

A Randomized Controlled Trial Comparing Transilluminated Powered Phlebectomy with Hook Avulsions

An Adjunct to Day Surgery?

SB RAY-CHAUDHURI, Z HUQ, RG SOUTER, D MCWHINNIE

Keywords: *transilluminated powered phlebectomy, varicose veins, hook avulsion*

The aim of this study was to compare transilluminated powered phlebectomy (TriVex™) with conventional hook avulsion with respect to operative time, number of incisions and patient outcomes. Forty legs in 30 patients undergoing surgery for uncomplicated varicose veins were randomised to either TriVex™ (n=21) or conventional hook phlebectomies (n=19). Other adjunctive varicose vein procedures indicated were performed by conventional methods. The duration of each procedure and the number of incisions were noted. Patients completed linear analogue pain and cosmesis scores post-operatively. Transilluminated powered phlebectomy was achieved with a significantly shorter operative time (mean 17.1 mins vs 33.7 mins, $p < 0.0001$) through significantly fewer incisions (mean 4.0 vs 18.9, $p < 0.0001$). There was no significant difference in pain scores at one or 14 days, cosmesis scores at 14 days or rates of adverse events. TriVex™ halves operating time and reduces the number of incisions with no increase in post-operative pain or difference in cosmesis in varicose vein patients.

Introduction

Minimally invasive varicose vein surgery has become a practical reality in recent years. Several innovative procedures have been described. Endovenous laser treatment (E.V.L.T.) uses diode laser energy, delivered percutaneously under local anaesthesia, to occlude the long saphenous vein (1,2). The VNUS technique is similar, but employs radio-frequency resistive heating to ablate the long saphenous vein, again using a catheter inserted percutaneously under local anaesthetic (3–6). Occlusion of the long saphenous vein by injection of foam sclerosant (Varisol) under Duplex ultrasound control has also been described. Such techniques offer the prospect of the treatment of varicose veins on a day case or out-patient basis, often without the need for general anaesthesia. While these techniques address management of proximal reflux in the long saphenous vein, they cannot be applied to superficial varicosities, which are usually treated in the conventional way with multiple stab avulsions. While some centres do perform limited phlebectomies as an out-patient procedure, particularly in the United States, most are carried out under general anaesthesia. In the case of extensive bilateral varicosities particularly, this can be very time-consuming requiring a prolonged anaesthetic

time. This may preclude the procedure being carried out as a day case. The novel minimally-invasive technique of transilluminated powered phlebectomy (TIPP) offers the prospect of equally effective removal of varicosities, but with a much reduced operative time. We present here a randomised controlled study comparing this new technique with hook avulsion phlebectomy in patients with primary uncomplicated varicose veins.

Methods

All patients presenting to the outpatients clinic with primary, uncomplicated varicose veins (CEAP classification C2) and with none of the exclusion criteria (Table 1), were randomised by the use of sealed envelopes to either conventional hook avulsions or TIPP. All patients had previously undergone duplex ultrasound examination of deep and superficial veins to locate anatomical sites of venous incompetence. All patients

Correspondence to:

MR D MCWHINNIE, Milton Keynes General Hospital, Milton Keynes, Bucks MK6 5LD Tel. 01908 660033 E-mail: dmcwhinnie@aol.com

Table 1 Exclusion Criteria.

Recurrent varicose veins
Varicosities contained within a single area of 30 cm circumference
Varicose eczema
Lipodermatosclerosis
Deep venous incompetence
Ulceration
Unfit for day surgery/ extended day surgery

were treated as day cases or extended day cases and as such had no serious co-morbidities and Body Mass Indices of less than 35. Prior to surgery, visible varicosities were marked with the patient erect using indelible ink. In patients undergoing hook avulsion phlebectomy, each individual varicosity was marked. In those undergoing TIPP, the affected areas of the leg were more broadly marked. At the time of surgery, any sites of superficial incompetence detected by duplex were treated in the conventional way (high saphenous ligation, stripping of the long saphenous vein to the knee, short saphenous ligation or ligation of incompetent perforators as appropriate).

