

Insertion of pleuro–amniotic shunt for fetal pleural effusion

1 Guidance

- 1.1 Current evidence on the safety and efficacy of pleuro–amniotic shunts to drain fetal pleural effusions appears adequate. However, there are uncertainties about the natural history of fetal pleural effusion and about patient selection. Therefore, this procedure should not be used without special arrangements for consent and for audit or research.
- 1.2 Clinicians wishing to undertake insertion of pleuro–amniotic shunt for fetal pleural effusion should take the following actions.
- Inform the clinical governance leads in their Trusts.
 - Ensure that parents understand the uncertainties around the natural history of the condition and case selection, and provide them with clear written information. Use of the Institute's information for patients ('Understanding NICE guidance') is recommended (available from www.nice.org.uk/IPG190publicinfo).
 - Audit and review clinical outcomes of all patients who undergo insertion of pleuro–amniotic shunt for fetal pleural effusion (see section 3.1).
- 1.3 This procedure should only be performed in centres that specialise in invasive fetal medicine and in the context of a multidisciplinary team, which should include a consultant in fetal medicine, a neonatologist and a specialist midwife.
- 1.4 Further evidence on case selection will be useful. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

- 2.1.1 A fetal pleural effusion may be associated with many different conditions, such as chromosomal abnormalities, congenital malformations, chylothorax, anaemia, heart defects and infections. Some resolve spontaneously before birth.
- 2.1.2 The presence of a large persistent pleural effusion can prevent normal lung growth and development, and progression in size can result in fetal death. Major factors influencing postnatal survival are underlying aetiology, whether delivery is preterm and whether pulmonary hypoplasia or hydrops fetalis are present.
- 2.1.3 Prenatal interventions include thoracocentesis and drainage. If fluid re-accumulates, repeated procedures may be required. Postnatally, if the effusion (with or without pulmonary hypoplasia) causes respiratory compromise, immediate drainage and intensive respiratory support are required.

2.2 Outline of the procedure

- 2.2.1 The procedure involves insertion of a drainage tube through the fetal chest wall into the pleural space, allowing drainage of fluid into the amniotic cavity. Different types of drainage tubes may be used.
- 2.2.2 Under ultrasound guidance and using sedation and local anaesthesia, a cannula on a trochar is introduced through the mother's abdominal and uterine walls into the amniotic cavity and inserted through the fetal chest wall, into the effusion. A drainage catheter is inserted into the cannula and placed with one end in the pleural cavity and the other in the amniotic cavity. The final position of the catheter is confirmed by ultrasound. Serial ultrasound scans are used to monitor resolution of the effusion, absence or resolution of hydrops

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This guidance is written in the following context

This guidance represents the view of the Institute, which 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.

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This guidance is endorsed by NHS QIS for implementation by NHSScotland.

fetalis and lung growth. If fluid re-accumulates, another shunt may be inserted. After delivery, the drainage tube is immediately clamped and removed to prevent the development of pneumothorax.

2.3 Efficacy

- 2.3.1 In one case series, effective drainage and lung expansion was achieved in 98% (46/47) of fetuses treated with pleuro-amniotic shunt. This produced resolution (where present) of polyhydramnios in 67% (20/30) and of hydrops fetalis in 46% (13/28) of fetuses.
- 2.3.2 Postnatal respiratory morbidity did not occur in any infant included in two case series (n = 47 and n = 21) at follow-up of between 2 months and 6 years. Another case series reported that none of 17 infants had respiratory symptoms at the time of final follow-up, although 35% (6/17) did have respiratory problems requiring medication at some stage of postnatal development.
- 2.3.3 Survival beyond the neonatal period following the insertion of a shunt to drain a pleural effusion was reported across case series to be 48% (10/21), 58% (28/48), 66% (29/44), 67% (6/9) and 100% (3/3), although the severity of the effusion and underlying pathology varied across the studies. In two case series, survival of fetuses with pleural effusions not associated with hydrops fetalis was 60% (3/5) and 100% (15/15).
- 2.3.4 One study found that re-accumulation of the pleural effusion required a new shunt to be inserted in 8% (4/49) of fetuses. In another series, repeat shunt placement was required in 33% (3/9) of fetuses, and in a third series re-accumulation of pleural effusion occurred in 6% (1/17) of fetuses. For more details, refer to the 'Sources of evidence' section.
- 2.3.5 The Specialist Advisers commented that, in some instances, a fetal pleural effusion may resolve spontaneously, and there has to be a balance between treatment risks and the natural progression of the effusion. They also commented that treatment outcomes may be related to case selection, and that indications for the procedure are not yet well established.

2.4 Safety

- 2.4.1 Only one study (n = 13) provided details about intraoperative complications. In one fetus with bilateral effusions, a traumatic haemothorax occurred during insertion of a second shunt.

2.4.2 The most commonly reported complications arose during the gestational period following insertion of a shunt. In one case series, 1 of 10 fetuses died as a result of shunt complications; in another study, 1 of 9 fetuses died as a result of a shunt insertion complication. Unilateral arm oedema in a fetus was also reported in a series of 10 cases.

2.4.3 Displacement of the shunt into the thorax was reported in 23% (3/13) of fetuses at three separate centres within one case series. All three fetuses with shunt displacement into the chest were asymptomatic at the final follow-up, despite the shunt not being removed. For more details, refer to the 'Sources of evidence' section.

2.4.4 The Specialist Advisers noted a range of adverse events, including complications related to the shunt, such as displacement and blockage, trauma to the fetus, maternal infection and incidents of preterm labour and fetal death.

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) available from www.nice.org.uk/IPG190

Andrew Dillon
Chief Executive
September 2006

'Understanding NICE guidance'

NICE has produced information describing its guidance on this procedure for patients and carers ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with patient consent in mind. This information is available from www.nice.org.uk/IPG190publicinfo

Sources of evidence

The evidence considered by the Interventional Procedures Advisory Committee is described in the following document. 'Interventional procedure overview of insertion of pleuro-amniotic shunt for fetal pleural effusion', March 2006.

Available from: www.nice.org.uk/IP333overview

Ordering information

Copies of this guidance can be obtained from the NHS Response Line by telephoning 0870 1555 455 and quoting reference number N1118. 'Understanding NICE guidance' can be obtained by quoting reference number N1119.

The distribution list for this guidance is available at www.nice.org.uk/IPG190distributionlist

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Interventional procedures guidance makes recommendations on the safety and efficacy of a procedure. 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 the clinical effectiveness of the procedure and whether it represents value for money for the NHS.

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