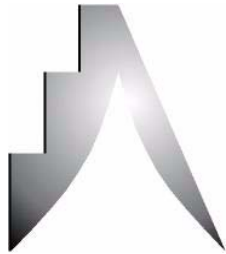


ASERNIP/S



Australian Safety
and Efficacy
Register of New
Interventional
Procedures - Surgical

Evidence Essential

Endoscopic thoracic sympathectomy

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Endoscopic thoracic sympathectomy

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**The Evidence Essential of
Endoscopic thoracic sympathectomy**

**Was ratified by the ASERNIP-S Advisory Committee on
June 1 2009**

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ASERNIP-S Evidence Essentials

PURPOSE AND SCOPE

The ASERNIP-S Evidence Essentials document is a structured literature review on a given health technology (procedure or device). It may be produced where current published systematic review evidence is available on a procedure nominated for ASERNIP-S assessment.

The Evidence Essentials is designed to inform on the existence and findings of high-level evidence such as systematic reviews and health technology assessments. In this way it reduces duplication of endeavour and provides rapid and timely information to interested end-users, particularly those who have approached ASERNIP-S to investigate the given topic. Evidence Essentials intends to provide a summary of the high-level evidence base, including an appraisal of the quality and appropriateness of the published evidence; a commentary on the appropriateness of the data to the Australian locality (if possible); and a summary of the overall conclusions of the published evidence.

METHODOLOGY

Evidence Essentials presents summary high-level evidence arising from current, English language systematic reviews (published within two years as either a full systematic review/health technology assessment or a peer-reviewed publication). For this purpose, systematic reviews are defined as those studies that meet all the following criteria as defined by Cook et al (1997) (focused clinical question, explicit search strategy, use of explicit, reproducible and uniformly applied criteria for article selection, critical appraisal of the included studies, qualitative or quantitative data synthesis). Evidence Essentials does not encompass any new synthesis of primary data.

Evidence Essentials also provides a comment on any clinical trials in progress, to provide an indication of the current status of research, and also presents available clinical practice guidelines.

Where necessary, recent non-systematic clinical reviews are used to provide background information on the indications and technology. These papers are cited at the end of the document. Evidence Essentials provides a summary on available high-level evidence on a given topic, but does not include direct input from clinical experts as it is anticipated that the included studies have incorporated clinical input as part of their methodology.

INTRODUCTION

DEVICE/PROCEDURE

Endoscopic thoracic sympathectomy (ETS).

ETS involves cutting the sympathetic nerve at a level corresponding to the first to fourth thoracic segment. Many different procedures have used to achieve this: resection of the sympathetic ganglion; transaction or ablation with cautery; and clipping of the sympathetic chain with titanium clips (Yano & Fujii 2006). The procedure is performed as an inpatient procedure under general anaesthetic and requires a surgeon with extensive experience (Hjalmarsson 1999).

INDICATION

Hyperhidrosis (excessive sweating) refractory to first-line, non-surgical treatments (topical aluminium chloride hexahydrate; intradermal botulinum toxin A; anticholinergics).

ALTERNATIVE TREATMENTS

Sympathectomy does not have a direct surgical comparator, as it adds to the existing clinical matrix as a final treatment option for patients with refractory hyperhidrosis.

CURRENT FUNDING STATUS IN AUSTRALIA

MBS item number	Descriptor	Reimbursement
35003	Cervical or upper thoracic sympathectomy by any surgical approach	Fee: \$828.50 Benefit: 75% = \$621.40
35006	Cervical or upper thoracic sympathectomy, where operation is a reoperation for previous incomplete sympathectomy by any surgical approach	Fee: \$1039.05 Benefit: 75% = \$779.30

NOTES: MBS Medicare Benefits Schedule

AVAILABLE HIGH LEVEL EVIDENCE

A systematic search of the literature was carried out to identify available, current, English-language systematic reviews and health technology assessments. The databases searched and terminologies used are included at Appendix A.

RELEVANT UNIQUE CITATIONS IDENTIFIED

- Evidence-based review of the surgical management of hyperhidrosis (Henteloff et al, *Thoracic Surgery Clinics* 2008).
- Effectiveness and safety of endoscopic thoracic sympathectomy for excessive sweating and facial blushing: A systematic review (Malmivaara et al, *International Journal of Technology Assessment in Health Care* 2007). This manuscript is based on a full systematic review published by FinOHTA. The full text article is available only in Finnish, and may contain more detail than found in the peer-reviewed manuscript.

