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[Intervention Review]

Surgery for deep venous incompetence

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ABSTRACT

Background

Chronic deep venous incompetence (DVI) is caused by incompetent vein valves and/or blockage of large-calibre leg veins and causes a range of symptoms including recurrent ulcers, pain and swelling. Most surgeons accept that well-fitted graduated compression stockings (GCS) and local care of wounds serve as adequate treatment for most patients, but sometimes symptoms are not controlled and ulcers recur frequently, or they do not heal despite compliance with conservative measures. In these situations, in the presence of severe venous dysfunction, surgery has been advocated by some vascular surgeons. This is an update of the review first published in 2000.

Objectives

To assess the effects of surgical management of deep venous incompetence in terms of ulcer healing, ulcer recurrence and alleviation of symptoms.

Search methods

For this update, the Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator searched the Specialised Register (last searched October 2014) and the Cochrane Central Register of Controlled Trials (CENTRAL) (2014, Issue 9).

Selection criteria

Randomised controlled trials of surgical treatment for patients with DVI.

Data collection and analysis

For this update, two review authors (RRG and SCH) extracted data independently. All included studies required full risk of bias assessment in line with current procedures of The Cochrane Collaboration. Two review authors (RRG and SCH) independently assessed risk of bias and consulted with a third review author (AA) when necessary.

Main results

Four studies with 273 participants were included. All included studies reported clinical outcomes following valvuloplasty. We found no studies investigating other surgical procedures for the treatment of patients with DVI. All included studies investigated primary valve incompetence. We found no trials that investigated the results of surgery for secondary valvular incompetence or the obstructive form of DVI. Because different outcome measures were used, it was not possible to pool the results of included studies. The methodological quality of the included studies was low, mainly because information regarding randomisation and blinding was missing, or because data were incomplete or were presented poorly. Ulcer healing and ulcer recurrence were not reported in one study, and the remaining three studies did not include participants with ulcers or with active ulceration. Three studies reported no significant complications of surgery and no incidence of DVT during follow-up. One study did not report on the occurrence of complications. Clinical changes were

Surgery for deep venous incompetence (Review)

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assessed by subjective and objective measurements, as specified in the clinical, aetiological, anatomical, and pathophysiological (CEAP) classification score. This requires vascular laboratory measurements of lower limb haemodynamics before and after surgery. Tests include an overall evaluation of venous function with venous refilling time (VRT) or ambulatory venous pressure (AVP). Two small trials comparing external valvuloplasty using limited anterior plication in combination with ligation of incompetent superficial veins against ligation alone (L) showed that ligation plus limited anterior plication produced significant improvement in AVP: The mean difference was -15 mm Hg (95% confidence interval (CI) -20.9 to -9.0) at one year and -15 mm Hg (95% CI -21 to -8.9) at two years. Sustainable statistically significant improvement in AVP and VRT was achieved by ligation and limited anterior plication at 10 years in one study. However, AVP values after surgery remained relatively high, causing its benefit to be questioned. Similarly, another study including participants who were deteriorating preoperatively showed sustained mild clinical improvement for seven years in those subjected to valvuloplasty compared with participants undergoing superficial venous surgery alone. However, this benefit was lost when the condition of participants was stable preoperatively. One small study (n = 40) with grade 3 reflux and no participants with ulcers reported that external valvuloplasty of the femoral vein combined with surgical repair of the superficial venous system improved the haemodynamic status of the lower limbs, restored valvular function more effectively and achieved better outcomes than surgical repair of the superficial venous system alone.

Authors' conclusions

No evidence was found for benefit or harm of valvuloplasty in the treatment of patients with DVI secondary to primary valvular incompetence. The individual trials included in this review were small; they used different methods of assessment and overall were of poor quality. They did not include participants with severe DVI. Trials investigating the effects of other surgical procedures on deep veins are needed. Until the findings of such trials become available, the benefit of valvuloplasty remains uncertain.

PLAIN LANGUAGE SUMMARY

Surgery for deep venous incompetence

Deep venous incompetence (DVI) is a problem in the veins that can lead to leg ulcers (sores), pain and swelling. It may be caused by a problem in the valves of the vein, by a blockage of the veins or by a combination of these events. For most people, wearing special compression stockings and treating the ulcers is enough. When this does not ease the problem, surgery is sometimes tried. This review includes four studies with a total of 273 participants. All included studies reported on outcomes following surgical repair of venous valves (valvuloplasty). We did not identify studies investigating other surgical procedures for the treatment of patients with DVI. All included studies investigated primary valve incompetence (when valves do not close properly because of laxity of the vein wall or valve cusps). We found no trials that investigated the results of surgery for secondary valvular incompetence (when valves do not close properly, for example, when valves are damaged as a result of deep vein thrombosis) or for the obstructive form of DVI. As different outcomes were reported, it was not possible to combine the results of these studies. The methodological quality of the included studies was low, mainly because information regarding allocation of treatment and blinding was missing, or because data were incomplete or were poorly presented. Ulcer healing and ulcer recurrence were not reported in one study, and the remaining three studies did not include patients with ulcers or active ulceration. Three studies reported no significant complications of surgery or no incidence of DVT during follow-up. One study did not report on the occurrence of complications.

Clinical changes were assessed by subjective and objective measurements, as specified in the clinical, aetiological, anatomical, and pathophysiological (CEAP) classification score. This requires vascular laboratory measurements of lower limb haemodynamics before and after surgery. Tests include an overall evaluation of venous function with venous refilling time (VRT) or ambulatory venous pressure (AVP). Results show improvement in clinical symptoms and muscle pumping function and significant improvement in the haemodynamic status of patients who had external valvuloplasty along with surgery to the superficial venous system. In patients who had surgery to the superficial venous system only, clinical symptoms improved, but no improvement in muscle pumping function was reported.

Evidence is not sufficient to show the effects of surgery on the treatment of patients with DVI. The individual trials included in this review have demonstrated possible long-term benefit in certain groups of patients, but these trials were small, used different methods of assessment and overall were of poor quality. They did not include patients with severe DVI. Trials investigating the effects of other surgical procedures on the deep veins are needed. Until evidence from such trials becomes available, conventional conservative measures, such as high compression therapy or elasticated hosiery, remain the treatments of choice.

BACKGROUND

Description of the condition

Chronic deep venous incompetence (DVI) is a troublesome condition that is associated with a variable range of distressing symptoms such as recurrent ulcers, leg pain and leg swelling. The underlying defect could be valvular incompetence (when the valve does not close tightly and allows blood to leak back into the vein), obstruction of large-calibre veins or a combination of these two events. Valvular incompetence may be primary or secondary. Primary valve incompetence is not associated with post-thrombotic changes, and the defect is sometimes congenital, leading to early development of symptoms. Secondary valve incompetence and the obstructive form of DVI are post-thrombotic phenomena and account for 80% to 95% of cases (Bauer 1948; Browse 1998; Perrin 2004). The obstructive form is less common, affecting 3% to 9% of patients (Halliday 1985; Raju 1988).

Description of the intervention

Chronic DVI represents a therapeutic challenge for vascular surgeons. Most surgeons accept that well-fitted graduated compression stockings (GCS) and local care of wounds provide adequate treatment for the majority of patients (Lancet 1982). Sometimes symptoms are not controlled and ulcers recur frequently, or they do not heal despite compliance with conservative measures. In these situations, in the presence of severe venous dysfunction, surgery has been advocated by some vascular surgeons (Eriksson 1988; Kistner 1980).

