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Local Anaesthetic Flush Reduces Postoperative Pain and Haematoma Formation After Great Saphenous Vein Stripping—A Randomised Controlled Trial

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Objectives. *To observe the effect of local anaesthetic flush through the great saphenous vein (GSV) tunnel on postoperative pain and haematoma formation following saphenous vein stripping operations.*
Design. *Prospective, double-blind, randomised, control trial.*
Methods. *One hundred patients were randomized to receive 20 ml of local anaesthetic (bupivacaine 0.25% + adrenaline) or saline control flush through the GSV tunnel after stripping in a double-blind study. Visual analogue pain scores were used to measure postoperative pain daily for the 1st week, then at 3 weeks and 6 weeks. Patients were examined during the 1st, 3rd and 6th week for haematoma formation.*
Results. *In the control group the median postoperative pain score was 4 (range 0–7) in the immediate postoperative period compared to a median of 1 (range 0–4) in the LA group* ($p < 0.001$). *The median pain score on day-4 was 4 (range 1–6) (control)* vs. *1 (range 0–3) (LA group)* ($p < 0.001$, *Mann–Whitney* U*test) and on day-6 it was 1 (range 0–5) (control)* vs. *0 (range 0–5) (LA group)* ($p < 0.001$, *Mann–Whitney). Twelve patients (24%) developed a haematoma in the GSV tunnel in the control group compared to three patients (6%) in the LA group* ($p = 0.007$).
Conclusion. *Flushing of the GSV tunnel with bupivacaine plus adrenaline significantly reduces postoperative pain and haematoma formation in patients undergoing GSV stripping for varicose veins.*

Keywords: Varicose veins; Bupivacaine; Long saphenous tunnel; Haematoma; Postoperative pain control; Saphenous vein stripping.

Introduction

Stripping of the great saphenous vein is an integral part of the treatment of patients with sapheno-femoral reflux. It significantly reduces the incidence of recurrent varicosities.[1] Major postoperative complications are uncommon,[2,3] however, minor complications including infection, ecchymosis, abscess and haematoma formation are seen in up to 17% of patients.[2] Thigh haematoma formation, leading to extensive bruising and postoperative pain, is a well documented complication which may occasionally result in readmission to hospital.[4,5] The reported incidence of thigh haematoma after varicose veins surgery is as high as 39%.[6]

Local anaesthetic infiltration of the groin wound is commonly used for postoperative pain relief in varicose veins operations. However, the effect of local anaesthetic flush through the long saphenous tunnel on postoperative pain and haematoma formation has not been previously studied.

The purpose of our study was to observe the effect of local anaesthetic flush through the great saphenous vein tunnel on postoperative pain and haematoma formation following vein stripping. We introduce a simple technique of local anaesthetic flush through the great saphenous tunnel.

Patients and Methods

This trial was carried out at a regional vascular centre, the Mid-Western Regional and St John's Hospitals, Limerick. Regional ethical committee approval was sought and granted for this study. Written informed consent was obtained from all patients recruited into the study. Varicose veins were defined according to reporting standards in venous disease.[7] Patients were

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Table 1. Demographics and patient characteristics

	LA group ($n=50$)	Controls ($N=50$)
Demographic characteristics		
Age (mean (SD))	54 (11.4)	49 (10)
Sex (% male)	34%	40%
Clinical characteristics		
% Symptomatic	84%	76%
Clinical grade*, median (range)	2 (0–4)	2 (0–4)
C0	3s	7s
C1	2s	1s
C2	35 (27s, 8a)	38 (26s, 12a)
C3	2s	1s
C4	8s	3s
C5	0	0
C6	0	0
Etiology* (*n* primary)	50	50
Pathology* (*n* reflux)	50	50
Anatomical distribution* (*n* superficial)	50	50
Above knee	5	3
Below knee	40	39
No visible varicosities	5	8

* CEAP classification: C, clinical signs (grade: 0–6), supplemented by (s) for symptomatic and (a) for asymptomatic presentation; E, etiologic classification (congenital, primary, secondary); A, anatomic distribution (superficial, deep, or perforator, alone or in combination); P, pathophysiologic dysfunction (reflux or obstruction, alone or in combination).

classified according to the CEAP system[7] (Table 1). Inclusion criteria were adults with primary varicose veins secondary to great saphenous vein incompetence proven by clinical or colour duplex ultrasound examination. The clinical examination included the Trendelenburg test and hand held continuous wave Doppler. If the clinical examination was inconclusive a colour duplex scan of the leg was performed. Patients with previous groin surgery, secondary or recurrent varicose veins, isolated or concomitant saphenopopliteal incompetence, ASA grade greater than 3 and those with active ulceration were excluded. Information on the trial was posted to the patients on the waiting list one to 2 weeks preoperatively and informed consent obtained on admission to hospital.

