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A prospective randomised trial of PIN versus conventional stripping in varicose vein surgery

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A prospective, randomised trial was carried out to examine the efficacy of perforate invagination (PIN, Credenhill Ltd, Derbyshire, UK) stripping of the long saphenous vein (LSV) in comparison to conventional stripping (Astratech AB, Sweden) in the surgical management of primary varicose veins.

Eighty patients with primary varicosities secondary to sapheno-femoral junction (SFJ) incompetence and LSV reflux were recruited. Patients were randomised to PIN or conventional stripping with all other operative techniques remaining constant. Follow-up was performed at 1 and 6 weeks postoperatively.

There were no statistically significant differences between the two techniques in terms of time taken to strip the vein, percentage of vein stripped or the area of bruising at 1 week. The size of the exit site was significantly smaller with the PIN device ($P \leq 0.01$).

Optimal use of the conventional stripper provides results comparable to the PIN device. Choice of stripping device remains the surgeon's, bearing in mind that the PIN stripper achieves slightly better cosmesis.

Key words: Varicose vein surgery – Long saphenous vein stripping – Randomised trial.

Stripping of the LSV is an essential prerequisite in the successful treatment of primary varicose veins when incompetence is present.[1] Ensuring that the procedure of SFJ ligation and stripping is appropriate and effective can also help prevent recurrence and potential ulceration.[1,2]

Use of the conventional stripper has been criticised for several reasons.[3] Early re-usable designs had a large olive head, which inevitably caused tissue trauma as it was pulled down the leg. The large space created could then potentially allow the accumulation of blood clot despite adequate compression. Neuralgia and paraesthesia may also be caused from damage to the saphenous nerve, particularly when the vein was stripped to the ankle. Modifications of the conventional stripper have been sought to address these criticisms.

The PIN device is a rigid wire stripper. In contrast to the conventional stripper, the PIN uses an invagination method.[4] Proponents claim this technique causes less trauma to surrounding tissue as the vein inverts and,

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Table 1 Comparative data of LSV stripping

		Time taken	Length stripped	Exit wound	Bruising area
Conventional					
	Median	5.6 min	89.6%	0.6 cm	91.5cm^2
	IQR	4.5–8.2	67–100	0.5–0.7	68–153
PIN					
	Median	5.3 min	85.7%	0.4 cm	84cm^2
	IQR	4.4–9.4	52.5–100	0.4–0.5	54–167
	P	0.74	0.5	0.005	0.75

IQR, interquartile range: *P* values from Mann-Whitney U test.

therefore, reduces the incidence of postoperative haematoma, pain and leaves a smaller exit scar.[3,5] There have, however, been no randomised clinical trials to compare these two methods.

The aim of this study was to examine the efficacy of LSV stripping using the PIN stripper, in comparison to the optimal use of the conventional method, in terms of time taken to strip the vein, the length of vein stripped, the size of the exit wound and the area of bruising. Optimal use of the conventional stripper can be gained by using a small olive head, stripping from groin to knee, with retrieval of the stripper and head from the groin incision.

Patients and Methods

The study was a prospective, randomised trial performed in a dedicated vascular surgery unit of a University Teaching Hospital. Ethics Committee approval was obtained and informed consent given by each patient. Patients were recruited pre-operatively from the venous outpatients clinic. All had primary varicosities secondary to SFJ incompetence and LSV reflux was confirmed by duplex scanning. Patients were randomised to either the PIN device (43 patients) or conventional stripping (37 patients) using computer generated random numbers. The surgeons were informed of the result and, therefore, which procedure to use immediately prior to stripping. All other operative techniques remained constant. Every patient received pre-operative subcutaneous Clexane (20 mg; Rhône-Poulenc Rorer, Eastbourne, UK), peroperative intravenous Cefuroxime (750 mg; Glaxo Laboratories Ltd, Uxbridge, UK), and all were treated as day cases. Only one leg was operated on in each case and no short saphenous vein surgery was undertaken simultaneously on these patients.

