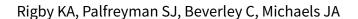


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## **Surgery for varicose veins: use of tourniquet (Review)**



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## TABLE OF CONTENTS

HEADER	1
ABSTRACT	1
PLAIN LANGUAGE SUMMARY	2
BACKGROUND	3
OBJECTIVES	3
METHODS	3
RESULTS	4
DISCUSSION	6
AUTHORS' CONCLUSIONS	6
ACKNOWLEDGEMENTS	6
REFERENCES	7
CHARACTERISTICS OF STUDIES	8
ADDITIONAL TABLES	12
APPENDICES	13
WHAT'S NEW	16
HISTORY	17
CONTRIBUTIONS OF AUTHORS	17
DECLARATIONS OF INTEREST	17
SOURCES OF SUPPORT	17
INDEX TERMS	18



#### [Intervention Review]

## Surgery for varicose veins: use of tourniquet

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#### **ABSTRACT**

#### **Background**

Varicose vein surgery is a common surgical procedure but there is no consensus regarding the best surgical technique. The use of tourniquets during varicose vein surgery has been advocated as a means of reducing the potential for blood loss during the operation.

#### Objectives

To identify whether the use of a tourniquet should be recommended when undertaking surgery for the management of primary varicose veins

#### **Search methods**

For this update the Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator searched the Specialised Register (last searched April 2013) and the CENTRAL (2013, Issue 3).

#### **Selection criteria**

All studies described as randomised controlled trials that examined the use of tourniquets during surgery for patients with primary varicose veins were included.

## **Data collection and analysis**

Data from eligible studies were extracted and summarised independently by two authors. All studies were cross-checked independently by the authors.

#### Main results

No additional studies were included or excluded in the updated review. Twenty papers detailing 18 trials were considered. Only three trials were randomised controlled trials and were included in the review. The remaining fifteen studies were excluded for various reasons. All three included trials had a small sample size and reported the trial design, outcome measures and analysis poorly. There were also variations in the outcome measures used between the trials. In addition, there was no consistency on the reporting of mean and medians for blood loss during the operation. It was therefore not possible to pool the data to perform meta-analysis. However, the reported blood loss when using a tourniquet was between 0 and 16 ml compared to between 107 to 133 ml when not using a tourniquet (P < 0.01).



#### **Authors' conclusions**

Although there were significant quality issues with the available evidence, the use of a tourniquet would appear to reduce blood loss during surgery. There were no reported differences between the use or non-use of a tourniquet in terms of complications and morbidity. However, the available trials were not of sufficient size to detect rarer complications such as nerve damage.

#### PLAIN LANGUAGE SUMMARY

#### Use of a tourniquet during surgery for varicose veins

Varicose veins are obvious, dilated veins just under the skin. In normal veins the valves make sure blood only moves in one direction. The valves in varicose veins are faulty, allowing blood to pool and the veins to enlarge. This can cause aching legs, itching and poor cosmetic appearance. People with varicose veins may wear compression stockings, have an injection of irritant substance to close the veins under the skin (sclerotherapy), or have the veins removed surgically. There is a potential for large blood loss during surgery, especially if both legs are operated on at the same time. Tourniquets on the upper leg during surgery may be useful to minimise blood loss.

This review found that the amount of blood loss was clearly reduced when a tourniquet was used during surgery for varicose veins, with no overall increase in operative time, reported adverse events or change in patient reported pain and activity after surgery. Three trials were included in the review, in which a total of 176 men and women (211 legs) were randomised to either use or non-use of a tourniquet. All trials took place in the UK between 1989 and 2000. Those patients who did not have a tourniquet had a wider range of total blood loss and patients in the upper limits lost a significant amount of blood. A reduction in blood loss may also result in a reduction in post-operative bruising but only one of the trials (50 patients) looked at this. It found a clear reduction in the area of bruising with the use of a tourniquet. The trials did not have a large enough number of participants to determine any rarer complications of surgery with the use of a tourniquet such as nerve damage or arterial injury, especially in older patients.



#### BACKGROUND

In the adult population, the age-adjusted prevalence of trunk varices (varicose veins of the deep veins of the legs) has been estimated as 40% in men and 32% in women (Evans 1999). Varicose veins account for 50,000 in-patient hospital episodes per year in England alone (London 2000). Primary varicose veins are due to valvular failure. Treatment for primary varicose veins is considered appropriate if the veins are symptomatic (NICE 2001). Common symptoms attributable to varicose veins include aching, itching and poor cosmesis (cosmetic appearance). Less common, but more serious, symptoms include haemorrhage and thrombophlebitis (inflammation of a vein with accompanying formation of a blood clot).

There are a variety of treatments available for varicose veins including compression stockings, injection sclerotherapy (injection of an irritant substance), as well as surgical methods of treatment. Many surgical treatments are practiced. These may involve ligation (tying) of the affected vein (long or short saphenous veins), stripping of the affected trunk veins and avulsions (removal) of the varicosities (dilated segments). Some surgeons use a combination of surgery and injection sclerotherapy. Newer surgical treatments include subfascial ligation and pin stripping. Subfascial ligation is a procedure that involves cutting through the skin and deep fascia (a sheet of connective tissue) and tying off the incompetent perforating veins that link the veins in the skin to the deep veins in the muscle. PIN-stripping (Perforate INvaginate stripping) is a technique that involves stripping the vein into itself in a manner similar to turning a stocking inside out. This results in a smaller exit wound. However, there is no consensus as to which is the best surgical technique to treat varicose veins.

