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What has NICE said?

There is evidence that <u>telemetric adjustable (remote-controlled) pulmonary artery banding</u> works but the evidence does not clearly show which babies benefit from having this procedure. There is not much good evidence about how safe this procedure is. It should only be used if extra care is taken to explain the risks and extra steps are put in place to record and review what happens.

What does this mean for me and my baby?

Your health professional should fully explain what is involved in having this procedure and discuss the possible benefits and risks for your baby with you. In particular, they should explain the uncertainty about the evidence on how likely it is to improve your baby's symptoms and the possible complications. You should also be told how to find more

information about the procedure. You should only be asked if you want to agree to this procedure after having this discussion.

Your health professional should ask you if details of your baby's procedure can be collected.

Your healthcare team

A healthcare team experienced in managing babies and children with congenital heart defects, in a paediatric cardiac centre, should decide which patients should be offered this procedure.

The condition

Congenital heart defects develop in the womb, before a baby is born. There are many different types of congenital heart defects. Some heart defects allow blood to flow from the left to the right side of the heart. For example, the pumping chambers of the heart may not be properly formed, the valves of the heart may not work properly or the main blood vessels (aorta and pulmonary artery) may not be connected to the heart correctly. These types of defects need open heart surgery to fix them, but this cannot be done until the baby is big enough. Pulmonary artery banding is a procedure used in babies before open heart surgery to correct a heart defect. It does not fix the defect but aims to improve symptoms, decrease blood flow and reduce blood pressure in the pulmonary artery. In standard pulmonary artery banding, frequent surgery is needed to adjust the band as the baby grows. NICE has looked at using a type of pulmonary artery band that can be adjusted without further surgery, using a remote control, as another treatment option.

NHS Choices may be a good place to find out more.

The procedure

Pulmonary artery banding is done under general anaesthetic. A small cut is made in the front or side of the baby's chest. The telemetric adjustable (remote-controlled) band is passed through this opening, placed around the pulmonary artery and stitched in place. The band is then adjusted using a hand-held remote control to activate a small motor in the band. This tightens or loosens the band to control the blood flow and reduce blood

pressure in the pulmonary artery. As the baby grows the band can be adjusted by a doctor at an outpatient appointment. Later, when the child is older, the band is removed during open heart surgery to fix the heart defect.

Benefits and risks

When NICE looked at the evidence, it decided that there was some evidence that the procedure worked but the evidence did not clearly show which babies benefit from having this procedure. It also decided that there was not enough evidence to know whether the procedure is safe enough. The procedure should therefore only be used when extra steps are put in place. The 8 studies that NICE looked at involved a total of 64 babies.

Generally, they showed the following benefits:

- a study of 40 babies showed that, compared to standard pulmonary artery banding, babies who had a remote-controlled adjustable band spent a shorter time on a ventilator after the operation, needed a shorter period in intensive care and left hospital quicker. But another study of 19 babies showed no difference in these outcomes
- in a study of 20 babies, open heart surgery to fix a large hole in the middle of the heart was not delayed in 7 babies who had an adjustable band. But of 13 babies who had a standard band, 6 had to wait longer for open heart surgery
- in a study of 20 babies with a leaky heart valve, the flow of blood through the heart improved in 2 babies who had an adjustable band but became worse in 2 babies who had a standard band
- in a study of 10 babies who had pulmonary artery banding to retrain the left ventricle of the heart, improvements in pulmonary blood pressure at 20-month follow-up were similar in babies who had a standard band and in babies who had an adjustable band.

The studies showed that the risks of the procedure included:

 in a study of 40 babies, 2 babies who had an adjustable band died 30 days after having the procedure. Five babies who had a standard band died (3 within 30 days and 2 after 30 days)

- in 1 baby the band cut through the pulmonary artery and caused a blood clot. The baby needed further surgery to remove the clot and reconstruct the pulmonary artery, and then recovered
- in 2 babies who had an adjustable band,1 baby needed more surgery to drain excess fluid from around the heart and 1 baby needed more surgery to remove the band because it was too big
- in a study of 19 babies, at the time of open heart surgery to fix the defect, a patch to strengthen the pulmonary artery was needed in 4 babies who had an adjustable band and in 1 baby who had a standard band
- 3 babies who had an adjustable band developed blood poisoning, which was successfully treated with antibiotics.

NICE was also told about some other possible risks. The band may move from its correct position or have to be taken out because of complications; the band may lose the wireless connection with the remote control so that it cannot be adjusted; the remote control may stop working; the band may not adjust properly; it may cause a leak in the pulmonary valve in the heart; or put pressure on the heart.

If you want to know more about the studies, see the <u>guidance</u>. Ask your health professional to explain anything you don't understand.

Questions to ask your health professional

- What does the procedure involve?
- What are the benefits I might get?
- How good are my chances of getting those benefits? Could having the procedure make me feel 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 I need after the procedure?

- · What happens if something goes wrong?
- What may happen if I don't have the procedure?

About this information

NICE <u>interventional procedures guidance</u> advises the NHS on the safety of a procedure and how well it works.

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Accreditation

