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ECMO in Neonates: An Update

In This Issue...

Extracorporeal membrane oxygenation (ECMO) is defined as the use of a modified heart-lung machine combined with a membrane oxygenator to provide cardiopulmonary support for patients with reversible pulmonary and/or cardiac failure in whom maximal conventional therapies have failed. While ECMO is now well accepted as a standard treatment for neonatal respiratory failure unresponsive to conventional therapies, over the last decade a number of new treatments have been used – including high frequency ventilation, surfactant replacement, and inhaled nitric oxide therapy – that, in many cases, can replace ECMO.

In this issue, we explore the current state of ECMO from a variety of perspectives, reviewing the overall demographics of neonates treated with ECMO and its use in neonates with congenital diaphragmatic hernia and agenesis. We will also discuss a promising new non-invasive technology for measuring cerebral perfusion in venovenous ECMO (VV-ECMO) patients, the long-term neurodevelopmental outcomes in ECMO-treated neonates, and the effect of the ECMO procedure itself on cerebral vascular activity.

THIS ISSUE

- [IN THIS ISSUE](#)
- [MAY PODCAST](#)
- [COMMENTARY from our Guest Editor](#)
[Opinion](#)
- [ECMO FOR NEONATAL RESPIRATORY FAILURE](#)
- [ECMO AND CONGENITAL DIAPHRAGMATIC HERNIA](#)
- [NIRS AND CEREBRAL OXIMETRY IN VV-ECMO](#)
- [ECMO AND NEURODEVELOPMENTAL OUTCOME](#)
- [EFFECT OF THE ECMO PROCEDURE ON CEREBRAL VASCULAR REACTIVITY](#)

Course Directors

Edward E. Lawson, MD

Professor
Department of Pediatrics - Neonatology
The Johns Hopkins University
School of Medicine

Christoph U. Lehmann, MD

Assistant Professor
Department of Pediatrics - Neonatology
The Johns Hopkins University
School of Medicine

Lawrence M. Noguee, MD

Associate Professor
Department of Pediatrics - Neonatology
The Johns Hopkins University
School of Medicine

Mary Terhaar

Assistant Professor
Undergraduate Instruction
JHU School of Nursing

Robert J. Kopotic, MSN, RRT,

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- [CE Info](#)
- [Accreditation](#)
- [Credit Designations](#)
- [Target Audience](#)
- [Learning Objectives](#)
- [Internet CME/CNE Policy](#)
- [Faculty Disclosure](#)
- [Disclaimer Statement](#)

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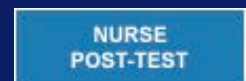
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Billie Lou Short, MD

Professor of Pediatrics
The George Washington
University School of
Medicine and Health
Sciences
Chief, Division of
Neonatology Department of
Neonatology Children's
National Medical Center
Washington, DC

Guest Faculty Disclosure

Billie Lou Short, MD, has disclosed no relationship with any commercial supporters.

K. Rais-Bahrami, MD, has received grant and/or research support from CAS Medical System Inc.

Penny Glass, PhD, has disclosed no relationship with any commercial supporters.



Commentary & Reviews:
K. Rais-Bahrami, MD

Professor of Pediatrics
The George Washington
University School of
Medicine and Health
Sciences
Department of Neonatology
Children's National Medical
Center
Washington, DC

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Commentary & Reviews:
Penny Glass, PhD

Associate Professor of
Pediatrics
The George Washington
University School of
Medicine and Health
Sciences
Director, Child Development
Clinic Children's National
Medical Center
Washington, DC.

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At the conclusion of this activity, participants should be able to:

- Describe the current indications, management parameters and newer monitoring techniques used in neonatal extracorporeal membrane oxygenation (ECMO)
- Discuss the management and outcome of infants with congenital diaphragmatic hernia (CDH)
- Understand the neurologic complications and associated risk factors in the ECMO population, including those related to the ECMO procedure itself

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This audio interview with Billie Lou Short, MD, K. Rais-Bahrami, MD, and Penny Glass, PhD, all affiliated with The George Washington University School of Medicine and Health Sciences and Children's National Medical Center in Washington, DC, discusses additional topics related to ECMO.

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COMMENTARY

There have been many changes in the demographics of neonates treated with ECMO, with the neonatal ELSO Registry data for June 2006 reporting a decline in ECMO use (1226 neonatal cases reported to the Registry for 2006, down from 1800). Much of this change is due to alternative therapies that have been observed to decrease the need for ECMO. There has been a steady downward trend in the use of ECMO for neonatal respiratory failure, from a high of 1500 per year to now around 700 per year^[1]. There has been a significant change in the management of infants with CDH, with less frequent use of ECMO and a greater use of inhaled nitric oxide (iNO) in high-risk patients with a potential improvement in survival^[2]. On the other hand, the number of neonates receiving ECMO for post-operative cardiac surgery has been steadily increasing^[1].