The most common surgical operation is ligation of the sapheno-femoral vein, stripping of the long saphenous vein (LSV) and avulsions. The operation can be associated with significant blood loss, especially if it is a bilateral procedure. Tourniquets have been used as a means to exsanguinate (remove all blood from) limbs where there can be a risk of significant blood loss such as in orthopaedic surgery (Wakankar 1999), and arterial bypass surgery (Eyers 2000). There are potential problems with the use of tourniquets on lower limbs including thrombosis (Kumar 1998), and nerve damage (On 2000). The nature of varicose vein surgery is such that the potential for blood loss could be significant and this has led to some authors advocating the use of tourniquets (Farrands 1987; Robinson 2000; Sykes 2000).

There are a number of potential tourniquets in widespread use; these include the Rhys-Davies Cuff and Lofquist cuff. The Rhys-Davies cuff was developed as a means for exsanguination of limbs during orthopaedic operations (Rhys-Davies 1985). The Lofquist cuff, also known by its manufacturers name the Boazal cuff, is a pneumatic tourniquet originally invented by Dr. Johan Löfqvist.

#### **OBJECTIVES**

To determine whether the use or non-use of tourniquet has any effect on the outcomes of varicose vein surgery, including blood loss and operative time.

#### **METHODS**

## Criteria for considering studies for this review

#### Types of studies

All randomised controlled trials that evaluate the use of a tourniquet in varicose vein surgery.

#### **Types of participants**

All patients having surgery for primary varicose veins. Those treated for cosmesis and also for symptomatic varicose veins (ache, itch, etc.) were included. It was intended to include sub-group analysis according to the severity and symptomology of the veins. It is hoped that future updates of this review will include such information from any identified studies.

Trials including patients undergoing treatment for the complications of varicose veins, venous ulceration and chronic venous insufficiency were excluded.

#### Types of interventions

All types of tourniquets used in varicose vein surgery compared to not using a tourniquet.

#### Types of outcome measures

#### **Primary outcome**

1. Blood loss: total blood loss during varicose vein surgery.

## **Secondary outcomes**

- 1. Operative time: the total operative time was examined to assess the impact of using tourniquets.
- Complications and morbidity: the complications and morbidity
  associated with the use or non-use of tourniquets was
  examined. Common complications were identified and
  compared between use of and non-use of tourniquets and
  between different types of tourniquet. It was envisaged
  that potential complications could include nerve damage,
  ischaemia, bruising and pain.
- Patient satisfaction and quality of life (QoL) data: Quality of life assessment using either generic or disease specific measures was analysed, where included.
- 4. Economic analysis: It was intended to include cost-effective analysis and resource usage.

## Search methods for identification of studies

The search aimed to identify all papers relating to the use of tourniquets in surgical interventions for varicose veins.

For the original (2002) review where possible (e.g. in the smaller databases), searches were not restricted by publication type or study design. However, methodological filters aimed at identifying guidelines, systematic reviews and clinical trials were applied in the larger databases such as MEDLINE. Date and language restrictions were not used.

## **Electronic searches**

## 2013 searches

For this update the Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator (TSC) searched the Specialised



Register (last searched April 2013) and the Cochrane Central Register of Controlled Trials (CENTRAL) 2013, Issue 3, part of *The Cochrane Library*, (www.thecochranelibrary.com). See (Appendix 1) for details of the search strategy used to search CENTRAL. The Specialised Register is maintained by the TSC and is constructed from weekly electronic searches of MEDLINE, EMBASE, CINAHL, AMED, and through handsearching relevant journals. The full list of the databases, journals and conference proceedings which have been searched, as well as the search strategies used are described in the (Specialised Register) section of the Cochrane Peripheral Vascular Diseases Group module in *The Cochrane Library* (www.thecochranelibrary.com).

#### 2001 searches

For the original review the authors searched 13 electronic bibliographic databases covering biomedical science, social science, health economic and grey literature (including current research). Various health services research related resources were consulted via the Internet. These included health economics and HTA organisations, guideline producing agencies, generic research and trials registers, and specialist sites. The searches were originally conducted during April 2000, although the major database searches were re-run in October 2000 and March 2001. Further details are given in Table 1; Table 2; Appendix 2; Appendix 3; Appendix 4 and Appendix 5.

## **Searching other resources**

The reference lists of relevant articles were checked.

#### Data collection and analysis

#### **Selection of trials**

Two authors (KR, SP) independently assessed and selected trials for inclusion to the review. Suitability for inclusion was determined on the basis of the inclusion and exclusion criteria. Any disagreements were adjudicated by a third author (CB). Where data were missing, authors were contacted to provide additional details.

#### **Methodological quality**

The quality of the studies was assessed by examining the following areas which have been shown to be indicators of trial quality:

- 1) comparability of groups in control and intervention arms at baseline,
- 2) the analysis of results on an intention-to-treat basis,
- 3) completeness of follow-up,
- 4) the blinding and objectivity of outcome assessment,
- 5) the appropriateness and completeness of statistical analysis of results.

#### **Data extraction**

Data from the trials were extracted by KR and SP independently and then cross-checked for agreement. Any disagreements were arbitrated by JAM. The following data were extracted where possible:

- · method of randomisation,
- criteria for participant inclusion and exclusion,
- · details of types of tourniquet and surgery,
- duration of surgery,

- patient characteristics,
- number of participants assigned to each treatment group,
- number of participants with co-morbid conditions,
- baseline comparability of treatment groups,
- outcome measures including blood loss, operative time, complications and morbidity, patient satisfaction and QoL data,
- · economic analysis,
- · blinding,
- number of participants withdrawn and reasons for withdrawal.

