NICE guidance

Subfascial endoscopic perforator vein surgery

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 subfascial endoscopic perforator vein surgery (SEPS) 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 undertake SEPS should take the following action.

- 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. Use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having SEPS.

1.3 Publication of safety and efficacy outcomes will be useful in reducing the current uncertainty. NICE may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 The procedure is used for patients with either healed or active ulcers (CEAP classifications 5 or 6), caused by chronic venous insufficiency, in whom incompetent calf perforating veins are thought to be an important contributing factor, particularly where conservative management (such as leg elevation, compression therapy and medication) has failed. CEAP is a standardised

classification system for rating the severity of venous disease where 'C' is for clinical signs, 'E' is for etiologic classification, 'A' is for anatomic distribution and 'P' is for pathophysiologic dysfunction. Deep venous occlusion and/or infected ulcers are usually contraindications to subfascial endoscopic perforator vein surgery (SEPS).

2.1.2 SEPS has also been used for patients with post-thrombotic valvular incompetence, but there is now evidence that this particular group of patients may have poorer outcomes following SEPS, compared with patients with primary valvular incompetence.

2.1.3 SEPS is a minimally invasive alternative to open subfascial perforator vein surgery.

2.2 Outline of the procedure

2.2.1 Preoperative evaluation is performed by duplex scanning of the superficial, deep and perforator venous systems to diagnose both valvular incompetence and obstruction. During the operation, the limb is exsanguinated and two endoscopic ports are placed in the subfascial space in the calf at sites remote from the area of venous ulceration. A space-maker balloon is introduced and inflated in this subfascial space to improve access. Carbon dioxide is then insufflated to facilitate dissection. The incompetent perforating veins are clipped and divided with endoscopic scissors or, alternatively, coagulated and divided with an ultrasonic coagulator (harmonic scalpel).

2.3 Efficacy

2.3.1 One randomised controlled trial (RCT), two non-randomised comparative studies and two case series were reviewed. The studies showed great potential for bias: there were large losses to follow-up, considerable discrepancies in length of follow-up between SEPS and open procedure groups, and uncertainties about patient selection. The studies that compared SEPS with open procedures found ulcer-healing to be 85% (17 out of 20 patients) to 90% (18 out of 20 patients) in

the SEPS groups and 100% (18 out of 18, and 19 out of 19 patients) in the open procedure groups. Ulcer recurrence rates in these studies were 12% (2 out of 17 patients) to 28% (5 out of 18 patients) in the SEPS groups and 22% (4 out of 18 patients) to 68% (13 out of 19 patients) in the open procedure groups. For more details, see the overview.

2.3.2 The Specialist Advisors considered the efficacy of this procedure to be unproven. They also noted that the indications for SEPS are not well established.

2.4 Safety

2.4.1 The results of the RCT showed a considerably lower wound infection rate in the SEPS group of 0% (0 out of 20 patients) compared with the open procedure group's rate of 53% (10 out of 19 patients). This trial was closed early because the high rate of wound infection in the open procedure group made it unethical to continue. One of the non-randomised comparative studies also found the wound complication rate to be lower in the SEPS group (7%, 2 out of 27 patients) when compared with the open procedure group (45%, 13 out of 29 patients). For more details, see the overview.

2.4.2 Other reported complications of the SEPS procedure included nerve injury and deep vein thrombosis (DVT). The reported incidence of nerve injury ranged from 0% (0 out of 20 patients) to 7% (2 out of 30 patients); and incidence of DVT ranged from 0% (0 out of 27 patients) to 14% (21 out of 146 limbs). The study that reported 14% incidence of DVT originally had a total of 254 patients, of which data from only 130 patients (146 limbs) were analysed due to high loss to follow-up. In this study, DVTs occurred in 2 patients directly after surgery and in an additional 19 patients during the follow-up period. For more details, see the overview.

2.4.3 The Specialist Advisors noted safety concerns similar to those reported in the studies: wound infection, nerve injury, DVT and haematoma.

2.5 Other comments

2.5.1 It was noted that the indications for this procedure are uncertain, and that careful patient selection is particularly important.

3 Further information

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.