CHAPTER 4

PATIENT SELECTION GUIDELINES FOR ECMO

Conventional ventilatory management, including Nitric Oxide and HFO, saves the lives of most neonates with respiratory failure. ECMO is only used for patients who are responding poorly to optimal ventilatory, surgical, and medical treatment. We will consider neonates for ECMO only if they have an estimated 80% or greater mortality risk despite our usual maximal therapy. The predictors of mortality that will be used at Le Bonheur Children's Medical Center will be taken from those accepted and utilized at Children's Hospital in Washington, D.C..

ECMO is a temporary artificial lung. If a neonate's respiratory disorder can be reversed within a 10 to 14 day period, it is feasible for ECMO to safely support the patient. After a few days on ECMO, complications such as bleeding become more difficult to control. For this reason, it is not practical to use ECMO to treat a disease process such as bronchopulmonary dysplasia, which is reversible, but not in one week. One way to be certain that a neonate does not have significant BPD is to limit initiation of ECMO to the first seven days of assisted ventilation. Some centers will use 10 days, but a proper evaluation of the chest x-ray findings must be done before consideration for ECMO therapy. The common causes of respiratory failure in neonates are generally reversible within a few days.

NEONATAL PATIENT SELECTION GUIDELINES

- ***Weight greater than 2.0 kilograms***
  - Many very low-birth-weight infants have severe RDS and would appear to be good candidates, but 40% of these infants will develop a hemorrhage in the germinal matrix or ventricles without the stress of ECMO. The heparinization and/or the alterations in pulsatility of blood flow created by ECMO causes a significant incidence of ICH, and thus a prohibitive mortality in this group of infants.
- ***Gestational age greater than 35 weeks***
  - Same as above

- ***Reversible lung disease***
  - In evaluating an infant for ECMO, the most important assessment is whether or not a reversible process causes the patient’s poor respiratory function. Reversibility on ECMO is achieved by a combination of time and good oxygenation, allowing the baseline disease process to resolve. The good oxygenation supplied by ECMO breaks the vicious cycle of PPHN, allowing the pulmonary hypertension to resolve and thus stopping the right to left shunting. Most common neonatal diseases causing severe respiratory failure, which are reversible within a week, are: RDS, PPHN, MAS, and CDH.

- ***An O2 gradient (AaDO2) > 610 and OI > 25 for at least 8 hours despite maximal therapy***
    - All infants should have had attempts at routine maximal therapy and have failed. After maximal therapy has failed then criteria predicting a 80% or greater mortality must be used. The two methods most commonly used for predicting an 80% mortality are the alveolar arterial oxygen gradient (A-a gradient) which simply measures the difference between the oxygen content in the lung and that in the artery, and the oxygen index (OI), which gives a measure of ventilatory support required to yield a certain degree of oxygenation. Maximal therapy should include 100% oxygen, muscle paralysis, hyperventilation, vasodilator therapy, dopamine and possibly sodium bicarbonate. The aim of therapy is to decrease pulmonary vascular resistance to improve oxygenation.

$$AaDO2 = [(BP - 47)\ FiO2 - \frac{PaCO2}{0.8}] - PaO2$$

$$OI = \frac{\text{Mean Airway Pressure X FiO2 X 100}}{PaO2}$$

- ***Conventional therapy for less than 7 days***
    - Disappointing outcomes have been repeatedly documented among those patients who have required high ventilator pressures and oxygen concentrations for longer than 7 days. The longer a patient has required ventilator support prior to starting ECMO, the less the likelihood of recovery.

- ***No lethal congenital heart disease or irreversible cardiac failure.***
    - Congenital heart disease should be ruled out by cardiac echo, but if the infant is dying, ECMO can support these infants until cardiac surgery can be achieved. Post-op patients that are unable to weaned from bypass in the OR can benefit from ECMO and are considered candidates.

- ***No intraventricular hemorrhage >grade I***
    - Because infants must be systemically heparinized, the IVH may increase. Thus a head ultrasound must be done before going on ECMO.

- ***No evidence of coagulopathy***
    - Because infants must be systemically heparinized any infant with a severe coagulopathy which cannot be corrected or bleeding complication should not be considered for ECMO.

- ***No lethal chromosomal abnormalities***
    - Major chromosomal anomalies i.e. Trisomy 13 or Trisomy 18 is contraindicated due to the short life expectancy.
- ***Absence of prolonged asphyxia***
    - Infants with serious or irreversible brain damage should not be considered for ECMO.

NOTE: No single value can predict outcome.

PEDIATRIC PATIENT SELECTION GUIDELINES

Patients must meet all of the following criteria:

- ***Reversible lung diseases.***
  - Reasonable expectation on basis of diagnosis, or
  - Biopsy

- ***Failure to optimize non-ECMO therapy.***
  - Permissive Hypoxemia (SATs tolerance of 80% with Hct $\geq$ 45)
  - Permissive Hypercapnia (PaCO2 to 70 with pH $\geq$ 7.28)
  - PEEP trial to 15 cmH2O
  - HFOV

- ***Failure Criteria for non-ECMO therapies.***
  - AaDO2 > 350 X 8 hours
  - PIP limit of 40 cmH2O
  - Inability to wean FiO2 to < 65% within 8 hours.
  - Refractory Barotrauma (Persistent and uncontrolled air leaks)

- ***Exclusion Criteria***
  - Irreversible lung disease
  - Severe CNS disease with poor prognosis
  - Hemorrhagic CNS disorder
  - Terminal stage of lethal condition or life-threatening complication of lethal disease
  - Recent GI bleeding
  - Mechanical ventilation > 10 days

ADULT PATIENT SELECTION GUIDELINES

Consideration of ECLS in the adult patient with severe respiratory and/or cardiac failure unresponsive to conventional management is reasonable when four criteria are met:

- When the underlying process is reversible
- Logistics permit
- The patient has a reasonable chance for survival
- There are no contraindications of ECLS

A major challenge is to identify which patients actually have a reversible process and to begin ECLS before the patient experiences the irreversible damaging effects of hypoxia, high ventilator settings, and/or low cardiac output.

CARDIOVASCULAR ECMO GUIDELINES

- ***Potentially Reversible Cardiac Disease***
  - Myocarditis
  - Sepsis
  - Post-op Bypass

- ***Low Cardiac output in patients with Swan Ganz***
  - Low Cardiac output state for 8 hours
    1. Cardiac Index < 2.0
    2. Maximal Therapy
       a. 2 inotropes at maximal doses
       b. afterload reduction (or failed attempt to start)
  - PCWP $\geq$ 18
  - Rising serum lactate

- ***Low Cardiac Output In Patients without Swan Ganz***
  - Low cardiac output state for 8 hours
    1. Capillary refill > 5 seconds
    2. +/- hypotension
    3. Urine output < 0.3 ml/kg/hr
    4. Maximal Therapy
       a. 2 inotropes at maximal doses
       b. afterload reduction (or failed attempt to start)

  - Rising serum lactate

- ***Pre and Post-op Pulmonary Hypertension***
  - ECHO Criteria

- ***Low Cardiac Output Following Cardiopulmonary Bypass***
  - Corrective (vs. palliative) surgery
  - Successful but Temporary Weaning of Bypass

- **Exclusion Criteria**
  - Severe CNS disease with poor prognosis
  - Hemorrhagic CNS disorders
  - Terminal stage of lethal condition or life-threatening complication of lethal disease
  - Recent GI Bleeding