NICE guidance

Therapeutic amnioinfusion for oligohydramnios during pregnancy (excluding labour)

Interventional procedures guidance
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Your responsibility

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

Commissioners and/or providers have a responsibility to implement the guidance, in their local context, in light of their duties to have due regard to the need to eliminate unlawful discrimination, advance equality of opportunity, and foster good relations. Nothing in this guidance should be interpreted in a way that would be inconsistent with compliance with those duties.

Commissioners and providers have a responsibility to promote an environmentally sustainable health and care system and should assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

1 Guidance

1.1 Current evidence on the safety and efficacy of therapeutic amnioinfusion for oligohydramnios during pregnancy (excluding labour) does not appear adequate for this procedure to be used without special arrangements for consent and for

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audit or research. Most of the evidence on the procedure relates to preterm premature rupture of membranes, rather than other causes of oligohydramnios.

1.2 Clinicians wishing to undertake therapeutic amnioinfusion for oligohydramnios during pregnancy (excluding labour) 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, including the potential risks to the mother, and provide them with clear written information. In addition, use of the Institute's information for patients is recommended.
- Audit and review clinical outcomes of all patients having therapeutic amnioinfusion for oligohydramnios during pregnancy (see section 3.1).

1.3 Therapeutic amnioinfusion for oligohydramnios during pregnancy should only be performed in centres specialising in invasive fetal medicine and in the context of a multidisciplinary team, which may include a consultant in fetal medicine, a neonatologist and a specialist midwife.

1.4 Further research will be useful. Clinicians are encouraged to enter patients into well-designed randomised controlled trials comparing therapeutic amnioinfusion with no intervention. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 An abnormally low volume of amniotic fluid surrounding the fetus is termed oligohydramnios.

2.1.2 Oligohydramnios may be the result of decreased fetal urine production or excretion, or excessive loss of amniotic fluid. Causes of oligohydramnios include premature preterm rupture of amniotic membranes, congenital abnormalities of the fetus's urinary tract, placental insufficiency, twin-to-twin transfusion syndrome, post-maturity (more than 42 weeks' gestation), problems with maternal health, such as high blood pressure, and some medications. Severe

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oligohydramnios in early pregnancy may lead to the underdevelopment of fetal lung tissue (pulmonary hypoplasia) and limb defects and is associated with poor fetal growth. There is also an increased risk of miscarriage, premature birth and stillbirth.

2.1.3 Oligohydramnios is not routinely treated during pregnancy. There is some evidence that maternal hydration can increase the volume of amniotic fluid.

2.2 Outline of the procedure

2.2.1 Under ultrasound guidance, isotonic fluid, such as normal saline or Ringer's lactate, is infused into the amniotic cavity via a needle inserted through the uterine wall, to restore the volume of amniotic fluid to normal. The procedure may be repeated on a regular basis if oligohydramnios recurs (serial amnioinfusion).

2.3 Efficacy

2.3.1 A randomised controlled trial of 34 pregnant women reported a significantly lower incidence of pulmonary hypoplasia among fetuses of pregnancies treated with amnioinfusion compared with the controls – (12% (2/17) versus 53%(9/17); relative risk 0.22; 95% confidence interval 0.05 to 0.87, $p < 0.05$). A non-randomised comparative study reported a rate of pulmonary hypoplasia among neonates of 23% (6/26) in the treated group compared with 31% (4/13) in the control group (not significantly different).

2.3.2 In a randomised controlled trial comparing amnioinfusion with expectant management, neonatal mortality was 6% (1/17) in both the treated group and the control group 6% (1/17). A non-randomised controlled study reported neonatal mortality (excluding stillbirths) of 18% (2/11) in the treated group compared with 71% (5/7) in the expectant-management group ($p = 0.05$). In another non-randomised comparative study, mortality within the first week after birth was 23% (6/26) in the treated group compared with 38% (5/13) in the expectant-management group (not significantly different). A third non-randomised comparative study reported a survival rate of 73% (8/11) for neonates treated with amnioinfusion and 21% (6/29) for those managed expectantly ($p < 0.05$). For more details, refer to the 'Sources of evidence' section.

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2.3.3 The Specialist Advisers stated that key efficacy outcomes include prolongation of gestation, reduced incidence of pulmonary hypoplasia and improved neonatal survival.

2.4 Safety

2.4.1 A non-randomised comparative study including 45 women treated with serial amnioinfusion reported onset of labour shortly after the procedure in one case (2%).

2.4.2 One non-randomised comparative study reported miscarriage in 11% (3/28) of women with unruptured membranes and 21% (5/24) of women with ruptured membranes treated with amnioinfusion. A second non-randomised, retrospective case series reported miscarriage in 12% (2/17) of pregnancies. Four studies reported intrauterine fetal death rates ranging from 0% (0/15) to 14% (4/28) in pregnancies treated with amnioinfusion, and from 0% (0/14) to 38% (11/29) in pregnancies managed expectantly.

2.4.3 Other complications included placental abruption in 0% (0/11) to 25% (3/12) of cases and chorioamnionitis in 0% (0/11) to 32% (8/25) of cases. A study including 12 women treated with amnioinfusion reported that one neonate had a laceration on the leg that required sutures, which was attributed to the procedure. For more details, refer to the 'Sources of evidence' section.

2.4.4 The Specialist Advisers listed potential adverse events as including premature labour and delivery, fetal death, fetal trauma, infection, uterine perforation and premature rupture of membranes.

3 Further information

3.1 This guidance requires that clinicians undertaking the procedure make special arrangements for audit. The Institute has identified relevant audit criteria and developed an audit tool (which is for use at local discretion).

Andrew Dillon
Chief Executive
November 2006

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Sources of evidence

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

'Interventional procedures overview of therapeutic amnioinfusion for oligohydramnios during pregnancy (excluding labour)', April 2006.

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 November 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. Tools to help you put the guidance into practice and information about the evidence it is based on are also available.

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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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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

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