

Balloon valvuloplasty for aortic valve stenosis in adults and children

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1 Guidance

- 1.1 Current evidence on the safety and efficacy of balloon valvuloplasty for aortic valve stenosis 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 In adults, the procedure should only be used to treat patients who are unsuitable for surgery, as the efficacy is usually shortlived.
- 1.3 In infants and children, the procedure should be undertaken in specialist paediatric cardiology units.
- 1.4 The Department of Health 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 Balloon valvuloplasty is used to treat aortic valve stenosis (narrowing). This condition may be congenital, or it may develop later in life as a result of rheumatic fever or calcium build-up on the valve that occurs in some people as part of the aging process. The narrowing of the aortic valve causes the pressure in the left ventricle to increase. In order to continue to pump blood through this narrowed area, the left ventricle must pump harder, causing hypertrophy of the left ventricular muscle. Symptoms include angina, shortness of breath or fainting on exertion, and palpitations. Aortic valve stenosis may eventually lead to heart failure.
- 2.1.2 In infants and children, critical aortic stenosis is very rare and balloon valvuloplasty is usually used palliatively until the child is old enough to have valve replacement.
- 2.1.3 Standard treatment involves open chest surgery to perform a valvotomy or to replace the valve.

2.2 Outline of the procedure

- 2.2.1 Balloon valvuloplasty involves inserting a catheter into a large blood vessel, and passing it into the narrowed aortic valve under radiological guidance. A balloon is then inflated to dilate the aortic valve orifice. This can prevent the need for open chest surgery.

2.3 Efficacy

- 2.3.1 The evidence was limited to non-randomised controlled studies and case series studies. One of the studies that looked at 110 neonates found the mean reduction in systolic gradient to be 65% for the balloon valvuloplasty group, compared with 41% for the open surgery group. A study of adults older than 75 years found the mean gradient decrease to be 24 mmHg for the balloon

valvuloplasty group, and 55 mmHg for the open surgery group. In another study, in which 80% (539/674) of patients were considered inappropriate for valve replacement because of age or disease, the mean pressure gradient was reduced by 26 mmHg, but follow-up was only reported for 5 weeks. For more details, refer to the Sources of evidence section.

- 2.3.2 The Specialist Advisors noted that in adults, surgery was generally the first choice of procedure, but balloon valvuloplasty was useful when surgery was contraindicated.

2.4 Safety

- 2.4.1 The comparative study of neonates found aortic regurgitation rates of 18% (15/82) in the balloon valvuloplasty group, compared with 3% (1/28) in the open surgery group. In this study, immediate major complications were reported in 4% (3/82) of the balloon valvuloplasty group and 0% (0/28) of the open surgery group. However, the two groups differed in their baseline characteristics. The comparative study of patients older than 75 years showed the death rate in the postoperative and follow-up periods to be 59% (27/46) in the balloon valvuloplasty group and 22% (5/23) in the open surgery group. However, the mean follow-up intervals differed between the groups (22 months for balloon valvuloplasty and 28 months for surgery). 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 myocardial infarction, stroke, aortic valve disruption or regurgitation, myocardial rupture or perforation, mitral valve damage, arterial damage or occlusion, and arrhythmia.

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 valvuloplasty for aortic valve stenosis'](#), March 2003.

Information for patients

NICE has produced [information on this procedure for patients and carers](#) ('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 [interventional procedure guidance](#) process.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

Changes since publication

8 May 2012: 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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