

NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of transilluminated powered phlebectomy for 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

Transilluminated powered phlebectomy (TIPP)

Specialty society

Vascular Surgical Society of Great Britain and Ireland

Description

Indications:

Varicose veins are a relatively common problem affecting around 25-33% of adult women and 10-15% of adult men. They are a visible surface manifestation of an underlying syndrome of venous insufficiency.

Most patients with venous insufficiency have subjective symptoms that may include feelings of fatigue, heaviness, aching, burning, throbbing, itching and cramps in the legs. Over time chronic venous insufficiency can lead to changes such as skin discolouration, inflammatory dermatitis, recurrent or chronic cellulitis, cutaneous infarction and ulceration.

Current Treatment and Alternatives

The transilluminated powered phlebectomy procedure is intended as an alternative to traditional phlebectomy for symptomatic varicosities of the leg and as an adjuvant to surgical removal of the saphenous vein.

What the procedure involves:

Transilluminated powered phlebectomy is performed under general, regional or local anaesthesia.

The first step in the procedure is to instil a solution around the veins. An endoscopic transilluminator is then inserted underneath the skin. The light produced from this device allows illumination of the the vein clusters that need to be resected.

A suction device with guarded blades (resector device) is then introduced via another incision at the other end of the varicose vein and the varicosities are cut and removed by suction.

Once removal of the veins is complete a second stage anaesthetic is then injected to minimise bruising, pain and haematoma formation. The incisions are then closed with sutures or tape.

The resector device can also be inserted through the first incision, minimising the number of incisions made during the procedure.

Efficacy:

- Pain and satisfaction were the main outcomes reported in the studies. Comparative data suggested that transilluminated powered phlebectomy resulted in similar or less pain at six weeks and greater cosmetic satisfaction compared to hook phlebectomy. The evidence reported in the non-comparative studies supported these findings.
- Evidence also indicated that fewer incisions (range 2-10) were required for transilluminated powered phlebectomy. There was also some evidence to suggest that the number of incisions reduced with surgeon experience.
- One Specialist Advisor commented that the cosmetic results can be indifferent due to the damage to the subcutaneous fat. While a second Advisor thought that while the procedure appeared to work it did not seem to have any benefits over standard practice.

Safety:

- The comparative data indicated that transilluminated powered phlebectomy had fewer complications than standard phlebectomy. Common complications observed in the studies included haematomas, bruising and paraesthesia (nerve damage). It is possible that some of the cases of paraesthesia may be attributed to patients undergoing saphenous vein surgery rather than the removal of varicosities.
- One case of deep vein thrombosis in a study of 114 patients (0.9%) was also reported as a complication of the procedure.
- Specialist Advisors listed the main potential complications as haematoma, pain and bruising. Neuropraxia, causing sensory disturbance was also listed by one Advisor, although it was felt the incidence of this would be low.

Literature review

The medical literature was searched to identify studies and reviews relevant to transilluminated powered phlebectomy. 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) was 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. Abstracts 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	Transilluminated powered phlebectomy
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 five studies.

Two of these papers are comparative non-randomised studies ^[1;2].

The remaining three papers include a multi-centre trial ^[3] and two case series reports ^[4;5].

Table 2 Controlled evidence on the efficacy and safety of transilluminated powered phlebectomy

Authors, location, date, number of patients	Key efficacy findings		Key safety findings		Comments
	TIPP	Hook phlebectomy	TIPP	Hook phlebectomy	
<p>Scavee et al (2003)^[1] Study Design: Non-randomised controlled trial January and April 2001 Belgium 2 institutions</p> <p>80 consecutive patients 40 TRIPP 40 Hook phlebectomy</p> <p>All had greater saphenous reflux</p> <p>All patients TIPP patients 34-79 years, 70% women Hook patients 20-71 years, 75% women</p> <p>Unilateral procedures performed by two surgeons</p>	<p>Pain (10 point scale: 1 no pain – 10 terrible pain) Mean score 5 (48 hours) Mean score 2 (7 days) Mean score 0 (6 weeks)</p> <p>Cosmetic concern (10 point scale: – 10 best result) Mean score 8.9 ±1.2 (6 weeks)</p> <p>Mean operation time 56 min Mean number of incisions 6 (2-8)</p>	<p>Pain (10 point scale: 1 no pain – 10 terrible pain) Mean score 4 (48 hours) Mean score 2 (7 days) Mean score 0 (6 weeks)</p> <p>Cosmetic concern (10 point scale: 1 best – 10 worst result) Mean score 8.6 ±1.1 (6 weeks)</p> <p>Mean operation time 45 min Mean number of incisions 8 (2-8)</p> <p>After one year recurrences in one limb (2.5%)</p>	<p>Complications</p> <p>Ankle paraesthesia 2 (5%) Haematomas 23 (57%) Residual varicose veins 2 (5%)</p>	<p>Complications</p> <p>Ankle paraesthesia 5 (13%) Haematomas 9 (22%) Residual varicose veins 2 (5%)</p>	<p>Non random allocation</p> <p>Table and text don't reconcile</p> <p>Unclear how selection made – although patients paid for device</p> <p>Suggestion of a learning curve with procedure</p> <p>Unclear how many people were available for follow-up at 1 year (both groups)</p>

