NICE guidance

Fetoscopic prenatal repair for open neural tube defects in the fetus

Interventional procedures guidance
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www.nice.org.uk/guidance/ipg667

1 Recommendations

1.1 Evidence on the safety and efficacy of fetoscopic prenatal repair of open neural tube defects in the fetus is inadequate in quantity and quality. Therefore, this procedure should only be used in the context of research. This could be in the form of randomised controlled trials or published registry data. Find out what only in research means on the NICE interventional procedures guidance page.

1.2 The procedure is technically challenging and should only be done in specialised centres, and only by clinicians and teams with specific training and experience in fetoscopic prenatal repair.

1.3 Patient selection should only be done by a multidisciplinary team, which should include a consultant in fetal medicine, an obstetric surgeon, a paediatric neurosurgeon, a radiologist with experience in fetal imaging

and an anaesthetist.

1.4 Further research should report details of risks to the mother (including her subsequent pregnancies), risks to the fetus (including the need for further surgery), and long-term disability after birth.

2 The condition, current treatments and procedure

The condition

2.1 Neural tube defects happen because the neural tube does not fuse during early embryonic development. Open neural tube defects are those in which the affected region of the neural tube is exposed on the body's surface. The most common neural tube defect is spina bifida where the defect is in the spine. Myelomeningocele (open spina bifida) is the most severe type of spina bifida, in which the baby's spinal canal remains open along several vertebrae in the back. The spinal cord and protective membranes around it push out and form a sac which is exposed on the baby's back. Children born with myelomeningocele may experience motor neurological deficits including muscle weakness and paralysis of the lower limbs, sensory deficit, bowel, bladder and sexual dysfunctions and learning difficulties. The condition can be associated with Chiari II malformation (hindbrain herniation) and hydrocephalus.

Current treatments

2.2 Conventional treatment for myelomeningocele (open spina bifida) is immediate surgical repair of the defect within days of birth to prevent further damage to nervous tissue and reduce the risk of central nervous system infection. The immediate management may also include ventricular-peritoneal shunt placement to relieve hydrocephalus. The condition can also be treated prenatally with the aim of decreasing morbidity in the child.

The procedure

2.3 Fetoscopic prenatal repair is typically done before 26 weeks of pregnancy. It is done using general anaesthesia and with partial CO_2 insufflation of the uterine cavity. Under ultrasound guidance an endoscope is introduced through a port followed by the introduction of additional ports to allow the passage of instruments. Once the fetus is positioned adequately, the skin around the fetal neural placode/elements is dissected. Occasionally a biocellulose patch may be placed between the neural elements (defect) and the skin. Myofascial flaps are created and sutured on top of the biocellulose patch. The skin is then sutured using interrupted stitches over the patch or, for a large defect, a dermal regeneration patch substitute can be used for repair.

2.4 A number of variations to the procedure have been described and the technique is still evolving.

3 Committee considerations

The evidence

3.1 NICE did a rapid review of the published literature on the efficacy and safety of this procedure. This comprised a comprehensive literature search and detailed review of the evidence from 5 sources, which was discussed by the committee. The evidence included 4 systematic reviews and meta-analysis and 1 case report. It is presented in table 2 of the interventional procedures overview. Other relevant literature is in the appendix of the overview.

3.2 The specialist advisers and the committee considered the key efficacy outcomes in the baby to be: motor function, hind brain herniation, hydrocephalus, bowel and bladder function and need for further surgery.

3.3 The specialist advisers and the committee considered the key safety outcomes in the baby to be: fetal mortality, perinatal death, premature birth, premature rupture of membranes, cerebrospinal fluid leakage and the potential for late spinal cord complications including tethered spinal

cord and syringomyelia. Key safety outcomes for the mother are: operative mortality, morbidity, incisional hernia, amniotic fluid leakage, uterine dehiscence or rupture in the current or subsequent pregnancy and morbidly adherent placenta in subsequent pregnancies.

3.4 Patient commentary was sought but none was received.

Committee comments

3.5 The committee was advised that fetoscopic approaches may have reduced risks for the mother, in particular the risk of uterine rupture in a subsequent pregnancy.

3.6 The committee was advised that there is a registry based in the US for this procedure.

3.7 The committee noted the need to identify the risks and benefits for both the fetus and mother (including her subsequent pregnancies) including long-term outcomes, and that these need to be discussed during parental counselling by the multidisciplinary team.

3.8 The committee noted that some of the data it considered was from operations done at a gestational age above 26 weeks.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

Accreditation