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Clinical Research Paper

Variation in practice and outcomes of extracorporeal life support (ECLS) in congenital diaphragmatic hernia (CDH) between North American and European centres☆,☆☆

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ABSTRACT

Background: Previous studies suggest discrepancy between North American and European centres in use of extracorporeal life support (ECLS) in infants with congenital diaphragmatic hernia (CDH). The impact of this on outcomes is unknown. We aimed to compare indications, management and outcomes of infants with CDH receiving ECLS between North American and European centres.

Methods: ECLS organisation (ELSO) prospective registry study including infants with CDH receiving ECLS over 11 years starting January 2012. Outcomes were mortality, ECLS-related complications and length of inpatient stay. Propensity score weighted analysis adjusted for differences in infant and disease-related factors.

Results: There were 3,087 infants, with 2382 (77.1%) infants treated in North American centres while 705 (22.9%) were treated at European centres with similar birth demographics. Case volume per year was less for those treated in North American centres compared to European centres (4 [IQR 2–7, range 1–34] vs 5 [IQR 3–15, range 1–35] cases per year, $p < 0.001$). Unadjusted mortality was greater in North American infants (OR 1.40 [95% CI 1.18 to 1.66]) but similar after propensity score matching and adjustment for treatment factors (OR 0.93 [95% CI 0.70 to 1.22]). After propensity matching and adjustment, complication rate (OR 1.51 [1.15 to 1.97]) was greater and length of stay in survivors was longer (mean difference 38.6 [29.4 to 47.7] days) in North America.

Conclusions: Infants with CDH selected for ECLS had greater physiological derangement in North America than Europe and several differences were identified in management strategies. Further work is required to explore reasons for the increased ECLS-related complication rate and length of stay observed in North American infants.

1. Introduction

Congenital diaphragmatic hernia (CDH) is a rare condition with an incidence of 2.3 per 10,000 births [1]. Herniation of abdominal contents early in gestation prevents normal lung development resulting in abnormal pulmonary vasculature and pulmonary hypertension with variable severity [2–4]. The most severely affected infants develop respiratory and haemodynamic failure despite optimised ventilatory and cardiovascular support and may be offered treatment with extracorporeal life support (ECLS) [5]. There are many reports on the benefits of ECLS in CDH including

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reduced mortality when adjusting for disease severity [5,6]. However, ECLS is expensive for health care providers and associated with significant complications in newborns including intracranial haemorrhage, cerebral infarction, renal failure and bloodstream infection [7]. Less is known about longer term outcomes. Whilst some large international studies [8] report ECLS use in as many as 29% of infants with CDH there is wide variation in ECLS use between countries. In the United Kingdom, a prospective population-based study [2] showed that ECLS was only used in 4.1% of cases. Better description of characteristics, management and outcomes of those receiving ECLS in these different regions may allow better understanding of this inter-regional variation in ECLS use.

Various methods have been reported to guide treatment in infants with CDH which help determine whether ECLS is indicated. These include echocardiographic features [9], blood gas parameters [10], oxygen index [11] and other published criteria [12–14]. The Extracorporeal Life Support Organization (ELSO) provides indications for ECLS in their red book with criteria for use based on measures of hypoxia, acidosis, hypercarbia and hypotension [15]. In 2021, ELSO published more detailed interim guidance regarding ECLS use in CDH that includes recommendations for the criteria of hypoxic/hypercapnic respiratory failure, circulatory failure and acute clinical deterioration [12]. There is also guidance available based on consensus reached at the European CDH consortium in 2015 [13]. These criteria are broadly similar to the ELSO criteria but also include consideration of oxygenation index.

To be certain that ECLS is only used in infants with CDH that will benefit most, it is important to better understand which indications are being used for ECLS, differences in patient populations and clinically important outcomes such as mortality and ECLS-related complications. Given the previously reported differences in use of ECLS between geographical regions [2,8], we hypothesised that there will be differences in thresholds for starting ECLS between infants treated in North American and European centres but that outcomes will be broadly similar. We therefore compare ECLS use in CDH between North America and Europe with focus on physiology at time of starting ECLS (i.e. threshold for starting) and treatment-related outcomes.

