NHS

National Institute for Clinical Excellence

Balloon dilatation of pulmonary valve stenosis

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

June 2004

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Issue date: June 2004

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Copies of this booklet can be ordered from the NHS Response Line; telephone 0870 1555 455 and quote reference number N0601. A version in Welsh and English is also available, reference number N0602. Mae fersiwn yn Gymraeg ac yn Saesneg ar gael hefyd, rhif cyfeirnod N0602. The NICE interventional procedures guidance on which this information is based is available from the NICE website (www.nice.org.uk). Copies can also be obtained from the NHS Response Line, reference number N0600.

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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 pulmonary valve stenosis. 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 pulmonary valve stenosis 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 balloon dilatation of pulmonary valve stenosis 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 pulmonary valve stenosis

In pulmonary valve stenosis, one of the valves in the heart is thicker than normal, deformed and/or narrower than normal. Instead of doing its normal job, which is to stop blood flowing in the wrong direction through the heart, it gets in the way of blood flowing in the right direction. The nearby heart muscle may become thicker in an attempt to push the blood harder through the blockage. Pulmonary valve stenosis is usually 'congenital' – that is, it is present at birth.

A balloon dilatation involves passing a small deflated balloon up through a blood vessel at the top of the leg and into the blocked area in the heart. The balloon is then gently inflated to widen the blocked area so blood can flow more easily.

How well it works

What the studies said

All the studies NICE found showed that, after patients had a balloon dilatation, blood could flow more easily through the valve. This effect seemed to be long-lasting, as it was still there in patients who were checked again more than 11 months after they'd had the procedure. In one

study that involved 533 children, three-quarters had an immediate improvement in the blood flow through their heart after the procedure.

What the experts said

The experts said that this procedure was already being used and they did not have concerns about how well it worked.

Risks and possible problems

What the studies said

Not many of the studies described the problems that patients had. The one study that went into most detail involved 811 patients. This study reported that patients had:

- problems with the heart beat (8 patients)
- bleeding at the site where the narrow tube was inserted into the body (this is the tube that the balloon is passed through to get to the heart) (7 patients)
- a blood clot in the blood vessel in the leg that the tube is put into (5 patients)
- low oxygen in the body (3 patients)

- blood flowing backwards in the heart (2 patients)
- damage to the blood vessel in the leg (2 patients)
- a blood clot in an artery (2 patients)
- damage to the heart muscle (1 patient)
- respiratory arrest, where breathing stops (1 patient).

Two people died out of the 811 patients who had the procedure.

What the experts said

The experts said that it was common for some blood to flow backwards through the heart after the procedure, but that the long-term effects of this were not known.

The experts thought that the risk of these things would be higher in newborn babies than in older babies and children, and they said that it should be carried out in children's heart units where the staff are experienced in this area.

What has NICE decided?

NICE has considered the evidence on balloon dilatation. It has recommended that when doctors use it for people with pulmonary valve stenosis, they should be sure that:

- the patient, their carers or both understand what is involved and agree (consent) to the treatment, and
- the results of the procedure are monitored.

NICE has recommended that balloon dilatation for pulmonary valve stenosis should only be carried out in specialist units where children's heart surgery is carried out.

NICE has also encouraged doctors to send information about every patient who has the operation 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 has pointed out that specialist doctors believe balloon dilatation works. But because there haven't been many studies looking at the

procedure, there isn't a lot of scientific evidence to show that it works well or how commonly it causes problems.

Although most of the information about the procedure is on its use in babies and children, it can also be done in adults.

What the decision means for you

Your doctor may have offered your child balloon dilatation for pulmonary valve stenosis. 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 before agreeing to it. Your doctor should discuss the benefits and risks. 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. A clinician 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 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 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 balloon dilatation of pulmonary valve stenosis is on the NICE website (www.nice.org.uk/IPG067guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0600. The evidence that NICE considered in developing this guidance is also available from the NICE website.

If you want more information on heart problems, a good starting point would be NHS Direct (telephone 0845 4647) or NHS Direct Online (www.nhsdirect.nhs.uk).

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