NICE guidance

High-intensity focused ultrasound for atrial fibrillation in association with other cardiac surgery

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg184

1 Guidance

1.1 Current evidence on the safety and efficacy of high-intensity focused ultrasound (HIFU) for atrial fibrillation in association with other cardiac surgery is insufficient for this procedure to be used without special arrangements for consent and for audit or research.

1.2 Clinicians wishing to undertake HIFU for atrial fibrillation in association with other cardiac surgery should take the following actions.

- Inform the clinical governance leads in their Trusts.

- Ensure that patients understand the uncertainty about the procedure's safety and efficacy and provide them with clear written information. In addition, use of NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients undergoing HIFU for atrial fibrillation in association with other cardiac surgery.

1.3 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 high-intensity focused ultrasound equipment.

1.4 Publication of safety and efficacy outcomes will be useful. NICE may review the procedure upon publication of further evidence.

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 can be classified as paroxysmal, persistent or permanent. Patients with atrial fibrillation may be asymptomatic or may have symptoms such as palpitations, dizziness, breathlessness and fatigue. They 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.

2.1.3 Conservative treatments are medication to control the heart rhythm and rate, electrical cardioversion and anticoagulation to prevent the formation of blood clots. Surgery for atrial fibrillation is usually performed at the same time as open heart surgery for another indication, such as the correction of mitral-valve disease. The conventional surgical approach, including the maze procedure, involves making multiple, strategically placed incisions in both atria to isolate and stop the abnormal electrical impulses. Alternative non-surgical methods of creating lesions in the atria

by ablation have been developed using energy sources such as radiofrequency, microwave, cryotherapy, laser and ultrasound.

2.2 Outline of the procedure

2.2.1 HIFU for atrial fibrillation is typically carried out in patients undergoing concomitant open heart surgery (often for mitral-valve replacement or repair). An ultrasound device is placed outside the left atrium of the beating heart and delivers focused ultrasound energy across the wall of the heart. Absorption of the ultrasound energy creates a rise in temperature, which destroys the cardiac tissue within the focal area and disrupts the transmission of the abnormal electrical impulses.

2.3 Efficacy

2.3.1 Efficacy is based on the results of one case series of 103 patients, in which 85% (80/94) of patients were free from atrial fibrillation at 6 months' follow-up, including 80% of patients who had permanent atrial fibrillation and 100% of patients who had intermittent (paroxysmal or persistent) atrial fibrillation. For more details, refer to the 'Sources of evidence' section.

2.3.2 The Specialist Advisers stated that the key efficacy outcomes should include normalisation of sinus rhythm, persistence or recurrence of atrial fibrillation, atrial transport function and quality of life.

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 HIFU ablation.

2.4.2 Evidence of safety was based on the same case series of 103 patients. Early (up to 30 days after the operation) and late (more than 30 days after the operation) complications were reported in the case series, but none were considered to be related to the device or the procedure. Early complications included: bleeding that required surgical exploration in 6%

(6/103) of patients; complete heart block in 4% (4/103) and sinus node dysfunction in 1% (1/103), both of which required implantation of permanent pacemakers; stroke in 3% (3/103) and serious deep wound infection in 1% (1/103). Late complications included sinus node dysfunction requiring implantation of a permanent pacemaker in 3% (3/103) of patients, multiple organ failure in 1% (1/103), delayed cardiac tamponade in 1% (1/103) and transient ischaemic attack in 1% (1/103).

2.4.3 Mortality at 6 months' follow-up was 6% (6/103) in this case series: 4% (4/103) early deaths and 2% (2/103) late non-cardiac deaths. For more details, refer to the 'Sources of evidence' section.

2.4.4 The Specialist Advisers noted that theoretical adverse events include excess myocardial damage (resulting in lack of atrial transportation), damage to adjacent structures (particularly the pulmonary veins, oesophagus and phrenic nerve) and an increase in surgical risk resulting from prolonged bypass time (if bypass is required).

2.5 Other comments

2.5.1 It was noted that technique and HIFU settings used for this procedure varied. It was also noted that it may be difficult to determine when full-thickness ablation has been achieved.

3 Further information

NICE has issued guidance on radiofrequency ablation, microwave ablation and cryoablation for atrial fibrillation in association with other cardiac surgery. It has also issued guidance on percutaneous radiofrequency ablation for atrial fibrillation.

NICE has issued a guideline on atrial fibrillation.

Sources of evidence

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

Interventional procedure overview of high-intensity focused ultrasound ablation for atrial fibrillation as an associated procedure with other cardiac surgery, October 2005.

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.

Update information

Minor changes since publication

January 2012: minor maintenance.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.