Most surgeons accept that primary surgical treatment for concomitant superficial system insufficiency and perforators in the absence of major vein obstruction is essential for good results (Wilson 1991). Reconstructive surgery of the deep venous system is usually directed towards correcting the underlying defect by bypassing the obstructed segment or by restoring the valve mechanism (O'Donnell 1987). Examples include valvuloplasty, venous segmental transposition and venous segmental transplantation. Use of prosthetic valve material still has no place in venous surgery in human beings. Postoperative complications include deep venous thrombosis (DVT), pulmonary embolism (PE), venous occlusion and venous incompetence.

Why it is important to do this review

The value of surgery in DVI has not been fully determined (Gloor 1997). Results of surgery have not consistently shown long-term improvement in symptoms nor in the abnormal venous haemodynamics associated with this condition. This is an update of a review first published in 2000.

OBJECTIVES

To assess the effects of surgical management of deep venous incompetence in terms of ulcer healing, ulcer recurrence and alleviation of symptoms.

METHODS

Criteria for considering studies for this review

Types of studies

All randomised controlled trials of surgical management of deep venous incompetence (DVI) in which a surgical procedure was compared with:

- another surgical procedure;
- conventional conservative management; or
- no treatment

were considered for this review.

Trials in which perforator ligation was performed without deep vein surgery were excluded.

Types of participants

All patients requiring an intervention for the treatment of DVI.

Types of interventions

Any surgical procedure performed to treat DVI (valvuloplasty, venous segmental transposition, venous segmental transplantation or venous bypass surgery). Trials were excluded if no clear distinction was made between the types of procedures performed. No trials were found in which perforator ligation was performed simultaneously with surgery to deep veins. However, these will be included in future updates, should any be found. These study findings will be analysed separately to avoid bias in the results, as any symptomatic improvement could be attributed to either procedure.

Types of outcome measures

Primary outcomes

- Ulcer healing and recurrence.
- Complications of surgery.

Secondary outcomes

- Clinical changes: certain subjective and objective assessments as specified by clinical, etiological, anatomical, and pathophysiological (CEAP) classification scoring for chronic venous disease (CVD) and by CEAP classification scoring for clinical outcomes after surgery (Beebe 1996; Porter 1995). This requires vascular laboratory measurements of lower limb haemodynamics before and after surgery. Tests include an overall evaluation of venous function with venous refilling time (VRT) or ambulatory venous pressure (AVP). Patients undergoing surgery for valvular incompetence should undergo duplex assessment of venous reflux and possibly radiological investigation of competence and patency. Patients undergoing surgery for deep venous obstruction should undergo measurements of maximum venous outflow for assessment of outcome and duplex scanning, or phlebography for assessment of patency and degree of reflux. An overall evaluation of the clinical outcome will be given on the following basis: +3 (asymptomatic = no symptoms of CVD, improvement in VRT of at least +5 seconds and improvement in AVP of at least -10 mm Hg), +2 (moderate improvement = mild symptoms with changes in VRT and AVP as in +3), +1 (mild improvement = clinical

improvement or improvement in VRT or AVP), 0 (no symptomatic or laboratory changes), -1 (mild worsening = deterioration in symptoms or in VRT or AVP results), -2 (significant worsening = deterioration in symptoms and in VRT or AVP results) and -3 (marked worsening = that seen with -2 accompanied by new or worsening venous claudication).

In future updates of this review, in studies in which the CEAP classification system has not been used to assess the outcome of surgery, available data from such studies will be used and, if possible, applied to the CEAP classification method. Trials in which follow-up assessment does not differentiate ulcer recurrence from symptomatic results will not be included.

Search methods for identification of studies

Electronic searches

For this update, the Cochrane Peripheral Vascular Diseases Group Trials Search Co-ordinator (TSC) searched the Specialised Register (last searched October 2014) and the Cochrane Central Register of Controlled Trials (CENTRAL) (2014, Issue 9), 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 as the result of weekly electronic searches of MEDLINE, EMBASE, CINAHL and AMED, and handsearching of relevant journals. The full list of the databases, journals and conference proceedings that have been searched and the search strategies used are provided in the [Specialised Register](#) section of the Cochrane Peripheral Vascular Diseases Group module in *The Cochrane Library* (www.thecochranelibrary.com).

Searching other resources

Additional articles were sought by review of the references of relevant papers identified by electronic searches.

Data collection and analysis

Selection of studies

For this 2014 update, SCH and RRG selected possible trials for inclusion. For the 2004 update of this review, SCH selected possible additional trials for inclusion or exclusion. For the original review, SCH and AA selected all possible trials for inclusion.

Data extraction and management

For this 2014 update, RRG extracted the new data, which were cross-checked by SCH. In the original review, AA and SCH extracted the data. Extracted data included information on participants (age, sex, severity of disease as measured by the CEAP classification scoring system for CVD, past history of DVT); interventions (type of procedure performed, use of anticoagulants, use of external pneumatic compression stocking, use of GCS after surgery, smoking habits after surgery, use of intermittent leg elevation during the day); and outcomes (as specified in the section [Criteria for considering studies for this review](#)).

Assessment of risk of bias in included studies

SCH and RRG independently assessed the methodological quality of trials using the checklist provided by the PVD Group and the 'Risk of bias' tool of The Cochrane Collaboration ([Higgins 2011](#)). This tool assesses the risk of bias in each study using six domains

(randomisation, allocation concealment, blinding of participants and personnel, blinding of outcome assessors, incomplete data and selection bias). Disagreements were resolved by discussion or by consultation with the third review author (AA) when necessary..

Measures of treatment effect

We analysed outcomes that are continuous variables using mean differences (MDs) and 95% confidence intervals (CIs) for studies using the same outcome measurement scale. When studies reported the same outcome (i.e. measures of clinical changes) but used different measurement scales, we reported data within the text. If possible in future updates, we will use standardised mean difference (SMDs) and 95% CIs to report data.

Unit of analysis issues

In some studies, for outcomes such as lower limb haemodynamics for which bilateral procedures are possible and are reported, each treated limb was considered as an individual unit of analysis.

Dealing with missing data

We contacted the authors of studies with missing data, but we received no reply. We intended to use intention-to-treat analysis to pool data when possible.

Assessment of heterogeneity

Heterogeneity was assessed clinically on the basis of study descriptions.

Assessment of reporting biases

Reporting bias was assessed through review of identified studies. Funnel plots were considered to be inappropriate, as only four studies are included in this review.

Data synthesis

To date insufficient trials have been conducted to allow pooled statistical analysis. The included trials did not report outcomes of interest or reported different measurements of clinical change. If more trials are included in future updates, heterogeneity between trial results will be tested both subjectively by clinical judgement of differences in participant populations, interventions and outcome assessment; and objectively by performing appropriate statistical tests. The data will be synthesised through comparisons of group results.

Subgroup analysis and investigation of heterogeneity

To date, insufficient data are available to allow subgroup analysis. If appropriate in future updates, subgroup analyses will be carried out according to the surgical intervention.

Sensitivity analysis

Sensitivity analysis will be carried out when appropriate.

RESULTS

Description of studies

Results of the search

See [Figure 1](#).

Figure 1. Study flow diagram.

Included studies

For this update, one new study was identified for inclusion ([Wang 2006](#)).

Four studies with a total of 273 participants were included in this review ([Belcaro 1993](#); [Belcaro 1999](#); [Makarova 2001](#); [Wang 2006](#)). Details are given in the [Characteristics of included studies](#) table.

