

NATIONAL INSTITUTE FOR HEALTH AND CARE EXCELLENCE

Interventional procedure consultation document

Percutaneous endoscopic laser balloon pulmonary vein isolation for atrial fibrillation

Atrial fibrillation is the irregular, and typically rapid, beating of the upper 2 chambers of the heart (the atria). It is caused by abnormal electrical impulses thought to start in the pulmonary veins (the blood vessels carrying blood from the lungs to the heart). Symptoms include palpitations, dizziness, shortness of breath and fatigue. Complications can include stroke.

In this procedure, a catheter with a laser is inserted through the femoral vein in the groin and up into the heart. The laser is used to destroy the areas around the pulmonary veins that cause the abnormal electrical impulses, to help maintain a normal heartbeat. This procedure may be suitable for patients whose atrial fibrillation has not responded to medication.

The National Institute for Health and Care Excellence (NICE) is examining percutaneous endoscopic laser balloon pulmonary vein isolation for atrial fibrillation and will publish guidance on its safety and efficacy to the NHS. NICE's interventional procedures advisory committee has considered the available evidence and the views of specialist advisers, who are consultants with knowledge of the procedure. The advisory committee has made draft recommendations about percutaneous endoscopic laser balloon pulmonary vein isolation for atrial fibrillation.

This document summarises the procedure and sets out the draft recommendations made by the advisory committee. It has been prepared for public consultation. The advisory committee particularly welcomes:

- comments on the draft recommendations
- the identification of factual inaccuracies
- additional relevant evidence, with bibliographic references where possible.

Note that this document is not NICE's formal guidance on this procedure. The recommendations are provisional and may change after consultation.

The process that NICE will follow after the consultation period ends is as follows.

- The advisory committee will meet again to consider the original evidence and its draft recommendations in the light of the comments received during consultation.
- The advisory committee will then prepare draft guidance which will be the basis for NICE's guidance on the use of the procedure in the NHS.

For further details, see the [Interventional Procedures Programme process guide](#), which is available from the NICE website.

Through its guidance NICE is committed to promoting race and disability equality, equality between men and women, and to eliminating all forms of discrimination. One of the ways we do this is by trying to involve as wide a range of people and interest groups as possible in the development of our interventional procedures guidance. In particular, we aim to encourage people and organisations from groups who might not normally comment on our guidance to do so.

In order to help us promote equality through our guidance, we should be grateful if you would consider the following question:

- Are there any issues that require special attention in light of NICE's duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations between people with a characteristic protected by the equalities legislation and others?

Please note that NICE reserves the right to summarise and edit comments received during consultations or not to publish them at all where in the reasonable opinion of NICE, the comments are voluminous, publication would be unlawful or publication would otherwise be inappropriate.

Closing date for comments: 22 April 2016

Target date for publication of guidance: July 2016

1 Draft recommendations

1.1 Current evidence on the safety of percutaneous endoscopic laser balloon pulmonary vein isolation for atrial fibrillation shows there are serious but well-recognised complications. Evidence on efficacy is adequate in quantity and quality to support the use of this procedure provided that standard arrangements are in place for clinical governance, consent and audit.

1.2 Clinicians should ensure that patients fully understand the potential complications, the uncertainty about the success of the procedure

in the short term and the risk of recurrent atrial fibrillation. In addition, the use of NICE's [information for the public](#) *[[URL to be added at publication]]* is recommended.

- 1.3 Patient selection and treatment should be carried out only by interventional cardiologists with expertise in electrophysiology and experience of doing complex ablation procedures.
- 1.4 This procedure should be done only in units with arrangements for emergency cardiac surgical support.
- 1.5 Clinicians should enter details about all patients having percutaneous endoscopic laser balloon pulmonary vein isolation for atrial fibrillation onto the [UK Central Cardiac Audit Database](#) and review local clinical outcomes.

2 Indications and current treatments

- 2.1 Atrial fibrillation (AF) is the most common type of cardiac arrhythmia. It is caused by the uncoordinated electrical stimulation of the atrial walls, which stop contracting as they fibrillate. This causes the ventricle to beat at an irregular and sometimes rapid rate. Patients with AF may be asymptomatic or have palpitations, dizziness, shortness of breath, fatigue and chest pain.
- 2.2 Atrial fibrillation is associated with increased risk of embolic stroke from atrial thrombus, and death. Depending on risk stratification, oral anticoagulation treatment may be indicated. Such treatment needs monitoring and is associated with risk of haemorrhage. Drugs may be used to prevent AF and maintain sinus rhythm (anti-arrhythmics) or may be used to control the ventricular rate when AF occurs (usually beta blockers).
- 2.3 Ablation procedures are typically used in patients with non-permanent AF when drug therapy is either not tolerated or is ineffective.