Sample size was calculated prior to commencement of the trial. In order for the study to have 80% power to detect a difference of 30% in the postoperative visual analogue pain scores between the two groups, 45 patients per group were required, with a two-sided significance level of 0.05.

One hundred patients were recruited to the study between March and September 2002. The patients were randomised into two equal groups; a local anaesthetic (LA) group who received standardised local anaesthetic solution (20 ml of bupivacaine 0.25% with adrenaline 1:200,000; Marcaine®, AstraZeneca, Dublin, Ireland) and a control group who received 20 ml of normal saline.

Randomisation was by a sealed envelope method. Envelopes were opened at the time of surgery by the circulating theatre nurse in the anaesthetic room and either 20 ml of saline or 20 ml of bupivacaine with adrenaline was prepared accordingly. The patient, operating surgeon, assistant surgeon and scrub nurse were unaware of which solution was being used to flush the GSV tunnel. The theatre nursing staff recorded the patient's name, chart number and type of solution used and the envelope was resealed. These envelopes were reopened at the end of the trial to reveal which patients had received which solution.

Anaesthesia

All procedures were carried out under standardised general anaesthesia. All the patients received similar preoperative, intraoperative and postoperative analgesia. All patients received celecoxib 200 mg orally as premedication and fentanyl 0.15 mg/kg, morphine 0.1 mg/kg and cyclizine 50 mg intravenous at induction. Anaesthesia was maintained by ventilation with oxygen in nitrous oxide supplemented by isoflurane. Postoperatively, all patients received standardised take home analgesia in the form of paracetamol 1 g orally 6-hourly and codeine phosphate 60 mg 6-hourly.

Surgical technique

All the surgical procedures were standardised and carried out in the same sequence by the two senior vascular surgeons or under their direct supervision.

After flush ligation of the sapheno–femoral junction, the great saphenous vein was stripped from the groin to just below the knee using a conventional (Babcock type) stripper (Braun Venostrip®, Germany) with a standardised medium head. After vein stripping, the feeding tube was attached to the end of the stripper and drawn up through the groin wound (Fig. 1). At this stage the groin wound was covered with a swab and hook avulsions of below knee varicosities were carried out through small stab wounds which were later closed with SteriStrips® (3M Health Care, Germany). The thigh was then milked five times (standardised) from below upwards to remove any tunnel haematoma. Twenty millilitres of solution was flushed evenly through the feeding tube as it was withdrawn along the length of the GSV tunnel from the groin to below the knee (Figs. 1 and 2).

The groin wound was then closed in two layers. A separate local anaesthetic was injected into the skin

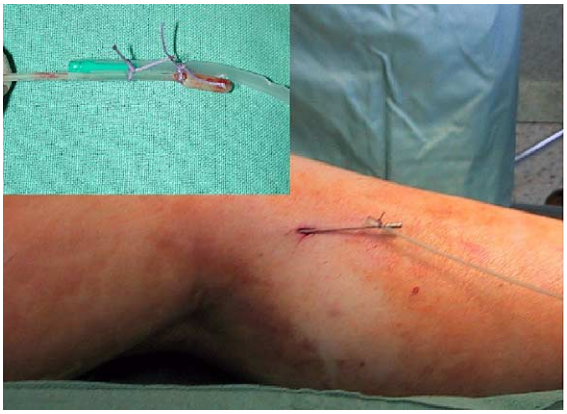

Fig. 1. Feeding tube tied to the end of the stripper (inset) and being pulled up retrograde through the GSV tunnel after stripping.

around the groin wound in all one hundred patients irrespective of their group. After completion of the wound closure, a standardised compression dressing (Netlast® Bastos, Viegas S.A., Portugal) (CoPlus®, Smith and Nephew, Hull, UK) was applied. Postoperative dressings were replaced with TED stockings after 3 days and worn for 6 weeks.

