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ORIGINAL PAPER

Development and selected complications in children with congenital diaphragmatic hernia during the first four years of life – a single-center study from a paediatric hospital in Warsaw

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ABSTRACT

Introduction: The aim of our study was to evaluate development and selected complications in children with congenital diaphragmatic hernia (CDH) during the first four years of life. This single-centre study was conducted at a paediatric hospital in Warsaw. We focused on the relationship between anthropometric measurements, CDH occurrence, and the development of complications.

Material and methods: We conducted a survey study aimed at parents of children with CDH who had undergone surgical treatment in 2007–2021. The questionnaire consisted of 11 sections, including an introduction, consent for participation, and questions concerning anthropometric measurements, gastroenterological and pneumonological complications. Respondents were also asked about rarer CDH-associated complications.

Results: We identified 121 children with CDH, and 90 parents completed the survey: 75 (83.33%) with left-sided hernia, 17 (18.89%) with another congenital accompanying anomaly. Recurrence of the hernia occurred in 21 (23.33%) cases, with 90.48% of recurrences occurring on the left side. Significant changes were observed in the percent distribution of patients on growth, weight, and body mass index (BMI) centile charts during the first two years of life. At birth, 55.56% of children (50/90) were above the 97th percentile for height, and 42.22% (38/90) were below the 3rd percentile for BMI. In the second year of life, these values were 11.69% (9/77) and 24.68% (19/77), respectively. A relationship was found between the recurrence of diaphragmatic hernia and the surgery with the patch (p = 0.002) as well as the presence of lung hypoplasia (p = 0.001). No correlation was found between symptoms and diaphragmatic hernia lateralization.

Conclusions: The study highlights the impact of CDH on physical development and gastroenterological and pulmonological complications. Early growth deficiencies were common, improving from the second month. Hernia recurrence correlated with lung hypoplasia and patch surgery, and gastro-oesophageal reflux disease was frequent. Long-term multidisciplinary follow-up is essential, and further research on larger cohorts is needed to clarify complications' impact.

KEY WORDS:

complications, congenital diaphragmatic hernia, lung hypoplasia, failure to thrive, postnatal management.

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INTRODUCTION

Congenital diaphragmatic hernia (CDH) is a relatively rare congenital defect in foetuses, characterised by a defect in the diaphragm and the displacement of abdominal organs into the chest cavity. Its incidence is approximately 3.30 per 10,000 live and stillbirths [1]. This condition can be fatal, with survival rates of 60–81% [2, 3]. No significant differences in survival have been reported based on the side of the defect [4] however, the condition is more commonly observed on the left side [5]. Despite the possibility of detecting CDH in the first trimester of pregnancy through ultrasound, infants born with this defect are a group of patients who, despite advances in treatment, remain insufficiently studied.

Considerable progress in the postnatal management of patients with CDH has led to a significant improvement in survival rates over the last two decades, although survival is particularly dependent on the size of the defect [6]. In 2013, the CDH study group developed a system to classify diaphragmatic defects based on their size: type A defects have an almost completely preserved diaphragm, type B are partially preserved, type C have less than half remaining, and type D involve an almost complete absence of the diaphragm. Nevertheless, surgical treatment is associated with a risk of various complications, especially those related to CDH recurrence, chest wall deformities and gastroenterology [7, 8]. In patients with CDH, research is increasingly focusing on monitoring and treating comorbidities such as pulmonary, cardiovascular and musculoskeletal disorders [9, 10]. Neurological development disorders are also a concern as CDH patients very often require long intensive care with cardiovascular and respiratory stabilization, sometimes including extracorporeal membrane oxygenation (ECMO). What is also emphasized is the need for genetic consultations because CDH can be part of a genetic syndrome [11]. In infants with CDH, early anthropometric measurements often show poorer results, although these tend to improve as development progresses [12]. Growth catch-up is expected to begin around 2 months of age [13], while Apgar scores at birth are typically low [14]. Growth delay is linked to impaired neurological development [15], and recent studies have highlighted the occurrence of hypermetabolism in CDH children with increased energy expenditure [13].