Neurologic complications such as intracranial hemorrhage are the primary cause of death in the neonatal respiratory failure population, and are thought to be related to pre-ECMO hypoxic events. To fully understand the neurologic outcome of infants who present as candidates for ECMO, we need more definitive methods of measuring cerebral perfusion, both pre-, during, and post-therapies such as ECMO. As newer techniques, such as near infrared spectroscopy (NIRS) attain wider usage, we can expect additional information on cerebral perfusion to be available in the near future. Currently, NIRS techniques are being studied in the VV-ECMO population^[3].

Long-term outcome data is now available from the randomized United Kingdom (UK) ECMO trial, and other centers following ECMO children into school and beyond^[4,5]. While outcome data on these children are encouraging, the power of the randomized UK trial is that risks related to the disease process can be separated from those related to the ECMO procedure. Further, recent laboratory data indicates that risk factors for neurologic injury in the ECMO population are not only related to pre-ECMO events such as severe hypoxia, asphyxia, and pre-ECMO treatment modalities such as severe hyperventilation, but may also be due to the cerebral vascular changes caused by the VA-ECMO pumping systems^[6].

As the articles reviewed herein show, clinicians considering an ECMO procedure must be aware of the selection criteria for neonatal ECMO, the clinical management of neonates on ECMO, the long-term outcome of neonates treated with ECMO, and the risk factors related to the ECMO procedure itself.

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ECMO FOR NEONATAL RESPIRATORY FAILURE

Rais-Bahrami K, Van Meurs KP. **ECMO for neonatal respiratory failure**. Semin Perinatol. 2005 Feb;29(1):15-23.

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This review article discusses the demographic changes in neonatal ECMO with the advent of new therapies such as surfactant replacement therapy, iNO and changes in mechanical ventilation strategies, and summarizes the current selection criteria, clinical management, and long-term outcomes of neonates treated with ECMO. The authors describe how ECMO has been used in the treatment of neonates with a variety of cardio-respiratory problems, including meconium aspiration syndrome (MAS), persistent pulmonary hypertension of the neonate (PPHN), CDH, sepsis/pneumonia, respiratory distress syndrome (RDS), air leak syndrome, and cardiac anomalies.

While specific indication criteria vary from center to center, there are both absolute and relative contraindications to ECMO. The specific clinical circumstance and the predicted risk of death or reversibility of the underlying disease process often are the deciding factors. Important inclusion and exclusion criteria reported by the authors include:

- Gestational age \geq 34 weeks or birth weight \geq 2000g
- No evidence of significant coagulopathy or uncontrolled bleeding
- No major intracranial hemorrhage, $>$ grade 2 IVH
- Reversible lung disease with length of mechanical ventilation $<$ 10-14 days
- No uncorrectable congenital heart disease
- No lethal congenital anomalies
- No evidence of irreversible brain damage

At the time of cannulation, a decision must first be made as to whether the infant would best be served with venovenous (VV) or venoarterial (VA) support. VA-ECMO provides both cardiac and pulmonary support, and is the treatment of choice for patients with significant blood pressure instability and for cases of primary cardiac dysfunction. However, in neonates with respiratory failure, VA-ECMO is gradually being replaced by VV-ECMO, which uses a single double-lumen catheter. To ensure adequate tissue oxygenation during VV-ECMO, non-

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invasive techniques are being developed to monitor cerebral oximetry (as described herein in the article by Rais-Bahrami, Rivera, and Short).

The authors report that neonatal ECMO has resulted in a significant improvement in the survival of neonates with cardiopulmonary failure refractory to maximal medical therapy. Patients with an anticipated mortality rate of 80–85% have an overall survival rate of 84%, with recent data showing nearly 100% survival in many diagnostic groups. Further, long-term neurodevelopmental outcome has been encouraging.

The biggest challenge over the next few years will be to determine whether ECMO should remain as a "rescue therapy" or should it be considered first line for some disease states. It may be time for a trial of early intervention with ECMO vs present therapies to evaluate morbidity and cost of care as the primary outcome variables, instead of mortality alone. The cost of some new therapies (such as iNO), which decrease the need for ECMO but have not shown differences in long-term outcome when compared to the ECMO-treated infants, makes this question compelling.