2. Methods

2.1. Data source and participants

Infants were included if they received ECLS for CDH prior to 28 days of age and were treated in a North American or European centre between January 2012 and December 2022. A full list of each centre location is available from ELSO (https://www.elso.org/membership/centermap.aspx). Data were obtained from the ELSO dataset following approval from the ELSO Scientific and Oversight Committee.

2.2. Outcomes

Outcomes of interest were mortality, presence of any complication, length of inpatient stay in survivors, severe neurological injury and presence of a positive blood culture. Any complication was taken as at least one of a mechanical, haemorrhagic, neurologic, renal, cardiovascular, pulmonary, infectious, metabolic or limb complication. All outcomes were measured to hospital discharge. The definition used for severe neurological injury is defined within the ELSO dataset as a composite of acute neurological events (central nervous system haemorrhage, infarct and/or intraventricular haemorrhage (IVH) grade 3 or 4) [15]. Cerebral infarction or intracerebral/intraventricular haemorrhage reported to the ELSO dataset are diagnosed using cranial ultrasonography or computerized tomography [16].

2.3. Statistical analysis

If an infant received multiple ECLS runs, physiological data were reported from their first ECLS run and outcomes reported related to initial and any subsequent runs. Critical congenital cardiac disease was defined as per previous ELSO studies and included diagnoses of common arterial trunk, congenital tricuspid stenosis, discordant ventriculoarterial connection, hypoplastic left heart syndrome, pulmonary valve atresia, tetralogy of Fallot and total anomalous pulmonary venous connection [17]. Acidosis was defined as arterial lactate >5 mmol/L or pH < 7.20 and hypercarbia was defined as PaCO2 >70 and pH < 7.20 [15]. Previously developed criteria for using ECLS in CDH were taken from the ELSO interim guidelines, by Guner et al. and CDH Euro guidelines from Snoek et al. [12,13] Infants were grouped by the location of the centre they were treated in, which was either a North American or European centre.

Data are reported as n (%) or median (interquartile range). Univariable analysis utilised the chi squared test for categorical data and the Mann–Whitney U test for continuous data. Logistic or linear regression were also used to assess association with hospital location and outcomes reported as odds ratio (OR) with 95% confidence interval (CI) or mean difference with 95% CI. Propensity score matching was used to account for baseline differences between infants treated in North American and European centres. A propensity score representing the probability of being treated in a North American centre, versus a European one, conditional on demographic and physiological characteristics at commencement of ECLS, was estimated. These were sex, birthweight, presence of antenatal diagnosis of CDH, Apgar score at 5 min, critical congenital heart disease, chromosomal anomalies, CDH laterality, arterial pH, arterial CO_2, inspired oxygen fraction, arterial O_2 saturations and mean blood pressure. They were selected due to either their clinical significance or statistically significant difference identified in univariate analysis between both groups. Variables related to treatment choice, such as use of nitric oxide or ECLS cannulation method were not included.

Kernel propensity score matching uses a weighted function to match each treated individual to controls where closer matches have higher weight. This approach was taken rather than alternatives such as nearest neighbour matching due to significantly imbalanced group sizes. Therefore, no fixed matching ratio (e.g. 1:1 or 2:1) was specified. Instead, all control observations within a calliper of 0.1 contributed to the matched estimate with weights proportional to proximity in propensity score, with observations outside of the region of common support excluded. Propensity score weights derived from matching were then applied in outcome analyses comparing infants treated in North American and European centres. Propensity score weights derived from matching were applied to estimate adjusted odds ratios and mean differences for outcomes between infants treated in North American and European centres. Further models were also created to adjust for differences in treatment between both groups after propensity matching. These treatment variables were nitric oxide use, timing of repair in relation to ECLS, mode of cannulation, vasoactive use, age at starting ECLS and total days of ECLS. Sensitivity analyses were also undertaken excluding infants treated in centres with a yearly case volume in the lowest quartile of the dataset and also including centres with a yearly case volume in the highest quartile only (supplementary materials).

