

NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of lower limb deep vein valve reconstruction for chronic deep venous incompetence

Chronic deep venous incompetence is a condition in which the valves in the deep veins stop working properly. It can cause a range of symptoms in the legs, including pain, swelling, skin changes and recurrent ulcers. Deep vein valve reconstruction involves surgical techniques aiming to restore the function of the valve.

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in October 2006.

Procedure name

- Deep venous valve reconstruction
- Valvuloplasty

Specialty societies

- The Vascular Society of Great Britain and Northern Ireland

Description

Indications

Chronic deep venous incompetence (deep venous reflux disease)

Chronic deep venous incompetence causes a range of symptoms and signs in the legs, including pain, swelling, skin changes (lipodermatosclerosis) and recurrent ulcers. The condition may be caused by incompetence of the valves

in the deep veins (when valves do not close properly, allowing blood to reflux back down the veins), by obstruction of vein lumen (for example after deep vein thrombosis or trauma to the vein), or a combination of the two. Incompetence of the valve may be primary (for example, due to laxity of the vein wall or valve cusps) or secondary (for example when valves are damaged as a result of deep vein thrombosis). Reflux or obstruction in deep veins of the legs interferes with venous return (venous insufficiency) and causes high pressure in the veins of the lower leg (venous hypertension). These can lead to swelling and skin damage.

Duplex scanning and sometimes venography are used to assess the patency of the veins and the competence of their valves. Other investigations are sometimes used in complex cases. Photoplethysmography can measure venous refilling time, which is the time necessary for the lower leg to refill with blood after specific exercises to empty it (faster refilling times indicate venous incompetence). Ambulatory venous pressure may be measured by inserting a needle into the foot vein to determine venous pressure before and after exercise (the normal drop in pressure with exercise is less marked if reflux is present).

The severity of venous disease is usually rated using the CEAP classification system:

- C – clinical signs (scored 0–6 where 0 = no visible signs and 6 = skin changes with active ulceration)
- E – (a)etiological classification (congenital, primary, secondary)
- A – anatomical distribution (superficial, deep, or perforator)
- P – pathophysiological dysfunction (reflux, obstruction, or both).

Current treatment and alternatives

Chronic deep venous incompetence is usually treated conservatively, with graduated compression stockings. Advice about elevation of the limb and about skin care may also be helpful. Ulcers are treated by compression bandaging. If symptoms persist and ulcers fail to respond to conservative treatments, surgery may be considered – usually operation for coexisting incompetence of superficial or perforating veins but occasionally surgery on the deep veins. Decisions about surgery for deep venous incompetence are difficult.

Surgery for chronic deep venous incompetence may be directed at relieving venous obstruction (for example by vein transposition or venous bypass grafting) or designed to restore competent valves. Vein segment transposition involves dissecting and mobilising the incompetent vein and joining it to a normal vein distal to a valve with normal function. Vein valve transplantation involves excising the incompetent segment of the leg vein and replacing it with a valve-containing segment of a competent vein (for example from the axillary or brachial vein).

What the procedure involves

Deep venous valve reconstruction is usually performed under general anaesthesia. A number of techniques exist for reconstructing the venous valves, the most common of which is valvuloplasty (internal or external). The appropriate segment of vein is accessed through an incision in the leg and dissected free from surrounding tissue. Internal valvuloplasty involves tightening the valve cusps by stitches. An angioscope is sometimes used to aid visualisation. The aim is to tighten the two cusps of the valve when the valve is closed.

External valvuloplasty involves suturing a fold into the external vein wall to reduce the diameter of the vein and allow the valve cusps within to meet properly. A variation of this technique is limited anterior plication, which is carried out only on the anterior side of the vein after limited dissection of the anterior circumference of the vein.

Another method of deep venous valve reconstruction is external banding. This involves wrapping a sleeve made of synthetic or natural tissue around the vein and tightening it to reduce the diameter of the vein.

Efficacy

The efficacy evidence in this overview relates to three randomised controlled trials, one non-randomised controlled trial and four case series.^{1-6, 8,9}

The specialist advisers listed the key efficacy outcomes as valvular competence and patency, improved quantifiable tests of venous function, and clinical benefit such as healing of leg ulcers.

Clinical outcomes

One randomised controlled trial reported no increase in disease severity class during follow-up for 86% (54/63) patients receiving valvuloplasty and superficial venous surgery compared with 64% (40/62) of patients in the control group receiving superficial venous surgery alone ($p < 0.05$).¹ A second randomised controlled trial of 44 patients stated that patients receiving valvuloplasty reported a significantly better quality of life than patients receiving superficial venous surgery alone at 10-year follow-up ($p < 0.05$).²

One case series of 169 legs reported an ulcer recurrence-free survival of 64% for patients with primary valvular incompetence and 47% for patients with secondary valvular incompetence at 2 years.⁵ A second case series of 141 legs reported that 90% (76/84) ulcers healed within 3 months and 17% (13/76) recurred during the follow-up period (1–42 months).⁶ A third case series including 61 valvuloplasties reported that 87% (52/60) of patients had reduction in pain, 83% (50/60) had reduction in swelling, and 63% (25/40) had sustained and complete healing of ulcer after a minimum 2-year follow-up.⁸ A case series of 51 legs reported that 33% (17/51) of legs were symptom-free after a mean follow-up of 10.6 years.⁹

Valve competency

Two randomised controlled trials reported that 82% (9/11) and 71% (45/63) of valves treated by valvuloplasty were competent after 2 years and 7–8 years respectively.^{1,3} A non-randomised controlled trial reported that 94% (16/17) of valves were competent after valvuloplasty compared with 29% (4/14) valves in patients treated with superficial venous surgery alone, at a mean follow-up of 25 months ($p < 0.01$).⁴ A case series of 141 legs reported cumulative competency rates of 84% at 12 months and 59% at 30 months.⁶

Venous function

One randomised controlled trial reported that the mean ambulatory venous pressure in 35 legs followed up for 10 years was significantly lower after valvuloplasty with superficial venous surgery than after superficial venous surgery alone (44 mm Hg versus 62 mm Hg, $p < 0.05$). The mean refilling time was also significantly longer (16 seconds versus 12 seconds, $p < 0.05$).²

Safety

The safety evidence in this overview relates to five case series, including a total of 612 legs.^{5–9}

The specialist advisers stated that the main potential adverse effects of the procedure are deep vein thrombosis, pulmonary embolism and bleeding.

