NATIONAL INSTITUTE FOR CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedures overview of subfascial endoscopic perforator vein surgery for varicose veins

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee advise on the safety and efficacy of an interventional procedure previously reviewed by SERNIP. It is based on a rapid survey of published literature, review of the procedure by specialist advisors and review of the content of the SERNIP file. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared by ASERNIP-S in November 2002

Procedure name

- Subfascial endoscopic perforator vein surgery.
- Endoscopic subfascial division of incompetent perforating veins.
- Endoscopic perforator vein surgery.
- Endoscopic perforator vein ligation.
- Endoscopic perforator vein ablation.
- Endoscopic subfascial perforating vein ligation.
- Subfascial perforator vein ablation .
- Subfascial endoscopic ligation of perforator veins.

Specialty societies

- *Vascular Surgical Society of Great Britain and Ireland.*

Description

Executive Summary

Wound complication rates for subfascial endoscopic perforator vein surgery (SEPS) appear to be consistently less than those observed following the open Linton procedure. However, the rate of primary ulcer healing and the cumulative ulcer recurrence rates are comparable for both open and SEPS procedures.

Length of stay was significantly shorter for the SEPS procedure in two of the three studies reporting this outcome but not in the randomised controlled trial (RCT) by Sybrandy *et al* [4], however, the reported mean value of '1' reported in this study seems an unlikely mean with a range of 3 to 39 days. Mean operating time did differ

significantly in the one included study that measured this outcome. Mean intraoperative blood loss was significantly greater for the open Linton procedure.

In the one study that compared clinical venous dysfunction scores, the clinical improvement observed after SEPS was not significantly better than that observed in the open Linton procedure group. Clinical results for patients with post-thrombotic syndrome appear to be worse than in those patients with primary valvular incompetence who have undergone SEPS.

Indications

The primary indication for SEPS is patients with either healed or active ulcers (CEAP classifications 5 or 6) caused by chronic venous insufficiency when conservative management has failed. Deep venous occlusion and/or infected ulcers are usually contraindications to SEPS surgery.

SEPS had also been previously used for patients with post-thrombotic valvular incompetence, but there is now evidence in the literature that this particular group of patients may have poorer outcomes following SEPS compared with patients with primary valvular incompetence.[1-3]

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

Summary of procedure

Preoperative evaluation is performed by duplex scanning of the superficial, deep and perforator venous systems to diagnose both valvular incompetence and obstruction.

At operation the limb is exsanguinated, and two endoscopic ports (typically a 10 mm and a 5 mm port) are placed in the subfascial space in the calf at two 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 using endoscopic scissors or alternatively, coagulated and divided using an ultrasonic coagulator (harmonic scalpel).

Literature reviews

Rapid review of literature

A systematic search of MEDLINE, PREMEDLINE, EMBASE, Current Contents, PubMed, Cochrane Library and Science Citation Index using Boolean search terms was conducted, covering the period from the inception of the databases until November 2002. The York Centre for Reviews and Dissemination, Clinicaltrials.gov, National Research Register, SIGLE, Grey Literature Reports, relevant online journals and the Internet were also searched in November 2002. Searches were conducted without language restriction.

Articles were obtained on the basis of the abstract containing safety and efficacy data on the subfascial endoscopic perforator vein surgery in the form of randomised controlled trials (RCTs), other controlled or comparative studies, case series and case reports. Conference abstracts and manufacturer's information were retrieved if they contained relevant safety and efficacy data. The English abstracts from foreign language papers were also retrieved if they contained safety and efficacy data. In the

case of duplicate publications, the publication with the most safety and efficacy data was retrieved.

Studies that examined the use of SEPS in active or healed venous ulcers were included. Studies that examined the use of SEPS in uncomplicated varicose veins were excluded.

List of studies included in the overview

Total number of studies 29:

- randomised controlled trials 1
- non-randomised comparative studies 3
- case series 22
- case reports 3

The references for the five papers considered to be most useful are highlighted in bold in the reference list.

