

Percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for atrial fibrillation

1 Guidance

- 1.1 Current evidence on the safety and efficacy of percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for atrial fibrillation (AF) is inadequate in quantity. Therefore this procedure should only be used with special arrangements for clinical governance and consent.
- 1.2 Clinicians wishing to undertake percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for AF should take the following actions.
- 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. In addition, the use of NICE's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG294publicinfo).
- 1.3 Patient selection and treatment should be carried out only by a team specialising in the treatment of cardiac arrhythmias that includes experts in electrophysiology and ablation.
- 1.4 The procedure should only be carried out by interventional cardiologists with specific training in electrophysiology, and in accessing the pericardial space and performing complex ablation procedures.
- 1.5 The procedure should only be carried out in units with arrangements for emergency cardiac surgical support in case of complications.

- 1.6 The NHS Information Centre for health and social care runs the UK Central Cardiac Audit Database, and clinicians should enter details about all patients undergoing percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for AF onto this database (www.ccad.org.uk).
- 1.7 Clinicians are encouraged to enter patients into research studies that aim to provide more information about patient selection, the use of this procedure as an adjunct to other procedures, freedom from AF in the long term and relief of associated symptoms, and the safety profile of the procedure. NICE may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Atrial fibrillation is the most common type of cardiac arrhythmia, and is caused by the irregular and rapid beating of the atria. It can be classified as paroxysmal, persistent or permanent, depending on episode duration and the patient's response to treatment. People with AF may be asymptomatic or they may have symptoms such as palpitations, dizziness, breathlessness and fatigue. Atrial fibrillation is associated with increased risk of death and of embolic stroke from atrial thrombus. Anticoagulation treatment is used to reduce this risk.
- 2.1.2 Antiarrhythmic medication is used either to help maintain a normal cardiac rhythm following successful cardioversion or to help reduce the heart rate. Ablation procedures can be used when drug therapy is either not tolerated or is ineffective.

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland. This guidance is endorsed by NHS QIS for implementation by NHSScotland.

2.2 Outline of the procedure

- 2.2.1 Percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for AF is carried out with the patient under sedation or general anaesthesia. The pericardial space is accessed by a subxiphoid needle puncture under fluoroscopic guidance. A guidewire is introduced through the needle and a sheath is advanced over the guidewire so that the tip is placed inside the pericardial sac. The sheath is aspirated to check for bleeding. A radiofrequency catheter is inserted into the sheath. After electrophysiological mapping to determine target sites for ablation, radiofrequency energy pulses are applied to the epicardium.
- 2.2.2 During the procedure, catheter position is monitored with a three-dimensional mapping system to avoid collateral damage. Saline is placed in the pericardial space to reduce the risk of oesophageal injury, and steroids are administered to reduce the risk of pericarditis.

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/IP261overview

2.3 Efficacy

- 2.3.1 In a case series of five patients, all of them had percutaneous epicardial catheter radiofrequency ablation after failed endocardial ablation. Four patients were AF free and not on antiarrhythmic medication at 2-month, 6-month, 13-month and 15-month follow-up, respectively. The fifth patient was AF free but on antiarrhythmic medication at 4-month follow-up.
- 2.3.2 A case report of a patient with persistent AF (refractory to antiarrhythmic medication and with two previous failed electrical cardioversions) reported that the patient was symptom free at 1 month postoperatively.

- 2.3.3 One Specialist Adviser thought that the key efficacy outcome was freedom from AF. One Specialist Adviser commented that there was uncertainty about the efficacy of the procedure because of the small number of cases reported in the literature.

2.4 Safety

- 2.4.1 In the case series of five patients, one patient developed haemopericardium during the percutaneous epicardial puncture, which was successfully drained. In another patient, a tachycardia originating from the left inferior pulmonary vein was observed during the procedure but this was successfully terminated with delivery of further epicardial and endocardial radiofrequency pulses.
- 2.4.2 The Specialist Advisers considered that potential safety concerns included myocardial puncture; pericarditis; coronary artery damage; perforation of the right ventricle; damage to the oesophagus, bronchi and phrenic nerve; gastric puncture; and damage to abdominal vessels and organs when accessing the pericardial space. One Specialist Adviser considered there to be uncertainty about the long-term safety of the procedure.

3 Further information

- 3.1 NICE has published a clinical guideline on AF and interventional procedures guidance on several procedures for AF, with or without cardiac surgery. NICE has also published interventional procedures guidance on percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for ventricular tachycardia. For more information 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/IPG294publicinfo

Ordering printed copies

Contact NICE publications (phone 0845 003 7783 or email publications@nice.org.uk) and quote reference number N1835 for this guidance or N1836 for the 'Understanding NICE guidance'.

This guidance represents the view of NICE, which was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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