Postoperative visual analogue pain score was the primary outcome variable. Other variables included presence or absence of thigh haematoma on clinical examination and analgesic intake. Severity of postoperative pain was determined on a subjective 10 cm visual linear analogue pain scale (1 = no pain and 10 = worst possible pain). Pain scores were taken in the immediate postoperative period before discharging the patient (a mean of three scores over 6 h). Pain scores were then recorded on days 1–7 and at 3 and 6 weeks postoperatively. Patients were given a diary to keep a note of their maximum daily pain scores, frequency of analgesic intake for the 1st week and details of any visits to their general practitioners related to the surgery. These diaries were returned at clinical review 6 weeks postoperatively.

Fig. 2. Feeding tube in the GSV tunnel and the flush solution being distributed into the tunnel as the feeding tube is being withdrawn. Superficial varicosities are marked.

Analgesic use was scored according to frequency of analgesic requirement; none = 0, occasional (less than twice) = 1, frequent/regular (more than twice) = 2. Patients were examined in the outpatients department by an independent observer blinded to the study at the 1st, 3rd and the 6th week postoperatively for the presence of haematoma in the GSV tunnel. Thigh haematoma was defined as a palpable swelling in the thigh noted on first follow-up visit.

Statistical Analysis

For both postoperative pain score and frequency of analgesia the area under the curve (AUC) was calculated and used as a suitable summary measure of the average effect.[8] As age was found to differ significantly between the groups (54 *vs.* 49 years), differences in AUC between groups were compared using linear regression, in order to estimate the effect of treatment after adjustment for the effect of age. For postoperative pain score, as the result of the analysis of the AUC was significant and age was not found to be significantly related to the outcome, the Mann–Whitney *U*-test was used post hoc to explore differences between the groups at each time-point. For the postoperative frequency of analgesia, as both group and age were significantly related to postoperative pain score AUC, ordinal logistic regression was used to explore the difference between groups at each time period. This allowed for the effect of each group to be evaluated after adjustment for age. All tests were two-sided and the analysis was conducted using SPSS for windows version 11.0.1.

Results

One hundred patients participated in the study. There were 63 women and 37 men. The patient characteristics and demographics in the two groups are given in the Table 1. The flow diagram shows the patients at stage of the trial (Fig. 3). Out of the 100 patients, 99 had their surgery as day cases and only one patient required an overnight stay due to anaesthetic complications. None of the patients were excluded from the trial after randomisation. Four patients did not attend

