NICE guidance

Endoaortic balloon occlusion for cardiac 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 Current evidence on the safety and efficacy of endoaortic balloon occlusion for cardiac surgery is adequate to support the use of this procedure provided that normal arrangements are in place for consent, audit and clinical governance.

1.2 The procedure should only be carried out by a highly experienced team and with the use of continuous transoesophageal echocardiography.

2 The procedure

2.1 Indications and current treatments

2.1.1 Endoaortic balloon occlusion is performed to achieve temporary obstruction of the aorta during cardiac surgery, including mitral valve repair or replacement and coronary artery bypass grafting.

2.1.2 Occlusion of the aorta is required in a number of cardiac operations. This is normally achieved by external application of an aortic cross-clamp, either during conventional open surgery or during minimally invasive cardiac procedures.

2.2 Outline of the procedure

2.2.1 This procedure is usually employed during minimally invasive cardiac operations (also known as port-access surgery) that require endovascular aortic occlusion, cardioplegia and left ventricular decompression.

2.2.2 A balloon catheter is inserted through the skin into an artery (normally the femoral artery in the groin) and manipulated towards the aortic root. The balloon at the tip of the catheter is filled with saline to occlude the aorta and prevent blood flow. Various devices can be used for this procedure.

2.2.3 Continuous transoesophageal echocardiographic monitoring is used to detect balloon migration along with other forms of monitoring such as radial arterial pressure monitoring and direct monitoring of the surgical field, as necessary.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes which were available in the published literature and which the committee considered as part of the evidence about this procedure. For more details, refer to the sources of evidence.

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

2.3.2 The specialist advisers considered key efficacy outcomes to include efficiency of cardioprotection, reduced length of hospital stay, duration of cardiac arrest and avoidance of the use of a cross-clamp from outside.

2.4 Safety

2.4.1 In a case series of 306 patients treated with endoaortic balloon occlusion, the 30-day mortality rate was 1% (3/306) and the rate of late deaths (mean follow-up 20 months) was 2% (6/306). A case series comparing 117 patients treated with endoaortic balloon occlusion with 117 matched controls treated with conventional aortic cross-clamping reported one perioperative death in each group. In four case series, 5% (11/209), 4% (6/151), 1% (1/127) and 25% (13/52) of patients who were treated with endoaortic balloon occlusion died in hospital.

2.4.2 The three case series of 306, 209 and 117 patients treated with endoaortic balloon occlusion all reported aortic dissection in 1% (3/306, 3/209, and 1/117) of

patients. One aortic dissection in the case series of 151 patients was judged by the authors to be unrelated to the endoaortic balloon occlusion device. In the case series that described 58, 120 and 127 patients, no aortic dissections occurred.

2.4.3 In a case series of 449 patients, there were no significant differences in the incidences of arrhythmias, pulmonary dysfunction, bleeding, renal failure or low cardiac output between those treated with endoaortic balloon occlusion and those treated with transthoracic clamping. However, the rates of neurological complications were higher in patients who had endoaortic balloon occlusion ($p<0.05$; absolute numbers not given). (Neurological complications were defined as stroke and transient hemiplegia.)

2.4.4 In five case series, 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.

2.4.5 In seven case series, 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 treated with endoaortic balloon occlusion.

2.4.6 In the case series of 306 and 151 patients, myocardial infarction was reported in 1 and 2 patients, respectively.

2.4.7 The specialist advisers reported anecdotal adverse events including aortic dissection, balloon puncture, balloon migration, damage to aortic intima, device movement causing loss of occlusion, femoral artery damage, difficulty positioning the balloon, death due to failure to deliver cardioplegia, and inability to complete planned surgery due to occlusion failure. Additional theoretical adverse events noted by the advisers were stroke, inadequate myocardial protection and cerebral ischaemia due to balloon misplacement and arterial embolism. The advisers noted that this procedure has the potential to reduce stroke risk in patients who have a very calcified aorta.

2.5 Other comments

2.5.1 The Committee noted that there have been technical modifications to and

evolution in the design of the endoaortic balloons with the intention of improving their performance; and that newer designs may be associated with lower complication rates.

3 Further information

Sources of evidence

The evidence considered by the interventional procedures advisory committee is described in the overview for this guidance.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.