ECMO Center Organization and Regional Coordination.

ELSO Webinar: “ECMO in COVID-19: What have we learned”

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Introduction to COVID-19 Pandemic

- Unprecedented pandemic attributed to SARS-COV-2. (WHO 3/11/2020)
- Highly Contagious: 40-60% of the population may be infected.
- Multi-organ involvement (Pulmonary > Renal > Liver > Cardiovascular > CNS).
- ICU admission rate 5-12% and ICU capacity may be exceeded 5-15 fold.
- High need of IMV (30-35%).
- Potential of a massive surge of unclear proportion.

Like never before we needed to make decisions with very little guidance and data.
Coordinated Mobilization of a Health Care System in Response to the Coronavirus Disease 2019 Pandemic

**Incident Command Structure**

- Communication Structure
- Develop and apply Organizational Framework
- Synchronize work cycles
- Establish Competencies
- Build teams
- Development of strike teams (Intubation)

- Sustained response over a prolonged period
- Limited workforce itself, requiring a layered approach to staffing models due to its nature

JAMA Surgery Published online April 14, 2020
ROLE of ECMO in COVID-19? (I)

The current clinical uses of ECMO for COVID-19:

<table>
<thead>
<tr>
<th>Application</th>
<th>Study design</th>
<th>Cases on ECMO (total cases)</th>
<th>Outcomes of ECMO</th>
<th>Reference</th>
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<tbody>
<tr>
<td>Critically ill patients with SARS-CoV-2 pneumonia</td>
<td>Single center, retrospective study</td>
<td>6 (52)</td>
<td>Five patients died while one patient was still on ECMO at the endpoint</td>
<td>(Yang et al., 2020)</td>
</tr>
<tr>
<td>Patients with ARDS caused by SARS-CoV-2</td>
<td>Single center, retrospective study</td>
<td>10 (221)</td>
<td>Two patients were discharged; three patients died, and five patients were still on ECMO at the endpoint</td>
<td>(Guo et al., 2020)</td>
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<tr>
<td>Critically ill patients with SARS-CoV-2 pneumonia</td>
<td>Single center, retrospective study</td>
<td>4 (138)</td>
<td>NA</td>
<td>(Guan et al., 2020)</td>
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<tr>
<td>Critically ill patients with SARS-CoV-2 pneumonia</td>
<td>Multicenter retrospective study</td>
<td>5 (1099)</td>
<td>NA</td>
<td>(Huang et al., 2020)</td>
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<tr>
<td>Critically ill patients with SARS-CoV-2 pneumonia</td>
<td>Single center prospective study</td>
<td>2 (41)</td>
<td>NA</td>
<td>(Brodie et al., 2019)</td>
</tr>
</tbody>
</table>

The European Survey on ECMO in Adult COVID-19 Pts at 20/03/2020:

- 65 ECMO cases logged
- 37 VV ECMO
- 4 VA ECMO
- 1st Largest reported experience: 16 cases at Pitié-Salpêtrière Hospital, Paris, France
Preparation for the Most Critically Ill Patients With COVID-19
The Potential Role of Extracorporeal Membrane Oxygenation

ECMO is not a therapy to be rushed to the frontline when all resources are stretched in a pandemic.

Clinical management of severe acute respiratory infection (SARI) when COVID-19 disease is suspected.
Interim guidance
13 March 2020

WHO/2019-nCoV/Clinical/2020.4

Remarks for adult and children: An RCT of ECMO for adult patients with ARDS was stopped early and found no statistically significant difference in the primary outcome of 60-day mortality between ECMO and standard medical management (including prone positioning and neuromuscular blockade) (47). However, ECMO was associated with a reduced risk of the composite outcome of mortality and crossover to ECMO (47), and a post hoc Bayesian analysis of this RCT showed that ECMO is very likely to reduce mortality across a range of prior assumptions (48). In patients with MERS-CoV infection, ECMO vs conventional treatment was associated with reduced mortality in a cohort study (49). ECMO should only be offered in expert centres with a sufficient case volume to maintain expertise and that can apply the IPC measures required for adult and paediatric COVID-19 patients (50, 51).

