NATIONAL INSTITUTE FOR HEALTH AND CLINICAL EXCELLENCE

INTERVENTIONAL PROCEDURES PROGRAMME

Interventional procedure overview of endoaortic balloon occlusion for cardiac surgery

During major heart surgery, the flow of blood through the heart needs to be stopped temporarily. In endoaortic balloon occlusion, a flexible tube (catheter) with a balloon attached to its tip is inserted into an artery in the groin (femoral artery) and threaded up to the heart. When the catheter is in the correct position in the heart, the balloon is filled with saline. As the balloon expands it blocks the aorta, which is the largest artery in the body. With the aorta blocked, the heart surgery can be performed. After heart surgery, the balloon and catheter are removed and the blood flow is restored.

Introduction

This overview has been prepared to assist members of the Interventional Procedures Advisory Committee (IPAC) in making recommendations about the safety and efficacy of an interventional procedure. It is based on a rapid review of the medical literature and specialist opinion. It should not be regarded as a definitive assessment of the procedure.

Date prepared

This overview was prepared in October 2007.

Procedure name

- Endoaortic balloon occlusion

Specialty societies

The following societies were approached to nominate Specialist Advisers

- Society for Cardiothoracic Surgery in Great Britain and Ireland
- British Cardiovascular Intervention Society
- Society of Clinical Perfusion Scientists of Great Britain and Ireland
- Association of Cardiothoracic Anaesthetists

Description

Indications

Endoaortic balloon clamping is performed to achieve temporary obstruction of the aorta during cardiac surgery including mitral valve repair or replacement and coronary artery bypass grafting (CABG).

Current treatment and alternatives

Occlusion of the aorta is required in a number of cardiac surgery operations. This is achieved by external application of an aortic cross-clamp, which can be applied either through conventional 'open' surgery approaches, or through minimally invasive cardiac surgery approaches.

What the procedure involves

This procedure is usually part of a technology for minimally invasive cardiac surgery (known as port-access) that involves endovascular aortic occlusion, cardioplegia and left ventricular decompression.

A balloon catheter is inserted through the skin into an artery (normally the femoral artery in the groin) and threaded towards the aortic root. The balloon at the tip of the catheter is filled with saline to block blood flow and achieve aortic occlusion. Continuous echocardiographic monitoring is necessary to detect balloon migration. Various devices can be used for this procedure.

Efficacy

There were no outcomes reported in the literature that related directly to the efficacy of endoaortic balloon occlusion alone.

Safety

Mortality

In a case series of 449 patients, 5% (11/209) of those who had endoaortic balloon occlusion and 3% (7/226) of those who had transthoracic aortic clamp occlusion died in hospital[1]. A case series comparing 117 patients who had endoaortic balloon occlusion during minimally invasive mitral valve surgery with 117 matched controls who had conventional aortic cross-clamping reported one perioperative death in each group[2].

In two case series of 151 and 127 patients who had endoaortic balloon occlusion, there were 6 and 1 in-hospital deaths respectively[3,4]. In another case series, the 30-day mortality rate was 1% (3/306) and the rate of late deaths (mean follow-up 20 months) was 2% (6/306)[5]. In a case series of 52 patients with aortic atherosclerosis who had endoaortic balloon occlusion, the mortality rate was 25% (13/52). This study also reported mortality for 2120

patients who had conventional aortic cross-clamping during cardiac surgery, of whom 4% (90/2120) died[6].

Aortic dissection and balloon rupture

In three case series, the following rates of aortic dissection were reported in patients who underwent endoaortic balloon occlusion: 1% (3/209), 1% (3/306) and 1% (1/117)[1, 5, 2]. One aortic dissection occurred in a case series of 151 patients; however, this was said to be unrelated to the endoaortic balloon occlusion device[3]. In three case series of 58, 120 and 127 patients, no aortic dissections occurred[7, 4, 8]. One case of aortic dissection occurred in a patient who underwent transthoracic aortic clamping (n = 35)[7].

Other complications

In the case series of 449 patients, there were no significant differences in arrthymias, pulmonary dysfunction, bleeding, renal failure or low cardiac output between those who had endoaortic balloon occlusion and those who had transthoracic clamping. However, the rates of neurological complications were higher in the former group ($p < 0.05$)[1].

Stroke or transient ischaemic attack was reported in 4% (2/52), 2% (2/127), 0.4% (1/306), 1% (1/117) and 1% (1/151) of patients in five case series [6, 4, 5, 2, 3]. Myocardial infarction was reported in two patients in one case series (2/151) and one patient in another (1/306)[3,5].

Re-exploration for bleeding or tamponade was required in 10% (6/60), 9% (26/306), 7% (14/209), 6% (9/151), 4% (5/117), 4% (1/23) and 2% (3/127) of patients who underwent endoaortic balloon occlusion in six case series[8, 5, 1, 3, 2, 7, 4].

Literature review

Rapid review of literature

The medical literature was searched to identify studies and reviews relevant to endoaortic balloon clamping for cardiac surgery. Searches were conducted via the following databases, covering the period from their commencement to 12 October 2007: MEDLINE, PREMEDLINE, EMBASE, Cochrane Library and other databases. Trial registries and the Internet were also searched. No language restriction was applied to the searches. (See appendix C for details of search strategy.)

The following selection criteria (Table 1) were applied to the abstracts identified by the literature search. Where these criteria could not be determined from the abstracts the full paper was retrieved.

