NHS

National Institute for
Clinical Excellence

Endovascular atrial septostomy

Understanding NICE guidance – information for people considering the procedure, and for the public

August 2004

Information from Interventional Procedure Guidance 86

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Understanding NICE guidance – information for people considering the procedure, and for the public

Issue date: August 2004

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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 atrial septostomy. 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 atrial septostomy is safe enough and works well enough for it to be used routinely.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of endovascular atrial septostomy and how well it works

- asked experts for their opinions

- 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 10).

About endovascular atrial septostomy

Endovascular atrial septostomy is carried out to help babies with what's known as cyanotic congenital heart disease. This is when a problem with the heart means that there's not enough oxygen being circulated around the body in the blood. The baby turns blue as a result.

There are several causes. One is when the two 'circuits' of blood vessels running from the heart haven't developed in the right way. Normally, these circuits are connected in the heart. In one circuit, the blood picks up oxygen from the lungs and brings it back to the heart, where it goes into the second circuit to get pumped around the body. When the blood has been 'used', it returns to the heart, and goes back through the first circuit to the lungs to pick up more oxygen.

In cyanotic congenital heart disease, the circuits have developed in the wrong way, so the two circuits aren't connected in the heart. This means the blood and oxygen just goes around the first circuit from the lungs to the heart. And the 'used' blood in the second circuit just keeps being pumped out from the heart back around the body.

Normally a baby with this can survive for a few days after birth because of a small hole called the foramen ovale that connects the upper halves of the heart. Some of the blood going around the first circuit can leak into the second circuit through this hole, so some of that blood's oxygen gets around the body. Normally, though, this hole closes up when the baby is a few days old.

In endovascular septostomy, a narrow tube called a catheter with a deflated balloon attached is passed up into the heart through the blood vessels (it's usually put into a blood vessel at the top of the leg and then fed upwards to the heart). When it gets to the heart, it's guided into the foramen ovale. Once in place, the balloon is gently inflated to try to make the hole bigger so that it doesn't close up completely. This is called simple balloon atrial septostomy.

A similar procedure called static balloon atrial septostomy is used when the first procedure hasn't been successful or isn't possible. In this case, a surgical blade attached to the catheter is used to make a hole between the two halves of the heart. The balloon is then used to enlarge this hole.

In both procedures, the aim is to help the patient live long enough to have major surgery to correct the problem.

How well it works

What the studies said

In one of the studies NICE looked at, there was an immediate effect on blood flow in most of the patients, which shows that the widened hole was working. Other studies showed that, on average, there was more oxygen in the blood circulating round the body after patients had had the procedure.

What the experts said

The experts said that they thought that doctors were already using this procedure routinely to treat cyanotic congenital heart disease. They also said that the hole made by the procedure could close on its own, in which case, it would need to be opened up again in another operation.

Risks and possible problems

What the studies said

In the studies NICE looked at, 2 to 3% of patients died as a result of having the procedure (2% is the same as saying 2 people in 100, 3% is 3 in 100).

In one study of 248 patients, 26 patients had minor problems from having the procedure. Three patients had serious problems that led to death.

What the experts said

The experts said that their main safety concern was that the procedure could result in the patient dying. Other possible problems were a temporary effect on the heartbeat and injury to the heart.

What has NICE decided?

NICE has considered the evidence on endovascular atrial septostomy. It has recommended that when doctors use it for babies with cyanotic congenital heart disease, they should be sure that:

- the parent or carer understands what is involved and agrees (consents) to the treatment, and

- the results of the procedure are monitored.

Endovascular atrial septostomy should be carried out in units that specialise in heart surgery on children.

NICE has encouraged doctors to send information about every patient who has the procedure 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, and it is being run by the Department of Health.

Other comments from NICE

NICE noted that this procedure is generally used in hospitals as a life-saving operation because babies with this condition are very ill, but there is very little evidence about its use. Most of the information that is available comes from studies that look at the ‘simple’ method rather than the ‘static’ procedure.

What the decision means for you

Your doctor may have offered you an endovascular atrial septostomy for your baby. 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 atrial septostomy 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 atrial septostomy, you may be asked to agree to your baby’s details being entered into an electronic database for this purpose. The doctor looking after your baby 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 will still be able 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 receives. You may want to discuss this guidance with the doctors and nurses looking after your child.

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 atrial septostomy is on the NICE website (www.nice.org.uk/IPG086guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0680. The evidence that NICE considered in developing this guidance is also available from the NICE website.

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