3 The procedure

- 3.1 Percutaneous endoscopic laser balloon pulmonary vein isolation for atrial fibrillation (AF) aims to maintain normal heart rhythm. It uses laser ablation to isolate the electrical impulses originating in the pulmonary veins, which are thought to be responsible for triggering AF.
- 3.2 The laser balloon catheter comprises an inflatable balloon mounted on a catheter shaft, an endoscope lumen, and an optical fibre that can also deliver laser energy.
- 3.3 The procedure is done with the patient under general anaesthesia or sedation. A deflectable sheath introducer is inserted in the femoral vein and advanced into the left atrium through a trans-septal puncture. A circular mapping catheter is introduced, which may need a second trans-septal puncture. A balloon catheter is passed through the deflectable sheath and the balloon is inflated at the ostium of the target pulmonary vein. The endoscope tip is positioned at the proximal end of the balloon, allowing direct visualisation of the cardiac tissue and assessment of the degree of contact between the balloon and cardiac muscle. Laser energy is delivered around the circumference of the pulmonary vein to isolate the source of the abnormal electrical activity. The circular mapping catheter is then used to assess whether electrical isolation of the pulmonary vein has been achieved. Ablation and assessment are repeated sequentially for each pulmonary vein. During ablation of the right-sided pulmonary veins, phrenic nerve pacing is done from the superior vena cava to monitor for phrenic nerve injury.

4 Efficacy

This section describes efficacy 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 [interventional procedure overview](#).

- 4.1 In a randomised controlled trial of 342 patients with atrial fibrillation (AF) treated by laser balloon pulmonary vein isolation or radiofrequency ablation, 61% and 62% of patients (actual numbers not reported) respectively ($p=0.003$ for non-inferiority) did not have protocol-defined treatment failure (documented symptomatic AF of 1 minute or more; ablation-induced left atrial flutter or atrial tachycardia; failure to acutely isolate all pulmonary veins; use of any anti-arrhythmic drug; or left heart ablation or surgery or implantable cardioverter-defibrillator placement for AF) at 12-month follow-up. The percentage of patients who were drug-free at 12 months and free from symptomatic AF or atypical atrial flutter or atrial tachycardia was 64% (106/167 and 106/166) in both treatment groups ($p=0.94$). In a case series of 200 patients, 60% (95% confidence interval [CI] 53% to 67%) of patients were free from AF and were off anti-arrhythmic drugs (class I or III) at 12-month follow-up.
- 4.2 In a non-randomised comparative study of 140 patients treated by laser balloon pulmonary vein isolation or cryoballoon ablation, AF recurred between 90 and 365 days after ablation in 27% (18/68) and 37% (24/65) of patients respectively ($p=0.18$). In a non-randomised comparative study of 80 patients with early persistent AF treated by laser balloon pulmonary vein isolation or radiofrequency ablation, AF recurred in 28% (11/40) and 23% (9/40) of patients respectively ($p=0.79$) after a single procedure at 12-month follow-up. In a case series of 194 patients, 82% (130/158) of patients with paroxysmal AF and 75% (9/12) of patients with persistent AF were free from AF at 12-month follow-up. For patients with paroxysmal AF, 76%, 76% and 75% of patients were free from AF at 24-, 36- and 48-month follow-up respectively.
- 4.3 In the non-randomised comparative study of 80 patients, 25% (10/40) and 23% (9/40) of patients treated by laser balloon

pulmonary vein isolation or radiofrequency ablation respectively had a repeat procedure. In the case series of 194 patients, 6% (11/194) of patients had a repeat procedure.

- 4.4 The specialist advisers listed key efficacy outcomes as persistent isolation of pulmonary veins, freedom from AF, freedom from atrial arrhythmias, freedom from atrial arrhythmias when off anti-arrhythmic drug therapy, the single or multiple procedure success rate and improvement in quality of life.

5 Safety

This section describes 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 [interventional procedure overview](#).

- 5.1 Stroke was reported in 2 patients treated by laser balloon pulmonary vein isolation (1 before discharge and 1 a week after discharge) and in 1 patient treated by radiofrequency ablation ($p=0.56$) in a randomised controlled trial (RCT) of 342 patients. All 3 strokes completely resolved. Transient ischaemic attack was reported in 1 patient treated by laser balloon pulmonary vein isolation in a non-randomised comparative study of 140 patients. Stroke or transient ischaemic attack was reported in 1 patient in a case series of 194 patients; the patient showed symptoms of verbal confusion 2 hours after the procedure, but this resolved within 24 hours.
- 5.2 Cardiac tamponade, perforation, or significant effusion was reported in 1% (2/170) of patients treated by laser balloon pulmonary vein isolation and 2% (3/172) of patients treated by radiofrequency ablation ($p=0.66$) in the RCT of 342 patients. Cardiac tamponade was reported in 1 patient in the non-randomised comparative study of 140 patients; this was treated by drainage of 300 ml of blood. Pericardial effusion was reported in

3% (6/200) of patients in a case series of 200 patients; 4 patients developed haemodynamic compromise or cardiac tamponade. All of these tamponades occurred during the procedure and were successfully drained.

5.3 One patient died suddenly 6 days after the procedure, in the case series of 200 patients. The patient was found to have unrecognised critical triple vessel coronary artery disease. An independent Data Safety and Monitoring Board considered that this event was not related specifically to the laser ablation catheter. Cardiac tamponade or pericardial effusion was reported in 1 patient in the case series of 194 patients.

