Evolution in ECLS
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TandemLife Products Indications for Use

- **TandemHeart Controller**: The TandemHeart Escort Controller is intended to be used with the TandemHeart System. The TandemHeart System consists of the TandemHeart Blood Pump, a single use, disposable device; the TandemHeart Escort (T.H.E.) Controller, a reusable control system for the TandemHeart Blood Pump; and disposable accessory items used in conjunction with the TandemHeart System.

- **TandemHeart Pump**: The TandemHeart pump is intended to pump the blood through an extracorporeal circuit for periods lasting less than 6 hours for the purpose of providing either: (i) Full or partial cardiopulmonary bypass (i.e., circuit includes an oxygenator) during open surgical procedures on the heart or great vessels; or (ii) Temporary circulatory bypass for diversion of flow around a planned disruption of the circulatory pathway necessary for open surgical procedures on the aorta or vena cava.

- **ProtekSolo 62 and 72 cm Transseptal Cannulae**: The Transseptal Cannula Set-EF is intended for transseptal catheterization of the left atrium via the femoral vein for the purpose of providing a means for temporary (six hours or less) left ventricular bypass when connected to the TandemHeart extracorporeal blood pump, which returns blood to the patient via the femoral artery or other appropriate site.

- **ProtekSolo 15 and 17 Fr Arterial Cannulae**: The Femoral Arterial Cannula and Introducer are intended to cannulate vessels, perfuse vessels or organs, and/or connect with accessory extracorporeal circulatory support equipment for a duration of six hours or less. The cannula introducer is intended to facilitate proper insertion and placement of the cannula within the vessel for extracorporeal support. These devices are to be used by a trained physician only.

- **ProtekDuo 29 and 31 Fr Veno-Venous Cannulae**: The ProtekDuo Veno-Venous Cannula Set is intended for use as a single cannula for both venous drainage and reinfusion of blood via an internal jugular vein during extracorporeal life support procedures.

- **TandemLung Oxygenator**: The TandemLung Oxygenator is intended for use in an extracorporeal circuit requiring cardiopulmonary bypass for application duration limited to six hours. Within the specified flow rate range, the device oxygenates the blood and removes carbon dioxide from the blood. Responsibility for clinical application of the oxygenator rests solely with the attending physician.

- **Voyager Vest**: The Voyager Vest is intended to provide secure attachment of Extracorporeal Life Support (ECLS) components (pump, oxygenator, and tubing) to the patient during cardiopulmonary bypass.

### DISCLAIMER
- Consultant Abbott
- Consultant TandemLife (LivaNova)
**Global Trends**

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>Sedation, paralysis</td>
<td>Awake, spontaneous breathing</td>
<td>Awake, ambulatory</td>
<td>Extubated</td>
</tr>
<tr>
<td>Ventilation</td>
<td>Tissue plasty, intubate</td>
<td>Extubated</td>
<td>Extubated</td>
</tr>
<tr>
<td>Non-vent settings</td>
<td>ECMO</td>
<td>Off-vent</td>
<td>ECMO</td>
</tr>
<tr>
<td>Specialist</td>
<td>24/7</td>
<td>ECMO team support</td>
<td>ECMO</td>
</tr>
<tr>
<td>Lung recruitment</td>
<td>Watch and wait</td>
<td>Spontaneous breathing</td>
<td>No anticoagulation</td>
</tr>
<tr>
<td>Blood flow</td>
<td>Blood flow: minor</td>
<td>No anticoagulation</td>
<td>No anticoagulation</td>
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**Current ECMO circuits – Many variations and complexity are limiting adoption**

- Non-standard equipment – specialized training required
- Longer tubing, higher priming volume, prone to kinking, more complex
- LV: No ability to unload LV with these product offerings
- RV: No ability to bypass the RV
- VA: Difficult set up and transport
- VV: Higher recirculation, no tubing management system

**Central Cannulation Technique**

- **Right Thoracotomy:**
  - Don’t or short incision
  - Standard cannulation technique
  - Spinal anaesthesia & Supreme
  - Cannula tunnelled under skin to exit through chest wall

- **VA**
  - Right atrium (32-40 F)
  - Aorta (20-22 F)

- **VV**
  - Right atrium (32-40 F)
  - Pulmonary artery (20-22 F)
  - Sometimes difficult to access PA from right
INNOVATIONS: AVALON

Ambulatory extracorporeal membrane oxygenation: A new approach for bridge to lung transplantation

Scott B. Forrester, MD; James P. Scaduto, MD; Michael C. Halbach, MD; William S. Robbins, MD

Central Cannulation Technique

Disadvantage:
Difficulty in stabilizing the device with head motion
Recirculation

The Elite cannula has recirculation that is exacerbated during ambulation or even head movement.

