ECMO

Quantitative Measurements during ECMO with the ELSA Monitor

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THE MEASURE OF BETTER RESULTS.

Acknowledgment

Transonic®, a measurement innovations company, pioneered ultrasound dilution technology for proactive arteriovenous (AV) vascular access surveillance during hemodialysis. This recognized gold standard technology has now been refined to provide valuable hemodynamic data at the beside of critically ill ECMO patients.

The development of these measurement modalities was supported, in part, by grants from the National Institutes of Health. We gratefully acknowledge their significant financial assistance.

We especially thank Transonic Senior Scientist Nikolai Krivitski Ph.D., D.Sc., for his tireless dedication to the development of Extracorporeal Life Support Assurance (ELSA®) Monitor and to the collaborators who have validated the hemodynamic capabilities of the device.

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I. The ELSA Monitor

HCE101 ELSA Monitor

Over the past quarter century, ultrasound dilution technology, pioneered by Nikolai Krivitski Ph.D., D.Sc. and Transonic, is the recognized gold standard for measurement of hemodialysis vascular access flows. Since its introduction in 1995, more than 200 publications have presented flow/dilution technology studies in peer-reviewed journals.

This revolutionary technology has now been refined in the Extracorporeal Life Support Assurance (ELSA®) Monitor to provide quantitative flow measurements in all extracorporeal membrane oxygenation (ECMO) configurations.

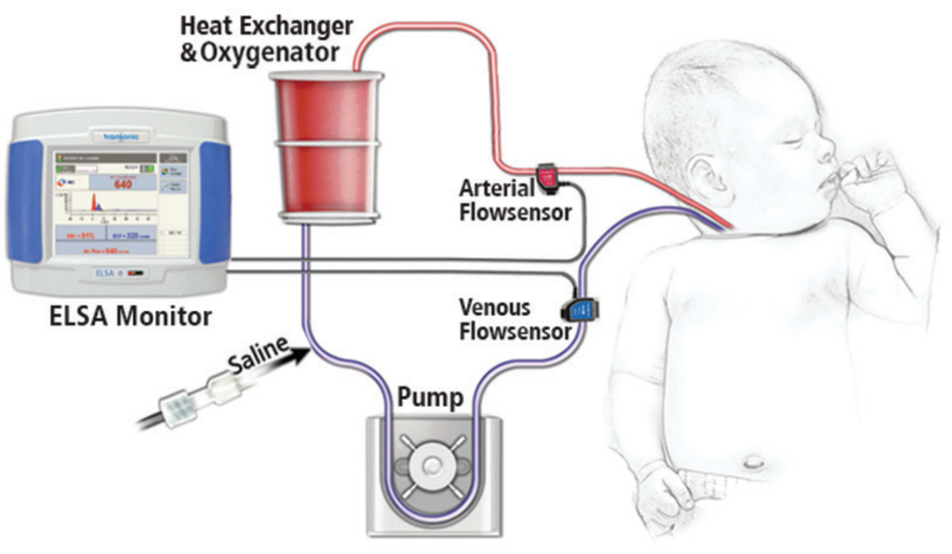
Although ECMO therapy has improved significantly over the past several decades, clinicians still need to be able to know exactly how much oxygen is being delivered to the patient, how much of the delivery is recirculating and the oxygenator's clotting status. ELSA measurements provide actual quantitative data to address these concerns.

I. The ELSA Monitor
Hemodynamic Measurements

The ELSA Monitor measures:

- True Delivered Blood Flow for all ECMO configurations
- Recirculation in VV ECMO
- Oxygenator blood volumes in VV & VA ECMO

In short, the ELSA Monitor provides the clinician with a quantitative measurement tool to optimize ECMO therapy in all ECMO patients.

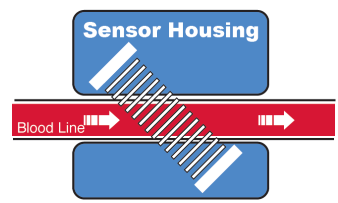


VV ECMO: Schematic above shows placement of Flow/dilution Sensors and site of saline bolus injection into the VV ECMO circuit. Picture at right shows arterial and venous sensors on ECMO circuit of baby model..

