NICE guidance

Thoracoscopically assisted mitral valve surgery

Interventional procedures guidance
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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 Recommendations

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 out of 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 equals no regurgitation, to 4 equals 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 out of 215), 26% (56 out of 215) and 7% (14 out of 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 out of 114) had a regurgitation grade of 0 immediately after surgery and 89% (87 out of 98) had a regurgitation grade of 0 at a mean follow-up of 8.4 months.

2.3.5 Approximately 76% (91 out of 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, see the overview.

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 out of 120), 0.8% (1 out of 127), 4% (39 out of 1,059) and 4% (18 out of 449) in patients who underwent thoracoscopically assisted mitral valve surgery. In a further three case series, mortality was reported as 2% (9 out of 441), 0.2% (1 out of 430), and 1% (3 out of 306) of patients at 30-day follow-up.

2.4.2 Five studies reported that bleeding requiring repeat surgery occurred in 0.9% (4 out of 430), 3% (3 out of 121), 4% (17 out of 441), 5% (48 out of 1,059) and 8% (26 out of 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 1,059 patients who underwent thoracoscopically assisted mitral valve surgery in an international registry and reported in 3% (12 out of 430), 17% (absolute numbers not reported),

17% (20 out of 120) and 18% (22 out of 121) of patients in four further studies.

2.4.4 Conversion to sternotomy was reported in 0% (0 out of 120), 0.8% (1 out of 127), 1% (4 out of 449), 2% (6 out of 306), 4% (50 out of 1,311) and 4% (5 out of 127) of patients. (The study of 1,311 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, see the overview.

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.

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.