

Cryoablation for atrial fibrillation in association with other cardiac surgery

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 (see overleaf).
- 2.3.3 The Specialist Advisors considered this procedure to be a variation on the Cox maze technique.

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This guidance is written in the following context:

This guidance represents the view of the Institute which was arrived at after careful consideration of the available evidence. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for health professionals and people using the NHS in England, Wales and Scotland.

This guidance is endorsed by NHS QIS for implementation by NHSScotland.

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 (www.nice.org.uk/IPG121guidance) and microwave ablation for atrial fibrillation (www.nice.org.uk/IPG122guidance). The Institute is also currently developing a guideline for the diagnosis and treatment of atrial fibrillation. For further information, see www.nice.org.uk

Andrew Dillon
Chief Executive
May 2005

Information for the public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG123publicinfo

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

Available from www.nice.org.uk/ip271overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0866. *Information for the public* can be obtained by quoting reference number N0867.

The distribution list for this guidance is available from www.nice.org.uk/IPG123distributionlist

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