

Radiofrequency valvotomy for pulmonary atresia

**Understanding NICE guidance –
information for parents and carers
considering the procedure for their baby,
and for the public**

October 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 N0722.

A version in English only is also available, quote reference N0721.

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 N0720.

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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 radiofrequency valvotomy. It is not a complete description of what is involved in the procedure – the baby’s healthcare team should describe it in detail.

NICE has looked at whether radiofrequency valvotomy is safe enough and works well enough for it to be used routinely for the treatment of pulmonary atresia.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of radiofrequency valvotomy and how well it works
- asked experts for their opinion
- asked the views of the organisations that speak for the healthcare professionals and the 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 radiofrequency valvotomy for pulmonary atresia

Pulmonary atresia is a heart problem that some babies are born with. One of the valves in the heart doesn't develop properly and stays closed up. The result is that blood can't flow from the heart to the lungs, so it can't pick up oxygen from the air. This means that the rest of the body doesn't get all the oxygen it needs.

The aim of a radiofrequency valvotomy is to open up the closed valve. Working through small cuts in the baby's chest, the doctor makes a hole in the blocked valve using special surgical equipment. A small deflated balloon is then put into the hole and gently inflated to widen it. Because this is all done through small cuts, it means that the baby doesn't have to have open surgery, in which the chest and ribs are opened up to get to the heart. But some babies will need to have more surgery at a later time for this heart problem.

How well it works

What the studies said

NICE found several small studies that reported what had happened in babies who'd had radiofrequency valvotomy. In one study, the

procedure was successful in three-quarters of the babies who'd had it (9 out of 12 babies). In another study, it worked in nearly all the babies (14 out of 15 babies).

What the experts said

One expert said that it was important that doctors only use radiofrequency valvotomy when there's a good chance that it will be successful.

Risks and possible problems

What the studies said

One study compared the safety of radiofrequency valvotomy with the safety of open surgery to open up the valve. Three of the 19 babies who had the radiofrequency valvotomy died (as a percentage, this is 16%). In comparison, 4 out of 14 babies who had the open operation died (29%).

In another study that followed what happened in babies who had radiofrequency valvotomy, 3 out of 30 babies died soon after the procedure and 2 more babies died some time afterwards.

The studies also showed up other problems in some of the babies who had radiofrequency valvotomy. In a small number of babies, one of

the main blood vessels became damaged – in a study of 30 babies, 1 baby was affected by this, whereas in another study, it happened in 4 out of 12 babies. In another study, 3 out of 18 babies had damage to an area where the blood leaves the heart.

What the experts said

The experts thought that the main risks were likely to be damage to the heart or blood vessels, infection, changes to the heartbeat, and problems with other organs in the body. Cardiac tamponade, in which the heart becomes compressed and tightens up, was another possible problem. They also said that there was a risk that the baby could die during or after the procedure.

What has NICE decided?

Because pulmonary atresia is rare, the studies carried out on radiofrequency valvotomy for pulmonary atresia have involved only small numbers of babies. This means that the results from these studies (the evidence that NICE looks at) might not show up the true picture of how well the procedure works and how safe it is. But on the basis of the evidence that is currently available, NICE has made the following recommendations.

When doctors use radiofrequency valvotomy for seriously ill babies with pulmonary atresia, they should be sure that:

- the 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 radiofrequency valvotomy for pulmonary atresia should be carried out only in carefully selected patients in specialist centres with paediatric cardiac surgery facilities.

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 (www.ucl.ac.uk/nicor), and is being run by the Department of Health.

Other comments from NICE

Experts in this area have pointed out that doctors are already using radiofrequency valvotomy for seriously ill babies who would die

if they didn't have treatment. This was taken into account by NICE when the recommendations were being made.

What the decision means for you

You may have been offered radiofrequency valvotomy for your baby's pulmonary atresia. 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 selected babies in the NHS. Your doctor should discuss the benefits and risks of radiofrequency valvotomy before you agree to it.

NICE has also encouraged doctors to collect some details about every baby who has this procedure in England and Wales. These details will be held confidentially and will not include babies' 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 radiofrequency valvotomy, you may be asked to agree to your baby's details being entered into an electronic database for this purpose. A clinician looking after your baby 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 baby 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 baby receives. You may want to discuss this guidance with the doctors and nurses looking after them.

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 radiofrequency valvotomy for pulmonary atresia is on the NICE website (www.nice.org.uk/IPG095guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0720. 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 is NHS Direct (telephone 0845 4647), or NHS Direct Online (www.nhsdirect.nhs.uk).

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