



Endoscopic thoracic sympathectomy for primary hyperhidrosis of the upper limb

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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 <u>assess and reduce the environmental impact of implementing NICE recommendations</u> wherever possible.

1 Recommendations

- 1.1 Current evidence on the efficacy and safety of endoscopic thoracic sympathectomy (ETS) for primary hyperhidrosis of the upper limb is adequate to support the use of this procedure with normal arrangements for clinical governance, consent and audit.
- 1.2 Clinicians wishing to undertake ETS for primary hyperhidrosis of the upper limb should ensure that patients understand the risks of the procedure. In particular they must explain that:
 - there is a risk of serious complications
 - hyperhidrosis elsewhere on the body is usual after the procedure: this can be severe and distressing, and some patients regret having had the procedure (especially because of subsequent and persistent hyperhidrosis elsewhere)
 - the procedure sometimes does not reduce upper limb hyperhidrosis.

Clinicians should also provide patients considering the procedure with clear written information.

- In view of the risk of side effects, this procedure should only be considered in patients suffering from severe and debilitating primary hyperhidrosis that has been refractory to other treatments.
- 1.4 This procedure should only be undertaken by clinicians trained and experienced in thoracic endoscopy, and there should be the capacity to deal with intraoperative complications.

1.5 Further research into ETS for primary hyperhidrosis of the upper limb should include clear information on patient selection and should seek to identify which patient characteristics might predict severe side effects. All complications should be reported. Outcomes should include measurements of efficacy, including quality of life and social functioning both in the short and long term and in particular the frequency and severity of compensatory hyperhidrosis.

2 Indications and current treatments

- 2.1 Primary hyperhidrosis of the upper limb is characterised by excessive sweating of the palms and/or axillae. It typically begins during childhood or adolescence, but can occur at any age and is usually life-long. In a few people, symptoms can spontaneously improve over time. Excessive sweating can have a profound effect on quality of life, interfering with daily activities and causing anxiety and embarrassment.
- 2.2 First-line management of primary hyperhidrosis includes lifestyle measures such as avoiding known triggers and tight clothing, and using antiperspirants (including aluminium chloride hexahydrate). Other treatments include iontophoresis and botulinum-toxin A injection, and oral medications such as anticholinergics, antimuscarinics, beta-blockers, antihypertensives and anxiolytics. If these do not work, surgical options include local sweat-gland excision by subcutaneous curettage or tumescent liposuction, or sympathectomy. Sympathectomy can be done either by open or endoscopic approaches: endoscopic sympathectomy is now usually the preferred technique because it is associated with less pain, improved cosmesis and more rapid recovery than open sympathectomy.

3 The procedure

The aim of endoscopic thoracic sympathectomy (ETS) for primary hyperhidrosis of the upper limb is to relieve primary hyperhidrosis from the palms and axillae permanently by dividing the sympathetic nerves that lie along the sympathetic chain beside the vertebral column.

3.2 ETS is usually done with the patient under general anaesthesia. Small incisions are made in the axilla and an endoscope is inserted. The lung is partially collapsed. The sympathetic chain is visualised and the chosen part of the chain is divided by electrocautery or endoscopic scissors, or surgical clips may be applied. The extent of division varies but usually involves the part of the sympathetic chain over the second or third ribs, or both. Gas is removed from the pleural space, allowing the lung to re-expand, and the wounds are closed. The procedure is then usually repeated on the other side.

4 Efficacy

This section describes efficacy outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

- A non-randomised comparative study of 154 patients with palmar hyperhidrosis treated by endoscopic thoracic sympathectomy (ETS) or botulinum-toxin A injection reported statistically significant improvements in both groups at 6- and 12-month follow-up, assessed objectively using an iodine starch test and pad glove test (p<0.05). The improvement was significantly higher in the ETS group than the botulinum-toxin A injection group (94% and 30% change on the iodine starch test respectively, p=0.01).
- A case series of 1,700 patients (1,052 [62%] patients with hyperhidrosis, 536 [32%] patients with facial blushing and 112 [7%] patients with combinations of blushing and hyperhidrosis) reported that 85% of patients had a 'satisfactory and lasting effect' from the procedure at a mean follow-up of 15 years (absolute number not reported). A case series of 406 patients with palmar and/or axillary hyperhidrosis reported that 91% (n=239) of patients treated by conventional ETS had dry limbs at a mean follow-up of 17 years.
- The non-randomised comparative study of 154 patients reported a statistically significant higher mean satisfaction score for ETS compared with botulinum-toxin A injection at 12-month follow-up (4.52 and 3.12, respectively [score range 1 to 5 with 1 being very poor and 5 being excellent], p=0.001). The case series of 1,700 patients reported satisfaction rates of 87% and 67% for palmar and axillary

hyperhidrosis respectively (p<0.001). Overall, 75% of patients stated that the procedure had improved their quality of life (absolute numbers not reported).

