NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of endovenous laser treatment of varicose veins

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 April 2003

Procedure name

Endovenous laser venous treatment (EVLT) (ELT)
Endovenous ablation

Specialty society

Vascular Surgical Society of Great Britain and Ireland

Description

Indications:

Venous insufficiency is a relatively common problem affecting around 10-15% of adult men and 25-33% of adult women. Saphenous vein insufficiency is the most common form of venous insufficiency in those presenting with symptoms.

Symptoms of vein insufficiency include pain, leg fatigue, oedema, skin changes and venous ulcers.

Current Treatments and Alternatives

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

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

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 association with standard surgical techniques.

What the procedure involves:

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

An anaesthetic agent is then injected and the fibre is slowly withdrawn while laser energy from a diode laser is applied in short pulses (once per second).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 greater 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If the vein is small the laser energy may be adjusted to a lower intensity after the laser fibre has been withdrawn below the saphenofemoral junction.

Efficacy

- The evidence on efficacy was based on four case series studies. In these studies mean follow-up ranged from 1 to 6 months. Saphenous vein closure rates at 6 months were between 95 and 100%To date there is no available published evidence of long-term outcomes.

- Limited evidence also suggested that endovenous laser could reduce pain and oedema.

- 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 are 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. Other more serious complications such as paraesthesia and burns and scaring were also reported although less frequently. There was one reported case of deep vein thrombosis (DVT) in a patient with a history of multiple deep vein thrombosis.

- Specialist Advisors listed potential complications of endovenous laser as: sensory loss; skin burns; perforation of deep veins; and pulmonary embolism/deep vein thrombosis. 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 truncal varicose veins. Searches were conducted via the following databases 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; the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded due to 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 the safety and/or efficacy.
Language	Non-english language articles will be excluded unless they are thought to add substantively to the English language evidence base.

List of studies included in the overview

- This overview is based on six case series studies [1] [2] [3] [4]. In two of these case series only the abstract was available [5] [6].

- One paper was also identified that reported on the use of Nd:YAG laser in the treatment of varicose veins [7]. This paper was excluded as sapheno-femoral ligation was also performed surgery and a much higher laser dose was used than in other studies

Other identified papers

- A number of abstracts on endovenous laser were also identified from both the 2001 and 2002 American College of Phlebology Annual Congress.

- These abstracts included a report from both Min (n=289) [8] and Navarro and Bone (n=128) [9] on 2-year follow-up of endovenous laser treatment.

- The 2001 paper by Bone and Navarro (2001) [6] would seem to be a report on these results however the full text paper was not available at the time of writing this overview.

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

Authors, location, date, number of patients	Type of laser	Key efficacy findings	Key safety findings	Comments
Min et al (2001) [1] **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.
Navarro (2001) [2] **Study Design: Uncontrolled** US and Spain 33 patients (40 GSV) Patients with SFJ reflux associated with GSC 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 have 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.

Authors, location, date, number of patients	Type of laser	Key efficacy findings	Key safety findings	Comments
Proebstle (2002) [3] **Study Design: Uncontrolled** Germany 26 patients (31 limbs) 21 unilateral 5 bilateral Median age: 57 years (range 27-83). Patients were Class II-VI CEAP with an incompetent SFJ and reflux in the GSV Maximum follow up: 4 weeks	Diode laser 940 15 W 1 seconds	**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 if learning curve involved in procedure. Reported in terms of limbs rather than patients.
Proebstle (2003) [4] **Study Design: Uncontrolled** Germany 33 patients (41 legs) Only 31 pts evaluable (39 legs) Patients had incompetent LSV – reflux operated at the lower end of the calf. Unilateral and bilateral procedures Follow-up: median 6 months	Diode laser 940 15 W 0.5-1.0 sec	**LSV closure (follow-up 6 months)** 37 legs no recanalisation required (1 person died not related to EVLT- 2 legs). **3 month outcomes (report by patients)** **Oedema – (0-3 where 0 is not present)** **0 1 2 3** Pre 9% 16% 51% 24% Post 56% 32% 3% 6% **Pain (0-3 where 0 is not present)** **0 1 2 3** Pre 27% 11% 40% 22% Post 91% 6% 0% 3% **Pruritus (0-3 where 0 is not present)** **0 1 2 3** Pre 56% 8% 14% 22% Post 91% 9% 0% 0%	**Complications (n= legs)** ▪ Pain 20 (54%) ▪ Analgesics 18 (49%) ▪ Ecchymoses 17 (46%) ▪ Induration 14 (38%) ▪ Paraesthesia 4 (11%) ▪ Periphlebitis 3 (8%) ▪ DVT 1 (3%) Only paraesthesia was longer than 4 weeks duration	Patients offered to undergo procedure. In two patients ELT could not be completed successfully for technical reasons.

Table 3 Summary of key efficacy and safety findings (from full text published papers where only abstract is available)

Authors, location, date, number of patients	Type of laser	Key efficacy findings	Key safety findings	Comments
Proebstel (2002). [5] **Study Design: Uncontrolled** German Incompetence of GSV 95 patients	Diode laser 940	**GSV closure** 92/95 cases occlusion was observed (96.8%)	Authors report that severe side effects were not observed.	Paper in German. Possible some of the same patients are reported in other papers.
Bone and Navarro (2001) [6] **Study Design: Uncontrolled** Patients with GSV incompetence 105 patients (125 GSV) Also patients with branch varicosities (100 patients)	Diode laser 810nm 940nm, 980nm	**GSV closure** 97% closure of GSV incompetents (18 months) 100% closure of branch varicosities (36 months)	Authors report that no significant complications were observed.	Full text paper not able to be supplied. Possible some of the same patients are reported in other papers.

Validity and generalisability of the studies

- In general the studies are small and of low methodological quality.
- Mean follow-up ranged from 1 to 6 months.
- The majority of studies reported on patients presenting with greater saphenous vein reflux. One study reported on the use of endovenous laser of the lesser saphenous vein [4] while in a second paper patients with isolated branch varicosities were included.
- Endovenous laser was delivered using a diode laser (810, 940, 980-nm wavelengths). It is unclear whether the differing wavelengths had an influence on the reported complications.
- In one study endovenous laser treatment extended down to the calf region [3].
- Outcomes such as pain and reduction in fatigue were reported in a minority of studies.

Specialist advisor's opinion / advisors' opinions

- 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.
- Leeds are 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, Zimmet SE, Isaacs MN, Forrestal MD. Endovenous laser treatment of the incompetent greater saphenous vein. J Vasc Interv Radiol 2001; 12(10):1167-1171.

2 Navarro L, Min RJ, Bone C. Endovenous laser: a new minimally invasive method of treatment for varicose veins--preliminary observations using an 810 nm diode laser. Dermatol Surg 2001; 27(2):117-122.

3 Proebstle TM, Lehr HA, Kargl A, Espinola-Klein C, Rother W, Bethge S et al. 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 2002; 35(4):729-736.

4 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):357-361.

5 Proebstle TM. Endovenous laser therapy (EVLT) of the greater saphenous vein with a 940 nm diode laser. Vasomed 2002; 14(3):98-104.

6 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):184-188.

7 Chang CJ, Chua JJ. Endovenous laser photocoagulation (EVLP) for varicose veins. Lasers Surg Med 2002; 31(4):257-262.

8 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.

9 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