Gastro-oesophageal reflux disease (GORD) is one of the most commonly reported complications in patients with CDH [16], and it may contribute to the development of oesophageal disorders, such as Barrett's oesophagus (BO) [17]. The incidence of GORD in patients with CDH varies significantly, affecting 52.7% of infants and 35.1% of children over one year old [8]. Gastro-oesophageal reflux disease can also impact lung function. Infants are particularly vulnerable to upper respiratory infections, and children diagnosed with CDH are at an increased risk of pulmonary hypoplasia, which can lead to additional developmental issues or recurring lung infections. Studies have shown that these children are more likely to require extracorporeal membrane oxygenation after birth [18].

The aim of this single-centre study, conducted at a paediatric hospital in Warsaw, was to assess the development and selected complications in children with CDH during the first four years of childhood. Specifically, we sought to investigate the relationship between anthropometric measurements and the occurrence of CDH, along with gastroenterological complications, including gastro-oesophageal reflux, gastrointestinal obstructions, recurrent diaphragmatic hernia, and an increased risk of respiratory infections. Additionally, we aimed to examine the impact of CDH on the development of children depending on whether the defect occurred on the right or left side.

MATERIAL AND METHODS

STUDY DESIGN

We conducted a survey study using an online questionnaire created with Google forms, which was distributed *via* email from June to September 2024. The introduction to the questionnaire included a description of the study and an obligatory consent form for participation. The study targeted parents of children with CDH who had undergone surgery in 2007–2021. Ninety completed forms were collected. Following the survey, statistical analysis of the responses was conducted, and the relationships were analysed.

QUESTIONNAIRE

The study was conducted using a proprietary questionnaire that included 11 main sections: (1) an introduction and general information about the study, (2) consent to participate, along with general demographic information such as gender, age, and details about diaphragmatic hernia, including disease lateralization and recurrence, (3–8) information on anthropometric measurements collected at birth, at 6 months, and at 1, 2, 3 and 4 years of age, (9) gastroenterological complications, including issues such as vomiting, regurgitation, GORD and its symptoms, intestinal obstruction, and peritonitis, (10) pulmonary complications, which encompass respiratory support, pulmonary hypoplasia, pneumonia, pulmonary hypertension (PH), and asthma, (11) additional questions that may be relevant to the condition being investigated, including inquiries about chest wall deformity. The information reported in the questionnaires was, to the extent feasible, cross-checked and validated against the patients' medical records maintained by the hospital.

TABLE 1. Clinical characteristics of subjects

	N	Median	Min	Max	Q1	Q3
Hbd	90	38.0	31.0	41.0	37.0	39.0
Apgar score at 1 min	90	7.0	1.0	10.0	6.0	8.0
Mother's age (years)	90	30.0	19.0	41.0	27.0	33.0
Height at birth [cm]	88	53.0	43.0	62.0	51.0	55.5
Weight at birth [kg]	90	3.0	1.7	4.2	2.8	3.4
BMI at birth	88	10.6	8.0	13.8	9.9	11.7

BMI – body mass index, Hbd – gestational age at birth, IQR – interquartile range

DATA ANALYSIS

The anthropometric measurements used in the study, such as weight, height and body mass index (BMI) (calculated based on weight and height), were plotted on growth charts. For premature infants, Fenton growth charts and the Fenton 2013 calculator (PediTools) [19] were used for weight and height at birth. Olsen growth charts and calculator (PediTools) [19] were used for BMI. For BMI and other anthropometric data of premature infants at 6 months and 1 year of age, corrected age was taken into account using World Health Organization (WHO) growth charts. For full-term infants, WHO growth charts appropriate for age were used. The study was conducted at a paediatric hospital in Warsaw.