Table 1 Inclusion criteria for identification of relevant studies

Characteristic	Criteria
Publication type	Clinical studies were included. Emphasis was placed on identifying good quality studies. Abstracts were excluded where no clinical outcomes were reported, or where the paper was a review, editorial, laboratory or animal study. Conference abstracts were also excluded because of the difficulty of appraising methodology.
Patient	Patients requiring cardiac surgery.
Intervention/test	Endoaortic balloon occlusion.
Outcome	Articles were retrieved if the abstract contained information relevant to the safety and/or efficacy.
Language	Non-English-language articles were excluded unless they were thought to add substantively to the English-language evidence base.

List of studies included in the overview

This overview is based on eight case series.

Other studies that were considered to be relevant to the procedure but were not included in the main extraction table (Table 2) have been listed in Appendix A.

Existing reviews on this procedure

There were no published systematic reviews with meta-analysis or evidence based guidelines identified at the time of the literature search.

Related NICE guidance

Below is a list of NICE guidance related to this procedure. Appendix B details the recommendations made in each piece of guidance listed below.

Interventional procedures:

In progress:

Thoracoscopically-assisted mitral valve surgery. NICE interventional procedure consultation. Available from www.nice.org.uk/ip402.

Table 2 Summary of key efficacy and safety findings on endoaortic balloon occlusion for cardiac surgery

Abbreviations used: ASD, atrial septal defect, AVR, aortic valve replacement, CABG, coronary artery bypass graft, CPB, cardiopulmonary bypass, ICU, intensive care unit, MV, mitral valve, MVP, mitral valve repair, MVR, mitral valve replacement, TEE, transoesphageal echocardiography

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Onnasch et al. (2002)[1]
Five years of less invasive mitral valve surgery: From experimental to routine approach

Case series
Germany
Study period: 1996–2001

n = 449

Population: patients undergoing MVP (n = 327) or MVR (n = 122)
Mean age: 59 years
Male: 47%
Reoperation: 9% (42/449)

Technique: port-access mitral valve surgery.
Aortic occlusion: endoaortic balloon catheter (Endoclamp) in the first 209 patients and all reoperations; transthoracic aortic clamp in the latter 226 patients.

Mean follow-up: 11 months

Conflict of interest: none stated</td>
<td>Conversion to sternotomy
• Port-access endoclamp: 2% (4/209)
Reasons for conversion: aortic dissection (3), left ventricular wall injury (1)
• Transthoracic clamp: 0/226

Operative and hospital outcomes
There were no statistically significant differences in operative and hospital outcomes between patients who had the Port-access endoclamp method and those who had transthoracic clamp method.</td>
<td>Mortality and postoperative complications
<table>
<tr><th></th><th>Endoclamp</th><th>Transthoracic clamp</th></tr>
<tr><td>In-hospital mortality</td><td>5% (11/209)</td><td>3% (7/226)</td></tr>
<tr><td>Arrhythmias</td><td>22% (45/209)</td><td>19% (43/226)</td></tr>
<tr><td>Pulmonary</td><td>10% (21/209)</td><td>6% (14/226)</td></tr>
<tr><td>Bleeding</td><td>7% (14/209)</td><td>5% (11/226)</td></tr>
<tr><td>Neurological (stroke, transient hemiplegia)*</td><td>8% (17/209)</td><td>2% (4/226)</td></tr>
<tr><td>Renal failure</td><td>2% (4/209)</td><td>2% (4/226)</td></tr>
<tr><td>Low cardiac output</td><td>2% (4/209)</td><td>0.5% (1/226)</td></tr>
<tr><td>Aortic dissection</td><td>1% (3/209)</td><td>0</td></tr>
</table>
* $p < 0.05$ between groups

The authors stated that initial results were disappointing and reflected a learning curve both surgically and technically. Most complications in the port-access group occurred in the early phase of the study and results improved after modifications to the technique. In particular, no further aortic dissections occurred after a new design of endoclamp was introduced.

Furthermore, neurological complications in the port-access group decreased after the introduction of transcranial Doppler monitoring for the detection of balloon migration.</td>
<td>Study objective: To review the authors' experience in less invasive MV surgery.

There is a discrepancy in the paper between the numbers of patients for whom outcomes are reported (n = 435) and the total number in the series (n = 449).</td>
</tr>
</table>

Abbreviations used: ASD, atrial septal defect, AVR, aortic valve replacement, CABG, coronary artery bypass graft, CPB, cardiopulmonary bypass, ICU, intensive care unit, MV, mitral valve, MVP, mitral valve repair, MVR, mitral valve replacement, TEE, transoesphageal echocardiography

Study details	Key efficacy findings	Key safety findings	Comments
Casselman et al. (2003)[5] *Mitral valve surgery can now routinely be performed endoscopically.* **Case series** Belgium Study period: 1997–2002 **n = 306** Population: patients undergoing MVP (n = 226) or MVR (n = 80). Mean age: 62 years Male: 53% Technique: port-access MV surgery. Aortic occlusion: endoaortic balloon occlusion (EndoClamp) **Mean follow-up: 20 months (range 0–60 months)** Conflict of interest: none stated	**Conversion to sternotomy: 2% (6/306)** *Reasons for conversion:* • Aortic dissection (2) • Inadequate CPB flow (3) • Iliac artery perforation (1)	**30-day mortality: 1% (3/306)** Causes of death: aortic dissection during procedure; low cardiac output syndrome on postoperative day 5; disseminated intravascular coagulation on postoperative day 4 after reinterventions for bleeding **Late deaths (mean follow-up 20 months): 2.0% (6/306)** Causes of death: sudden death, after cholecystectomy; pneumonia; small bowel perforation; stroke; sternitis (in a sternotomy patient) **Postoperative complications** Myocardial infarction: 1% (2/306) Stroke: 0.3% (1/306) Bleeding requiring reintervention: 9% (26/306) New-onset atrial fibrillation: 17% (52/306) Groin lymphocoele: 5% (14/306) Subcutaneous emphysema: 3% (9/306) Renal insufficiency: 3% (8/306) Pneumonia: 3% (8/306) Pacemaker implantation: 2% (7/306) Pleural effusion: 2% (6/306)	Study objective: To report the authors' total experience for MV surgery using a minimally invasive endoscopic approach.

