

Repairing perimembranous ventricular septal defects using a cardiac catheter

NICE 'interventional procedures guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how a cardiac catheter (a thin, flexible tube) can be used in the NHS to repair a perimembranous ventricular septal defect (VSD), which is also known as a hole in the heart. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

Interventional procedures guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

This leaflet is written to help people who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe perimembranous VSD or the procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on page 7.



What has NICE said?

This procedure can be offered routinely as a treatment option for people with a perimembranous VSD provided that doctors are sure that:

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

A team of healthcare professionals experienced in the management of perimembranous VSD should decide who should have this procedure. The team should include an interventional cardiologist (a doctor who specialises in treating heart problems using catheters) and a heart surgeon with expertise in the management of congenital heart disease (which means the condition has been present from birth). For children, this procedure should only be carried out in specialist paediatric cardiology units. For all patients it should only be carried out by a cardiologist trained in both the procedure and managing complications. There should be access to emergency heart surgery by a surgeon with experience in treating congenital heart disease.

NICE is asking doctors to send information about everyone who has the procedure and what happens to them afterwards to a central store of information at the UK Central Cardiac Audit Database (www.ucl.ac.uk/nicor) so that the safety of the procedure and/or how well it works can be checked over time.

NICE has encouraged further research into the procedure.

Other comments from NICE

There is not much evidence comparing how many people have heart block after this procedure and after open surgery for perimembranous VSD.

This procedure may not be the only possible treatment for perimembranous ventricular septal defect. Your healthcare team should talk to you about whether it is suitable for you and about any other treatment options available.

Repairing perimembranous VSD using a cardiac catheter

The medical name for this procedure is ‘transcatheter endovascular closure of perimembranous ventricular septal defect’. The procedure is not described in detail here – please talk to your doctor for a full description.

Ventricular septal defect (VSD) is the presence of one or more holes in the thin wall (the septum) that separates the two lower chambers of the heart (the ventricles). It causes blood to leak back from the left to the right ventricle. It is the most common birth defect of the heart. A perimembranous VSD is a hole in the membranous upper part of the septum. Most VSDs usually close on their own after birth, but large ones may need surgery to close them.

This procedure is usually performed with the patient under local anaesthesia. Catheters are placed in the heart using a guidewire, which is inserted via an artery and a vein in the groin and passed along the major blood vessels into the heart. They are then used to deliver a small device (an occluder) to close the VSD. There is no need for open heart surgery. Ultrasound or special X-rays are used to guide the device into position.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your doctor thinks it is a suitable treatment option for you, he or she should still make sure you understand the benefits and risks before asking you to agree to it. NICE has also decided that more information is needed about this procedure. Your doctor may ask you if details of your procedure can be used to help collect more information and will give you more information about this.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will I need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at 10 studies on this procedure.

How well does the procedure work?

A study of 2178 patients comparing the procedure with open surgery reported that the VSD was closed successfully in almost all patients. Abnormal blood flow between the ventricles was reported in 4 patients of 852 who had the procedure and in 8 patients of 1326 who had open surgery. In 4 studies (1238 patients) the rate of immediate closure of VSD varied from 35% to 93% of patients. In the same studies the rate of VSD closure varied from 83% to 98% of patients when assessed between 1 day and 1 year after the procedure.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that key success factors are successful closure of the VSD, improvement in symptoms, an end to abnormal blood flow between the ventricles and a decrease in ventricle size while they are filling with blood.

Risks and possible problems

In 2 studies involving a total of 590 patients who had the procedure, 1 patient with several VSDs died during the procedure from cardiac arrest. One patient died during additional surgery for complications that occurred during the original procedure, and 2 others died around 18 months after the procedure. In 3 studies, the device blocked a blood vessel in 8 of the 584 patients who had the procedure. In all patients the device was retrieved successfully but 1 needed open surgery for this.

In the study of 2178 patients, the occluder failed to work in 1 out of 852 patients who had the procedure, resulting in a leaking heart valve. The patient later needed open surgery including a heart-lung bypass. In 5 studies involving a total of 1750 patients who had the procedure, 24 had atrioventricular (AV) block, which is a problem with the transmission of nerve impulses in the heart that can affect the rhythm of the heart beat. Nerve transmission was completely blocked in 22 patients. Of these, 3 had surgery, 12 were fitted with a permanent pacemaker, 1 had a temporary pacemaker and 6 were managed with drugs. The 2 other patients had less severe AV block, which improved by 5 days after the procedure. In 1 of these studies, the nerve transmission was blocked on the left side of the heart in a further 3 out of 852 patients.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that possible problems include the device moving from its proper position or being inserted incorrectly, blood or other fluid collecting in the sac around the heart, problems with the device interfering with the heart valves, bleeding from the veins, the need for open surgery, and a change in the structure of the heart.

More information about ventricular septal defect

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information and support. For details of all NICE guidance on VSD, visit our website at www.nice.org.uk

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see www.nice.org.uk/aboutguidance

This leaflet is about 'transcatheter endovascular closure of perimembranous ventricular septal defect'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG336

*You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2123). The NICE website has a screen reader service called *Browsealoud*, which allows you to listen to our guidance. Click on the *Browsealoud* logo on the NICE website to use this service.*

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

National Institute for Health and Clinical Excellence

MidCity Place, 71 High Holborn, London, WC1V 6NA; www.nice.org.uk

Information about NICE interventional procedure guidance 336

ISBN 978-1-84936-197-2

N2123 1P March 10

© National Institute for Health and Clinical Excellence, 2010. All rights reserved. This material may be freely reproduced for educational and not-for-profit purposes. No reproduction by or for commercial organisations, or for commercial purposes, is allowed without the express written permission of NICE.