

Percutaneous balloon cryoablation for pulmonary vein isolation in atrial fibrillation

Interventional procedures guidance

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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 Current evidence on the efficacy and safety of percutaneous balloon cryoablation for pulmonary vein isolation in atrial fibrillation is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.
- 1.2 Patient selection and treatment should only be carried out by interventional cardiologists with expertise in electrophysiology and complex ablation procedures.
- 1.3 This procedure should be carried out only in units with arrangements for emergency cardiac surgical support in case of complications.
- 1.4 Clinicians should enter details about all patients undergoing percutaneous balloon cryoablation for pulmonary vein isolation in atrial fibrillation onto the UK Central Cardiac Audit Database (UKCCAD) run by the National Institute for Cardiovascular Outcomes Research.
- 1.5 NICE encourages clinicians to enter patients into research studies with the particular aims of guiding selection of patients and of defining the place of percutaneous balloon cryoablation in relation to other procedures for treating atrial fibrillation. Further research should define patient selection criteria clearly and should document adverse events and long-term control of atrial fibrillation.

2 The procedure

2.1 Indications and current treatments

- 2.1.1 Atrial fibrillation is the irregular and rapid activation of the atria. It is caused by uncoordinated electrical stimulation of the atrial muscle. Atrial fibrillation may be classified as paroxysmal, persistent or permanent. Patients may be asymptomatic or have symptoms such as palpitations, fatigue and chest pain.
- 2.1.2 Patients considered to be at high risk of embolic stroke from thrombus in the fibrillating left atrium are usually treated with anticoagulation therapy. Medical treatment for atrial fibrillation includes drugs to control heart rate or to help maintain a normal cardiac rhythm after cardioversion. Ablation procedures, designed to disrupt abnormal conduction pathways, may be used when drug therapy is either not tolerated or is ineffective. Several methods are available to deliver cardiac ablation including cryoablation with or without a balloon.

2.2 Outline of the procedure

- 2.2.1 Percutaneous balloon cryoablation for pulmonary vein isolation in atrial fibrillation helps maintain normal heart rhythm by isolating the electrical impulses originating in the pulmonary veins that are thought to be responsible for 'triggering' atrial fibrillation.
- 2.2.2 With the patient under general anaesthesia, or using local anaesthesia and sedation, catheters are introduced percutaneously through one or both femoral veins. One or more electrode catheters are placed in the heart to allow pacing. An additional electrode catheter is placed in a vein or the heart to allow stimulation of the phrenic nerve. One or two sheaths are advanced into the left atrium transseptally. A multipolar circular mapping catheter (to record electrical signals from the pulmonary vein ostia) and the balloon cryoablation catheter are passed through the two sheaths. The balloon cryoablation catheter is placed at one of the pulmonary vein ostia and the balloon is inflated to allow continuous contact between the balloon and the atrial myocardium. Good contact is confirmed fluoroscopically by injecting contrast into the pulmonary vein through the lumen

of the balloon catheter.

- 2.2.3 When the balloon catheter has been positioned satisfactorily, it is cooled in bursts of approximately 4 minutes, to achieve circumferential isolation of the cells responsible for the arrhythmia. This is assessed using the mapping catheter. Each of the pulmonary veins is treated in the same way, until all are electrically isolated.

2.3 Efficacy

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](#).

- 2.3.1 A systematic review with 1,308 patients (23 studies) reported acute procedural success (defined as complete isolation of all targeted pulmonary veins) in 99% (95% confidence interval [CI] 98 to 99) of patients (19 studies; n=924; $I^2=0%$ [no heterogeneity]; timing of assessment unclear). A comparative case series of 94 patients treated by balloon cryoablation (n=30), radiofrequency ablation (n=29) or robotically assisted radiofrequency ablation (n=35) reported procedure success (defined as 'no atrial tachyarrhythmias [symptomatic or asymptomatic] lasting ≥ 30 seconds, identified on surface electrocardiogram [ECG], Holter monitoring or 7-day ECG recording') without anti-arrhythmic drugs in 66% (23), 66% (19) and 67% (20) of patients respectively at a mean follow-up of 13 months ($p=0.625$; denominator not reported).
- 2.3.2 The systematic review reported 1-year freedom from atrial fibrillation in 73% of patients (95% CI 69 to 77) with paroxysmal atrial fibrillation after a 3-month blanking period (time period during which transient episodes of arrhythmia were not considered recurrences; 5 studies; n=519; $I^2=0%$ [no heterogeneity]); in 60% of patients (95% CI 55 to 66) with paroxysmal atrial fibrillation without a 3-month blanking period (3 studies; n=316; $I^2=0%$ [no heterogeneity]); and in 45% of patients (95% CI 32 to 58) with persistent atrial fibrillation after a 3-month blanking period (2 studies; n=62; $I^2=0%$ [no heterogeneity]).
- 2.3.3 In a case series of 346 patients treated by balloon cryoablation (treatment