O2 Delivery (DO2) decreases as recirculation increases.

INNOVATIONS: NOVALUNG

- Heparin-coated hollow-fiber diffusion membrane
- Removes carbon dioxide effectively using low blood flows of ~1 L/min
- May be used in a pumpless configuration (arterial–venous)
- Often referred to as "pecla" (pumpless extracorporeal lung assist) or "AVCO2R" (arterio–venous CO2 removal)

NEWER DEVICES and Cannula Innovation
Time to Decide Strategy

- Rapid deployment of VA ECLS
- Stabilize patient quickly
- Rapid, repeatable deployment of VA ECLS with streamlined device
- Pre-connected pump and oxygenator enable ease of use and focus on the patient and not on the circuit
- Provide adequate oxygen and blood flow to the patient
- Determine long term strategy

Left Atrial Veno-Arterial (LAVA)

- Some patients require a higher level of care with LV Unloading.
  - A 2017 retrospective study showed that 30 day survival was superior with ECLS + LV unloading in patients with severe cardiogenic shock.
  - Transseptal cannula can be added later for LV unloading.

LA-FA Bypass

- Cannula position matters
  - Physiologic levels of pressure (90 mmHg) and
  - Full power support (0-6.0 l/min) for organ perfusion
  - Maximum left ventricular unloading, up to 50-60%
  - Decreased myocardial oxygen demand for potential

Minimizing Circuit Size

- Average Hgb level higher due to less hemodilution
- Fewer blood transfusions
- Mayo Clinic has increased small circuit utilization from 35% in 2011 to > 62% in 2013 based on better patient outcomes and cost savings
ProtekDuo is placed via the Right Internal Jugular Vein.
Deoxygenated blood is pulled from the Right Atrium and returned to the Pulmonary Artery to be oxygenated by the lungs.

System benefits:
- RV Bypass
- 5 L/min flow (with 31 Fr)
- Enhanced mobility
- Optional oxygenation

ProtekDuo 29 and 31 Fr Veno-Venous Cannulae: The ProtekDuo Veno-Venous Cannula Set is intended for use as a single cannula for both venous drainage and reinfusion of blood via an internal jugular during extracorporeal life support procedures.

Recirculation & RV Protection

The Elite cannula has recirculation that is exacerbated during ambulation or even head movement.

The inventors of the Elite have published that recirculation occurs.

The Duo cannula is designed to reduce recirculation due to the large distance and two valves between inflow and outflow.

O2 Delivery (DO2) decreases as recirculation increases.

Transport Issues

- Components all on the patient allowing easier set up, transport, patient management; ability to unload if necessary.
- Voyager Vest used for managing tubing, pump, and TLO.

Are there benefits to the smaller circuit other than just convenience?
Recent literature suggests that enhancing patient mobility while on VV ECLS can reduce patient mortality and hospital costs by as much as 30%.

Implementing this treatment strategy has historically been difficult due to the size and complexity of conventional ECLS systems. However, by combining the ProtekDuo cannula, sterile, on-patient pump, and streamlined oxygenator for a miniaturized circuit, enhanced mobility is possible.

Ambulatory ECLS may significantly reduce hospital stay and total admission costs compared to conventional ECLS.


42 y/o woman, h/o post-partum CM Bi-Ventricular Failure

Thank You!
TandemLung and TandemLife: System Set-up & Cases

Rajan Patel, MD FACC FAHA FSCAI
Program Director, Interventional Cardiology Fellowship
Ochsner Medical Center
New Orleans, LA

- TandemLung & TandemLife Set-up
- Techniques in peripheral ECLS
- V-V ECLS Case
- V-A ECLS Case
Tandem Heart RA-PA:
29 or 31 Fr Protek Duo Cannula

Tandem Life: V-V or V-A ECLS

Turn on Device

Prime
a. Open infusate package and remove assembly
b. Plug in transducer, calibrate and prime infusate line
c. Fill a 20 cc syringe with saline
Prime

Inject 15 cc of saline into pump's lower chamber and then refill the syringe with 15 cc of saline.