Once any primary procedures had been completed, residual superficial varicosities were treated in the method selected at randomisation. In patients randomised to hook avulsions, a number of stab incisions were made along the length of the marked vein using the trocar from a 25G cannula. The veins were then avulsed using Oersch hooks.

The TriVex™ system consists of two handpieces (Figure 1), an illumination/irrigation catheter and a powered resector, attached to a control unit. Each is introduced into the subcutaneous plane via 4mm skin incisions. The illuminator is passed deep to the varicosity to enable its trans-illumination. Tumescence irrigation fluid (comprising 50ml of 1% lignocaine and 2ml 1:1000 adrenaline in 1L of 0.9% normal saline) is infused into the tissues surrounding the vein at a pressure of 4–500 mmHg. The resector is placed in the same plane as the vein. When the resector is activated, the vein is sucked into the

window of a rotating cutter which macerates it, the fragments being removed by suction. In this way, the entire vein can be removed under direct vision. In patients randomised to TriVex™, all varicosities within the areas marked pre-operatively were removed, using the minimum number of skin incisions required to achieve this. Where incisions made for the primary procedure were conveniently placed, these were also employed as entry sites for the hand pieces.

At the time of surgery, a proforma was completed noting the procedures performed, the numbers of incisions made and the duration of superficial vein removal, starting at the end of the primary procedure, and including any set-up time required for the TriVex™ system. Where more than one surgeon was performing avulsions, the duration per operator was calculated.

Patients were reviewed one day and 2 weeks post-operatively, at which time they were requested to complete visual analogue scores for pain, with no pain scoring 0 and the worst imaginable pain scoring 10. A visual analogue scale for cosmesis was also completed 2 weeks after surgery with the worst result scoring 0 and the best 10. A note was also made of any complications, with regard to wound infection or cellulitis, haematoma, bruising, numbness or any other reported problems. All post-operative assessments were carried out by a consultant surgeon, senior specialist registrar or vascular nurse practitioner.

Results

Thirty patients (20 women) who were entered into the study subsequently underwent surgery. Fifteen patients (19 legs) were randomised to hook avulsion phlebectomy and 15 patients (21 legs) to TIPP. The two groups were comparable for mean age, gender and primary procedures performed (Table 2). Table 3 shows median duration of procedure for hook avulsions or TIPP and median number of incisions for each technique. Transilluminated powered phlebectomies were achieved in a significantly shorter time (mean 17.1 minutes vs 33.7 minutes, $p < 0.0001$), using significantly fewer incisions (mean 4.0 incisions vs 18.9, $p < 0.0001$) (Table 3). Follow-up data was available for 31

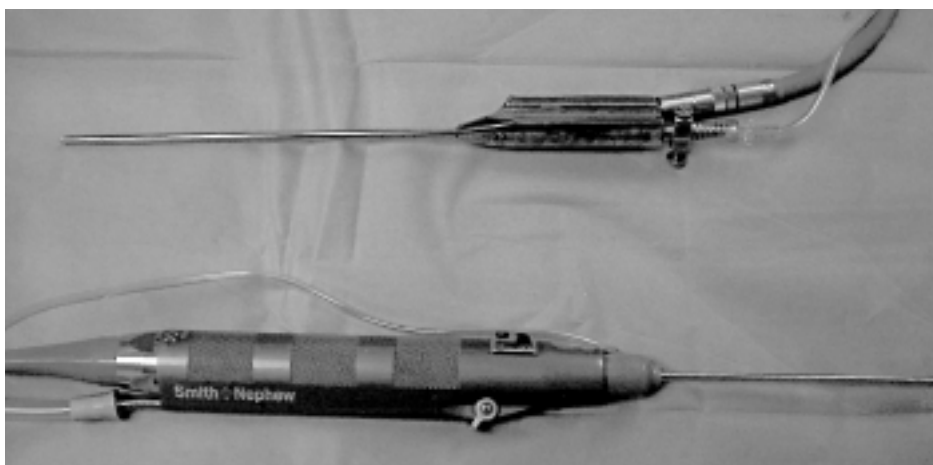


Figure 1 The TriVex™ system.