Wang 2006: This study investigated the efficacy of external valvuloplasty of the femoral vein in the treatment of participants with primary chronic venous insufficiency (PCVI). The study included 40 participants with bilateral PCVI who were classified as CEAP C2 to C4, with moderate incompetence of the deep vein. The limbs of each participant (total 80 limbs) were randomly assigned to two groups, each consisting of 40 limbs. Group A limbs underwent external valvuloplasty of the femoral vein combined with surgery of the superficial venous system; Group B limbs underwent surgery to

the superficial venous system only. Participants were followed up for three years after surgery was performed. Participants with ulcers were excluded, so no new evidence of ulcer healing was identified.

Belcaro 1993 and Belcaro 1999: Both of these studies compared external valvuloplasty using limited anterior plication (LAP) in combination with ligation of incompetent superficial veins (ligation and LAP group) versus only ligation of incompetent superficial veins (ligation only group). The number of participants was relatively small. All participants were deemed to have DVI due to primary valvular incompetence. Criteria for making the diagnosis were referred to in another article published by the same author ([Belcaro 1993a](#)). The clinical scores of included participants may be converted to "C4s, Ep, As, d, p, Pr" (translated as symptomatic skin changes ascribed to venous disease; CVD of undetermined cause; involvement of superficial, deep and perforator veins; and underlying pathophysiology of reflux) according to the CEAP classification system. Inclusion and exclusion criteria are listed in

the [Characteristics of included studies](#) table. In both trials, the ligation and LAP group received subcutaneous heparin (dose and frequency not stated) on a daily basis for five days after surgery. In addition, elasticated GCS were used to prevent DVT for five days following surgery in [Belcaro 1999](#). A brief description of LAP is given in the [Characteristics of included studies](#) table for each review.

[Makarova 2001](#) compared participants with primary valvular incompetence undergoing superficial venous surgery alone versus participants having an additional internal valvuloplasty of the superficial femoral vein. In all, 128 participants of CEAP C2 to C4 were initially treated with elasticated compression for five years before entry into the trial. [Makarova 2001](#) stratified participants into two groups according to change in CEAP class during five years of observation: those with "progressive clinical dynamics" (worsening of CEAP class by at least one level) and those with "stable clinical dynamics" (no change in CEAP class). Participants were further stratified according to changing CEAP class, yielding six separate subgroups for random assignment to treatment and control arms of the study. A total of 27 participants had developed active ulceration (C6), but no healed ulcers (C5) were reported. All participants had undergone yearly preoperative ultrasound scans to mark out sites of reflux and to measure reflux time (RT) and reflux volume index (RVI). Participants then underwent superficial venous surgery

(including subfascial perforator ligation) with or without internal valvuloplasty to the proximal superficial femoral valve. Participants were followed up by annual duplex scan for seven to eight years after surgery.

We found no trials that investigated the results of surgery for secondary valvular incompetence or the obstructive form of DVI. Moreover, we identified no trials that compared the results of surgery versus those of conventional conservative measures.

Excluded studies

For this update, three additional studies were excluded, as participants underwent perforator ligation ([Pierik 1997](#); [Sybrandy 2001](#)) or surgery to superficial veins ([Rass 2012](#)) without surgery to deep veins. One study ([Ktenidis 2002](#)) was previously excluded, as it did not include a control group. See the [Characteristics of excluded studies](#) table.

Risk of bias in included studies

The overall quality of the studies is poor because methods of randomisation and blinding are unclear for three of the four included studies ([Belcaro 1993](#); [Belcaro 1999](#); [Makarova 2001](#)). See [Figure 2](#) and [Figure 3](#).

Figure 2. Risk of bias graph: review authors' judgements about each risk of bias item presented as percentages across all included studies.

Figure 3. Risk of bias summary: review authors' judgements about each risk of bias item for each included study.

	Random sequence generation (selection bias)	Allocation concealment (selection bias)	Blinding of participants and personnel (performance bias)	Blinding of outcome assessment (detection bias)	Incomplete outcome data (attrition bias)	Selective reporting (reporting bias)	Other bias
Belcaro 1993	⊖	⊖	⊖	⊖	⊖	⊕	⊕
Belcaro 1999	⊖	⊖	⊖	⊖	⊕	⊕	⊕
Makarova 2001	⊖	⊖	⊖	⊖	⊕	⊕	⊕
Wang 2006	⊕	⊕	⊕	⊕	⊕	⊕	⊕

Allocation

[Wang 2006](#): Randomisation was done by limb rather than by individual participant with PCVI. Each of the 40 participants drew lots twice under the observation of researchers. One lot was drawn to determine the operative procedure, and the other to determine the leg assigned for the procedure. When one limb was randomly assigned to Group A regardless of whether it was the right or left, the other leg was assigned to Group B.

In [Belcaro 1993](#), [Belcaro 1999](#) and [Makarova 2001](#), participants were randomly assigned, but the method of randomisation used was not stated.

Blinding

Blinding of participants or personnel is not described in [Belcaro 1993](#), [Belcaro 1999](#) or [Makarova 2001](#). In [Wang 2006](#), participants, technical personnel performing air plethysmography (APG) and duplex analysis and data analysts—but not surgeons—were blinded to the operative procedure performed. Another clinician who did not participate in the surgical procedure determined clinical scores.

Incomplete outcome data

[Belcaro 1993](#): No description was given for the figures representing the main outcome measures. After discussions with a statistician, the review authors concluded that these figures represented means and standard deviations. The methods used to calculate statistical significance were Mann-Whitney U and Chi² tests.

Nine participants were reported to have dropped out of the [Belcaro 1999](#) study.

[Makarova 2001](#): 168 CEAP C2 to C4 participants were stratified after five years of observation as "progressive" or "stable," depending on the change/stability of their CEAP class over these five years. A total of 40 participants withdrew. Twenty-seven participants had developed venous ulceration but were not considered separately in the study. No mention was made of any participants improving over five years. Inclusion and exclusion criteria were otherwise clearly stated. In all, 128 participants were included in the treatment phase, three of whom subsequently dropped out. The main outcome measures were clinical changes (i.e. deterioration/stability of CEAP class) and duplex scanning for RT and RVI. AVP and VRT were not performed, as they were not planned. Follow-up was provided yearly for seven to eight years. None of the data were provided in sufficient detail to allow independent statistical analysis. The main method of calculating significance was Chi². Valve failure was not analysed through time-based methods.

Three participants declined to draw lots for method of randomisation and procedure and so were excluded from [Wang 2006](#).

Selective reporting

In [Makarova 2001](#), the main outcome measures were clinical changes (i.e. deterioration/stability of CEAP class) and duplex scanning for RT and RVI. Valve failure was not analysed through time-based methods.

All outcomes were reported in [Belcaro 1993](#), [Belcaro 1999](#) and [Wang 2006](#).

Other potential sources of bias

No other potential sources of bias were identified.

Effects of interventions

All four included studies reported clinical outcomes following valvuloplasty. We did not identify studies investigating other surgical procedures for the treatment of patients with DVI.

Study results have been grouped under three subheadings, which reflect the underlying causes of DVI. Data within these headings have been reported according to information provided by each article.

Results of surgery on primary valvular incompetence

Ulcer healing and ulcer recurrence

[Makarova 2001](#) included 27 participants with active venous ulceration who underwent surgery. Outcomes for these individuals are not clear.

Neither of the [Belcaro](#) studies ([Belcaro 1993](#); [Belcaro 1999](#)) included participants with active venous ulceration.

[Wang 2006](#) did not include participants with ulcers.

