NICE guidance

Balloon angioplasty with or without stenting for coarctation or recoarctation of the aorta in adults and children

Interventional procedures guidance
Published: 28 July 2004

www.nice.org.uk/guidance/ipg74

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 balloon angioplasty with or without stenting for coarctation or recoarctation of the aorta in adults and children appears adequate to support the use of this procedure, provided that the normal arrangements are in place for consent, audit and clinical governance.

1.2 The procedure should be performed by a multidisciplinary team in specialist centres with cardiac surgery facilities.

1.3 The National Institute for Cardiovascular Outcomes Research runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians are encouraged to enter all patients into this database.

2 The procedure

2.1 Indications

2.1.1 Aortic coarctation is a congenital narrowing of part of the aorta, most commonly the aortic arch, usually close to the origin of the left subclavian artery. This results in high blood pressure in the upper body and arms and low blood pressure in the legs.

2.1.2 Standard treatment for native coarctation and recoarctation (see Section 2.2.1) involves open chest surgery. The type of surgery used depends on the anatomy of the lesion and preference of the surgeon, but may include resection of the coarctation site and end-to-end anastomosis repair, patch aortoplasty, left subclavian flap angioplasty, or bypass graft repair.

2.2 Outline of the procedure

2.2.1 Balloon angioplasty of aortic coarctation is a minimally invasive procedure that involves inserting a catheter into a large blood vessel, usually in the groin, and passing it up to the narrowed area under radiological guidance. A balloon is then inflated within the narrowed area and a stent may be placed there to keep the area dilated. Balloon angioplasty and stenting may be carried out as a first treatment (in native coarctation) or if previous surgical or angioplasty fails and coarctation recurs (recoarctation).

2.3 Efficacy

2.3.1 One small randomised controlled trial (RCT) was identified, along with a non-randomised comparative study and several case series. The RCT reported an 86% reduction in peak systolic pressure gradient in both the balloon angioplasty group and the surgery group. The non-randomised study comparing balloon angioplasty with and without stent placement reported a statistically significant reduction in peak systolic gradient of 83% in the angioplasty alone group and 96% in the angioplasty with stent group ($p<0.001$). For more details, see the overview.

2.3.2 One Specialist Advisor noted that results could be improved by concomitant stenting. Another considered residual stenosis to be an efficacy concern.

2.4 Safety

2.4.1 In the RCT, the main complications reported were: aneurysm in 20% (4 out of 20)

of the angioplasty group and 0% (0 out of 16) of the surgery group; diminished pulse (in the leg through which angioplasty was performed) in 10% (2 out of 20) of the angioplasty group and 0% (0 out of 16) of the surgery group; bleeding in 5% (1 out of 20) of the angioplasty group and 13% (2 out of 16) of the surgery group; and hypertension in 5% (1 out of 20) of the angioplasty group and 0% (0 out of 16) of the surgery group. For more details, see the overview.

2.4.2 The Specialist Advisors considered the main potential adverse effects of the procedure to be death, aortic rupture, aneurysm, femoral artery damage, neurological damage and stroke. One Advisor noted that there were possible safety concerns if the procedure was performed for recoarctation after previous patch repair, but not for other types of surgery.

2.5 Other comments

2.5.1 There were limited data on the use of the procedure in infants because these patients are usually treated surgically.

2.5.2 The alternative to this procedure is major surgery.

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.

ISBN: 978-1-4731-6213-6

Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.