



Thoracoscopic repair of congenital diaphragmatic hernia in neonates

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www.nice.org.uk/guidance/ipg379

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.
- 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 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.
- 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 CO₂ 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.

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 Efficacy

- 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% (10/62) and 5% (4/81) 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% (15/18) and 42% (5/12) of patients respectively; 'difficult reduction' in 11% (2/18) and 33% (4/12); and that it was impossible to reduce the hernia in 6% (1/18) and 25% (3/12) of patients respectively. A case series of 45 patients reported that reduction of hernia contents was 'easily accomplished' in 67% (30/45) 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% (4/45) 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% (2/62) in the thoracoscopic group compared with 12% (10/81) 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 abdominal wall patch infection) in the thoracoscopic group compared with the open group (17% [5/29] vs 4% [1/28], p = 0.19) (not otherwise described).
- 2.4.4 Gastrointestinal perforation rates of 7% (2/29) in the thoracoscopic group and 7% (2/28) in the open group were reported in the non-randomised comparative study of 57 patients.
- 2.4.5 The Specialist Advisers considered theoretical adverse events to include solid/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

3.1 For related NICE guidance see our website.

Information for patients

NICE has produced <u>information on this procedure for patients and carers</u> ('Understanding NICE guidance'). It explains the nature of the procedure and the guidance issued by NICE, and has been written with patient 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.

We have produced a <u>summary of this guidance for patients and carers</u>. Information about the evidence it is based on is also available.

Changes since publication

2 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.

Accreditation