Complications

[Belcaro 1993](#) reported no significant complications and no incidence of DVT in either group during two years of follow-up.

[Belcaro 1999](#) reported that no complications occurred.

[Makarova 2001](#) did not report whether complications occurred.

[Wang 2006](#) reported no incidence of DVT and revealed that surgical incisions healed well. No deaths among participants were reported.

Clinical changes

[Belcaro 1993](#) reported subjective improvement in symptoms in the experimental group. However, the data were not given, the method used for assessment was not described and significance values were not stated.

[Belcaro 1999](#) reported subjective improvement in the clinical degree of venous incompetence. This was measured by a quality of life (QoL) questionnaire, for which a range of 0 to 100 was used; the higher the score, the lower was the quality of life. The overall score for the treatment group was 49 at inclusion compared with 11 after 10 years—a reduction of 76% ($P < 0.05$). The overall score for the control group was 48 at inclusion compared with 36 after 10 years—for a reduction of 25% ($P < 0.05$). The difference between treatment and control groups was significant ($P < 0.05$).

[Makarova 2001](#) reported significant improvement in clinical outcomes of treated patients after seven years. Participants with deteriorating clinical dynamics over the five years preceding surgery had significantly higher rates of improvement in clinical condition in the treatment group (valvuloplasty plus ligation) compared with the control group (ligation only) (81% vs 51%; $P < 0.05$) after seven years of follow-up. Participants with stable preoperative clinical dynamics demonstrated similar rates of improvement in both groups (96% vs 90%; $P > 0.1$).

[Wang 2006](#) reported improvement in symptoms with significant differences between limbs in the groups selected for the study. Group A (external valvuloplasty of the femoral vein combined with surgery of the superficial venous system) showed improvement in leg heaviness of 90% compared with 55% in Group B (superficial venous system surgery only). [Wang 2006](#) showed improvement in deep venous function after femoral vein external valvuloplasty was combined with surgery to the superficial venous system. This improvement continued for three years.

Ambulatory venous pressure (AVP)

[Belcaro 1993](#) measured AVP in the affected limb before the intervention and at one and two years of follow-up. [Belcaro 1999](#) measured AVP at baseline and after 10 years of follow-up. Statistically significant improvement in the ligation and LAP group was observed in both studies. The mean change at one year was -20 mm Hg in the ligation and LAP group and -7 mm Hg in the ligation only group ($P < 0.05$). Respective changes at two years were -19 mm Hg and -6 mm Hg ($P < 0.05$). The mean difference (MD) between groups was -15 mm Hg (95% CI -20.9 to -9.0) at one year and -15 mm Hg (95% CI -21.1 to -8.9) at two years.

The change in AVP between baseline and 10 years was -21 mm Hg for the treatment group and -3 mm Hg for the control group ($P < 0.05$). The MD between groups was -18 mm Hg (95% CI -21.4 to -14.6).

When a cuff was applied to occlude the superficial system, changes in AVP in the ligation and LAP group were -16 mm Hg at one year and -14 mm Hg at two years ([Belcaro 1993](#)). Changes in AVP in the

ligation only group were -4 mm Hg at one year and -3 mm Hg at two years. The MD between the two groups was -12 mm Hg (95% CI -17.2 to -6.8) at one year and -11 mm Hg (95% CI -17.5 to -4.5) at two years.

At 10 years (Belcaro 1999), respective changes in AVP were -19 mm Hg for the treatment group and -4 mm Hg for the control group. The MD was -7 mm Hg (95% CI -10.0 to -4.0).

Ambulatory venous pressure was not reported in Makarova 2001 or Wang 2006.

Venous refill time (VRT)

Belcaro 1993 measured VRT before the intervention and at one and two years of follow-up. Improvement in VRT was noted in both treatment and control groups at one year (11.7 seconds in the ligation and LAP group compared with 10 seconds in the ligation only group) and at two years (11.7 seconds in the ligation and LAP group compared with eight seconds in the ligation only group), but this finding was not statistically significant. The mean difference at one year was two seconds (95% CI -2.8 to 6.8) and at two years was four seconds (95% CI -0.7 to 8.7).

With the application of a cuff, the difference in VRT at one year was 5.5 seconds in the treatment group and four seconds in the control group. At two years, this was reduced to 4.5 seconds in the treatment group and to two seconds in the control group. It should be noted that the layout of data in the trial article suggested that these VRT values corresponded to cuff application, although this was not made explicitly clear.

Belcaro 1999 measured VRT at baseline and at 10 years of follow-up. Improvement in VRT reached statistical significance: seven seconds in the treatment group compared with two seconds in the control group after 10 years ($P < 0.05$). The MD between the two groups was four seconds (95% CI 1.9 to 6.1).

With the application of a cuff to occlude the superficial venous system, the significant difference between the two groups was maintained at 10 years (Belcaro 1999) with a VRT of six seconds in the ligation and LAP group compared with two seconds in the ligation only group. The MD between the two groups was four seconds (95% CI 1.3 to 6.7).

Makarova 2001 did not measure VRT, and valve failure was not analysed using time-based methods. Wang 2006 did not report on VRT.

Venous filling index (VFI), ejection fraction (EF), reserve volume fraction (RVF) and CEAP severity score

Wang 2006 repeated these measures of haemodynamic indices during the study period of three years. It is reported that the repaired valve group experienced a greater effect in the sustained reduction of deep vein reflux and showed improvement in muscle pumping after three years compared with the non-repaired valve group. These haemodynamic indices and muscle pumping indices improved in Group A limbs postoperatively. In Group B limbs, muscle pumping indices did not improve significantly postoperatively ($P > 0.05$). Significant differences were noted in the amount of venous reflux, in VFI and in CEAP severity scores between Group A and B limbs at one month and one year postoperatively ($P < 0.01$). Significant differences were observed in all parameters assessed between Group A and B limbs three years postoperatively ($P < 0.05$). During the study period of three years, significant

improvement in reflux volume was noted—preoperative values of 84.4 ± 29.2 mL/min in Group A limbs and 79.2 ± 4.3 mL/min in Group B limbs improved to 43.0 ± 19.1 mL/min and 68.7 ± 2.1 mL/min, respectively ($P < 0.01$). Further, improvement of 8 to 9 mL/min in Group A and 3 to 4 mL/min in Group B was reported with regard to VFI ($P < 0.01$). Improvement in the EF of about 10% was described in Group A and about 2% in Group B. RVF also improved by about 13% in Group A and 4% in Group B. Overall CEAP severity score showed improvement among 13 in Group A and among 8 in Group B at three years.

These outcomes were not measured by Belcaro 1993, Belcaro 1999 or Makarova 2001.

Residual incompetence

Belcaro 1993 measured residual incompetence in repaired valves using colour duplex scanning. The criteria used were different from those used for inclusion (reflux longer than three seconds for inclusion, reflux longer than two seconds for follow-up). However, this change in criteria increases the sensitivity of the test and therefore is acceptable in the ligation and LAP group. At two years of follow-up, two of 11 valves repaired were incompetent. As the control group did not undergo valvuloplasty, no figures were given for comparison.

Belcaro 1999 stated that at 10 years, colour duplex indicated no superficial femoral incompetence in the treatment group, whilst all control limbs showed the same level of femoral incompetence.

Makarova 2001 reported no immediate residual incompetence (RT < 0.5 seconds). In 12 of 63 participants undergoing valvuloplasty, reflux reappeared or worsened postoperatively. Changes in RT and RVI (10 participants) were presented graphically by time. However, no data were provided on the other participants treated with valvuloplasty nor on the controls for comparison. Statistical analysis of time-based data was not presented, and it was not possible to extract this information from the data given in the paper. The relationship between clinical change and valvuloplasty failure was not made clear.

