

Endovascular closure of patent ductus arteriosus

Understanding NICE guidance –
information for parents and carers
considering the procedure for their baby
or child, and for the public

October 2004



Corporate member of
Plain English Campaign.
Committed to clearer communication.

197

Endovascular closure of patent ductus arteriosus

Understanding NICE guidance – information for parents and carers considering the procedure for their baby or child, and for the public

Issue date: October 2004

To order copies

Copies of this booklet can be ordered from the NHS Response Line; telephone 0870 1555 455 and quote reference number N0727. A version in Welsh and English is also available, reference number N0728. Mae fersiwn yn Gymraeg ac yn Saesneg ar gael hefyd, rhif cyfeirnod N0728. The NICE interventional procedures guidance on which this information is based is available from the NICE website (www.nice.org.uk). Copies can also be obtained from the NHS Response Line, reference number N0726.

National Institute for Clinical Excellence

MidCity Place
71 High Holborn
London
WC1V 6NA

Website: www.nice.org.uk

ISBN: 978-1-4731-8806-8

Published by the National Institute for Clinical Excellence
October 2004

Typeset by Icon Design, Eton
Print on Demand

© National Institute for Clinical Excellence, October 2004. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes within the NHS. No reproduction by or for commercial organisations is allowed without the express written permission of the National Institute for Clinical Excellence.

Contents

About this information	4
About endovascular closure of patent ductus arteriosus	5
What has NICE decided?	9
What the decision means for you	10
Further information	12

About this information

This information describes the guidance that the National Institute for Clinical Excellence (NICE) has issued to the NHS on a procedure called endovascular closure of patent ductus arteriosus. It is not a complete description of what is involved in the procedure – the patient's healthcare team should describe it in detail.

NICE has looked at whether endovascular closure is safe enough and works well enough for it to be used routinely for patent ductus arteriosus.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of endovascular closure and how well it works
- asked experts for their opinion
- asked the views of the organisations that speak for the healthcare professionals and the patients and carers who will be affected by this guidance.

This guidance is part of NICE's work on 'interventional procedures' (see 'Further information' on page 12).

About endovascular closure of patent ductus arteriosus

Babies in the womb have slightly different blood systems compared with babies that are a few days old. One of the differences is that, before birth, a baby has a special blood vessel in the heart that connects two major arteries. This blood vessel is called the ductus arteriosus. It is there so that the blood can bypass the lungs because, in the womb, the baby doesn't use its lungs. The ductus arteriosus usually closes up when the baby is born, or soon after. But sometimes this doesn't happen and it stays open – this is called patent or persistent ductus arteriosus (sometimes called PDA for short).

The problem is that if the blood vessel is still open, the two arteries are still connected and too much blood can end up being pumped towards the lungs. Eventually, if the condition isn't treated, the blood vessels in the lungs can become damaged.

In an endovascular closure, a narrow tube called a catheter is passed through a blood vessel and into the heart. The doctor usually measures the PDA and checks its shape, and then puts a small blocking device through the tube, into the PDA. The doctor uses X-rays to check that the blocker is in the right position. The blocking device might be a small coil or something slightly larger

if there's a big opening. The blocking device stays in place permanently and the body's tissue grows around it.

The standard treatment for PDA is open surgery (an operation that involves opening up the chest and ribs to get to the heart). The ductus arteriosus is stitched or clipped at each end so that blood can't flow through it.

How well it works

What the studies said

There were three studies that compared what happened in patients who had the endovascular closure with patients who had open surgery. In one study, the PDA was closed straight away in 71 out of 105 patients who had endovascular closure, whereas in another study, this happened in 23 out of 30 patients who had the new procedure (as percentages, these results are 68% and 77%, respectively). In the same two studies, the PDA was closed immediately in 8 out of 9, and 140 out of 146 babies who had the open surgery (89% and 96%, respectively).

In the third study, the endovascular closure was said to have been immediately successful in 93 out of 99 patients (94%), whereas the open surgery was said to have been immediately successful in 109 out of 110 patients (99%).

