NICE guidance

Thoracoscopic epicardial radiofrequency ablation for atrial fibrillation

Interventional procedures guidance
Published: 28 January 2009

www.nice.org.uk/guidance/ipg286

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 Recommendations

1.1 There is evidence of efficacy for thoracoscopic epicardial radiofrequency ablation for atrial fibrillation (AF) in the short term and in small numbers of patients. The assessment of cardiac rhythm during follow-up varied between studies, and some patients were concomitantly treated with anti-arrhythmic medication. Evidence on safety shows a low incidence of serious complications but this is also based on a limited number of patients. Therefore, the procedure should only be used with special arrangements for clinical governance, consent and audit or research.

1.2 Clinicians wishing to undertake thoracoscopic epicardial 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, NICE's information for the public is recommended.

1.3 Patient selection for thoracoscopic epicardial radiofrequency ablation for AF should involve a multidisciplinary team including a cardiologist and a cardiac surgeon, both with training and experience in the use of intraoperative electrophysiology.

1.4 The procedure should only be carried out by surgeons with specific training and experience in both thoracoscopic surgery and radiofrequency ablation.

1.5 The NHS Information Centre for Health and Social Care runs the UK Central Cardiac Audit Database (CCAD), and is developing a database for this procedure. Clinicians should collect data on the procedure and submit them to the database when it becomes available.

1.6 NICE encourages further comparative research into the treatment and management of AF, with clearly defined outcomes. NICE may review this procedure on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Atrial fibrillation is irregular and rapid beating of the atria. It can be classified as paroxysmal, persistent or permanent, depending on the duration of episodes and patients' response to treatment. Atrial fibrillation can cause fatigue, palpitations, chest pain, shortness of breath and fainting. There is an increased risk of death and stroke.

2.1.2 Medication for atrial fibrillation (AF) may aim either to maintain a normal cardiac rhythm or control the rate of the ventricular response, and to reduce the risk of thromboembolism (which may cause stroke). Ablation procedures are used when drug therapy is either not tolerated or is ineffective.

2.2 Outline of the procedure

2.2.1 Thoracoscopic epicardial radiofrequency ablation is carried out with the patient under general anaesthesia. Two or more small incisions are made in the chest wall. The right lung is deflated and the right pulmonary veins are accessed via blunt dissection. A bipolar radiofrequency device is inserted through a catheter and positioned around the atrium adjacent to the pulmonary veins. Radiofrequency energy is applied to create full thickness ablation in the myocardium, with the aim of electrically isolating the pulmonary veins.

Intraoperative electrophysiological testing may be used to check whether isolation has been achieved. The procedure is repeated on the left pulmonary veins.

2.2.2 The left atrial appendage may be excised during the procedure, to minimise the risk of subsequent thromboembolic events.

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 for this guidance.

2.3.1 In four case series of 70, 26, 22 and 20 patients with paroxysmal or persistent AF, 93% (65 out of 70), 81% (21 out of 26), 91% (20 out of 22) and 90% (18 out of 20) were in sinus rhythm at follow-up ranging from 6 to 18 months.

2.3.2 In the case series of 70 patients, 43%, 23% and 14% of patients with paroxysmal AF (n=42) were using anti-arrhythmic medication at 3, 6 and 12 months, respectively (absolute numbers not reported). In the same study, 61%, 26% and 38% of patients with persistent AF (n=28) were using anti-arrhythmic medication at 3, 6 and 12 months, respectively (absolute numbers not reported). In two case series of 27 and 26 patients, 65% (15 of the 23 patients with follow-up of at least 3 months) and 57% (12 of the 21 patients in sinus rhythm at 6-month follow-up), respectively, were no longer using anti-arrhythmic medication. In the case series of 22 and 20 patients, 91% (20 out of 22) and 85% (17 out of 20) were not using anti-arrhythmic medication at their last follow-up (mean follow-up 18 and 17 months, respectively).

2.3.3 The specialist advisers considered key efficacy outcomes to include reduced use of anti-arrhythmic medication and decreased burden of AF for patients with paroxysmal AF. One specialist adviser stated that the procedure's long-term efficacy was uncertain.

2.4 Safety

2.4.1 The case series of 70 patients reported two major complications: 1 patient required revision surgery 10 days postoperatively because of fistula formation between the left atrium and the oesophagus, and another required angioplasty and stent insertion for stenosis of the circumflex coronary artery 6 weeks after the procedure. The case series of 27 patients reported one case each of right pneumothorax and suspected pericarditis. In the case series of 26 patients, 1 patient required aspiration of pleural effusion.

2.4.2 The specialist advisers stated that theoretical and anecdotal adverse events included injury to the heart or adjacent structures, bleeding from the atrial appendage, coronary artery occlusion, pulmonary vein stenosis and increased risk of arrhythmias postoperatively.

2.5 Other comments

2.5.1 The fact that that some patients had concomitant excision of the left atrial appendage, and others did not, complicated interpretation of the evidence.

3 Further information

3.1 To find NICE guidance on related topics, including guidance in development, see the NICE topic page on heart rhythm conditions.

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.

ISBN: 978-1-4731-5900-6

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.