Prime

Plug power chord into console.

Prime Tubing

Fill basin with 4L Normal Saline.

Tandem Life ECLS System

Attach the gas line (green tubing) to the GAS IN port.
### Tandem Heart

<table>
<thead>
<tr>
<th>Access Type</th>
<th>Left (Traditional)</th>
<th>RA/PA (Protek Duo)</th>
<th>V-V ECLS (TandemLung)</th>
<th>V-A ECLS (TandemLife)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Percutaneous Access</td>
<td>Femoral Internal</td>
<td>Internal Jugular</td>
<td>Internal Jugular Vein</td>
<td>Femoral/IJ Vein</td>
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<tr>
<td>Surgical Access</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
<td>NA</td>
</tr>
<tr>
<td>Sheath size</td>
<td>21 Fr transeptal LA cannula</td>
<td>29Fr or 31 Fr RA/PA</td>
<td>29Fr or 31 Fr RA/PA</td>
<td>21Fr Venous 17 Fr Arterial</td>
</tr>
<tr>
<td>Flow</td>
<td>4-5 L/min</td>
<td>4-5 L/min</td>
<td>4-5 L/min</td>
<td>4-5 L/min</td>
</tr>
</tbody>
</table>

### V-V ECLS Case

- 29 y/o woman with h/o cystic fibrosis
- s/p double lung transplant
- Increasing FiO2 requirement
- Re-listed for lung transplantation

**Goals:**
- Provide oxygenation & ventilation without intubation
- Maintain ambulatory status & start PT/rehab

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**Pre-dilating Right IJV**

Wedge catheter inserted Lunderquist Wire

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**V-V ECLS**
• 49 y/o gentleman with ICM LVEF=20%
• Being evaluated for OHT
• 1 month prior to admission acute cholecystitis
• Percutaneous drain placement + antibiotics
• Completed antibiotics, but still symptomatic
• Planned laproscopic cholecystectomy
• < 5% ischemia on nuclear stress test

VA ECLS Case

VA ECLS Case

• 12 PM PACU – tachycardia 120 bpm
• 2 PM PACU – hypotensive SBP 80’s
• 5 PM - surgery resident starts norepi
• 6 PM – hypoxic SaO2 in 80’s on FiO2 = 100%
• 7 PM - cardiology called after VF arrest
• EKG: Sinus tachycardia; No ST elevation
• TTE: LVEF = 10%

Cath Lab

• 7:12 PM patient arrives in cath lab
  – Maximal dose epi & norepi
• 7:19 PM – VF arrest with immediate defib and ROSC
• 7:20 PM – amiodarone started

Occluded LAD & LCx
Patent LIMA to LAD

Known RCA CTO with R → L Collaterals

Swan Ganz Placed
- Mean RA = 15mmHg
- RVSP = 47mmHg
- PA = 47/28 (35) mmHg
- MV SaO2 = 29%
- Arterial SaO2 = 60% on FiO2 = 100%
- Max dose norepi & epi

Impella CP Placed
VA ECLS Decision

- MAP = 90 mmHg
- Epi & Norepi weaned off
- Arterial SaO₂ = 80% on FIO2 = 100%
- Decision made to initiate VA ECLS

- Goal: provide short-term support to recovery or OHT

Left CFA Access

6Fr Sheath Placed Antegrade via CFA into SFA

VA ECLS CASE

- 17 Fr Arterial Return Cannula placed via left CFA
- 21 Fr Venous Cannula placed via left CFV
- Amplatz Extra-Stiff Wire
VA ECLS Case

- Tandem Life flow at 4 L/min
- Impella power decreased to P3 (LV vent)
- Right radial A-line placed
  - $\text{S}_\text{a}O_2 = 100\%$
  - MAP = 90mmHg
- ABG normal within 1 hour
- Mental status normal on arrival to CICU
- Lactate 5 mmol/L $\Rightarrow$ normal 24 hours

96 Hours later Tandem Life Weaned
Flow Around 17Fr Tandem Cannula

8X20 Balloon Tamponade of 17Fr Access Site

Left CFA Final Angiogram
Summary

• TandemLung & TandemLife
• Simple & rapid set-up
• Rapid percutaneous initiation
• Adequate support for emergency oxygenation & organ perfusion