3. Results

There were 3,213 ECLS runs on 3,087 infants with a diagnosis of CDH of which 2382 (77.1%) infants were treated in North American centres and 705 (22.9%) in European centres. In total, there were 183 centres which provided ECLS to infants with CDH during the study period, with 143 centres in North America and 40 in Europe. Infants treated in North American centres had a lower 5-min Apgar score and were more likely to have a chromosomal anomaly (Table 1). Pre-ECLS arterial blood gas parameters were generally worse for infants treated in North American with a greater frequency of acidosis and hypercarbia (Table 1). Nitric oxide and vasoactive drugs were used more frequently in European treated infants whilst high frequency ventilation was used less frequently compared to those treated in North America. Case volume per year was less in North American centres compared to European centres (4 [IQR 2–7, range 1–34] vs 5 [IQR 3–15, range 1–35] cases per year, $p < 0.001$).

The median age at commencing ECLS was 1 (0–2) day. Overall, 2613 (84.7%) of infants met the ELSO criteria for receiving ECLS whilst 2216 (71.8%) met the CDH Euro criteria. The CDH Euro criteria were met more frequently in North American infants (Table 2). North American infants received ECLS for longer, were more likely to undergo veno-venous cannulation and to have their CDH repair on ECLS when compared to European infants (Table 2). Additionally, North American infants who received ECLS post-CDH repair were more likely to undergo veno-venous cannulation than those who underwent CDH repair pre or on ECLS (16.1% v 9.2% v 6.9%, $p < 0.001$) rather than other methods of cannulation. Of note, approximately 13% of infants never underwent CDH repair despite

Table 1
Demographics and physiological variables at time of starting ECLS in infants treated in North American and European centres.

	North American (n = 2,382)	European (n = 705)	p value
Male	1,331 (56.8%)	387 (55.6%)	0.57
Birthweight, kg	3.00 (2.68–3.32)	3.00 (2.70–3.39)	0.41
Gestational age, weeks	38.0 (37.0–39.0)	38.0 (37.0–39.0)	0.16
Antenatal CDH diagnosis	1,989 (84.7%)	594 (85.1%)	0.80
Apgar score at 5 min	6 (5–8)	7 (6–8)	<0.001
Critical congenital heart disease	63 (2.6%)	18 (2.6%)	0.89
Chromosomal anomaly	83 (3.5%)	6 (0.9%)	<0.001
CDH laterality			
Left	1,787 (76.0%)	536 (77.0%)	0.11
Right	514 (21.9%)	137 (19.7%)	
Bilateral	50 (2.1%)	23 (3.3%)	
Pre-ECLS arrest	176 (7.4%)	46 (6.6%)	0.45
Lactate, mmol/L	2.55 (1.50–4.85)	2.70 (1.60–4.70)	0.29
pH	7.14 (7.02–7.24)	7.19 (7.09–7.29)	<0.001
PaCO2, mmHg	68 (54–90)	59 (47–75)	<0.001
Acidosis[a]	2,081 (87.4%)	530 (75.2%)	<0.001
Hypercarbia[b]	1,015 (42.6%)	201 (28.5%)	<0.001
FiO2, %	100 (100–100)	100 (100–100)	0.36
PIP, cm H_2O	36 (27–42)	30 (26–45)	0.14
MAP, cm H_2O	15 (13–17)	15 (13–18)	0.13
Peripheral O_2 sats, %	78 (67–87)	81 (68–91)	0.01
Arterial O_2 sats, %	59 (39–76)	77 (63–88)	<0.001
Mean BP, mmHg	43 (36–51)	45 (39–51)	<0.001
iNO used	1,804 (75.7%)	594 (84.3%)	<0.001
High frequency ventilation	1,690 (74.7%)	408 (60.7%)	<0.001
Vasoactive drug used	1,840 (77.2%)	614 (87.1%)	<0.001

ECLS = extracorporeal life support, CDH = congenital diaphragmatic hernia, PaCO2 = partial pressure of carbon dioxide, FiO2 = fraction of inspired oxygen, PIP = peak inspiratory pressure, MAP = mean airway pressure, cm H_2O = centre metres of water, O_2 = oxygen, sats = saturations, BP = blood pressure, mmHg = millimetres of mercury, iNO = nitric oxide. Data are n (%) or median (IQR).
[a] Acidosis defined as lactate >5 mmol/L or pH <7.20.
[b] Hypercarbia defined as PaCO2 >70 and pH <7.20.