Wang 2006 reported that competency of the valve was maintained to 90.9% at three years postoperatively (100% at one month) in Group A, whereas Group B showed persistent incompetence.

Number of sites of incompetence

Belcaro 1993 measured the number of incompetent valves (defined as reflux longer than three seconds) using colour duplex scanning before the intervention, after six months and after two years. The mean number of incompetent valves in the ligation and LAP group was reduced by 11.9 and 9.9 at six months and two years, respectively. The mean number of incompetent valves in the ligation only group was reduced by 6.0 and 5.0 at six months and two years, respectively. The MD between groups was -4.9 (95% CI -6.8 to -3.0) at six months and -3.9 (95% CI -6.5 to -1.4) at two years. This difference was statistically significant and may represent a protective effect of LAP; may show that more efficient ligation of the superficial incompetent veins was performed in the ligation and LAP group in comparison with the ligation only group; or may suggest a combination of the two. The 10-year results were not reported, as Belcaro 1999 did not state the number of sites of incompetence identified.

[Makarova 2001](#) reported that among clinically stable participants preoperatively, only one participant in each of the valvuloplasty ($n = 22$) and control ($n = 21$) groups developed recurrence of varicose veins. In contrast, among participants for whom disease was progressive, two of 41 (5%) of those treated with valvuloplasty developed recurrence, whilst six of 41 (15%) in the control group developed recurrence.

[Wang 2006](#) did not report the number of sites of incompetence identified.

Colour duplex scanning

[Wang 2006](#) used this method to evaluate deep vein reflux grading. At three-year postoperative assessment using the CEAP classification, investigators reported 25 limbs in Group A graded at zero to 1, 14 limbs graded at 2 and one limb graded as 3. Within Group B, 12 limbs were graded at 2 and 28 limbs were graded at 3 for reflux. These findings were reported as significantly different between Group A and Group B ($P < 0.05$).

At 36 months, [Belcaro 1993](#) reported no superficial femoral incompetence in limbs among those in Group 2 (ligation and LAP), and all limbs in Group 1 (ligation only) showed the same level of incompetence.

This outcome measure was not reported by [Belcaro 1999](#) or [Makarova 2001](#).

Overall score for clinical outcome

[Belcaro 1993](#) did not provide individual data for included patients. The overall score for mean results in the ligation and LAP group was +2 (moderate improvement). This is represented by mild symptoms of chronic venous insufficiency, improvement in VRT of at least five seconds and improvement in AVP of at least -10 mm Hg. The overall score for the ligation only group was +1 (mild improvement), represented by clinical improvement or laboratory improvement in VRT or AVP.

[Belcaro 1999](#) reported a degree of subjective improvement, as measured by a QoL questionnaire. However, information was insufficient to infer an overall score for clinical outcome.

[Makarova 2001](#) did not provide individual data for included participants. However, it is possible to make some comment on changes in CEAP class over the seven years of follow-up, as reported in the paper. Among all participants who were clinically stable before surgery (21 in control group, 22 in valvuloplasty group), only one participant in the control group showed deterioration compared with none in the treatment group. Among 41 participants who demonstrated deterioration in CEAP class preoperatively, 14 continued to show deterioration after superficial venous surgery alone, 21 stabilised and six developed recurrent varicose veins. By comparison, progression was significantly halted in participants undergoing a valvuloplasty, with only six of 41 deteriorating and 33 stabilising (two developed recurrent varicose veins). Therefore, in the absence of individual data, the overall score for mean results of ligation and valvuloplasty, whether stable or progressive preoperatively, was +1 (clinical improvement but no physiological pressure data). A similar score was reported in the control group among participants who were stable preoperatively. However, among control participants with progressive disease preoperatively, a score of zero or -1 was documented in the study.

[Wang 2006](#) did not present individual data for included participants. However this study reports that in Group A (external valvuloplasty with surgery to the superficial venous system), compared with preoperative baseline data, the amount of venous reflux, the VFI and the CEAP severity score at one month, one year and three years postoperatively, and the EF and RVF at one year and three years, were significantly less. Significant differences in venous reflux, reflux indices and CEAP severity scores were noted between the limbs of both groups, when compared postoperatively at one month ($P < 0.1$) and at one year ($P < 0.1$), and in all parameters at three years ($P < 0.5$). In Group B (surgery to the superficial venous system only), compared with preoperative baseline data, the amount of venous reflux, the VFI and the CEAP severity were less, and the EF and RVF were not significantly different. Overall moderate improvement (+2) was noted.

These results show improvement in clinical symptoms and muscle pumping function and significant improvement in the haemodynamic status of participants in Group A limbs (external valvuloplasty with surgery to the superficial venous system). In Group B limbs (surgery to the superficial venous system only), improvement in clinical symptoms was reported with no improvement in muscle pumping function.

Results of surgery on secondary valvular incompetence

No trials under this subheading were identified.

Results of surgery for the obstructive form of DVI

No trials under this subheading were identified.

DISCUSSION

Summary of main results

The only available randomised controlled trials involved performing ligation and valvuloplasty in study participants with primary valvular incompetence ([Belcaro 1993](#); [Belcaro 1999](#); [Makarova 2001](#); [Wang 2006](#)). This treatment was compared with ligation only. No trials investigated surgical treatment of participants with DVI due to secondary valvular incompetence or the obstructive form of DVI. Moreover, no trials compared the results of surgical procedures versus those of high compression therapy in participants with venous ulcers secondary to DVI. The included trials were of small scale. Participants suffered from mild to moderate DVI, and none was reported to have a past or present history of venous ulcers. Many of the measures used in these trials are no longer used in clinical practice.

Ulcer healing and ulcer recurrence were not reported in one study ([Makarova 2001](#)), and the remaining three studies did not include participants with ulcers or active ulceration ([Belcaro 1993](#); [Belcaro 1999](#); [Wang 2006](#)). Three studies reported no significant complications of surgery and no incidence of DVT during follow-up ([Belcaro 1993](#); [Belcaro 1999](#); [Wang 2006](#)). One study did not report on the occurrence of complications ([Makarova 2001](#)).

Sustainable statistically significant improvement in AVP and VRT was achieved by ligation and LAP at 10 years ([Belcaro 1999](#)). Significance was maintained when AVP and VRT were measured with a cuff while the superficial system was excluded. However, AVP values after surgery remained relatively high, allowing the benefit of surgery to be questioned. Nevertheless, the benefit of

valve repair was sustained at 10 years of follow-up, and the clinical outcome score for the ligation and LAP group was +2 compared with +1 for the ligation only group.

Similarly, [Makarova 2001](#) demonstrated in participants who were deteriorating preoperatively sustained mild clinical improvement for seven years among those subjected to valvuloplasty compared with participants undergoing superficial venous surgery alone (zero or -1). However, this benefit was lost when the participant's condition was stable preoperatively.

[Wang 2006](#) reported that external valvuloplasty of the femoral vein combined with surgical repair of the superficial venous system improved the haemodynamic status of the lower limbs, restored valvular function more effectively and achieved better outcomes than surgical repair of the superficial venous system alone. However the study sample was small—40 participants (80 limbs) with only grade 3 reflux—and did not include participants with ulcers.

