CURRENT STATUS OF EXTRACORPOREAL LIFE SUPPORT FOR CARDIOPULMONARY FAILURE

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Consultant Cardiologist & Intensivist
Royal Brompton Hospital, London
DECLARATION OF INTERESTS

- Educational contract, Medtronic
- Medical Advisory Board, Abbott (MitraClip)
KEY MESSAGES

• ECLS for cardiopulmonary failure is not a treatment per se
• Technique in principle is simple, our understanding is incomplete
• Appropriate patient selection is pivotal to success
OUTLINE

- Background: aims, indications, contraindications, complications and principles
- Evidence
- Guidelines
- Challenges
WHAT IS ECMO?

- Form of extracorporeal life support where an artificial circuit carries venous blood from the patient to an oxygenator, where $O_2$ is added and $CO_2$ removed

- Blood is then returned via central vein (VV) or artery (VA)
WHAT ARE PHYSIOLOGICAL GOALS

“To improve tissue $O_2$ delivery, remove $CO_2$ and allow normal aerobic metabolism whilst the lung “rests”, or as cardiac assist”

Bob Bartlett

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## TERMINOLOGY

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Commonly used terms</th>
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<tbody>
<tr>
<td><strong>Abbreviation</strong></td>
<td><strong>Definition</strong></td>
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<tr>
<td>ECLS</td>
<td>Extracorporeal life support</td>
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<tr>
<td>ECMO</td>
<td>Extracorporeal membrane oxygenation</td>
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<td>VV ECLS</td>
<td>Venous-venous extracorporeal life support</td>
</tr>
<tr>
<td>VA ECLS</td>
<td>Venous-arterial extracorporeal life support</td>
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<tr>
<td>ECPR</td>
<td>Extracorporeal cardiopulmonary resuscitation</td>
</tr>
<tr>
<td>ECCO2R</td>
<td>Extracorporeal membrane carbon dioxide removal</td>
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JICS, 2012

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WHAT ECMO ISN’T

• Treatment for cardiopulmonary failure
INDICATIONS: cardiopulmonary support

- Estimated 80% mortality despite conventional supportive therapy
- Cardiogenic or septic shock requiring two or more infusions of vasoactive agents
- Acute
- Severe, life-threatening
- Reversible
- Unresponsive to conventional treatment

- Potentially reversible pathology
CONTRAINDICATIONS

Absolute

• No “exit” strategy/irreversible pathology
• Contraindication to anticoagulation
• Terminal disease
• MODS (>2 organ system failure)
• Moderate-severe COPD
• Uncontrolled metabolic acidosis
• Neurological injury
• Immunosuppression

Relative

• Pulmonary hypertension (MPAP >45, or >75% systemic)
• Uncontrolled sepsis
• Cardiac arrest with inadequate perfusion
• >65 years of age
• Ventilation >7 days
### ADDITIONAL CARDIAC CONTRAINDICATIONS

<table>
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<tr>
<th>ECHO FINDING</th>
<th>IMPORTANCE</th>
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<tr>
<td>Severe AR (&gt;grade 2)</td>
<td>+++</td>
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<tr>
<td>Severe AS</td>
<td>+++</td>
</tr>
<tr>
<td>Coarctation</td>
<td>+++</td>
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<tr>
<td>Dissection</td>
<td>+++</td>
</tr>
<tr>
<td>Severe arch atheroma</td>
<td>+</td>
</tr>
<tr>
<td>Abdominal/thoracic aneurysm with intraluminal thrombus</td>
<td>+</td>
</tr>
</tbody>
</table>

*Caledron & Janvier, ed Cholley, 2011*
COMPLICATIONS

- Bleeding
- Ischaemic limb
- Stroke
- Ischaemia
- Infection
- Kit failure (clot, oxygenator, cannula, pump malfunction, cracks in circuit)
- Embolisation
- Haemolysis
- Hepatic/renal dysfunction
- Hypertension
HISTORY OF ECMO

- 1915 Heparin
- 1930s Animal ECMO
- 1950s CPB clinical use
- 1970s ECMO trials
- 1980s ECCO₂R trials
- 1980s neonatal ECMO trials
- 1990s IVOX
- 1990s Adult ECMO series
- 2000s iLA
- 2007 CESAR trial
- 2009/10 H1N1 pandemic
FIGURE 3.4  The first successful extracorporeal life support patient, treated by J. Donald Hill using the Bramson oxygenator (foreground), Santa Barbara, 1971.
hypoxia or hypercarbia?

\[ \text{O}_2 \quad \text{CO}_2 \]

which organ needs support?

modality: circulatory connections

\[ \text{AV} \quad \text{VA} \quad \text{VV} \]

Blood pump?