Table 2
Criteria at starting ECLS and characteristics of ECLS in infants treated in North American and European centres.

	North American (n = 2,382)	European (n = 705)	p value
Age at ECLS, days	1 (0–2)	1 (0–3)	<0.001
Meets ELSO interim criteria	2,004 (84.1%)	609 (86.4%)	0.15
Meets Euro CDH criteria	1,757 (73.8%)	459 (65.1%)	<0.001
Duration of ECLS, days	11.17 (6.71–18.21)	8.75 (5.92–12.79)	<0.001
Cannulation method			
VA	2,092 (88.1%)	655 (93.2%)	0.001
VV	242 (10.2%)	37 (5.3%)	
Conversion	35 (1.5%)	10 (1.4%)	
VVA	5 (0.2%)	1 (0.1%)	
Timing of CDH repair			
Pre-ECLS	218 (9.5%)	103 (14.9%)	<0.001
On ECLS	1,173 (51.0%)	247 (35.7%)	
Post-ECLS	600 (26.1%)	254 (36.8%)	
None	309 (13.4%)	87 (12.6%)	

ECLS = extracorporeal life support, CDH = congenital diaphragmatic hernia, VV = veno-venous, VA = veno-arterial, VVA = veno–veno–arterial. Data are n (%) or median (IQR).

treatment with ECLS (similar proportion in North America and Europe).

Mortality and the development of any complication were experienced more frequently in North American infants while length of stay was also longer (Table 3). Frequency of severe neurological injury and infants who had a positive blood culture were similar between groups (Table 3). Propensity score matching resulted in good covariate balance between infants treated in North American and European centres demonstrated by overlap of cumulative propensity score distributions (Fig. 1) and reduction in standardised mean differences post-matching (Fig. 2). Following matching, 56 infants were excluded as they fell outside of the prespecified calliper (0.1). After propensity matching, mortality was similar between groups (OR 1.02 [0.79 to 1.31], p = 0.88) however development of any complication was more likely (OR 1.82 [1.40 to 2.36], p < 0.001) for North American infants and length of stay was longer (mean difference of (38.8 [29.1 to 48.6] days, p < 0.001) compared to European infants. When the same analyses were undertaken with adjustment post propensity score matching for other treatment related variables, findings were similar (Table 4). Outcomes were also similar when excluding infants treated at centres within the lowest quartile for case volume per year which was 2 or fewer cases per year (Supplementary Table S1) and for only centres in the highest quartile for case volume per year which was 6 or more cases per year (Supplementary Table S2).

4. Discussion

This study has found important differences in practice and outcomes for infants with CDH treated with ECLS in North America and Europe. Despite similar demographics at birth, infants treated

Table 3
Outcomes of infants treated in North American and European centres.

	North American (n = 2,382)	European (n = 705)	p value
Mortality	1,141 (47.9%)	280 (39.7%)	<0.001
Length of stay[a], days	86 (59–130)	47 (23–79)	<0.001
Any complication[b]	1,804 (75.7%)	449 (63.7%)	<0.001
Mechanical complication	1,344 (56.4%)	289 (41.0%)	<0.001
Haemorrhagic complication	344 (14.4%)	122 (17.3%)	0.06
Neurologic complication	300 (12.6%)	60 (8.5%)	0.003
Renal complication	698 (29.3%)	135 (19.1%)	<0.001
Cardiovascular complication	285 (12.0%)	44 (6.2%)	<0.001
Pulmonary complication	245 (10.3%)	94 (13.3%)	0.02
Infectious complication	10 (0.4%)	0 (0.0%)	0.09
Metabolic complication	480 (20.2%)	34 (4.8%)	<0.001
Limb complication	12 (0.5%)	2 (0.3%)	0.45
Severe neurological injury	189 (7.9%)	45 (6.4%)	0.17
Positive blood culture	176 (7.4%)	44 (6.2%)	0.30

Data are n (%) or median (IQR).
[a] Survivors only.
[b] Some infants experienced more than one type of complications.