STATISTICAL ANALYSIS

The distribution of continuous variables were tested by Shapiro-Wilk and Kolmogorov-Smirnoff tests. Numerical data were expressed as median and interquartile range. Categorical variables were expressed as percentages and group comparisons were analysed with the use of χ^2 test, with Yates correction, if necessary. A $p < 0.05$ was considered statistically significant. The statistical analysis was performed using Statistica 13.3 (Tulsa, USA).

RESULTS

A total of 121 CDH cases were identified during the study period, and 90 parents consented to participate and submitted completed questionnaires. The study included 90 children (48 boys, 53.33%). Clinical characteristics of the participants are presented in Table 1. Congenital diaphragmatic hernia was diagnosed prenatally in 74 patients (82.22%), with a predominance of the left-sided hernia (75 patients, 83.33%). Only four children (4.44%) were conceived *via* fertilisation. Other congenital abnormalities were detected in 17 children (18.89%), including heart defects, hypospadias, cryptorchidism, inguinal hernia, kidney agenesis, renal pelvis duplication, chest deformities, clubfoot, cleft palate and Kabuki syndrome. In the study group, one patient (1.1%) had a sibling with CDH, but no other family members had the condition

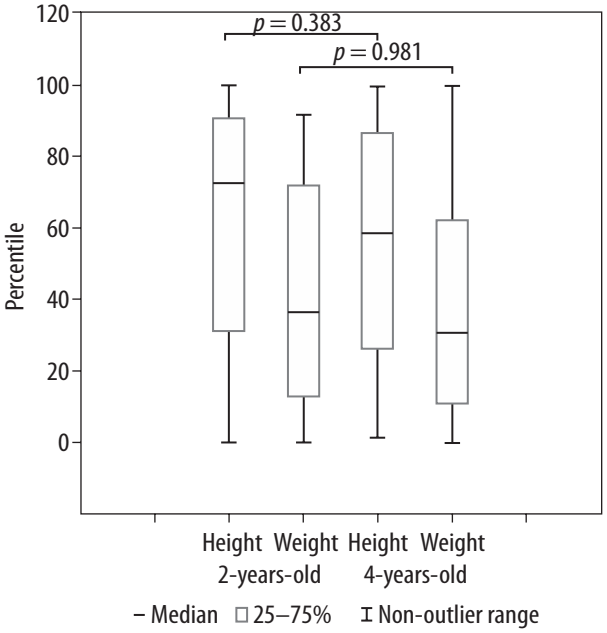

FIGURE 1. Comparison between median percentile of height and weight for 2–4 years of age

(100%). The large diaphragmatic defect was present in 30 out of 90 patients (33.33%). In this group, the patch with GoreTex material was used during the surgical procedure. Recurrent hernia occurred in 21/90 children (23.33%), with the recurrence occurring more frequently on the left side (19/21, 90.48%) and most often within the first 6 months of childhood (7/21 patients, 33.33%).

GROWTH DURING THE FIRST FOUR YEARS OF LIFE

There were no significant differences in height and weight at 2 and 4 years of age. The median height and weight decreased in the fourth year compared with the second year, but this was not statistically significant (Figure 1). Detailed parameters for height and weight by age and percentile are summarised in Table 2. By the age of 1, nearly half of the children (31/75) had a BMI below the third percentile, but by ≥ 2 years, the proportion of children below the third percentile decreased (19/77). Significant fluctuations in weight were observed in the first two years of childhood, with a more consistent distribution between the 15th and 50th percentiles in the third