ECMO CIRCUIT MANAGEMENT

Peter Arlia, BS, MBA, CCP, LP
Perfusion Director
UPMC Presbyterian

DAILY ECMO MANAGEMENT

• Hemodynamic parameters
  • MAP, CVP, PAP
• ECMO flow parameters
  • Adequate Perfusion?
  • Ejection in VA ECMO
• Blood gas parameters
  • Titrate to goal pCO2, pH
  • Frequency of ABG
• Return to dry weight
  • Diuresis, CRRT
• Target Hb, Platelet count

ECMO Daily Medical Orders

MAP: x x x x
CVP: x x x x
SaO2: x x x x
FiO2: x x x x
Heart Rate: x x x x
Blood Flow: x x x x
Platelets: x x x x
Hemoglobin: x x x x
Urine Output: x x x x
 Fluid Balance: x x x x
APTT: x x x x
**ECMO Order Set**

<table>
<thead>
<tr>
<th>Test</th>
<th>Description</th>
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<tbody>
<tr>
<td>Hemolysis</td>
<td>LDH Daily</td>
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<tr>
<td>Plasma Free Hb</td>
<td>Bilirubin</td>
</tr>
<tr>
<td>Lactate</td>
<td></td>
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</table>

**ECMO Labs**

- Hemolysis
- LDH Daily
- Plasma Free Hb
- >50 = hemolysis (ELSO)
- Platelet Count
- Bilirubin
- Lactate

**MANAGING AN ECMO PATIENT IN THE ICU**

**Respiratory**
- Adequate CO2 removal/Oxygenation
- pH/PaO2
- pHb>7.0: ECMO ARDS from RRT: radial line line
- Non-patient gas

**Cannula sites**
- Sterile dressing change
- Monitor for integrity of cannula and infection
- Cannula Position
- Care when turning/moving patient

**Cardiovascular**
- Adequate perfusion/output
- Hemodynamics: goals
- Ejection to prevent thrombus
- Vent/arterial line site
- Cannulated limb perfusion
  - Ejection output 4-7 hours
  - CXR/ECG monitor
  - Intermittent heparin

**Neurological Status**
- Sedation/Paralytics
- Cough
- Agitation
- Hemorrhagic/Embolic Stroke

**Temperature**
- Fever may be masked by circuit
- Sepsis always a concern
- Hypothermic protocol for arrest

**Skin**
- Turn and position q. 2 hours
- Safety when turning patient

**Psychosocial Concerns**
- CC Environment
- Long-term sedation
- Family understanding
- Withdrawal of care
BLOOD GAS MANAGEMENT

- Frequency of patient gases dependent on condition
- Oxygenator blood gases
  - Frequency range from q4hr to daily to PRN
  - Check after making adjustments to GQ
- VA ECMO – expect high pO2, high SaO2, low SvO2
- VV ECMO – expect lower pO2, lower SaO2, high SvO2

Goals
- Normalize pH (7.35-7.45)
- pCO2 (35-45mmHg)
  - permissive hypercapnia
- Normalize NaHCO3 (24)
- Upon initiation of ECMO
  - GQ:BQ set at 1:1

What do we do to correct pH?
DECREASE SWEEP GAS RATE

<table>
<thead>
<tr>
<th>pH</th>
<th>pCO2</th>
<th>pO2</th>
</tr>
</thead>
<tbody>
<tr>
<td>7.46</td>
<td>32</td>
<td>148</td>
</tr>
</tbody>
</table>

What do we do?
Is FiO2 100%? AVO2 difference?
Check O2 connections, send oxy ABG/pt ABG
Increase Blood Flow, Decrease patient O2 consumption
**Oxygen Delivery (DO2)**

- **Increase Supply**
  - Increase Flow
  - Increase Hb
  - Increase pO2 on ECMO

- **Decrease Demand**
  - Paralyze, sedate
  - Cool
  - Lower CO

**Oxygenation on ECMO**

- Oxygenation on ECMO is dependent upon how much of the patients cardiac output is being captured by the circuit....