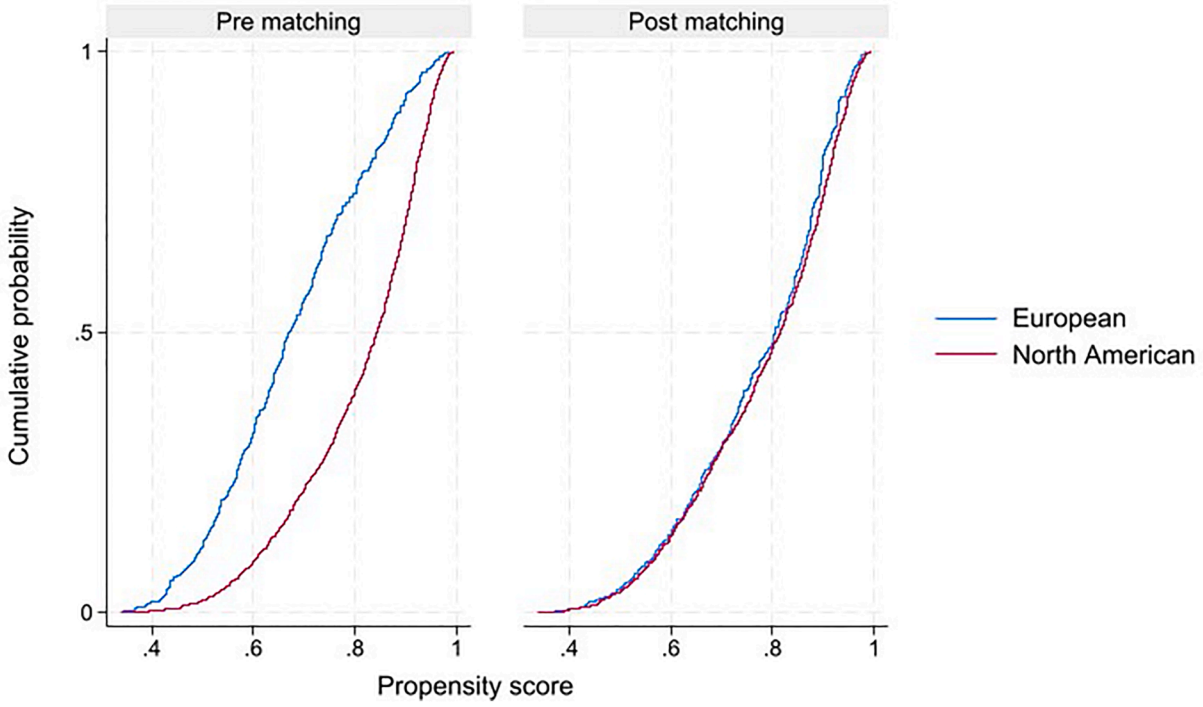

Fig. 1. Cumulative distribution of propensity scores pre and post matching for infants treated in North American (red) versus European (blue).