Overall completeness and applicability of evidence

This review included four small studies that reported clinical outcomes following valvuloplasty. We did not identify studies investigating other surgical procedures for the treatment of patients with DVI. Included studies reported different measures of clinical outcomes. Meta-analysis therefore was not possible, and we were not able to address all of our objectives. Individually, the studies reported promising results, but they included only participants with mild to moderate DVI, and so findings may not be applicable to patients with more severe DVI. One small trial showed continuous improvement for three years following external valvuloplasty of the femoral vein, in addition to surgery to the superficial venous system ([Wang 2006](#)). This improved the haemodynamic status of lower limbs and restored valvular function more effectively, achieving better outcomes when compared with surgery to the superficial venous system alone showing benefit in a group of patients not usually considered for surgery for DVI ([Wang 2006](#)). Results from three additional studies indicate that ligation and valvuloplasty may have produced moderate and sustained improvement for seven to 10 years after surgery among patients with mild to moderate DVI caused by primary valvular incompetence ([Belcaro 1993](#); [Belcaro 1999](#); [Makarova 2001](#)).

Very little information was available from the included studies on the primary outcome of ulcer healing and recurrence. Three studies excluded patients with ulcers or active ulceration, and one study did not report on ulcer healing and recurrence.

Some of the measures used in the included studies to assess clinical changes, for example, APG and RVI, are no longer used in clinical practice, and consensus has not been reached on how venous haemodynamics should be assessed and quantified. A clinically useful robust measure for the pathophysiology of deep venous incompetence is needed for future trials.

Quality of the evidence

Overall the quality of available evidence was low, which does not allow a robust conclusion regarding the effectiveness of surgical procedures in the treatment of patients with DVI, and we were unable to compare the results of surgical treatment of patients with DVI versus conventional medical treatment. Three of the four included studies provided no details of randomisation or blinding ([Belcaro 1993](#); [Belcaro 1999](#); [Makarova 2001](#)). Data within two trials were incomplete or were presented in such a way that further analysis was not possible ([Belcaro 1993](#); [Makarova 2001](#)). This assessment is made more difficult by the lack of a clinically generalised robust measure of deep venous function.

Potential biases in the review process

We believe that all relevant studies have been identified by our searches, but this review has been limited by the number of suitable RCTs and the small numbers of participants treated in these trials. Most participants are treated on an individual basis, and study results should be interpreted with considerable caution.

Agreements and disagreements with other studies or reviews

We are not aware of any other evidence regarding this topic.

AUTHORS' CONCLUSIONS

Implications for practice

No evidence was found for benefit or harm of valvuloplasty in the treatment of patients with DVI secondary to primary valvular incompetence. The individual trials included in this review are small, used different methods of assessment and overall were of poor quality. They did not include participants with severe DVI. Trials investigating the effects of other surgical procedures on deep veins are needed. Until the findings of such trials become available, the benefit of valvuloplasty remains uncertain.

Implications for research

Well-designed, large, randomised trials with long-term follow-up are needed to investigate surgical procedures for the treatment of patients with DVI. A clinically useful robust measure for pathophysiology of deep venous incompetence is needed for future trials. In the absence of this, trials should be designed and powered for clinically important outcomes such as ulcer healing, pain scores and QoL. In particular, trials including participants with venous ulcers secondary to DVI, trials reporting on ulcer healing and ulcer recurrence and trials comparing surgery with high compression therapy are required.

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CHARACTERISTICS OF STUDIES

Characteristics of included studies [ordered by study ID]

Belcaro 1993

Methods	Study design: randomised, parallel trial Method of randomisation: not stated Blinding: not stated Exclusions post randomisation: not stated Exclusions for failure to consent: not stated Dropouts: none Duration of study: 2 years Comparable treatment and control groups
Participants	Country: Italy No: 21 randomly assigned Age: mean 38 years experimental group, 37.9 years control group Sex: five males, six females in experimental group; five males, five females control group Inclusion criteria: primary femoral valve incompetence, signs of venous hypertension (large varicose veins, lipodermatosclerosis, perimalleolar skin changes), DVI defined as high AVP only partially affected by exclusion of the superficial system using an ankle tourniquet, significant reflux (on standing) at the common femoral vein defined as reflux lasting > 3 seconds as seen by a colour duplex scan, presence of vein cusps by high-resolution ultrasound Exclusion criteria: none mentioned
Interventions	Treatment: femoral vein external valvuloplasty using LAP in combination with ligation of incompetent superficial veins. Technique of LAP was described in detail in the published article. In brief, after the long saphenous vein was disconnected, the anterior surface of the common femoral vein was exposed. The anterior surface of the vein was plicated (3 mm in width stitches) longitudinally over the insertion line of the valve cusps for a length of 5 mm Treatment group also received subcutaneous heparin (dose and frequency not stated) on a daily basis for 5 days after the procedure. No reference was made to the use of compression bandages, elasticated hosiery or intermittent leg elevation after the operation Control: ligation of incompetent superficial veins only

Belcaro 1993 (Continued)

Outcomes	Subjective assessment, AVP, VRT, residual incompetence in repaired valves, number of sites of incompetence, common femoral vein diameter, approximation of vein cusps
Notes	No description was given of the figures representing the main outcome measures. After discussions with a statistician, it was concluded that these figures represented the mean and the standard deviation. Methods used to calculate significance level in this trial were not described Outcome measures were given in a selection of 6 months, 1 year and 2 years, but the data provided in the paper were not complete for each time point

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	No details given
Allocation concealment (selection bias)	High risk	No details given
Blinding of participants and personnel (performance bias) All outcomes	High risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	No details given
Incomplete outcome data (attrition bias) All outcomes	High risk	No description given for figures reported, incomplete data reported for each time point
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	None

Belcaro 1999

Methods	Study design: randomised, parallel trial Method of randomisation: not stated Blinding: not stated Exclusions post randomisation: not stated Exclusions for failure to consent: 6 Dropouts: 9 Duration of study: 10 years Comparable treatment and control groups
Participants	Country: Italy No: 44 participants entered, 35 completed 10-year follow-up

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Belcaro 1999 (Continued)

Age (mean): 41 ± 8 years treatment group; 41 ± 12 years control group (participants completing the study)

Sex: 11 males, 6 females in treatment group; 11 males, 7 females in control group (participants completing the study)

Inclusion criteria: primary femoral valve incompetence

Signs of venous hypertension (large varicose veins, lipodermatosclerosis, perimalleolar skin changes)

DVI defined as high AVP > 50 mm Hg and shorter VRT (< 13 seconds) not significantly modified by the application of a below-knee cuff

Significant reflux (> 3 seconds) on standing as seen by colour duplex scan

Mobile vein cusps on high-resolution ultrasound

Exclusion criteria: not stated

Interventions	Treatment: femoral vein external valvuloplasty using LAP in combination with ligation of incompetent superficial veins. Technique of LAP was described in detail in the published article. In brief, after the long saphenous vein was disconnected, the anterior surface of the common femoral vein was exposed. The anterior surface of the vein was plicated (3 mm in width stitches) longitudinally over the insertion line of the valve cusps for a length of 5 mm Treatment group also received elasticated graduated compression stockings plus daily subcutaneous heparin (dose and frequency not stated) for 5 days after surgery Control: ligation of incompetent superficial veins only
Outcomes	Subjective assessment, duplex scanning, venous reflex, CEAP severity scores, APG indices
Notes	Duplex scanning, venous reflex, CEAP severity scores, APG indices sufficient for inclusion Study suggests possible benefit of valve repair at 10 years

