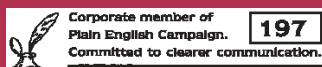


Balloon angioplasty with or without stenting for coarctation or recoarctation of the aorta in adults and in children

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

July 2004



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To order copies

Copies of this booklet can be ordered from the NHS Response Line; telephone 0870 1555 455 and quote reference number N0641. A version in Welsh and English is also available, reference number N0642. Mae fersiwn yn Gymraeg ac yn Saesneg ar gael hefyd, rhif cyfeirnod N0642. 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 N0640.

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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 angioplasty with or without stenting for coarctation or recoarctation of the aorta. 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 angioplasty with or without stenting is safe enough and works well enough for it to be used routinely for the treatment of coarctation or recoarctation of the aorta.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of balloon angioplasty with or without stenting for coarctation or recoarctation of the aorta 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 angioplasty with or without stenting for coarctation or recoarctation of the aorta

Coarctation means narrowing, and aortic coarctation is when a part of the aorta (the main artery that takes blood away from the heart) is narrower than it should be. This is something that babies can be born with, and the result is that they have high blood pressure in the upper part of their body and arms, and low blood pressure in their legs.

Sometimes the problem is not discovered until later in life. Recoarctation is the medical name for what happens if the area becomes narrow again after an operation to widen it.

Balloon angioplasty involves gently inflating a balloon in the narrow area of the aorta to widen it so blood can flow more easily. The deflated balloon is attached to a narrow tube called a catheter. This is then moved up to the aorta through blood vessels in the body. It's usually (but not always) put into a blood vessel at the top of the leg to start off. The doctors use X-rays to check that they are putting the catheter and balloon into the right position. When the balloon is in the narrow area, it's gently inflated. Once it has been used to widen the area, the balloon is deflated and removed. Sometimes a strong piece of tube called a stent is left in the narrowed area to keep it open.

The standard treatment for coarctation and recoarctation is open chest surgery, where the patient's chest is opened up.

How well it works

What the studies said

One study compared what happened to patients who had the balloon procedure with what happened to patients who had open chest surgery. Both the balloon procedure and the open surgery reduced the pressure in the area by the same amount, 86% (the pressure builds up as the blood can't flow through the narrow section very easily).

Another study compared the results in patients who had the balloon procedure and a stent with patients who had the balloon procedure but no stent. The patients who had the stent had a bigger reduction in pressure than the patients who just had the balloon procedure (a 96% reduction compared with an 83% reduction).

What the experts said

One expert said that it seemed patients would do better if stents were put in during the procedure. Another expert thought that if the area wasn't widened enough, blood still wouldn't be able to flow through easily, and this might have affected the results in the studies.

Risks and possible problems

What the studies said

In the study that compared patients who had the balloon procedure with patients who had open chest surgery, the main problems were:

- a section of the aorta became overwidened and bulged outwards (this is known as an aneurysm): this happened in 4 out of the 20 patients who had the balloon procedure, but in none of the 16 patients who had an open operation
- a weaker pulse in the leg that the catheter was put into: this happened in 2 out of the 20 patients who had the balloon procedure, but in none of the 16 patients who had an open operation
- bleeding: this happened in 1 patient out of the 20 who had the balloon procedure, and in 2 out of the 16 who had an open operation
- persistent high blood pressure (hypertension): this happened in 1 out of the 20 patients who had the balloon procedure, but in none of the patients who had an open operation.

What the experts said

The experts thought that the main possible problems would be bursting of the aorta, aneurysm, damage to the artery in the leg where the catheter was inserted, nerve damage and stroke. They also thought that patients could die as a result of the procedure.

One expert said that there were possible safety worries if the procedure was being done for recoarctation after an earlier operation called a patch repair, but not if it was being done after other types of operation.

What has NICE decided?

NICE has considered the evidence on balloon angioplasty with or without stenting. It has recommended that when doctors use it for people with coarctation or recoarctation of the aorta, they should be sure that:

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

NICE has also recommended that the procedure should only be done in a specialist centre that has the facilities for heart surgery. And it should only be done by a multidisciplinary team (a team of healthcare professionals who have different areas of expertise).

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

There was not much information on how well the procedure worked or how safe it was for very young children. This was because this age group usually has open surgery for the condition.

NICE has pointed out that the alternative to balloon angioplasty with or without stenting is a major operation.

What the decision means for you

You may have been offered balloon angioplasty with or without stenting for coarctation or recoarctation of the aorta. 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 angioplasty with or without stenting for coarctation or recoarctation of the aorta 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 angioplasty with or without stenting,

you may be asked to agree to your details or your child's details being entered into an electronic database for this purpose. A clinician 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 or your child receives. 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 angioplasty or stenting for coarctation or recoarctation of the aorta is on the NICE website (www.nice.org.uk/IPG074guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0640. The evidence that NICE considered in developing this guidance is also available from the NICE website.

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