

Cryoablation for atrial fibrillation in association with other cardiac surgery

Interventional procedures guidance

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[nice.org.uk/guidance/ipg123](https://www.nice.org.uk/guidance/ipg123)

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. However, 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.

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.

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 safety and efficacy of cryoablation for atrial fibrillation in association with other cardiac surgery appears adequate to support the use of this procedure provided that the normal arrangements are in place for consent, audit and clinical governance.

- 1.2 Patient selection and follow-up should be carried out by a multidisciplinary team. Cardiac surgeons undertaking this procedure should have specific training in the use of cryoablation equipment.

2 The procedure

2.1 *Indications*

- 2.1.1 Atrial fibrillation is the irregular and rapid beating of the upper two chambers of the heart (the atria). It may be classified as paroxysmal, persistent or permanent. It is the most common type of arrhythmia and the incidence increases markedly with age. Patients with atrial fibrillation may be asymptomatic or they may have symptoms such as palpitations, dizziness and breathlessness. They also have an increased risk of stroke as a result of blood clots forming in the left atrium and then embolising to the brain.
- 2.1.2 Atrial fibrillation usually occurs in the absence of structural heart disease. However, if structural heart disease is present, it is most commonly mitral stenosis.
- 2.1.3 Conservative treatments include medication, electrical cardioversion to control the heart rhythm, and anticoagulants to prevent the formation of blood clots. The conventional surgical approach, known as the Cox maze procedure, involves making multiple, strategically placed incisions in both atria to isolate and stop the abnormal electrical impulses. Alternative methods of creating lesions in the atria by ablation have been developed, using energy sources such as radiofrequency, microwave and ultrasound.

2.2 *Outline of the procedure*

- 2.2.1 Cryoablation for atrial fibrillation is typically carried out in patients undergoing concomitant open heart surgery (often mitral valve replacement or repair). A cryoprobe is used to freeze heart tissue. The damaged tissue forms linear scars or lesions that disrupt the transmission of the abnormal electrical impulses. The procedure may be carried out on both atria or on the left atrium only. It can be performed from within or outside the atrium.

2.3 *Efficacy*

- 2.3.1 One non-randomised trial compared patients treated with mitral valve surgery and cryoablation with patients who had mitral valve surgery and the Cox maze procedure. At discharge, 85% (94/110) of patients treated with cryoablation were in sinus rhythm, compared with 86% (95/110) of patients treated with the Cox maze procedure ($p = 0.84$). The survival rate at 3 years was 92% for the cryotherapy group and 98% for the Cox maze group ($p = 0.32$).
- 2.3.2 Two non-randomised trials compared patients who had cryoablation and concomitant heart valve surgery with patients who had heart valve surgery only. In the cryoablation groups, 100% (36/36) and 78% (25/32) of patients were in sinus rhythm immediately after surgery, compared with 33% (5/15) and 22% (4/18) of patients in the control groups. In one of these trials, 90% (26/29) of patients treated with cryoablation were in sinus rhythm at 9 months, compared with 25% (4/16) of patients in the control group. In the other trial, 78% (28/36) of patients treated with cryoablation and 20% (3/15) of patients in the control group were in sinus rhythm at 6 months. For more details, refer to the Sources of evidence.
- 2.3.3 The Specialist Advisors considered this procedure to be a variation on the Cox maze technique.

2.4 *Safety*

- 2.4.1 This procedure is performed during open heart surgery; therefore it is difficult to differentiate the complications that relate specifically to cryoablation.
- 2.4.2 Three studies reported in-hospital mortality, which ranged from 0% (0/28) to 3% (3/95, 1/32). In four studies, 3% (1/32) to 14% (4/28) of patients required a pacemaker following surgery. Other complications included re-operation; delayed cardiac tamponade; mediastinitis; low cardiac output; the need for an intra-aortic balloon pump; dialysis; and transient ischaemic attack. For more details, refer to the Sources of evidence.
- 2.4.3 The Specialist Advisors noted that oesophageal injury, heart block, damage to the circumflex coronary artery and intra-operative myocardial infarction were potential adverse effects of the procedure.

2.5 *Other comments*

- 2.5.1 Most of the data were on patients having mitral valve surgery. There was only limited evidence on the efficacy of cryoablation when performed with other procedures such as coronary artery bypass grafting.
- 2.5.2 This procedure appears to be more efficacious in patients whose atrial fibrillation has been of short duration (less than 1 year).
- 2.5.3 It was noted that there are variations in technique and cryotherapy parameters used for this procedure. It was also noted that it may be difficult to determine when a full-thickness ablation has been achieved.

3 Further information

- 3.1 The Institute has published guidance on [radiofrequency ablation for atrial fibrillation](#) and [microwave ablation for atrial fibrillation](#). The Institute is also currently developing a guideline for the diagnosis and treatment of atrial fibrillation. For further information, see our [website](#)

Andrew Dillon
Chief Executive
May 2005

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

['Interventional procedure overview of cryoablation for atrial fibrillation in association with other cardiac surgery'](#), July 2004.

Information for patients

NICE has produced [information on this procedure for patients and carers](#). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 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

29 November 2011: minor maintenance.

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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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Endorsing organisation

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