#### Statistical analysis

It was our intention to perform meta-analysis where sufficient homogeneity was found and to test for heterogeneity using subjective clinical judgement and the Chi-square test. However, as the data were not homogeneous, meta-analysis was not performed.

#### RESULTS

#### **Description of studies**

#### Results of the search

#### 2013 searches

See (Appendix 1).

No additional studies were found for Inclusion or Exclusion as a result of the 2013 searches.

#### 2001 searches

Full copies of 20 papers were screened from the search results.

#### **Included studies**

Summary details of included studies are given in the Characteristics of included studies table. Only three trials were suitable for inclusion in the review (Corbett 1989; Sykes 2000; Thompson 1990). One study identified from the National Research Register (Hickey 1998), was subsequently published and included in the review (Sykes 2000) together with a further duplicate publication of this study (Sykes 1999).

Corbett 1989 was a trial undertaken in a district general hospital in the UK. The study involved 26 participants and, using the toss of a coin, randomised 40 limbs between use or non-use of a tourniquet. In bilateral cases the coin was spun twice, once to decide the surgeon (consultant or registrar), and once to decide to which leg the tourniquet would be applied. Both groups were similar at baseline. The severity of varicose veins was assessed on a subjective basis as either mild, moderate or severe.

Varicose vein surgery was performed using a sapheno-femoral flush ligation, stripping of the long saphenous vein (LSV) to below the knee and avulsions of varices through multiple stab incisions.

The type of tourniquet used was an Esmarch bandage which was applied in the sterile field in a circular motion (centripetal) to exsanguinate the limb, and secured at mid-thigh. Post-operatively the limb was bandaged up to the tourniquet before it was removed. Groin wounds were closed using an absorbable suture (PDS,



Ethilon) and the stab incisions were closed with Micropore tape (See Table 3).

Sykes 2000 was a trial undertaken in a district general hospital in the UK. The trial randomised 50 participants between use or non-use of a tourniquet. The two groups were comparable at baseline. Treatment groups were allocated randomly using sealed envelopes on the day of the operation. The severity of varicose veins was assessed using a 1 to 5 scale based on symptoms:

- 1 = no symptoms
- 2 = symptoms
- 3 = skin changes
- 4 = healed ulcer
- 5 = active ulcer

People with varicose veins were recruited from the waiting list and assessed using a hand held Doppler. People with deep venous insufficiency, extensive anterior thigh veins, deep vein thrombosis (DVT), or sapheno-popliteal reflux were excluded.

The type of tourniquet used was a sterile Lofquist Cuff (Boazal, Sweden). This was inflated to 120 mmHg and secured to the upper thigh. All participants had a Trendelenberg 30° tilt, synchronous groin dissection and phlebectomies by a consultant and registrar, LSV stripping using a disposable Vasistrip (Astra), and phlebectomy using a stab incision and Oesch hooks. All legs had thromboembolic deterrent (TED) stockings, cotton wool and bandages applied post-operatively. The bandages were removed 48 hours post-operatively by the district nurse and the TED stockings were worn for two weeks. (See Table 3.)

Thompson 1990 was a trial conducted at a district general hospital in the UK. The trial randomised 100 consecutive participants to use or non-use of a tourniquet during varicose vein surgery. Twenty-one participants had bilateral (both legs) varicose veins and therefore a total of 121 limbs were included into the study. However, at the three month follow-up there were only 101 limbs available for analysis. No details were provided on the number of participants this equated to, or the reasons for withdrawals or losses to follow-up. No details were given regarding the method of randomisation or whether the unit of randomisation was the participant or the limb. Those with bilateral varicose veins had the tourniquet applied to the right leg only; the left leg acted as the non-tourniquet limb. Participants with vascular insufficiency, cardiovascular disease or previous DVT were excluded.

The type of tourniquet used was a Rhys-Davies cuff. This was applied to the leg and inflated to 500 mmHg. The non-tourniquet group was operated at a 30° Trendelenberg tilt. All participants in both groups had ligation of the sapheno-femoral junction flush with the femoral vein. Incisions were made using a number 11 scalpel blade and avulsions using Dunhill or mosquito forceps. Groin wounds were closed using either nylon or PDS (Ethicon) and stab wounds closed using steristrips. Legs were dressed with gauze, crepe and tubigrip. Participants were kept in overnight and the dressings were removed after three weeks (See Table 3).

#### **Excluded studies**

Ten studies were non-randomised cohort studies (Fischer 1994; Klenerman 1977; Lahl 2000; Lofqvist 1988; Meyer 1997; Mildner 2000; Robinson 2000; Royle 1984; Streichenberger 1991; Tsavellas 2000), two were review articles (Fischer 1991; Wigger 1998), one

was a description of surgical technique (Sachs 1994), one a postal questionnaire (Tsavellas 2000b), and one was a letter commenting on the use of tourniquets (Farrands 1987).

#### Risk of bias in included studies

The methodological quality of the included studies was relatively poor. All three studies had a small sample size and there were no a priori sample size calculations performed by any of the studies. The methods of randomisation were also poorly reported and the blinding to allocation was unclear. One trial (Corbett 1989), reported that randomisation was on the basis of toss of a coin by the anaesthetist. Another reported that sealed envelopes were used (Sykes 2000). However, there were details missing on how the randomisation sequence was generated and whether the envelopes were opaque. The final trial (Thompson 1990), merely reported that it was a randomised study in the abstract and provided no other details. There were also concerns that in bilateral operations treatment allocation was not random, for example, the right leg having the tourniquet applied and the left having no tourniquet.

