NICE guidance

Non-surgical reduction of the myocardial septum

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg40

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 safety and efficacy of non-surgical reduction of the myocardial septum appears adequate to support the use of the procedure, provided that normal arrangements are in place for consent, audit and clinical governance.

1.2 The procedure should only be performed in specialist units by clinicians who have had adequate training in the technique. The British Cardiovascular Intervention Society has agreed to produce standards for training.

2 The procedure

2.1 Indications

2.1.1 Non-surgical reduction of the myocardial septum is used to treat outflow tract obstruction in patients with hypertrophic obstructive cardiomyopathy (HOCM). Patients with HOCM have abnormally thickened heart muscle, which narrows the outflow tract from the left ventricle, often causing chest pain, breathlessness, palpitations and fainting spells. There is an increased risk of sudden death from heart attacks or abnormal heart rhythms.

2.1.2 Most patients with HOCM are treated with medication. More invasive treatments may be considered in patients who still get symptoms despite drug treatment. The standard surgical treatment is ventricular septal myotomy-myectomy, using an open surgical technique that requires cardiopulmonary bypass.

2.2 Outline of the procedure

2.2.1 Non-surgical reduction of the myocardial septum does not require open chest surgery or cardiopulmonary bypass. It involves inserting a catheter into the femoral artery and passing it up into the heart under X-ray control. Alcohol is injected into an artery that supplies blood to the septum. This destroys a part of the muscle in the septum, which then becomes thinner.

2.3 Efficacy

2.3.1 The studies showed that non-surgical reduction of the myocardial septum is efficacious in the short term. In three non-randomised studies, the mean reduction in gradient across the left ventricular outflow tract (LVOT) ranged from 22 mmHg to 42 mmHg, and compared favourably to the mean reduction in LVOT gradient for open surgery. The studies also reported reduced numbers of patients suffering from severe breathlessness and fainting spells after treatment. There is, however, a lack of long-term follow-up. For more details, see the overview.

2.3.2 The Specialist Advisors considered the procedure to be an established alternative to surgical relief of outflow tract obstruction in patients with HOCM.

2.4 Safety

2.4.1 In the studies, the most commonly reported complication was the need for patients to have a pacemaker implanted permanently because of complete heart block following the procedure. In one non-randomised study of 41 patients, 9 patients (22%) required a permanent pacemaker. The same study reported one procedure-related death. For more details, see the overview.

2.4.2 The Specialist Advisors cited a 10% risk of complete heart block, requiring patients to have a permanent pacemaker implanted after having the procedure. The Advisors considered the procedure to be safe when performed by experienced operators in specialist units with an established interest in HOCM.

2.5 Other comments

2.5.1 Skilled use of ultrasound is required to identify the blood supply to the hypertrophic myocardium, and thus control the infarct size.

2.5.2 Appropriate patient selection is essential.

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.