Fetal vesico–amniotic shunt for lower urinary tract outflow obstruction

Interventional procedures guidance
Published: 13 December 2006
www.nice.org.uk/guidance/ipg202

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 fetal vesico–amniotic shunt for lower urinary tract outflow obstruction 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 insertion of a fetal vesico–amniotic shunt for lower urinary tract outflow obstruction 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 and provide them with clear written information. In addition, use of the Institute's information for patients ('Understanding NICE guidance') is recommended.
- Audit and review clinical outcomes of all patients having fetal vesico–amniotic shunt for lower urinary tract outflow obstruction (see section 3.1).

1.3 This procedure 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 paediatric urologist, a neonatologist and a specialist midwife.

1.4 Publication of safety and efficacy outcomes will be useful. A randomised trial (PLUTO) comparing fetal vesico–amniotic shunt with no treatment is in progress. Clinicians are encouraged to enter patients into this trial or the associated registry. The Institute may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Fetal lower urinary tract outflow obstruction may be associated with various developmental abnormalities. Lower urinary tract outflow obstruction may develop in a fetus from a number of pathologies, including urethral atresia and posterior urethral valves, and can be partial or complete. Severe obstruction

may lead to oligohydramnios (that is, a reduction in amniotic fluid volume) and abnormal development of the lungs and kidneys (pulmonary and renal dysplasia). Pulmonary and renal dysplasia may cause death soon after birth from respiratory or renal failure, respectively, or the baby may require ventilatory support, renal dialysis or kidney transplantation. The long-term prognosis for children who require dialysis or transplantation in infancy is poor.

2.1.2 There is uncertainty about the criteria for appropriate selection of fetuses for treatment with vesico–amniotic shunting.

2.1.3 Fetal lower urinary tract outflow obstruction is usually managed expectantly or by repeat vesicocentesis. Some cases are managed by termination of the pregnancy.

2.2 Outline of the procedure

2.2.1 The aim of a fetal vesico–amniotic shunt for lower urinary tract outflow obstruction is to decompress the obstructed bladder and restore amniotic fluid dynamics and volume, thereby preventing oligohydramnios and consequent pulmonary and renal dysplasia. Fetal blood is also sampled for chromosomal analysis to help diagnose or exclude concomitant chromosomal abnormalities that may influence management decisions or treatment choices.

2.2.2 The procedure is performed under maternal local anaesthesia and ultrasound guidance. A cannula on a trocar is inserted through the mother's abdominal and uterine walls into the amniotic cavity and subsequently into the bladder of the fetus. A catheter is inserted through the cannula and positioned with one end in the bladder and the other in the amniotic cavity. The cannula is then removed and the final position of the catheter confirmed by ultrasonography. If the fluid reaccumulates or the catheter is dislodged, the procedure can be repeated.

2.3 Efficacy

2.3.1 A meta-analysis of three controlled trials that compared outcomes following vesico–amniotic shunting (n = 59) with no treatment (n = 33) found that vesico–amniotic shunting was associated with a statistically significant improvement in perinatal survival, with an odds ratio (OR) of 2.53 (95% confidence intervals [CI] 1.08 to 5.93, p = 0.03). Postnatal survival was also

better in the vesico–amniotic shunting group, but the results were not statistically significant (OR 2.24, 95% CI 0.89 to 5.59, p = 0.09). In four case series, survival into infancy ranged from 40% (2/5) to 91% (21/23).

2.3.2 In three of the case series, with a maximum of 5.5 years' follow-up, between 25% (2/8) and 33% (2/6 and 6/18) of children required dialysis or underwent renal transplantation. A case series reported renal function as acceptable in 44% (8/18) of infants followed up for a mean period of 5.8 years. Another case series reported good renal function in 75% (6/8) of infants at 1 year's follow-up. One case series reported asthma in 39% (7/18), recurrent pulmonary infections in 28% (5/18) and bladder dysfunction requiring catheterisation in 17% (3/18).

2.3.3 In a case series of 18 children, the mean child self-reported quality-of-life score was 84.2 points at 5.8 years' follow-up, which compared well with a score of 83.0 points in a control population of healthy children, and 77.2 points in chronically ill children in another study. For more details, refer to the 'Sources of evidence' section.

2.3.4 The Specialist Advisers considered vesico–amniotic shunting to be an established procedure but acknowledged that there were limited data to assess its efficacy. They stated that there is uncertainty about selection criteria and about whether the procedure improves outcomes.

2.4 Safety

2.4.1 The evidence on safety came from five case series. The most frequent prenatal complication was shunt displacement, which occurred in 22% (2/9), 28% (5/18) and 60% (9/15) of fetuses and often required insertion of a replacement shunt. One case series reported a single case out of 18 procedures (6%) of premature rupture of the amniotic membranes 4 days after placement of a shunt.

2.4.2 Postnatal complications included one report of bladder prolapse at birth and one report of requirement for intermittent catheterisation. For more details, refer to the 'Sources of evidence' section.

2.4.3 The Specialist Advisers stated that the main potential adverse events for the fetus include preterm labour or spontaneous abortion, shunt blockage or displacement, fetal trauma, fetal hydrops and urinary ascites. Potential

complications for the mother include trauma to the maternal organs and infection.

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
December 2006

Sources of evidence

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

'Interventional procedure overview of fetal vesico–amniotic shunt for lower urinary tract outflow obstruction', April 2006.

Information for patients

NICE has produced information on this procedure for patients and carers ('Understanding NICE guidance'). 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 December 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.

18 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.

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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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.