

Balloon dilatation of systemic to pulmonary arterial shunts in children

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 balloon dilatation of systemic to pulmonary arterial shunts. 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 balloon dilatation of systemic to pulmonary arterial shunts is safe enough and works well enough for it to be used routinely for children.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of balloon dilatation of systemic to pulmonary arterial shunts 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 balloon dilatation of systemic to pulmonary arterial shunts

Some children are born with heart conditions that mean their blood does not move around their heart properly. To help, surgeons may make a connection between two important blood vessels that run into the heart. These are the aorta and the pulmonary artery, and the connection between them is called a systemic to pulmonary artery shunt. Making this type of connection is a way of increasing the amount of blood getting to the lungs, and of getting more oxygen into the blood so that the child's condition improves.

The connections themselves may become blocked or narrowed over time because of scarring in the area or because they become clogged with blood. Balloon dilatation aims to open up the connection so that blood can pass through it more easily. It involves passing a piece of tubing (a catheter) with a deflated balloon attached to it up through a blood vessel, usually starting at the top of the leg, and guiding it into the connection between the two blood vessels. The doctors use X-rays to help them get the catheter and balloon to the right position. When the balloon is in the right place, it's gently inflated to widen the area so blood can flow through more easily. The deflated balloon is then removed.

The alternative to this is to repeat the original operation to remake the connection.

How well it works

What the studies said

There were not any good-quality studies that looked at how well balloon dilatation worked. In the studies that were found, the children who had the balloon procedure all had more oxygen in their blood after the procedure (the increase in oxygen went from 5% to 19%). In one study, nearly all the children (42 out of 46, or 91%) had an increase in blood oxygen of more than 20% (that means it increased by more than one-fifth).

What the experts said

The experts did not have any concerns about how well the procedure worked.

Risks and possible problems

What the studies said

The studies did not include many details of problems that patients had after the procedure. In a study that followed what happened in eight patients:

- one patient developed high pressure in the blood vessels in their lungs
- one patient died because of pneumonia.

Another study followed what happened in six patients:

- one patient had a blood clot in their leg
- the balloon burst in one patient
- in one patient, the walls of the blood vessels started to close in (this is called vasospasm).

What the experts said

The experts said that possible problems included tearing of the blood vessels or of the connection made between them, complete blockage of the connection, blood clots, bleeding, stroke caused by a blockage in the blood vessels that supply blood to the brain, and clots on the lungs.

What has NICE decided?

NICE has considered the evidence on balloon dilatation of systemic to pulmonary arterial shunts. It has recommended that when doctors use it for children with systemic to pulmonary arterial shunts, they should be sure that:

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

NICE has also recommended that the procedure should only be done in a specialist children's heart unit.

NICE has also 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.

What the decision means for you

Your doctor may have offered your child balloon dilatation of a systemic to pulmonary arterial shunt. 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 balloon dilatation of systemic to pulmonary arterial shunts before you agree to it. Your child's doctor should discuss the benefits and risks with you. Some of these benefits and risks 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 balloon dilatation, you may be asked to agree to your child's details being entered into an electronic database for this purpose. The doctor looking after your 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 child 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 child receives. You may want to discuss this guidance with the doctors and nurses looking after him or her.

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 balloon dilatation of systemic to pulmonary arterial shunts is on the NICE website (www.nice.org.uk/IPG077guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0649. The evidence that NICE considered in developing this guidance is also available from the NICE website.

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