TABLE 2. Percentage of patients according to age and percentile range

Percentiles range	0			6 months			1-years-old			2-years-old			3-years-old			4-years-old		
	Height (%)	Weight (%)	BMI (%)	Height (%)	Weight (%)	BMI (%)	Height (%)	Weight (%)	BMI (%)	Height (%)	Weight (%)	BMI (%)	Height (%)	Weight (%)	BMI (%)	Height (%)	Weight (%)	BMI (%)
< 3	1.11	2.22	42.22	12.66	23.86	37.21	10.67	9.52	41.33	9.09	12.20	24.68	1.69	13.33	32.20	4.17	8.22	30.14
3–15	–	4.44	25.56	5.06	25.00	19.77	2.67	17.86	13.33	5.19	18.29	12.99	10.17	16.67	15.25	8.33	20.55	20.55
15–50	4.44	45.56	22.22	29.11	27.27	19.77	18.67	32.14	20.00	16.88	36.59	37.66	37.29	40.00	23.73	30.56	43.84	31.51
50–85	8.89	32.22	4.44	20.25	15.91	9.30	20.00	23.81	14.67	33.77	28.05	15.58	32.20	23.33	22.03	29.17	20.55	9.59
85–97	27.78	14.44	2.22	8.86	4.55	3.49	16.00	9.52	5.33	23.38	4.88	6.49	8.47	3.33	5.08	20.83	5.48	5.48
> 97	55.56	1.11	–	1.25	3.41	10.47	30.67	3.57	5.33	11.69	–	2.60	10.17	3.33	1.69	6.94	1.37	2.74

BMI – body mass index

and fourth years of childhood. Regarding height, 55.56% (50/90) of children were above the 97th percentile at birth, but this percentage significantly decreased at subsequent measurement points.

ASSOCIATION BETWEEN RECURRENCE OF DIAPHRAGMATIC HERNIA AND THE OCCURRENCE OF OTHER SYMPTOMS

The frequency of recurrence was analysed in relation to the presence of specific symptoms. Recurrent hernia was relatively uncommon in patients with chronic vomiting and regurgitation ($p = 0.026$). Gastrointestinal obstruction occurred in 16.67% of patients, although its association with recurrent hernia was minimal. Most patients with peritonitis experienced recurrence, although they represented a small percentage of the study sample (3.33%). The relationship between recurrent diaphragmatic hernia and other clinical symptoms is detailed in Table 3. Among pulmonary conditions, pneumonia (43.33%) was common, while a smaller proportion of patients had PH, asthma or required respiratory support after discharge. In the majority of cases, a chest wall deformity was observed (60%). There was no statistically significant correlation between these symptoms and recurrent diaphragmatic hernia, but the relationship between recurrent hernia and pulmonary hypoplasia was significant ($p = 0.001$) (Table 3).

Almost half of the patients with a large diaphragmatic defect presented with recurrence (13/30, 43.33%). The large diaphragmatic defect was the significant risk factor for the recurrence of hernia (OR = 5.0; 95% CI: 1.76–14.02).

RELATIONSHIP BETWEEN THE OCCURRENCE OF OTHER DISEASE SYMPTOMS DEPENDING ON THE SIDE OF THE DIAPHRAGMATIC HERNIA (RIGHT/LEFT)

Fifteen patients (16.67%) presented with a right-sided diaphragmatic hernia however, no relationship was found between the presence of specific symptoms and the side of the hernia (Table 4).

DISCUSSION

This study represents the largest cohort of patients following diaphragmatic hernia surgery in Poland to date. The majority of patients were operated on for left-sided diaphragmatic hernia, with an additional group of children presenting other associated congenital abnormalities, which did not significantly impact the incidence of complications. A significant correlation occurred between the presence of lung hypoplasia and hernia recurrence, but no association was found between the side of the hernia and other clinical symptoms.

TABLE 3. Relationship between recurrence of diaphragmatic hernia and the occurrence of other symptoms