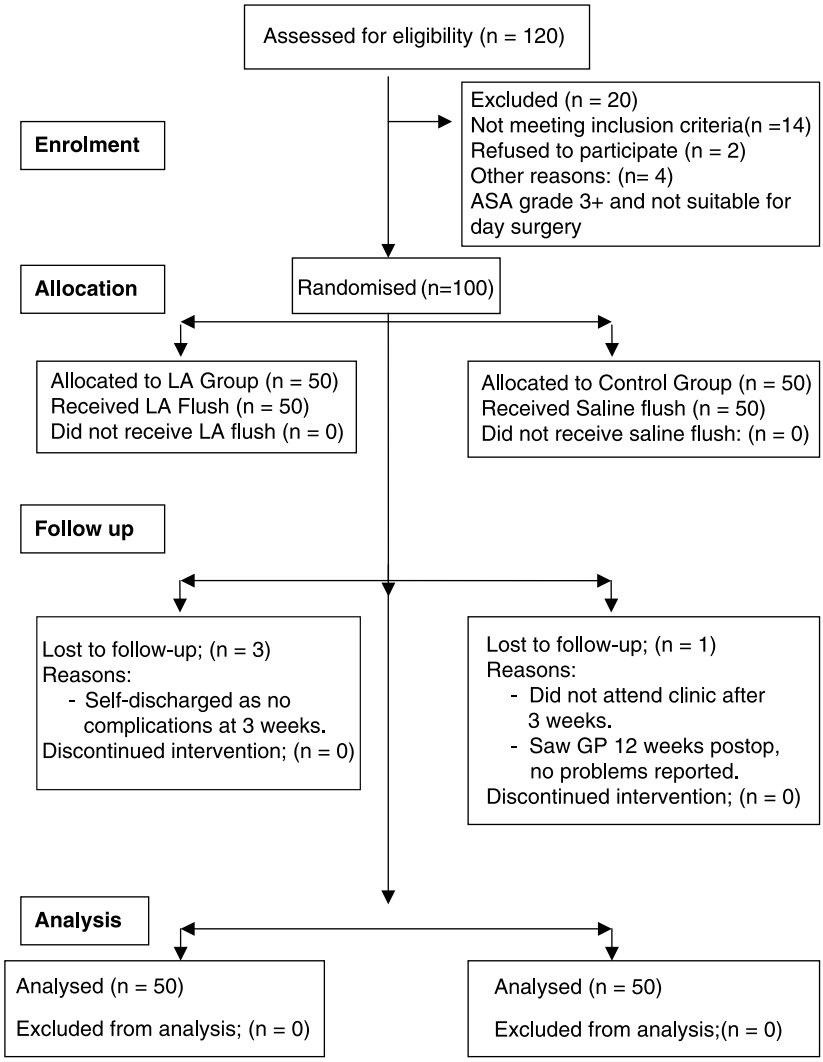

Fig. 3. Flow diagram showing patients at each stage of the trial.

for final follow up at 6 weeks, however, none of these patients showed any complications on their last visit at 3 weeks postoperatively.

Using area under the curve (AUC) as a measure of the average effect, the median and confidence intervals showed significant difference between the two groups both in terms of postoperative pain scores as well as analgesic intake (Table 2, Figs. 4 and 5). The postoperative visual analogue pain scores at each time point also differed significantly across the two groups during the 1st week achieving statistical significance ($p < 0.001$, Mann–Whitney U-test). There were no significant differences in the pain scores between the two groups after the 1st week (Table 3).

The analgesic requirement at each time point was also significantly reduced in the LA group during

Table 2. Results

	LA group	Controls	*P*-value for the difference
Postoperative pain AUC (median (range))	6.8 (0.0–77)	26 (13–87)	<0.001*
Postoperative analgesia AUC (median (range))	6.5 (2.5–16)	18 (4.5–46)	<0.001*
Haematoma in the GSV tunnel (proportion)	3 (0.06)	12 (0.24)	0.007†

* Linear regression, after adjustment for age.
† Logistic regression, after adjustment for age.

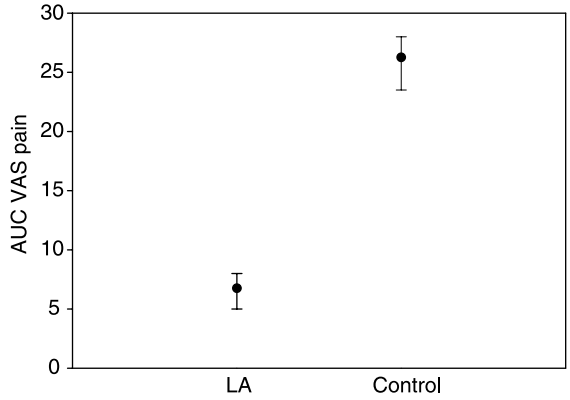

Fig. 4. AUC VAS pain, median and confidence interval (Gardner and Altman, 2002)[14].

the 1st week whereas the controls consumed significantly larger amounts of analgesia ($p<0.001$, ordinal logistic regression adjusted for age). There was no difference in the analgesic consumption after the 1st week (Table 4). Cramer's *V*-test for strength of association gave values ranging from 0.48 to 0.59 indicating reasonably strong evidence that the treatment reduces the need for analgesia.

Fifteen patients (15%) developed a haematoma in the GSV tunnel, 12 (24%) in the control group *vs.* three (6%) in the LA group ($p=0.007$, Chi-square test). Despite a statistically significant difference between treatment and control groups, Cramer's *V*-test for strength of association was 0.252 indicating quite a weak association. This is because there were only 4.5 fewer haematomas in the treatment group than expected by chance (7.5−3). All of the haematomas resolved with conservative treatment.

No adverse effects of local anaesthetic flush were found in our patients.