#### **Effects of interventions**

The extensive search strategy found a total of three trials that were included in the review. These trials randomised 176 participants and 211 limbs to either use or non-use of a tourniquet during varicose vein surgery.

#### Corbett 1989

The main outcome measures were intra-operative blood loss, operative time and weight of varices. The mean blood loss was estimated by weighing swabs but the authors state that blood loss onto drapes or surgeons' gowns was not taken into account. In addition, the measured blood loss was restricted to that lost during avulsing and did not include losses during groin dissection or stripping. The mean blood loss was 16 ml (range 0 to 136 ml) in the tourniquet group and 107 ml (range 16 to 581 ml) in the nontourniquet group (P < 0.001 using Wilcoxon's rank sum test). There was no statistically significant difference between the groups in terms of mean operating time or weight of varices. No details were provided regarding the blinding of outcome assessment. There were no reports of complications from use of the tourniquet.

## Sykes 2000

The main outcome measures were median peri-operative blood loss, operative time, bruising, patient pain and activity, and cosmesis. The median blood loss in the tourniquet group was 0 ml (range 0 to 20 ml) compared to 125 ml (range 20 to 300 ml) in the non-tourniquet group (P < 0.01). No details were provided on how blood loss was estimated. The mean operative time was shorter when the tourniquet was used (30 min, range 11 to 47 min), compared to not using the tourniquet (37 min, range 18 to 50 min; P < 0.01). Median bruising area of the thigh was reduced in the tourniquet group (72 cm<sup>2</sup>, range 30 to 429 cm<sup>2</sup>) compared to the non-tourniquet group (179 cm<sup>2</sup>, range 24 to 669 cm<sup>2</sup>; P < 0.01). There were no significant differences in terms of patient pain, activity and cosmesis, as assessed using a zero to seven visual analogue score (VAS). No details were given on blinding of outcome assessment. Three patients had temporary saphenous neuralgia (two in the non-tourniquet group), and two patients had wound complications post-operatively (both in the non-tourniquet group).



#### Thompson 1990

The main outcome measures were mean blood loss, bruising, length of operation and cosmetic result. Results were reported on 101 legs (47 in the tourniquet group and 54 in the non-tourniquet group). No details of the reasons for losses to follow-up were provided. The mean blood loss was less in the tourniquet group (13.5 ml, range 1 to 56 ml) compared to the non-tourniquet group (133 ml, range 5 to 430 ml; P < 0.01). No details were provided on how the blood loss was estimated. The cosmetic results at six weeks, as assessed by a blinded observer using a linear analogue score, were better in the tourniquet group (P < 0.01). The mean score for cosmesis as assessed by the participant was also better in the tourniquet group (P < 0.01). There were no statistically significant differences found in terms of length of the operation and bruising at three weeks.

All of the trials examined the effect of using a tourniquet in terms of total blood loss. However, there were variations in defining total blood loss and how it was measured, with only Corbett (Corbett 1989), reporting how blood loss was estimated. This lack of detail in the other two trials could mean that there were significant variations in how total blood loss was estimated. Furthermore, Corbett (Corbett 1989), and Thompson (Thompson 1990), reported mean blood loss whereas Sykes (Sykes 2000), reported median blood loss. A summary of the findings on blood loss is presented in Table 3.

All of the trials included operative time as an outcome measure but there were variations in how this was measured. Corbett (Corbett 1989), defined the operative time from the start of avulsing to dressing the wounds. However, Thompson (Thompson 1990), defined it as the time from entering theatre to completion of the dressings. No details were provided in the third trial (Sykes 2000).

None of the trials determined the relative cost-effectiveness of the use of a tourniquet.

#### DISCUSSION

The available evidence on the evaluation of the use of tourniquets in varicose vein operations is limited to three randomised controlled trials (Corbett 1989; Sykes 2000; Thompson 1990). These trials were all of poor quality and had deficiencies in trial design, sample size and measurement of outcomes. None of the trials had sufficient power and sample size to determine the differences between use or non-use of a tourniquet during varicose vein surgery. There were also variations in how outcomes were measured, with two trials reporting means (Corbett 1989; Thompson 1990), and the third reporting medians (Sykes 2000). The small sample size also meant that there were insufficient numbers included to detect any rare potential complications from the use of tourniquet.

However, despite these limitations, all three trials agreed that the amount of blood loss can be significantly reduced when a

tourniquet is used with no increase in operative time, reported adverse events or subjective outcome. The mean and median blood loss in the comparisons were relatively small and not necessarily clinically significant. However, those patients who did not have a tourniquet had a wider range of total blood loss, and those in the upper limits certainly lost a significant amount of blood. A further consideration is that any potential for reduction of exposure to blood for health care staff should be considered in light of the possibilities of blood-borne diseases such as HIV and hepatitis C.

A reduction in blood loss could result in a reduction of postoperative bruising, but only one trial (Sykes 2000), included this as an outcome measure. Although it did find a significant reduction in bruising area with the use of a tourniquet, the trial had a relatively small sample size of 25 patients in each group.

