NICE guidance

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

Interventional procedures guidance
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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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

# 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 the public is recommended.

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 National Institute for Cardiovascular Outcomes Research runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians should enter details about all patients undergoing percutaneous (non-thoracoscopic) epicardial catheter radiofrequency ablation for AF onto this database.

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 atrial fibrillation (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.

## 2.2 Outline of the procedure

2.2.1 The procedure 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. Patients can have a combined procedure that includes electrophysiological mapping and ablation by both endocardial and epicardial approaches.

## 2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

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 guideline on atrial fibrillation (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.

# Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the overview.

# Information for patients

NICE has produced information for the public on this procedure. 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.