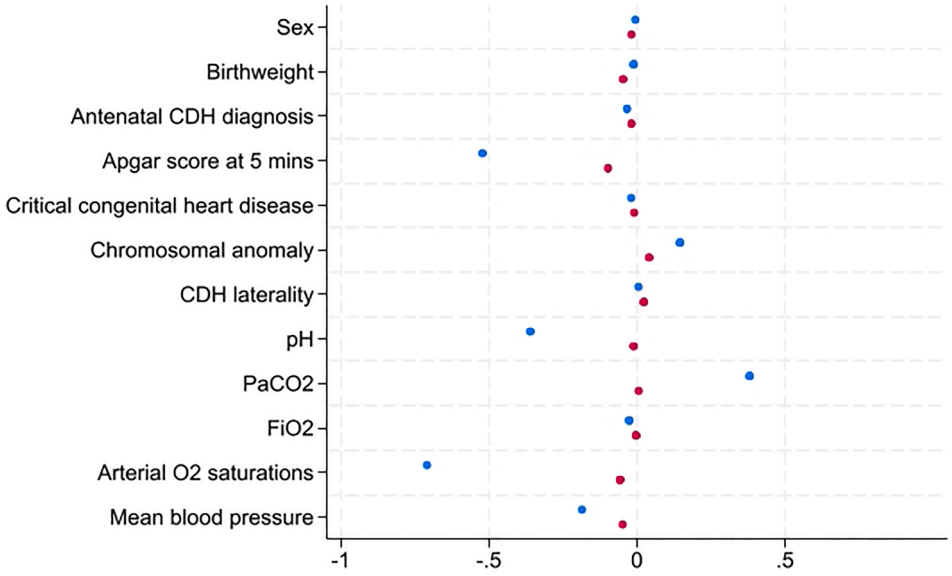

Fig. 2. Standardised mean differences for covariates pre (blue) and post (red) propensity score matching. A value of zero indicates perfect covariate balance.

Table 4
Propensity score matched outcomes of infants treated in North American and European centres with unadjusted outcomes for comparison.

Mortality						
	Unadjusted		**PS matched**		**Adjusted[a] PS matched**	
	OR (95% CI)	***p* value**	**OR (95% CI)**	***p* value**	**OR (95% CI)**	***p* value**
European	Reference	<0.001	Reference	0.88	Reference	0.60
North American	1.40 (1.18–1.66)		1.02 (0.79–1.31)		0.93 (0.70–1.22)	
Any complication						
	Unadjusted		**PS matched**		**Adjusted[a] PS matched**	
	OR (95% CI)	***p* value**	**OR (95% CI)**	***p* value**	**OR (95% CI)**	***p* value**
European	Reference	<0.001	Reference	<0.001	Reference	0.003
North American	1.78 (1.49–2.13)		1.82 (1.40–2.36)		1.51 (1.15–1.97)	
Length of stay						
	Unadjusted		**PS matched**		**Adjusted[a] PS matched**	
	Mean difference (95% CI)	***p* value**	**Mean difference (95% CI)**	**p value**	**Mean difference (95% CI)**	***p* value**
European	Reference	<0.001	Reference	<0.001	Reference	<0.001
North American	42.9 (33.3–52.5) days		38.8 (29.1–48.6) days		38.6 (29.4–47.7) days	

PS = propensity score, OR = odds ratio, CI = confidence interval.
[a] Adjusted for treatment variables: nitric oxide use, timing of repair in relation to ECLS, mode of cannulation, vasoactive use, age at starting ECLS and total days of ECLS.

in North American centres had worse physiological parameters at time of starting ECLS suggesting they were more unwell. Despite this, vasoactive drugs and nitric oxide were used less frequently in North American infants, VV cannulation was used more frequently, particularly for those who received ECLS post CDH repair, and duration of ECLS was longer. After adjusting for this variation, mortality was similar between continents, however complications were experienced more frequently in North America and length of stay was greater.

There are published criteria in both North America and Europe to guide indications for ECLS in CDH which include ventilatory support, blood gas findings and invasive monitoring findings [12,13]. Most infants in this current study met these criteria but some did not, particular with the slightly stricter CDH Euro guidance, adherence to which also differed between each continent. This suggests that additional criteria are guiding decision-making surrounding ECLS which might include use of echocardiography parameters or more nuanced decision-making guided by specific situations. Moreover, there was a higher rate of associated chromosomal anomalies in North American infants indicating there may be different approaches when considering contraindications to ECLS use. In order to robustly compare outcomes of ECLS use in CDH it is important that indications for use are standardised.

