

The use of extracorporeal life support (ECLS) has grown tremendously in recent years, especially since the range of possible applications has increased and the safety improved.^{1, 2}

By the year 2021, the Extracorporeal Life Support Organization (ELSO) has registered more than 170,000 runs of extracorporeal membrane oxygenation (ECMO).³

Approximately half of these were performed in neonatal and pediatric patients, the majority for pulmonary support.³

References

- 1 Fallon, B. P. et al.: Pediatric and neonatal extracorporeal life support: current state and continuing evolution. *Pediatr. Surg. Int.* 2021;37(1):17-35. doi: 10.1007/s00383-020-04800-2
- 2 Erdil, T. et al.: Extracorporeal membrane oxygenation support in pediatrics. *Ann. Cardiothorac. Surg.* 2019;8(1):109–115. doi: 10.21037/acs.2018.09.08
- 3 Extracorporeal Life Support Organization (ELSO), ECLS Registry Report, International Summary 2021, April 2022
- 4 Wild K. T. et al.: Extracorporeal Life Support Organization (ELSO): Guidelines for Neonatal Respiratory Failure. *ASAIO J.* 2020;66(5):463–470. doi: 10.1097/MAT.0000000000001153
- 5 Monfredini, C. et al.: Meconium Aspiration Syndrome: A Narrative Review. *Children.* 2021;8(3):230. doi: 10.3390/children8030230
- 6 Brogan, T. V. et al.: Extracorporeal life support : the ELSO red book, 5th edition, Ann Arbor, Extracorporeal Life Support Organization (ELSO), 2017
- 7 Guner, Y. et al.: Management of Congenital Diaphragmatic Hernia Treated With Extracorporeal Life Support: Interim Guidelines Consensus Statement From the Extracorporeal Life Support Organization. *ASAIO J.* 2021;67(2):113–120. doi: 10.1097/MAT.0000000000001338
- 8 Raitio, A. et al.: Congenital diaphragmatic hernia-does the presence of a hernia sac improve outcome? A systematic review of published studies. *Eur. J. Pediatr.* 2021;180(2):333-337. doi: 10.1007/s00431-020-03779-1
- 9 Jancelewicz, T. et al.: Survival Benefit Associated With the Use of Extracorporeal Life Support for Neonates With Congenital Diaphragmatic Hernia. *Ann. Surg.* 2022;275(1):e256-e263 doi: 10.1097/SLA.0000000000003928



Neonatal and Pediatric Extracorporeal Life Support

Heart and Lung Therapies

Respiratory indications for ECMO in infants

In infants, respiratory indications for ECMO include meconium aspiration syndrome (MAS) and congenital diaphragmatic hernia (CDH), with the latter being the most common in neonates.^{2, 4}

Meconium aspiration syndrome (MAS)

Meconium aspiration syndrome occurs in infants born through amniotic fluid stained with meconium – the first intestinal discharge consisting of components such as water, skin and intestinal desquamation cells, gastrointestinal secretions, and bile. MAS patients aspirate meconium-stained amniotic fluid either prenatally by gasping or

during the first breaths after birth. The pathophysiology can involve mechanical airway obstruction, inactivation of the pulmonary surfactant and persistent pulmonary hypertension.⁵

MAS accounts for about 10 percent of neonatal respiratory failure (Fig. 1).⁵

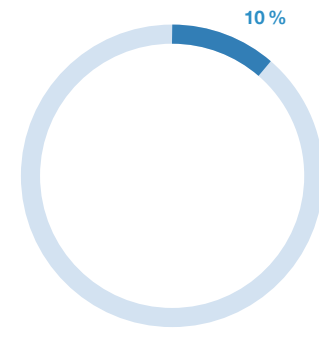


Fig. 1: Proportion of MAS cases in respiratory failure.⁵

Congenital diaphragmatic hernia (CDH)

In congenital diaphragmatic hernia, patients exhibit an abnormal development of the diaphragm, resulting in herniation of abdominal contents into the thoracic cavity. Major complications include pulmonary hypoplasia and pulmonary hypertension. Neonates may present with cyanosis and respiratory distress, leading to hypoxemia, hypercarbia, and respiratory acidosis.^{6,7}

CDH occurs approximately once in 2,200 live births, with male newborns being 1.5 times more frequently affected compared to female newborns (Fig. 2).^{6, 8} In about 75 percent of the cases, CDH is diagnosed prenatally by fetal ultrasound, which can reveal the position of the liver in relation to the diaphragm and a reduced lung volume.^{6,7} Regarding clinical management, CDH is one of the most complex anomalies in infants, providing unique challenges to pediatric and neonatal specialists.⁴

