

Endovascular closure of atrial septal defect

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 (www.ccad.org.uk).

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 occluder 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

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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. Health professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of health professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Interventional procedures guidance is for health professionals and people using the NHS in England, Wales and Scotland.

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 (see right).

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 (see right).

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

Information for the Public

The Institute 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, in English and Welsh, from www.nice.org.uk/IPG096publicinfo

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

Available from: www.nice.org.uk/ip146overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0723. *Information for the Public* can be obtained by quoting reference number N0724 for the English version and N0725 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at www.nice.org.uk/IPG096distributionlist

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