



Insertion of pleuro-amniotic shunt for fetal pleural effusion

Interventional procedures guidance Published: 27 September 2006

www.nice.org.uk/guidance/ipg190

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, and specifically any special arrangements relating to the introduction of new interventional procedures. 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.

All problems (adverse events) related to a medicine or medical device used for treatment or in a procedure should be reported to the Medicines and Healthcare products Regulatory Agency using the <u>Yellow Card Scheme</u>.

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. Providers should ensure that governance structures are in place to review, authorise and monitor the introduction of new devices and procedures.

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

1 Recommendations

- 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 NICE's information for the public is recommended.
 - Audit and review clinical outcomes of all patients who undergo insertion of pleuro-amniotic shunt for fetal pleural effusion (see <u>NICE's interventional</u> <u>procedures outcomes audit tool</u>).
- 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. NICE may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

- 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.
- 2.2.1 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.
- 2.2.2 Prenatal interventions include thoracocentesis and drainage. If fluid reaccumulates, 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.

2.3 Outline of the procedure

- 2.3.1 The procedure involves insertion of a drainage tube though the fetal chest wall into the pleural space, allowing drainage of fluid into the amniotic cavity. Different types of drainage tubes may be used.
- 2.3.2 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 1 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 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.

2.4 Efficacy

- In 1 case series, effective drainage and lung expansion was achieved in 98% (46 out of 47) of fetuses treated with pleuro–amniotic shunt. This produced resolution (where present) of polyhydramnios in 67% (20 out of 30) and of hydrops fetalis in 46% (13 out of 28) of fetuses.
- 2.4.2 Postnatal respiratory morbidity did not occur in any infant included in 2 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 out of 17) did have respiratory problems requiring medication at some stage of postnatal development.
- 2.4.3 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 out of 21), 58% (28 out of 48), 66% (29 out of 44), 67% (6 out of 9) and 100% (3 out of 3), although the severity of the effusion and underlying pathology varied across the studies. In 2 case series, survival of fetuses with pleural effusions not associated with hydrops fetalis was 60% (3 out of 5) and 100% (15 out of 15).
- One study found that re-accumulation of the pleural effusion required a new shunt to be inserted in 8% (4 out of 49) of fetuses. In another series, repeat shunt placement was required in 33% (3 out of 9) of fetuses, and in a third series reaccumulation of pleural effusion occurred in 6% (1 out of 17) of fetuses. For more details, see the <u>overview</u>.
- 2.4.5 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.

2.5 Safety

2.5.1 Only 1 study (n=13) provided details about intraoperative complications. In 1 fetus with bilateral effusions, a traumatic haemothorax occurred during insertion of a

second shunt.

- 2.5.2 The most commonly reported complications arose during the gestational period following insertion of a shunt. In 1 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.
- 2.5.3 Displacement of the shunt into the thorax was reported in 23% (3 out of 13) of fetuses at 3 separate centres within 1 case series. All 3 fetuses with shunt displacement into the chest were asymptomatic at the final follow-up, despite the shunt not being removed. For more details, see the overview.
- 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

Sources of evidence

The evidence considered by the interventional procedures advisory committee is described in the overview.

Information for patients

NICE has produced <u>information for the public on this procedure</u>. It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient consent in mind.

ISBN: 978-1-4731-4283-1

Endorsing organisation

This guidance has been endorsed by <u>Healthcare Improvement Scotland</u>.