EVIDENCE APPRAISAL

The quality of the identified systematic reviews was assessed using key items from the QUOROM statement (Moher et al 1999).

Henteloff et al (2008) considered a wide variety of studies, with diverse outcomes, patient populations and surgical approaches. Outcomes from each of the included studies were not consistently reported either narratively or quantitatively, and little attempt was made to separate different patient populations and surgical approaches.

Neither Henteloff et al (2008) nor Malmivaara et al (2007) provided adequate inclusion and exclusion criteria. While both reviews stated which outcomes they focused on, neither specified required study methodology, patient populations, interventions etc. This made it difficult to determine if their grouping of studies was valid.

Domain	Henteleff et al 2008	Malmivaara et al 2007
<i>Question</i>	In adult patients with severe, disabling primary hyperhidrosis, what is the effect of thoracic sympathectomy on short- & long-term freedom from excessive sweating & on patient quality of life?	Safety & effectiveness of ETS for hyperhidrosis & blushing
<i>Searching</i>	Medline, Cochrane Library, pearling 1990-October 2007 Search terms & limits stated	Medline & Cochrane Library 1966-June 2004 Search terms & limits stated
<i>Selecting</i>	Inclusion & exclusion criteria insufficient	Inclusion criteria insufficient
<i>Study flow</i>	Flow diagram	Not reported
<i>Validity assessment</i>	Reported to be undertaken; insufficiently described	Comprehensive
<i>Data abstraction</i>	Not reported	Processes described
<i>Study characteristics</i>	Insufficient	Brief
<i>Data synthesis</i>	Narrative description of selected studies	Brief narrative description from extensive tables

SUMMARY OF FINDINGS

No randomised controlled trials evaluating the safety and clinical effectiveness of ETS were included in either of the systematic reviews.

Based on cumulative experience in over 6000 patients, Henteleff et al (2008) suggested that ETS is “a safe, reproducible and effective procedure, and most patients are satisfied with the results of the surgery”. However, they did acknowledge that the majority of evidence arose from observational studies and those examining the merits of one surgical technique over another; these did not provide an assessment of the overall impact of ETS in the general population seeking this surgery.

Malmivaara et al (2007) took a more conservative view of the evidence included in their review, stating that “the evidence of the effectiveness of ETS is weak due to a lack of randomised trials”. The serious safety issues associated with the procedure were also emphasised.

OTHER CONSIDERATIONS

ETS is a difficult procedure on which to compile a randomised controlled trial and definitive systematic review. Issues may include:

- The procedure lacks a direct clinical comparator; non-surgical management cannot provide any appropriate comparative safety data.
- Different definitions of hyperhidrosis across primary studies.
- Variable measurements of adverse events across studies. For example, few studies employed an objective quantification of compensatory sweating, relying instead on subjective patient self-reporting.
- Variation in surgical approaches and techniques amongst primary studies
- Patients may be willing to trade-off the significant side effects of the procedure to achieve a reduction in obvious hyperhidrosis; this makes estimation of patient satisfaction problematic.

- No current controlled trials were located (see Appendix B)
- One available clinical practice guideline used an evidence-based approach to part of the guideline (Solish et al 2007, see Appendix B). The authors utilised a comprehensive literature search and designated each study a level of evidence. However, specific inclusion criteria were not defined, and no comment is provided on the quality of the included studies. The authors utilised citations in support of individual recommendations.

These features of the procedure and resultant evidence base limit the capacity of a systematic review to make consistent and useful clinical recommendations and would preclude statistical pooling of study results.

CONCLUSIONS

A lack of high quality randomised trial evidence on ETS means that it is difficult to make a judgment on the safety and effectiveness of this technique. There is potentially a number of safety issues associated with this procedure. ASERNIP-S suggests that a full systematic review including all available comparative and case series information, together with clinical input, should be undertaken to provide an up-to-date and comprehensive assessment of the safety and effectiveness of ETS.

Please note that this Evidence Essentials document is not a comprehensive systematic review of the safety and effectiveness of ETS for the treatment of hyperhidrosis, and should not be used for this purpose. This document presents a summary of the current, available high-level evidence and does not include direct input from clinical experts.

