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The use of ECMO for gastroschisis and omphalocele: Two decades of experience

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ABSTRACT

Purpose: The aim was to review the respiratory failure causes and outcomes of infants with omphalocele or gastroschisis receiving ECMO and reported to the Extracorporeal Life Support Organization (ELSO).
Methods: Gastroschisis and omphalocele infants supported with ECMO and reported to the ELSO Registry between 1992 and 2015 were retrospectively reviewed. Clinical variables, diagnosis of respiratory failure (pulmonary hypertension (PHN), congenital heart defects (CHD), congenital diaphragmatic hernia (CDH), and sepsis), and outcomes were recorded. Univariate analysis was performed using Student's *t*-test for continuous or Fisher's exact test for categorical variables.
Results: Fifty-two infants with gastroschisis (41) (79%) or omphalocele (11) (21%) were identified. The survival to discharge rate of 51% for gastroschisis remained stable and was significantly higher ($P = 0.05$). The overall mortality rate for omphalocele was 82%. Omphalocele had significantly more PHN ($P < 0.01$), CDH ($P < 0.01$), and multiple anomalies ($P = 0.04$) had significantly more sepsis ($P = 0.02$), and none had a CDH.
Conclusion: Infants with gastroschisis requiring ECMO support have significantly better survival than omphaloceles, and respiratory failure is significantly associated with sepsis. The majority of omphalocele infants die despite ECMO, and respiratory failure is associated PHN and CDH. The association of omphalocele, PHN, and CDH merits further investigation.
Study type and evidence level: Retrospective comparative study of Registry Database, Level 3.
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Despite improvements in respiratory failure management in infants with omphalocele and gastroschisis, some infants require support with extracorporeal membrane oxygenation (ECMO). Respiratory failure at birth, and specifically failure from pulmonary hypertension, were identified as independent predictors of mortality in infants with omphalocele [1,2]. There is one report of the successful use of ECMO for an infant with gastroschisis and PHN [3].

The literature provides only sporadic case reports and little guidance regarding the use of ECMO for infants with omphalocele or gastroschisis and respiratory failure. The objectives of this study are to review the causes of respiratory failure and the outcomes of infants with omphalocele and gastroschisis receiving ECMO over the past two decades reported to the Extracorporeal Life Support Organization (ELSO) Registry.

1. Methods

1.1. ELSO registry

ELSO was formed as a study group in 1989 by a collaboration of physicians, nurses, perfusionists, and scientists with an interest in ECMO [4]. The group provides an international registry that collects data from almost all ECMO centers in the United States and internationally. ECMO utilization data are self-reported by a member institution ECMO director to ELSO.

A retrospective analysis of all infants with gastroschisis and omphalocele, supported with ECMO and reported to the ELSO Registry (Registry) between 1992 and 2015 was performed. This review was exempt from Institutional Review Board (IRB) approval as it did not involve data merger or enhancement of multicenter data that would permit patient identification.

1.2. Cohort

The Registry collects data with the International Classification of Diseases Revision-9 (ICD-9), which is the standard international diagnostic classification system and maintained by the World Health Organization [5]. Each diagnosis was specified at the discretion of the treating physician. In the Registry, abdominal wall defects were reported with ICD-9 codes for omphalocele, gastroschisis and abdominal wall defect–not otherwise specified (AWD-NOS). Only infants with a specific diagnosis of omphalocele or gastroschisis were included. Infants with the diagnosis of AWD-NOS were excluded. The procedures recorded in the Registry were identified by Current Procedural Terminology (CPT) codes, which are maintained by the American Medical Association [6].

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1.3. Respiratory failure

For this study, respiratory failure was defined as hypoxemia in room air with progressive respiratory and metabolic acidosis and the need for mechanical ventilation [7]. Infants with hypercapnia, increased work of breathing, or increased inspired oxygen requirements and no response to noninvasive treatment require intubation [7]. If intubation and mechanical ventilation fail, infants could be supported with ECMO for sustained hypoxemia and acidosis [4,8]. Specific criteria for initiation of ECMO are center specific.

The Registry reports the following diagnoses contributing to respiratory failure in infants with omphalocele or gastroschisis requiring ECMO: pulmonary hypertension (PHN), sepsis, congenital heart defects (CHD) and congenital diaphragmatic hernia (CDH) [9].

PHN is defined by echocardiography findings, including flattening of the inter-ventricular septum during systole and/or a tricuspid regurgitant jet (TR) with an estimated right ventricular pressure greater than 40 mm Hg when observed in the setting of hypoxemia [10]. Echocardiogram is best obtained after the second day of life to avoid misdiagnosis of transitional circulation as PHN. However, no specific information regarding echocardiography results was available from the Registry. Pulmonary hypertension was reported at the discretion of the treating physician.

Sepsis is defined as a life-threatening condition characterized by systemic inflammatory response syndrome (SIRS) caused by suspected or present infection. In children younger than 1 year, SIRS is defined as persistent tachycardia or bradycardia, temperature greater than 38.5 °C or below 36 °C, tachypnea or need for mechanical ventilation, abnormal leukocyte count or greater than 10% bands on complete blood count and differential [12]. The diagnosis of sepsis reported to the Registry was at the discretion of the treating physician.

