

Balloon angioplasty of pulmonary vein stenosis in infants

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

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Information from Interventional Procedure Guidance 75

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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 used in babies called balloon angioplasty of pulmonary vein 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 angioplasty is safe enough and works well enough for it to be used routinely for pulmonary vein stenosis in babies.

To produce this guidance, NICE has:

- looked at the results of studies on the safety of balloon angioplasty of pulmonary vein 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 angioplasty of pulmonary vein stenosis

The pulmonary veins carry blood from the lungs to the heart. Stenosis means narrowing, so pulmonary vein stenosis is narrowing of a pulmonary vein. A baby can be born with this, or it can happen as a result of heart surgery for other reasons. If pulmonary vein stenosis isn't treated, it can cause lung damage.

Balloon angioplasty involves guiding a tube (called a catheter) that has a balloon attached into the narrow section of the pulmonary vein. 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 removed, but sometimes another strong piece of tube called a stent is left in the vein to keep it open.

How well it works

What the studies said

NICE only found four studies that looked at what happened in very young children who had balloon angioplasty. The studies were not very good and involved small numbers of children. The two biggest studies said that the procedure did not help any of the patients who had it. In another study, all three patients who had the procedure had an immediate improvement in their condition as shown by a reduction of pressure in the pulmonary vein (the narrowing makes the pressure in the vein high). In one of these patients, a method of showing what's happening in the vein called angiography showed that the area had been widened. But this patient died from an infection within 36 hours of having the procedure.

What the experts said

The experts thought that if the procedure worked at all, its effects would only last for a short time so the problems would come back quickly. But they also said that there was no other operation that doctors could offer for babies with pulmonary vein stenosis, so even if balloon angioplasty only made a slight difference, it might be better than nothing.

Risks and possible problems

What the studies said

In the studies NICE found, the main problems were:

- a tear in the vein leading to bleeding (haemorrhage) – this happened in one out of five patients in one study
- coughing up blood – this also happened in one out of five patients in one study
- death from infection – this happened in one out of three patients in one study
- a hole made in the end part of the vein – this also happened in one out of three patients in one study.

What the experts said

The experts thought patients could die as a result of having the procedure. They also thought there was a risk that the heart muscle or the pulmonary vein would burst, that there would be a blood clot on the brain or in another part of the body, and that the heartbeat could be affected. Infection was another possible risk.

What has NICE decided?

NICE has decided that if a doctor wants to carry out balloon angioplasty of pulmonary vein stenosis in a baby, he or she should make sure that the parents or carers understand what is involved and that it's not clear whether the procedure works. There should be special arrangements in place so that parents or carers only agree (consent) to the procedure after this discussion has taken place.

NICE has also recommended that balloon angioplasty should only be offered for very poorly babies, and that it should be carried out in specialist children's heart units.

NICE has 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.

NICE may look at the procedure again if new information becomes available.

What the decision means for you

Your doctor may have offered a balloon angioplasty for your baby. NICE has considered this procedure because it is relatively new. NICE has decided that there are uncertainties about the benefits of balloon angioplasty of pulmonary vein stenosis in babies which you need to understand before you agree to it. The doctor caring for your baby should discuss the benefits and risks with you. Some of them 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, you may be asked to agree to your baby's details being entered into an electronic database for this purpose. The doctor 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 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 angioplasty of pulmonary vein stenosis in infants is on the NICE website (www.nice.org.uk/IPG075guidance), or you can order a copy from the website or by telephoning the NHS Response Line on 0870 1555 455 and quoting reference number N0643. The evidence that NICE considered in developing this guidance is also available from the NICE website.

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