completed by cryoablation catheter if isolation was not achieved), sinus rhythm was maintained without anti-arrhythmic drugs in 74% (159, denominator not reported) of patients with paroxysmal atrial fibrillation and 42% (13 out of 31) of patients with persistent atrial fibrillation (follow-up not stated).

- 2.3.4 A case series of 141 patients reported recurrence of atrial fibrillation in 51% (71 out of 139) of patients after 1 procedure (follow-up 457 days).
- 2.3.5 A non-randomised comparative case series of 177 patients treated by balloon cryoablation or radiofrequency ablation reported that 14% (17) and 23% (12) of patients respectively needed retreatment for recurrent atrial fibrillation (denominators and timing of events not reported; mean follow-up 13 months).
- 2.3.6 The Specialist Advisers listed key efficacy outcomes as electrical isolation of 'all pulmonary veins' or 'all 4 pulmonary veins', procedure duration, freedom from atrial fibrillation, avoidance of repeat procedures and reduced use of anti-arrhythmic drugs.

2.4 Safety

- 2.4.1 The case series of 346 patients reported periprocedural pericardial tamponade in 2 patients, both successfully treated by pericardial drainage and without the need for surgery. A comparative case series of 133 patients reported pericardial effusion within 24 hours in 11% (5 out of 46) of patients treated by balloon cryoablation and in 16% (14 out of 87) of patients treated by radiofrequency ablation (drainage was needed in 1 patient in each group; all the other effusions resolved spontaneously).
- 2.4.2 The case series of 346 patients reported right phrenic nerve injury in 8% (26 out of 346) of patients during balloon cryoablation of the right superior pulmonary vein. Of these, 2 resolved during the procedure and full function recovered in all patients during follow-up of less than 1 year.
- 2.4.3 A comparative case series of 74 patients treated by balloon cryoablation (n=67) or cryocatheter (n=7) reported oesophageal ulceration identified by endoscopy in 17% (6 out of 35) of patients and 0 out of 7 patients respectively within 1 week of

the procedure. All were asymptomatic and resolved within 3 months.

- 2.4.4 Stroke or transient ischaemic attack was reported in less than 1% of patients (4 out of 1,241) in the systematic review. Three of the 4 cerebrovascular events were observed in the same study and resolved within 24 hours.
- 2.4.5 In the case series of 141 patients, 2 patients had haemoptysis during the first month after pulmonary vein isolation. This resolved after temporary cessation of oral anticoagulation therapy.
- 2.4.6 The Specialist Advisers listed adverse events reported in the literature as pulmonary vein stenosis, groin haematoma at venous entry site and pseudoaneurysm. They reported anecdotal adverse events of air embolus and phrenic nerve injury, and they considered theoretical adverse events to include death, atrio-oesophageal fistula, permanent phrenic nerve palsy, damage to structures anatomically close to pulmonary veins and deep vein thrombosis.

2.5 Other comments

- 2.5.1 The Committee noted the advances in the understanding of the causes of atrial fibrillation and acknowledged that this procedure is likely to be more effective in paroxysmal than persistent atrial fibrillation.
- 2.5.2 The Committee noted that asymptomatic cerebral lesions have been shown after percutaneous balloon cryoablation for pulmonary vein isolation in atrial fibrillation but that it is unknown whether these have clinical consequences.

3 Further information

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.

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Endorsing organisation

This guidance has been endorsed by [Healthcare Improvement Scotland](#).