NICE National Institute for Health and Care Excellence

NICE guidance

Fetal vesico–amniotic shunt for lower urinary tract outflow obstruction

HealthTech 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, 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 Yellow Card Scheme.

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 assess and reduce the environmental impact of implementing NICE recommendations wherever possible.

Contents

This guidance replaces IPG202.

1 Recommendations

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 NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having fetal vesico–amniotic shunt for lower urinary tract outflow obstruction.

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. Clinicians are encouraged to enter patients into randomised controlled trials or observational data studies, including registry studies and real-world evidence. NICE 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 1 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 3 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 4 case series, survival into infancy ranged from 40% (2 out of 5) to 91% (21 out of 23).

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

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 5 case series. The most frequent prenatal complication was shunt displacement, which occurred in 22% (2 out of 9), 28% (5 out of 18) and 60% (9 out of 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 1 report of bladder prolapse at birth and 1 report of requirement for intermittent catheterisation. For more details, see the overview.

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.

Update information

Minor changes after publication

January 2026: Interventional procedures guidance 202 has been migrated to HealthTech guidance 129. The recommendations and accompanying content remain unchanged.

December 2022: We amended recommendation 1.4 to remove reference to clinicians entering patients into the PLUTO trial, because this has now been completed and published. This was replaced with a recommendation to enter patients into randomised controlled trials or observational data studies.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.