Parameters	Has your child had a recurrence of diaphragmatic hernia?		*p*-value	OR	95% CI	
	Yes, *n*/*N* (%)	No, *n*/*N* (%)				
Has your child experienced persistent vomiting or regurgitation?	12/33 (36.36)	21/33 (63.64)	0.026	0.3	0.12	0.90
Has your child experienced intestinal obstruction (adhesions of the intestines)?	3/15 (20)	12/15 (80)	1.000	0.8	0.20	3.12
Has your child had peritonitis?	2/3 (66.67)	1/3 (33.33)	0.267	7.2	0.62	83.26
After discharge from the hospital, did your child require respiratory support?	0/2 (0)	2/2 (100)	0.955	1.0	0.10	10.42
Was your child diagnosed with pulmonary hypoplasia?	15/37 (40.54)	22/37 (59.46)	0.001	5.3	1.83	15.63
Did your child have pneumonia before the age of 4?	13/39 (33.33)	26/39 (66.67)	0.050	2.7	0.98	7.35
Does your child have diagnosed pulmonary hypertension?	6/19 (31.58)	13/19 (68.42)	0.515	1.7	0.56	5.30
Does your child have asthma?	5/11 (45.45)	6/11 (54.55)	0.141	3.3	0.89	12.13
Does your child have chest wall deformity?	16/54 (29.63)	38/54 (70.37)	0.084	2.6	0.86	7.93

TABLE 4. Relationship between the appearance of other disease symptoms depending on the side of the diaphragmatic hernia (right/left)

Parameters	On which side was the diaphragmatic hernia diagnosed in your child?		*p*-value	OR	95% CI	
	On the left side, *n*/*N* (%)	On the right side, *n*/*N* (%)				
Does a child experience recurrence of a diaphragmatic hernia?	19/21 (90.48)	2/21 (9.52)	0.504	0.5	0.09	2.19
Has your child experienced persistent vomiting or regurgitation?	27/33 (81.82)	6/33 (18.18)	1.000	0.8	0.27	2.63
Has your child experienced intestinal obstruction (adhesions of the intestines)?	13/15 (86.67)	2/15 (13.33)	1.000	0.7	0.15	3.65
Has your child had peritonitis?	2/3 (66.67)	1/3 (33.33)	1.000	2.6	0.22	30.75
After discharge from the hospital, did your child require respiratory support?	1/2 (50)	1/2 (50)	0.749	5.3	0.31	89.57
Was your child diagnosed with pulmonary hypoplasia?	32/37 (86.49)	5/37 (13.51)	0.502	0.7	0.21	2.16
Did your child have pneumonia before the age of 4?	33/39 (84.62)	6/39 (15.38)	0.775	0.8	0.27	2.62
Does your child have diagnosed pulmonary hypertension?	16/19 (84.21)	3/19 (15.79)	0.817	0.9	0.23	3.67
Does your child have asthma?	10/11 (90.91)	1/11 (9.09)	0.773	0.5	0.05	3.93
Does your child have chest wall deformity?	47/54 (87.04)	7/54 (12.96)	0.248	0.5	0.17	1.59

Studies indicate that the primary risk factor is the size of the diaphragmatic defect and the necessity of using a patch for its closure [20–22]. In cases of larger diaphragmatic defects, abdominal organs such as the intestines, spleen, stomach, and liver herniate into the chest cavity, exerting pressure on the developing lung. The displacement of these organs is associated with a higher degree of pulmonary hypoplasia and an increased risk of mortality [6, 20]. It is important to emphasise that pulmonary hypoplasia is a consequence of the size of the defect, not

a direct cause of recurrence. The use of a patch, which does not grow with the child, is the primary cause of recurrence [21], particularly during the period of rapid growth in infancy, especially during the first year of life [12].

Recurrent hernias were relatively rare among patients experiencing chronic vomiting and regurgitation. This suggests that, despite the potential for increased intra-abdominal pressure caused by persistent vomiting, the occurrence of recurrent hernias in this patient group is not as common as might be expected, unless the large defect of diaphragm/large diaphragmatic defect is present. Further research may be needed to explore the underlying mechanisms that could explain this observation, as well as to determine whether other factors, such as the duration and severity of symptoms, influence the likelihood of hernia recurrence in these patients.

