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Understanding NICE guidance

Information for people who use NHS services

Treating hernia of the diaphragm in newborn babies with keyhole surgery through the chest

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 keyhole surgery through the chest can be used in the NHS to treat newborn babies with hernia of the diaphragm. 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 people whose babies have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe hernia of the diaphragm or the procedure in detail – a member of your baby's healthcare team should also give you full information and advice about these. The leaflet includes some questions you may want to ask your baby's doctor to help you reach a decision. Some sources of further information and support are on page 6.

What has NICE said?

This procedure can be offered routinely as a treatment option for babies with hernia of the diaphragm provided that doctors are sure that:

- parents understand what is involved and agree to the treatment, and
- the results of the procedure are monitored.

Parents should be told that it is possible that the procedure could be changed to standard open abdominal surgery and that there is also a risk of the hernia recurring. Surgeons performing this procedure should have specific training and experience in keyhole thoracic surgery in newborn babies and children.

NICE encourages collaboration between hospital departments that perform this procedure to collect data and publish results.

Other comments

The evidence that NICE looked at included infants between 30 days and 12 months.

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

Treating hernia of the diaphragm in newborn babies with keyhole surgery through the chest

The medical name for this procedure is 'Thoracoscopic repair of congenital diaphragmatic hernia in the newborn'.

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

Congenital diaphragmatic hernia is a condition present at birth caused by failure of the diaphragm to form properly during a baby's

development in the womb. The most common defect is usually referred to as Bochdalek hernia; the other is called Morgagni's hernia.

This condition is currently managed initially with supportive care, which usually involves the baby being put on a ventilator to help or take over breathing and allow the baby's condition to improve sufficiently for surgery to be carried out.

The aim of the procedure, which is normally carried out for a Bochdalek hernia, is to push the abdominal organs that have moved into the chest cavity back to a normal position and to repair the abnormal diaphragm. It is carried out with the baby under general anaesthesia. Several small cuts are made into the chest to insert special surgical instruments. These are then used to move the abdominal organs back to their normal place and to repair the diaphragm with stitches or patches. After surgery, babies will normally need a temporary chest drain and continue to be on a ventilator until they are able to breathe by themselves.

What does this mean for me?

NICE has said that this procedure is safe enough and works well enough for use in the NHS. If your baby's doctor thinks treating hernia of the diaphragm with keyhole surgery through the chest is a suitable treatment option for your baby, he or she should still make sure you understand the benefits and risks before asking you to agree to it.

You may want to ask the questions below

- What does the procedure involve?
- What are the benefits my baby might get?
- How good are the baby's chances of getting those benefits? Could having the procedure make it worse?
- Are there alternative procedures?
- What are the risks of the procedure?
- Are the risks minor or serious? How likely are they to happen?
- What care will the baby need after the operation?
- What happens if something goes wrong?
- What may happen if my baby does not have the procedure?

You might decide your baby has this procedure, has a different procedure, or doesn't have a procedure at all.

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 10 studies on this procedure.

How well does the procedure work?

In 3 studies that looked at recurrence rates, overall the hernia returned in more patients treated by the thoracoscopic (keyhole surgery in the chest) procedure (10 out of 62 patients) compared with those treated by the open procedure (4 out of 81 patients).

A study of 30 patients reported that the hernia was easy to treat in 15 of the 18 patients who had the thoracoscopic procedure compared with 5 out of 12 patients who had the laparoscopic procedure (keyhole surgery within the abdomen or pelvic area.) There was a 'difficult' repair in 2 thoracoscopic and 4 laparoscopic patients, and it was impossible to reduce the hernia in 1 thoracoscopic patient and 3 laparoscopic patients. A study of 45 patients reported that repair of the hernia was 'easily accomplished' in 30 patients.

In 2 studies the thoracoscopic procedure had to be changed to an open procedure in a total of 5 out of 102 patients.

In a study of 73 patients, those in the thoracoscopic group had to be ventilated for around 2 days after the procedure, compared with around 4 days for the group that had open surgery. In a study of 57 patients, both groups were ventilated for around 5 days.

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 key success outcomes are a reduction in abdominal adhesions (internal scar tissue) after the operation, a

reduction in pain after the operation, duration of hospital stay, a quicker return to milk feeding and a better cosmetic appearance.

Risks and possible problems

In 3 studies the overall combined death rate was higher in patients in the open surgery group (10 out of 81 patients) compared with the thoracoscopic group (2 out of 62 patients).

In the study of 73 patients, 1 patient who had the open procedure died from haemorrhage (bleeding). In a study of 45 patients who had the thoracoscopic procedure 1 patient died from severe bronchopneumonia (inflammation in the airways of the lungs) and another died from pneumothorax (collapsed lung).

A study of 57 patients reported no significant difference in major infection rates in those who had the procedure compared with those who had open surgery (5 out of 29 patients in the thoracoscopic group and 1 out of 28 patients in the open group). In the same study 2 patients from both groups had perforations in their digestive tract.

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 in theory, problems could include injury to the abdominal organs, physiological instability and too much carbon dioxide in the blood.

More information about hernia

NHS Choices (www.nhs.uk) may be a good place to find out more. Your local patient advice and liaison service (usually known as PALS) may also be able to give you further information 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. This 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 www.nice.org.uk/aboutguidance

This leaflet is about 'thoracoscopic repair of congenital diaphragmatic hernia in the newborn'. This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/guidance/HTG247

You can order printed copies of this leaflet from NICE publications (phone 0845 003 7783 or email publications@nice.org.uk and quote reference N2420). The NICE website has a screen reader service called Browsealoud, which allows you to listen to our guidance. Click on the Browsealoud logo on the NICE website to use this service.

We encourage voluntary organisations, NHS organisations and clinicians to use text from this booklet in their own information about this procedure.

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