Surviving Sepsis Campaign: Guidelines on the Management of Critically Ill Adults with Coronavirus Disease 2019 (COVID-19)

In mechanically ventilated adults with COVID-19 and refractory hypoxemia despite optimizing ventilation, use of rescue therapies, and proning, we suggest using venovenous (VV) ECMO if available, or referring the patient to an ECMO center.

Remark: Due to the resource-intensive nature of ECMO, and the need for experienced centers and healthcare workers, and infrastructure, ECMO should only be considered in carefully selected patients with COVID-19 and severe ARDS.
Planning and provision of ECMO services for severe ARDS during the COVID-19 pandemic

<table>
<thead>
<tr>
<th>Panel: Key components in the planning and provision of ECMO during an outbreak of an emerging infectious disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>ECMO resource planning and allocation</td>
</tr>
<tr>
<td>Embed ECMO response into the broad epidemic response strategy; identify and engage all key stakeholders; maintain a log of multidisciplinary team members specifically trained in the care of patients receiving ECMO; maintain a contemporaneous log of ECMO machines serviced and ready to deploy; ensure supply of disposables and develop a regional tracking mechanism; prepare for surge of patients</td>
</tr>
<tr>
<td>Personnel assignment</td>
</tr>
<tr>
<td>Establish chain of command at ECMO centre level and regional level; formulate minimum and ideal staffing requirements; allocate roles in the ECMO process and allow for staff attrition; develop urgent mechanisms for ECMO credentials across institutions</td>
</tr>
<tr>
<td>Personnel training and ECMO use</td>
</tr>
<tr>
<td>Provide site-specific training and involve multidisciplinary team members; ensure correct use of PPE and the handling of infected bodily secretions; reinforce need for optimal conventional management of patients and review ECMO indications; simulate ECMO initiation and troubleshooting scenarios</td>
</tr>
<tr>
<td>Infection control measures before and during ECMO initiation</td>
</tr>
<tr>
<td>Group patients into cohorts for ECMO therapy and clearly mark all areas of increased precaution; ensure PPE stations are strategically placed to enhance compliance; strictly enforce all infection control protocols and PPE use for ECMO processes</td>
</tr>
<tr>
<td>Transport of patients receiving ECMO</td>
</tr>
<tr>
<td>Devise eligibility criteria for inter-hospital transfer and share them with referral centres; ensure effective communication and coordination; identify and address rate-limiting steps; strictly adhere to infection control protocols throughout patient transport</td>
</tr>
<tr>
<td>ECMO weaning, decannulation, and rehabilitation</td>
</tr>
<tr>
<td>Carry out ECMO weaning, decannulation and rehabilitation under strict infection control and personal protection measures; use caution while predicting native lung recovery on ECMO; arrange follow-up of patients who have been weaned from ECMO to ensure long-term outcomes</td>
</tr>
</tbody>
</table>

Post-mortem care

Map capacity of mortuary facilities in ECMO centres and review guidelines for post-mortem care; carry out post-mortem decannulation and transport of deceased under strict infection control and personal protection measures; follow national and international guidelines on disposal of infectious biological hazardous materials

Staff support

 Routinely monitor staff for their health and wellbeing; put in place protocols for contact tracing; ensure provision of a team of psychiatrists, psychologists, and social workers to monitor and treat the psychological effects on staff; ensure that sick personnel are quarantined for 2 weeks with a clear follow-up and escalation plan in place; provide protocols for contact tracing of staff members

Ethical considerations

Use predetermined consensus criteria for rationing of ECMO if indicated; reassess all aspects of a patient’s treatment plan regularly, including the need to continue or terminate ECMO; invoke distributive justice only in circumstances where rationing precludes the ability to care for each individual optimally; seek opinions from hospital ethics and medicolegal committees in ethically challenging scenarios

Quality assurance and collaborative research

Maintain quality assurance and clinical governance frameworks with frequent ECMO quality reviews; ensure collection and sharing of data to inform preparedness and patient care; aim to have ethics approval in place or develop mechanisms for expedient ethics review and approval processes

ECMO=extracorporeal membrane oxygenation. PPE=personal protective equipment.

