NHS

National Institute for Clinical Excellence

Balloon dilatation with or without stenting for pulmonary artery or non-valvar right ventricular outflow tract obstruction in children

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

July 2004

Information from Interventional Procedure Guidance 76

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National Institute for Clinical Excellence

MidCity Place
71 High Holborn
London
WC1V 6NA

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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 with or without stenting when it's used in children with pulmonary artery or non-valvar right ventricular outflow tract obstruction. 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 with or without stenting is safe enough and works well enough for it to be used routinely for the treatment of pulmonary artery or non-valvar right ventricular outflow tract obstruction.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of balloon dilatation with or without stenting 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 with or without stenting for pulmonary artery or non-valvar right ventricular outflow tract obstruction

The procedure NICE has looked at is a way of widening a section in or near to the heart that is narrower than it should be. The aim is to let blood flow through it more easily (the narrowing stops blood flowing through the area normally, with the result that pressure builds up).

This NICE guidance covers the use of the procedure when the narrowed section is either above or below an important valve in the heart called the pulmonary valve. When the narrowing is above the valve, it's known as supravalvar stenosis (stenosis means narrowing). When it's below the valve, it's known as subvalvar stenosis. The guidance also covers the use of the procedure when the narrowing is further out from the valve in the blood vessel called the pulmonary artery, or in one of the blood vessels that branch off from this.

A baby may be born with the narrowed section, or the narrowing may happen in children as a result of an operation to correct another heart defect.

A balloon dilatation involves attaching a deflated balloon to a narrow tube called a catheter. This is then passed up through a blood vessel, usually starting at the top of the leg, and guided into the narrow area in the heart. 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 balloon is then deflated and removed. Sometimes, a small piece of tubing called a stent is left in the narrow section to keep it open.

The procedure is known as a minimally invasive procedure because it's carried out through small cuts rather than a large opening.

The standard operation for this type of narrowing in or near the heart is open surgery, which means that the patient's chest is opened and the operation is done through this opening.

How well it works

What the studies said

In two studies that NICE looked at, the procedure was said to have been successful if there was an improvement in the narrowing or the pressure abnormalities it caused.

In one of the studies, the balloon dilatation was said to be successful in 97 out of 162 patients who had it (60% of the patients). A stent was used in 79 patients. Of these patients, the procedure was said to be successful in 77 (which is the same as 97%).

In the other study, the balloon dilatation was said to have been successful in 39 out of 74 patients who had the procedure (53%).

What the experts said

The experts thought the procedure worked.

Risks and possible problems

What the studies said

In one of the studies, 5 out of 162 patients had a problem after the procedure:

- one patient had a blood clot in their leg
- in three patients, the lining of the pulmonary artery tore badly
- one patient's lungs became overloaded with fluid for a short time (the medical term for this is pulmonary oedema).

In one study that looked at 79 patients who had a stent put into the narrow area, one patient had damage to the covering of the lung and a build up of blood in the area around the heart.

What the experts said

The experts said that possible problems included changes in the pattern of the heartbeat, bleeding (haemorrhage), movement of the stent once inserted, clots, the balloon bursting while it's being inflated, damage to blood vessels and damage to one of the valves in the heart.

What has NICE decided?

NICE has considered the evidence on balloon dilatation with or without stenting. It has recommended that when doctors use it for children with pulmonary artery or non-valvar right ventricular outflow tract obstruction, 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 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 child 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

Most of the results from the studies NICE looked at involved patients with narrowing in the pulmonary artery or one of its branches. So less

is known about how well the procedure works or how safe it is when it's used for patients where the narrowing is near to the pulmonary valve.

What the decision means for you

Your doctor may have offered balloon dilatation with or without stenting for your child. 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 with or without stenting 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 with or without stenting, 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 with or without stenting for pulmonary artery or non-valvar right ventricular outflow tract obstruction is on the NICE website (www.nice.org.uk/IPG076guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0646. The evidence that NICE considered in developing this guidance is also available from the NICE website.

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WC1V 6NA

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