Deep vein thrombosis and pulmonary embolism

Four case series reported deep vein thrombosis rates of 4% (5/141), 7% (8/107), 12% (21/169) and 13% (11/85).^{5–8} A case series of 141 legs reported one case of pulmonary embolism (1%).⁶

Haematoma and postoperative bleeding

Four case series reported rates of haematoma between 3% (5/144) and 10% (17/169).^{5–8} Two case series reported postoperative bleeding after 1% (2/144) and 16% (8/51) of valve reconstructions.^{7,9}

Wound infections

Four case series reported rates of wound infection between 1% (2/141) and 7% (12/169).^{5,6,8,9}

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to deep venous valve reconstruction. Searches were conducted via the following databases, covering the period from their commencement to June 2006: Medline, PreMedline, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches. (See appendix B for details of search strategy.)

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients with chronic deep venous incompetence
Intervention/test	Deep venous valve reconstruction
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on three randomised controlled trials, one non-randomised controlled trial and five case series.¹⁻⁹ All the comparative studies compared superficial venous surgery and valvuloplasty with superficial venous surgery alone.¹⁻⁴

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (table 2) have been listed in appendix A.

Existing reviews on this procedure

A Cochrane Review on surgery for deep venous incompetence was published in 2000 and updated in 2004.¹⁰ Three randomised controlled trials were included in the updated review, all of which are summarised in table 2.¹⁻³ There were insufficient trials to allow pooled statistical analysis. The review concluded that there was insufficient evidence to recommend any form of valvuloplasty for the treatment of deep venous incompetence due to primary valvular incompetence. However, the small trials included in the review demonstrated a possible long-term benefit in certain groups of patients.

Related NICE guidance

There is currently no other NICE guidance related to this procedure.

Table 2 Summary of key efficacy and safety findings on deep venous valve reconstruction

Abbreviations used: CEAP, clinical etiological anatomical pathological classification; CVI, chronic venous insufficiency; GSV, greater saphenous vein; SFV, superficial femoral vein			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Makarova NP (2001)¹</p> <p>Randomised controlled trial</p> <p>Russia</p> <p>Study recruitment period: 1983–1984</p> <p>n = 125 legs (125 patients)</p> <ul style="list-style-type: none"> • Superficial venous surgery plus internal valvuloplasty of SFV = 50% (63/125) • Superficial venous surgery alone (control group) = 50% (62/125) <p>Population: patients with primary CVI treated with elastic compression and observed for 5 years before undergoing surgery</p> <p>Indications: Inclusion criteria included clinical class C2, C3 or C4 disease (CEAP classification); reflux demonstrated by duplex ultrasound scan in both the proximal GSV and SFV. Exclusion criteria included history of deep venous thrombosis; episodes of acute oedema of the lower extremity; trauma; major surgery; hospital stay with bed rest > 3 days; ultrasound scan findings of segmental thickening of venous wall or complete occlusions of the vein</p> <p>Technique: superficial vein surgery included phlebectomy and subfascial ligation of perforating veins</p> <p>Follow-up: 7 to 8 years</p> <p>Conflict of interest: none stated</p>	<p>No increase in clinical disease severity class identified during follow-up:</p> <ul style="list-style-type: none"> • Valvuloplasty group = 85.7% (54/63) • Control group = 64.5% (40/62) <p>p < 0.05</p> <p>No increase in clinical disease severity class in patients with progressive type of clinical disease before surgery:</p> <ul style="list-style-type: none"> • Valvuloplasty group = 80% • Control group = 51% <p>p < 0.05</p> <p>No increase in clinical disease severity class in patients with stable type of clinical disease before surgery:</p> <ul style="list-style-type: none"> • Valvuloplasty group = 95% • Control group = 90% <p>p > 0.1</p> <p>Competence of corrected valve during follow-up = 71.4% (45/63)</p> <p>Reappearance of reflux in valvuloplasty group = 19% (12/63)</p> <p>Increase in reflux during follow-up:</p> <ul style="list-style-type: none"> • Valvuloplasty group = 15.9% (10/63) • Control group = 53.2% (33/62) <p>p value not stated</p>	<p>No complications were described.</p>	<p>168 patients were initially recruited to study; 149 completed initial 5 year observation period, 19 withdrew because they refused to undergo surgery and 3 were lost to follow-up after surgery (2 in control group and 1 in study group).</p> <p>Before randomisation, patients were stratified according to clinical disease severity score over 5 year observation period (stable if CEAP did not change or progressive if there was an increase of at least one clinical class).</p>

