

# Endovascular closure of patent ductus arteriosus

## 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 ([www.ccad.org.uk](http://www.ccad.org.uk)).

## 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)

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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.

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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 (see right).

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 (see right).

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

## 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/IPG097publicinfo](http://www.nice.org.uk/IPG097publicinfo)

## 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

Available from: [www.nice.org.uk/ip163overview](http://www.nice.org.uk/ip163overview)

### Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N0726. *Information for the Public* can be obtained by quoting reference number N0727 for the English version and N0728 for a version in English and Welsh.

The distribution list for this guidance is available on the NICE website at [www.nice.org.uk/IPG097distributionlist](http://www.nice.org.uk/IPG097distributionlist)

Published by the National Institute for Clinical Excellence, October 2004 ISBN: 1-84257-794-8

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N0726 1P 20k Oct 04 (OAK)