UK randomised controlled trial just completed

- Another UK randomised controlled trial has also been recently (September 2002) completed. The results of this trial have yet to be published in the peer-reviewed literature that was searched for this particular review. The trial investigated the role of SEPS in the prevention of recurrence in primary long saphenous varicose veins.

Summary of key efficacy and safety findings

See following tables.

Abbreviations

CEAP	A standardised classification system for rating the severity of venous disease, where 'C' is for clinical signs, 'E' is for etiologic classification (that is,. congenital, primary, secondary), 'A' is for anatomic distribution (that is,.. superficial, deep, perforator) and 'P' is pathophysiologic dysfunction (that is,.. reflux, obstruction, or both)
CVI	Chronic venous insufficiency
DVI	Deep venous insufficiency
DVT	Deep venous thrombosis
LOS	Length of stay
NS	Not statistically significant
Open	Open Linton procedure
OSPS	Open subfascial perforator vein surgery
SEPS	Subfascial endoscopic perforator vein surgery

Table 2 Summary of key efficacy and safety findings

Study details	Key efficacy findings	Key safety findings	Appraisal/comments
Randomised controlled trials			
Sybrandy et al. [4] 2001 The Netherlands Feb 94 to April 95 Patients randomised to receive either the SEPS or the open Linton procedure 20 SEPS patients, mean follow-up of 46.1 months 19 open Linton patients, mean follow-up of 50.6 months Selection criteria: Patients with active, open venous ulcerations (CEAP class 6) on the medial side of the lower leg. Patients with arterial disease (ankle/brachial index <0.8) were excluded.	**Number of patients with incompetent perforating veins:** SEPS: 6 weeks postoperatively 4/19 (20%); 48 months postoperatively 5/12 (42%) Open: 6 weeks postoperatively 0/20 (0%); 48 months postoperatively 5/11 (45%) Mean operating time (min): SEPS 43 (20-90); Open 41 (19-70); P value NS LOS (days): SEPS 4 (2-6); Open 1* (3-39); P value 0.001 * The reported mean value of '1' seems an unlikely mean with a reported range of 3 to 39 days. The two other papers that report LOS data (Sato *et al*.[5] and Stuart *et al*.[6]) report a significantly shorter LOS with SEPS.	One patients developed a squamous cell carcinoma in the venous ulcer – a below-knee amputation was then required SEPS / Open / P value: Ulcer healing: 17 (85%) / 18 (100%) Ulcer recurrence: 2 (12%) / 4 (22%) / NS Wound infections: 0 / 10/19 (53%) / <0.001 Nerve injury: 0 / 2 (11%) / .23 Mean blood loss (ml): 43 (10-150) / 170 (30-300) / <0.001 Readmission: 0 / 2 / NS	**Potential for bias:** Large losses to follow-up (42% for open Linton group and 40% for SEPS group) but reasons are given. **Note:** RCT was closed early because the high rate of wound complications experienced by the open Linton group was deemed to be unacceptably high so the researchers considered it unethical to continue the trial