Abbreviations used: CEAP, clinical etiological anatomical pathological classification; CVI, chronic venous insufficiency; GSV, greater saphenous vein; SFV, superficial femoral vein			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Belcaro G (1999)²</p> <p>Randomised controlled trial</p> <p>England, Italy</p> <p>Study period: not stated</p> <p>n = 44 legs (44 patients)</p> <ul style="list-style-type: none"> • Superficial venous surgery plus deep vein external valvuloplasty (SFV) = 50% (22/44) • Superficial venous surgery alone (control group) = 50% (22/44) <p>Population: patients with primary superficial femoral vein incompetence and signs of venous hypertension (large varicose veins, lipodermatosclerosis, and perimalleolar skin changes) without a history of venous thrombosis</p> <p>Mean age (years):</p> <ul style="list-style-type: none"> • Valvuloplasty = 42 (range 25–63) • Control group = 42 (range 25–65) <p>Male:</p> <ul style="list-style-type: none"> • Valvuloplasty = 73% (16/22) • Control group = 64% (14/22) <p>Indications: Exclusion criteria included obesity, and other vascular, metabolic or cardiac disease.</p> <p>Technique: External valvuloplasty with limited anterior plication. Superficial vein surgery included ligation and section of major incompetent superficial veins</p> <p>Follow-up: 10 years</p> <p>Conflict of interest: none stated</p>	<p>Valve competency was achieved intraoperatively in all treated veins, assessed clinically by the Raju test (compressing and emptying with fingers the common femoral vein 3 to 5 cm proximally and distally to the suture and suddenly releasing the proximal compression. The filling to the level of the valve with the vein being empty below indicated competence).</p> <p>Mean ambulatory venous pressure at 10 years (n = 35):</p> <ul style="list-style-type: none"> • Valvuloplasty = 44 mm Hg • Control group = 62 mm Hg, p < 0.05 <p>Mean refilling time at 10 years (n = 35):</p> <ul style="list-style-type: none"> • Valvuloplasty = 16 seconds • Control group = 12 seconds, p < 0.05 <p>Mean ambulatory venous pressure at 10 years with cuff to exclude superficial venous system (n = 35):</p> <ul style="list-style-type: none"> • Valvuloplasty = 45 mm Hg • Control group = 52 mm Hg, p < 0.05 <p>Mean refilling time at 10 years with cuff (n = 35):</p> <ul style="list-style-type: none"> • Valvuloplasty = 17 seconds • Control group = 13 seconds, p < 0.05 <p>Total quality-of-life score at inclusion to study (10 items assessed were pain/discomfort, oedema/swelling, mobility limitation, cosmetic aspects, need to wear stockings, need to see a doctor, expenses, lost working days, other limitations, and social embarrassment. Each item was scored 0 for no problems to 10 for most severe problems):</p> <ul style="list-style-type: none"> • Valvuloplasty = 49 • Control group = 48 <p>Total quality-of life score at 10 years:</p> <ul style="list-style-type: none"> • Valvuloplasty = 11 • Control group = 36, p < 0.05 	<p>During the follow-up, no superficial or deep venous thrombosis or other complication was observed.</p>	<p>An additional 6 patients were eligible for study but chose not to take part as the 10-year follow-up was too difficult or impractical.</p> <p>9 patients were lost to follow-up (4 in the control group and 5 in the valvuloplasty group).</p> <p>The authors suggested that limited anterior plication could be used when the incompetence is moderate (for example, in younger subjects) and localised to the larger venous segments.</p>

Abbreviations used: CEAP, clinical etiological anatomical pathological classification; CVI, chronic venous insufficiency; GSV, greater saphenous vein; SFV, superficial femoral vein			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Belcaro G (1993)³</p> <p>Randomised controlled trial</p> <p>Italy</p> <p>Study period: not stated</p> <p>n = 21 patients</p> <ul style="list-style-type: none"> • Superficial venous surgery plus external valvuloplasty of femoral vein = 52% (11/21) • Superficial venous surgery alone (control group) = 48% (10/21) <p>Population: patients with primary femoral valve incompetence and signs of venous hypertension (large varicose veins, lipodermatosclerosis and perimalleolar skin changes)</p> <p>Mean age (years):</p> <ul style="list-style-type: none"> • Valvuloplasty = 42 (range 25–63) • Control group = 42 (range 25–65) <p>Male:</p> <ul style="list-style-type: none"> • Valvuloplasty = 45% (5/11) • Control group = 50% (5/10) <p>Indications: increased ambulatory venous pressure only partially modified by the application of an ankle tourniquet excluding the superficial system; a significant (> 3 seconds) reflux on standing at the common femoral vein as seen by colour duplex; presence of vein cusps by high resolution ultrasound scanning</p> <p>Technique: External valvuloplasty with limited anterior plication. Superficial vein surgery included ligation and section of incompetent superficial veins</p> <p>Follow-up: 2 years</p> <p>Conflict of interest: none stated</p>	<p>Mean ambulatory venous pressure measurements at 24-month follow-up:</p> <ul style="list-style-type: none"> • Valvuloplasty = 45 mm Hg • Control group = 60 mm Hg <p>p < 0.05</p> <p>Mean refilling time at 24-month follow-up:</p> <ul style="list-style-type: none"> • Valvuloplasty = 19 seconds • Control group = 15 seconds <p>p < 0.05</p> <p>Mean ambulatory venous pressure measurements at 24-month follow-up (with cuff to occlude superficial system) :</p> <ul style="list-style-type: none"> • Valvuloplasty = 42 mm Hg • Control group = 53 mm Hg <p>p = not stated</p> <p>Mean refilling time at 24-month follow-up (with cuff):</p> <ul style="list-style-type: none"> • Valvuloplasty = 19 seconds • Control group = 16 seconds <p>p < 0.05</p> <p>Valve incompetence at 24 months in valvuloplasty group = 18% (2/11)</p> <p>Mean number of sites of incompetence after 24-month follow-up:</p> <ul style="list-style-type: none"> • Valvuloplasty = 3.1 • Control group = 7 <p>p = not stated</p>	<p>'No deep vein thrombosis or significant complication was observed in the 2 groups.'</p>	<p>Same study centre as reference 2 (Belcaro et al 1999). There may be some patients common to both studies.</p> <p>There were no losses to follow-up.</p>

