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Understanding NICE guidance

Information for people who use NHS services

National Institute for Health and Clinical Excellence

First-stage treatment of babies with an underdeveloped left side of the heart by minimal access surgery (hybrid procedure)

NICE 'HealthTech guidance' advises the NHS on when and how new procedures can be used in clinical practice.

This leaflet is about when and how minimal access surgery ('hybrid procedure') can be used in the NHS to treat newborn babies with an underdeveloped left side of the heart. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

This HealthTech guidance makes recommendations on the safety of a procedure and how well it works. An interventional procedure is a test, treatment or surgery that involves a cut or puncture of the skin, or an endoscope to look inside the body, or energy sources such as X-rays, heat or ultrasound. The guidance does not cover whether or not the NHS should fund a procedure. Decisions about funding are taken by local NHS bodies (primary care trusts and hospital trusts) after considering how well the procedure works and whether it represents value for money for the NHS.

NICE has produced this guidance because the procedure is quite new. This means that there is not a lot of information yet about how well it works, how safe it is and which patients will benefit most from it.

This leaflet is written to help parents and guardians whose baby has been offered this procedure to decide whether to agree (consent) to it or not. It does not describe underdeveloped hearts or the hybrid procedure in detail – a member of your healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your doctor to help you reach a decision. Some sources of further information and support are on page 6.

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What has NICE said?

There is not a lot of information about how well the hybrid procedure works and how safe it is. If a doctor suggests using the hybrid procedure, they should make sure that extra steps are taken to explain the uncertainties about the procedure, its potential risks and the need for further operations. This should happen before the parent or guardian agrees (or doesn't agree) to the hybrid procedure. They should be given this leaflet and other written information as part of the discussion.

NICE has said that there should be special arrangements for monitoring what happens after the procedure. In addition, this procedure should only be done in hospital units that specialise in treating babies with an underdeveloped left side of the heart.

NICE is asking doctors to send information about every infant who has the operation and what happens to them afterwards to a central store of information at the UK Central Cardiac Audit Database (www.ccad.org.uk) so that the safety of the procedure and/or how well it works can be checked over time.

NICE has also said that further information about which babies should be chosen for the hybrid procedure and which parts of the hybrid procedure performed together are most effective would be useful.

This procedure may not be the only possible treatment for newborn babies with an underdeveloped heart.
Your healthcare team should talk to you about whether it is suitable for your baby and about any other treatment options available.

The hybrid procedure

The hybrid procedure is not described in detail here – please talk to your specialist for a full description.

When a baby is born with an underdeveloped left side of the heart, the left side of the heart cannot fill with oxygen-rich blood from the lungs or pump it around the body. Instead, this blood is forced back into the right side through a small hole joining the two sides of the heart. From here, blood can only reach the rest of the body by bypassing the lungs through a small duct joining the major vessels from each side of the heart (the 'ductus arteriosus'). This duct is normal before birth but usually closes in the first few days after birth. Once the duct closes, babies with an underdeveloped left side of the heart are likely to die within the first few weeks of life.

The first stage of standard treatment is a complex, high-risk open heart operation involving heart–lung bypass machinery, which is performed soon after birth (called the 'Norwood procedure').

The hybrid procedure is an alternative that avoids major open heart surgery until the patient is older. It involves two or three parts that may be done together or separately. Two parts are usually performed through the blood vessels ('interventional radiology') and involve a puncture to the skin for access. The first improves the blood flow to the right side of the heart by enlarging the hole in the wall between the left and right sides of the heart, while the second prevents the duct from closing by using an expandable tube (called a 'stent'). Together these enable the right heart to pump blood more easily around the body. The third part of the hybrid procedure involves placing tight bands around the arteries that carry blood from the right side of the heart to the lungs (the 'pulmonary arteries'). These further encourage blood flow through the duct to the body. This part may be done by open chest surgery or

by keyhole surgery, but does not need a heart–lung bypass. Not all babies require all three procedures to be carried out.

Further operations (known as stages 2 and 3) will need to be carried out following the Norwood or hybrid procedure, over three or more years. The patient may need still further operations or a heart transplant later in life.

What does this mean for me and my baby?

If your doctor has offered your baby the hybrid procedure, they should tell you that NICE has decided that the benefits and risks are uncertain. This does not mean that the procedure should not be done, but that your doctor should fully explain what is involved in having the procedure and discuss the possible benefits and risks with you. You should only be asked if you want to agree to this procedure after this discussion has taken place. You should be given written information, including this leaflet, and have the opportunity to discuss it with your doctor before making your decision.

You may want to ask the questions below

- What does the procedure involve?
- Are there alternative procedures?
- What are the risks? How likely are they to happen?
- What care will my baby need after the operation?
- What may happen if my baby doesn't have the procedure?

Summary of possible benefits and risks

Some of the benefits and risks seen in the studies considered by NICE are briefly described below. NICE looked at five studies on this procedure.

How well does the procedure work?

In a study of 58 babies treated by the hybrid procedure, 54 survived the procedure. In this study, 52 babies went on to have the stage 2 operation, of whom 46 survived. In another study of 29 babies, 18 survived the hybrid procedure and went on to have the stage 2 operation. In a smaller study of 14 babies, 8 survived to undergo the stage 2 operation and 6 were still alive after the second operation. Two deaths were reported between the hybrid procedure and stage 2 operations.

In a study of 17 babies treated by the hybrid procedure, 15 survived. Of these, 10 needed a heart transplant and 4 died before they could receive further treatment.

Another study reported on 5 babies treated by the hybrid procedure and 17 treated by the standard Norwood procedure. All 5 babies who had the hybrid procedure survived, but 2 died before they were able to have the stage 2 operation. Of the 17 babies who had the Norwood procedure, 11 survived initially and 1 died later.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that it is hard to tell how well the procedure works as only small numbers of babies have had the procedure. One adviser noted that there was not much information about how well the hybrid procedure works in the long term compared with the standard more complex open heart operation.

Risks and possible problems

In the study of 58 babies, 2 died within 30 days of the operation, and in the study of 29 babies, 5 died while still in hospital. In the study of 17 babies who had the hybrid procedure, 6 had complications with the bands used to narrow the pulmonary arteries. In 2 babies the artery was blocked completely, and in 2 others the restriction of blood flow was too great.

As well as looking at these studies, NICE also asked expert advisers for their views. These advisers are clinical specialists in this field of medicine. The advisers said that the potential complications of the hybrid procedure include death, brain damage, bleeding, infection, heart failure, the stent moving, blocking or narrowing, the bands moving and damage to the pulmonary arteries or the duct.

More information about babies with underdeveloped hearts

NHS Direct online may be a good starting point for finding out more. Your local Patient Advice and Liaison Service (PALS) may also be able to give you further advice and support.

About NICE

NICE produces guidance (advice) for the NHS about preventing, diagnosing and treating different medical conditions. The guidance is written by independent experts including healthcare professionals and people representing patients and carers. They consider how well an interventional procedure works and how safe it is, and ask the opinions of expert advisers. Interventional procedures guidance applies to the whole of the NHS in England, Wales, Scotland and Northern Ireland. Staff working in the NHS are expected to follow this guidance.

To find out more about NICE, its work and how it reaches decisions, see NICE's about our guidance page.

This leaflet is about 'Hybrid procedure for interim management of hypoplastic left heart syndrome in neonates'. This leaflet and the full guidance aimed at healthcare professionals are also available at www.nice.org.uk/guidance/HTG158

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1437).

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