As well as these studies, NICE looked at four more reports that followed what happened in patients who had endovascular closure. In total, these looked at 2035 patients. The results for complete success straight after the operation went from 90 out of 205 patients (44%) in one report to 214 out of 218 patients (98%) in another one. But each report said that when doctors checked on the patients some time after the procedure, the number of patients with closed PDAs was higher than it was straight after the procedure. For example, in one report of 1258 patients, the PDA was closed up in just over half of the patients straight after the endovascular closure, but it was closed up in nearly all of them 2 years later.

What the experts said

The experts pointed out that a few babies and children who had endovascular closure were likely to have a small amount of leakage of blood through the remains of the ductus arteriosus (this leakage is called a shunt). This often sorts itself out as the body tissue grows around the blocking device and plugs any gaps. If that doesn't happen, another operation may be needed.

Risks and possible problems

What the studies said

The most common problems reported in the studies were the breakdown of some of the blood cells in the blood, and the blocking device moving out of the PDA into another part of the circulation. The type of breakdown of blood cells that was reported is called haemolysis – it happened in 3 out of 34 patients in one study. The device moved out of the PDA in 2 out of 316 patients in one study (0.6%), but 7 out of 105 patients in another study (7%). In a study that involved 316 patients, 1 patient died as a result of having the endovascular closure.

What the experts said

The experts thought that, in addition to haemolysis and the device moving out of the PDA, there was a risk that blood vessels could be damaged during the procedure. They also said there was a risk of death.

What has NICE decided?

NICE has considered the evidence on endovascular closure of patent ductus arteriosus. It has recommended that when doctors use it for babies and children with patent ductus arteriosus, they should be sure that:

- the parents or carers, and patient if possible, understand what is involved and agree (consent) to the treatment, and
- the results of the procedure are monitored.

NICE has recommended that endovascular closure of patent ductus arteriosus should only be carried out in units that have emergency arrangements in place to deal with any problems during or straight after the procedure.

NICE has also encouraged doctors to send information about every patient who has the operation and what happens to them afterwards to a central store of information. This is so the safety of the procedure and how well it works can be checked over time. The central store of information is called the UK Central Cardiac Audit Database (www.ucl.ac.uk/nicor), and is being run by the Department of Health.

Other comments from NICE

NICE has reminded doctors to report any problems with the blocking devices to the Medicines and Healthcare products Regulatory Agency (a national organisation that checks and controls the safety and quality of medicines and medical equipment).

The studies published on endovascular closure used one specific make of blocking device. NICE may look at the procedure again if studies that have used other makes of blocking device are published.

What the decision means for you

Your doctor may have offered you an endovascular closure for your baby's or child's patent ductus arteriosus. NICE has considered this procedure because it is relatively new. NICE has decided that the procedure is safe enough and works well enough for use in the NHS. Nonetheless, you should understand the benefits and risks of endovascular closure of patent ductus arteriosus before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these may be described above.

NICE has also encouraged doctors to collect some details about every patient who has this procedure in England and Wales. These details will be held confidentially and will not include patients' names. The information will be used only to see how safe the procedure is and how well it works. If you decide to go ahead with the endovascular closure, you may be asked to agree to your baby's or child's details being entered into an electronic database for this purpose. A clinician looking after your baby or child will fully explain the purpose of collecting the data and what details will be held. You will be asked to sign a consent form. If you do not agree to the details being entered into an electronic database, your baby or child will still be allowed to have the procedure.

Further information

You have the right to be fully informed and to share in decision-making about the treatment your baby or child receives. You may want to discuss this guidance with the doctors and nurses looking after them.

You can visit the NICE website (www.nice.org.uk) for further information about the National Institute for Clinical Excellence and the Interventional Procedures Programme. A copy of the full guidance on endovascular closure of patent ductus arteriosus is on the NICE website (www.nice.org.uk/IPG097guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0726. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you want more information on heart problems, a good starting point is NHS Direct (telephone 0845 4647), or NHS Direct Online (www.nhsdirect.nhs.uk).

Date: October 2004

**National Institute for
Clinical Excellence**

MidCity Place
71 High Holborn
London
WC1V 6NA

www.nice.org.uk