

Endovascular closure of perimembranous ventricular septal defect

1 Guidance

- 1.1 Current evidence on the safety and efficacy of endovascular closure of perimembranous ventricular septal defect (VSD) 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 Patient selection is important, especially in children and asymptomatic patients.
- 1.3 When performed on children, this procedure should only be undertaken in specialist paediatric cardiology units with onsite surgical facilities.
- 1.4 The Department of Health runs the Central Cardiac Audit Database (CCAD), and clinicians are encouraged to enter all patients undergoing endovascular closure of perimembranous VSD onto this database (www.ccad.org.uk).
- 1.5 Publication of further long-term follow-up data would be useful.

2 The procedure

2.1 Indications

- 2.1.1 A 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. The cause of a congenital VSD is unknown and the defect may occur in association with other congenital heart defects. The most common type of VSD is a perimembranous VSD located close to the tricuspid and aortic valves. Muscular VSDs are less common and can be located anywhere in the muscular part of the ventricular septum.
- 2.1.2 A VSD allows blood to pass directly from the left ventricle through to the right ventricle, increasing the flow of blood to the lungs. This may have several consequences, including congestive heart

failure, pulmonary vascular disease (particularly from large defects) and an increase in the risk of infective endocarditis (particularly from small defects).

- 2.1.3 In adults, a VSD may be acquired as a complication of a myocardial infarction or trauma. This guidance does not address the use of endovascular closure for this type of VSD.
- 2.1.4 Most VSDs in infants are small and cause no symptoms. They usually close spontaneously after birth. Infants with symptoms of congestive heart failure can be treated conservatively with medication. However, if the defect is large, surgical closure is usually recommended. Conventional surgery for VSD is performed through an incision in the front of the chest. Cardiopulmonary bypass is established and the defect is usually closed with a patch.

2.2 Outline of the procedure

- 2.2.1 Endovascular closure of a VSD involves introducing one guidewire into the femoral artery in the groin and another into the femoral vein to establish an arteriovenous wire loop. A delivery sheath is advanced over the wires across the defect, usually through the right-heart system. Echocardiographic and fluoroscopic guidance are used to determine the size, position and number of defects and their relation to adjacent structures, and to assist in placing the occluder device. The occluder device is pushed through the delivery sheath and expanded in the defect to close it. Small residual shunts after the procedure often resolve as endothelial tissue grows over and around the device.

2.3 Efficacy

- 2.3.1 The data reviewed were based on a single device designed for closure of perimembranous VSD, and devices designed for other types of defects. These

Interventional Procedure Guidance 172

This guidance is written in the following context

This guidance represents the view of the Institute which 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.

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This guidance is endorsed by NHS QIS for implementation by NHSScotland.

included muscular VSD occluder devices, umbrella devices and detachable steel coils.

- 2.3.2 In a case series of 107 patients with perimembranous or muscular VSDs in whom VSD occluder devices were implanted (17 perimembranous and 90 muscular VSD occluders), successful implantation of the device was reported in 97% (104/107) of patients and complete closure of the defect was reported in all 104 patients at 1–48 months' follow-up.
- 2.3.3 In the largest case series of 186 patients in whom a perimembranous VSD occluder device was used, patients were divided into three groups: single defects without aneurysm; single defects with aneurysm; and multiple defects with aneurysm. Immediate closure rates in the three groups were 90%, 98% and 89%, respectively; complete closure rates at 1-year follow-up were 100%, 98% and 89%, respectively.
- 2.3.4 In one case series using a double umbrella device, successful implantation was achieved in 86% (24/28) of patients with perimembranous VSDs. Complete closure of the defect was achieved in 67% (16/24) of patients immediately after the procedure and at a mean follow-up of 17 months. This includes one patient in whom a detachable coil device was implanted after placement of the umbrella device failed. For more details, refer to the 'Sources of evidence' section.
- 2.3.5 The Specialist Advisors stated that some patients need surgical repair after failed device implantation. They noted a risk of residual shunting following successful device implantation; this risk is usually higher for defects with aneurysms, especially if the defects are fenestrated.

2.4 Safety

- 2.4.1 Misplacement of the device was reported on in two case series, occurring in 0% (0/27) and 15% (2/13) of patients. In a case series using the perimembranous VSD occluder device, transient ventricular arrhythmias were reported in all 27 patients.
- 2.4.2 Complications reported after the procedure using perimembranous and muscular VSD occluder devices included: transient ventricular arrhythmias in 100% (27/27) of patients; left bundle branch block in 0% (0/13) to 4% (1/25); complete heart block in 0% (0/25) to 2% (2/107);

aortic regurgitation in 0% (0/13) to 4% (1/25); tricuspid regurgitation in 0% (0/13) to 8% (2/25); tricuspid stenosis in 0% (0/25) to 1% (1/107) and device embolisation in 0% (0/107) to 8% (1/13). One case series of 87 patients with perimembranous VSD reported two cases of delayed complete heart block after 5 and 12 months, requiring pacemakers. For more details, refer to the 'Sources of evidence' section.

- 2.4.3 The Specialist Advisors stated that the risk of complications is potentially much greater in infants than in older patients. Complications involving the aortic valve, the tricuspid valve and the atrioventricular node may potentially arise during and after device implantation because of the close proximity of these structures to the membranous septum. The Specialist Advisors also noted a potential risk of haemolysis.

2.5 Other comments

- 2.5.1 It was noted that devices not specifically designed for this procedure were used in some of the reported studies.

3 Further information

- 3.1 The Institute has issued guidance on endovascular closure of atrial septal defect (www.nice.org.uk/IPG096).

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Information for the public

NICE has produced information describing its guidance on this procedure for patients, carers and those with a wider interest in healthcare. It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG172publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of endovascular closure of perimembranous ventricular septal defect', September 2005.

Available from: www.nice.org.uk/IP286overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1035. *Information for the public* can be obtained by quoting reference number N1036.

The distribution list for this guidance is available at www.nice.org.uk/IPG172distributionlist

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