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	High risk	No details given
Allocation concealment (selection bias)	High risk	No details given
Blinding of participants and personnel (performance bias) All outcomes	High risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	No details given
Incomplete outcome data (attrition bias) All outcomes	Low risk	All data accounted for
Selective reporting (reporting bias)	Low risk	All outcomes reported
Other bias	Low risk	None

Makarova 2001

Methods	Study design: randomised, parallel trial Method of randomisation: not stated. Patients treated by elasticated compression for 5 years before study and divided into stable (unchanging CEAP clinical class) and progressive (deteriorating CEAP class) on entry into study Blinding not stated Exclusions post randomisation: not stated Exclusions for failure to consent: 40 Dropouts (lost to follow-up): 3 Duration of study (postoperatively): 7 years Comparable treatment and control groups
Participants	Country: Russia No: 168 participants entered. 149 completed 5-year observation period. 19 refused surgery. 128 entered surgical period. 125 completed 7 years of follow-up (63 treatment, 62 control) Age: not stated Sex: not stated Inclusion criteria: CEAP C2 to C4 Ultrasound reflux in both GSV and SFV Exclusion criteria: history of DVT, episodes of acute oedema of lower extremity, trauma, major surgery, hospital stay with bed rest longer than 3 days. Ultrasound findings (confirmed on phlebography) of occlusion/stenosis of femoral vein or massive collateral venous pathways
Interventions	Treatment: unilateral GSV stripping and stab avulsions of varicose tributaries. Phlebographically confirmed incompetent perforating veins subfascially ligated in 20 participants by open long medial vertical approach. All 63 participants underwent SFV valve correction by internal valvuloplasty Control: unilateral GSV stripping and stab avulsions of varicose tributaries. Phlebographically confirmed incompetent perforating veins subfascially ligated in 21 participants by open long medial vertical approach No reference made to the use of low-dose heparin and graduated compression stockings
Outcomes	No change in CEAP clinical class (defined as stable improvement) nor increase in clinical class (defined as aggravation), recurrent varicose veins RT and RVI were measured yearly by duplex scanning for 7 or 8 years postoperatively
Notes	Complications not mentioned Healing of 27 venous ulcers developing during 5 years prestudy; observation not mentioned separately 12 valvuloplasty failures (of 64) mainly during third year postoperatively of follow-up Large quantity of data not suitable for analysis Study suggests possible benefit of valve repair at 7 years
Risk of bias	
Bias	Authors' judgement Support for judgement

Makarova 2001 (Continued)

Random sequence generation (selection bias)	High risk	No details given
Allocation concealment (selection bias)	High risk	No details given
Blinding of participants and personnel (performance bias) All outcomes	High risk	No details given
Blinding of outcome assessment (detection bias) All outcomes	High risk	No details given
Incomplete outcome data (attrition bias) All outcomes	Low risk	At the end of the fifth year, 19 participants withdrew from the study and were not included in the final data analysis
Selective reporting (reporting bias)	Low risk	All outcomes reported as planned
Other bias	Low risk	None

Wang 2006

Methods	Study design: randomised, prospective and self-controlled Method of randomisation: Each of 40 participants drew lots under the observation of researchers, randomly assigned according to limb regardless of side Blinding: blinded Duration of study: 4 years Comparable treatment and control groups
Participants	Country: China No: 40 participants entered, 80 limbs Age: younger than 70 years Inclusion criteria: CEAP clinical class 2 to 4 with grade 3 reflux of deep veins, RT time longer than 0.5 seconds, PCVI of bilateral lower extremities; agreed to undergo simultaneous repair of both extremities Diagnosis confirmed in all cases by colour duplex scanning, APG or venography Exclusion criteria: 3 patients declined to draw lots for method of randomisation and procedure and hence were excluded from the study; CEAP clinical class 5 or 6, post-thrombotic venous insufficiency, pregnancy, current anticoagulation therapy, serious arterial occlusive disease of lower extremity, malignant tumours and serious cardiac, pulmonary, hematological or central nervous system disease
Interventions	Treatment: divided into 2 groups: Group A (40 limbs), "repaired valve group": femoral vein external valvuloplasty was combined with high ligation and stripping of great saphenous vein and percutaneous continuous circumsuture. Technique of modified external valvuloplasty was described in the published article. In brief, intermittent sutures were replaced with continuous double sutures. Advantage of doing so was ability to replicate

Wang 2006 (Continued)

and reinforce the commissural lines of first valves on venous wall of the femoral vein. Competence was demonstrated during the operation

- Group B (40 limbs), "non-repaired valve group": underwent high ligation and stripping of the GSV and percutaneous continuous circumsuture of varicose veins of the legs.

Anticoagulation was not given postoperatively and compression stockings were not used

Control: ligature of incompetent superficial veins only

Outcomes	Subjective assessment, duplex scanning, venous reflex, CEAP severity scores, APG indices; postoperative assessment shows significant improvement in symptoms and venous function in Group A compared with Group B
Notes	Duplex scanning, venous reflex, CEAP severity scores; APG indices show significant differences between groups 3 years postoperatively Study suggests possible benefit of valve repair at 3 years

Risk of bias

Bias	Authors' judgement	Support for judgement
Random sequence generation (selection bias)	Low risk	Each of the 40 participants drew lots twice under the observation of researchers. One lot was drawn to determine the operative procedure, and the other to determine the leg assigned for the procedure. When one limb was randomly assigned to Group A, regardless of whether it was right or left, the other leg was assigned to Group B
Allocation concealment (selection bias)	Low risk	Selected participants with CEAP clinical class 2 to 4 with grade 3 reflux of deep veins
Blinding of participants and personnel (performance bias) All outcomes	Low risk	Participants, technical personnel performing APG or colour duplex and another clinician who was not involved in the surgery but measured the clinical score were blinded The performing surgeon was not blinded
Blinding of outcome assessment (detection bias) All outcomes	Low risk	Clinician not involved in surgery measured clinical score and was blinded
Incomplete outcome data (attrition bias) All outcomes	Low risk	Well reported
Selective reporting (reporting bias)	Low risk	Comparison of haemodynamic indices was well reported
Other bias	Low risk	None

APG: air plethysmography.

AVP: ambulatory venous pressure.

CEAP: clinical, aetiological, anatomical, and pathophysiological classification score.

DVI: deep venous incompetence.

DVT: deep vein thrombosis.

GSV: greater saphenous vein.

LAP: limited anterior plication.

PCVI: primary chronic venous insufficiency.

RT: reflux time.

RVI: reflux volume index.

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SFV: superficial femoral vein.

VRT: venous refill time.

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

Study	Reason for exclusion
Ktenidis 2002	No control group
Pierik 1997	Participants underwent perforator ligation without surgery to deep veins
Rass 2012	Participants underwent surgery to superficial veins, not to deep veins
Sybrandy 2001	Participants underwent perforator ligation without surgery to deep veins

DATA AND ANALYSES

Comparison 1. Intervention versus control: trials on primary valvular incompetence

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
1 Ambulatory venous pressure (AVP)	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
1.1 At 1 year	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.2 At 2 years	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
1.3 At 10 years	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2 AVP with cuff application	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
2.1 At 1 year	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.2 At 2 years	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
2.3 At 10 years	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3 Venous refill time (VRT)	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
3.1 At 1 year	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.2 At 2 years	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
3.3 At 10 years	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4 Venous refill time with cuff	2		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
4.1 At 1 year	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
4.2 At 2 years	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Surgery for deep venous incompetence (Review)

Outcome or subgroup title	No. of studies	No. of participants	Statistical method	Effect size
4.3 At 10 years	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5 Number of sites of incompetence	1		Mean Difference (IV, Fixed, 95% CI)	Totals not selected
5.1 At 6 months	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]
5.2 At 2 years	1		Mean Difference (IV, Fixed, 95% CI)	0.0 [0.0, 0.0]

Analysis 1.1. Comparison 1 Intervention versus control: trials on primary valvular incompetence, Outcome 1 Ambulatory venous pressure (AVP).

