NICE National Institute for Health and Care Excellence

NICE guidance

Transcatheter endovascular closure of perimembranous ventricular septal defect

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 IPG172 and IPG336.

1 Recommendations

1.1 Current evidence on the safety and efficacy of transcatheter endovascular closure of perimembranous ventricular septal defect (VSD) is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance, consent and audit.

1.2 Patient selection is important, especially in children and in asymptomatic patients, and should be carried out by a multidisciplinary team including an interventional cardiologist and a cardiac surgeon with specific expertise in the management of congenital heart disease.

1.3 When carried out on children, this procedure should only be undertaken in specialist paediatric cardiology units. For patients of all ages, this procedure should only be undertaken by cardiologists trained in the technique, including the management of complications. There should be access to emergency cardiac surgery by a surgeon experienced in the treatment of congenital heart disease.

1.4 The National Institute for Cardiovascular Outcomes Research runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians should enter details about all patients undergoing transcatheter endovascular closure of perimembranous VSD.

1.5 NICE encourages publication of further long-term follow-up data, specifically on the occurrence of heart block compared with open surgery.

2 The procedure

2.1 Indications and current treatments

2.1.1 Ventricular septal defect (VSD) is the persistence of one or more holes in the septum that separates the left and right ventricles of the heart. VSD is the most common congenital heart defect. Left untreated, VSD may be associated with congestive heart failure, pulmonary vascular disease and an increased risk of infective endocarditis.

2.1.2 The cause of congenital VSD is unknown. Most infants have small VSDs that are asymptomatic and that usually close spontaneously after birth. However, if a VSD is large, surgical closure may be recommended.

2.1.3 In adults, a VSD may be acquired as a complication of a myocardial infarction or trauma. These are generally muscular VSDs and therefore not addressed in this guidance.

2.2 Outline of the procedure

2.2.1 In transcatheter endovascular closure of perimembranous VSD, a guidewire is introduced into the femoral artery and vein in the groin, to establish an arteriovenous wire loop. A delivery sheath is advanced over the wire across the VSD, via the right or left side of the heart. Echocardiographic and fluoroscopic guidance are used to guide the occluder device as it is advanced through the delivery sheath and expanded to close the defect.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3.1 A non-randomised comparative study of 2,178 patients reported immediately successful closure rates of 99.8% (850 out of 852) in patients treated by the procedure and 100% in patients treated by surgical closure (difference reported as 'not significant').

2.3.2 Case series of 430, 412, 210 and 186 patients reported final follow-up closure rates of 83% (absolute figures not stated), 97% (398 out of 412), 97% (200 out of 206) and 98% (175 out of 178) respectively at follow-ups ranging from 1 postoperative day to 1 year. In the same case series, immediate closure rates of 40% (absolute figures not stated), 93% (382 out of 412), 35% (72 out of 206) and 92% (172 out of 186) were reported respectively.

2.3.3 In the non-randomised comparative study of 2,178 patients treated by the procedure or surgical closure, residual shunts were reported in 0.5% (4 out of 852) and 0.6% (8 out of 1,326) of patients respectively (difference reported as 'not significant').

2.3.4 The Specialist Advisers listed key efficacy outcomes as successful closure of VSD, symptomatic improvement post procedure, abolition of left-to-right interventricular blood flow and reduction in left ventricular diastolic diameter.

2.4 Safety

2.4.1 The case series of 430 patients reported that 1 patient with multiple VSDs died during the procedure from cardiac arrest after a second occluder was implanted. A prospective register of 160 patients treated by the procedure reported 3 postoperative deaths: 1 after additional surgery for complications that occurred during the procedure (timing of event not stated), 1 at 476 postoperative days and 1 at 536 postoperative days.

2.4.2 Device embolisation rates of 1% (4 out of 430), 2% (2 out of 100) and 4% (2 out of 54) were reported in case series of 430, 100 and 65 patients respectively. In the case series of 430 patients, all devices were retrieved (1 by open surgery).

2.4.3 The non-randomised study of 2,178 patients reported failure of occlusion associated with tricuspid regurgitation in 1 patient treated by the procedure who

subsequently required cardiac surgery under cardiopulmonary bypass.

2.4.4 The same study reported third-degree atrioventricular (AV) block in 1 patient treated by the procedure; this patient needed cardiac surgery under cardiopulmonary bypass 3 days after the procedure. In addition, second-degree AV block was reported in 2 patients treated by the procedure but this changed to first-degree AV block at 4 and 5 days respectively.

2.4.5 Case series of 430, 186, 182 and 100 patients reported the occurrence of complete AV block in 4% (16 out of 430), 1% (2 out of 186), 1% (1 out of 182) and 2% (2 out of 100) of patients respectively. Of these 21 patients, 2 had surgery, 12 were fitted with a permanent pacemaker, 1 was fitted with a temporary pacemaker and 6 were managed medically.

2.4.6 The non-randomised comparative study of 2,178 patients reported left bundle branch block in 0.4% (3 out of 852) of patients treated by the procedure.

2.4.7 The Specialist Advisers listed theoretical adverse events as device displacement or misplacement, cardiac tamponade, interference with the mitral or aortic valve (specifically including aortic incompetence), venous bleeding, the need to convert to open surgery, and alteration to the morphology of the heart which may become more pronounced with growth.

2.5 Other comments

2.5.1 The Committee noted that there is a lack of evidence comparing the incidence of heart block following this procedure with that following open surgery for VSD.

Update information

Minor changes since publication

January 2026: Interventional procedures guidance 336 has been migrated to HealthTech guidance 213. The recommendations and accompanying content remain unchanged.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.