Table 2 Patient demographics and primary procedures performed.

	Hook avulsions	TriVex
Numbers	15, 19 legs	15, 21 legs
Mean Age (range)	47.0 (31–63)	48.4 (24–63)
Men	5	5
High Saphenous Ligation (legs)	15	19
LSV Stripped (legs)	17	20
Short Saphenous Ligation (legs)	2	4

legs. Mean analogue pain scores on Day 1 and Day 14 post-operatively did not differ significantly between the two groups and cosmesis scores at two weeks similarly did not differ significantly (Table 4). Complication rates in the two groups were not significantly different (Table 5).

Discussion

A variety of methods for the surgical treatment of superficial varicose veins have been described. Most have involved the segmental avulsion of the varicosity through a series of small incisions along its course, most recently with the use of various designs of hooks. Such techniques have been widely demonstrated to be safe and efficacious, providing good cosmesis with a low complication rate. However, they can be very time-consuming, particularly where very extensive varicosities require treatment. Where severely affected patients need bilateral surgery, this often

precludes their treatment as day cases due to the excessive operative time required. TIPP addresses this problem by providing a method for the rapid treatment of superficial varicosities using minimally invasive techniques, with similar cosmetic results and complication rates. A number of previously published studies provide evidence of the safety and efficacy of this technique (7–10).

The TIPP procedure took significantly less time than hook avulsions and was achieved through significantly fewer incisions. Differences in duration would undoubtedly have been less marked if no allowance had been for when two surgeons were performing hook phlebectomies simultaneously. However, TIPP can be performed with only one surgeon and an assistant, so it seems appropriate to compare hook avulsions in a similar context. Senior surgeons are increasingly having to operate alone as the number of hours elective work that juniors can perform is eroded, so many varicose vein operations will be performed by a single surgeon. Overall, a mean of 16.6 minutes was saved per case by the use of TIPP. This would typically allow at least one extra intermediate case to be performed per half day session.

There was no significant difference between TIPP and hook avulsion phlebectomies for any of the complications studied. The commonest complications in each group were bruising and haematoma. Low rates of nerve damage, wound infection and phlebitis were seen in the current study, with no significant difference between hook phlebectomies and TIPP. The incidence of these events was within the range seen in other studies, though the rates of nerve damage in particular reported in the TIPP literature vary widely from 0 to 27%. Whilst there is a theoretical

Table 3 Comparison of number of incisions and duration of procedure.

	Hook avulsions (n=19 legs)	TriVex (n= 21 legs)	P*
Mean number of incisions+/-S.E. (range)	18.9+/- 2.42(5–40)	4.0+/-0.51(1–8)	< 0.0001
Mean duration of procedure in operator minutes+/-S.E.(range)	33.7+/-2.35(17–54)	17.1+/-1.66 (7 ^o –35)	< 0.0001

* Mann-Whitney U Test

Table 4 Post-operative pain and cosmesis scores.

	Hook avulsions (n=15 legs)	TriVex (n= 16 legs)	P*
Mean day 1 Pain score+/- S.E. (range)	4.7+/-0.69(0–10.0)	5.9+/-0.66(0.9–9.4)	NS
Mean day 14 Pain score+/- S.E. (range)	2.6+/-0.75(0–8.0)	1.9+/-0.57(0–7.1)	NS
Mean cosmesis score+/-S.E. (range)	6.9+/-0.68(0.6–9.4)	5.9+/-0.61(2.0–9.0)	NS

* Mann-Whitney U Test

Table 5 Complications.

