

Living FRIendly Summaries of the Body of Evidence using Epistemonikos (FRISBEE)

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Early versus late surgical correction in congenital diaphragmatic hernia

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Abstract

INTRODUCTION

The timing of surgical repair in patients with congenital diaphragmatic hernia has been a controversial topic over the years, and there is still no agreement as to whether immediate repair or late surgery with preoperative stabilization is preferable.

METHODS

To answer this question we used Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others. We extracted data from the systematic reviews, reanalyzed data of primary studies, conducted a meta-analysis and generated a summary of findings table using the GRADE approach.

RESULTS AND CONCLUSIONS

We identified four systematic reviews including 38 studies overall, of which two were randomized trials. We concluded it is not clear whether immediate surgical repair in congenital diaphragmatic hernia increases mortality or decreases hospitalization days compared to late repair because the certainty of evidence is very low.

Problem

Congenital diaphragmatic hernia presents with a prevalence of 2 to 4 per 10,000 live births and is associated with high mortality and high costs. Despite significant advances in neonatal and surgical care, management of newborns with congenital diaphragmatic hernia remains a challenge. As for timing of surgical repair, since the 1980s most investigators have advocated delayed surgery, post-operative stabilization, using a variety of ventilatory

strategies. If late surgery is beneficial compared to immediate repair is still a controversial issue; a convincing improvement in survival has not yet been documented after this strategy is implemented. Patients who survive the neonatal period require long-term follow-up as they are more likely to develop important morbidity, such as chronic lung disease, gastroesophageal reflux, growth restriction, neurological and sensory abnormalities. Due to the high mortality and associated morbidity, it is important to find

the best possible alternative to lower these rates. In congenital diaphragmatic hernia, there is a defect in the diaphragm that allows the passage of intra-abdominal organs (small intestine, stomach, spleen, liver, etc.) to the thoracic cavity; this occupation determines compression of the thoracic organs during its development, which causes hypoplasia and pulmonary hypertension, which affect the normal transition of the cardiorespiratory system at the time of birth. One of the most important prognostic factors in these patients is the presence of pulmonary hypertension, also called persistent fetal circulation. Immediate repair may be beneficial in avoiding persistent pulmonary compression, making ventilation easier for these patients in theory. On the other hand, delayed surgery would allow the patient to make a more adequate transition to extra uterine life, allowing time for hemodynamic adaptation to better cope with the impact of early surgery that could aggravate preexisting pulmonary hypertension. Our purpose is to review available evidence about the optimum timing of repair.

Methods

To answer the question, we used Epistemonikos, the largest database of systematic reviews in health, which is maintained by screening multiple information sources, including MEDLINE, EMBASE, Cochrane, among others, to identify systematic reviews and their included primary studies. We extracted data from the identified reviews and reanalyzed data from primary studies included in those reviews. With this information, we generated a structured summary denominated FRISBEE (Friendly Summary of Body of Evidence using Epistemonikos) using a pre-established format, which includes key messages, a summary of the body of evidence (presented as an evidence matrix in Epistemonikos), meta-analysis of the total of studies when it is possible, a summary of findings table following the GRADE approach and a table of other considerations for decision-making.

Key messages

- It is not clear whether immediate surgical repair in congenital diaphragmatic hernia increases mortality because the certainty of the evidence is very low.
- It is not clear whether immediate surgical repair in congenital diaphragmatic hernia decreases the days of hospitalization because the certainty of the evidence is very low.
- Given the uncertainty derived from the available evidence, it is not possible to make an adequate balance on the risk / benefit of early intervention.

About the body of evidence for this question

<p>What is the evidence. See evidence matrix in Epistemonikos later</p>	<p>We found four systematic reviews [1],[2],[3],[4] which together include 38 primary studies [5],[6],[7],[8],[9],[10],[11],[12],[13],[14],[15],[16],[17],[18],[19],[20],[21],[22],[23],[24],[25],[26],[27],[28],[29],[30],[31],[32],[33],[34],[35],[36],[37],[38],[39],[40],[41],[42], of which two are randomized controlled trials [5],[6]. This table and the summary in general are based on the latter, since the inclusion of the rest of the studies does not increase the certainty of the evidence nor provides relevant additional information.</p>
<p>What types of patients were included*</p>	<p>The two randomized trials [5],[6] included newborn patients with congenital diaphragmatic hernia which were symptomatic at birth; one of these with the additional requirement that they were symptomatic at within the 12 hours from birth [6].</p>
<p>What types of interventions were included*</p>	<p>The two trials [5],[6] evaluated immediate surgical repair, and compared it with late repair. One trial [5] defined immediate repair to the surgery performed within the first 4 hours of admission to the center, and late repair to that performed at least after 24 hours, at the time when the patient was considered stable. The other trial [6] defined immediate repair to the surgery performed within the first 6 hours of admission to the center, and late repair to that performed after 96 hours, when there was no evidence of pulmonary hypertension.</p>
<p>What types of outcomes were measured</p>	<p>The studies measured multiple outcomes, however, those that were grouped in the identified reviews were: Mortality Time of hospitalization in survivors Use of extracorporeal membrane oxygenation Type of procedure used Complications</p>

* The information about primary studies is extracted from the systematic reviews identified, unless otherwise specified.