Improvements in anthropometric parameters began as early as the second month of childhood. Similar trends were noted in a study conducted in a Japanese population [13]. However, a separate Japanese study found that significant weight gain in children occurred later in development, specifically between 18 months and 3 years of age [23]. In contrast, data from Australia found that growth acceleration occurred in the second half of the first year of childhood [12]. It is also worth noting that an Italian study provided different observations for a specific group of children with CDH and lung hypoplasia. These children had significantly lower body weight at 12 and 24 months and lower height at 24 months, compared with children with normally developed lungs [24]. There are no studies on these relationships for the Polish population. Studies conducted in Germany found that the average weight percentile for children < 24 months of age was 14.2%; for those aged 24–72, it was 20.2%; and for children > 72 months, it was 22.2%. In this study, the average weight percentile for 24–48 months was 61.73 and 56.43, respectively, but children of 72 months of age were not assessed. Nevertheless, these data show a trend towards a slight decrease in weight percentiles in the cohort of children from the paediatric hospital in Warsaw compared with the German population, where the weight percentile increased significantly [15].

Physical developmental delay is a well-known complication. It is common for children with CDH to experience weight and growth deficiencies initially. This is a serious issue, as these deficiencies are strongly correlated with somatic and neurological development. Weight gain is likely reduced due to several factors, including gastro-oesophageal reflux, restricted lung development, food aversion, feeding difficulties and mechanical ventilation. Another potential factor is increased energy demand, possibly due to greater respiratory effort, although this is hypothesis requires further research. Prolonged mechanical ventilation increases energy requirements and hinders effective oral feeding, further impeding proper development [13, 25]. However, as children age, most become independent of mechanical ventilation, their energy needs decrease and feeding becomes easier.

Gastro-oesophageal reflux disease is a common complication in patients following CDH surgery, and its incidence decreases over time. However, this incidence is higher than reported in the literature, possibly due to the predominance of non-acid reflux, which can only be detected using pH-metry with impedance [25, 26]. In this study, one-third of patients presented with reflux symptoms, primarily in the form of persistent regurgitation in the early years of childhood. One-fifth were on long-term proton pump inhibitors therapy. Thirty-three children (36.67%) had symptoms of gastro-oesophageal reflux. Eight patients (8.9%) underwent gastroscopy before the age of 4, and 18 (20%) were diagnosed with GORD. The vast majority of children did not undergo pH-metry/pH-impedance testing, which may have hindered an accurate diagnosis. Other studies have reported a GORD incidence in the first year of childhood of 20–84% [27]. The main risk factors for GORD include the presence of a patch, stomach position in the chest and oesophageal motility disorders, with the latter being the most significant [26]. Early detection of the disease does not protect against its later development, which demonstrates the need for long-term follow-up of patients after CDH repair [28]. In adult CDH patients, GORD is reported in 63% of cases, with BO occurring in 54% of cases. Barrett's oesophagus changes typically develop at a younger age, at an average of 17 years old [25, 27]. Early gastroenterological assessment, particularly for patients with GORD symptoms, is crucial due to the potential negative impact of GORD on lung function later in life [15, 29] The literature shows inconsistencies concerning the implementation of prophylactic fundoplication, as well as the clinical justification for the routine 24-hour pH-impedance monitoring [17, 29]. Current recommendations support a symptom-based diagnostic approach, limiting investigations to patients presenting with clinical manifestations of GORD, thereby minimizing unnecessary procedures. It is noteworthy that this strategy deviates from official gastroenterological guidelines [17]. Gastrointestinal symptoms like dysphagia, chest and abdominal pain or pharyngeal reflex should be carefully evaluated to distinguish between gastroesophageal reflux and a possible recurrent hiatal hernia. In some cases, acute bowel obstruction may be the initial manifestation of an undiagnosed recurrence [20].