Abbreviations used: ASD, atrial septal defect, AVR, aortic valve replacement, CABG, coronary artery bypass graft, CPB, cardiopulmonary bypass, ICU, intensive care unit, MV, mitral valve, MVP, mitral valve repair, MVR, mitral valve replacement, TEE, transoesphageal echocardiography

Study details	Key efficacy findings	Key safety findings	Comments
Murphy et al. (2006)[4] *Endoscopic robotic mitral valve surgery.* **Case series** USA Study period: Dec 2002–Nov 2005 **n = 127** Population: patients undergoing MVR (n = 7), or MVP (n = 114) (procedures could not be completed for 6 patients) Mean age: 54 years (range 21–78 years) Male: 58% Technique: endoscopic robotic MV surgery (Da Vinci robotic surgical system) Aortic occlusion: endoaortic balloon occlusion **Mean follow-up: 14 months (± 9 months)** Conflict of interest: none stated	**Conversion to sternotomy (5) or thoracotomy with rib-spreading (1): 5% (6/127)** *Reasons for conversion:* • Ruptured breast implant • Insufficient venous return • Vision system failure • Femoral arterial disease • Insufficient working space • Marked aortic tortuosity	*Outcomes are reported here as in the literature, i.e. there is no disaggregation between outcomes that authors attribute to the overall cardiac procedure or the aortic occlusion method used.* **Mortality** • One in-hospital death (the patient had a stroke after sternotomy and died in hospital on postoperative day 48). • One late death 2 months after surgery (the patient had mild regurgitation: autopsy showed intact MV repair). **Complications (of 121 patients treated endoscopically)** ***Perioperative*** • Blood transfusion: 31% (37/121) • Re-exploration for bleeding: 2% (3/121) ***Postoperative*** • Stroke: 2% (2/121) • New-onset atrial fibrillation: 18% (22/121) • Groin lymphocoele: 2% (2/121) • Right pleural effusion: 2% (2/121) • Pneumonitis: 2% (2/121) • Ventilation > 24 hours: 2% (2/121) • Prolonged air leak: 1% (1/121) • Transient renal dysfunction: 1% (1/121) • Groin wound cellulitis: 1% (1/121) • Paravalvular leak: 1% (1/121) – occurred 6 weeks after surgery: repaired successfully via minithoracotomy. There were no cases of aortic dissection, myocardial infarction, low cardiac output, chest incision infection, limb ischaemia or deep vein thrombosis.	Study objective: To determine the safety and efficacy of endoscopic MV surgery using robotic instruments

Abbreviations used: ASD, atrial septal defect, AVR, aortic valve replacement, CABG, coronary artery bypass graft, CPB, cardiopulmonary bypass, ICU, intensive care unit, MV, mitral valve, MVP, mitral valve repair, MVR, mitral valve replacement, TEE, transoesphageal echocardiography			
Study details	**Key efficacy findings**	**Key safety findings**	**Comments**
Colvin et al. (1998)[3] *Port-access mitral valve surgery: summary of results.* **Case series** USA Study period: Oct 1995–Oct 1997 n = 151 Population: patients undergoing MVR (n = 36), MVP (n = 56), aortic valve replacement (n = 35) or complex valve procedures (n = 24) Mean age: 58 years (range 21-–91 years) Male: 50% Technique: Minimally invasive port-access valve surgery Aortic occlusion: endoaortic balloon occlusion Mean follow-up: 14 months (± 9 months) Conflict of interest: none stated	No conversions to sternotomy or other aortic occlusion methods were reported	**Mortality** Operative deaths: 4% (6/151) **Complications** Reoperation for bleeding or tamponade: 6% (9/151) Myocardial infarction: 1% (2/151) Transient ischaemic attack: 1% (1/151) Wound infection: 1% (1/151) Aortic dissection leading to death of patient: 1% (1/151) (Resulting from femoral cannulation and not related to Endoclamp)	Study objective: To review short-term results of an initial experience with minimally invasive cardiac valve surgery using the port-access approach

Abbreviations used: ASD, atrial septal defect, AVR, aortic valve replacement, CABG, coronary artery bypass graft, CPB, cardiopulmonary bypass, ICU, intensive care unit, MV, mitral valve, MVP, mitral valve repair, MVR, mitral valve replacement, TEE, transoesphageal echocardiography

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Reichenspurner H (2005)[8]
Video and robotic-assisted minimally invasive mitral valve surgery: a comparison of the Port-Access and transthoracic clamp techniques.

Case series
Germany
Study period: May 1997 – Nov 2002

n = 120

Population: patients undergoing combined or isolated MVR (n = 39) or MVP (n = 81)
Mean age: 62 years (range SD 10.5 years)
Male: 29%

Technique: video- and robot-assisted (75%) port-access MV surger.
Aortic occlusion: endoaortic balloon catheter for the first 60 patients and transthoracic aortic clamp for last 60.

