

Percutaneous radiofrequency ablation for atrial fibrillation

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 (available from www.nice.org.uk/IPG168publicinfo).
- 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 (www.ccad.org.uk).

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.

Interventional Procedure Guidance 168

This guidance is written in the following context

This guidance represents the view of the Institute 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.

Interventional procedures guidance is for healthcare professionals and people using the NHS in England, Wales and Scotland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

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 ($p < 0.001$). Patients receiving percutaneous radiofrequency ablation had a 54% reduction in risk of death compared with those receiving medication ($p < 0.001$).
- 2.3.3 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.
- 2.3.4 The Specialist Advisors noted the lack of long-term data.

2.4 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 ($< 1\%$).
- 2.4.2 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).

2.4.3 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.

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

3 Further information

- 3.1 The Institute has issued guidance on radiofrequency ablation (available from www.nice.org.uk/IPG121), microwave ablation (www.nice.org.uk/IPG122) and cryoablation for atrial fibrillation in association with other cardiac surgery (www.nice.org.uk/IPG123).
- 3.2 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 (www.nice.org.uk/ip_312) and a clinical guideline on atrial fibrillation due to be published in June 2006.
- Andrew Dillon
Chief Executive
April 2006

Information for the public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG168publicinfo

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.

Available from: www.nice.org.uk/ip300overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1020. *Information for the public* can be obtained by quoting reference number N1021.

The distribution list for this guidance is available at www.nice.org.uk/IPG168distributionlist

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