow up: 6 months	Diode laser 810 10-12 W and 0.8-1.0 second pulse duration	**GSV closure** Months — Ratio closed 3 82/83 (99%) 6 61/62 (98%) 9 26/27 (96%) Three GSV required repeat procedures	**Complications** Most patients experienced self-limited ecchymoses and mild discomfort Soreness along the GSV for 1–2 weeks 5 patients Localised skin paraesthesia 1 patient	States consecutive but notes in the text that patients were given a choice. Reports on GSVs rather than patients. Outcomes measured Duplex US. Unclear about how many patients available for follow up.

Study details	Type of laser	Key efficacy findings	Key safety findings	Comments
Navarro (2001) [3] Study design: uncontrolled US and Spain 33 patients (40 GSV) with SFJ reflux associated with GSV incompetence and enlargement of branch varicosities 80 patients with competent SFJ and GSV and isolated branch varicosities Mean follow up: 4.2 months	Diode laser 810 10-14 W 1-2 seconds (33 pts) 3-4 W for 1-2 secs (80 pts)	**GSV closure** (33 pts) Reported that 100% were closed. Follow up 24 hours, 7 days and various intervals up to 14 months **GSV closure** (80 pts) Stated that all varicosities remained closed in a mean follow-up period of 18 months	**Complications** (33 pts) Authors stated that no complications were identified after procedure. **Complications (**80 pts) One case of mild pigmentation	Patients given a choice. Short-term follow up. Limited information.

Study details	Type of laser	Key efficacy findings	Key safety findings	Comments
Proebstle et al (2003) [4] Study design: uncontrolled Germany 85 patients (109 legs) • 62 women • 23 men Patients were Class II-VI CEAP with an incompetent SFJ and reflux in the GSV Procedure performed in one limb in 61 patients and in both in 24 patients Mean age: 57 years (range 17–83 years) Follow up: 12 months (82 patients, 104 limbs)	Diode laser 940 15 J 1 second pulses	**GSV closure** (12 months 82 patients) 94/104 limbs (90.4%) stable occlusion 73/82 patients. 10 GSVs demonstrated more or less prononounced recanalisation or relevant incompetent closure. Nine of these merited repeat treatment with high ligation and stripping.	**Complications** 70 patients (67% limbs) had pain along the vein for a median duration of 1 week 47 patients (45% limbs) a palpable induration was noted along the treated GSV (3 weeks) 10 patients (10% limbs) had overt thrombophlebitis of the treated GSV or adjunct varicose tributary vessels, with redness and swelling	Exclusion criteria noted. Three patients with five treated vessels did not complete the 12-month follow up (reasons stated). Percentages calculated on limbs. Outcomes assessed with duplex ultrasound.
Proebstle (2002) [5] Study design: uncontrolled Germany 26 patients (31 limbs) • 21 unilateral • 5 bilateral Patients were Class II-VI CEAP with an incompetent SFJ and reflux in the GSV Median age: 57 years (range 27–83). Maximum follow up: 4 weeks	Diode laser 940 15 W 1 second	**GSV closure** (26 pts) 25 patients had an occluded GSV (on day 1, 7 and 28) 96% 1 patient showed incomplete occlusion	**Complications** Transient pain Moderate ecchymoses in all patients (2 weeks) Thrombophlebitic 2 patients Hyperpigmentation 1 patient	Patients given a choice of procedures. Technical difficulties noted. Unclear whether learning curve involved in procedure. Reported in terms of limbs rather than patients.

Validity and generalisability of the studies

- Endovenous laser was delivered using a diode laser (810 and 940 nm wavelengths). It is unclear whether the differing wavelengths had an influence on the reported complications.
- Outcomes such as pain and reduction in fatigue were not generally reported or well measured.
- Most to the studies reported used limbs as a denominator rather than patients.
- It is unclear whether some of the patients were included in multiple publications, with the more recent publication being a report with longer-term follow-up.
- The authors of one of the papers suggest that recurrences may not be true recurrences but rather inadequate initial treatments. However, the studies do not include information on the experience of surgeons.

Specialist advisors' opinions

Specialist advice was sought from *Vascular Surgical Society of Great Britain and Ireland.*

- Advantages of endovenous laser are that it may be result in less bruising, quicker return to work and fewer and smaller incisions.
- Definitely novel, and of uncertain safety and efficacy.
- One centre in the UK with significant experience in this new technique.
- Potential adverse events include DVT, sensory loss, perforation of deep veins, failure to close veins, skin burns.

Issues for consideration by IPAC

- A UK randomised controlled trial (EVLT vs conventional surgery) is scheduled to start in June 2003 at Leeds Hospital.
- Leeds Hospital is also maintaining a registry on the procedure.
- There is currently an Australian health technology assessment underway on endovenous laser treatment. It is anticipated that this assessment will be published late 2003/early 2004.