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
Non randomised comparative studies			
Sato et al. [5] 1999 USA SEPS vs Open OSPS SEPS – 25 pts with 27 SEPS procedures, Mean follow-up of 6.2 months +/- 5.0 months (Feb 96 to Aug 97) OSPS – 22 pts with 29 OSPS procedures. Mean follow-up of 56 months +/- 62 months (Mar 78 to May 93) Selection criteria: Patients with chronic venous insufficiency	SEPS (n=20 limbs) / OSPS (n=19 limbs) Ulcers healed: 18 (90%) / 19 (100%) Months until healed (mean [SD]): 2.4 [2.0] / 5.0 [7.8] Ulcer recurrence: 5 (28%) / 13 [68%] Months until recurrence: 7.5 [5.4] / 19 [29] LOS (days) (p<0.001): 3.0 [2.8] / 16 [9] Clinical CEAP venous dysfunction score*: Improved from 10.0 [3.6] to 5.4 [4.1] / Improved from 10.0 [3.2] to 6.7 [3.6] * Both the SEPS and OSPS patients significantly improved from baseline (p<0.001). However, the difference between post CEAP scores for SEPS and OSPS was not significantly different	SEPS (n=27 procedures) / OSPS (n=29 procedures) / P value Postoperative mortality: 0 / 0 / NS Wound complications: 2 (7%) / 13 (45%) / <0.005 Rehospitalisation: 1 (4%) / 4 (14%) / NS DVT: 0 / 1 (1.4%) / NS	**Potetial for bias:** Losses to follow-up in both the SEPS (5 pts) and OSPS (3 pts) groups. Large discrepancy between follow-up periods for the two groups. A historical comparison group only SEPS group had a higher frequency of concomitant greater saphenous vein ligation and stripping than the OSPS group Two groups similar in age, sex, history of previous venous Sx, healed active ulcers, etiology, deep venous incompetency, pathophysiology and venous refill times **Outcome measures:** CEAP score is a standardised, well accepted method of measuring level of venous dysfunction
Stuart *et al.*[6] 1997 UK SEPS versus open Linton procedure 30 SEPS and 31 open Linton patients, Follow-up not reported (30 patients underwent 30 SEPS	SEPS / Open Postoperative LOS (days) (median (range))(p<0.01): 2 (1-49) / 9 (3-36)	SEPS (n=30) / Open (n=37) Calf wound complications: 0 / 9* Groin wound complications: 3 / 3	**Potential for Bias:** Retrospective case note review with a historical control group Patients operated on at widely different time periods (SEPS Sep 93 to July 1996 and Open Linton from Jan 78 to July 92)

Study details	Key efficacy findings	Key safety findings			Appraisal/Comments
procedures from Sep 93 to Jul 96) (31 patients underwent 37 open Linton procedures from Jan 78 to July 97) Selection criteria: Interruption of calf perforating veins for lipodermatosclerosis with or without ulceration		Saphenous nerve injury DVT Readmission * Of which 3 cases were delayed wound healing, infection in 2 cases and flap necrosis in 2 cases	2 1 5	0 1 5	Method of patient selection for inclusion in either group not stated More of the SEPS patients also underwent a supplementary operative procedure of long saphenous vein stripping which confounds the results **Other comments:** Authors note that 'SEPS can be performed safely at the same time as skin grafting and in the presence of open ulcers without an increase in wound complications'.

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
Case series			
Ciostek et al.[7] 2002 Poland SEPS (using Hauer's technique) * 224 patients with 254 SEPS procedures from 1989 to 1999 Mean follow-up of 4 years, 8 months (maximum of 10 years) Selection criteria: Chronic venous insufficiency 65 patients had post-thrombotic syndrome (65.3% of sample) 48 limbs also had deep vein insufficiency (32.9%) * Analysis covered all documented data of the 130 patients (146 limbs) which were not lost to follow-up	**Patient reported clinical result** 83 (63.8%) detected postop improvement 28 (21.5%) detected no difference 19 (14.6%) noted deterioration postop **Surgeon reported clinical result** 63.8% improvement of condition 14.6% worsening of clinical condition Mean inconvenience CVI index improved from 5.09 preop to 2.36 postop (p<0.001) Recurrent varices noted in 27 (18.6%) of patients	No severe or life threatening complications were observed **Minor post-op complications** Tenderness on palpation, pain on walking and lower limb muscle tension present — n(%): 19 (13) Surgical wound infection — 5 (3.4) Hypoesthesia and paraesthesia of the medial ankle and/or plantar surface of the foot* — 19 (13) DVT immediately postop — 2 (1.4) DVT in postop period — 19 (13) Erysipelas — 3 (2.1) Recurrent varices — 27 legs (18.5% of legs) Cellulitis — 18 (12.3) * In six of these 19 patients, this symptom was still not resolved at final clinical examination	**Potential for bias:** 42% loss to follow-up It is not clear whether the case series involved consecutive patients or whether there were patient selection issues involved. Mixture of factors within case series such as post-thrombotic syndrome and deep vein insufficiency, which could confound outcomes presented in study. **Outcome measures:** Researchers devised their own, non-validated ratings system for assessing symptomatology.
Gloviczki et al,[1] 1999 USA Results from the North American Subfascial Endoscopic Perforator Surgery Register (NASEPS), which contains data on 146 cases from 17 centres across the US and Canada 146 patients, average follow up 24	Clinical score improved from 8.93 to 3.98 at last follow-up (p<0.0001) Cumulative ulcer healing rate: At 6 months: 31/36 (86.1%) At 1 year : 88% At 2 years: 95% Higher 2-year cumulative recurrence rate	**Complications** Pulmonary emboli — n (%): 0 (0) Death (recurrent DVT and sepsis) — 1 (0.69) Stroke and above knee amputation — 1 (0.69) Wound complication — 9 (6)	**Potential for bias:** Not clear from this paper but it seems that the registry contains retrospectively retrieved information on this patient group. This raises the issue of patient selection. For instance, how were the patients selected for inclusion from these centres? Was consent required of each patient in the registry and could some