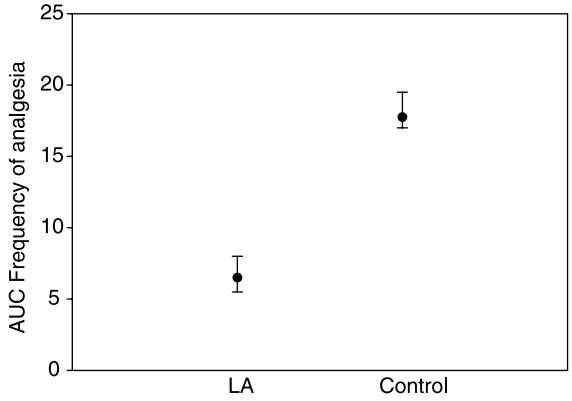

Fig. 5. AUC frequency of analgesia, median and confidence interval (Gardner and Altman, 2002)[14].

Table 3. Median postoperative pain scores at each time point (VAS scale 1–10)

	LA group (median (range))	Controls (median (range))	*P*-value*
Immediately post-op	1 (0–4)	4 (0–7)	<0.001
Day 1	1 (0–4)	4.5 (0–6)	<0.001
Day 2	1 (0–3)	4 (2–6)	<0.001
Day 3	1 (0–3)	4 (2–6)	<0.001
Day 4	1 (0–3)	4 (1–6)	<0.001
Day 5	0 (0–4)	2 (0–5)	<0.001
Day 6	0 (0–5)	1 (0–5)	<0.001
Day 7	0 (0–7)	0 (0–5)	0.01
Week 3	0 (0–3)	0 (0–1)	0.28
Week 6	0 (0–1)	0 (0–0)	0.31

* Mann–Whitney *U*-test.

Discussion

Postoperative pain and thigh haematoma formation are causes of significant postoperative morbidity after GSV stripping. Local anaesthetic is commonly injected subcutaneously in surgical wounds for control of postoperative pain. However, the infiltration of groin wound with local anaesthetic does not provide good pain relief for thigh discomfort after GSV stripping. In our study, we flushed the GSV tunnel with a combination of bupivacaine and adrenaline which significantly reduced pain in the study group in the immediate post operative period (median 4 *vs.* 1) $p<$ .001. The median pain score was significantly different in the two groups during the first postoperative week. There was also a significant difference in the requirement of oral analgesia following discharge from hospital between the two groups achieving statistical significance ($p<0.001$ on days 1–6).

Surgery for varicose veins may cause significant bleeding, occasionally requiring blood transfusion.[4]

Table 4. Median frequency of analgesia at each time point (0=none, 1=one or two, 2=more than 2)

	LA group (median (range))	Controls (median (range))	*P*-value*
Immediately post-op	1 (0–2)	2 (0–2)	<0.001
Day 1	1 (0–2)	2 (1–2)	<0.001
Day 2	1 (0–2)	2 (1–2)	<0.001
Day 3	1 (0–2)	1.5 (1–2)	<0.001
Day 4	1 (0–2)	1 (0–2)	<0.001
Day 5	0.5 (0–2)	1 (0–2)	<0.001
Day 6	0 (0–2)	1 (0–2)	<0.001
Day 7	0 (0–1)	1 (0–2)	<0.001
Week 3	0 (0–0)	0 (0–1)	†
Week 6	0 (0–0)	0 (0–0)	†

* Ordinal logistic regression, adjusted for age.
† Not possible to calculate as the value was a constant (0) in both groups.

Such bleeding can lead to bruising and thigh haematoma formation and may contribute to postoperative pain and a poor cosmetic result. Various techniques have been suggested to minimise these complications. In a series of 1000 patients, Coget and Millien looked at different factors responsible for postoperative haematoma formation. Besides stripping techniques, patient factors and general anaesthesia, injection of xylocaine and adrenaline was an important factor in reducing bleeding from the perforating veins.[5] Local tumescent anaesthesia has shown similar advantages in terms of reduced postoperative pain, analgesia requirement and haematoma formation,[9] however, accurate tumescent anaesthesia requires ultrasound guidance and is time consuming. Our method of direct infiltration of the saphenous vein tunnel appears to show the same benefits but is much cheaper and simpler.