Abbreviations used: CEAP, clinical etiological anatomical pathological classification; CVI, chronic venous insufficiency; GSV, greater saphenous vein; SFV, superficial femoral vein			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Sakuda H (2002)⁴</p> <p>Non randomised controlled trial (prospective)</p> <p>Japan</p> <p>Study period: 1998–2001</p> <p>n = 31 legs (25 patients)</p> <ul style="list-style-type: none"> • Superficial venous surgery plus external valvuloplasty of femoral vein = 55% (17/31) • Superficial venous surgery alone (control group) = 45% (14/31) <p>Population: Patients with CVI caused by chronic valvular incompetence of deep veins, saphenous veins and perforators.</p> <p>Male = 48% (12/25)</p> <p>Mean age = 56 years (range 33–80)</p> <p>CEAP classification C4 to C6:</p> <ul style="list-style-type: none"> • Superficial venous surgery plus external valvuloplasty of femoral vein = 100% (17/17) • Control group = 36% (5/14), p < 0.001 <p>Inclusion criteria: deep venous incompetence was defined as moderate to severe reflux of grade 3 or 4 (Herman and Kistner classification) on descending phlebography. Exclusion criteria: post-thrombotic syndrome, clinical history of deep vein thrombosis, or recurrent varicose veins/ulcers after stripping.</p> <p>Technique: external valvuloplasty (with use of angioscope).</p> <p>Mean follow-up: 25 months (range 12–37)</p> <p>Conflict of interest: none</p>	<p>Percentage of patients wearing elastic stockings daily:</p> <ul style="list-style-type: none"> • Valvuloplasty = 23.5 • Control group = 64.3, p < 0.05 <p>Venous clinical severity score:</p> <ul style="list-style-type: none"> • Valvuloplasty = 2.1 • Control group = 3.4, p < 0.05 <p>Venous disability score:</p> <ul style="list-style-type: none"> • Valvuloplasty = 0.8 • Control group = 1.4, p < 0.05 <p>Mean postoperative venous volume (at 1 month):</p> <ul style="list-style-type: none"> • Valvuloplasty = 123 ml • Control group = 142 ml, p < 0.01 <p>Mean postoperative venous filling index (at 1 month):</p> <ul style="list-style-type: none"> • Valvuloplasty = 2.8 ml/s • Control group = 7.0 ml/s, p < 0.01 <p>Mean postoperative ejection fraction (at 1 month):</p> <ul style="list-style-type: none"> • Valvuloplasty = 49.1% • Control group = 52.6%, p = not stated <p>Mean residual volume fraction (at 1 month):</p> <ul style="list-style-type: none"> • Valvuloplasty = 46.1% • Control group = 44.5%, p = not stated <p>Competent valvular function of femoral veins:</p> <ul style="list-style-type: none"> • Valvuloplasty = 94% (16/17) • Control group = 29% (4/14), p < 0.01 <p>No new ulcers appeared in either group.</p>	<p>Perioperative complications</p> <p>'Mild' wound infection</p> <ul style="list-style-type: none"> • Valvuloplasty = 6% (1/17) • Control group = 0% (0/14) <p>No deep vein thrombosis or other complications were observed during follow-up.</p>	<p>Patients were divided into two treatment groups, depending on preference of the patient.</p> <p>There was a significantly higher proportion of patients classified as C4 to C6 (CEAP classification) in the valvuloplasty group than in the control group.</p> <p>The paper does not describe details of the venous clinical severity score or the venous disability score.</p>

Abbreviations used: CEAP, clinical etiological anatomical pathological classification; CVI, chronic venous insufficiency; GSV, greater saphenous vein; SFV, superficial femoral vein			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Tripathi R (2004)⁵</p> <p>Case series</p> <p>Australia, India</p> <p>Study period: 1994–1999</p> <p>n = 169 legs (137 patients)</p> <p>Population: patients undergoing deep vein reconstructions for non-healing venous leg ulcers of CEAP C6 class as a 'last resort' treatment</p> <p>Primary reflux disease = 70% (118/169) Secondary reflux disease = 30% (51/169)</p> <p>Mean age = 38.7 years (range 17–75)</p> <p>Male = 69% (94/137)</p> <p>Indications: Inclusion criteria were CEAP C6 ulceration of leg \geq 3 cm diameter and present for > 3 months duration unhealed; evidence of severe deep venous reflux: Kistner's grade III/IV reflux on descending venogram and valve closure time > 3 seconds associated with reflux velocities > 5 cm/s by standing Duplex scan with patient performing Valsalva manoeuvre; failure of conservative therapy > 3 months; previous superficial or perforator vein operation(s) with no current duplex-recorded superficial or perforator vein incompetence; open surgical demonstration of a repairable, refluxive valve. Exclusion criteria: segmental deep venous reflux; coagulopathy; obstructions; fixed equinus deformity of ankle or operative findings of valveless syndrome</p>	<p>Primary reflux disease Healing of skin ulcer at follow-up:</p> <ul style="list-style-type: none"> External valvuloplasty = 50% (6/12) Internal valvuloplasty = 68% (61/90) <p>Valve station competency (valve closure time < 0.5 seconds) at follow-up:</p> <ul style="list-style-type: none"> External valvuloplasty = 32% (6/19) Internal valvuloplasty = 80% (115/144) <p>Of 105 valves with single-level repair, 59% (62/105) were competent with an ulcer healing in 55% limbs. Of the 74 valves with multilevel repairs, 80% (59/74) were competent with ulcer healing in 73% of limbs.</p> <p>Ulcer recurrence-free survival at 2 years = 63.5%</p> <p>Secondary reflux disease Valve patency at 2 years = 58% Valve competency at 2 years = 47% Leg ulcer healing at 2 years = 55%</p> <p>Ulcer recurrence-free survival at 2 years = 47%</p> <p>18 valve segments underwent single-level repair and 40% (7/18) were competent with ulcer healing in 46% of limbs. Of 20 valve segments with multilevel repairs, 56% (24/43) of valves were competent with ulcer healing in 57% of limbs.</p>	<p>Complications</p> <ul style="list-style-type: none"> Wound haematoma = 10% (17/169) Wound infections = 7% (12/169) Postoperative serosanguineous drainage > 500 ml in first 3 postoperative days requiring blood transfusion = 7% (9/137) Postoperative deep vein thrombosis = 12% (21/169) (significantly fewer patients with primary reflux disease had DVT compared with patients treated for secondary reflux disease, 7% versus 25%, p = 0.001) 'Valve resorption' = 6% (11/179 valve stations) 	<p>A variety of techniques for internal and external valvuloplasty were used.</p> <p>The authors stated that they no longer use external cuffing because of unsatisfactory results.</p>

