NICE guidance

Lower limb deep vein valve reconstruction for chronic deep venous incompetence

Interventional procedures guidance
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Your responsibility

This guidance represents the view of NICE, arrived at after careful consideration of the evidence available. When exercising their judgement, healthcare professionals are expected to take this guidance fully into account, and specifically any special arrangements relating to the introduction of new interventional procedures. The guidance does not override the individual responsibility of healthcare professionals to make decisions appropriate to the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the Yellow Card Scheme.

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful

discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

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 NICE's information for the public is recommended.
- 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. NICE 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 out of 63] compared with 64% [40 out of 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 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 out of 84) of ulcers healed within 3 months of valvuloplasty and 17% (13 out of 76) recurred during the follow-up period (1 to 42 months).

2.3.2 Two randomised controlled trials reported that 82% (9 out of 11) and 71% (45 out of 63) of valves treated by valvuloplasty were competent, as assessed by duplex ultrasound scanning, after 2 years and 7 to 8 years, respectively. A non-randomised controlled trial reported that 94% (16 out of 17) of valves were competent after valvuloplasty compared with 29% (4 out of 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, see the overview.

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 out of 141), 7% (8 out of 107), 12% (21 out of 169) and 13% (11 out of 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 out of 144) and 10% (17 out of 169) in four of the case series. Two case series reported postoperative bleeding after 1% (2 out of 144) and 16% (8 out of 51) of valve reconstructions.

2.4.3 Four case series reported rates of wound infection between 1% (2 out of 141) and 7% (12 out of 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. NICE has identified relevant audit criteria and developed an audit tool (which is for use at local discretion).

Sources of evidence

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

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.