Anticoagulation

Gas

membrane
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CURRENT CIRCUITS

Peripheral VV ECLS

Peripheral VA ECLS
INAPPROPRIATE UNLOADING

- Biphasic backflow across MV during diastole
- Inappropriate discharge due to retrograde aortic backflow
- Retrograde systolic pulmonary flow due to high LAP
- Additional LV discharge is required

De Backer et al., 2011
LEFT VENTRICULAR OFFLOADING

- LV vent may be required
- Generally surgical approach, but:
  - Paediatrics: transfemoral atrial septostomy
  - Trans-septal atrial sheath
  - Impella LP
  - IABP
  - Trans-aortic catheter
- PFO may provide innate means to offload

Subclavian artery: ECLS – pulsatile with IABP

De Backer et al., 2011
## HOW MUCH SUPPORT

<table>
<thead>
<tr>
<th>DEVICE</th>
<th>FLOW l/min</th>
<th>REMARKS</th>
</tr>
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<tbody>
<tr>
<td>Impella (Abiomed)</td>
<td>2.5</td>
<td>Exact positioning</td>
</tr>
<tr>
<td>Tandem</td>
<td>4.0</td>
<td>CC. trans-septal</td>
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<tr>
<td>Centrifugal pumps (Biomedicus)</td>
<td>9-10</td>
<td>Rapid insert</td>
</tr>
<tr>
<td>Centrifugal+ VA ECLS IABP + ELS</td>
<td>9-10</td>
<td>Surgery/percutaneous</td>
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<td>9-10</td>
<td></td>
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<tr>
<td>Levitronix-Centrimag</td>
<td>Up to 9.0</td>
<td>Surgery/percutaneous</td>
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OUTCOMES: ELSO REGISTRY

- International ECLS registry, >4,400 adult patients treated with ECMO, 1990-

- Approved ECMO centres


Table 2 Indications for respiratory ECMO. 53% adult ELSO cases 54% survival to discharge

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Table 3 Indications for cardiac ECMO. 39% survival to discharge

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GROWING BODY OF EVIDENCE

The graph shows a growing number of papers published over the decades.

- **1960s**: Very few papers, indicating a lack of research or interest in the field.
- **1970s**: A slight increase in the number of papers, possibly due to initial exploration.
- **1980s**: A moderate increase, suggesting a growing interest and activity in the field.
- **1990s**: A significant increase, highlighting a substantial growth in research.
- **2000s**: The most significant increase, with a sharp rise in the number of papers, indicating a thriving field with a high demand for research.

The overall trend is upward, with a notable spike in the last decade, suggesting a dedicated focus and a massive surge in research activities.
First RCT: National Institutes for Health (NIH) study

METHODS
- Prospective randomised study
- 90 patients treated at 9 US hospitals
- Enrolled if either:
  - $pO_2<6.7\text{kPa}$, $FiO_2=1.0$, and $PEEP>5$
  - $pO_2<6.7\text{kPa}$ for over 12 h, $FiO_2>0.6$, Shunt fraction $>30$

RESULTS
- 48 received conventional mechanical ventilation
- 42 received mechanical ventilation with VA-ECMO
- Majority had bacterial or viral pneumonia
- 4 survivors in each group in each group
- Most died of progressive respiratory failure
- Considerable problems with bleeding

JAMA 1979; 242: 2193-96
National Institutes for Health (NIH) study

Conclusion
- VA-ECMO provided no benefit in acute adult respiratory failure

But...
- Why VA-ECMO (effectively partial bypass supporting circulation)?
- What are the effects of no pulmonary blood flow?
- Anticoagulation was equivalent for cardiopulmonary bypass
- Ventilator settings not reduced

JAMA 1979; 242: 2193-96

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Subsequent literature

- Successive non-randomised studies and case series
- Survival rates 50-55% (similar to non-ECMO despite being sicker)
- One study concluded 80% would have died without ECMO
- Improvements: protective strategies for ventilation, changes in ECMO techniques
- Reduction in transfusion rate on ECMO (2.5L/day to 400ml/day)


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Bartlett RH, Roloff DW, Cornell RG, Andrews AF, Dillon PW, Zwischenberger JB.