Abbreviations used: CEAP, clinical etiological anatomical pathological classification; CVI, chronic venous insufficiency; GSV, greater saphenous vein; SFV, superficial femoral vein			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Tripathi R (2004)⁵ continued.</p> <p>Technique: Primary reflux disease was treated by internal valvuloplasty (n = 90), external valvuloplasty (n = 12), external supports (n = 16). Secondary reflux disease was treated by axillary-femoral vein or saphenofemoral vein valve transplant (n = 38), saphenofemoral venous transposition (n = 4), femoral or popliteal vein ligation (n = 9)</p> <p>Follow-up: 24 months</p> <p>Conflict of interest: none stated</p>			

Abbreviations used: CEAP, clinical etiological anatomical pathological classification; CVI, chronic venous insufficiency; GSV, greater saphenous vein; SFV, superficial femoral vein			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Raju S (2000)⁶</p> <p>Case series</p> <p>USA</p> <p>Study period: not stated</p> <p>n = 141 legs (129 patients)</p> <p>Population: patients with primary or secondary deep venous reflux disease.</p> <p>Median age = 56 years (range 32–86)</p> <p>Male = 46% (59/129)</p> <p>Clinical class (CEAP classification):</p> <ul style="list-style-type: none"> • 2 = 3% (4/141) • 3 = 19% (27/141) • 4 = 13% (18/141) • 5 = 14% (20/141) • 6 = 51% (72/141) <p>Indications: inclusion and exclusion criteria not stated</p> <p>Technique: transcommissural valvuloplasty (transluminal resuspension suture used without a venotomy)</p> <p>Follow-up: 1 to 42 months</p> <p>Conflict of interest: none</p>	<p>Reflux time < 0.5 seconds = 78%</p> <p>Cumulative competency rates (reflux time < 0.5 seconds) of 140 sites:</p> <ul style="list-style-type: none"> • 12 months = 84% • 24 months = 72% • 30 months = 59% <p>Median time to failure was 11 to 16 months (range 2–35), depending on criteria used.</p> <p>Ulcers healed within 3 months = 90% (76/84)</p> <p>Recurrence of ulcer during follow-up = 17% (13/76)</p> <p>3 of 13 limbs with ulcer recurrence had a failure of the repaired valve site.</p> <p>Frequency of totally pain-free patients:</p> <ul style="list-style-type: none"> • Before surgery = 15% • At follow-up = 64% <p>Complete absence of swelling:</p> <ul style="list-style-type: none"> • Before surgery = 14% • At follow-up = 51% <p>Mean ambulatory pressure drop (n = 76):</p> <ul style="list-style-type: none"> • Before surgery = 46% • At follow-up = 57%, p < 0.001 <p>Mean venous recovery time (n = 76):</p> <ul style="list-style-type: none"> • Before surgery = 12 seconds • At follow-up = 23 seconds, p < 0.001 <p>Mean venous filling index (n = 76):</p> <ul style="list-style-type: none"> • Before surgery = 4.1 ml/s • At follow-up = 3.1 ml/s, p < 0.05 <p>Hand/foot pressure differential (n = 76):</p> <ul style="list-style-type: none"> • Before surgery = 1.8 mm Hg • At follow-up = 1.2 mm Hg, p < 0.05 	<p>Postoperative complications (< 30 days)</p> <ul style="list-style-type: none"> • Superficial wound infection = 1% (1/141) • Deep wound infection = 1% (1/141) • Large wound haematoma = 3% (4/141) • Seroma = 1% (1/141) • Deep vein thrombosis = 4% (5/141) • Two deep vein thromboses involved the repaired valve, one of which was salvaged. • Pulmonary embolus = 1% (1/141) <p>One patient with a prior history of dysrhythmia died at home 2 weeks postoperatively from unknown causes. He had discontinued anticoagulation and refused admission for evaluation of weakness and shortness of breath.</p> <p>Three cases of interval recurrent thromboses were detected during routine scanning at 6 months, 3 years and 4 years after surgery. In two, the repaired valve site was involved and the leg ulcer recurred.</p>	<p>In 83 limbs, removal of an incompetent long saphenous vein was performed simultaneously.</p> <p>Assessment of patency and competency of the repaired vein site with duplex Doppler ultrasound was possible in 78% (140/179) sites and 84% (109/141) limbs.</p> <p>Clinical outcome was reported for 93% (131/141) limbs.</p>