ECMO AND CONGENITAL DIAPHRAGMATIC HERNIA

Congenital Diaphragmatic Hernia Study Group. **Treatment evolution in high-risk congenital diaphragmatic hernia: ten years' experience with diaphragmatic agenesis.** *Ann Surg.* 2006 Oct;244(4):505-13.

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CDH occurs in approximately 1 in 2500 to 1 in 4000 live births, with an overall mortality at around 50%. The application of the newer therapies for infants with respiratory failure — ECMO, high frequency oscillatory ventilation (HFOV), exogenous surfactant, and iNO — to infants with CDH has been based on anecdotal case reports and retrospective reviews such as Lally's 2006 article. The authors' objective was to evaluate the impact of these newer therapies on highest risk patients: infants with CDH and those with agenesis of the diaphragm.

The authors reviewed outcomes from 20 centers, comprising 1569 patients diagnosed with CDH between January 1995 and December 2004. A total of 218 patients (14%) had diaphragmatic agenesis and underwent repair. The overall survival for all patients was 68%, while survival of agenesis patients was 54%. When patients with diaphragmatic agenesis from the first 2 years studied were compared with similar patients from the last 2 years, the reviewers found significantly less use of ECMO (75% vs 52%) and an increased use of iNO (30% vs 80%). They also report a trend toward improved survival in patients with agenesis, from 47% in the first 2 years studied to 59% in the last 2 years. Survivors with diaphragmatic agenesis had prolonged hospital stays compared to patients without agenesis (median, 68 vs 30 days). During the last 2 years of the study, 36% of the patients with agenesis were discharged on tube feedings and 22% on oxygen therapy.

While CDH has been viewed by some as a homogeneous disease process, the authors note that there are clear differences in outcomes between certain groups of patients. One example they cite is that infants with larger defects have been shown to have a poorer survival compared with those with smaller defects — although it has been difficult to demonstrate differences in outcome, as the anomaly is uncommon and no single center can accrue enough high-risk patients to draw meaningful conclusions.

The results of this study demonstrate that there has been a significant change in



the management of infants with CDH, with less frequent use of ECMO and a greater use of iNO in high-risk patients with a potential improvement in survival. However, the mortality, hospital length of stay, and morbidity in CDH and agenesis patients remain significant despite the application of advanced therapies. As survival of these patients improves, the focus on long-term issues will become increasingly important.

NIRS AND CEREBRAL OXIMETRY IN VV-ECMO

Rais-Bahrami K, Rivera O, Short BL. **Validation of a Non-Invasive Neonatal Optical Cerebral Oximeter in Venovenous ECMO Patients with a Cephalad Catheter.** J Perinatol. 2006 Oct;26(10):628-35.

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There has been renewed interest in near infrared spectroscopy (NIRS) monitors, such as cerebral oximetry, as an easy-to-use and non-invasive technique for measuring tissue oxygenation in the brain. Recent technical advances have led to the development of compact, portable instruments that detect changes in optical attenuation of several wavelengths of light. This 2006 study by Rais-Bahrami et al in neonates on venovenous ECMO (VV-ECMO) sought to compare and validate cerebral oximetry measurements obtained with a prototype neonatal cerebral oximeter developed by CAS Medical Systems (Branford, CT, USA) vs blood analysis of oxygen saturation from an existing cephalad catheter.

17 neonates receiving VV-ECMO were evaluated with 1718 hours of noninvasive cerebral oximetry data collected using the CAS Medical Systems prototype neonatal cerebral oximeter. During the same time frame 225 blood samples were drawn from the cephalad catheter for functional O₂ saturation by CO-oximetry, ranging from 5 to 28 samples per subject. The results demonstrated that cerebral tissue oxygen saturation (SctO₂) measured by the prototype cerebral oximeter and SvO₂ showed a high level of agreement (bias ± precision of 0.4 ± 5.1% vs 0.6 ± 7.3%, respectively).

As the cerebral oximeter measurements agreed well with the measured cerebral venous saturation, the authors recommend this non-invasive method of measuring cerebral tissue and venous saturation as a substitute for drawing venous blood samples in neonates requiring extracorporeal life support. They state goals for VV-ECMO patients of maintaining cephalad SvO₂ = 60% and a SctO₂ = 60%. They note that as most VV-ECMO and VA-ECMO procedures do not use cephalad catheters, cerebral oximetry offers an alternative, non-invasive means to monitor brain oxygenation, and that NIRS shows future promise as a clinical tool for bedside cerebral blood flow measurements and as a cerebral imaging modality for mapping structure and function.

ECMO AND NEURODEVELOPMENTAL OUTCOME

Bennett, CC, Johnson A, Field DJ, Elbourne D. **UK collaborative randomised trial of neonatal extracorporeal membrane oxygenation: follow-up to age 4 years.** Lancet. 2001 Apr 7;357(9262):1094-6.

