NICE National Institute for Health and Care Excellence

NICE guidance

Balloon valvuloplasty for aortic valve stenosis in adults and children

HealthTech 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.

Contents

This guidance replaces IPG78.

1 Recommendations

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 short-lived.

1.3 In infants and children, the procedure should be undertaken in specialist paediatric cardiology units.

1.4 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 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 out of 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, see the overview.

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 out of 82) in the balloon valvuloplasty group, compared with 3% (1 out of 28) in the open surgery group. In this study, immediate major complications were reported in 4% (3 out of 82) of the balloon valvuloplasty group and 0% (0 out of 28) of the open surgery group. However, the 2 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 out of 46) in the balloon valvuloplasty group and 22% (5 out of 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, see the overview.

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.

3 Further information

Sources of evidence

The evidence considered by the committee is 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.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 78 has been migrated to HealthTech guidance 49. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.