NICE guidance

Fetal cystoscopy for the diagnosis and treatment of lower urinary outflow tract obstruction

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, 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.

1 Guidance

1.1 Current evidence on the safety and efficacy of fetal cystoscopy for the diagnosis and treatment of lower urinary outflow tract obstruction is not adequate for this procedure to be used without special arrangements for consent and for audit or research.

1.2 Clinicians wishing to undertake fetal cystoscopy for diagnosis and treatment of lower urinary outflow tract obstruction should take the following actions.

- Inform the clinical governance leads in their Trusts.
- Ensure that the parents understand that the efficacy of the procedure is unproven and that the safety of the procedure is unknown. Clinicians should provide parents with clear written information. Use of the NICE's information for the public is recommended.
- Audit and review clinical outcomes of all patients having fetal cystoscopy for diagnosis and treatment of lower urinary outflow tract 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 an appropriate multidisciplinary team, which should usually include a consultant in fetal medicine, a paediatric urologist, a neonatologist and a specialist midwife.

1.4 Further evidence is required, particularly in relation to appropriate case selection

and outcomes. Reports should separate diagnostic cystoscopy from cystoscopy used with therapeutic procedures. NICE may review the procedure upon publication of further evidence.

2 The procedure

2.1 Indications

2.1.1 Lower urinary outflow tract obstruction in a fetus may be associated with various developmental abnormalities. The obstruction may result from a number of pathologies, including urethral atresia or posterior urethral valves, and can be partial or complete. Severe obstruction may lead to oligohydramnios and pulmonary and/or renal dysplasia. If severe, pulmonary and/or renal dysplasia may cause death soon after birth from respiratory or renal failure, respectively, or the baby may require ventilatory support and/or renal dialysis or kidney transplantation. The long-term prognosis for children who require dialysis or transplantation in infancy is poor. Fetal cystoscopy is therefore indicated only if there is preserved kidney function.

2.1.2 Alternative treatment options include expectant management, termination of the pregnancy, repeat vesicocentesis, open fetal vesicotomy or insertion of a vesico–amniotic shunt. Shunting aims to bypass the obstruction, with a view to definitive treatment of obstructive lesion(s) postnatally.

2.2 Outline of the procedure

2.2.1 Fetal cystoscopy is, in principle, a diagnostic procedure, but it can also be performed with therapeutic intent.

2.2.2 The procedure can be undertaken under maternal general anaesthesia or local anaesthetic infiltration. Under ultrasound guidance, a trocar and cannula are introduced through the maternal abdominal and uterine walls into the amniotic cavity, and then through the fetal abdomen into the bladder. A flexible endoscope

is introduced through the trocar or via the cannula. The bladder wall, ureteric orifices and the orifice of the urethra are inspected, and then the posterior urethra is entered. Posterior urethral valves may be obliterated with hydro-ablation, guide-wire probing or may be ablated with electrocoagulation or laser. The success of treatment is assessed by Doppler imaging of fluid flow from the posterior urethra into the amniotic cavity.

2.3 Efficacy

2.3.1 In a case series, good visualisation of the fetal bladder was achieved in 92% (12 out of 13) of fetuses, and it was possible to enter the posterior urethra in six of these (50%), and to identify the anatomical location of the urinary obstruction in five (42%). All 13 fetuses were suspected of having posterior urethral valves but an alternative diagnosis was reached following cystoscopy in two (15%). In one fetus with a preprocedural diagnosis of urethral atresia, no urethral atresia was found at cystoscopy.

2.3.2 The data relating to cystoscopy-guided therapeutic interventions originated from uncontrolled studies and were of poor quality; they included limited data on clinical outcome. One case series demonstrated successful hydro-ablation of posterior urethral valves in one of four fetuses. In the same series, guide-wire manipulation of posterior urethral valves was successful in five of nine fetuses. Overall in this case series, normal renal function was achieved in five of eight fetuses who survived to a live birth. A second case series reported urethral patency and complete bladder emptying after guide-wire probing in one of 11 fetuses (9%). In the same series, the urethra was successfully cannulated in three of 11 fetuses (27%).

2.3.3 The case series and case reports recorded survival in 0 out of 1, 1 out of 2, 9 out of 13 (69%) and 1 out of 1 fetuses treated. For more details, see the overview.

2.3.4 All the Specialist Advisers considered the procedure to be novel and of uncertain safety and efficacy.

2.4 Safety

2.4.1 In one case series, urinary ascites was reported in 38% (5 out of 13) of fetuses after cystoscopy and either hydro-ablation or guide-wire probing, requiring prenatal aspiration in one (8%). In another case series of 13 fetuses, small bladder perforations were noted during cystoscopy in 9% (1 out of 11) of fetuses undergoing guide-wire cannulation of the urethra. Many of the fetuses included in the evidence had a number of comorbidities, and it is unclear whether the complications were a result of the procedure or the comorbidities.

2.4.2 In three case reports describing four fetuses, premature rupture of the membranes occurred in one pregnancy on the third day after the procedure. This was treated with an amniopatch but the fetus died 3 days later. For more details, see the overview.

2.4.3 The Specialist Advisers stated that adverse events include miscarriage, preterm delivery, premature rupture of membranes, maternal infection, urinary ascites and damage to the anterior abdominal wall or bladder of the fetus.

2.5 Other comments

2.5.1 It was noted that the instruments used in this procedure require further development.

3 Further information

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

Sources of evidence

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

Information for patients

NICE has produced information for the public on this procedure. It explains the nature of the procedure and the decision made, and has been written with parental consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.