Summary of findings

The information on the effects of immediate versus late surgical repair in patients with congenital diaphragmatic hernia is based on two randomized trials [5],[6] including 84 patients in total. Both trials reported the outcome mortality and hospitalization time in survivors. One trial [6] further measured the use of extracorporeal membrane oxygenation, the type of procedure used and the complications associated with the interventions. The summary of findings is as follows:

- It is not clear whether immediate surgical repair in congenital diaphragmatic hernia increases mortality because the certainty of the evidence is very low.
- It is not clear whether immediate surgical repair in congenital diaphragmatic hernia decreases the length of hospitalization, because the certainty of the evidence is very low.

Early versus late surgical correction in congenital diaphragmatic hernia				
Patients	Newborns with congenital diaphragmatic hernia			
Intervention	Immediate surgical correction (within 4-6 hours from admission)			
Comparison	Late surgical correction (after 24-96 hours with stable patient)			
Outcomes	Absolute effect*		Relative effect (95% CI)	Certainty of the evidence (GRADE)
	Late surgical correction	Early surgical correction		
	Difference: patients per 1000			
Mortality	370 per 1000	440 per 1000	RR 1.19 (0.72 a 1.97)	⊕○○○ ^{1,2} Very low
	Difference: 70 patients more per 1000 (Margin of error: from 103 to 358 more)			
Hospitalization time	63.5 days	49.6 days	--	⊕○○○ ^{1,2} Very low
	MD 13.9 less (53.72 less to 25.92 more)			
RR= Risk ratio. MD = Mean difference Margin of error = 95% confidence interval (CI). GRADE: evidence grades of the GRADE Working Group (see later in this article)				
* The risk with late surgical correction is based on the risk in the control group of the trials. The risk with early surgical correction (and its margin of error) is calculated from relative effect (and its margin of error)				
¹ One level of certainty of evidence was reduced by risk of serious bias, as they were not blinded trials. While it may be impracticable to perform a blinded trial in this case, since depriving the treating team of the knowledge of the time the patient was operated would not be considered ethical, this factor may incorporate bias.				
² It was diminished in two levels of certainty of evidence by imprecision, since the confidence interval is very broad, and the decisions at both ends of it are completely opposite.				

About the certainty of the evidence (GRADE)*
⊕⊕⊕⊕ High: This research provides a very good indication of the likely effect. The likelihood that the effect will be substantially different† is low.
⊕⊕⊕○ Moderate: This research provides a good indication of the likely effect. The likelihood that the effect will be substantially different† is moderate
⊕⊕○○ Low: This research provides some indication of the likely effect. However, the likelihood that it will be substantially different† is high.
⊕○○○ Very low: This research does not provide a reliable indication of the likely effect. The likelihood that the effect will be substantially different† is very high.
*This concept is also called 'quality of the evidence' or 'confidence in effect estimates'. † Substantially different = a large enough difference that it might affect a decision.

Other considerations for decision-making

To whom this evidence does and does not apply

- The evidence presented in this summary applies to newborn patients with congenital diaphragmatic hernia. It excludes patients with late presentation of diaphragmatic hernia, referring to patients who present symptoms after 12 hours from birth and patients with acquired diaphragmatic hernia.
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About the outcomes included in this summary

- The outcomes included in the summary of findings table are those considered critical for decision-making by the authors of this summary. These generally coincide with those evaluated in the systematic reviews identified and in the main clinical guidelines.
 - It should be noted that these trials did not analyze how other factors affect outcomes, such as the use of prenatal steroids, ventilation, the severity of pulmonary hypertension, therapies to treat pulmonary hypertension and the use of oxygenation of extracorporeal membrane.
 - In addition, there is bias in the risk of morbidity and mortality in these patients, due to what is known as "hidden mortality", determined by patients who die before reaching the referral center, or by patients (mainly with poor prognosis) that are aborted before birth.
-

Balance between benefits and risks, and certainty of the evidence

- Given the uncertainty derived from the available evidence, it is not possible to make an adequate balance on the risk/benefit of this intervention.
-

Resource considerations

- Although late surgery could prolong hospital stay, it is not possible to make an adequate balance between cost and benefit because of the uncertainty regarding the latter, as there is no clear difference in mortality between one intervention and another.
-