References

1 Min RJ, Khilnani N, Zimmet SE (2003) Endovenous laser treatment of saphenous vein reflux: long-term results. *Journal of Vascular & Interventional Radiology* 14(8):991–6.

2 Min RJ, Zimmet SE, Isaacs MN, Forrestal MD (2001) Endovenous laser treatment of the incompetent greater saphenous vein. *Journal of Vascular & Interventional Radiology* 12(10):1167–71.

3 Navarro L, Min RJ, Bone C (2001) Endovenous laser: a new minimally invasive method of treatment for varicose veins--preliminary observations using an 810 nm diode laser.[comment]. *Dermatol Surg* 27(2):117–22.

4 Proebstle TM, Gul D, Lehr HA, Kargl A, et al (2003) Infrequent early recanalization of greater saphenous vein after endovenous laser treatment. *Journal of Vascular Surgery* 38(3):511–6.

5 Proebstle TM, Lehr HA, Kargl A, Espinola-Klein C, et al. (2002) Endovenous treatment of the greater saphenous vein with a 940-nm diode laser: thrombotic occlusion after endoluminal thermal damage by laser-generated steam bubbles.[comment]. *J Vasc Surg* 35(4):729–36.

Appendix A: Additional relevant studies not included in the summary tables.

Study details	Patients/ Follow-up	Comments
Proebstle TM, Gul D, Kargl A, Knop J. Endovenous laser treatment of the lesser saphenous vein with a 940-nm diode laser: early results. *Dermatol Surg* 2003; 29(4):357–61.	33 patients (41 legs) Only 31 patients evaluable (39 legs) Follow up: median 6 months	Patients had incompetent LSV – reflux operated at the lower end of the calf.
Chang CJ, Chua JJ. Endovenous laser photocoagulation (EVLP) for varicose veins. *Lasers Surg Med* 2002; 31(4):257–62.	149 patients with 252 varicose veins Mean follow-up period was 19 months (range 12–28 months)	Use of Nd:YAG laser Spheno-femoral ligation was also performed
Proebstle TM. Endovenous laser therapy (EVLT) of the greater saphenous vein with a 940 nm diode laser. *Vasomed* 2002; 14(3):98–104.	95 patients Follow up unclear from abstract	Paper in German – only English abstract available
Bone C, Navarro L. Endovenous laser: A new minimally invasive technique for the treatment of varicose veins. Endolaser. *Anales de Cirugia Cardiaca y Cirugia Vascular* 2001; 7(3):184–8.	105 patients (125 GSV) Follow up unclear from abstract.	Full text paper unable to be supplied at time of writing
Min, R.J. *2-year follow up results on endovenous laser treatment of the incompetent greater saphenous vein.* 16th Annual Congress of the American College of Phlebology La Quinta, California. 2002.	289 patients (326 GSV) Follow up: 2 years	Abstract Published results presented (1)
Navarro L, Bone C. *Endovenous laser treatment of greater saphenous vein reflux: a two year report on a minimally invasive ultrasound guided technique.* 15th Annual Congress of the American College of Phlebology La Quinta, California. 2001. Abstract	128 patients Follow up: 2 years.	Abstract
Proebstle TM, Sandhofer M, Kargl A, Gul D, Rother W, Knop J et al. Thermal damage of the inner vein wall during endovenous laser treatment: key role of energy absorption by intravascular blood. *Dermatologic Surgery* 2002; 28(7):596–600.	2 patients	Evaluating thermal damage using different lasers

Please note that this is not an exhaustive list.

A number of abstracts (not listed) on this procedure were identified from both the 2001 and 2002 American College of Phlebology Annual Congress.

Appendix B: Literature search for endovenous laser treatment

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in EMBASE, Current Contents, PredMedline and all EMB databases.

For all other databases a simple search strategy using the key words in the title was employed.

#	Search history
1	(endovenous adj4 laser).mp. [mp=title, abstract, subject headings, drug trade name, original title, device manufacturer, drug manufacturer name]
2	EVLT.mp.
3	EVLP.mp.
4	laser coagulation.mp. or exp Laser Coagulation/
5	laser treament.mp.
6	(percutaneous adj4 laser).mp. [mp=title, abstract, subject headings, drug trade name, original title, device manufacturer, drug manufacturer name]
7	saphenous vein.mp. or exp Saphenous Vein/
8	*Chronic Vein Insufficiency/ or *Varicosis/ or truncal veins.mp. or Vein Insufficiency/
9	or/1-3
10	or/4-6
11	7 or 8
12	10 and 11
13	9 or 12