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 Guidance

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, the
  use of NICE's information for patients ('Understanding NICE guidance') 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 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.

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 Efficacy

2.3.1 In four case series of 70, 26, 22 and 20 patients with paroxysmal or persistent AF, 93% (65/70), 81% (21/26), 91% (20/22) and 90% (18/20) 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% (20/22) and 85% (17/20) 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 some patients had concomitant excision of the left atrial appendage, and others did not, complicated interpretation of the evidence.

3 Further information

3.1 NICE has published a clinical guideline on AF and interventional procedures guidance on a number of procedures for AF, with or without cardiac surgery. For more information go to our website.

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.

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 2012: minor maintenance.

Your responsibility

This guidance represents the views of NICE and 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.

Copyright

© National Institute for Health and Clinical Excellence 2009. All rights reserved. NICE copyright material can be downloaded for private research and study, and may be reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the written permission of NICE.

Contact NICE
Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation

NICE accredited

www.nice.org.uk/accreditation