	Hook avulsions (n=15 legs)	TriVex (n= 16 legs)	P*
Bruising	7(47%)	9(56%)	NS
Haematoma	4(27%)	4(25%)	NS
Numbness	1(7%)	2(13%)	NS
Wound infection	1(7%)	1(6%)	NS
Phlebitis	0	2(13%)	NS

* Fisher's Exact Test

risk of skin necrosis secondary to undermining and toxic effects from the tumescent fluid (particularly lidocaine), there was no incidence of these in this small study.

Pain scores, at both day 1 and day 14 post-operatively, and cosmesis scores at day 14 did not differ significantly between the two techniques. It might have been expected that TIPP would be superior in both these respects, given the minimally invasive nature of the technique, coupled with the use of a local anaesthetic irrigation fluid. However, in this study, proximal reflux has been treated in the conventional way, usually by high saphenous ligation and stripping. It may be that the pain and bruising from these procedures dominate in the early post-operative period and obscure benefits of the TIPP procedure. Use of an endovascular procedure to treat the long saphenous vein in combination with TIPP might allow these advantages to become apparent.

This study supports the findings of previous safety and efficacy studies of transilluminated powered phlebectomy. In addition the results of this randomized controlled study suggest that TIPP is as effective as conventional treatments in the removal of varicosities with no excess of adverse events, no worse post-operative pain and comparable cosmesis. The main benefit of TIPP evident in this study is of markedly reduced operative time, with phlebectomies by this method taking around half the time they would if using hook avulsions. Such benefits are likely to be even more pronounced in some sub-groups, such as copious or recurrent bilateral varicosities. This makes the treatment of very extensive varicosities as day cases a realistic proposition (7). As minimally invasive techniques for the management of long saphenous venous reflux evolve, it is important that treatment of the superficial component does not become the 'rate-limiting step' in the move to shorter in-hospital stays.

References

- 1 Min RJ ZS, Isaacs MN, Forrestal MD. Endovenous Laser Treatment of the Incompetent Greater Saphenous Vein. *J Vasc Interv Radiol* 2001;12(10):1167–1171.
- 2 Proebstle TM LH, Kargl A, Espinola-Klein C, Rother W, Bethge S, Knop J. Endovenous treatment of the greater saphenous vein with a 940-nm diode laser: Thrombotic occlusion after endoluminal thermal damage by laser-generated steam bubbles. *J Vasc Surg* 2002;35(4):729–736.
- 3 Fassiadis N, Kianifard, B., Holdstock, J. M., Whiteley, M. S. No recurrence of reflux following endovascular radiofrequency ablation of the long saphenous vein (VNUS Closure) at one year. *British Journal of Surgery – Supplement*. 88 (Supplement 1):49–50, May 2001 2001;88(Supp 1):49–50.
- 4 Merchant RF DR, Kabnick LS. Endovascular obliteration of saphenous reflux: A multicenter study. *J Vasc Surg* 2002;35(6):1190–1196.
- 5 Rautio TT, Perala, Jukka M., Wiik, Heikki T., Juvonen, Tatu S., Haukipuro, Kari A. Endovenous Obliteration with Radiofrequency-resistive Heating for Greater Saphenous Vein Insufficiency: A Feasibility Study. *J Vasc Interv Radiol* 2002;13(6):569–75.
- 6 Sybrandy JEM WC. Initial experiences in endovenous treatment of saphenous vein reflux. *J Vasc Surg* 2002;36(6):1207–1212.
- 7 Spitz GA BJ, Bergan JJ. Outpatient varicose vein surgery with transilluminated powered phlebectomy. *Vasc Surg* 2000;34(6):547–555.
- 8 Arumugasamy M MG, O'Connor A, Kelly A, 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;23:180–182.
- 9 Cheshire N ES, Keagy B, Kolvenbach R, Leahy AL, Marston W, Pannier-Fischer F, Rabe E, Spitz GA. Powered phlebectomy (TriVex) in treatment of varicose veins. *Ann Vasc Surg* 2002;16(4):488–94.
- 10 Scavee V TS, Schoevaerdt J-C. Transilluminated powered mni-phlebectomy: early clinical experience. *Acta Chir Belg* 2001;101:247–249.