Abstract

A prospective controlled randomized study of the use of extracorporeal membrane oxygenation to treat newborns with respiratory failure was carried out using the "randomized play-the-winner" statistical method. In this method the chance of randomly assigning an infant to one treatment or the other is influenced by the outcome of treatment of each patient in the study. If one treatment is more successful, more patients are randomly assigned to that treatment. A group of 12 infants with birth weight greater than 2 kg met objective criteria for high mortality risk. One patient was randomly assigned to conventional treatment and died. 11 patients were randomly chosen for extracorporeal membrane oxygenation (all survived). Intracerebral hemorrhage occurred in one of 11 surviving children. Extracorporeal membrane oxygenation allows lung rest and improves survival compared to conventional ventilator therapy in newborn infants with severe respiratory failure.

PMID: 3900904 [PubMed - indexed for MEDLINE]

UK collaborative randomised trial of neonatal extracorporeal membrane oxygenation

UK Collaborative ECMO Trial Group

Study organisation and participants listed at end of article

ELSO data 1987-1993
Survival 81.3% (6856 neonates)
VV ECMO: INCREASING AND EMERGING EVIDENCE

CESAR: conventional ventilatory support vs extracorporeal membrane oxygenation for severe adult respiratory failure

Giles J Peek, Felicity Clemens, Diana Elbourne, Richard Firmin, Pollyanna Hardy, Clare Hibbert, Hiliary Killer, Miranda Mugford, Mariamma Thalanan, Ravin Tiruvoipati, Ann Truesdale, and Andrew Wilson

Referral to an extracorporeal membrane oxygenation center and mortality among patients with severe 2009 influenza A(H1N1).


Heartlink ECMO Centre, Glenfield Hospital, Leicester, England.
80 patients referred and transferred for ECMO
- Propensity matched (ICNARC)
- 69 received ECMO for median of 7 days
- 23.7% mortality in ECMO-referred (cf.52.5%, p=0.006)
VA ECMO evidence and indications?

- No RCTs
- Number of studies/case series
- Majority post-cardiotomy, and all with high mortality (near 100%) without ECMO
- Outcome survival 19-76% (depending upon underlying pathology)

- ELSO registry data
Outcomes, adult ECLS

Survival to discharge:
ESLO, 46%
Chou 2010, 21/40, 53%
Marasco 2010, 74%

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**Table 3** Indications for cardiac ECMO.
Outcomes, adult ECLS

Survival to discharge:
ELSO 2011, 30%
Rastan 2010, 128/517, 24%
Liden 2009, 11/33, 33%
Li 2009, 16/50, 32%

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Table 3 Indications for cardiac ECMO.
### Outcomes, adult ECLS

**Survival to discharge:**
- ELSO, 38%
- Liden, 2009 12/19, 63%

**ECMO-CPR**
- ELSO, 28%, Lin 2010, 29%, 18.6% (vs 12.3, 9.7)

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**Table 3** Indications for cardiac ECMO.
Outcomes, adult ECLS

Survival to discharge:
Case series
Daubin, 2009, 76%

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Outcomes, adult ECLS

Survival to discharge:
ELSO, 69%
Asaumi, 71%

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Table 3: Indications for cardiac ECMO.
ESC Guidelines for the diagnosis and treatment of acute and chronic heart failure 2012

The Task Force for the Diagnosis and Treatment of Acute and Chronic Heart Failure 2012 of the European Society of Cardiology. Developed in collaboration with the Heart Failure Association (HFA) of the ESC

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12.7.4 Perioperative acute heart failure
AHF may occur in patients before (e.g. because of pre-operative infarction), during (‘failure to wean’), and after (mechanical complications and pericardial tamponade must be excluded) cardiac surgery. The specialized management of this group of patients is described in detail elsewhere\textsuperscript{241} and may involve use of mechanical support, including extracorporeal membrane oxygenation (ECMO).

