NICE National Institute for Health and Care Excellence

NICE guidance

Balloon dilatation of pulmonary valve stenosis

HealthTech guidance
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This guidance replaces IPG67.

1 Recommendations

1.1 Current evidence on the safety and efficacy of balloon dilatation of pulmonary valve stenosis 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 Balloon dilatation of pulmonary valve stenosis should only be performed in a specialist unit where paediatric cardiac surgery is available.

1.3 The Department of Health runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians are encouraged to enter all patients undergoing paediatric cardiovascular interventions onto this database.

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2 The procedure

2.1 Indications

2.1.1 Pulmonary valve stenosis is narrowing of the pulmonary valve in the heart. It is usually congenital. The outflow of blood from the right ventricle of the heart to the lungs is obstructed. Symptoms include shortness of breath, chest pains, fainting and, in some instances, sudden death.

2.1.2 Balloon dilatation is an alternative to open surgical valvotomy.

2.2 Outline of the procedure

2.2.1 Balloon dilatation is a minimally invasive transvenous procedure to dilate the pulmonary valve orifice during cardiac catheterisation.

2.3 Efficacy

2.3.1 The evidence identified was limited to case series and 1 historical controlled study. All the studies reported a reduction in the residual pressure gradient across the pulmonary valve. In addition, the studies that reported data with more than 11 months follow-up showed that the reduction in pressure gradient persisted. In a case series of 533 children who received the procedure, an immediate residual gradient of less than 36 mmHg was reported in 74% of patients (394 of 533). No clinical outcomes were reported. For more details, see the overview.

2.3.2 The specialist advisors considered this procedure to be established practice and had no concerns about its efficacy.

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2.4 Safety

2.4.1 Most of the studies identified did not report safety findings in detail. The study that described safety findings in most detail reported the following immediate complications among 811 patients: arrhythmia, 1% (8 of 811); bleeding from catheter site, 0.9% (7 of 811); femoral vein thrombosis, 0.6% (5 of 811); hypoxia, 0.4% (3 of 811); death, 0.2% (2 of 811); tricuspid regurgitation, 0.2% (2 of 811); femoral vein tears, 0.2% (2 of 811); arterial thrombosis, 0.2% (2 of 811); cardiac perforation, 0.1% (1 of 811); and respiratory arrest, 0.1% (1 of 811). For more details, see the overview.

2.4.2 The specialist advisors commented that pulmonary regurgitation was common after the procedure, but that the long-term effects of this were unknown. They considered the risks to be greater in neonates than in older infants and children. The advisors also recommended that the procedure should be carried out only in paediatric cardiology units with special expertise.

2.5 Other comments

2.5.1 This procedure has become established practice on the basis of clinical experience. There is very limited research evidence published.

2.5.2 Most of the data relates to neonates and children, but the procedure can also be performed in adults.

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3 Further information

Sources of evidence

The evidence considered by the committee is in the overview.

Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

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Update information

Minor changes since publication

January 2026: Interventional procedures guidance 67 has been migrated to HealthTech guidance 40. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

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