The trials were also not of sufficient size to determine the incidence of potential relatively rare complications such as nerve damage or arterial injury (especially in older patients). This is a consideration when recommending the use of tourniquets as large numbers of varicose vein operations are undertaken, and so there could be the potential for significant number of additional complications caused by using a tourniquet.

None of the trials explored the cost-effectiveness of the use or non-use of a tourniquet. The trials did not find any increase in the length of operation, which has a significant impact in terms of overall costs. However, there was no discussion of the costs of the tourniquets, other equipment or any additional potential costs such as staffing or training.

## **AUTHORS' CONCLUSIONS**

#### Implications for practice

The limited evidence would seem to suggest that the use of a tourniquet in routine varicose vein surgery may reduce the blood loss during the operation.

## Implications for research

There is a need for a large randomised controlled trial, which includes an economic evaluation using a bottom up approach to costings, to determine whether the limited evidence for the use of tourniquets can be validated.

## ACKNOWLEDGEMENTS

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Hickey NC. Prospective randomised trial of varicose vein surgery with or without tourniquet. National Research Register. http://www.nrr.nhs.uk/ViewDocument.asp?ID=N0282000633 (accessed 15 December 2001).

#### **Kumar 1998**

Kumar SN, Chapman JA, Rawlins I, Kumar SN, Chapman JA, Rawlins I. Vascular injuries in total knee arthroplasty. A review of the problem with special reference to the possible effects of the tourniquet. *Journal of Arthroplasty* 1998;**13**(2):211-6.

#### London 2000

London NJ, Nash R. ABC of arterial and venous disease. Varicose veins. *British Medical Journal* 2000;**320**(7246):1391-4.

#### **NICE 2001**

National Institute for Clinical Excellence (NICE). Referral Advice. A guide to appropriate referral from general to specialist services. http://www.nice.org.uk/pdf/Referraladvice.pdf (accessed 15 December 2001).

#### On 2000

Corbett 1989

On AY, Ozdemir O, Aksit R. Tourniquet paralysis after primary nerve repair. *American Journal of Physical Medicine and Rehabilitation* 2000;**79**(3):298-300.

#### CHARACTERISTICS OF STUDIES

**Characteristics of included studies** [ordered by study ID]

#### **Rhys-Davies 1985**

Rhys-Davies NC, Stotter AT. The Rhys-Davies exsanguinator. Annals of the Royal College of Surgeons of England 1985;67(3):193-5.

#### **Sykes 1999**

Sykes TCF, Brookes P, Hickey NC. A prospective randomised trial of tourniquet in varicose vein surgery. *British Journal of Surgery* 1999;**86**(Suppl. 1):14. [MEDLINE: 837]

#### Wakankar 1999

Wakankar HM, Nicholl JE, Koka R, D'Arcy JC. The tourniquet in total knee arthroplasty. A prospective, randomised study. *Journal of Bone and Joint Surgery - British Volume* 1999;**81**(1):30-3.

# References to other published versions of this review Rigby 2002

Rigby KA, Palfreyman SSJ, Beverley C, Michaels JA. Surgery for varicose veins: use of tourniquet. *Cochrane Database of Systematic Reviews* 2002, Issue 2. [DOI: 10.1002/14651858.CD001486]

Corpett 1989	
Methods	Study design: RCT.
	Method of randomisation: Coin spun by anaesthetist to decide if tourniquet should be used (for bilateral cases coin spun twice).
	Blinding: No blinding of assessors indicated.
	Exclusions post-randomisation: None stated.
	Losses to follow-up: None stated.
Participants	Country: UK.
	Setting: Hospital.
	No. of participants: 26 No. of limbs: 40
	Age mean (years): 51.
	Gender: 9 men, 17 women.
	Inclusion criteria: Participants undergoing operation for primary varicose veins.
	Exclusion criteria: None stated.
Interventions	Treatment: Tourniquet - Esmarsh bandage (n = 20).
	Control: No tourniquet.
	7 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 -

<sup>\*</sup> Indicates the major publication for the study



Corbett 1989 (Continued)			
, ,	Note: in bilateral cases a tourniquet was always applied to one limb.		
	All patients had SFJ liga	ation, strip of LSV to below knee and avulsions.	
Outcomes	<ol> <li>Mean blood loss:         Treatment: 16 ml (range 0 to 56).         Control: 107 ml (range 16 to 581); P &lt; 0.01. </li> <li>Weight of excised varices         (washed and dried before weighing): no differences between groups.     </li> </ol>		
		ete avulsions (start of avulsing to dressing): no difference between groups.	
Notes	Blood loss estimated by weighing swabs not gown or drapes.		
	No significant difference	ce for other outcome measures.	
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Allocation concealment (selection bias)	Low risk	A - Adequate	

## **Sykes 2000**

Methods	Study design: RCT.		
	Method of randomisation: Sealed envelopes on day of operation.		
	Blinding of assessment: Unclear.		
	Exclusions post-randomisation: None stated.		
	Losses to follow-up: None stated.		
Participants	Country: UK.		
	Setting: Hospital.		
	No. of participants: 50.		
	Age mean (years): 49 (32 to 65) no tourniquet; 47 (29 to 80) tourniquet.		
	Gender: M:F 1:4 no tourniquet; 1:2 tourniquet.		
	Inclusion criteria: Unilateral SFJ ligation strip and avulsions.		
	Exclusion criteria: History of DVT or deep venous insufficiency, extensive anterior thigh veins, saphenopopliteal reflux.		
	Groups "similar" for age, sex and VV grade.		
Interventions	Treatment: Sterile Loquist (Boazal cuff) inflated to 120 mm Hg.		
	Control: no Boazal cuff.		
	All patients had SFJ ligation strip using disposable Astra vasistrip and avulsions. 30° head down tilt. Cotton wool and crepe bandages applied for 48 hrs then TED stockings for 2 weeks.		
Outcomes	Median blood loss:		



Sykes 2000 (Continued)

Treatment: 0 ml.

