NHS

National Institute for Clinical Excellence

Balloon valvuloplasty for aortic valve stenosis in adults and children

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

July 2004

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Balloon valvuloplasty for aortic valve stenosis in adults and children
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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 valvuloplasty for aortic 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 valvuloplasty is safe enough and works well enough for it to be used routinely for the treatment of aortic valve stenosis.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of balloon valvuloplasty 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 valvuloplasty for aortic valve stenosis

Stenosis means narrowing, and in aortic valve stenosis, the aortic valve in the heart has become narrow. Normally, this valve lets blood flow forward and out of the heart, and stops it from flowing backwards. But when the valve becomes narrow, it doesn't open properly, so blood can't flow so easily out of the heart. This puts a strain on the heart, and the nearby heart muscle may get thicker in an attempt to push the blood harder through the partly open valve.

Babies may be born with aortic valve stenosis, or it can happen in older people as a result of rheumatic fever or because calcium has built up on the valve (this happens in some people as part of the ageing process).

A balloon valvuloplasty involves attaching a deflated balloon to a narrow tube called a catheter, and then passing this through a large blood vessel and into the narrow valve. X-rays are used to make sure the catheter and balloon are being put into the correct position. When the balloon is in the right place, it's gently inflated to widen the opening in the valve so blood can flow out more easily. At the end of the procedure, the balloon is deflated and removed.

The standard operations for aortic valve stenosis involve opening up the chest (this is called open surgery). The narrowing in the valve can then be widened in an operation called a valvotomy, or the valve can be replaced.

How well it works

What the studies said

One of the studies NICE looked at involved 110 babies. The researchers compared the pressure building up around the valve before and after the balloon procedure in some babies, and before and after open surgery in others. They found that babies who had the balloon procedure had a bigger reduction in pressure than the babies who had the open surgery (a 65% reduction compared with a 41% reduction).

In a study that looked at older people (over 75), the average reduction in pressure in people who had the balloon procedure was just under half of what it was in people who had open surgery.

And in a third study where most of the patients weren't suitable for a valve replacement operation because of their age or health, the balloon procedure reduced the pressure in their heart, though the study only reported what happened up to 5 weeks after the procedure.

What the experts said

The experts said that open surgery would normally be offered to adults rather than the balloon procedure. But balloon valvuloplasty was useful if a patient couldn't have major surgery for some reason.

Risks and possible problems

What the studies said

One problem that can happen if the valve opening is widened is that it doesn't then close properly, so it lets blood run back into the heart. This is called regurgitation (or sometimes the valve is said to be leaky). In the study that looked at young babies (see above), 15 out of 82 babies had regurgitation after the balloon procedure compared with 1 out of 28 babies who had open surgery (18% compared with 3%). Other results from this study showed that immediate major problems happened in 3 out of the 82 babies who had the balloon procedure, but none of the babies who'd had open surgery. These results have to be treated with caution though, because there were differences between the babies in the two groups that may have meant that problems were more likely in the group that had the balloon procedure.

In the study that involved people over 75, 27 out of 46 patients (59%) who'd had the balloon procedure died in the period afterwards, compared with 5 out of 23 patients (22%) who'd had open surgery. These 'follow up' periods were 22 months on average for the patients who had the balloon procedure, and 28 months on average for the patients who had the open surgery.

What the experts said

The experts thought that the main possible problems would be heart attack (the medical term is myocardial infarction), stroke, problems affecting the aortic valve such as regurgitation, damage to the heart muscle or another valve in the heart or to blood vessels in the area, and problems affecting the heartbeat.

What has NICE decided?

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

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

NICE has recommended that for adults, balloon valvuloplasty should only be used if open surgery isn't suitable. This is because the results of the balloon procedure don't usually last for long.

For babies and children, 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

You may have been offered balloon valvuloplasty for you or 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 valvuloplasty before you agree to it. Your doctor or 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 or your child's details being entered into an electronic database for this purpose. The doctor looking after you or 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, 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 or 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 valvuloplasty for aortic valve stenosis is on the NICE website (www.nice.org.uk/IPG078guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0652. The evidence that NICE considered in developing this guidance is also available from the NICE website.

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