

Subfascial endoscopic perforator vein surgery

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg59

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 the Institute'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. The Institute 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^[1] 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. Deep venous occlusion and/or infected ulcers are usually contraindications to 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% (17/20 patients) to 90% (18/20 patients) in the SEPS groups and 100% (18/18 and 19/19 patients) in the open procedure groups. Ulcer recurrence rates in these studies were 12% (2/17 patients) to 28% (5/18 patients) in the SEPS groups and 22% (4/18 patients) to 68% (13/19 patients) in the open procedure groups. For more details, refer to the 'Sources of evidence' section.
- 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% (0/20 patients) compared with the open procedure group's rate of 53% (10/19 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%, 2/27 patients) when compared with the open procedure group (45%, 13/29 patients). For more details, refer to the 'Sources of evidence' section.
- 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% (0/20 patients) to 7% (2/30 patients); and incidence of DVT ranged from 0% (0/27 patients) to 14% (21/146 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, refer to the 'Sources of evidence' section.

- 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.

Andrew Dillon
Chief Executive
May 2004

^[1] 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.

3 Further information

Sources of evidence

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

'Interventional procedure overview of subfascial endoscopic perforator vein surgery', November 2002.

Information for patients

NICE has produced [information on this procedure for patients and carers](#) ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Changes since publication

The guidance was considered for reassessment in January 2009 and it was concluded that NICE will not be updating this guidance at this stage. However, if you believe there is new evidence which should warrant a review of our guidance, please [contact us](#).

28 January 2012: minor maintenance.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

Your responsibility

This guidance represents the views of NICE and 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.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).