

Lower limb deep vein valve reconstruction for chronic deep venous incompetence

1 Guidance

- 1.1 Current evidence on the safety and efficacy of lower limb deep vein valve reconstruction for chronic deep venous incompetence does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to use lower limb deep vein valve reconstruction for chronic deep venous incompetence should take the following actions.
- Inform the clinical governance leads in their Trusts.
 - Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG219publicinfo).
 - Audit and review clinical outcomes of all patients having lower limb deep vein valve reconstruction for chronic deep venous incompetence (see section 3.1).
- 1.3 Further research on the procedure would be useful. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

- 2.1.1 Chronic deep venous incompetence in the lower limbs may be caused by primary incompetence of the venous valves or by damage to the valves 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). Chronic deep venous incompetence can cause a range of symptoms

and signs in the legs, including pain, swelling, lipodermatosclerosis and recurrent ulcers.

- 2.1.2 Chronic deep venous incompetence is usually treated conservatively, with graduated compression stockings. Ulcers are treated by compression bandaging. If symptoms persist and ulcers fail to respond to conservative treatments, surgery may be considered.

2.2 Outline of the procedure

- 2.2.1 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). Internal valvuloplasty involves tightening the valve cusps by stitches. An angioscope is sometimes used to aid visualisation. External valvuloplasty involves suturing a fold into the external vein wall to reduce the diameter of the vein, allowing the valve cusps within to meet properly. A variation of this technique is limited anterior plication, which is carried out only on the anterior aspect of the vein. Another method, external banding, involves wrapping and tightening a sleeve made of synthetic or natural tissue around the vein to reduce its diameter.

2.3 Efficacy

- 2.3.1 One randomised controlled trial comparing a combination of valvuloplasty and superficial venous surgery with superficial venous surgery alone reported that a significantly higher proportion of patients who had valvuloplasty (86% [54/63] compared with 64% [40/62], respectively [$p < 0.05$]) showed no further increase in disease severity during follow-up. A second randomised controlled trial of 44 patients found that those receiving valvuloplasty reported a significantly better quality of life than patients

Interventional procedure guidance 219

This guidance is written in the following context

This guidance represents the view of the Institute, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

receiving superficial venous surgery alone at 10-year follow-up ($p < 0.05$). One case series of 169 legs reported that 64% and 47% of patients with primary and secondary valvular incompetence, respectively, had no recurrence of ulcer at 2 years (absolute numbers were not provided in the paper). A second case series of 141 legs reported that 90% (76/84) of ulcers healed within 3 months of valvuloplasty and 17% (13/76) recurred during the follow-up period (1–42 months).

2.3.2 Two randomised controlled trials reported that 82% (9/11) and 71% (45/63) of valves treated by valvuloplasty were competent, as assessed by duplex ultrasound scanning, after 2 years and 7–8 years, respectively. A non-randomised controlled trial reported that 94% (16/17) of valves were competent after valvuloplasty compared with 29% (4/14) of valves in patients treated with superficial venous surgery alone, at a mean follow-up of 25 months ($p < 0.01$).

2.3.3 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, $p < 0.05$). The studies used a variety of methods for undertaking valvuloplasty although the most common was internal valvuloplasty. For more details, refer to the 'Sources of evidence' section.

2.3.4 The Specialist Advisers expressed some uncertainty about the efficacy of the procedure and, in particular, uncertainties as to which valve(s) to repair and which patients may benefit.

2.4 Safety

2.4.1 The safety evidence relates to five case series, including a total of 612 legs. Four case series reported deep vein thrombosis rates of 4% (5/141), 7% (8/107), 12% (21/169) and 13% (11/85) after deep venous valve reconstruction/repair. A single case of pulmonary embolism was reported in the case series of 141 legs ($< 1\%$).

2.4.2 Reported rates of haematoma ranged between 3% (5/144) and 10% (17/169) in four of the case series. Two case series reported postoperative

bleeding after 1% (2/144) and 16% (8/51) of valve reconstructions.

2.4.3 Four case series reported rates of wound infection between 1% (2/141) and 7% (12/169). For more details, refer to the 'Sources of evidence' section.

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

2.5 Other comments

2.5.1 It was noted that there was more published evidence about the efficacy of the procedure in patients with primary vein incompetence than in patients with secondary venous incompetence following deep vein thrombosis.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. The Institute has identified relevant audit criteria and developed an audit tool (which is for use at local discretion) available from www.nice.org.uk/219

Andrew Dillon
Chief Executive
May 2007

Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG219publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of lower limb deep vein valve reconstruction for chronic deep venous incompetence', October 2006.

Available from: www.nice.org.uk/ip367overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1259. 'Understanding NICE guidance' can be obtained by quoting reference number N1260.

The distribution list for this guidance is available at www.nice.org.uk/IPG219distributionlist

Published by the National Institute for Health and Clinical Excellence, May 2007; ISBN 1-84629-416-9

Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

© National Institute for Health and Clinical Excellence, May 2007. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of the Institute.