On admission, the varicose veins were marked by a consultant vascular surgeon with the patient standing in an upright position. Peroperatively, the varicosities in the calf and the thigh were avulsed with Oesch hooks (Credenhill Ltd, Derbyshire, UK) through small stab incisions. The groin was dissected and the SFJ fully exposed. The LSV was divided and ligated from the femoral vein. Side branches were ligated with 2/0 vicryl (Ethicon, Edinburgh, UK). Following ligation of the LSV, the proximal end in the groin was secured with 2 clips. The procedure for use of the PIN stripper is described as follows. The stripper was fed down the length of vein to just below the knee. A double length of number 2 silk (Ethicon) was tied securely to the proximal end of the PIN. Another knot was created 2–3 cm above this in silk. The stripper was pulled through the distal incision until the upper knot has passed 2–3 cm down the proximal end of the LSV. The silk was finally secured to the proximal end of the LSV with further throws. As the stripper is rigid, the angled distal end is easily visualised subcutaneously just below the knee. A small incision can be made and the tip of the stripper is pushed out of the skin. Invagination is initiated by pulling the distal end of the stripper down and is continued until the proximal end, consisting of the silk knot and the inverted vein, is visible. They are removed by further gentle tension and the exit site is then closed with steri-strips along with the multiple avulsion sites. The groin site is sutured using a subcuticular technique.

The Vastrip conventional stripper used for the purpose of the study was a flexible, disposable device which had one straight and one spiral end. There is a choice of three olive heads (9, 12, 15 mm), of which the 9 mm was used in all cases. The stripper was threaded into the LSV and passed to just below the knee. A stab incision was made directly over the distal wire tip and the device pulled through enough to enable the olive head to be tied on to the LSV. The vein was then stripped from groin to knee. Following stripping both the conventional device and the head were retrieved from the groin in an attempt to reduce the need to enlarge the exit site.

The stripping process was timed using a stop clock from the point that the stripper was inserted into the

LSV until the device and the vein were retrieved. Once completed, the length of stripped vein and the distance from the groin incision to the exit site were measured. All patients had their wounds covered with Release non-adherent dressings (Johnson and Johnson, Texas, USA), and Panelast bandages (Lohmann, Germany) were worn for 1 week followed by grade II compression stockings for a further 5 weeks.

The patients returned to the clinic for an examination at 1 week postoperatively. At this point, the size of the exit site was measured. The exact area of bruising was determined by measuring the area traced onto transparent acetate.

Statistics

Data were treated as non-parametric. All statistical analysis was performed using the Mann-Whitney U test.

Results

Eighty patients (52 women, 28 men) were recruited for the study. The median age of the women was 41.5 years (interquartile range 23–70 years), and 56.5 years for the men (interquartile range 22–70 years). All patients attended for their surgery.

The time to strip the vein, the percentage of vein stripped, size of the exit site and area of bruising were used to compare the efficacy of the two strippers (Table 1). There were no significant differences between the two techniques in terms of time, completeness of vein stripped, and the area of bruising ($P > 0.05$). The use of the PIN stripper resulted in a smaller exit scar than the conventional stripper which was statistically significant ($P < 0.001$).

There were problems experienced when using the two devices. The rigid PIN exited the vein mid-thigh in 4 cases. Use of the conventional device resulted in an enlarged exit wound in 4 cases, which needed suturing. It was used unsuccessfully in one case where the stripping was completed by avulsing the LSV through stab incisions.

There were 8 cases of incomplete PIN stripping with 4 attempts to use the retriever. Two succeeded and 2 were completed by avulsing the LSV. It was not appropriate to use the retriever in 4 instances because there was no thread visible to tie on the device. Multiple avulsions of the LSV completed the stripping in these cases.

Four patients did not attend the one week postoperative appointment and were not available to measure the size of the exit site and area of bruising. Postoperative complications of the surgery were recorded in relation to the stripping procedure used (Table 2). In the group of patients where the PIN stripper was used (n = 43), there were 6 with superficial groin infections, 1 with calf paraesthesia (100% follow-up). In the group where the conventional stripper was used (n = 33, 4 patients missed this appointment), there were 2 cases of calf cellulitis, 2 patients with calf paraesthesia, 1 with a groin infection and 1 with thigh paraesthesia.

