NHS
National Institute for Health and Clinical Excellence

Understanding NICE guidance

Information for people who use NHS services

Treatment of tumours with percutaneous laser therapy in unborn babies

NICE 'interventional procedure guidance' advises the NHS on when and how new surgical procedures or procedures that use electromagnetic radiation (such as X-rays, lasers and gamma rays) can be used.

This leaflet is about when and how percutaneous laser therapy can be used to treat tumours in unborn babies in the NHS in England, Wales and Scotland. It explains guidance (advice) from NICE (the National Institute for Health and Clinical Excellence).

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 who have been offered this procedure to decide whether to agree (consent) to it or not. It does not describe tumours in unborn babies or the 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.

Information about NICE interventional procedure guidance 180
Issue date: June 2006

What has NICE said?

There are still uncertainties over the safety of this procedure and how well it works. If a doctor wants to use percutaneous laser therapy, he or she should make sure that extra steps are taken to explain the uncertainty and the likely benefits and potential risks of the procedure. This should happen before the parents agree (or don't agree) to the procedure. The parents should be given this leaflet and other written information as part of the discussion.

There should also be special arrangements for monitoring what happens when an unborn baby has had this procedure. NICE is asking doctors to send information about every unborn baby that has the operation and what happens afterwards to a central store of information so that the safety of the procedure and/or how well it works can be checked over time.

This procedure should only be carried out in specialist centres, by a multidisciplinary team.

Other comments from NICE

The procedure might also be used to treat other fetal tumours.

Percutaneous laser therapy

This procedure may not be the only possible treatment for tumours in unborn babies. Your healthcare team should talk to you about whether this is suitable for your baby and about any other treatment options available.

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

During development, an unborn baby may develop a tumour. The tumour may be a:

- congenital cystic adenomatoid malformation (CCAM), which is usually non-cancerous (benign)
- sacrococcygeal teratoma, which may be benign or cancerous (malignant).

The outlook for a baby with these tumours is poor. Many babies die in the womb before birth, at birth or soon afterwards. Other risks include premature (early) labour and difficulties with the birth.

This procedure may be an option for unborn babies who have heart or lung problems. The mother is lightly sedated and local anaesthetic is applied to her abdomen. A needle is inserted through the mother's abdomen and a pain killer is injected into the baby. The needle is then inserted into the tumour. Laser energy is passed down the needle causing it to shrink. The procedure can be repeated if needed.

Summary of possible risks and benefits

Some of the benefits and risks seen in the studies considered by NICE are **briefly** described below. NICE looked at reports of seven unborn babies who underwent this procedure.

You might decide to have this procedure, to have a different procedure, or not to have a procedure at all.

How well does the procedure work?

The studies NICE looked at included a total of 98 unborn babies. Seven were treated with percutaneous laser therapy – five had sacrococcygeal teratomas and two had CCAM. Two of the five babies who had teratomas died in the womb, one died at birth and two were born alive. One of the babies that was born alive had two treatments in the womb. The baby was delivered by caesarean section at 37 weeks' gestation and the tumour was removed by surgery after birth. The baby was healthy and developing normally at 8 months of age.

What does this mean for me?

If your doctor has offered percutaneous laser therapy for treating a tumour in your baby, he or she 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 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.

NICE has recommended that some details should be collected about every patient who has this procedure in England and Wales. If you decide to have this procedure, you will be asked to agree to your details being collected. You will be asked to sign a consent form. If you do not agree to the details being collected, you can still have the procedure.

You may want to ask the questions below

- What does the procedure involve?
- What might the benefits for my unborn baby be?
- How good are the chances of my baby 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 and my unborn baby need after the operation?
- What happens if something goes wrong?
- What may happen if I don't have the procedure?

One of the unborn babies with CCAM had two treatments in the womb. The first treatment improved heart function and decreased blood flow in the tumour. The baby was delivered at 38 weeks' gestation and the tumour was removed by surgery after birth.

The other baby also had two treatments but both had to be stopped early because its heart rate decreased during the procedure. The first treatment reduced the size of the tumour but hydrops fetalis (excess fluid in the unborn baby) was worse 4 days after the treatment. The outcome after the second treatment was not reported.

Expert advisers stated that the benefits of this procedure are uncertain.

Risks and possible problems

The baby with CCAM who survived to birth died 4 days after birth from infection. The other baby with CCAM was found to have died in the womb at a routine antenatal visit 3 days after the second treatment.

One of the unborn babies with sacrococcygeal teratoma had to have a blood transfusion in the womb because it developed bleeding after the first treatment. The blood was drained from the tumour area and amniotic fluid during the second treatment.

The expert advisers stated that there is a risk of excessive bleeding or death of the unborn baby as a result of the procedure. Also, the tumour may continue to grow. The effects on other parts of the unborn baby's body are not known. Risks to the mother include premature labour and burn from the needle.

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. 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/about guidance

This leaflet and the full guidance aimed at healthcare professionals are available at www.nice.org.uk/IPG180

You can order printed copies of this leaflet from the NHS Response Line (phone 0870 1555 455 and quote reference N1065).

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ISBN
978-1-4731-9149-5
N1065 1P Jun 06