NICE guidance

Thoracoscopically assisted mitral valve surgery

Interventional procedures guidance
Published: 12 December 2007

www.nice.org.uk/guidance/ipg245

1 Guidance

1.1 Evidence from large case series supports the safety and efficacy of thoracoscopically assisted mitral valve surgery. Therefore, clinicians wishing to use this procedure should do so with normal arrangements for clinical governance and consent.

1.2 Thoracoscopically assisted mitral valve surgery is technically demanding. Surgeons undertaking it should have special expertise and specific training in thoracoscopic cardiac surgery, and should perform their initial procedures with an experienced mentor.

2 The procedure

2.1 Indications

2.1.1 Mitral valve surgery includes operations to repair or replace the mitral valve in patients with mitral stenosis, regurgitation or a combination of both.

2.1.2 Mitral valve disease can be treated medically to reduce the risk of congestive heart failure and to control atrial fibrillation (which often co-exists in these patients and is associated with a risk of thromboembolic stroke). However, many patients require surgery. Traditionally, mitral valve surgery is carried out through a median sternotomy. This allows complete access to the heart and major vessels but recovery may be prolonged.

2.2 Outline of the procedure

2.2.1 This guidance relates to mitral valve surgery procedures that use thoracoscopic visualisation of the operative field for at least part of the operation.

2.2.2 Thoracoscopically assisted mitral valve surgery is carried out under general anaesthesia. Cardiopulmonary bypass (CPB) is established using peripheral cannulation of arteries and veins in the thigh and neck. The aorta is occluded by inflation of an endoaortic balloon or placement of a transthoracic aortic cross-clamp. Cardioplegic solution is administered to achieve cardiac arrest and myocardial protection.

2.2.3 A number of small incisions are made in the chest wall between the ribs, without bone separation. Thoracoscopic (or indirect) visualisation may be used during part or all of the procedure. Alternatively, hybrid approaches that combine direct and thoracoscopic visualisation of the operative field may be used. The procedure may also be carried out with computer assistance.

2.3 Efficacy

2.3.1 A case series of 449 patients reported normal intraoperative valve function in 97% (318/327) of mitral valve repairs, and good functional results in all patients who underwent mitral valve replacement (n = 122).

2.3.2 A case series of 430 patients (62 undergoing valve repair) reported that mitral regurgitation (measured on a scale from 0 = no regurgitation to 4 = severe regurgitation) decreased from 3.1 preoperatively to 0.4 at a mean follow-up of 38 months after the procedure.

2.3.3 A case series of 306 patients (215 of whom underwent valve repair) with a median preoperative mitral regurgitation grade of 4 reported regurgitation grades of 0, 1 and 2 or 3 in 67% (145/215), 26% (56/215) and 7% (14/215) of patients respectively at a mean follow-up of 15 months.

2.3.4 A case series of 127 patients (114 of whom underwent mitral valve repair) reported that 95% (121) of patients had a preoperative mitral regurgitation grade of 4. Of those who underwent mitral valve repair, 91% (104/114) had a regurgitation grade of 0 immediately after surgery and 89% (87/98) had a regurgitation grade of 0 at a mean follow-up of 8.4 months.

2.3.5 Approximately 76% (91/120) of patients in a further case series had a regurgitation grade of 0 at discharge.

2.3.6 The case series of 430 and 127 patients reported that the mean preoperative and postoperative heart failure New York Heart Association (NYHA) class improved from 2.8 to 1.4 (mean follow-up of 38 months) and 2.5 to 1.0 (mean follow-up of 14 months), respectively. The case series of 120 patients reported that 85% of patients (absolute numbers not given) were in NYHA class 1 at 3-month follow-up. For more details, refer to the 'Sources of evidence' section.

2.3.7 The Specialist Advisers listed key efficacy outcomes as survival, success of the operation in repairing or replacing the valve, long-term durability of repair or replacement, postoperative pain, operating time, CPB time,

duration of intensive care, length of hospital stay, return to full activity, requirement for blood transfusion, cosmetic results and unplanned repeat operation.

2.4 Safety

2.4.1 Four of the eight case series reported hospital mortality of 0% (0/120), 0.8% (1/127), 4% (39/1059) and 4% (18/449) in patients who underwent thoracoscopically assisted mitral valve surgery. In a further three case series, mortality was reported as 2% (9/441), 0.2% (1/430), and 1% (3/306) of patients at 30-day follow-up.

2.4.2 Five studies reported that bleeding requiring repeat surgery occurred in 0.9% (4/430), 3% (3/121), 4% (17/441), 5% (48/1059) and 8% (26/306) of patients.

2.4.3 New-onset atrial fibrillation was the most common perioperative complication in the eight case series, occurring in approximately 10% of 1059 patients who underwent thoracoscopically assisted mitral valve surgery in an international registry and reported in 3% (12/430), 17% (absolute numbers not reported), 17% (20/120) and 18% (22/121) of patients in four further studies.

2.4.4 Conversion to sternotomy was reported in 0% (0/120), 0.8% (1/127), 1% (4/449), 2% (6/306), 4% (50/1311) and 4% (5/127) of patients. (The study of 1311 patients included 252 who had thoracoscopically-assisted aortic valve procedures.) The reasons for conversion included aortic dissection, left ventricular wall injury, inadequate CPB flow, 'vascular injury', 'patient anatomy', 'poor visualisation', insufficient venous return, ruptured breast implant, failure of the thoracoscope system, insufficient working space, femoral arterial disease and marked aortic tortuosity. For more details, refer to the 'Sources of evidence' section.

2.4.5 The Specialist Advisers stated that the potential adverse events include death, aortic dissection, myocardial infarction, prolonged cross-clamp and CPB times leading to poor myocardial preservation, maintenance of satisfactory cardioplegia, compromised quality of mitral valve repair (possibly requiring repeat surgery), damage to peripheral vessels due to

cannulation, paravalvular leakage, stroke, perioperative bleeding, lung injury, heart failure and renal failure. One Specialist Adviser reported two intraoperative deaths associated with poor myocardial protection and difficulties in accurate balloon placement and cardioplegia delivery.

Andrew Dillon
Chief Executive
December 2007

3 Further information

Sources of evidence

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

'Interventional procedure overview of thoracoscopically assisted mitral valve surgery', April 2007.

Information for patients

NICE has produced information describing its guidance on this procedure for patients and their carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, 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

14 January 2012: minor maintenance.

Your responsibility

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

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.