TheLancet/Resp Medicine, March 20, 2020
Preparing For ECMO in Covid-19 (Hospital)

Staff:

- Modification to ECMO team deployment (ECMO Attending, CT Surg-CCM)
- Similar ECMO care model (ECMO trained nurse/Specialist/Covid Units)
- ECMO consult team x COVID patients (MED/SURG Directors - Arbitrator)
- Changes in ECMO alert (No active ECPR with active CCP)
- Education COVID Units staff and ED on ECMO
- Re-education team; COVID Specific protective measure (PAPR, PPE)
- Considerations for ECMO transport

Space:

- ECMO only within COVID units/ Flexible
- Negative Airflow room/unit.

Equipment:

- Definition maximal and optimal ECMO support capacity.
- Equipment stock/replacement plan. (pump, oxyg, cann.)
- Airborne PPE, and team protective equipment

Putting on (Donning) PPE

- Gather Supplies
  - PAPR Assembly
  - Yellow Isolation Gown
  - 1 Pair Nitrile Gloves
- Perform Hand Hygiene
- Clip Battery to Waist (Pocket, Pants or Belt)
- Place PAPR on Head
  - Leave Ears Exposed
  - Adjust Ratchet to a Snug Fit

COVID-19 Pt Notes:
1) Avoid eCPR cannulations
2) 4 person max in room
3) DO NOT DISCONNECT FROM VENT
Planning for Surge: Response based on system capacity

Conventional Capacity:
- Ordinary use of resources (spaces, staff, and supplies) and standard of care

Contingency Capacity:
- Disruption of ordinary use of resources and practices, but care provided is functionally equivalent to usual standards

Crisis Capacity:
- Disruption to standard of care due to inadequate resources, but goal is sufficiency of care (provide the best possible care given the circumstances)

Capacity exists
- Judicious patient selection
- Offer V-V, V-A ECMO in selected COVID-19 patients based on usual criteria
- Offer ECMO for non COVID-19 indications
- ECPR only in expert centres

Capacity overwhelmed
- ECMO not feasible in both COVID-19 and non-COVID-19 patients
- Triage ICU admissions
- Consider ceasing all futile care to create capacity in the system

Expanded capacity
- Triage to maximise resource:benefit ratio
- V-V, V-A ECMO in younger COVID-19 patients with single organ failure
- Judicious ECMO use for non COVID-19 indications
- ECPR not offered

Capacity Saturated
- Restrictive ECMO criteria for all indications
- Prioritise non COVID-19 indications with better chance of survival
- V-V ECMO in younger, single organ failure COVID-19 patients
- V-A ECMO and ECPR not offered

CHEST 2014; 146 (4 Suppl): 85 - 345
It soon became evident that the surge would differ in timing and possibly in severity in the different regions of the US, and also that similar regional differences may occur.
Hospital networks providing ECMO support in the Pennsylvania region have joined forces to provide Uniform Regional Criteria for the selection and transport of patients that may benefit from ECMO. The criteria are in line with the current ELSO COVID-19 ECMO national guidelines and are not intended to be used as the sole determinant of ECMO eligibility in a resource limited scenario.

Established ECMO centers:

1. Abington Hospital
2. Allegheny General
3. Christiana HS
4. Cooper
5. Deborah Hospital
6. Geisinger MC
7. Hershey (PSHMC)
8. Lancaster General
9. Lankenau (MLHS)
10. Lehigh Valley
11. Penn Medicine
12. Redaing Hospital
13. Temple UH
14. UPMC-Presbyterian (PITT)
15. York Hospital

- Weekly teleconference (2/4/2020)
- Identify Regional/Center Coordinators
- Definition of regional COVID status
- Assessment of ECMO need/capacity
- Indication/Contraindication Criteria.
- Regional ECMO Criteria statement
- Ethics and Legal Considerations
Pennsylvania Regional Consortium

- Allowed Regional Coordination and Understanding of ECMO capacity
- Improved communication and early experience sharing
- Dissipated concerns and built team approach.
- Made us all feel better prepared for the unknown and that we had the capacity to support our patients even in period of crisis.

