

# Transcatheter endovascular closure of perimembranous ventricular septal defect

Interventional procedures guidance

Published: 24 March 2010

[www.nice.org.uk/guidance/ipg336](http://www.nice.org.uk/guidance/ipg336)

## 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. However, 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.

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.

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.

This guidance replaces IPG172.

# 1 Guidance

This guidance replaces previous guidance on endovascular closure of perimembranous ventricular septal defect (interventional procedure guidance 172).

- 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 Clinicians should enter details about all patients undergoing transcatheter endovascular closure of perimembranous VSD onto the [UK Central Cardiac Audit Database](#).
- 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 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.

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 Efficacy

2.3.1 A non-randomised comparative study of 2178 patients reported immediately successful closure rates of 99.8% (850/852) 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% (398/412), 97% (200/206) and 98% (175/178) 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% (382/412), 35% (72/206) and 92% (172/186) were reported

respectively.

- 2.3.3 In the non-randomised comparative study of 2178 patients treated by the procedure or surgical closure, residual shunts were reported in 0.5% (4/852) and 0.6% (8/1326) 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% (4/430), 2% (2/100) and 4% (2/54) 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 2178 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% (16/430), 1% (2/186), 1% (1/182) and 2% (2/100) 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 2178 patients reported left bundle branch block in 0.4% (3/852) of patients treated by the procedure.
- 2.4.7 The Specialist Advisers listed theoretical adverse events as device displacement/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.

## 3 Further information

- 3.1 For related NICE guidance see our [website](#).

## 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.

## 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.

It updates and replaces NICE interventional procedure guidance 172.

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

This guidance has been endorsed by [Healthcare Improvement Scotland](#).

## Accreditation

