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Percutaneous laser therapy for fetal tumours

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NICE interventional procedure guidance 180

www.nice.org.uk/ipg180

Contents

1 Guidance	3
2 The procedure	4
2.1 Indications	4
2.2 Outline of the procedure	4
2.3 Efficacy	5
2.4 Safety	6
2.5 Other comments	6
3 Further information	7
Sources of evidence	7
Information for patients	7
4 Changes since publication	8
5 About this guidance	9

1 Guidance

- 1.1 Current evidence on the safety and efficacy of percutaneous laser therapy for fetal tumours does not appear adequate for this procedure to be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake percutaneous laser therapy for fetal tumours should take the following actions.
- Inform the clinical governance leads in their Trusts.
 - Ensure that parents understand the uncertainty about the procedure's safety and efficacy. Clinicians should provide parents with clear written information and counselling support, both before and after the procedure. In addition, use of the Institute's [information for the public](#) is recommended.
 - Audit and review clinical outcomes of all patients undergoing percutaneous laser therapy for fetal tumours.
- 1.3 This procedure should only be performed in centres specialising in invasive fetal medicine and in the context of a multidisciplinary team that includes a consultant in fetal medicine, a midwife, a neonatologist and a paediatric surgeon.
- 1.4 Data on all procedures should be entered onto the [European Commission registry](#), which is endorsed by the British Maternal and Fetal Medicine Society.
- 1.5 Publication of safety and efficacy outcomes will be useful. The Institute may review the procedure on publication of further evidence.

2 The procedure

2.1 Indications

- 2.1.1 Congenital cystic adenomatoid malformations (CCAM) are usually benign tumours, although sacrococcygeal teratomas may be malignant. These tumours can become very large and highly vascular, causing stress on the heart of the fetus. They can lead to the development of non-immune hydrops fetalis (in utero heart failure) and may be complicated by polyhydramnios (excessive accumulation of amniotic fluid). Non-immune hydrops fetalis, placentomegaly, cardiomegaly, large tumour size and high tumour growth rate are associated with poor prognosis, and fetal mortality is high. Obstetric complications include preterm labour and dystocia.
- 2.1.2 The current options in managing pregnancies with these fetal tumours are: termination of the pregnancy; continuation of the pregnancy without intervention; interventional treatments such as alcohol sclerosis or cyst drainage; and early elective caesarean delivery if significant problems develop. In the latter case, the prognosis is poor even when the fetus is approaching term.

2.2 Outline of the procedure

- 2.2.1 Percutaneous laser therapy for fetal tumours is performed under maternal local anaesthesia and light sedation. A needle is inserted through the mother's abdomen into the uterine cavity under ultrasonographic guidance. An analgesic is then injected subcutaneously or intramuscularly into the fetus, before advancing the needle to the site of the tumour. Colour Doppler imaging is used to guide placement of the needle. A laser fibre is passed through the needle lumen and laser energy is delivered in pulses, causing the blood vessels within the tumour to coagulate. If necessary, laser therapy can be repeated in a further session, usually 1 or more weeks later. Cystic components of tumours may be aspirated during the procedure.

2.3 Efficacy

- 2.3.1 The efficacy and safety of the procedure are based on reports on seven fetuses: two with CCAM and five with sacrococcygeal teratoma.
- 2.3.2 In a case series of 29 fetuses with sacrococcygeal teratomas, four were treated by percutaneous laser therapy; there were two intrauterine fetal deaths, one neonatal death and one live birth.
- 2.3.3 In a case series of 67 fetuses diagnosed with cystic lung abnormalities, one fetus with CCAM received two percutaneous laser treatments. Reductions in non-immune hydrops fetalis, mediastinal shift, ascites and blood flow within the tumour were reported following the first treatment. The neonate was delivered at 38 weeks' gestation; surgical excision of the tumour was performed after birth.
- 2.3.4 In one case report, a fetus with CCAM received two percutaneous laser treatments, both of which had to be terminated early because of fetal bradycardia. Reduction in tumour size was reported following the first treatment. No outcomes were reported following the second treatment.
- 2.3.5 In another case report, a fetus with sacrococcygeal teratoma received two percutaneous laser treatments. The neonate was delivered by elective caesarean section at 37 weeks' gestation and the tumour was surgically excised after birth. The baby was reported to be healthy and developing normally at 8 months of age. For more details, refer to the 'Sources of evidence' section.
- 2.3.6 The Specialist Advisers stated that there is uncertainty about the effectiveness of the procedure. Key efficacy outcomes include a decrease in the vascularity of the fetal tumour, leading to potential shrinkage of the tumour in utero, and reduction in cardiac failure in the fetus.

2.4 Safety

- 2.4.1 In the case series of 67 fetuses with cystic lung abnormalities, the fetus who received two percutaneous laser treatments died 4 days after birth from sepsis-related complications.
- 2.4.2 In the case report of a fetus with CCAM, worsening of non-immune hydrops fetalis was reported 4 days after the first treatment. Three days after the second treatment (at a scheduled visit), the fetus was found to have died.
- 2.4.3 In another case report of a fetus with sacrococcygeal teratoma, bleeding (possibly within the cystic area) occurred following the first treatment, requiring intrauterine blood transfusion. Drainage of blood from the cystic area and drainage of amniotic fluid were performed during the second treatment. For more details, refer to the 'Sources of evidence' section.
- 2.4.4 The Specialist Advisers stated that theoretical risks include haemorrhage and procedure-related fetal death. There are also uncertainties about the potentially harmful effects of the procedure on other anatomical areas. The theoretical risks to the mother include preterm labour following the procedure, and laser burn if the needle is not sited correctly.

2.5 Other comments

- 2.5.1 It was noted that the procedure might also be used to treat other fetal tumours such as cystic hygromas.

Andrew Dillon
Chief Executive
June 2006

3 Further information

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document.

'Interventional procedure overview of percutaneous laser therapy for fetal tumours', October 2005.

Information for patients

NICE has produced information on this procedure for patients and carers. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

4 Changes since publication

The guidance was considered for reassessment in June 2009 and it was concluded that NICE will not be updating this guidance at this stage. However, if you believe there is new evidence which should warrant a review of our guidance, please [contact us](#).

19 January 2012: minor maintenance.

5 About this guidance

NICE interventional procedure guidance makes recommendations on the safety and efficacy of the procedure. It does not cover whether or not the NHS should fund a procedure. Funding decisions are taken by local NHS bodies after considering the clinical effectiveness of the procedure and whether it represents value for money for the NHS. It is for healthcare professionals and people using the NHS in England, Wales, Scotland and Northern Ireland, and is endorsed by Healthcare Improvement Scotland for implementation by NHSScotland.

This guidance was developed using the NICE [interventional procedure guidance](#) process.

It has been incorporated into the [NICE pathway on antenatal care](#), along with other related guidance and products.

We have produced a [summary of this guidance for patients and carers](#). Information about the evidence it is based on is also [available](#).

Your responsibility

This guidance represents the views of NICE and was arrived at after careful consideration of the available evidence. Healthcare professionals are expected to take it fully into account when exercising their clinical judgement. This guidance does not, however, override the individual responsibility of healthcare professionals to make appropriate decisions in the circumstances of the individual patient, in consultation with the patient and/or guardian or carer.

Implementation of this guidance is the responsibility of local commissioners and/or providers. Commissioners and providers are reminded that it is their responsibility to implement the guidance, in their local context, in light of their duties to avoid unlawful discrimination and to have regard to promoting equality of opportunity. Nothing in this guidance should be interpreted in a way which would be inconsistent with compliance with those duties.

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