Abbreviations used: CEAP, clinical etiological anatomical pathological classification; CVI, chronic venous insufficiency; GSV, greater saphenous vein; SFV, superficial femoral vein			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Perrin M (2000)⁷</p> <p>Case series</p> <p>France</p> <p>Study period: 1983–1997</p> <p>n = 144 legs (133 patients)</p> <p>47% (68/144) patients had primary venous insufficiency 51% (74/144) patients had post-thrombotic syndrome</p> <p>Population: patients with symptomatic deep venous reflux</p> <p>Clinical class (CEAP classification):</p> <ul style="list-style-type: none"> • C3 = 9% (13/144) • C4 = 40% (57/144) • C5, C6 = 51% (74/144) <p>All patients had previously undergone conservative management and/or venous surgery Indications: Exclusion criteria were severe, irreversible lesions affecting the muscular pumping system of the calf muscle; blockage of the tarso-tibial joint after physical therapy; neurologic syndrome affecting the diseased leg; severe, permanent coagulation disorder</p> <p>Technique: internal valvuloplasty (n = 85), transplantation (n = 32), transposition (n = 18), Psathakis type II procedures (n = 9)</p> <p>Follow-up: 12–168 months</p> <p>Conflict of interest: none stated</p>	<p>Results of postoperative duplex scan in valvuloplasty patients followed up for more than one year (n = 83):</p> <ul style="list-style-type: none"> • Major reflux = 20.5% (17/83) • Minor reflux = 15.7% (13/83) • No reflux = 62.2% (51/83) <p>Ulcer recurrence or non-healing ulcer in valvuloplasty patients classified C5 or C6 followed by more than one year = 28.6% (10/35)</p> <p>Photoplethysmography showed that venous return was normalised in 63.2% (43/68) valvuloplasties at the last examination.</p>	<ul style="list-style-type: none"> • Bleeding requiring repeat surgery = 1.3% (2/144) • 'Major' haematoma = 3.4% (5/144) (2 of which underwent further surgery) • Deep vein thrombosis = 20.3% (29/144) (in valvuloplasty, thrombosis rate was 12.9% (11/85)) 	<p>Although patients with a severe, permanent coagulation disorder should have been excluded from the study, some were included as the disorder was not identified until later.</p> <p>The authors stated that they abandoned the Psathakis procedure after 18 months as none of the patients had haemodynamic improvement.</p> <p>2% (2/85) valvuloplasty patients were not evaluated with a postoperative duplex scan.</p> <p>The authors suggested that the high rate of thrombosis is due to the routine use of postoperative venography within the first 48 hours. They suggested that this would be overlooked in other studies.</p>

Abbreviations used: CEAP, clinical etiological anatomical pathological classification; CVI, chronic venous insufficiency; GSV, greater saphenous vein; SFV, superficial femoral vein			
Study details	Key efficacy findings	Key safety findings	Comments
<p>Raju S (1988)⁸</p> <p>Case series</p> <p>USA</p> <p>Study period: 1976–1987</p> <p>n = 107 legs</p> <p>Population: Patients with non-obstructive venous insufficiency</p> <p>Indications: Stasis ulceration was the primary indication for operation in 68% (73/107) legs.</p> <p>Technique: Internal valvuloplasty (n = 61), valvuloplasty/Dacron sleeve (n = 10), axillary vein transfer (n = 18), axillary vein transfer/Dacron sleeve (n = 6), Dacron sleeve in situ (n = 12)</p> <p>Follow-up: 2–8 years</p> <p>Conflict of interest: none stated</p>	<p>Postoperative sustained and complete healing of ulcer (> 24 months follow-up):</p> <ul style="list-style-type: none"> Valvuloplasty = 63% (25/40) Valvuloplasty/Dacron sleeve = 50% (3/6) Axillary vein transfer = 46% (6/13) Axillary vein transfer/Dacron sleeve = 33% (2/6) Dacron sleeve in situ = 63% (5/8) <p>Postoperative improvement in leg pain (> 24 months follow-up, subjective assessment):</p> <ul style="list-style-type: none"> Valvuloplasty = 87% (52/60) Valvuloplasty/Dacron sleeve = 60% (6/10) Axillary vein transfer = 50% (8/16) Axillary vein transfer/Dacron sleeve = 50% (3/6) Dacron sleeve in situ = 83% (10/12) <p>Postoperative improvement in swelling (> 24 months follow-up, subjective assessment):</p> <ul style="list-style-type: none"> Valvuloplasty = 83% (50/60) Valvuloplasty/Dacron sleeve = 60% (6/10) Axillary vein transfer = 39% (7/18) Axillary vein transfer/Dacron sleeve = 50% (3/6) Dacron sleeve in situ = 91% (10/11) <p>Mean Valsalva-induced foot venous pressure elevation (Valvuloplasty, n = 40):</p> <ul style="list-style-type: none"> Before surgery = 7.5 mm Hg At follow-up = 3.2 mm Hg, p < 0.001 <p>Mean ambulatory venous pressure recovery time (Valvuloplasty, n = 50):</p> <ul style="list-style-type: none"> Before surgery = 9.0 seconds At follow-up = 14.1 seconds, p < 0.001 	<ul style="list-style-type: none"> Mortality rate = 0% (0/107) Superficial wound infection = 2% (2/107) Deep wound infection = 2% (2/107) Wound seroma or haematoma = 4% (4/107) Lymphocele = 1% (1/107) Deep vein thrombosis = 7% (8/107) <p>(with involvement and loss of valve repair in two limbs)</p>	<p>Surgery was performed on 153 limbs using a variety of valve reconstruction procedures; results were presented for 107 cases with more than two years of follow-up.</p> <p>Valsalva-induced foot venous pressure elevation and ambulatory venous pressure recovery time were not reported for all patients.</p>