The Registry records subtypes of sepsis including pneumonia, septicemia, sepsis from intestinal necrosis, and sepsis with multisystem organ failure. The clinician can report the infectious organism. Pneumonia is further classified as meconium aspiration, pneumonia caused by a specific bacteria or virus, and pneumonia NOS. This information was identified.

Congenital heart defects (CHD) were defined as abnormalities of cardiac structure involving walls, valves or vasculature present at birth [13]. The specific CHD was recorded when available. The Registry classified CHD as atrial septal defect (ASD), ventricular septal defect (VSD), total anomalous pulmonary venous return (TAPVR), Tetralogy of Fallot (TOF), double outlet right ventricle (DORV), aortic stenosis, pulmonary artery stenosis, and unspecified cardiac anomaly (CHD-NOS).

Congenital diaphragmatic hernia (CDH) was defined as a defect in the diaphragm. The most common CDH is a posterolateral Bochdalek hernia and is associated with respiratory failure from pulmonary hypoplasia and pulmonary hypertension [11]. CDH with refractory PHN is a common indication for ECMO [11].

Pulmonary hypoplasia is defined as incomplete development of the lungs with decreased bronchopulmonary segments and diminished alveolar septation [14]. However, pulmonary hypoplasia is not recorded as a specific diagnosis for respiratory failure in the Registry and could not be evaluated.

1.4. Variables

Clinical variables reported to the Registry included in the analysis were gender, birth weight, gestational age, APGARS at 1 and 5 min, age and weight at ECMO. The length of the ECMO run in hours, the mode of cannulation, whether venoarterial (VA) or venovenous with a double lumen catheter (VVDL), the number of ECMO runs and conversions from VV to VA ECMO, were recorded.

Clinicians report the arterial blood gas and ventilator settings at the time of worsening respiratory failure and decision for ECMO to the Registry. To compare the severity of respiratory failure in infants with omphalocele or gastroschisis, a pH equal or less than 7.20, and a $PaCO_2$ equal or greater than 50 were recorded [15]. The need for pre-ECMO inotropic support was documented, but the database does not document specific medications or time administered. The use of high frequency oscillating ventilation (HFOV), nitric oxide (NO) or bicarbonate administration was recorded. The presence of multiple anomalies, and comorbidities such as renal failure or a central nervous system (CNS) hemorrhage while on ECMO was recorded.

1.5. Outcomes

The outcomes identified from the database were: infant mortality on ECMO, ECMO discontinuation but subsequent in-hospital mortality or survival to hospital discharge. The time to each outcome variable was recorded.

1.6. Statistical analysis

Infants with omphalocele or gastroschisis were compared with the paired Student *t*-test for continuous and the two-tailed Fisher-exact test for categorical variables. A *p*-value of 0.05 was considered significant. Continuous data were reported as means and standard deviations, medians and ranges.

2. Results

Between 1992 and 2015, 110 infants with omphalocele, gastroschisis or an AWD-NOS had severe respiratory failure, underwent ECMO and were reported to the Registry. A specific diagnosis was available in 52 infants, eleven had omphalocele (21%) and 41 had gastroschisis (79%). The 52 (47.3%) infants were included and the 58 (52.7%) with AWD-NOS were excluded.

One of eleven infants with an omphalocele underwent two ECMO runs. Two infants with gastroschisis were converted from VV to VA, but all 41 infants with gastroschisis underwent one ECMO run.

Table 1 compares the outcomes, ECMO run times and hospital stay for the cohort. Of the eleven infants with omphalocele that underwent ECMO between 2011 and 2015, nine died (81.8%). Three died on

Table 1
Outcomes for infants with omphalocele or gastroschisis that required ECMO.

	Omphalocele, $n = 11$ (%)	Gastroschisis, $n = 41$ (%)	p
Died on ECMO, *n* (%)	3 (27.3)	9 (22.0)	0.44
Time to death on ECMO (hours)[a]	88.3 (130.5) 15 (11–239)	139.3 (173.0) 25 (1–358)	0.67
Died within 2 h of ECMO discontinuation, *n* (%)	1 (9)	5 (12.2)	
ECMO run time (hours) for deaths within 2 h of discontinuation	157	202 (86.4) 183 (123–337)	n/a
Decannulated, *n* (%)	7 (63.6)	27 (66)	
Died before discharge, *n* (%)	5 (45.5)	6 (14.6)	
Time to in-hospital death after decannulation (days)	62.4 (67.6) 41 (9–180)	28.4 (45.1) 12 (1–119)	0.35
Discharged alive n(%)	2 (18.2)	21 (51.0)	**0.05**
Hospital stay for survivors after decannulation (days)	48.5 (10.6) (41, 56)	103.7 (129) 67 (1–530)	0.57

Bold text denotes statistical significance.
[a] Data reported as mean, standard deviation, median and range.

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