Control: 125 ml (range 20 to 300); P < 0.01.

Mean operative time:

Treatment: 30 mins (range 11 to 47). Control: 37 mins (range 18 to 50); P < 0.01.

Median area of bruising thigh at 7 days: Treatment: 77 cm<sup>2</sup> (range 30 to 429).

Control:  $179 \text{ cm}^2$ ; P < 0.01.

Pain (VAS 0 to 10): No significant difference.

Patient activity over first week (VAS 0 to 7): No significant difference.

Cosmetic appearance at 6 weeks: No significant difference.

Notes 3 patients had temporary sensory neuralgia - one in treatment group and two in control group.

Two patients had wound complications (one infection and one haematoma - both in I2.

#### Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

## **Thompson 1990**

Methods	Study design: RCT.

Method of randomisation: Method not stated but if bilateral then right leg allocated to treatment and

left leg to control.

Blinding of assessment: Unclear.

Exclusions post-randomisation: None stated.

Losses to follow-up: None stated.

#### Participants Country: UK.

Setting: Hospital.

No. participants: 100 consecutive.

No. limbs: 121 (i.e. 21 bilaterals) only 101 limbs included in analysis.

Age mean (years): Similar for the two groups.

Gender: Male/Female ratio: 68% (37/54) of the non-tourniquet group were female compared to 57%

(27/47) in the tourniquet group.

Inclusion criteria:

Referral for varicose vein surgery.

Exclusion criteria:

 $Vascular\,in sufficiency, cardiovas cular\,disease\,or\,previous\,DVT.$ 

Baseline characteristics



Thompson 1990 (Continued)			
•		: there were no differences between the groups in terms of the main presenting (cosmetic, pain, swelling or eczema, ulceration and bleeding).	
Interventions	Treatment: Rhys-Davies cuff to exsanguinate leg inflated to 500 mmHg and ischaemia maintained with a pneumatic tourniquet (n = 47).		
	Control: no tourniquet	. (n = 54).	
		the femoral vein and avulsions, dressed with gauze, crepe and tubigrip, ssings removed after three weeks.	
Outcomes	Mean blood loss: Treatment: 13.5 ml (range 1 to 56). Control: 133 ml (range 5 to 430); P < 0.01		
	Operative time (entere	d theatre to completion of dressings): No significant difference.	
	Cosmesis (Linear Analo the patient and blinded (P < 0.01).	ogue Score): Improved cosmetic result in the tourniquet group assessed by both d observer	
	Bruising (Linear Analogue Score): No significant difference.		
Notes	Authors acknowledge the lack of formal cosmetic assessment of the severity of the varicose veins but felt the large numbers balanced this out.		
Risk of bias			
Bias	Authors' judgement	Support for judgement	
Allocation concealment (selection bias)	High risk	C - Inadequate	

DVT: deep vein thrombosis LSV: long saphenous vein RCT: randomised controlled trial SFJ: sapheno-femoral junction TED: thrombo-embolic deterrant VAS: visual analogue scale

VV: varicose veins

## **Characteristics of excluded studies** [ordered by study ID]

Study	Reason for exclusion	
Farrands 1987	Letter; not enough information.	
Fischer 1991	Review article.	
Fischer 1994	Non-randomised retrospective study.	
Klenerman 1977	Cohort study examining use of tourniquet in prophylactic treatment of DVT.	
Lahl 2000	Non-randomised study.	
Lofqvist 1988	Non-randomised study.	



Study	Reason for exclusion
Meyer 1997	Non-randomised study.
Mildner 2000	Non-randomised study.
Robinson 2000	Non-randomised study.
Royle 1984	Non-randomised study.
Sachs 1994	Non-randomised study. Description of surgical technique.
Streichenberger 1991	Non-randomised study.
Tsavellas 2000	Non-randomised study.
Tsavellas 2000b	Postal questionnaire.
Wigger 1998	Review article.

#### **ADDITIONAL TABLES**

## Table 1. Electronic bibliographic databases searched

#### Sources searched

- 1. AMED
- 2. Best Evidence
- 3. Biological Abstracts
- 4. CCTR (Cochrane Controlled Trials Register) (last searched Issue 3, 2001)
- 5. CDSR (Cochrane Database of Systematic Reviews)
- 6. EMBASE
- 7. HMIC (Health Information Management Consortium comprising DH-Data, the King's Fund Database, and Helmis)
- 8. Medline
- 9. NHS DARE (Database of Assessments of Reviews of Effectiveness)
- 10. NHS EED (Economic Evaluations Database)
- 11. NHS HTA (Health Technology Assessment)
- 12. PubMed (last 180 days)
- 13. Science Citation Index

#### Table 2. Other sources searched

## Other sources

- 1. AHRQ (Agency for Healthcare Research and Quality)
- 2. ARIF (Aggressive Research Intelligence Facility)
- 3. Bandolier
- 4. CCOHTA (Canadian Co-ordinating Centre for Health Technology Assessment)
- 5. CCT (Current Controlled Trials)
- 6. CenterWatch Trials Register
- 7. Clinical Trials.gov, NIH Clinical Trials Database
- 8. COIN (Department of Health Circulars)
- 9. CRiB (Current Research in Britain)
- 10. CRW (Current Research Worldwide)



