NICE National Institute for Health and Care Excellence

NICE guidance

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

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg205

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 Institute's information for patients ('Understanding NICE guidance') 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. The Institute 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% (12/13) 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 0/1, 1/2, 9/13 (69%) and 1/1 fetuses treated. For more details, refer to the 'Sources of evidence' section.

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% (5/13) 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% (1/11) 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, refer to the 'Sources of evidence' section.

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. The Institute has identified relevant audit criteria and developed an audit tool (which is for use at local discretion).

Andrew Dillon
Chief Executive
January 2007

Sources of evidence

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

'Interventional procedure overview of fetal cystoscopy for the diagnosis and treatment of lower urinary outflow tract obstruction', June 2006.

Information for patients

NICE has produced information describing its guidance on this procedure for parents ('Understanding NICE guidance'). It explains the nature of the procedure and the decision made, and has been written with parental consent in mind.

4 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.

Changes since publication

17 January 2012: minor maintenance.

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.