NICE guidance

Thoracoscopic repair of congenital diaphragmatic hernia in neonates

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.

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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

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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 thoracoscopic repair of congenital diaphragmatic hernia (CDH) in neonates is adequate to support the use of this procedure provided that normal arrangements are in place for clinical governance and audit.

1.2 During the consent process, parents should be informed in particular about the possibility of conversion to abdominal repair and about the risk of recurrence.

1.3 This procedure should only be carried out by surgeons with specific training and experience in laparoscopic and thoracoscopic surgery in neonates and children.

1.4 NICE encourages collaboration between the units performing this procedure in the collection of data and publication of results.

2 The procedure

2.1 Indications and current treatments

2.1.1 Congenital diaphragmatic hernia (CDH) results from failure of complete fusion of the developing fetal diaphragm – a process that normally occurs between gestational weeks 6 and 8. The defect may be anterior (Morgagni's hernia) or posterolateral (Bochdalek hernia). Migration of abdominal organs into the thoracic cavity, pulmonary hypoplasia and respiratory failure at birth can occur.

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2.1.2 Current management of CDH in neonates usually involves initial ventilatory support and supportive care, to allow labile cardiopulmonary physiology to improve, followed by surgical reduction of the hernia, usually through an abdominal approach, and repair of the diaphragmatic defect.

2.2 Outline of the procedure

2.2.1 The aim of this procedure is to reduce the herniated abdominal organs and repair the diaphragmatic defect. It is normally carried out for posterolateral Bochdalek defects.

2.2.2 Thoracoscopic repair of CDH in neonates is carried out with the patient under general anaesthesia and in the lateral decubitus position. Between 2 and 4 trocars can be used, with carbon dioxide (CO_2) insufflation of the pleural space to partially collapse the lung sufficiently to achieve good exposure of the defect and to reduce the herniated viscera within the abdomen. Following reduction, the diaphragm is repaired using non-absorbable interrupted sutures or patches (if defects are relatively large). Where technically possible, posterolateral diaphragm stitches are passed around the ribs and tied extracorporeally. Patients usually require temporary chest drain insertion and ventilatory support.

2.3 Efficacy

Sections 2.3 and 2.4 describe efficacy and safety outcomes from the published literature that the Committee considered as part of the evidence about this procedure. For more detailed information on the evidence, see the overview.

2.3.1 A meta-analysis of 3 non-randomised comparative studies including a total of 143 patients treated by thoracoscopic (n=62) or open (n=81) repair reported recurrence rates of 16% (10 out of 62) and 5% (4 out of 81) respectively (follow-up not stated), and a risk ratio of 3.21 (95% confidence interval [CI] 1.11 to 9.29).

2.3.2 A non-randomised comparative study of 30 patients treated by thoracoscopic (n=18) or laparoscopic repair (n=12) reported 'easy reduction' in 83% (15 out of

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18) and 42% (5 out of 12) of patients respectively; 'difficult reduction' in 11% (2 out of 18) and 33% (4 out of 12); and that it was impossible to reduce the hernia in 6% (1 out of 18) and 25% (3 out of 12) of patients respectively. A case series of 45 patients reported that reduction of hernia contents was 'easily accomplished' in 67% (30 out of 45) of patients.

2.3.3 A non-randomised comparative study of 57 patients reported conversion from a thoracoscopic to an open procedure in 1 patient (the liver could not be reduced into the abdomen). The case series of 45 patients reported conversion to an open procedure in 9% (4 out of 45) of patients (3 conversions were due to difficulty in reducing the hernia and 1 was due to a decrease in oxygen saturation).

2.3.4 Median duration of postoperative ventilation was 2 and 4 days after thoracoscopic and open repair, respectively, in the non-randomised comparative study of 73 patients (p=0.04) but was similar in the 2 groups in the study of 57 patients (5 days in each group; p=0.56).

2.3.5 The Specialist Advisers listed key efficacy outcomes as reduction in postoperative abdominal adhesions, improved postoperative pain, duration of hospital stay, resumption of enteral nutrition and cosmetic appearance.

2.4 Safety

2.4.1 A mortality rate of 3% (2 out of 62) in the thoracoscopic group compared with 12% (10 out of 81) in the open group, and a mortality risk ratio of 0.33 (95% CI 0.01 to 1.13) was reported in the meta-analysis of 143 patients (follow-up not stated).

2.4.2 Death due to haemorrhage in 1 patient was reported in the open group of the non-randomised comparative study of 73 patients. Death after severe bronchopneumonia and pneumothorax was reported in 1 patient each in the case series of 45 patients (timing not stated).

2.4.3 The non-randomised comparative study of 57 patients reported no significant difference in major infection rates (defined as abscess, systemic sepsis or

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abdominal wall patch infection) in the thoracoscopic group compared with the open group (17% [5 out of 29] versus 4% [1 out of 28], p=0.19; not otherwise described).

2.4.4 Gastrointestinal perforation rates of 7% (2 out of 29) in the thoracoscopic group and 7% (2 out of 28) in the open group were reported in the non-randomised comparative study of 57 patients.

The Specialist Advisers considered theoretical adverse events to include solid or hollow visceral injury, physiological instability and hypercarbia if not carefully insufflated.

2.5 Other comments

2.5.1 The Committee considered evidence that included infants over 30 days but less than 12 months.

3 Further information

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 guidance issued by NICE, and has been written with patient consent in mind.

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Endorsing organisation

This guidance has been endorsed by Healthcare Improvement Scotland.

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