Abbreviations used: CEAP, clinical etiological anatomical pathological classification; CVI, chronic venous insufficiency; GSV, greater saphenous vein; SFV, superficial femoral vein																			
Study details	Key efficacy findings		Key safety findings	Comments															
<p>Masuda E (1994)⁹</p> <p>Case series</p> <p>USA</p> <p>Study period: 1968–1990</p> <p>n = 51 legs (48 patients)</p> <p>Population: patients with CVI with a minimum follow-up of 4 years</p> <p>43% (22/51) legs had primary valve insufficiency, 31% (16/51) legs had post-thrombotic syndrome and 26% (13/51) legs had a combination of the two.</p> <p>76% (39/51) legs had previously failed one or more treatment modalities including elastic support, saphenous vein ligation and stripping, and perforator interruption.</p> <p>Indications: Inclusion and exclusion criteria not otherwise stated.</p> <p>Technique: Internal valvuloplasty, valve transposition, transplantation and combined repair and transposition were performed. Perforator interruption and saphenous vein ligation and stripping were performed selectively.</p> <p>Mean follow-up: 10.6 years (range 4–21)</p> <p>Conflict of interest: none stated</p>	<p>Clinical class</p> <table border="1"> <thead> <tr> <th>Clinical class</th> <th>Pre-operative</th> <th>At follow-up</th> </tr> </thead> <tbody> <tr> <td>0</td> <td>0% (0/51)</td> <td>33% (17/51)</td> </tr> <tr> <td>1</td> <td>0% (0/51)</td> <td>26% (13/51)</td> </tr> <tr> <td>2</td> <td>4% (2/51)</td> <td>2% (1/51)</td> </tr> <tr> <td>3</td> <td>96% (49/51)</td> <td>39% (20/51)</td> </tr> </tbody> </table> <p>Class 0 = asymptomatic; Class 1 = mild symptoms and signs of stasis including mild swelling, pain, or indurative changes; Class 2 = pre-ulcerative changes or moderate swelling, pain, or indurative symptoms; Class 3 = ulceration or severe, disabling swelling, pain or induration.</p> <p>At 10 years, the cumulative rate of a clinical success (defined as class 0 or 1) = 60%</p> <p>10-year cumulative success rate by cause:</p> <ul style="list-style-type: none"> • Primary valve insufficiency = 73% • Post thrombotic syndrome = 43% <p>p = 0.029</p> <p>10-year cumulative success rate by type of procedure:</p> <ul style="list-style-type: none"> • Valve repair = 72% • Other procedures = 40% <p>p = 0.018</p> <p>Ulcer-free rate at 10 years = 50%</p> <p>The results remained stable beyond 6 years of follow-up.</p> <p>Of 29 limbs treated for ulceration, 14 (48%) had no ulcer recurrence during late follow-up.</p> <p>Failed reconstructions = 20% (10/51)</p>		Clinical class	Pre-operative	At follow-up	0	0% (0/51)	33% (17/51)	1	0% (0/51)	26% (13/51)	2	4% (2/51)	2% (1/51)	3	96% (49/51)	39% (20/51)	<ul style="list-style-type: none"> • Postoperative bleeding = 16% (8/51) (7 required surgical evacuation for haematoma formation) • Late occlusion of vein valve repair = 2% (1/51) • Wound infection = 2% (1/51) • Seroma = 2% (1/51) 	<p>30 additional reconstructions were performed during the study period but were not included in the report as they had less than the minimum follow-up; 17 procedures were performed within the past 4 years and 13 patients had either died or moved out of the area.</p> <p>22 limbs had comparable preoperative and postoperative physiological tests.</p>
Clinical class	Pre-operative	At follow-up																	
0	0% (0/51)	33% (17/51)																	
1	0% (0/51)	26% (13/51)																	
2	4% (2/51)	2% (1/51)																	
3	96% (49/51)	39% (20/51)																	

Abbreviations used: CEAP, clinical etiological anatomical pathological classification; CVI, chronic venous insufficiency; GSV, greater saphenous vein; SFV, superficial femoral vein			
Study details	Key efficacy findings	Key safety findings	Comments
Masuda E (1994) continued.	<p>Mean percent fall (post exercise) in ambulatory venous pressure (n = 22):</p> <ul style="list-style-type: none"> • Preoperative = 26.2 ± 16.6 mm Hg • Postoperative = 42.2 ± 19.7 mm Hg <p>p = 0.006</p> <p>Mean refill time (n = 22):</p> <ul style="list-style-type: none"> • Preoperative = 12.8 ± 5.5 seconds • Postoperative = 19.9 ± 6.6 seconds <p>p < 0.0001</p> <p>Postoperative presence of reflux on imaging (31 duplex scans and 18 descending venograms):</p> <ul style="list-style-type: none"> • Total competence = 35% (17/49) • Mild incompetence = 39% (19/49) • Severe incompetence = 26% (13/49) <p>The largest proportion of competent or mild reflux imaging results were found in the valve repair group.</p>		

Validity and generalisability of the studies

- Several different techniques are used for reconstructing deep venous valves. Most of the reviewed studies also included transplantation and transposition procedures.
- The three randomised controlled trials both compared valvuloplasty in combination with superficial venous surgery with superficial venous surgery alone. All three trials only included patients with primary valvular incompetence.
- Only two studies specifically stated that all patients had previously undergone conservative management or superficial venous surgery.^{5,7} One case series stated that one or more treatment modalities had previously been unsuccessful in 76% (39/51) of limbs.⁹
- Four studies included patients with primary or secondary valvular incompetence.^{5,6,7,9} One of these studies reported a significantly lower success rate for patients with post-thrombotic syndrome than for those with primary valve insufficiency.⁹
- Several studies focused mainly on physiological surrogate outcomes, and there is relative paucity of information on patient-focused outcomes.

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Mr S Darke, Mr T Lees

- The procedure is rarely performed in the UK.
- The main theoretical adverse events are deep vein thrombosis and pulmonary embolism.
- There are uncertainties about the efficacy of the procedure. In particular, there is uncertainty about which valve(s) to repair and which patients might benefit.
- There are several methods in use and there is uncertainty about which is best.
- Relevant outcomes of benefit include valvular competence, valvular patency, improved haemodynamics (less reflux), ulcer healing and quality of life measures.
- The potential impact of the procedure on the NHS, in terms of numbers of patients and use of resources, is minor.

Issues for consideration by IPAC

There are no additional issues for consideration.

