

Endovascular closure of atrial septal defect

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg96

1 Guidance

- 1.1 Current evidence on the safety and efficacy of endovascular closure of atrial septal defect 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 The procedure should be performed in units where there are arrangements for cardiac surgical support in the event of complications.
- 1.3 The Department of Health runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians are encouraged to enter all patients onto this database.

2 The procedure

2.1 Indications

- 2.1.1 An atrial septal defect is the persistence of a hole (the foramen ovale) in the wall (septum) between the right atrium and left atrium of the heart. The foramen ovale usually closes spontaneously after birth; an atrial septal defect is present when this closure does not occur. In the most common type, called an ostium secundum atrial septal defect, the septum between the atria fails to form properly during foetal development, resulting in a permanent hole. An atrial septal defect allows blood to flow from the left atrium to the right atrium, thereby increasing the flow of blood to the lungs. This is known as a shunt. Patients with atrial septal defects are usually asymptomatic through infancy and childhood. Symptoms such as exertional dyspnoea, fatigue, palpitations and syncope can occur and increasing age carries a higher risk of stroke. Some patients may develop congestive heart failure.
- 2.1.2 Not all atrial septal defects require treatment, but it is generally agreed that larger defects and those associated with either symptoms or significant enlargement of the heart should be closed electively. Conventional surgery for atrial septal defect is performed through an incision in the front of the chest. After establishing cardiopulmonary bypass, the right atrium is opened to gain access to the interatrial septum. The defect is then repaired using a patch or stitches. Patients usually stay in hospital for several days after the operation.

2.2 Outline of the procedure

- 2.2.1 Endovascular closure of an atrial septal defect involves making a small incision in the groin to introduce a guidewire and delivery sheath into the femoral vein. An occluder device is then introduced through the delivery sheath on a semi-rigid cable and expanded within the atrial septal defect to close it. Echocardiography and fluoroscopic guidance are used to determine the size and position of the defect and to place the occlude device. A balloon may be used to measure the diameter of the defect. Patients can usually go home the next day. Small residual shunts after

the procedure often resolve as endothelial tissue grows over and around the device. The claimed advantages compared with open surgery are shorter hospital stay, earlier return to normal activities and fewer complications.

2.3 Efficacy

- 2.3.1 Three non-randomised controlled studies reported successful closure rates immediately after the endovascular procedure of 96% (423/442), 98% (60/61) and 97% (28/29), compared with rates of 100% (154/154), 98% (60/61) and 100% (64/64), respectively, for conventional surgery. A large case series of 3460 patients reported that 97% (3301/3391) of atrial septal defects were successfully closed immediately after the procedure. Of the 4% (147/3460) of patients followed up for 2 years in this study, all maintained successful closure. A further case series reported that 1% (4/314) of patients had a significant residual shunt immediately after the procedure and 93% (99/107) of patients had a successful closure 1 year after the procedure. For more details, refer to the Sources of evidence section.
- 2.3.2 The Specialist Advisors noted that a small proportion of patients might be left with a residual shunt.

2.4 Safety

- 2.4.1 The reported complication rates were low. They included malpositioning of the device, requiring endovascular or surgical retrieval 1% (6/417) to 5% (16/334); arrhythmia 0.4% (2/459) to 5% (3/61); embolisation of the device 0.4% (14/3460) to 4% (14/334); thrombus formation 0.4% (1/258) to 3% (1/37); brachial plexus injury 3% (1/39); right iliac vein dissection 0.6% (1/159); stroke 0.1% (5/3460) to 0.3% (1/334); cardiac tamponade 0.1% (2/3460); cardiac perforation 0.03% (1/3460); and endocarditis 0.03% (1/3460). For more details, refer to the Sources of evidence section.
- 2.4.2 The Specialist Advisors listed arrhythmias, stroke, device embolisation and cardiac tamponade as potential adverse effects of the procedure.

2.5 Other comments

- 2.5.1 There is the potential for long-term adverse effects and clinicians should report these to the Medicines and Healthcare products Regulatory Agency (MHRA).
- 2.5.2 These recommendations were based on evidence on the use of the Amplatzer[®], CardioSEAL[®], STARFlex[®] and Helex[®] devices for the endovascular closure of atrial septal defect. The Institute may review the procedure if further data relating to other devices become available.

Andrew Dillon
Chief Executive
October 2004

3 Further information

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 atrial septal defect', March 2004.

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.

4 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.

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