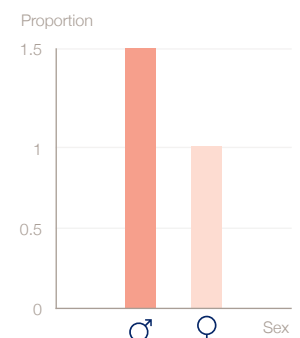


Fig. 2: Proportion of female and male newborns in CDH cases.⁶



Ventilation management in CDH

Postnatal ventilatory management of CDH aims to stabilize the patient while barotrauma and volutrauma should be reduced. Ventilation recommendations include limiting the peak inspiratory pressure, increasing the respiratory rates, and shortening the inspiratory times.⁷

Vascular resistance has been shown to be effectively reduced by hyperventilation techniques, but ventilator-associated lung injury remains a concern.⁶

In CDH, ECLS is not only a rescue therapy, but also a method for lung protection and preoperative stabilization of the patients.⁶

ECMO for pulmonary support

According to the ELSO Registry 2021 International Summary, pulmonary ECMO has the highest survival rates in neonatal and pediatric patients:

73 percent and 61 percent at hospital discharge, respectively (Fig. 3).³

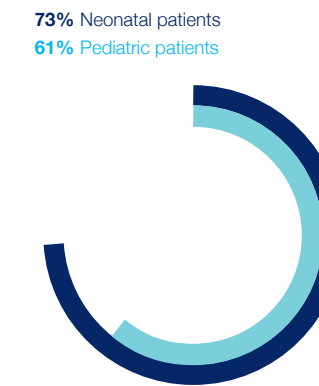


Fig. 3: Survival rates for pulmonary ECMO at hospital discharge.³

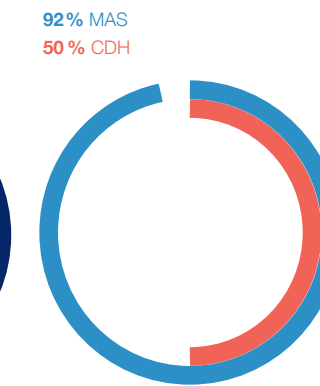


Fig. 4: ECMO survival rates for individual respiratory indications.⁴

Among individual respiratory indications, the survival rates vary considerably – it is about 92 percent for MAS and averages 50 percent for CDH (Fig. 4),⁴ although it is higher for high-risk patients and in centers with a lot of experience.⁹

In CDH, but also in general, ECLS practices vary between individual centers, for instance in terms of support mode and technologies used.^{4, 7}



Our solution: Novalung® kits for neonatal and pediatric ECMO

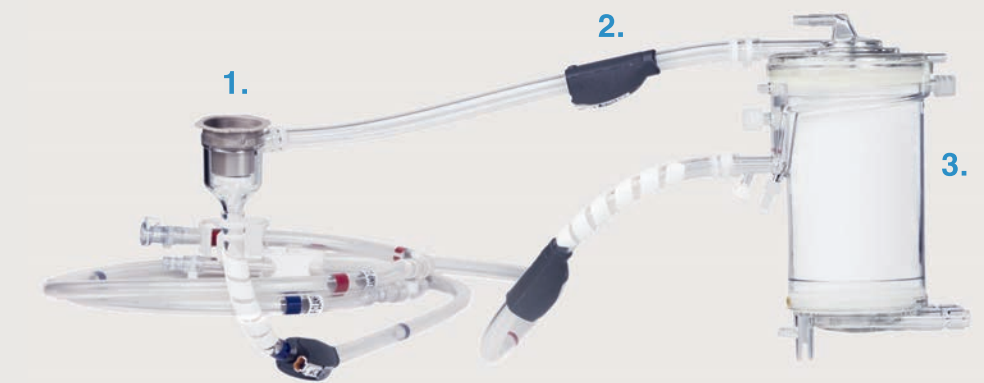
Novalung® kits are pump-driven ECLS devices specifically developed for neonatal and pediatric patients. They are designed as part of the Xenios system* and contain a centrifugal pump head (DP3) [1], integrated pressure sensors (IPS) [2], an oxygenator [3], blood flow direction indicators, tubing, robot clamps and separating points.

The kits are intended for prolonged (up to 29 days) respiratory as well as cardiopulmonary support. Indications include severe or hypercapnic respiratory failure or cardiovascular failure due to various etiologies related to cardiac surgery and catheterization, as well as lack of response to conventional mechanical ventilation and/or other forms of rescue therapy.**

The MiniLung petite kit is for neonates and children whose blood volume is adequate to the extracorporeal priming volume (195 ml).

The MiniLung kit ¼" is for children (and adults) whose blood volume is adequate to the extracorporeal priming volume (240 ml).

1. DP3 pump head
2. Integrated pressure sensors (IPS)
3. Oxygenator



All blood-contacting surfaces of the Novalung® kits, except the pump head, are coated with the x.ellence coating, a biocompatible surface coating consisting of high-molecular-weight heparin derived from porcine intestinal mucosa and recombinant human albumin (rHA).

* Xenios system: Hardware: Xenios console, holding system, trolley; disposable: tubing kit
 ** For more detailed information on indications for use, intended patient population etc., see IFU Novalung® kits.