Study details	Key efficacy findings	Key safety findings	Appraisal/Comments
months (range of 1 to 53 months) All patients had advanced CVI where 101 (69%) had CEAP class 6 active ulcers and 21 (14%) of sample had CEAP class 5 healed ulcers 103 (71%) underwent concomitant venous procedures such as vein stripping (70 pts), high ligation (17 pts), varicosity avulsion alone (16 pts).	in post-thrombotic limbs compared with those with primary valvular incompetence (40% compared with 20%) ($p < 0.05$) Median time to ulcer healing: 54 days Re-ulceration rate: 11 pts (5 recurrent and 6 new ulcers) At 2 years follow up: No. of patients(%) Asymptomatic 32 (35) Moderate improvement 30 (33) Mild improvement 14 (15) Unchanged 8 (8.5) Worse 8 (8.5)	Saphenous neuralgia 10 (7) Superficial thrombophlebitis 5 (3) Additional procedures required 11 (7.5)	patients refuse participation? If so, results would be confounded by selection bias. **Other comments:** Authors noted that 'concomitant ablation of superficial reflux and lack of deep venous obstruction predicted ulcer healing ($p<0.05$)'. Concomitant procedures could confound the overall clinical end result. The authors also noted that a 're-evaluation of the indications for SEPS was warranted as operations in patients with no previous DVT are successful whilst those in patients with previous DVT are less successful'. Also 'operations in patients with deep vein occlusion have poor outcomes'. **Outcomes measures:** CEAP classification system used which is a standardised, well accepted measure for rating the severity of chronic venous disease

Specialist Advisor's opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College.

Advisors noted that SEPS may no longer be classified as a new procedure. One Advisor noted that "most district general hospitals would be likely to be performing SEPS procedures".

The impact on the NHS was considered to be "minor" because the SEPS procedure would be "rarely indicated" (perhaps "two or three procedures in a year for most vascular surgeons'"). The equipment required for SEPS can be readily adapted from that generally used for endoscopic urology and GI surgery, so this required equipment would be "already available in most hospitals".

The Advisors provided complication rate data. These are presented in the following table.

Complication	**Surgeon**	
	Advisor 1	**Advisor 2**
Subfascial haematoma	< 10%	–
Wound haematoma	–	5%
Wound infection	–	9%
Sensory nerve injury	< 5%	9% saphenous or sural nerve injury
Technical failure to ligate all perforators	< 20% depending on case selection	-
DVT	< 2%	1%

They raised concerns that the indications for the SEPS procedure have not yet been fully established. It was noted that SEPS has no proven role in the management of uncomplicated varicose veins. It was also pointed out that the role of calf perforating veins as the instigating mechanism for chronic venous ulcers is also still being debated within the vascular surgical community.

They were not aware of any RCTs published to date.

Issues for consideration by IPAC

The advent of SEPS has renewed the ongoing debate concerning the general efficacy of perforator ligation in the surgical management of advanced chronic venous insufficiency and venous ulceration.

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Appendix: additional studies not included in the summary table

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