Authors, location, date, number of patients	Key efficacy findings		Key safety findings		Comments
	TIPP	Hook phlebectomy	TIPP	Hook phlebectomy	
<p>Spitz et al (2000) ^[2] Study Design: Non-randomised controlled study US TIPP 56 patients (59 limbs) Majority women. Mean age 44.6 yrs (range 23-66).</p> <p>Historical controls: 114 patients underwent ligation and hook phlebectomy with Varady hooks Mean age 46.8 (range 21 –78 years)</p> <p>Majority were unilateral procedures</p>	<p>Pain (10 point scale: 1 no pain – 10 terrible pain)</p> <p>Mean score 3 (48 hours) Mean score 2 (7 days) Mean score 0 (6 weeks)</p> <p>Cosmetic concern (10 point scale: 1 best – 10 worst result)</p> <p>Mean score 2.5 (6 weeks) Mean score 1.0 (3 months)</p> <p>Median duration of the operative procedure is 41 min Mean number of incisions 5.6 (range 3-10)</p>	<p>Pain (10 point scale: 1 no pain – 10 terrible pain)</p> <p>Mean score 6.5 (48 hours) Mean score 6 (7 days) Mean score 4 (6 weeks)</p> <p>Cosmetic concern (10 point scale: 1 best – 10 worst result)</p> <p>Mean score 6 (6 weeks) Mean score 4 (3 months)</p> <p>Median duration of the operative procedure is 75 min Mean number of incisions 17 (range 10-55)</p>	<p>Complications</p> <p>Cellulitis, small haematoma, swelling or bruising 4 limbs (7%)</p>	<p>Complications</p> <p>Cellulitis, small haematoma, swelling or bruising 40 patients (35%)</p> <p>Other noted complications included DVT (2) Lymphoceles (2) Phlebitis (12) Paresthesias (5) Fever (4).</p>	<p>Historical control – problems with bias. Unsure of timeframe.</p> <p>Unclear how selection made.</p>

Table 3 Non comparative evidence on the efficacy and safety of transilluminated powered phlebectomy