Mean follow-up: 3 months

Conflict of interest: none stated</td>
<td>Conversion to sternotomy
None in either group

Operative and hospital outcomes
There were no statistically significant differences in operative and hospital outcomes between patients who had the endoclamp occlusion method and those who had transthoracic clamping.

Echocardiographic outcomes at discharge
There were no statistically significant differences in regurgitation grade between patients who had the endoclamp occlusion method and those who had the transthoracic clamping.</td>
<td>Intra- and post-operative complications
<table>
<tr><th></th><th>Endo-clamp</th><th>Trans-thoracic clamp</th><th>p-value</th></tr>
<tr><td>Re-exploration for bleeding</td><td>10% (6/60)</td><td>2% (1/60)</td><td>0.11</td></tr>
<tr><td>Impaired wound healing</td><td>7% (4/60)</td><td>0</td><td>0.12</td></tr>
<tr><td>Lymphatic fistula (groin)</td><td>3% (2/60)</td><td>0</td><td>0.50</td></tr>
<tr><td>Femoral artery injury</td><td>3% (2/60)</td><td>0</td><td>0.50</td></tr>
<tr><td>Ventricle perforation by endopulmonary vent</td><td>2% (1/60)</td><td>0</td><td>Not significant</td></tr>
<tr><td>Tracheal injury</td><td>0</td><td>2% 1/60)</td><td>Not significant</td></tr>
<tr><td>Total complications</td><td>15</td><td>2</td><td>0.001</td></tr>
</table>
There were no reported cerebrovascular accidents or aortic dissections in either group.

Results at discharge
<table>
<tr><th></th><th>Endo-clamp</th><th>Trans-thoracic clamp</th><th>p-value</th></tr>
<tr><td>Hospital mortality</td><td>0</td><td>0</td><td>0</td></tr>
<tr><td>Minor paravalvular leak</td><td>2% (1/60)</td><td>0</td><td>1.00</td></tr>
<tr><td>New-onset atrial fibrillation</td><td>18% (11/60)</td><td>15% (9/60)</td><td>Not significant</td></tr>
<tr><td>Minor/no postoperative pain</td><td>72% (43/60)</td><td>73% (44/60)</td><td>Not significant</td></tr>
<tr><td>Moderate postoperative pain</td><td>28% (17/60)</td><td>25% (15/60)</td><td>Not significant</td></tr>
</table>
</td>
<td>Study objective: To retrospectively compare the port-access MV surgery technique (including endoaortic balloon occlusion) with the transthoracic cross-clamp technique.

The authors do not state whether the patient groups (endoaortic vs transthoracic occlusion) differed in any way except for the stage of the series in which they had the operation (first 60 vs latter 60).</td>
</tr>
</table>

Abbreviations used: ASD, atrial septal defect, AVR, aortic valve replacement, CABG, coronary artery bypass graft, CPB, cardiopulmonary bypass, ICU, intensive care unit, MV, mitral valve, MVP, mitral valve repair, MVR, mitral valve replacement, TEE, transoesphageal echocardiography

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Ryan et al (2005)
Mitral valve surgery using the Classical Heartport Technique

Case series
USA
Study period: Dec 1997–Dec 2004

n = 117

Population: patients undergoing MVR (n = 25) or MVP (n = 92)
Plus 117 matched controls who had MVR or MVP by conventional sternotomy (matched for age, ejection fraction, presence of cerebrovascular disease and inotrope use)
Mean age: 54 years (± 14 years)
Male: 53%

Technique: minimally invasive ‘Heartport’ MV surgery.
Aortic occlusion: endoaortic balloon catheter.

Follow-up: not reported

Conflict of interest: none stated</td>
<td>Conversion to sternotomy
One case (1%) of aortic dissection by the wire was recognised by TEE. The procedure was terminated and open MV repair was performed 3 weeks later.

Conversion to alternative occlusion method
No patients required conversion to transthoracic aortic cross-clamping.

Operative and hospital outcomes
There were no statistically significant differences in duration of hospital stay, ICU stay, ventilation between patients who had the endoclamp occlusion method and matched controls who had a conventional sternotomy for MV surgery.

• For both patients who had MVR and those who had MVP, mean cross-clamp time was significantly longer than for matched controls (p = 0.02 and p < 0.001)
• Perfusion time was significantly longer in patients who had MVP than matched controls (p < 0.001)</td>
<td>Mortality , perioperative and 30-day outcomes

<table>
<tr><th></th><th>Endoaortic occlusion</th><th>Standard aortic occlusion</th><th>p-value</th></tr>
<tr><td>Mortality</td><td>1% (1/117)</td><td>1% (1/117)</td><td>Not significant</td></tr>
<tr><td>Atrial fibrillation</td><td>24% (28/117)</td><td>24% (28/117)</td><td>Not significant</td></tr>
<tr><td>Reoperative bleed</td><td>4% (5/117)</td><td>2% (2/117)</td><td>Not significant</td></tr>
<tr><td>Stroke</td><td>1% (1/117)</td><td>3% (3/117)</td><td>Not significant</td></tr>
<tr><td>Prolonged ventilation</td><td>4% (5/117)</td><td>2% (2/117)</td><td>Not significant</td></tr>
<tr><td>Readmission within 30 days</td><td>8% (9/117)</td><td>3% (4/117)</td><td>Not significant</td></tr>
</table>
</td>
<td>Study objective: To retrospectively compare consecutive patients undergoing minimally invasive MV surgery with consecutive patients undergoing MV surgery by conventional sternotomy during the same period.