Table 2 Postoperative complications according to the stripper used

Complication	Conventional $n = 33$	PIN $n = 43$
Superficial groin infection*	1	6
Calf cellulitis	2	0
Calf paraesthesia	2	1
Thigh paraesthesia	1	0

*Not isolated by culture and sensitivity. Classified as 'infection' by the general practitioner and treated with oral antibiotic therapy.

Discussion

Stripping the LSV is important in the modern surgical treatment of SFJ and LSV incompetence, as it reduces recurrence.[6] Evidence for this is examined in a study by Sarin *et al.* where stripping of the LSV and SFJ ligation was compared with high tie alone.[6] Forty-six limbs were treated with SFJ ligation alone. At 21 months, 8 had no signs of clinical recurrence in comparison to 28 out of the 43 limbs treated with an additional LSV strip ($P < 0.001$).

The importance of stripping the LSV is still questioned by some surgeons who consider the incidence of postoperative morbidity to be unacceptably high. The risk of neuralgia and paraesthesia associated with stripping can be significantly reduced. Stripping the LSV to the ankle can cause nerve damage and is no longer necessary.[7] Stripping to below the knee is less likely to interfere with the nerve and can be just as effective.[2]

However, another often cited argument for leaving the LSV intact is that stripping removes a possible conduit for future bypass surgery. Sutton and Darke concluded by using peroperative retrograde saphenography, that 65% of LSVs were too damaged to be used for coronary bypass surgery.[8] Veins harvested from the arm can provide a suitable alternative,[9] along with the internal mammary and radial arteries in coronary bypass surgery.

Previous papers have reported good results when using the PIN device and one may have presumed it

would compare favourably to conventional methods of stripping.[4,5] In fact, the conventional device can be just as effective as the PIN. Returning the head through the groin can leave a smaller scar in comparison to removing the olive from the distal incision. In 1993, Beam and Fox reported a non-randomised study for 3000 cases in which they endorsed the method as safe and noted a reduced incidence of large scars.[10]

The flexible conventional stripper is easier to thread down the vein and strip a more complete length. In the study, this flexibility was not always advantageous, as it was more difficult to find the distal end through the exit site. This may explain why in comparison the PIN stripper still achieves slightly better cosmesis at the exit site (median size of wound 0.4 cm).

Obviously there is a case for stripping the LSV but controversy exists over which method causes less complications. Staelens and Van der Strict described a different method of invagination stripping where they successfully removed the LSV without the use of a stripper.[3] This technique was carried out on 1,300 patients. A guide wire was inserted into the vein and then replaced by a nylon thread in a method similar to PIN stripping. The LSV was removed causing less damage to surrounding tissue. This anecdotal paper evaluated the technique without comparison to any other and as such is difficult to interpret.

Conrad and Gassner have reported the use of the PIN stripper. They treated 100 legs in a method described previously. A postoperative subjective assessment of the patients compared this to the authors past experience of using the conventional stripper. At 26 days there were no complications such as haematoma, infection, neuralgia. In a retrospective comparison, the author claimed it caused less bruising than conventional methods.[5]

Our randomised, prospective study has shown that the optimal use of a conventional stripper can match the results achieved with the PIN device. Stripping from groin to knee and returning the olive of the conventional stripper through the groin can leave a smaller scar in comparison to removing the olive from the distal incision. However, in our study the PIN device achieved slightly better cosmesis at the exit site (median size of wound 0.4 cm).

In terms of cost, the conventional stripper is disposable and costs £2226 for 300 operations involving stripping. If three PIN strippers and one retriever were purchased for this period of time, there would be no extra costs for reprocessing if they were re-sterilised with the varicose vein set or using the autoclave in the theatre suite. The instruments cost £733 and can theoretically be re-used for many years. If the instruments are re-sterilised separately there is a potential cost of £1725 which, including the instruments, brings the total to £2458. If they are re-sterilised together this figure is reduced to £2233. How the equipment is resterilised is, therefore, of paramount importance in deciding which method is the most cost effective.

Conclusion

There appears to be no significant difference at 1 week between PIN verses conventional stripping, apart from a slightly smaller exit wound when the PIN device was used. The PIN stripper could also be more cost effective. Therefore, the stripping device used remains the surgeon's choice based on personal preference and clinical judgement.

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