#### **Table 2. Other sources searched** (Continued)

- 11. Department of Health
- 12. eMC(Electronic Medicines Compendium)
- 13. Health Care Needs Assessment
- 14. Health Evidence Bulletins, Wales
- 15. HSTAT (Health Services/Technology Assessment Text, US National Library of Medicine)
- 16. INAHTA (International Network of Agencies for Health Technology Assessment) Clearinghouse
- 17. Index to Theses
- 18. ISTP (Index to Scientific and Technical Proceedings)
- 19. MRC (Medical Research Council) Funded Projects Database
- 20. National Guideline Clearinghouse
- 21. National Research Register
- 22. NCCHTA (National Co-ordinating Centre for Health Technology Assessment)
- 23. NHS CRD (Centre for Reviews and Dissemination), University of York
- 24. NHS R&D Programmes
- 25. OMNI (Organising Medical Networked Information)
- 26. POINT (Department of Health publications)
- 27. ReFeR (Research Findings Register)
- 28. ScHARR Library Catalogue
- 29. SIGN (Scottish Intercollegiate Guidelines Network)
- 30. SumSearch
- 31. Trent Working Group on Acute Purchasing
- 32. TRIP (Turning Research into Practice) Database
- 33. UK Official Publications
- 34. Uncover
- 35. Wessex DEC (Development and Evaluation Committee) Reports
- 36. West Midlands DES (Development and Evaluation Services) Reports

#### Table 3. Results - blood loss

Study ID	Tourniquet type	Tourniquet	No tourniquet
Corbett 1989	Esmarch bandage	16 (range 0 to 136 ml)	107 (range 16 to 581 ml)
Sykes 2000	Lofquist Cuff (Boazal)	0	Median 125 ml (range 20 to 300 ml)
Thompson 1990	Rhys-Davies Cuff	13.5 (range 1 to 56 ml)	133 (range 5 to 430 ml)

## APPENDICES

#### Appendix 1. CENTRAL search strategy 2013

#1	MeSH descriptor: [Varicose Veins] explode all trees	757
#2	varicos*	1195
#3	(tortu* near/3 (vein* or veno* or saphenous))	16
#4	(incomp* near/3 (vein* or veno* or saphenous or valv*))	134
#5	(insuffic* near/3 (vein* or veno* or saphenous))	724



(Continued)		
#6	((saphenous or vein* or veno*) near/3 reflux)	101
#7	(dilated near/3 (vein* or veno* or saphenous))	33
#8	MeSH descriptor: [Saphenous Vein] explode all trees and with qualifiers: [Surgery - SU]	172
#9	GSV	79
#10	MeSH descriptor: [Venous Insufficiency] explode all trees	350
#11	(#1 or #2 or #3 or #4 or #5 or #6 or #8 or #9 or #10)	1832
#12	MeSH descriptor: [Vascular Surgical Procedures] explode all trees	11204
#13	MeSH descriptor: [Ligation] explode all trees	511
#14	ligat*:ti,ab,kw (Word variations have been searched)	1305
#15	strip*:ti,ab,kw (Word variations have been searched)	1115
#16	avuls*:ti,ab,kw (Word variations have been searched)	128
#17	surg* or Linton:ti,ab,kw (Word variations have been searched)	76452
#18	phlebectom*:ti,ab,kw (Word variations have been searched)	34
#19	#12 or #13 or #14 or #15 or #16 or #17 or #18	83906
#20	MeSH descriptor: [Tourniquets] explode all trees	325
#21	l*fquist:ti,ab,kw (Word variations have been searched)	1
#22	Rhys*:ti,ab,kw (Word variations have been searched)	4
#23	cuff*:ti,ab,kw (Word variations have been searched)	1399
#24	tourniquet	836
#25	#20 or #21 or #22 or #23 or #24	2170
#26	#11 and #19 and #25 in Trials	16

## Appendix 2. Search strategies used in the major databases

#1 varicose-veins\*:ME

#2 saphenous-vein\*:ME

#3 (varicose near5 vein\*)

#4 (saphenous near5 vein\*)

#5 #1 or #2 or #3 or #4

#6 surgery\*:ME

#7 surgical-procedures-operative\*:ME

#8 surg\*

#9 ligation\*:ME



```
#10 sclerotherapy*:ME
#11 strip*
#12 ligation*
#13 avulsion*
#14 (high tie or high-tie)
#15 sclerotherapy
#16 tourniquet*
#17 (compression near5 stocking*)
#18 (compression near5 hosiery)
#19 #6 or #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18
#20 #5 and #19
```

## Appendix 3. Search strategy for EMBASE 1980 - 2001 (SilverPlatter WebSPIRS)

## Searched April 2001

```
#1 varicosis / all subheadings
#2 explode leg varicosis / all subheadings
#3 saphenous vein / al subheadings
#4 (varicose near5 vein*) in ti, ab
#5 (saphenous near5 vein*) in ti, ab
#6 #1 or #2 or #3 or #4 or #5
#7 surgery / all subheadings
#8 surgical technique / all subheadings
#9 surg* in ti, ab
#10 ligation / all subheadings
#11 explode vein ligation / all subheadings
#12 sclerotherapy / all subheadings
#13 strip* in ti, ab
#14 ligation* in ti, ab
#15 avulsion* in ti, ab
#16 (high-tie or high tie) in ti, ab
#17 sclerotherapy in ti, ab
#18 (compression near5 stocking*) in ti, ab
#19 (compression near5 hosiery) in ti, ab
#20 tourniquet* in ti, ab
#21 Esmarch in ti, ab
#22 Lofquist in ti, ab
#23 Cuff in ti, ab
#24 #7 or #8 or #9 or #10 or #11 or #12 or #13 or #14 or #15 or #16 or #17 or #18 or #19 or #20 or #21 or #22 or #23
#25 #6 and #24
```