REFERENCES

SYSTEMATIC REVIEW EVIDENCE USED TO PRODUCE THIS EVIDENCE ESSENTIALS DOCUMENT

Henteleff H, Kalavrouziotis D. Evidence-based review of the surgical management of hyperhidrosis. *Thoracic Surgery Clinics* 2008; 18: 209-216.

Malmivaara A, Kuukasjärvi P, Autti-Rämö I, Kovanen N, Mäkelä M. Effectiveness and safety of endoscopic thoracic sympathectomy for excessive sweating and facial blushing: A systematic review. *International Journal of Technology Assessment in Health Care* 2007; 23(1): 54-62.

FURTHER REFERENCES USED

CKS Clinical Knowledge Summaries. Hyperhidrosis. NLH National Library of Guidelines 2005. Online, available from: <http://cks.library.nhs.uk/hyperhidrosis> [accessed 14 October 2008].

Cook DJ, Mulrow CD, Haynes BR. Systematic Reviews: Synthesis of Best Evidence for Clinical Decisions. *Annals of Internal Medicine* 1997; 126(5): 376–380.

Hjalmarsson A. Endoscopic transthoracic sympathectomy (ETS). SBU Alert 1999. Online, available from: <http://www.sbu.se/en/Published/Alert/Endoscopic-transthoracic-sympathectomy-ETS/> [accessed 10 October 2008].

Moher D, Cook D, Eastwood S, Olkin I, Rennie D, Stroup D. Improving the quality of reports of meta-analyses of randomised controlled trials: the QUOROM statement. *The Lancet* 1999; 354(27): 1896-1900.

Solish N, Bertucci V, Dansereau A, Hong H, Lynde C, Lupin M, Smith K, Storwick G. A comprehensive approach to the recognition, diagnosis and severity-based treatment of focal hyperhidrosis: recommendations of the Canadian Hyperhidrosis Advisory Committee. *Dermatologic Surgery* 2007; 33(8): 908-923.

Yano M & Fujii Y. Endoscopic sympathectomy for palmar hyperhidrosis. *Annals of Thoracic and Cardiovascular Surgery* 2006; 12(2): 81-82.

APPENDIX A

DATABASES SEARCHED AND SEARCH TERMS USED

	Database	Search terms	Date searched
Systematic reviews/health technology assessments	York CRD http://www.crd.york.ac.uk/crdweb/	'thoracic sympathectomy'	02 October 2008
Systematic reviews/health technology assessments	Entrez PubMed http://www.ncbi.nlm.nih.gov/sites/entrez	(endoscopic thoracic sympathectomy) AND systematic [sb]	02 October 2008
Systematic reviews/health technology assessments	The Cochrane Library http://www.cochrane.org/	thoracic sympathectomy	02 October 2008
Current trials	Current Controlled Trials http://www.controlled-trials.com/	sympathectomy	09 October 2008
Current trials	Clinical Trials.gov http://www.clinicaltrials.gov/	sympathectomy	09 October 2008
Current trials	Australian New Zealand Clinical Trials Registry http://www.anzctr.org.au/Default.aspx	sympathectomy	09 October 2008
Clinical practice guidelines	Trip database http://www.tripdatabase.com/index.html	endoscopic thoracic sympathectomy	14 October 2008
Clinical practice guidelines	NLH National Library of Guidelines http://www.library.nhs.uk/guidelinesfinder/Default.aspx?pagename=HOME	thoracic sympathectomy	14 October 2008

SEARCH STRATEGY

NOTES: CRD Centre for Reviews and Dissemination

CLINICAL PRACTICE GUIDELINES AND CURRENT CLINICAL TRIALS

CLINICAL GUIDELINES

- A comprehensive approach to the recognition, diagnosis and severity-based treatment of focal hyperhidrosis: recommendations of the Canadian Hyperhidrosis Advisory Committee (Solish et al, *Dermatologic Surgery* 2007)
- Hyperhidrosis (Clinical Knowledge Summaries 2005) (no longer available outside of the UK)

CURRENT CLINICAL TRIALS IDENTIFIED

There were no current clinical trials of ETS for hyperhidrosis identified.
