NICE National Institute for Health and Care Excellence

NICE guidance

# Endovascular closure of atrial septal defect

HealthTech guidance
Published: 27 October 2004

www.nice.org.uk/guidance/htg58

# 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.

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This guidance replaces IPG96.

# 1 Recommendations

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 National Institute for Cardiovascular Outcomes Research runs the UK Central Cardiac Audit Database (UKCCAD) and clinicians are encouraged to enter all patients into 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 out of 442), 98% (60 out of 61) and 97% (28 out of 29), compared with rates of 100% (154 out of 154), 98% (60 out of 61) and 100% (64 out of 64), respectively, for conventional surgery. A large case series of 3,460 patients reported that 97% (3,301 out of 3,391) of atrial septal defects were successfully closed immediately after the procedure. Of the 4% (147 out of 3,460) of patients followed up for 2 years in this study, all maintained successful closure. A further case series reported that 1% (4 out of 314) of patients had a significant residual shunt immediately after the procedure and 93% (99 out of 107) of patients had a successful closure 1 year after the procedure. For more details, see the overview.

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 out of 417) to 5% (16 out of 334); arrhythmia 0.4% (2 out of 459) to 5% (3 out of 61); embolisation of the device 0.4% (14 out of 3,460) to 4% (14 out of 334); thrombus formation 0.4% (1 out of 258) to 3% (1 out of 37); brachial plexus injury 3% (1 out of 39); right iliac vein dissection 0.6% (1 out of 159); stroke 0.1% (5 out of 3,460) to 0.3% (1 out of 334); cardiac tamponade 0.1% (2 out of 3,460); cardiac perforation 0.03% (1 out of 3,460); and endocarditis 0.03% (1 out of 3,460). For more details, see the overview.

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. NICE may review the procedure if further data relating to other devices become available.

# 3 Further information

## Sources of evidence

The evidence considered by the committee is in the overview.

## Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

# Update information

**Minor changes since publication**

**January 2026:** Interventional procedures guidance 96 has been migrated to HealthTech guidance 58. The recommendations and accompanying content remain unchanged.

ISBN: 978-1-4731-8803-7

# Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.