What would patients and their doctors think about this intervention

- Faced with the evidence presented in this summary there should be wide variability in individual decisions. However, today it is more likely to opt to operate late, when sustained stability has been achieved, assuming that patients are better prepared to undergo surgery. In addition, if the patient does not reach hemodynamic stability to be operated, the use of extracorporeal membrane oxygenation provides an alternative of stabilization in order to be able to perform surgery under cardiorespiratory bypass.
 - It is especially important to convey the existing uncertainty to patients and their families.
-

Differences between this summary and other sources

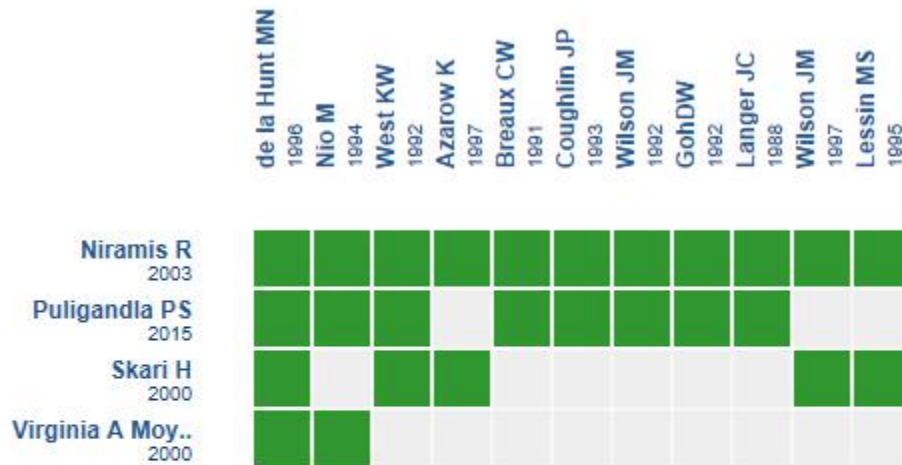
- The conclusions of this summary are consistent with the four identified systematic reviews [1],[2],[3],[4].
 - Our summary does not coincide with the Consensus of the European Congenital Diaphragmatic Hernia Consortium (updated in 2015) [43], which gives standardized recommendations on the postnatal management of children with congenital diaphragmatic hernia in Europe. They recommend that surgical repair of the diaphragmatic defect should be performed after clinical stabilization, defined by normal mean arterial pressure for gestation, pre-ductal saturation levels of 85-95% with FiO2 below 50%, lactate below 3 mmol/l and urine diuresis at 1 ml/kg/hr. Although they recognize that the evidence in this respect is limited.
-

Could this evidence change in the future?

- The probability that the conclusions reached in this summary change with future trials is high, due to the uncertainty that exists, and to the technological and therapy changes that are being applied in this specific condition.
 - We did not identify any ongoing trial evaluating this question in the International Clinical Trials Registry Platform of the World Health Organization. How we conducted this summary.
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How we conducted this summary

Using automated and collaborative means, we compiled all the relevant evidence for the question of interest and we present it as a matrix of evidence.



An evidence matrix is a table that compares systematic reviews that answer the same question.

Rows represent systematic reviews, and columns show primary studies.

The boxes in green correspond to studies included in the respective revisions.

The system automatically detects new systematic reviews including any of the primary studies in the matrix, which will be added if they actually answer the same question.

Follow the link to access the **interactive version**: [Late versus early surgical correction for congenital diaphragmatic hernia.](http://dx.doi.org/10.5867/medwave.2014.06.5997)

Notes

The upper portion of the matrix of evidence will display a warning of “new evidence” if new systematic reviews are published after the publication of this summary. Even though the project considers the periodical update of these summaries, users are invited to comment in *Medwave* or to contact the authors through email if they find new evidence and the summary should be updated earlier.

After creating an account in Epistemonikos, users will be able to save the matrixes and to receive automated notifications any time new evidence potentially relevant for the question appears.

This article is part of the Epistemonikos Evidence Synthesis project. It is elaborated with a pre-established methodology, following rigorous methodological standards and internal peer review process. Each of these articles corresponds to a summary, denominated FRISBEE (Friendly Summary of Body of Evidence using

Epistemonikos), whose main objective is to synthesize the body of evidence for a specific question, with a friendly format to clinical professionals. Its main resources are based on the evidence matrix of Epistemonikos and analysis of results using GRADE methodology. Further details of the methods for developing this FRISBEE are described here

(<http://dx.doi.org/10.5867/medwave.2014.06.5997>)

Epistemonikos foundation is a non-for-profit organization aiming to bring information closer to health decision-makers with technology. Its main development is Epistemonikos database (www.epistemonikos.org).

Potential conflicts of interest

The authors do not have relevant interests to declare.

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