

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

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#### 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 Department of Health runs the <u>UK Central Cardiac Audit Database</u> (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, refer to the Sources of evidence section.

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% (4/20) of the angioplasty group and 0% (0/16) of the surgery group; diminished pulse (in the leg through which angioplasty was performed) in 10% (2/20) of the angioplasty group and 0% (0/16) of the surgery group; bleeding in 5% (1/20) of the angioplasty group and 13% (2/16) of the surgery group; and hypertension in 5% (1/20) of the angioplasty group and 0% (0/16) of the surgery group. For more details, refer to the Sources of evidence section.
- 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.

Andrew Dillon Chief Executive July 2004

#### 3 Further information

#### Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of balloon angioplasty or stenting for coarctation or recoarctation of the aorta', April 2003.

# Information for patients

NICE has produced <u>information on this procedure for patients and carers</u> ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

## 4 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE <u>interventional procedure guidance</u> process.

We have produced a <u>summary of this guidance for patients and carers</u>. Information about the evidence it is based on is also <u>available</u>.

#### Changes since publication

8 May: minor maintenance.

#### Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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