- Improve oxygenation by maximizing flows and capturing more native CO

**Hypoxia on ECMO**

- **Capture Larger % of Total CO**
  - **VA ECMO**
    - Increase Flow
      - Physical limitations of cannulas/oxy
      - Unload the heart (60-80% total CO)
  - Check Oxygenator Function
    - Oxygenator BG – pO2 > 350?!
    - AVO2 difference
    - RARE with PMP oxy
  - Decrease O2 consumption

- **VV ECMO**
  - Increase Flow
    - Higher CO due to disease process
  - Decrease CO
    - Diuresis (SV)
    - Beta Blocker (HR)

**Recirculation – VV ECMO**

- Identified by “flash” in venous return line
  - Bright red blood appears in Venous line
  - Little/no AV-O2 difference (both bright red)
  - High Venous/pre-oxygenator pO2

- Fem-JV>Fem-Fem>VVDL (Avalon)

- Check Cannula placement – CXR
  - Can withdraw femoral cannula if Fem-JV
  - Decreasing flows decreases recirculation
HYPOVOLEMIA

• Pump needs preload to run
• Suckdown/Venous Line Chatter  [link]
• Flows drop

• Lower RPMs temporarily
• Infuse volume to patient

• May happen when intrathoracic pressure increases
  – Coughing, tamponad, pneumothorax

MANAGING THE ECMO CIRCUIT

AN ECMO SHIFT...

SHIFT REPORT

• Patient Information
  – Diagnosis
  – Relevant H&P
  – Pre-ECMO Course

• Cannulation
  – Cannula sites, sizes
  – Any issues noted at cannulation site
    • Bleeding, infection, migration of cannula, integrity of sutures
**ANTICOAGULATION**

- Current Anticoagulant drip rate
- Titration Protocol
  - Anti Xa, aPTT?
  - Goal
  - Frequency
- Last level
  - Time next test is due
  - Trends

**SHIFT REPORT**

- Events during ECMO run leading up to today
  - Changeouts, Cannulation changes, Ongoing issues
- Hemodynamics
  - MAP, CVP, PAP
  - HR, arrhythmias?

**CIRCUIT REPORT**

- Flows, RPM
- Location of any clot noted in circuit
- Flow issues
  - Chatter? High Pressures?
- Volume given on shift
  - Blood Products? Albumin?
- Gas Flow Rate (sweep), FiO2
- Recent blood gases, Labs
  - Adjustments made? Next gas?

**CIRCUIT CHECKS**

- Follow the circuit from cannula to cannula checking lines
  - Fibrin/clot
  - Connections secure
  - Stopcocks closed/closed caps
  - Air
  - Kinked Tubing
CIRCUIT CHECKS

- Power
  - Is pump securely plugged in?
  - Battery functioning?
  - Handcrank/backup pump available?
  - Cables secure? (drive motor, flow probe, pressure monitoring)

- Alarms set/functioning
  - Flow (+/-)
  - Pressure
  - Battery/Power

- Gases
  - Blender functioning, set at proper gas flow rate, fio2?
  - Gas line connected to oxygenator?
  - Air/oxygen lines connected to wall?
  - Backup oxygen tank full w/tubing
  - Confirm a/v color change

- Clamps available at bedside

- Heater cooler functioning/set

EMERGENCY BACKUP SUPPLIES

- ECMO Circuit (Setup? Primed?)
- Oxygenator
- Pump Head
- Priming solution
- Sterile scissors
- Clamps
- Connectors/tubing
- Cannulas

SHIFT CHECKLIST

- Gases
  - Blender functioning, set at proper gas flow rate, fio2?
  - Gas line connected to oxygenator?
  - Air/oxygen lines connected to wall?
  - Backup oxygen tank full w/tubing
  - Confirm a/v color change

- Clamps available at bedside

- Heater cooler functioning/set

HOURLY CHECKS

- Check circuit, esp. oxygenator, connectors
- Sigh oxygenator
  - Turn GO briefly
  - Exhausts condensation from gas phase of oxygenator
- Check pulses in UE/LE – ESPECIALLY in cannulated limb
  - Mottled? Cold? May need to add a distal perfusion cannula
- Cannula
  - Is it secure? Site dressing clean, dry intact?
SAFETY

- Always secure lines when turning/moving patient or patient bed
- In any emergency – CLAMP lines to protect patient

DON'T FORGET THE PATIENT!

- Neuro status
- Bleeding
- Temperature
- Pain Control
- Psychological Comfort

REFERENCES

- Always secure lines when turning/moving patient or patient bed
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REFERENCES

- Neuro status
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