5.4 Diaphragmatic paralysis persisting beyond 90 days was reported in 4% (6/170) of patients treated by laser balloon pulmonary vein isolation (3 persisted at 12 months, 1 resolved after 12 months) and 1% (1/172) of patients treated by radiofrequency ablation (persistent at 12 months; $p=0.05$) in the RCT of 342 patients. Phrenic nerve palsy was reported in 4% (3/70) of patients treated by laser balloon pulmonary vein isolation and 6% (4/70) of patients treated by cryoballoon ablation in the non-randomised comparative study of 140 patients. Phrenic nerve injury was reported in 3% (5/200) of patients in the case series of 200 patients (1 remained unresolved at 12-month follow-up). Acute phrenic nerve injury was reported in 2% (4/194) of patients in the case series of 194 patients; none persisted beyond 6 months.

5.5 Thermal lesions in the oesophagus, identified by endoscopy, were reported in 82% (33/40) of patients treated by laser balloon pulmonary vein isolation and 85% (17/20) of patients treated by radiofrequency ablation in a non-randomised comparative study of 60 patients. Ulceration was reported in 10% (4/40) of patients treated by laser balloon pulmonary vein isolation and no patients treated by radiofrequency ablation.

- 5.6 A patient with pulmonary vein stenosis 6 months after laser balloon pulmonary vein isolation was described in a case report. The first attempt to isolate the pulmonary vein was unsuccessful and additional energy applications were needed. Significant pulmonary vein stenosis (more than a 50% decrease in diameter on CT or cardiac MRI) at 3-month follow-up was reported in no patients treated by laser balloon pulmonary vein isolation and 3% (5/172) of patients treated by radiofrequency ablation ($p=0.03$) in the RCT of 342 patients. Pulmonary vein narrowing (more than 20% but not more than 50% decrease in diameter) evaluated on a per-vein basis was reported in 22% and 25% of patients respectively, in the same study (p value not reported). The mean decrease in pulmonary vein diameter was 4% at 3-month follow-up in the case series of 200 patients. Mild narrowing (1–25% decrease in diameter) was present in 44% of pulmonary veins and moderate narrowing (26–50%) in 6% of pulmonary veins.
- 5.7 An endoscopically visible steam ‘pop’ was described in a case report. During ablation at the antrum of the left superior pulmonary vein, a sudden steam pop was witnessed, with displacement of the laser balloon catheter. The left superior pulmonary vein antrum showed a red discolouration, most likely a haematoma in the antral wall. The discolouration was still present 1 hour after the procedure. The patient did not develop any symptoms related to the steam pop and echocardiography did not reveal any abnormalities.
- 5.8 Laceration of the right femoral vein by mechanical trauma was reported in 1 patient in the non-randomised comparative study of 140 patients. This was treated by surgery. In the same study, minor vascular complications (false aneurysms or haematoma) were reported in 4% (3/40) of patients treated by laser balloon pulmonary vein isolation and 3% (2/70) of patients treated by cryoballoon ablation. False aneurysm was reported in 1 patient treated by laser

balloon and 1 patient treated by radiofrequency ablation in a non-randomised comparative study of 80 patients. Vascular injury was reported in 3% (6/194) of patients in the case series of 194 patients; 2 patients had surgical repair and 4 patients had prolonged hospitalisation because of bleeding.

- 5.9 Cardioversion for atrial arrhythmia was reported in 8% (14/170) of patients treated by laser balloon pulmonary vein isolation and 9% (16/172) of patients treated by radiofrequency ablation ($p=0.73$) in the RCT of 342 patients.
- 5.10 Asymptomatic cerebral lesions were detected by MRI 1–2 days after the procedure in 24% (8/33) of patients treated by laser balloon pulmonary vein isolation, 24% (8/33) of patients treated by radiofrequency ablation and 18% (6/33) of patients treated by cryoballoon ablation ($p=0.8$) in an RCT of 99 patients.
- 5.11 In addition to safety outcomes reported in the literature, specialist advisers are asked about anecdotal adverse events (events which they have heard about) and about theoretical adverse events (events which they think might possibly occur, even if they have never done so). For this procedure, specialist advisers listed the following anecdotal adverse event: catheter failure needing a minor surgical procedure to remove it safely from the femoral vein. They considered that the following were theoretical adverse events: atrial-oesophageal fistula, myocardial infarction and death.

6 Committee comments

- 6.1 The committee noted that most of the published evidence is on the use of this procedure in younger patients and in patients with paroxysmal atrial fibrillation. It may not be generalisable to all patients with atrial fibrillation.
- 6.2 The committee noted that the procedure may need to be repeated.

7 Further information

- 7.1 For related NICE guidance, see the [NICE website](#).
- 7.2 This guidance is a review of 'Percutaneous endoscopic catheter laser balloon pulmonary vein isolation for atrial fibrillation' NICE interventional procedure guidance 399 (2011).

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