Authors, location, date, number of patients	Key efficacy findings	Key safety findings	Comments									
<p>Cheshire et al (2002)^[3] Study Design: uncontrolled study 4 centres in Europe and 4 in US 114 patients (117 limbs) 89 women, 28 men</p> <p>Primary varicose veins, either with or without saphenous vein incompetence</p> <p>98% Class 2 CEAP (clinical, etiologic, anatomic pathophysiologic)</p> <p>93 limbs with stripping and TIPP 9 limbs ligation and TIPP 13 limbs alone</p> <p>Follow-up 6 weeks</p>	<p>Median ecchymosis (11 point scale: 0 no bruising, 10 severe – patient/surgeon)</p> <table border="0"> <tr> <td>TIPP only</td> <td>TIPP by ligation</td> <td>TIPP stripping</td> </tr> <tr> <td>Patient 2</td> <td>Patient 1</td> <td>Patient 1</td> </tr> <tr> <td>Surgeon 1</td> <td>Surgeon 0</td> <td>Surgeon 0</td> </tr> </table> <p>Cosmetic concern (11 point scale: - where 10 is the worse) Patients median score of 0 (satisfied)</p> <p>Median duration of the operative procedure is 45 min (phlebectomy portion was 14 min)</p> <p>Mean number of incisions 3 (range 2-5)</p>	TIPP only	TIPP by ligation	TIPP stripping	Patient 2	Patient 1	Patient 1	Surgeon 1	Surgeon 0	Surgeon 0	<p>Complications – 6 weeks (n=limbs, some patients experience more than one complication)</p> <ul style="list-style-type: none"> ▪ Death 1 patient (myocardial infraction) ▪ DVT 1 patient ▪ Nerve damage 43 limbs ▪ Ecchymosis 33 limbs ▪ Swelling 20 limbs ▪ Haematoma 14 limbs ▪ Pain 5 limbs ▪ Cellulitis 4 limbs ▪ Other 7 limbs 	<p>Analysed in terms of limbs rather than patients</p> <p>Short term follow-up</p> <p>Limited outcomes reported</p>
TIPP only	TIPP by ligation	TIPP stripping										
Patient 2	Patient 1	Patient 1										
Surgeon 1	Surgeon 0	Surgeon 0										
<p>Arumigasamy et al (2002) [4] Study Design: uncontrolled study Dublin UK 20 patients 16 women, 4 men average age 55</p> <p>Follow-up: 1 and 5 weeks</p>	<p>Satisfaction (10 point scale) (19 pts) – 6 weeks Patients median score of 0 (satisfied)</p> <p>Median duration of phlebectomy portion was 12min Mean number of incisions 3.6 (range 2-7)</p>	<ul style="list-style-type: none"> ▪ Skin perforation in the thigh 1 patient ▪ Haematomas or bruising 19 patients 	<p>Limited information provided Short term follow-up</p>									
<p>Scavee et al (2001) [5] Study Design: uncontrolled study Belgium January to February 2001</p> <p>15 patients Patients underwent stripping Unilateral operations</p> <p>Follow-up: 6 weeks</p>	<p>Pain (10 point scale: 1 no pain –10 terrible pain) Mean score 4 (48 hours) Mean score 2 (7 days) Mean score 0 (6 weeks)</p> <p>Cosmetic concern (10 point scale: – where 10 best result) Patients median score of 9</p> <p>Median duration of operation was 56 min Mean number of incisions 6 (range 2-8)</p>	<ul style="list-style-type: none"> ▪ Thigh bruising 6 patients ▪ Ankle numbness 1 patient 	<p>Limited information. Score for pain the same of Spitz. Small number of patients.</p>									

Validity and generalisability of the studies

- There is currently limited evidence available on this procedure. The first peer reviewed published paper on this procedure appeared in 2000. Publication bias and pipeline bias are issues that should be considered.
- Selection bias and recall bias are also issues that need to be considered in regards to the two comparative studies.
- There was also some indication in the papers that a learning curve existed in relation to the procedure however the experience of surgeons undertaking the procedure was not documented.#
- The number of varicosities was also not well documented. This may have implications for the number of incisions performed.
- In all studies a visual analogue scale was used to measure pain and satisfaction. Only one study^[3] included an objective assessment of an efficacy outcome.

Specialist advisor's opinion

Specialist Advisor 1

- Likely to be limited to private practice setting.
- No proven benefits over conventional hook phlebectomy.
- Requires special equipment and training.

Specialist Advisor 2

- Less than 10% of specialist engaged in this area of work.
- Appears to work but procedures a huge amount of bruising with a risk of skin damage.
- On site training at expert centre should be undertaken.

Specialist Advisor 3

- Recurrent varicosities can be difficult to hook, as such the procedure might be better in this setting, especially in varicosities that are extensive.
- Probably quite safe.
- There are some cosmetic reservations.

Issues for consideration by IPAC

None

References

- 1 Scavee C, Lesceu O, They S, Jamart J, Louagie Y, Schoevaerdt J-C. Hook Phlebectomy versus Transilluminated Powered Phlebectomy for Varicose Vein Surgery: Early Results. *Eur J Vasc Endovasc Surg* 2003; 25(5):473-5.
- 2 Spitz GA, Braxton JM, Bergan JJ. Outpatient varicose vein surgery with transilluminated powered phlebectomy. *Vascular Surgery* 2000; 34(6):547-555.
- 3 Cheshire N, Elias SM, Keagy B, Kolvenbach R, Leahy AL, Marston W et al. Powered phlebectomy (TriVex) in treatment of varicose veins. *Ann Vasc Surg* 2002; 16(4):488-494.
- 4 Arumugasamy M, McGreal G, Oangle quotation mark rA, Kelly C, Bouchier-Hayes D, Leahy A. The technique of transilluminated powered phlebectomy -- a novel, minimally invasive system for varicose vein surgery. *Eur J Vasc Endovasc Surg* 2002; 23(2):180-2.

- 5 Scavee V, Theys S, Schoevaerds JC. Transilluminated powered mini-phlebectomy: early clinical experience. *Acta Chir Belg* 2001; 101(5):247-9.