<table>
<thead>
<tr>
<th>Center</th>
<th>Current % Capacity (Standard)</th>
<th>Current % Capacity (Maximum)</th>
<th>Current COVID19 VV-ECMO</th>
<th>Current COVID19 VA-ECMO</th>
<th>Mean Duration (days)</th>
<th>Duration Range (days)</th>
<th># of Pts Weaned</th>
<th># Mortality on ECMO</th>
<th>Total Runs Completed</th>
<th>% Mortality on ECMO</th>
<th>Date Updated</th>
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</table>

| Region Summary       | 20                           | 0                            | 7                       | 0                       | 10                   | 1-11                  | 16              | 6                 | 16                  | 37.5%            |              |

Standard capacity for Eastern/Western Pennsylvania:124 ECMO systems.
ECMO in COVID-19 at PENN

- 8 patients supported on VVECMO x COVID-19 (represents 0.8% of 1128 COVID admissions to UPHS to 4/20/20)
- 4/8 females
- 3/8 patients weaned off ECMO
- Average Support for weaned patients: 6.6 days
- 2/8 died during support (2 ICH)
- 7/8 where LUNG Rescue (transport)

<table>
<thead>
<tr>
<th>Age</th>
<th>Kg</th>
<th>BMI</th>
<th>Hours on ECMO</th>
<th>Days on ECMO</th>
<th>Initial Type</th>
<th>Types Over Run</th>
<th>Cannulation</th>
<th>Cannulas</th>
<th>Insertion Sites</th>
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<td>25RFV Medtronic, 18RIJ Optisite</td>
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</table>

- 3 oxygenator exchange (2 failures).
- Anticoagulation: Heparin used in all except in 1 patient (argatroban)
ECMO Indications - Regional Criteria

PRC

Nominal Indications for VV ECMO in COVID-19
- ARF PaO₂/FiO₂ < 80mm Hg for >6h
- ARF PaO₂/FiO₂ < 50mm Hg for >3h
- pH<7.25 with PaCO₂>60mmHg>6h

- After failing 1-2 proning trials
- Prior neuromuscular blockade
- High Peep Strategy
- Expected recovery from ARDS

If mobile ECMO is unavailable, consider referring patients to ECMO centers “early,” such as when PaO₂: FiO₂ ≤ 100 mmHg.

Standard cannulation techniques

Other Considerations during evaluation
- Adequate and rationale screening
- Consider center/unit capacity.
- Consider benefit patient vs risk of dis. spread
- Potential Risk of overwhelming hospital system.
- Reduce unnecessary transfers to hub.
- MOBILE ECMO in programs with Lung Rescue teams
Special Considerations COVID-19

Variable Presentation ARDS. Better compliance and response to NIVM and prone position
Early vs delayed implantation?

Consideration of specific risk factors associated with high mortality: Age > 60, CVD, DM, HTN, Lymphopenia, CLD

High rate other organ involvement soon after presentation.

The Lancet Resp feb 21, 2020
Special Considerations COVID-19

High rate of TE complications
Thrombosis Research 2020.4.13

<table>
<thead>
<tr>
<th>Type of event</th>
<th>Number of cases</th>
<th>Relevant details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pulmonary embolism</td>
<td>25</td>
<td>– 18 cases with at least PE in segmental arteries, 7</td>
</tr>
<tr>
<td></td>
<td></td>
<td>cases PE limited to subsegmental arteries</td>
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<tr>
<td>Other venous thromboembolic events</td>
<td>3</td>
<td>– 1 proximal deep-vein thrombosis of the leg</td>
</tr>
<tr>
<td></td>
<td></td>
<td>– 2 catheter related upper extremity thrombosis</td>
</tr>
<tr>
<td>Arterial thrombotic events</td>
<td>3</td>
<td>– All ischemic strokes</td>
</tr>
</tbody>
</table>

- DAD: Alveolar hemorrhage and fibrin thrombi-rare consolidations
- Lymphocytic infiltrates
Contraindications VV ECMO COVID-19

