NICE guidance

Totally endoscopic robotically assisted coronary artery bypass grafting

Interventional procedures guidance
Published: 22 June 2005

www.nice.org.uk/guidance/ipg128

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 totally endoscopic robotically assisted coronary artery bypass grafting does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.

1.2 Clinicians wishing to undertake totally endoscopic robotically assisted coronary artery bypass grafting 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. Use of NICE's information for the public is recommended.
- Enter all patients having totally endoscopic robotically assisted coronary artery bypass grafting onto the National Institute for Cardiovascular Outcomes Research's National Congenital Heart Disease Audit Database. Contact bartshealth.nicor-generalenquiries@nhs.net for details.

1.3 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 In coronary artery disease, plaque deposits on the inner walls of the coronary arteries lead to narrowing or occlusion, and subsequently decreased oxygen supply to the heart. This may cause angina or myocardial infarction, and long-term weakening of the heart muscle leading to heart failure or arrhythmia.

2.1.2 The aim of a coronary artery bypass graft (CABG) is to increase the flow of blood to the heart by inserting grafts to bypass narrowed or obstructed coronary arteries.

2.1.3 CABG is usually performed with open surgery through a sternotomy. Less invasive approaches avoiding sternotomy, cardiopulmonary bypass and general anaesthesia have been developed, using either left anterior small thoracotomy (LAST), regional anaesthesia or catheter-based intervention.

2.2 Outline of the procedure

2.2.1 Totally endoscopic robotically assisted coronary artery bypass (TECAB) systems vary, but they generally include a surgeon's viewing and control console with display system. Remote-control handles control robotic arms that position and precisely manoeuvre an endoscope and endoscopic instruments within the patient. Some equipment uses voice-controlled robotic arms.

2.2.2 Following deflation of the lung, small port incisions are made in three intercostal spaces through which one robotic arm carrying the endoscope and two arms with surgical implement attachments are introduced. Grafts are harvested from suitable donor sites, and are used to bypass one or more diseased coronary arteries.

2.2.3 TECAB treatment of the beating heart is carried out using a stabilisation device consisting of two branches that immobilise the site for anastomosis while the heart continues to beat. This removes the need for cardiopulmonary bypass. The

stabilisation device is introduced into the chest through an additional port incision.

2.3 Efficacy

2.3.1 Fully patent grafts were achieved in 95% (21 of 22) of patients when assessed at 3 months by postoperative angiography, together with good functional results.

2.3.2 Most case series used duration of operation as a measure and this varied according to the type of procedure undertaken and the number of vessels bypassed. In 45 consecutive patients undergoing TECAB, the mean operating time was 4 hours 12 minutes for single vessel surgery and 6 hours 18 minutes for multiple vessel surgery. In 35 patients, including 8 in whom the procedure was performed on the beating heart, the operating time ranged from 3 hours 30 minutes to 8 hours (mean 5 hours 47 minutes). In a further 37 patients (29 of whom had the beating heart procedure), the mean operating time for the early cases in the series was 4 hours 40 minutes, but this was reduced to 3 hours 6 minutes following the introduction of endoscopic stabilisation. The mean length of stay in an intensive care unit varied from 14 hours to 74 hours, and the mean total length of hospital stay ranged from 5.0 to 15.4 days. The upper limits for length of stay were following multiple vessel surgery. For more details, refer to the sources of evidence.

2.3.3 The specialist advisors noted that bleeding could potentially make vessel identification difficult. They also noted that patency rates of coronary bypass grafts were not sufficiently well documented.

2.4 Safety

2.4.1 Conversion rates to open procedures (either mini-thoracotomy or full sternotomy) were reported in all case series and ranged from 19% (5 of 27) to 51% (19 of 37) of procedures initiated as TECAB.

2.4.2 There were no cases of operative mortality associated with the TECAB procedure

(n=142).

2.4.3 In a case series of 45 patients, operative complications included port access failure in 7% (3 of 45) of patients, prolonged cross clamp time in 9% (4 of 45), myocardial infarction in 2% (1 of 45), hypoxic brain damage in 2% (1 of 45) and internal thoracic artery injury in 2% (1 of 45) of patients.

2.4.4 In a series of 45 patients, 4% (2 of 45) needed secondary intervention because of bleeding from the site of anastomosis. There were no cases of wound infection at the port site throughout the series. For more details, refer to the sources of evidence.

2.4.5 The specialist advisors noted theoretical complications as myocardial infarction, pneumothorax, cardiac tamponade and fatal haemorrhage. They also noted that there is potential for stenosis or occlusion at the site of anastomosis.

2.5 Other comments

2.5.1 There are a number of other procedures for treating patients with coronary artery disease, but no good studies have been found that compare these with TECAB.

3 Further information

Sources of evidence

The evidence considered by the interventional procedures advisory committee is described in the interventional procedures overview of totally endoscopic robotically assisted coronary artery bypass surgery (November 2004).

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.

ISBN: 978-1-4731-4017-2

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.