NHS

National Institute for Clinical Excellence

Endovascular closure of atrial septal defect

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

October 2004

Information from Interventional Procedure Guidance 96

Endovascular closure of atrial septal defect
Understanding NICE guidance – information for people considering the procedure, and for the public

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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 closure of atrial septal defect. 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 of atrial septal defect is safe enough and works well enough for it to be used routinely for the treatment of atrial septal defects.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of endovascular closure of atrial septal defect 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 12).

About endovascular closure of atrial septal defect

Babies are born with a small opening between the top right and left chambers (called the atria) of the heart, but this normally closes up when the baby is a few days old. If it doesn't close up properly, the baby has what is called an atrial septal defect. This means that some of the blood from the left chamber leaks into the right chamber, increasing the amount of blood that is flowing into the lungs. And this can eventually cause damage to the heart muscle.

Babies and children who have an atrial septal defect usually don't have any symptoms, but as they get older, they may feel tired, have difficulty breathing, faint, or feel like their heart is beating hard. Some people may develop a condition called congestive heart failure. Increasing age carries a higher risk of stroke. Not all atrial septal defects need to be closed, but it is usually better to close them if there are symptoms, if the heart is very big, or if the hole itself is big. Usually, 'open' surgery, in which a cut is made in the chest to get to the heart, is needed to close the hole.

Endovascular closure of an atrial septal defect involves inserting a small blocking device into the heart. This is passed up through a narrow tube put in a blood vessel at the top of the leg, and is gently inflated to close the hole. Special X-rays and scans, and sometimes a small balloon, are used to measure the size and position of the hole. Any small areas that are still open after the procedure usually close up by themselves eventually. Patients have this procedure under general anaesthetic, and can usually go home the next day.

How well it works

What the studies said

NICE looked at three studies that compared the proportion of atrial septal defects that had been closed using the endovascular procedure with the proportion that had been closed using open surgery. The endovascular procedure closed atrial septal defects in 96%, 98% and 97% of patients, whereas open surgery closed the holes in 100%, 98% and 100% of patients (96% of patients is 96 patients in 100).

NICE also looked at two other studies. One showed that nearly all of the atrial septal defects treated were successfully closed by the endovascular procedure. A small proportion of these patients were checked on for 2 years after having the procedure, and after this time, all of the atrial septal defects were still closed. The other study showed that 1% of patients still had a small opening after having the procedure.

What the experts said

The experts noted that a small proportion of patients may still have a small opening after having the procedure.

Risks and possible problems

What the studies said

The studies that NICE looked at reported the following complications, but showed that these problems occurred in a small proportion of people:

- the device being badly positioned and needing to be taken out in another endovascular procedure or open surgery
- an irregular heartbeat

- the device moving away from its original site
- blood clots
- the nerves running to the arm and hand being injured
- damage to other blood vessels
- stroke
- the abnormal presence of blood or fluid in the linings of the heart
- the heart being punctured
- the heart becoming inflamed.

What the experts said

The experts said an irregular heartbeat, the device being blocked, stroke, and the abnormal presence of blood or fluid in the linings of the heart were particular problems with the endovascular procedure.

What has NICE decided?

NICE has considered the evidence on endovascular closure of atrial septal defect. It has recommended that when doctors use it for people with an atrial septal defect, they should be sure that:

- the patient understands what is involved and agrees (consents) to the treatment, and
- the results of the procedure are monitored.

NICE has also said that patients should be treated in hospitals where 'open' heart surgery can be arranged in case of complications.

There should also be special arrangements for monitoring what happens when a person has endovascular closure of atrial septal defect. NICE is asking doctors to send information about every patient who has the operation and what happens to them afterwards to a central store of information called the UK Central Cardiac Audit Database (www.ucl.ac.uk/nicor).

Other comments from NICE

NICE noted that there could be long-term complications and doctors should report these to the Medicines and Healthcare products Regulatory Agency (a national organisation that checks and controls the safety and quality of medicines and medical equipment). It also stated that the recommendations are based on using certain blocking devices, and it may look at the procedure again if more information on other devices becomes available.

What the decision means for you

Your doctor may have offered you endovascular closure of atrial septal defect. 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 atrial septal defect before you agree to it. Your doctor should discuss the benefits and risks with you. Some of these may be described above.

You should also be treated in a hospital where heart surgery can be arranged for you in case of problems with the endovascular procedure.

NICE has also decided that more information is needed about endovascular closure of atrial septal defect. So NICE has recommended that some details should be collected 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 have endovascular closure of atrial septal defect, you will be asked to agree to your details being entered into an electronic database for this purpose. A clinician looking after you 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, you 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 you receive. You may want to discuss this guidance with the doctors and nurses looking after you.

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 atrial septal defect is on the NICE website (www.nice.org.uk/IPG096guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0723. The evidence that NICE considered in developing this guidance is also available from the NICE website.

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