**Standard Contraindications**
- Unrevoked DNR
- Age > 65
- BMI > 45 with high risk vascular access
- Chronic non-recoverable lung disease
  - Severe COPD
- Home O2 requirement
- Mechanical ventilation > 10 days
- Non-recoverable co-morbidities
  - Severe CNS damage
  - End stage liver disease (MELD-Na > 20)
  - MOSF
  - DIC
  - Contraindications of anticoagulation
    - (profound persistent thrombocytopenia)
- Active malignancy with expected survival < 1y

**Relative Contraindications**
- Age > 60
- BMI > 35
- Mechanical Ventilation > 7 days
- Co-morbidities
  - Uncontrolled-poorly controlled DM2 with evidence of end-organ involvement
  - > 40 PPY smoking history
  - Renal Dysfunction
  - Currently on HD or ARF with unlikely recovery
    - Severe acute liver failure (significant INR, AST elevation) without pharmacological cause
    - Severe frailty or limited physical activity at baseline.
    - Current immunosuppression and recent BMT

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eCPR with ongoing chest compressions for COVID suspected or presumed positive patients will not be provided. VA ECMO can be considered selectively in patients with profound shock or with history of recent arrest after ROSC.
VA ECMO in COVID-19

- 1/5 patients with COVID-19 can present with cardiac complications

<table>
<thead>
<tr>
<th>Complications</th>
<th>Total (N = 138)</th>
<th>ICU (n = 36)</th>
<th>Non-ICU (n = 102)</th>
<th>P Value&lt;sup&gt;a&lt;/sup&gt;</th>
</tr>
</thead>
<tbody>
<tr>
<td>Shock</td>
<td>12 (8.7)</td>
<td>11 (30.6)</td>
<td>1 (1.0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Acute cardiac injury</td>
<td>10 (7.2)</td>
<td>8 (22.2)</td>
<td>2 (2.0)</td>
<td>&lt;.001</td>
</tr>
<tr>
<td>Arrhythmia</td>
<td>23 (16.7)</td>
<td>16 (44.4)</td>
<td>7 (6.9)</td>
<td>&lt;.001</td>
</tr>
</tbody>
</table>

- VA ECMO use has been low around 5% of total ECMO supported patients
- Standard Indications.
  - Refractory cardiogenic shock with persistent tissue hypoperfusion,
  - Systolic Blood Pressure <90 mmHg,
  - Cardiac Index < 2.2L/min/m² while receiving noradrenaline >0.5mcg/Kg/min, dobutamine >20mcg/Kg/ min or equivalent

- Standard Contraindications/ Include VV ECMO CI considerations. ECPR only in exceptional case.
The use of ECMO will be decided on an individual basis in a fair and transparent manner with input from the attending physician, and ECMO Medical/Surgical Team based on prognosis, suspected duration of ECMO run, and availability of personnel and other resources. If needed a member of the Pennsylvania Collaborative ECMO team may be called in to render an expert opinion on a case. Patients should have an estimated survival of >70% with an estimated ECMO run of <7-10 days. Patients and guidelines will be reevaluated by the ECMO Team regularly to ensure ongoing adjustments as needed.

Reviewed by ethics and approved by hospital CMO
ECMO use in COVID continues to increase. (>1000 cases)

Mortality close to 50% but many patients still on support or hospitalized.

“Too early to tell”
Summary

- Although ECMO use in Covid-19 is infrequent (<1-2% admitted patients) it may create important disruption in health care systems.

- ECMO preparedness plays a key role in a successful and seamless response.

- Due to the unprecedented size and length of the case surge, regional coordination in ECMO care delivery seems logical and has the potential to alleviate health system overload in periods of crisis allowing adequate redirection of critically ill patients requiring support.
Unanswered questions

- ECMO early vs late initiation?
- Cannulation: VV ECMO (DLC-Standard timing ) vs VA vs VAV
- Proning on ECMO.
- Best anticoagulation approach (increased risk of thromboembolic complications vs risk of ICH)
- Effect of ECMO associated treatment options (Antivirals, IL6 blockers, other )
- Hemofilters( cytosorb). Efficacy, timing, interactions with AB,AC
- Time of ECMO support.
- Associated Procedures-Timing-Risks

Not enough answers- Limited data