

Thoracoscopic exclusion of the left atrial appendage (with or without surgical ablation) for non-valvular atrial fibrillation for the prevention of thromboembolism

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg400

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. However, 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.

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.

Commissioners and providers have a responsibility to promote an environmentally sustainable

health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

- 1.1 Current evidence on the safety and efficacy of thoracoscopic exclusion of the left atrial appendage (LAA) for non-valvular atrial fibrillation (AF) for the prevention of thromboembolism as an adjunctive procedure to surgical ablative techniques is inadequate in quantity and quality. Therefore this procedure should only be used as an adjunct to surgical ablation with special arrangements for clinical governance, consent and audit or research.
- 1.2 Clinicians wishing to undertake thoracoscopic exclusion of the LAA for non-valvular AF for the prevention of thromboembolism as an adjunct to surgical ablation should take the following actions.
- Inform the clinical governance leads in their Trusts.
 - Ensure that patients and their carers understand the uncertainty about the procedure's safety and efficacy, and provide them with clear written information. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/guidance/IPG400/publicinfo).
 - Audit and review clinical outcomes of all patients having thoracoscopic exclusion of the LAA for non-valvular AF for the prevention of thromboembolism as an adjunctive procedure to ablative techniques (see section 3.1).
- 1.3 Current evidence on the safety and efficacy of thoracoscopic exclusion of the LAA for non-valvular AF for the prevention of thromboembolism when used in isolation is inadequate. Therefore this procedure should only be used in the context of research. Research studies should clearly define patient selection. They should report the cardiac rhythm achieved after surgery and also adverse events, particularly stroke and death, in both the short and longer term.
- 1.4 Patient selection should be carried out by a multidisciplinary team including a cardiac surgeon and other clinicians experienced in the management of patients with AF who are at risk of stroke. Patients should be considered for alternative treatments to reduce the risk of thromboembolism associated with AF, and should be informed about these alternatives.

- 1.5 This procedure should be carried out only by cardiac surgeons with experience in thoracoscopic surgery and specific training in the procedure.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Atrial fibrillation is the irregular and rapid beating of the atria. Patients with AF may be asymptomatic or may have symptoms such as fatigue, palpitations and chest pain. They also have an increased risk of thromboembolic stroke. In non-valvular AF, thrombi largely develop in the LAA.
- 2.1.2 Patients with AF who are considered to be at high risk of thromboembolic stroke are usually treated with anticoagulation therapy. If a patient is unable to tolerate anticoagulation, then surgical obliteration of the LAA through a percutaneous or open approach may be offered.

2.2 Outline of the procedure

- 2.2.1 Thoracoscopic exclusion of the LAA for non-valvular AF for the prevention of thromboembolism is usually carried out with the patient under general anaesthesia, and often alongside other procedures such as radiofrequency or microwave ablation to treat AF. Under thoracoscopic guidance the pericardium is opened and the atrial appendage excluded, usually using staples. A chest drain may be used to allow lung re-expansion. Postoperative transoesophageal echocardiography may be used to confirm exclusion of the LAA.

Sections 2.3 and 2.4 describe efficacy and 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, available at www.nice.org.uk/guidance/IP/857/overview

2.3 Efficacy

- 2.3.1 A case series of 100 patients treated by thoracoscopic LAA exclusion (n = 85) and epicardial radiofrequency ablation reported cerebrovascular accidents in 2% (2/88) of patients followed up and transient ischaemic attack (TIA) in 2% (2/

88) of patients over a mean follow-up of 23 months.

- 2.3.2 A case series of 15 patients treated by the procedure alone reported an overall stroke rate of 4% per patient-year (95% confidence interval 1.0 to 16) (mean follow-up 42 months). Of these, 1 patient had a fatal stroke 55 months after the procedure.
- 2.3.3 The Specialist Advisers listed key efficacy outcomes as total exclusion of the LAA with endothelialisation and a demonstrable absence of residual appendage on echocardiography, and prevention of sequelae of thrombus such as stroke or TIA.

2.4 Safety

- 2.4.1 Death was reported in 3% (3/100) of patients in the case series of 100 patients (not otherwise described).
- 2.4.2 Thoracotomy for postoperative bleeding from the LAA was reported in 1 patient in the case series of 15 patients. Intraoperative conversion to mini-thoracotomy to control bleeding was required in 3% (3/100) of patients in the case series of 100 patients.
- 2.4.3 Conversion to median sternotomy because of severe pleural adhesions was required in 1 patient in a case series of 30 patients; 7% (2/30) of patients required drainage of pneumothorax after removal of chest drains.
- 2.4.4 Prolonged postoperative air leak and chronic pleuritic pain were each reported in 1 patient in the case series of 15 patients.
- 2.4.5 Acute subendocardial infarction (recovery within 12 days) was reported in 1 patient in a case series of 81 patients.
- 2.4.6 The Specialist Advisers listed anecdotal adverse events as incomplete exclusion with residual appendage, and neuralgia from the thoracoscopic port sites.

2.5 Other comments

- 2.5.1 The Committee considered the prevention of stroke to be the most important

efficacy outcome of this procedure. However, its evaluation is complicated by the concomitant use of procedures to ablate AF and the variable use of anticoagulants.

- 2.5.2 The Committee was advised that new devices are available for this procedure that avoid the use of staples.

3 Further information

- 3.1 This guidance requires that clinicians undertaking the procedure as an adjunct to ablative techniques make special arrangements for audit. NICE has identified relevant audit criteria and has developed an audit tool (which is for use at local discretion), available from www.nice.org.uk/guidance/IPG400
- 3.2 For related NICE guidance see www.nice.org.uk

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. See www.nice.org.uk/guidance/IPG400/publicinfo

Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](http://www.healthcareimprovement.scot.nhs.uk).

Accreditation

