Percutaneous 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. 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 percutaneous radiofrequency ablation for atrial fibrillation appears adequate to support the use of this procedure in appropriately selected patients (see section 2.1.4) provided that normal arrangements are in place for audit and clinical governance.
1.2 Clinicians should ensure that patients fully understand the potential complications, the likelihood of success and the risk of recurrent atrial fibrillation associated with this procedure. In addition, use of the Institute's information for the public is recommended.

1.3 This procedure should only be performed in specialist units and with arrangements for cardiac surgical support in the event of complications.

1.4 This procedure should only be performed by cardiologists with extensive experience of other types of ablation procedures.

1.5 The Department of Health runs the Central Cardiac Audit Database (CCAD), and clinicians are encouraged to enter all patients undergoing percutaneous radiofrequency ablation for atrial fibrillation onto this database.

2 The procedure

2.1 Indications

2.1.1 Atrial fibrillation is the irregular and rapid beating of the upper two chambers of the heart (the atria). It may be classified as paroxysmal, persistent or permanent. Patients with atrial fibrillation may be asymptomatic or they may have symptoms including palpitations, dizziness, breathlessness and fatigue. They have an increased risk of stroke as a result of blood clots forming in the left atrium and then embolising to the brain.

2.1.2 Atrial fibrillation usually occurs in the absence of structural heart disease.

2.1.3 Conservative treatments include medication to control the heart rhythm and rate, electrical cardioversion and anticoagulation to prevent blood clots forming. Surgery for atrial fibrillation is usually performed at the same time as open heart surgery for another indication, such as for the correction of mitral valve disease. The conventional surgical approach, known as the Cox maze procedure, involves making multiple, strategically placed incisions in both atria to isolate and stop the abnormal electrical impulses. Alternative methods of creating lesions in the atria by ablation have been developed using energy sources such as radiofrequency, microwave, cryotherapy and ultrasound.
2.1.4 Percutaneous radiofrequency ablation is a treatment option for symptomatic patients with atrial fibrillation refractory to anti-arrhythmic drug therapy or where medical therapy is contraindicated because of co-morbidity or intolerance.

2.2 Outline of the procedure

2.2.1 Percutaneous radiofrequency ablation is a minimally invasive procedure that is usually carried out under sedation. A catheter is inserted into the femoral vein and advanced into the heart, using X-ray fluoroscopic guidance to ensure correct positioning. An attachment at the tip of the catheter sends out radiofrequency energy, producing heat that damages the targeted area of the conduction pathway. Electrophysiological testing is undertaken before the procedure to identify and map the source of the abnormal electrical signals. Advanced imaging and mapping techniques that do not require fluoroscopy have also been developed for use in this procedure.

2.2.2 Several different strategies may be used, including linear ablation in the left or right atrium and focal pulmonary vein to isolate triggers of atrial fibrillation that arise from within the pulmonary vein. This guidance does not refer to the procedure of atrioventricular node ablation and pacing.

2.3 Efficacy

2.3.1 In a randomised controlled trial of 70 patients, recurrence of atrial fibrillation at 1 year follow-up was 13% (4/32) after radiofrequency ablation compared with 63% (22/35) after anti-arrhythmic medication \((p < 0.001)\). There were also significantly fewer episodes of hospitalisation in the radiofrequency ablation group: 9% (3/32) and 54% (19/35) of patients, respectively \((p < 0.001)\). Quality-of-life measurements at 6 months favoured the radiofrequency ablation treatment. In a smaller randomised controlled trial, frequency of symptoms decreased from a mean of 42.8 attacks per month at baseline to 0.9 attacks per month at 1 year in 14 patients after percutaneous radiofrequency ablation \((p < 0.001)\).

2.3.2 In a non-randomised comparative study of 1171 patients, 78% of patients treated with radiofrequency ablation were estimated to be free of atrial fibrillation at 3 years, compared with 37% of patients treated with medication \((p\).
Patients receiving percutaneous radiofrequency ablation had a 54% reduction in risk of death compared with those receiving medication (p < 0.001).

A large survey reported that 76% (6644/8745) of treated patients had resolution of symptoms of atrial fibrillation after a median follow-up of 12 months (this proportion ranged from 22% to 91% among different centres). For more details, refer to the Sources of evidence.

The Specialist Advisors noted the lack of long-term data.

### Safety

#### 2.4.1
A complication rate of 6% (524/8745) was reported in the survey of 8745 patients who had undergone percutaneous radiofrequency ablation for atrial fibrillation. The most significant complications reported in this study were four early deaths (< 1%), 20 strokes (< 1%), 47 transient ischaemic attacks (1%), 117 cases of pulmonary vein stenosis (1%), 107 episodes of cardiac tamponade (1%) and 37 cases of arteriovenous fistula (< 1%).

In two comparative studies of 1171 and 30 patients, complications specific to percutaneous radiofrequency ablation included cardiac tamponade in less than 1% (4/589) of patients, stroke in 7% (1/14) and groin haematoma in 7% (1/14).

Two of the studies also reported that 2% and 4% of patients (12/589 and 340/8745, respectively) developed atypical atrial flutter of new onset after undergoing percutaneous radiofrequency ablation. In a case series of 632 procedures a cardiac perforation rate of 2% (15 procedures) was reported, each case requiring pericardiocentesis: all the patients affected survived. For more details, refer to the Sources of evidence.

The Specialist Advisors listed the potential adverse events as stroke, cardiac tamponade, atrio-oesophageal fistula and pulmonary vein stenosis.

### Further information

The Institute has issued guidance on radiofrequency ablation, microwave ablation and cryoablation for atrial fibrillation in association with other cardiac surgery.
The Institute is also developing interventional procedures guidance on high-intensity focused ultrasound ablation for atrial fibrillation as an associated procedure with other cardiac surgery [Now published as 'High intensity focused ultrasound ablation of atrial tissue for atrial fibrillation as an associated procedure with other cardiac surgery'] and a clinical guideline on atrial fibrillation due to be published in June 2006 [Now published as 'The management of atrial fibrillation'].

Andrew Dillon
Chief Executive
April 2006

Sources of evidence

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

'Interventional procedure overview of percutaneous radiofrequency catheter ablation for atrial fibrillation', May 2005.

Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE interventional procedure guidance process.

We have produced a summary of this guidance for patients and carers. Information about the evidence it is based on is also available.
Changes since publication

8 May: minor maintenance.

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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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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.