- 4.4 A case series of 2,000 patients reported recurrence rates of 0% and 4% for palmar and axillary hyperhidrosis respectively at 1-year follow-up and 1% and 17% respectively at 5-year follow-up. A case series of 9,988 patients with palmar hyperhidrosis reported that 'almost all' patients obtained satisfactory relief immediately after ETS; recurrence rates were about 1% at 1-year follow-up and less than 3% at 3-year follow-up (absolute numbers not reported).
- The case series of 453 patients with palmar, axillary or facial hyperhidrosis reported that 91% (412 out of 453) had better quality of life 30 days after ETS and 90% (409 out of 453) had better quality of life 5 years after ETS. All patients had poor or very poor quality of life before treatment.
- The specialist advisers stated that key efficacy outcomes were reduction in hyperhidrosis and patient satisfaction.

5 Safety

This section describes safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

- A non-systematic review article reported that 5 patients died because of major intrathoracic bleeding after endoscopic thoracic sympathectomy (ETS) but the total number of patients treated by the procedure was not documented: in 2 patients a trocar lacerated the subclavian artery; in 1 patient an intercostal vein was damaged; the causes in the other 2 patients were not described. Intrathoracic venous bleeding of more than 300 ml was reported in 1 patient in a case series of 453 patients. Bleeding needing chest tube drainage was reported in 'about 0.1%' of patients in the case series of 9,988 patients.
- An additional 4 deaths after ETS were reported in the non-systematic review article: 3 were due to problems related to anaesthetic technique, and 1 patient had an unexplained cerebral event 'some hours' after ETS. The total number of

patients treated by the procedure was not documented.

- 5.3 Compensatory hyperhidrosis was reported in 92% (416 out of 453), 86% (1,720 out of 2,000) and 74% (1,265 out of 1,700) of patients in 3 case series. In 2 of these studies, 33% (557 out of 1,700, and 150 out of 453) of patients reported compensatory hyperhidrosis that was either 'severe' or 'incapacitating'.
- Studies reported a wide range in the proportion of patients reporting dissatisfaction with the procedure. The case series of 453 patients reported that 2% (7 out of 453) of patients were dissatisfied with the results at 5-year follow-up. These patients had severe compensatory hyperhidrosis and said that they regretted having ETS. The case series of 406 patients reported that 7% (n=17) of patients treated by conventional ETS were dissatisfied and regretted the operation at a mean follow-up of 17 years. The case series of 1,700 patients with hyperhidrosis or facial blushing reported that 20% (absolute numbers not reported) of patients were dissatisfied or regretted having the procedure at a mean follow-up of 15 years.
- Pneumothorax requiring drainage was reported in 0.5% (10 out of 2,000) of patients and 1% (8 out of 734) of procedures in the 2 case series of 2,000 and 406 patients respectively. Pneumothorax or haemothorax that needed to be drained was reported in 'about 0.3%' of patients in a case series of 9,988 patients. Chylothorax was reported in 3 patients included in the non-systematic review article, 2 of whom were described in more detail: 1 patient needed postoperative tube drainage and parenteral nutrition for 6 days and in 1 patient the leak was recognised at surgery and the thoracic duct clipped.
- Intraoperative cardiac arrest was reported in 2 case reports. Both patients recovered after cardiopulmonary resuscitation.
- Horner's syndrome was reported in less than 0.1%, 0.2% (1 out of 453) and 2% of patients in the 3 case series of 9,988, 453 and 406 patients respectively. No cases of Horner's syndrome were reported in the case series of 2,000 patients.
- Other adverse events reported in case reports and in the non-systematic review included surgical emphysema, pleural effusion, bronchospasm, segmental collapse and atelectasis, wound infection, severe postoperative pain, brachial

plexus injury, extensor pollicis longus paralysis, distal upper limb ischaemia, paraparesis, rhinitis, persistent bradycardia, heatstroke, and gustatory sweating.

In addition to the above, the specialist advisers described conversion to open surgery because of lung adhesions as an anecdotal adverse event. Additional reported adverse events were cerebral oedema, pulmonary oedema, and pulmonary embolus.

6 Committee comments

- The Committee noted that techniques of endoscopic thoracic sympathectomy (ETS) vary in the way in which the sympathetic chain is dealt with and the precise extent of the sympathectomy for primary hyperhidrosis of the upper limb. These variations may affect the efficacy and safety outcomes of this procedure.
- The Committee noted that the primary indication for ETS is palmar hyperhidrosis.

 Axillary hyperhidrosis frequently coexists with this, but it is seldom the primary indication for using the procedure because its benefit is somewhat less assured.
- 6.3 The Committee received and considered comments from patients, some of whom described severe distress as a result of side effects following this procedure.

7 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the <u>overview</u>.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. 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.