The authors do not state whether the patient groups (endoaortic vs transthoracic occlusion) differed in any way.</td>
</tr>
</table>

Abbreviations used: ASD, atrial septal defect, AVR, aortic valve replacement, CABG, coronary artery bypass graft, CPB, cardiopulmonary bypass, ICU, intensive care unit, MV, mitral valve, MVP, mitral valve repair, MVR, mitral valve replacement, TEE, transoesphageal echocardiography

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>
Aybek et al (2000)[7]
The micro-mitral operation comparing the Port-access technique and the transthoracic clamp technique.

Case series

Germany

Study period: Sep 1996–Nov 1999

n = 58

Population:
<table>
<tr><th></th><th>Endoaortic occlusion (n = 23)</th><th>Trans-thoracic clamp (n = 35)</th></tr>
<tr><td>Mean age (years)</td><td>58 (± 16)</td><td>56 (± 13)</td></tr>
<tr><td>Male (%)</td><td>48</td><td>54</td></tr>
</table>
Technique: minimally invasive MV surgery.
Aortic occlusion: patients were assigned non-randomly to either the port-access technique with an endoaortic balloon clamp (n = 23) or the same procedure but with a specially designed transthoracic aortic clamp (Chitwood clamp) (n = 35)

Follow-up: 12 months

Conflict of interest: none stated
</td>
<td>
Conversion to alternative occlusion method
4 patients for whom endoaortic occlusion was intended were converted to transthoracic aortic clamp occlusion because of endoclamp dysfunction

Intraoperative outcomes
3 patients who underwent endoaortic occlusion and 2 patients who underwent transthoracic occlusion had an unacceptable intraoperative result and were converted to secondary MVR intraoperatively

Operative and hospital outcomes
Mean operating time, aortic occlusion time, CPB duration and postoperative blood loss were lower in the group that had transthoracic clamp ($p < 0.05$).
There were no statistically significant differences between the groups in mean ICU stay and hospital stay.
</td>
<td>
Mortality

No intraoperative deaths in either group.
1 patient who underwent endoaortic occlusion died on postoperative day 14 from septic multiorgan failure (following explantation of an infected pacemaker probe)
1 patient who underwent transthoracic clamp occlusion died from low output syndrome after complex MV surgery

Intra- and post-operative complications
<table>
<tr><th></th><th>Endoaortic occlusion (n = 23)</th><th>Tranthoracic clamp (n = 35)</th></tr>
<tr><td>Rexploration for bleeding</td><td>4% (1/23)</td><td>6% (2/35)</td></tr>
<tr><td>Wound infection</td><td>0</td><td>6% (2/35)</td></tr>
<tr><td>Retrograde aortic dissection</td><td>0</td><td>3% (1/35)</td></tr>
</table>
</td>
<td>
Study objective: to compare the port-access technique (including endoaortic balloon occlusion) with the transthoracic cross-clamp technique.

The authors do not state whether the patient groups (endoaortic vs transthoracic occlusion) differed in any way except to say that patients were assigned to either technique in a nonrandomised fashion.
</td>
</tr>
</table>

Abbreviations used: ASD, atrial septal defect, AVR, aortic valve replacement, CABG, coronary artery bypass graft, CPB, cardiopulmonary bypass, ICU, intensive care unit, MV, mitral valve, MVP, mitral valve repair, MVR, mitral valve replacement, TEE, transoesphageal echocardiography

<table>
<tr><th>Study details</th><th>Key efficacy findings</th><th>Key safety findings</th><th>Comments</th></tr>
<tr>
<td>Zingone et al (2006)[6]
Surgical management of the atherosclerotic ascending aorta: is endoaortic balloon occlusion safe?

Case series

Italy

Study period: Jan 2000–Aug 2004

n = 52

Population: patients were selected for endoaortic balloon occlusion if they had calcified aortas. This was determined by preoperative diagnosis of porcelain aorta or intraoperative findings at epiaortic ultrasonographic scanning (replaced by aortic palpation from Jan 2001 onwards). The operations were conducted within a series of 2172 patients, in total, undergoing various cardiac operations.
Mean age: Not reported
Male: Not reported

Technique: Various cardiac operations: isolated CABG (n = 27), isolated valve surgery (n = 13), combined valve surgery and CABG (n = 12).
Aortic occlusion: endoaortic balloon catheter (Foley [n = 30] or Pruitt catheter [n = 22]).
For the remaining 2120 patients in the series, a conventional aortic cross-clamp was used for aortic occlusion.

Follow-up: not stated

Conflict of interest: none stated</td>
<td>Conversion to standard cross-clamp: 19% (10/52)
Reasons for conversion:
• incomplete occlusion (5)
• hindered exposure (2)
• balloon rupture (3)</td>
<td>Comparison with other patients in the series

<table>
<tr><th></th><th>Endoaortic occlusion (n = 52)</th><th>Other patients (n = 2120)</th><th>p-value</th></tr>
<tr><td>Hospital mortality</td><td>25% (13/52)</td><td>4% (90/2120)</td><td>p < 0.0001</td></tr>
<tr><td>Early stroke</td><td>4% (2/52)</td><td>1% (16/2120)</td><td>p = 0.067</td></tr>
</table>
EuroSCORE (risk prediction system for patients undergoing cardiac surgery) expected mortality was 10.5% for the 52 patients treated with endoaortic occlusion and 6.6% for all other patients (p=0.16), indicating that patients treated with balloon occlusion were at higher relative risk (though this was not statistically significant)

Risk-adjusted EuroSCORE estimates showed that the increased risk profile of the patients who underwent endoaortic balloon occlusion partly explained this difference in death rates.
Patients undergoing endoaortic occlusion were significantly older and had a greater prevalence of: serum creatinine ≥ 2.3mg/dL, history of neoplastic disease, extracardiac arteriopathy and carotid artery disease.