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McNally H, Bennett CC, Elbourne D, Field DJ. **United Kingdom collaborative**

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The 2001 article by Bennett et al evaluated the neurodevelopmental outcome to age 4 years following a randomized trial of neonatal ECMO vs conventional respiratory treatment in the UK. The authors report that survival was improved with ECMO. Sixty-two ECMO survivors and 35 conventionally treated control children were assessed at age 4 years. Overall status by 4 years showed mean cognitive scores in the normal range: 93.1 and 92.4, respectively. In addition, 50% of ECMO-treated survivors had no disability, compared to 37% of the conventional treatment group. Moderate/severe disability was present in 19% of the ECMO-treated and 29% of the conventionally treated. While potential right-hemisphere deficit has long been a concern among ECMO-treated survivors, the investigators found that both groups had similar difficulty with visual/spatial tasks. No differences, however, were found between the groups regarding the proportion of children who had an asymmetry.

While this paper is an important contribution because of the randomization, there is some inconsistency in interpretation of the outcome data. For example, the denominator for cognitive outcome includes the non-survivors, whereas neuromotor outcome is based on survivors (the survivor denominator is preferred). In addition, subtle findings of neuromotor dysfunction suggest the need for a healthy control group for comparison. A 1995 study by Glass et al reported “suspect” neuromotor findings in 5-year-old children who were treated with ECMO as infants, but the authors also found a comparable proportion present in the normal control children^[1]. It is unfortunate that there are no neuroimaging data available for the UK Trial, as ECMO neonates are at high risk for brain injury^[2], but the timing of the injury (pre-ECMO vs during cannulation vs during bypass) has not been resolved. Furthermore, Glass et al previously reported a strong association between the severity of neonatal neuroimaging abnormality and neuropsychological outcome at age 5 years^[1].

In their seven-year follow-up, McNally et al reported similar findings compared to the earlier 4-year-old outcome data, with the mean cognitive scores 95.4 and 96.0 for the ECMO (n=56) and conventionally treated survivors (n=34) at age 7 years, with 55% of the ECMO and 50% of the conventionally treated children having no disability. The rate of moderate/severe disability was 16% and 9%, respectively. Problems with visual/spatial ability were again reported for both groups, with a high rate of reading comprehension problems (almost 40%). Behavioral problems (as reported by the parent) were noted in a significant number of the children, but this finding was less in the ECMO-treated children (18% vs 38%).

This important UK ECMO follow-up to age 7 years supports the validity of the earlier 4-year-outcome data, particularly in terms of the moderate/severe disability classification, and clarifies the anticipated learning problems as children negotiate formal schooling. Susceptibility of right-hemisphere vulnerability for the ECMO group was, again, not supported by the similar proportion of both groups with visual/spatial deficits. The UK randomized cohort was treated between 1993 and 1996; these findings are comparable to the previously published 5-year outcome of 150 (non-randomized) neonates treated with ECMO between 1984 through 1990 by Glass et al^[1]. However, a 2006 report by Khambekar et al indicates that the rate of severe disability may be increasing^[3].

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EFFECT OF THE ECMO PROCEDURE ON CEREBRAL VASCULAR REACTIVITY

Ingyinn M, Rais-Bahrami K, Viswanathan M, Short BL. **Altered cerebrovascular response after exposures to venoarterial extracorporeal membrane oxygenation: role of the nitric oxide pathway**. Pediatr Crit Care Med. 2006 Jul;7(4):368-73.

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Using a newborn lamb model, Ingyinn et al sought to study the mechanisms involved in altered cerebrovascular responses in vessels exposed to VA-ECMO. Animals were randomized to VA-ECMO vs control (no ECMO). ECMO animals were placed on 60% bypass for 2.5 hours, while controls remained on conventional ventilation. At the end of the study, cerebral middle arteries were studied for myotonic reactivity, response to acetylcholine, 3-morpholinyl-sydnoneimine chloride (SIN-1), and serotonin. The authors report that the VA-ECMO animals showed a markedly abnormal response to these agents: vasoconstriction with acetylcholine instead of dilation, and marked vasodilation to SIN-1 compared to controls.

Results of this study indicate that cerebral vessels exposed to the altered flow created by the ECMO pumping system do not respond to normal vasoactive agents, an effect most likely related to the alteration in the nitric oxide pathway. Further, these data indicate that the brain may be at risk during ECMO if exposed to significant cardiovascular changes such as extreme hypertension and/or hypotension during the ECMO process.

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