

Endovascular closure of patent ductus arteriosus

Interventional procedures guidance

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www.nice.org.uk/guidance/ipg97

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.

1 Guidance

1.1 Current evidence on the safety and efficacy of endovascular closure of patent

ductus arteriosus (PDA) 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 The ductus arteriosus is a normal vessel in the fetus that connects the pulmonary artery and the aorta. It allows the fetal blood flow to bypass the lungs, which are not used in utero. The ductus arteriosus usually closes at or shortly after birth. Sometimes it fails to close on its own; this is called a patent (or persistent) ductus arteriosus. Blood can then pass from the aorta into the pulmonary artery, exposing the lungs to increased blood flow and pressure. A large PDA may cause symptoms such as poor weight gain and breathlessness. Without medical treatment, blood vessels in the lung may eventually become damaged by the raised blood pressure. This puts strain on the heart and can lead to heart failure. Persistent ductus arteriosus is also associated with an increased risk of endocarditis, a life-threatening infection of the lining of the heart chambers and valves.
- 2.1.2 Open surgery is the standard treatment. Access to the heart is gained via an incision in the chest and a stitch and/or clip is placed around both ends of the ductus arteriosus (ligation), which is then cut in half if there is enough length (ligation and division).

2.2 Outline of the procedure

- 2.2.1 The endovascular procedure involves passing a catheter through a vein or artery into the heart. Pressure measurements and angiograms may be performed to assess the size and shape of the ductus. An occlusion device is

then introduced into the ductus through the catheter under X-ray guidance. The choice of device depends largely on the size of the PDA. Coils are suitable for closing PDAs of small to moderate size. Other occlusion devices are used to close larger PDAs. Small residual shunts after the procedure often resolve as endothelial tissue grows over and around the device.

2.3 Efficacy

- 2.3.1 Three non-randomised controlled studies reported efficacy data. In two of them, immediate occlusion was reported in 68% (71/105) and 77% (23/30) of patients treated with endovascular closure, and in 89% (8/9) and 96% (140/146) of patients treated with open surgery. The third study reported that 94% (93/99) of patients treated with endovascular closure had a successful outcome immediately after the procedure, compared with 99% (109/110) of patients treated with open surgery. The four case series, with a total of 2035 patients, reported rates of immediate complete occlusion between 44% (90/205) and 98% (214/218) following endovascular closure. In all studies, occlusion rates after a period of follow-up were higher than immediately after the procedure. In one case series of 1258 patients, the occlusion rate was 96% at 2-year follow-up compared with an immediate occlusion rate of 59%. For more details, refer to the Sources of evidence section.
- 2.3.2 The Specialist Advisors noted that a small proportion of patients would have a residual shunt.

2.4 Safety

- 2.4.1 The most commonly reported complications were haemolysis (most commonly mild to moderate) and embolisation of the device. Rates of haemolysis varied from 0.3% (1/316) to 9% (3/34), and rates of embolisation varied from 0.6% (2/316) to 7% (7/105). A study of 316 patients reported one death as a result of the procedure. For more details, refer to the Sources of evidence section.
- 2.4.2 The Specialist Advisors considered that device embolisation, haemolysis, vascular injury and death were potential adverse events.

2.5 Other comments

- 2.5.1 There is a 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[®] device and coil embolisation for patent (or persistent) ductus arteriosus. 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 patent ductus arteriosus', March 2003.

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.

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.

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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](#).