In multivariate analysis, the use of endoaortic balloon occlusion was independently associated with in-hospital deaths (OR: 5.61, 95% CI: 2.68 to 11.72)</td>
<td>Study objective: To retrospectively assess the outcomes associated with the use of endoaortic occlusion.

This study does not report outcomes for the port-access or a minimally invasive technique.

Authors state: “While coronary artery grafting on the beating heart, with or without CPB, assistance, was generally adopted to avoid aortic manipulations of atherosclerotic aortas, surgeons sometimes felt uncomfortable with that and resorted to endoaortic occlusion in the few patients included in this report”</td>
</tr>
</table>

Validity and generalisability of the studies

- Only efficacy outcomes that were specifically related to the method of aortic occlusion were included in Table 2. All relevant safety outcomes were reported.
- Studies were selected for inclusion in Table 2 if they specifically addressed the efficacy or safety of endoaortic balloon occlusion. In addition, any literature that reported on the safety of a cardiac procedure that incorporated endoaortic balloon occlusion and had sufficiently large patient numbers was also included.
- All but one study relate to the use of the procedure in the context of minimally invasive mitral valve surgery. This study (Zingone et al) used endoaortic balloon occlusion outside a 'minimally invasive' cardiothoracic surgery setting.
- There were several relevant studies that assessed other cardiac operations (such as coronary artery bypass grafting and atrial septal defect repair); however, these were included in the Appendix because they reported on small numbers of patients.
- Many studies were comparative, but patients were typically consecutive in a case series (most commonly with earlier patients in the series undergoing endoaortic occlusion and latter patients undergoing transthoracic aortic clamp). Only one study (Aybek et al) assigned patients to a treatment group and this was in a 'nonrandomised fashion'.
- Some studies compared an endoaortic balloon catheter with a transthoracic aortic cross-clamp and others compared this technique with a standard external aortic clamp which is used in mitral valve surgery through a median sternotomy.

Specialist advisers' opinions

Specialist advice was sought from consultants who have been nominated or ratified by their Specialist Society or Royal College. The advice received is their individual opinion and does not represent the view of the society

Mr Venkatachalam Chandrasekaran, Mr Steven Hunter, Mr Simon Kendall, Mr Steven Livesey, Mr Russell Millner, Mr David Richens (Society for Cardiothoracic Surgery in Great Britain and Ireland)
Dr John Kneeshaw (Association of Cardiothoracic Anaesthetists)
Mr Olaf Wendler (British Cardiovascular Intervention Society

Safety

- Theoretical adverse events included: death, aortic dissection or rupture, stroke, inadequate myocardial protection or cerebral ischaemia due to balloon misplacement and arterial embolism.
- Anecdotal adverse events included: aortic dissection, puncture of balloon during the procedure, balloon migration, death due to failure to deliver cardioplegia, damage to aortic intima, device movement causing loss of

occlusion, inability to complete planned surgery due to failure to occlude aorta, femoral artery damage, difficulty positioning the balloon

Efficacy

- Major efficacy outcomes included: the ability to perform less invasive/minimal access cardiac surgery, efficiency of cardioprotection, reduced length of hospital stay, reduced duration of cardiac arrest, avoidance of the use of a cross-clamp from outside and therefore reduced stroke risk in patients with very calcified aorta.

Current status

- One Specialist Adviser stated that this was the first in a new class of procedures. Two stated that it was novel and of uncertain safety and efficacy and four thought it was established practice and no longer new.
- Four Specialist Advisers stated that they stopped using this technique (or its use was stopped at their Institution). One Specialist Adviser stated that he stopped using this technique when in his opinion a safer technique became available. Another said he stopped following negative clinical experience. One Specialist Adviser stated that he was unhappy with the outcome despite appropriate positioning of the device.
- One Specialist Adviser stated that this technique has been supplanted by transthoracic aortic cross-clamping, which is perceived as being safer and easier to use, and less expensive.
- One Specialist Adviser stated that the technique has been available for over 10 years. He noted that there was an initial learning curve, but otherwise thought it was safe and effective when performed by those with special training in the use of the relevant equipment.

Comparator

- The main comparator is open heart cardiac surgery with conventional bypass via median sternotomy and external aortic cross-clamping. In minimally invasive surgery the comparator is the transthoracic aortic clamp (Chitwood clamp).

Impact

- The potential impact is minor with fewer than 10 specialist centres in the UK likely to perform this technique.

Training

- All Specialist Advisers thought there was a significant learning curve and several stated that specific training in the use of the device and balloon deployment is necessary. The procedure should be carried out with good transoesophageal echocardiographic views to allow correct positioning of the clamp.

References

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4. Murphy DA, Miller JS, Langford DA et al. (2006) Endoscopic robotic mitral valve surgery.[see comment]. *Journal of Thoracic & Cardiovascular Surgery* 132: 776-781.

5. Casselman FP, Van Slycke S, Wellens F et al. (2003) Mitral valve surgery can now routinely be performed endoscopically. *Circulation* Vol. 108: 09-

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7. Aybek T, Doss M, Abdel-Rahman U et al. (2005) Echocardiographic assessment in minimally invasive mitral valve surgery. *Medical Science Monitor* 11: MT27-MT32.

8. Reichenspurner H, Detter C, Deuse T et al. (2005) Video and robotic-assisted minimally invasive mitral valve surgery: a comparison of the Port-Access and transthoracic clamp techniques. *Annals of Thoracic Surgery* 79: 485-490.

