

# Subfascial endoscopic perforator vein surgery

## 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<sup>1</sup> 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

<sup>1</sup> 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.

# Interventional Procedure Guidance 59

### 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. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

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 (see below).

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 (see below).

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 (see below).

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

## Information for the Public

The Institute has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available, in English and Welsh, from [www.nice.org.uk/IPG059publicinfo](http://www.nice.org.uk/IPG059publicinfo).

## 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.

Available from: [www.nice.org.uk/ip088overview](http://www.nice.org.uk/ip088overview)

### Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0574. *Information for the Public* can be obtained by quoting reference number N0575 for the English version and N0576 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at URL [www.nice.org.uk/IPG059distributionlist](http://www.nice.org.uk/IPG059distributionlist)

Published by the National Institute for Clinical Excellence, May 2004 ISBN: 1-84257-638-0

© National Institute for Clinical Excellence May 2004. All rights reserved. This material may be freely reproduced for educational and not for profit purposes within the NHS. No reproduction by or for commercial organisations is permitted without the express written permission of the Institute.

National Institute for Clinical Excellence

MidCity Place, 71 High Holborn, London WC1V 6NA, website: [www.nice.org.uk](http://www.nice.org.uk)

N0574 1P 20k May 04 (HOBBS)