Study or subgroup	Treatment		Control		Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
	N	Mean(SD)	N	Mean(SD)		
1.1.1 At 1 year						
Belcaro 1993	11	44 (7)	10	59 (7)	+	-15[-20.99,-9.01]
1.1.2 At 2 years						
Belcaro 1993	11	45 (6)	10	60 (8)	+	-15[-21.1,-8.9]
1.1.3 At 10 years						
Belcaro 1999	17	44 (4)	18	62 (6)	+	-18[-21.36,-14.64]
					-100 -50 0 50 100	Favours Treatment Favours Control

Analysis 1.2. Comparison 1 Intervention versus control: trials on primary valvular incompetence, Outcome 2 AVP with cuff application.

Study or subgroup	Treatment		Control		Mean Difference Fixed, 95% CI	Mean Difference Fixed, 95% CI
	N	Mean(SD)	N	Mean(SD)		
1.2.1 At 1 year						
Belcaro 1993	11	40 (7)	10	52 (5)	+	-12[-17.17,-6.83]
1.2.2 At 2 years						
Belcaro 1993	11	42 (9)	10	53 (6)	+	-11[-17.49,-4.51]
1.2.3 At 10 years						
Belcaro 1999	17	45 (6)	18	52 (2)	+	-7[-10,-4]
					-100 -50 0 50 100	Favours Treatment Favours Control

Analysis 1.3. Comparison 1 Intervention versus control: trials on primary valvular incompetence, Outcome 3 Venous refill time (VRT).

Analysis 1.4. Comparison 1 Intervention versus control: trials on primary valvular incompetence, Outcome 4 Venous refill time with cuff.

Analysis 1.5. Comparison 1 Intervention versus control: trials on primary valvular incompetence, Outcome 5 Number of sites of incompetence.

APPENDICES

Appendix 1. CENTRAL search strategy

#1	MESH DESCRIPTOR Venous Insufficiency EXPLODE ALL TREES	329
#2	((ven* or vein*) near4 (insuffici* or insufici* or incompet*)):TI,AB,KY	733
#3	CVI:TI,AB,KY	118
#4	MESH DESCRIPTOR Iliac Vein EXPLODE ALL TREES WITH QUALIFIERS SU	5
#5	MESH DESCRIPTOR Popliteal Vein EXPLODE ALL TREES WITH QUALIFIERS SU	11
#6	MESH DESCRIPTOR Femoral Vein EXPLODE ALL TREES WITH QUALIFIERS SU	50
#7	MESH DESCRIPTOR Saphenous Vein EXPLODE ALL TREES WITH QUALIFIERS SU	171
#8	(femoral or popliteal):TI,AB,KY	5612
#9	(iliac* or sapheno*):TI,AB,KY	1921
#10	#4 OR #5 OR #6 OR #7 OR #8 OR #9	7160
#11	(insuffic* or insufic* or incomp*):TI,AB,KY	11654
#12	#10 AND #11	327
#13	#1 OR #2 OR #3 OR #12	958
#14	MESH DESCRIPTOR Vascular Surgical Procedures EXPLODE ALL TREES	10890
#15	MESH DESCRIPTOR Ligation EXPLODE ALL TREES	475
#16	MESH DESCRIPTOR Stents EXPLODE ALL TREES	2661
#17	ligat* :TI,AB,KY	1407
#18	plicat*:TI,AB,KY	87
#19	(segmental near3 trans*):TI,AB,KY	42
#20	bypass:TI,AB,KY	10367
#21	surg*:TI,AB,KY	97458
#22	(stab avulsion):TI,AB,KY	4
#23	strip*:TI,AB,KY	1247
#24	(valve near3 transplant*):TI,AB,KY	18
#25	(valve near3 transpos*):TI,AB,KY	0
#26	(valve near3 reconstruct*):TI,AB,KY	17
#27	valvuloplasty:TI,AB,KY	81
#28	stent*:TI,AB,KY	4848

(Continued)

#29	phlebectomy:TI,AB,KY	26
#30	MESH DESCRIPTOR Angioplasty EXPLODE ALL TREES	3968
#31	angioplasty:TI,AB,KY	5389
#32	#14 OR #15 OR #16 OR #17 OR #18 OR #19 OR #20 OR #21 OR #22 OR #23 OR #24 OR #25 OR #26 OR #27 OR #28 OR #29 OR #30 OR #31	107240
#33	#13 AND #32	274

WHAT'S NEW

Date	Event	Description
15 October 2014	New search has been performed	New search carried out. One new study included. Three new studies excluded
15 October 2014	New citation required but conclusions have not changed	New search carried out. One new study included. Three new studies excluded. Risk of bias assessed for all included studies and text updated. No changes made to conclusions

HISTORY

Protocol first published: Issue 2, 1998

Review first published: Issue 2, 2000

Date	Event	Description
3 November 2008	Amended	Converted to new review format
26 May 2004	New citation required but conclusions have not changed	This review has been updated by the addition of 2 new included studies and 1 excluded study. No changes were made to the conclusions of the review

CONTRIBUTIONS OF AUTHORS

Original version of review

Ahmed Abidia selected all possible trials for inclusion, decided which trials should be included, assessed methodological quality of included trials, extracted data and wrote the text of the review.

Simon Hardy reviewed potential trials to decide which should be included, assessed methodological quality of included trials, extracted data and checked the content of the review before submission.

Updated review (2004)

Simon Hardy assessed new trials for possible inclusion in the review, extracted data and amended the text and data of the review when necessary.

Graham Riding checked the methodological quality of new included trials and cross-checked the data.

Ahmed Abidia read and commented upon the updated review.

Updated review (2014)

Ravi Raj Goel and Simon Hardy assessed new trials for possible inclusion in the review.

Ravi Raj Goel and Simon Hardy assessed all included studies for risk of bias.

Ravi Raj Goel amended the text of the review.

Ahmed Abidia read and commented upon the updated review.

DECLARATIONS OF INTEREST

RRG: none known.

AA: none known

SCH has declared that he is a Consultant Vascular Surgeon (East Lancashire Hospitals Trust) and is currently involved in the reorganisation of arterial and venous services involving DVT and varicose veins (Greater Manchester, Lancashire and South Cumbria Strategic Clinical Network). He is involved in screening programmes and is the Clinical Director of the Cumbria and Lancashire AAA Screening Programme.

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DIFFERENCES BETWEEN PROTOCOL AND REVIEW

In the previous published version, the quality of trials was investigated using the methods of Jadad ([Jadad 1996](#)) and Schulz ([Schultz 1995](#)). In keeping with updated requirements of The Cochrane Collaboration, quality has now been assessed using the 'Risk of bias' tool as described in the *Cochrane Handbook for Systematic Reviews of Interventions* ([Higgins 2011](#)).

Outcomes and comparisons were reordered for this 2014 update for consistency with both clinical relevance and policies of The Cochrane Collaboration.

INDEX TERMS

Medical Subject Headings (MeSH)

Leg [*blood supply]; Peripheral Vascular Diseases [*surgery]; Randomized Controlled Trials as Topic; Venous Insufficiency [*surgery]; Venous Valves [*surgery]

MeSH check words

Humans