Appendix A: Additional papers on endoaortic balloon occlusion for cardiac surgery not included in summary Table 2

The following table outlines the studies that are considered potentially relevant to the overview but were not included in the main data extraction table (table 2). It is by no means an exhaustive list of potentially relevant studies.

Article title	Number of patients/ follow-up	Direction of conclusions	Reasons for non-inclusion in Table 2
Ak K, Aybek T, Wimmer-Greinecker G et al. (2007) Evolution of surgical techniques for atrial septal defect repair in adults: a 10-year single-institution experience. *Journal of Thoracic & Cardiovascular Surgery* 134: 757–64.	n = 64	No hospital deaths or major complications 2 conversions to minithoracotomy due to endoaortic balloon failure	Studies with more patients were included in Table 2
Argenziano M, Katz M, Bonatti J et al. (2006) Results of the prospective multicenter trial of robotically assisted totally endoscopic coronary artery bypass grafting. *Annals of Thoracic Surgery* 81: 1666–74.	n = 85	No hospital deaths or strokes 5 conversions to open techniques 1 myocardial infarction	Studies with more patients were included in Table 2
Byrne JG, Aklog L, Adams DH et al. (2001) Reoperative CABG using left thoracotomy: a tailored strategy. *Annals of Thoracic Surgery* 71: 196–200.	n = 50 (endoaortic balloon occlusion = 4)	Results not reported separately for patients who had endoaortic balloon occlusion and those who had other methods of aortic occlusion	
Casselman FP, Meir ML, Jeanmart H et al (2007) Endoscopic mitral and tricuspid valve surgery after previous cardiac surgery. *Circulation* 116: 270-275.	n = 80	3 deaths within 30 days 5 conversions to sternotomy (due to lung adhesions (5), cannulation problems (1) 2 strokes	Studies with more patients were included in Table 2
De Mulder W, Vanermen H. (2002) Repair of atrial septal defects via limited right anterolateral thoracotomy. *Acta Chirurgica Belgica* 102: 450–4.	n = 50	No conversions to sternotomy No hospital mortality No thromboembolic or peripheral ischaemic complications	Studies with more patients were included in Table 2
Diegeler A, Falk V, Krahling K et al. (1998) Less-invasive coronary artery bypass grafting: different techniques and approaches. *European Journal of Cardio-Thoracic Surgery* 14: Suppl-9. S13–S19.	n = 114 (endoaortic balloon occlusion = 9)	No complications in patients who had endoaortic balloon occlusion	Studies with more patients were included in Table 2

Dogan S, Aybek T, Andressen E et al. (2002) Totally endoscopic coronary artery bypass grafting on cardiopulmonary bypass with robotically enhanced telemanipulation: report of forty-five cases.[see comment]. *Journal of Thoracic & Cardiovascular Surgery* 123: 1125–31.	n = 45	10 conversions to open techniques due to: bleeding (4), prolonged cross-clamp time (2), intraoperative diagnosis of peripheral vascular disease (3), graft injury (1) 1 case each of: aortic dissection, hypoxic brain damage, myocardial infarction	Studies with more patients were included in Table 2
Galloway AC, Grossi EA, Bizekis CS et al. (2002) Evolving techniques for mitral valve reconstruction.[see comment]. *Annals of Surgery* 236: 288–93.	n = 64	Results not reported separately for patients who had endoaortic balloon occlusion and those who had other methods of aortic occlusion	
Glower DD et al. (1998) Mitral valve operation via Port Access versus median sternotomy. *European Journal of Cardio-Thoracic Surgery* 14: Suppl-1 S143–S147.	n = 41	Port-access operation provided smaller incision and faster return to normal activity than sternotomy	Studies with more patients were included in Table 2
Glower DD, Siegel LC, Frischmeyer KJ et al. (2000) Predictors of outcome in a multicenter port-access valve registry. *Annals of Thoracic Surgery* 70: 1054–9.	n = 64	Results not reported separately for patients who had endoaortic balloon occlusion and those who had other methods of aortic occlusion	
Glower DD, Siegel LC, Galloway AC et al. (2001) Predictors of operative time in multicenter port-access valve registry: institutional differences in learning. *Heart Surgery Forum* 4: 40–6.	n = 64	Study focuses on predictors of operative only	
Glower DD, Clements FM, Debruijn NP et al. (1999) Comparison of direct aortic and femoral cannulation for port-access cardiac operations. *Annals of Thoracic Surgery* 68: 1529–31.	n = 165 (endoaortic balloon occlusion = 36)	Results not reported separately for patients who had endoaortic balloon occlusion and those who had other methods of aortic occlusion	
Grossi EA, LaPietra A, Ribakove GH et al (2001) Minimally invasive versus sternotomy approaches for mitral reconstruction: comparison of intermediate-term results. *Journal of Thoracic and Cardiovascular Surgery* 121: 708–13.	n = 100	Awaiting full article	
Gulielmos V, Dangel M, Solowjowa N et al (1998) Clinical experiences with minimally invasive mitral valve surgery using a simplified Port-access technique. *European Journal of Cardio-Thoracic Surgery* 14: 141–7	n = 29	Awaiting full article	