Congenital diaphragmatic hernia is associated with lung hypoplasia, abnormal vasculature and ventilatory disturbances, leading to respiratory failure and persistent PH, which negatively affect neonatal prognosis [30]. Lung hypoplasia results from prenatal compression of the lung tissue by displaced viscera, which limits bronchial branching and pulmonary vessel development [29]. In this study, 41.11% of patients had lung hypoplasia, and two (2.22%) required respiratory support after

discharge from the hospital. Pulmonary dysfunction in patients with CDH is common and includes both restrictive and obstructive lung diseases, which can persist for many years post-surgery. Low vital capacity is prevalent, although the number of surgical interventions affects its value in only some patients [29]. In the CDH patient group, persistent PH is an important prognostic factor. It resolves in most patients between the first and third weeks of childhood however, neonates with prolonged PH require long-term respiratory support and chronic PH therapy [30]. In this study, the vast majority of children did not suffer from PH after hospital discharge, which may have been due, in part, to early diagnosis and prompt corrective surgery.

However, this study has several limitations. First, data were limited due to restricted access to the study cohort. Ninety children were included in the study out of 121 identified surgical cases. The time limitation – as the study only included the first four years of childhood – may not account for later complications or long-term health issues that could emerge after this period. Therefore, the study does not provide a full picture of the long-term development of children with CDH.

Second, the study involved parents of the children, who answered our questions remotely, and they may have made errors when sending responses – the data were not verifiable in all cases. Additionally, unlike physical development assessments, which rely on objective measurements, data regarding mental development, emotional and social interactions, or learning difficulties may be subjective and dependent on the evaluation of individual specialists. This may have led to a lack of significant differences over time in the analysis.

Another limitation of this study is that the diagnosis of GORD was based solely on parental reports of vomiting and regurgitation symptoms obtained through questionnaires, without instrumental or clinical confirmation. These symptoms may be non-specific and may be attributable to other causes, potentially introducing misclassification bias.

The study did not include a comparison of development results between children with CDH and a control group of healthy children. Such a group would have provided a reference point for assessing the impact of CDH on development. Nevertheless, it seems that the cohort was sufficient to demonstrate a trend towards lower anthropometric measurements in the short term post-surgery.

The study did not consider variables that could not be obtained due to the nature of the questionnaire-based study, or variables that are difficult to control, such as genetic differences, environmental factors or socioeconomic status, which may influence the results and development of children with CDH. It should be emphasised that aggressive management of acute malnutrition and intensive nutritional support play a key role in improving the physical development of children. These interventions significantly contribute to better anthropometric outcomes, positively influencing body weight and height in specific age groups [23, 24]. Due to a lack of detailed information about the diet of children participating in the study, we cannot definitively determine the impact diet had on children in the study.

CONCLUSIONS

This study, which included a cohort of 90 children with CDH from the paediatric hospital in Warsaw, found that children with CDH often experience initial weight and growth deficiencies, with a significant number having a BMI below the third percentile in their first year. Improvements were recorded in anthropometric parameters from the second month of childhood, which corresponds with the findings of previous studies [13, 23, 24], and a significant correlation occurred between lung hypoplasia (i.e. severity of CDH and size of the diaphragm defect) and hernia recurrence. Gastro-oesophageal reflux disease was also a common complication. There is a need for further research on larger study groups to evaluate the relationships between various complications and their impact on the development of children following CDH surgery. The crucial issue is the long-term and multidisciplinary follow-up of children with CDH. The most important aspects appear to be pulmonary, cardiovascular, gastrointestinal, and neurological assessments. Due to frequent respiratory infections and the possibility of PH, it is recommended to perform periodic chest X-rays, spirometry, and echocardiography. In the case of GORD, it may be necessary to perform pH-metry and gastroscopy.

DISCLOSURES

1. Institutional review board statement: Patients were under the care of the University Clinical Center of the Medical University of Warsaw, Poland. The study complied with the guidelines of the Institutional Ethics Committee and the Declaration of Helsinki (1964). It was approved by the Bioethics Committee of the Medical University of Warsaw (AKBE/179/2024).
2. Assistance with the article: None.
3. Financial support and sponsorship: None.
4. Conflicts of interest: None.

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