References

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Appendix A: Additional papers on deep venous valve reconstruction not included in summary table 2

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in table 2
Cheatle TR, Perrin M (1994) Venous valve repair: early results in fifty-two cases. <i>Journal of Vascular Surgery</i> 19: 404–13	52 limbs	85% reflux-free after 1 year Recurrent ulcer = 9% (1/11)	Small case series
De Souza GG, Pereira AH, Costa FM et al (2001) Hemodynamic results of femoral vein valve repair. <i>Cardiovascular Surgery</i> 9: 127–32	37 patients Mean follow-up = 24 months	Dacron sleeve technique. 85% ulcer-free, 44% pain-free, 21% oedema-free at follow-up	Small case series
Eriksson I, Almgren B (1986) Influence of the profunda femoris vein on venous hemodynamics of the limb. <i>Journal of Vascular Surgery</i> 4: 390–5	31 limbs Mean follow-up = 44 months.	32% valvuloplasties (6/19) failed. 67% (8/12) valve transplants failed	Small case series
Eriksson I, Almgren B (1988) Surgical reconstruction of incompetent deep vein valves. <i>Upsala Journal of Medical Sciences</i> 93: 139–43	27 direct valve repairs Mean follow-up = 49 months	Competent valve at follow-up = 70% (19/27)	Small case series
Ferris EB, Kistner RL (1982) Femoral vein reconstruction in the management of chronic venous insufficiency. <i>Archives of Surgery</i> 117: 1571–9	32 valve repairs Mean follow-up = 6 years	83% 'good' to 'excellent' long-term results for patients with ulceration	Small case series
Jamieson WG, Chinnick B (1997) Clinical results of deep venous repair for chronic venous insufficiency. <i>Canadian Journal of Surgery</i> 40: 294–9	16 venous valve repairs Minimum follow-up = 2 years	12 valvuloplasty, 4 valve transfer. 'Good' and 'excellent' results = 56% (9/16). No major complications	Small case series
Lermusiaux P, De Forges MR, Mans L (1996) Angioscopy-assisted valvuloplasty for primary deep venous valvular insufficiency. <i>Annals of Vascular Surgery</i> 10: 233–8	4 patients Mean follow-up = 12 months	3 out of 4 ulcers healed and did not recur. All repaired valves were patent and competent at follow-up	Small case series
Perrin M, Hiltbrand B, Bayon JM (1999) Results of valvuloplasty in patients presenting deep venous insufficiency and recurring ulceration. <i>Annals of Vascular Surgery</i> 13: 524–32	33 limbs Mean follow-up = 51 months	Early postoperative thrombosis = 15% (5/33). Complete healing or no further recurrence = 82% (27/33)	Small case series

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
Raju S, Hardy JD (1997) Technical options in venous valve reconstruction. <i>American Journal of Surgery</i> 173: 301–7	347 limbs (582 valve segments)	Postoperative competence = 78% 93% ulcers healed within 90 days	Results for a variety of techniques were reported together
Raju S, Fredericks RK, Neglen PN et al (1996) Durability of venous valve reconstruction techniques for 'primary' and postthrombotic reflux. <i>Journal of Vascular Surgery</i> 23: 357–67	423 valve repairs Follow-up = 1–12 years	75% (158/211) ulcer-free. Internal valvuloplasty and prosthetic sleeve in situ were more durable than external valvuloplasty and axillary vein transfer by Cox analysis ($p < 0.002$ and $p < 0.0001$)	Results for a variety of techniques were reported together
Schanzer H, Skladany M, Peirce II EC (1994) The role of external banding valvuloplasty in the surgical management of chronic deep venous disease. <i>Phlebology</i> 9: 8–12	13 limbs	Symptomatic improvement = 77%, complete correction of reflux = 67%	Small case series
Sottiurai VS (1997) Results of deep vein reconstruction. <i>Vascular Surgery</i> 31: 276–8	143 limbs Mean follow-up = 81 months	Valve compliance = 75% (107/143)	Limited information on safety and efficacy outcomes
Sottiurai VS (1990) Comparison of surgical modalities in the treatment of recurrent venous ulcer. <i>International Angiology</i> 9: 231–5	32 limbs Mean follow-up = 32 months	Valve repair healed 87.5% (14/16) ulcers compared with 25% (4/16) for superficial surgery alone ($p < 0.005$)	Results for valvuloplasty are presented together with valve transplantation
Welch HJ, McLaughlin RL, O'Donnell Jr TF (1992) Femoral vein valvuloplasty: intraoperative angioscopic evaluation and hemodynamic improvement. <i>Journal of Vascular Surgery</i> 16: 694–700	9 limbs Mean follow-up = 20 months	2 perioperative deep vein thromboses. Angioscopically guidance can achieve results equal to or better than standard femoral vein valvuloplasty	Small case series

Appendix C: Literature search for deep venous valve reconstruction

IP: 336 Deep venous valve reconstruction		
Database	Date searched	Version searched
Cochrane Library	26.06.06	Issue 2 2006
CRD databases	26.06.06	Issue 2 2006
Embase	22.06.06	1980 to 2006 Week 24
Medline	26.06.06	1966 to June Week 1 2006
Premedline	22.06.06	June 20, 2006
CINAHL	22.06.06	1982 to June Week 3 2006
British Library Inside Conferences	26.06.06	-
NRR	22.06.06	2006 Issue 2
Controlled Trials Registry	22.06.06	-

Search strategy used in Medline

The search was adapted for use in the databases above.

1	valve\$.tw.	66076
2	neovalve\$.tw.	3
3	valvular.tw.	13221
4	or/1-3	73230
5	surgery/	22187
6	transplantation autologous/	35651
7	((veno\$ or vein\$) adj3 (surg\$ or reconstruction or repair or transplantation or construction or implant\$)).tw.	5114
8	(segment adj3 transfer).tw.	68
9	(autologous or autogenous).tw.	51218
10	veins/su	2152
11	or/5-10	104294
12	((veno\$ or vein\$) adj3 reflux\$).tw.	725
13	((veno\$ or vein\$) adj3 (outflow adj3 (obstruct\$ or block\$))).tw.	341
14	leg ulcer/	5341
15	(leg\$ adj3 ulcer\$).tw.	3438
16	exp venous insufficiency/	4210
17	((post?thrombotic or post?phlebitic or post?phlebotic) adj3 (syndrome\$ or syndrone\$)).tw.	456
18	(deep adj3 (vein or venous) adj3 (incompet\$ or disease or damage or dysfunction or obstruc\$ or block\$ or insufficien\$)).tw.	366
19	or/12-18	11462
20	4 and 11 and 19	155