Gulielmos V, Wunderlich J, Dangel M et al (1998) Minimally invasive mitral valve surgery – clinical experiences with a Port-access system. *European Journal of Cardio-Thoracic Surgery* 14: S148–53.	n = 21	Awaiting full article	
Hesselvik JF, Ortega RA, Treanor P et al. (1999) Intraoperative rupture of the endoaortic clamp balloon in a patient undergoing port-access mitral valve repair. *Journal of Cardiothoracic & Vascular Anesthesia* 13: 462–5.	n = 1	Case report of a rupture of the endoaortic clamp balloon during MV surgery	
Mishra YK, Khanna SN, Wasir H et al. (2005) Port-access approach for cardiac surgical procedures: Our experience in 776 patients. *Indian Heart Journal* 57: 688–93.	n = 64	Results not reported separately for patients who had endoaortic balloon occlusion and those who had other methods of aortic occlusion	
Mohr FW, Onnasch JF, Falk V et al. (238) The evolution of minimally invasive valve surgery – 2 year experience. *European Journal of Cardio-Thoracic Surgery* 15: 233–8.	n = 129	7 deaths 6 reexplorations for bleeding 3 aortic dissections 8 neurological complications	More recent study from the same centre included in Table 2
Murphy D, Smith JM, Siwek L et a.l (2007) Multicenter mitral valve study: a lateral approach using the da Vinci surgical system. *Innovations* 2: 56–61.	n = 64	Results not reported separately for patients who had endoaortic balloon occlusion and those who had other methods of aortic occlusion	
Onnasch JF, Schneider F, Falk V et al. (2002) Minimally invasive approach for redo mitral valve surgery: a true benefit for the patient. *Journal of Cardiac Surgery* 17: 14–9.	n = 39	No conversions to sternotomy 2 deaths due to: aortic dissection and sepsis 1 transient hemiplegia due to endoclamp migration 2 reexplorations for bleeding	
Schroeyers P, Wellens F, De Geest R et al. (2001) Minimally invasive video-assisted mitral valve repair: short and mid-term results. *Journal of Heart Valve Disease* 10: 579–83.	n = 121	2 conversions to sternotomy due to aortic dissection caused by Endoclamp 1 hospital death 9 revisions for bleeding	Another study from the same centre with the same patients is included in Table 2
Schroeyers P, Wellens F, De Geest R et al. (2001) Minimally invasive video-assisted mitral valve surgery: our lessons after a 4-year experience. Annals of Thoracic Surgery 72: S1050-S1054.	n = 175	Mortality: 2/175 Conversion to sternotomy: 4/175 NYHA class: All improved at F/U	More recent study from the same centre included in Table 2

Vanermen H, Farhat F, Wellens F et al. (2000) Minimally invasive video-assisted mitral valve surgery: From Port-Access towards a totally endoscopic procedure. *Journal of Cardiac Surgery* 15: 51–60.	n = 121	1 operative death and 2 early postoperative deaths 5 conversions to sternotomy: due to aortic dissection (2) 1 neurological complications 3 cases of balloon being hit with needle and requiring replacement	More recent study from the same centre included in Table 2
Vanermen H, Wellens F, De Geest R et al. (1999) Video-assisted Port-Access mitral valve surgery: from debut to routine surgery. Will Trocar-Port-Access cardiac surgery ultimately lead to robotic cardiac surgery? *Seminars in Thoracic & Cardiovascular Surgery* 11: 223–34.	n = 75	2 conversions to sternotomy due to aortic dissection 2 deaths 1 minor cerebrovascular deficit 5 revisions for bleeding	More recent study from the same centre included in Table 2
Yozu R, Shin H, Maehara T et al. (2001) Port-access cardiac surgery. Experience with 34 cases at Keio University Hospital. *Japanese Journal of Thoracic & Cardiovascular Surgery* 49: 360–4.	n = 34	No hospital or late deaths 1 intraoperative balloon rupture requiring conversion alternative clamping method	Studies with more patients were included in Table 2

Appendix B: Related NICE guidance for endoaortic balloon occlusion for cardiac surgery

Guidance programme	Recommendation
Interventional procedures	**IP402 Thoracoscopically assisted mitral valve surgery (in progress)** 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. 1.3 Clinicians undertaking thoracoscopically-assisted mitral valve surgery should submit data on all patients to the Central Cardiac Audit Database (www.ccad.org.uk).
Technology appraisals	None applicable
Clinical guidelines	None applicable
Public health	None applicable

Appendix C: Literature search for endoaortic balloon occlusion for cardiac surgery

Database	Date searched	Version/files
CRD databases (DARE & HTA)		
CENTRAL	12/10/2007	Issue 3, 2007
EMBASE	12/10/2007	1980 to 2007 Week 40
Medline	12/10/2007	1950 to October Week 1 2007
Premedline	12/10/2007	October 11, 2007
CINAHL	12/10/2007	1982 to October Week 1 2007
BLIC		
National Research Register		
Controlled Trials Registry		

The following search strategy was used to identify papers in Medline. A similar strategy was used to identify papers in other databases.

1. (endoaortic or endo-aortic).tw. (82)
2. (endoballoon or endo-balloon).tw. (10)
3. 1 or 2 (92)
4. (occlu$ or clamp$).tw. (173242)
5. 3 and 4 (68)
6. (aort$ adj3 balloon$ adj3 (occlu$ or clamp$)).tw. (117)
7. (balloon$ adj3 (occlu$ or clamp$) adj3 aort$).tw. (136)
8. 6 or 7 (146)
9. endovascular$.tw. (11105)
10. (aort$ adj occlusion$).tw. (1137)
11. 9 and 10 (36)
12. (endoclamp or endo-clamp).tw. (18)
13. 5 or 8 or 11 or 12 (240)
14. Animal/ (4220069)
15. Human/ (10034045)
16. 14 not (14 and 15) (3194259)
17. 13 not 16 (174)