NHS
National Institute for Health and Clinical Excellence

Percutaneous endoscopic catheter laser balloon pulmonary vein isolation for atrial fibrillation

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NICE interventional procedure guidance 399

guidance.nice.org.uk/ipg399

Healthcare Improvement Scotland

NHS Evidence has accredited the process used by the NICE Interventional Procedures Programme to produce interventional procedures guidance. Accreditation is valid for 5 years from January 2010 and applies to guidance produced since January 2009 using the processes described in the 'Interventional Procedures Programme: Process guide, January 2009' and the 'Interventional Procedures Programme: Methods guide, June 2007'

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Contents

1 Guidance

1.1 Current evidence on the safety and efficacy of percutaneous endoscopic catheter laser balloon pulmonary vein isolation for atrial fibrillation (AF) is inadequate because of the limited number of patients reported. Therefore this procedure should only be used with special arrangements for clinical governance, consent and research.

1.2 Clinicians wishing to undertake percutaneous endoscopic catheter laser balloon pulmonary vein isolation for AF should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that patients and their carers 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 and treatment should be carried out only by interventional cardiologists with expertise in electrophysiology and with experience in performing complex ablation procedures.

1.4 This procedure should be carried out only in units with arrangements for emergency cardiac surgical support in case of complications.

1.5 Clinicians should enter details about all patients undergoing percutaneous endoscopic catheter laser balloon pulmonary vein isolation for AF onto the UK Central Cardiac Audit Database.

1.6 Further research should define patient-selection criteria and should clearly describe adverse events and long-term control of AF. NICE may review this guidance on publication of further evidence.

2 The procedure

2.1 Indications and current treatments

2.1.1 Atrial fibrillation is the irregular and rapid beating of the atria. Patients with AF may be asymptomatic or may have symptoms such as fatigue, palpitations and chest pain.

2.1.2 Patients considered to be at high risk of thromboembolic stroke are usually treated with anticoagulation therapy. Medication can be used either to help control the heart rate or to help maintain a normal cardiac rhythm following cardioversion. Ablation procedures may be used when drug therapy is either not tolerated or is ineffective.

2.2 Outline of the procedure

2.2.1 Percutaneous endoscopic catheter laser balloon pulmonary vein isolation for AF aims to isolate the electrical impulses at the pulmonary vein ostia responsible for 'triggering' AF using laser ablation, and to maintain a normal heart rhythm.

2.2.2 The procedure is usually done with the patient under general anaesthesia. The laser balloon catheter is introduced via the femoral vein. Catheter electrodes placed in the heart or pulmonary veins can stimulate the heart or phrenic nerve and record electrical signals from the pulmonary vein ostia and the laser balloon catheter. The catheter balloon is inflated and positioned at the ostium of a pulmonary vein. It has an endoscope lumen to allow direct visualisation of the cardiac tissue. Laser energy is delivered, and pacing and circular mapping catheters are used to assess whether electrical isolation of the pulmonary ostia has been achieved.

2.2.3 Ablation and assessment of successful electrical isolation are repeated for each pulmonary vein.

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that 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 Two case series, each of 30 patients, reported that 91% (105/116) and 98% (114/116) of pulmonary veins were successfully isolated (confirmed by pulmonary vein circular mapping catheter). A case series of 27 patients reported successful isolation in 100% (101/101) of pulmonary veins; 67% (12/18) of patients had complete pulmonary vein isolation confirmed by an electrophysiological remapping procedure under conscious sedation at 3-month follow-up.

2.3.2 The first case series of 30 patients reported that 60% (18/30) of patients were AF-free without medication at 12-month follow-up. The second case series of 30 patients reported that 80% (24/30) of patients were free from AF episodes lasting more than 1 minute at a median follow-up of 168 days.

2.3.3 The first case series of 30 patients reported 1 patient in whom pulmonary vein reconnections developed during 12-month follow-up; these were treated by radiofrequency ablation. The second case series of 30 patients and the case series of 27 patients each reported 2 patients who required repeat procedures during median follow-up of 168 days and 3 months respectively.

2.3.4 The Specialist Advisers listed key efficacy outcomes as vein isolation with no recurrence of AF, symptomatic improvement and quality of life.

2.4 Safety

2.4.1 Intraoperative cardiac tamponade related to transseptal puncture was reported in 1 patient in the first case series of 30 patients. This was successfully treated with pericardiocentesis. Perforation of the left atrium was reported in 1 patient in the second case series of 30 patients. This was treated with surgical intervention and the patient made a full recovery.

2.4.2 The second case series of 30 patients reported 'minimal thermal oesophageal lesions' (not otherwise described) and oesophageal ulceration (treated successfully with drug therapy) in 2 and 4 patients respectively (demonstrated on endoscopy at 48-hour follow-up).

2.4.3 The second case series of 30 patients and the case series of 27 patients reported that the procedure had to be interrupted because oesophageal temperature monitoring showed a rise to above 38.5ºC in 60% (18/30) and 33% (9/27) of patients respectively.

2.4.4 Asymptomatic right phrenic nerve palsy was diagnosed on routine post-procedure chest X-ray in 1 patient in the first case series of 30 patients. This resolved completely by 6-month follow-up.

2.4.5 The Specialist Advisers listed adverse events reported in the literature or known anecdotally as atrium–oesophageal fistulae, cardiac perforation and tamponade, pulmonary vein stenosis, stroke or transient ischaemic attack, phrenic nerve injury and permanent diaphragmatic paralysis, haemothorax, valve damage requiring surgery, pneumothorax, sepsis, abscesses, endocarditis and femoral pseudoaneurysm.

2.5 Other comments

2.5.1 The Committee noted that the actual number of treated patients in the reported case series may be limited by duplication.

3 Further information

3.1 For related NICE guidance see www.nice.org.uk

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 NHS Scotland.

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

We have produced a summary of this guidance for patients and carers. Tools to help you put the guidance into practice and information about the evidence it is based on are 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.

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