## Appendix 4. Search strategy for MEDLINE 1966 - 2001 (Ovid Biomed)

#### Searched March 2001

```
#1 exp varicose veins/
#2 saphenous vein/
#3 (varicose adj5 vein$).tw
#4 (saphenous adj5 vein$).tw
#5 or/1-4
#6 surgery/
```



(Continued)

#7 exp surgical procedures, operative/

#8 surg\$.tw

#9 ligation/

#10 sclerotherapy/

#11 strip\$.tw

#12 ligation\$.tw

#13 avulsion\$.tw

#14 (high tie or high-tie).tw

#15 sclerotherapy.tw

#16 tourniquet.tw

#17 Esmarch.tw

#18 Lofquist.tw

#19 Cuff.tw

#20 (compression adj5 stocking\$).tw

#21 (compression adj5 hosiery).tw

#22 or/6-19

#23 5 and 22

## Appendix 5. Methodological search filters used in Ovid Medline

Guidelines	Systematic reviews	RCTs
1 guideline.pt 2 practice guide- line.pt 3 exp guidelines/ 4 health planning guidelines/ 5 or/1-4	1 meta-analysis/ 2 exp review literature/ 3 (meta-analy\$ or meta analy\$ or metaanaly\$).tw 4 meta analysis.pt 5 review academic.pt 6 review literature.pt 7 letter.pt	1 randomized controlled trial.pt 2 controlled clinical trial.pt 3 randomized controlled trials/ 4 random allocation/ 5 double blind method/ 6 or/1-5 7 clinical trial.pt 8 exp clinical trials/
	8 review of reported cases.pt 9 historical article.pt 10 review multicase.pt 11 or/1-6 12 or/7-10 13 11 not 12	9 ((clin\$ adj25 trial\$)).ti, ab 10 ((singl\$ or doubl\$ or trebl\$ or tripl\$) adj25 (blind\$ or mask\$)).ti, ab 11 placebos/ 12 placebos.ti, ab 13 random.ti, ab 14 research design/ 15 or/7-14 16 comparative study/ 17 exp evaluation studies/ 18 follow up studies/ 19 (control\$ or prospectiv\$ or volunteer\$)).ti, ab 20 prospective studies/ 21 or/16-20 22 6 or 15 or 21

## WHAT'S NEW

Date	Event	Description
15 August 2013	Review declared as stable	This Cochrane review has been marked as stable and will only be updated when new studies are identified.



#### HISTORY

Protocol first published: Issue 1, 1999 Review first published: Issue 4, 2002

Date	Event	Description
9 April 2013	New citation required but conclusions have not changed	Searches of CENTRAL and Specialised Register were rerun. No new studies were found. Minor edits made. Conclusions not changed.
9 April 2013	New search has been performed	Searches of CENTRAL and Specialised Register were rerun. No new studies were found.
28 October 2008	New search has been performed	Searches re-run and no new trials found. Updated search strategy.
19 September 2008	Amended	Converted to new review format.
11 November 2007	New search has been performed	Re-ran searches; no new trials found. Updated search dates. Conclusions remain unchanged.
8 November 2006	New search has been performed	Made minor copy edits to table of Characteristics of Included Studies, table of Excluded Studies, reference list, and text. Added Plain Language Summary and acknowledgements. Updated search strategy. Added link to results table and linked an in-text citation. Changed dates of last search and most recent update. No new trials found; conclusions remain unchanged.
5 August 2004	New search has been performed	No new trials found. Updated with minor formatting changes.
4 November 2002	Amended	Synopsis incorporated into text.

## **CONTRIBUTIONS OF AUTHORS**

Kathryn Rigby - reviewed articles, extracted data, wrote text of review.

Simon Palfreyman - reviewed articles, extracted data, wrote text of review.

Catherine Beverley - searched electronic databases, handsearched journals, extracted data.

Jonathan Michaels - reviewed articles, contributed to writing the text of review.

## **DECLARATIONS OF INTEREST**

KR and JM report that this review was done as part of HTA commissioned research to look at cost-effectiveness of treatments for varicose veins. This included funds for a RCT of varicose veins treatments. JM reports having received funds for private research consultancy from various companies not relating to varicose veins, some relating to vascular disease and technology appraisal in general. JM has also been awarded an NIHR programme grant for research relating to vascular services.

## SOURCES OF SUPPORT

#### **Internal sources**

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## **External sources**

• NHS R&D HTA Programme, UK.



• Chief Scientist Office, Scottish Government Health Directorates, The Scottish Government, UK.

The PVD Group editorial base is supported by the Chief Scientist Office.

## INDEX TERMS

## **Medical Subject Headings (MeSH)**

\*Tourniquets; Blood Loss, Surgical [\*prevention & control]; Randomized Controlled Trials as Topic; Varicose Veins [\*surgery]

## MeSH check words

Humans