13.5.2 Acute heart failure
In addition to ventricular assist devices, other forms of short-term, temporary MCS may be used in selected patients with AHF, including intra-aortic balloon counterpulsation, other percutaneous cardiac support, and ECMO. In addition to the uses described above, MCS, particularly ECMO, can be used as a ‘bridge to decision (BTD)’ in patients with acute and rapidly deteriorating HF where full evaluation has not been possible and in whom death will occur without MCS. However, the difficult decision to withdraw MCS may need to be made if the patient is not eligible for conventional corrective surgery or longer term MCS.
CRITICISM OF VA ECLS

US Agency for Healthcare Research and Quality: Evidential Hierarchy

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<tr>
<td>1.</td>
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<td>Expert opinion</td>
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Critical of observational studies, critical of CESAR study
Quoted historical RCTs

Call for more RCTs
22 year old woman, 26 weeks pregnant, H1N1, cardiopulmonary failure, PO2 4kPa FiO2 1.0
We should abandon randomized controlled trials in the intensive care unit

Vincent, Jean-Louis MD, PhD, FCCM

Abstract

The randomized controlled trial is seen by many as the summit of evidence-based medicine, yet, in the intensive care unit, randomized controlled trials can be challenging to conduct, and results are often difficult to interpret and apply. Many randomized controlled trials in intensive care patients have not demonstrated beneficial effects of the intervention under investigation often despite good preclinical and even previous randomized controlled trial evidence. There are many reasons for these negative results including problems with timing, end point selection, and heterogeneous populations. In this article, we will discuss the limitations of randomized controlled trials in the intensive care unit population and highlight the importance of considering other study designs in the challenging intensive care unit environment.
Challenges/ongoing questions

- Anticoagulation: heparin-bonded circuits, citrate anticoagulation, novel anticoagulant agents
- Cannulation sites: limb ischaemia, impaired cerebral venous return, kit, optimal site/size/type
- Correction of metabolic abnormalities: how, when, how fast
- Timing of normoxia, normocapnoea: how, when, how fast
- Requirement for normalisation of cardiac output
- Pulsatility of flow?
- Global vs regional oxygen delivery
- What constitutes adequate cardiac rest
- How to monitor the cardiopulmonary function
- Weaning: timing, mechanism, iLA, other extracorporeal devices
- Prognosis: underlying disease vs delivery of ECLS
- Transportation: portable ECLS
- Indications/contra-indications
- Optimal targets: Hb/anticoagulation/pressures/gases
- Differences between adults and children
- How bad cardiac function tolerates VV ECMO/iLA
PHYSIOLOGICAL GOAL

“To improve tissue $O_2$ delivery, remove $CO_2$ and allow normal aerobic metabolism whilst the lung “rests”, or as cardiac assist”
OXYGEN DELIVERY

- Global DO2 does not equal regional DO2
- Regional DO2 abnormalities increasingly recognised in critically ill population
- Harlequin syndrome well-recognised
- Certain key organs may be compromised despite acceptable global values:
  - Brain
  - Myocardium
  - GIT
CORONARY ARTERY PERFUSION

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CORONARY ARTERY PERFUSION

- RCT for ECMO, hearts examined in non-survivors
- 26 babies hearts examined: 12 ECMO, 14 conventional
- Control: 4 minor histological changes, remainder normal
- ECMO: 4 multiple foci of microinfarction, variable thrombotic vascular occlusion. 3 normal
- No correlation with clinical features
- Main correlate: duration of therapy

Arch Dis Ch Fetal Neonatol 1999
OUTLINE

• Background: aims, indications, contraindications, complications and principles

• Evidence

• Guidelines

• Challenges
KEY MESSAGES

- ECLS for cardiopulmonary failure is not a treatment per se
- Technique in principle is simple, our understanding is incomplete
- Appropriate patient selection is pivotal to success
ALL WHO DRINK OF THIS TREATMENT RECOVER IN A SHORT TIME, EXCEPT THOSE WHOM IT DOES NOT HELP, WHO ALL DIE

IT IS OBVIOUS THEREFORE THAT IT FAILS ONLY IN INCURABLE CASES

Galen AD 129-c199