Some fundamental differences in management approach were detected in this current study. The lower use of vasoactive drugs and nitric oxide at time of starting ECLS in North American infants could be due to various reasons. This could suggest that infants were generally less sick requiring less physiological support, however the other physiological parameters measured would contradict this. Alternatively, given the larger number of centres providing ECLS in North America this could represent better access to ECLS hence these non-ECLS adjuncts were not started in infants who were able to start ECLS rapidly. It may, however, simply reflect different approaches to intensive care medicine between the two

continents. Previous research has attempted to define any benefit from early commencement of ECLS in CDH, however interpreting findings from observational study in this area is difficult as infants with the most severe disease tend to commence ECLS earlier than those who are initially more stable, creating a significant confounding factor [18]. There is also suggestion in this study that perinatal care differs between each continent as birth characteristics are broadly similar yet, at time of commencing ECLS, infants treated in North America appear less physiologically stable. Differences were also seen in the cannulation method, with greater veno-venous cannulation rates in North American centres. A number of reasons could explain this difference such as clinician preference, cannula availability or centre based practice.

Timing of CDH repair varied between continents with over half of infants in North America receiving ECLS undergoing repair before decannulation. Previous analysis of timing of surgery (on ECLS or after ECLS) has been reported in a recent ELSO study also using propensity matching. This found significantly lower mortality when repair of CDH occurred following ECLS [19]. Other smaller studies provide conflicting data [20] and a recent study of just those who did undergo repair on ECLS found that outcomes were better if CDH repair took place within the first 48 h [21]. This was also found within a previous analysis of the ELSO dataset where infants on ECLS undergoing early repair (median 2 days) had lower mortality than those with late repair on ECLS (median 12 days) [22]. In 2015 the American Pediatric Surgeons Association (APSA) outcomes and evidence committee undertook a systematic review and concluded that 'early repair on ECLS may have improved survival and shorter ECLS duration' however this was only a Grade D recommendation given the low quality evidence [23]. Observational methodology of this question will always be limited and a randomised study is much needed.

After adjustment, mortality was similar between continents, but other outcomes were less favourable in North American infants. This could be explained by variation in cohorts receiving ECLS on each continent. For example, infants deemed too sick for ECLS in Europe, who undergo redirection of care, may be offered ECLS in North America. It could also be possible than more pregnancies are terminated in Europe following antenatal diagnosis of CDH. Inclusion of antenatal data and data for those with CDH who didn't receive ECLS may allow further exploration of this. From a clinical perspective determining which infants are unlikely to survive even with ECLS is critical since it may reduce futile invasive treatment and cost. A previous study developed a risk model to predict poor outcome which enables risk stratification of infants either before ECLS or whilst on ECLS [24]. The finding of significantly longer length of stay in North American infants (mean 38 days) represents greater resource use and increased disruption for parents and families. This discrepancy has also been seen in studies from both continents on all those with CDH, not just those receiving ECLS. A UK population based study [25] found a median length of stay of 20 days however a recent US study [26] reported a median of 50 days. There was also centre based variation in the US study with 3.3 fold differences in length of stay between centres after adjustment for confounders [26]. Efforts to standardise care in CDH might address these discrepancies and allow length of stay to be reduced [27]. We acknowledge there may be other, perhaps non-clinical factors that influence length of stay, yet such wide variation is unlikely to be justified.

This study has some limitations. Firstly, this study uses registry data and is observational in nature. Data are not available for those with CDH who did not receive ECLS and therefore the incidence of ECLS use in CDH in both populations is unknown. Measures of CDH severity such as CDH study group defect type and observed to expected lung-to-head ratio were not collected within the registry whilst outcomes are also limited to those collected and don't include surgical outcomes such as re-herniation. We have taken effort to adjust for measured confounders however there may be other differences not accounted for such as variation in centre-based practice, and we were unable to adjust for anatomical measures of CDH severity. Finally, length of hospital stay might be influenced by non-clinical factors resulting from differences in healthcare systems between countries and continents.

This study has highlighted previously unreported differences in management and outcomes of infants with CDH who receive ECLS despite similar birth characteristics. Further work is needed to explore why these differences exist and international collaboration is required to determine best practice for ECLS use in CDH including indications, contraindications, timing of CDH repair and minimum centre volumes. Addressing these will ensure that all infants with CDH receive the best possible care regardless of treatment location.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jpedsurg.2026.163130.

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