Other techniques have been reported to reduce the blood loss during varicose vein surgery ranging from preoperative compression hosiery[5] to PIN stripping[6,12] and use of thigh tourniquet.[10,11] In a prospective, randomised trial on the use of a tourniquet involving 50 patients, Sykes[11] reported less peroperative blood loss, less operative time and thigh bruising, but there was no difference in pain and activity scores in the two groups and cosmetic results were also similar. The postoperative thigh bruising was 72 cm^2 in the tourniquet group compared to 179 cm^2 in the no tourniquet group. However, the use of tourniquet has certain disadvantages. It is not only cumbersome to use but can be hazardous in the presence of underlying atheromatous disease.[4]

Butler *et al.* showed that the PIN stripper does not reduce the incidence of thigh haematoma.[12] In a randomized controlled trial they showed that 24% of patients developed haematoma after conventional stripping compared to 35% in the PIN stripping group. Kent *et al.* did show small reduction in haematoma formation using Tm 99 labelled red cells from 39 to 36% with PIN stripper.[6]

Use of postoperative compression has been shown to reduce the incidence of subcutaneous haematoma formation and improved cosmesis.[13]

In our study, we 'milked' the saphenous vein tunnel after stripping to remove the fresh haematoma and then flushed the tunnel with bupivacaine and adrenaline in the study group. The safety of adrenaline has previously been proven in studies using the tumescent anaesthesia technique with the rate of haematoma decreased to nil and rate of hyper pigmentation falling from 3.6 to 0% with the use of adrenaline.[9]

Our technique had a significant haemostatic effect as evidenced by the lower incidence of thigh haematoma in the study group ($n=3$) compared to the control group ($n=12$) ($p=0.007$), however, the relatively weak strength of association indicates that a trial with larger numbers may be more convincing of this therapeutic benefit. A standardized compression dressing was used in both the groups in our study, however, it did not reduce the haematoma formation among controls which was comparable to results in the literature (24%).

Conclusion

This study suggests that flushing of the GSV tunnel with bupivacaine plus adrenaline significantly reduces postoperative pain and haematoma formation, and should be considered in all patients undergoing GSV stripping for varicose veins.

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References

1 Bergan JJ. Saphenous vein stripping and quality of outcome—leading article. *Br J Surg* 1996;**83**:1025–1027.
2 Critchley G, Handa A, Maw A, Harvey A, Harvey MR, Corbett CR. Complications of varicose vein surgery. *Ann R Coll Surg Engl* 1997;**79**:105–110.
3 Miller GV, Lewis WG, Sainsbury JR, Macdonald RC. Morbidity of varicose vein surgery: Auditing the benefit of changing clinical practice. *Ann R Coll Surg Engl* 1996;**78**:345–349.
4 Rehman A, Rallapalle VSP, Iqbal R, Grimley RP, Jayatunga AP. A simple technique to reduce blood loss and improve cosmesis in varicose veins surgery. *Phlebology* 1998;**13**:153–156.
5 Millien JP, Coget JM. Complications of superficial venous surgery of the legs: thigh haematomas and abscess. *Phlebologie* 1993;**46**:583–590.
6 Kent PJ, Maughan J, Burniston M, Nicholas T, Parkin A, Robinson PJ. Perforation-invagination (PIN) stripping of the great saphenous vein reduces thigh haematoma formation in varicose vein surgery. *Phlebology* 1999;**14**:43–47.
7 Porter JM, Moneta GL. Reporting standards in venous disease: an update. International Consensus Committee on Chronic Venous Disease. *J Vasc Surg* 1995;**21**:635–645.

8 Matthews JNS, Altman DG, Campbell MJ, Royston JP. Analysis of serial measurements in medical research. *BMJ* 1990; **300**:230–235.
9 Keel D, Goldman MP. Tumescent anesthesia in ambulatory phlebectomy: Addition of epinephrine. *Dermatol Surg* 1999;**25**: 371–372.
10 Corbett R, Jayakumar KN. Clean up varicose vein surgery—use of a tourniquet. *Ann R Coll Surg Engl* 1989;**71**:57–58.
11 Sykes TC, Brookes P, Hickey NC. A prospective randomised trial of tourniquet in varicose vein surgery. *Ann R Coll Surg Engl* 2000; **82**:280–282.
12 Butler CM, Coleridge-Smith PD, Scurr JH. Inverting stripping *versus* conventional stripping of the great saphenous vein. *Phlebology* 1995;**10**:128.
13 Travers JP, Rhodes JE, Hardy JG, Makin GS. Postoperative limb compression in reduction of haemorrhage after varicose vein surgery. *Ann R Coll Surg Engl* 1993;**75**:119–122.
14 Altman DG, Machin D, Bryant TN, Gardner MJ, eds. *Statistics with confidence*. 2nd ed London: BMJ Books: 2000.

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