II. ELSA Measurement Principle Ultrasound Indicator Dilution

The HC101 ELSA uses proven ultrasonic indicator dilution (UDT) technology to quantify delivered blood flow to the patient, recirculation and oxygenator blood volume during ECMO. UDT combines two technological principles: Differential Transit-time Ultrasound and Indicator Dilution, each described succinctly below.

Principle I: Differential Transit-Time Ultrasound



The blood line is inserted into the groove of the flow/dilution sensor body. Direction of flow is indicated by arrows. Ultrasonic beam is shown emanating from the two transducers in the sensor body.

Paired clip-on sensors transmit beams of ultrasound through the blood line many times per second. Transducers pass ultrasonic signals back and forth, alternately intersecting the flowing blood in upstream and downstream directions. The ELSA Monitor derives an accurate measure of the changes in the time it takes for the wave of ultrasound to travel from one transducer to the other (“transit time”) resulting from the flow of blood in the vessel/tube. The integrated differences between the upstream and downstream transit times over the distance of the tubing provide a measure of volume flow.

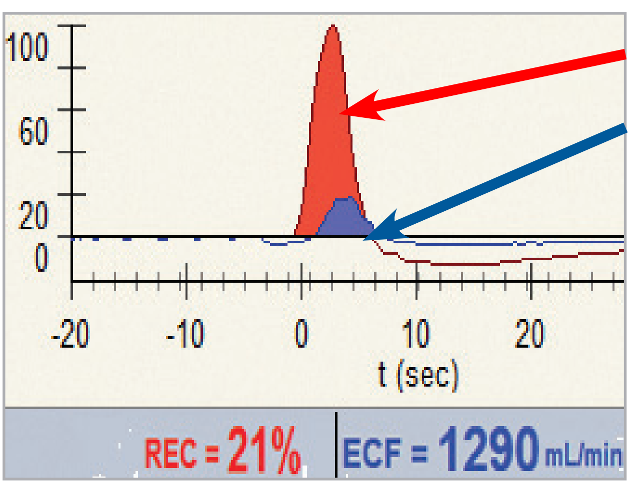
During ECMO, two matched flow/dilution sensors are clipped onto the arterial and venous lines, respectively. The ELSA Monitor continuously displays both blood flows (one from the arterial sensor and one from the venous sensor). Comparison of the readings with the pump flow setting (i.e., the flow the pump is assumed to deliver) provides an opportunity to identify and correct flow delivery problems.

II. ELSA Measurement Principle

Principle II: Indicator Dilution Measures Recirculation & Oxygenator Blood Volume

The ELSA Monitor and Flow/dilution Sensors measure ultrasound velocity. A bolus of isotonic saline (ultrasound velocity: 1533 m/sec) introduced into the blood stream dilutes the blood and thereby reduces the ultrasound velocity of the liquid. The paired flow dilution Sensors, attached to an ECMO circuit and connected to the ELSA Monitor, sense this decrease in the ultrasound velocity of blood dependent on its protein concentration.

The Flow/dilution Sensors record this saline bolus as a conventional indicator dilution curve. First, the ELSA Monitor displays a curve sensed by the arterial sensor and then a second curve sensed by the venous sensor. The area under the curves is calculated by the ELSA to produce the results for recirculation and oxygenator blood volumes that are then displayed on the ELSA screen.



Ultrasound Velocity
0.9% NaCl: 1533 m/sec
Blood: 1580 m/sec

Protected under USA patents # 5,453,576; 5,595,182; 5,685,989. International patent #EP 0 781 161 B1

II. ELSA Measurement Principle

ELSA Recirculation Calculation

The flow curve is plotted in red, and whatever is returned immediately through the return line to the venous cannula is plotted in blue. The two are compared, and recirculation and effective cardiac flow (ECF) are reported. Example: ELSA Results during VV ECMO (page 12). Recirculation (REC) is 24% and effective cardiac flow (ECF) is 1249 mL/min.

ELSA Oxygenator Blood Volume Calculation

The arterial sensor senses the increase in flow during the injection, and marks the time. When the saline bolus passes the sensor, the difference in wavelength is plotted in red. The flow from the injection to the center of the flow curve represents the total volume between the injection site and the sensor. As a clot increases in size, the blood volume decreases. To make oxygenator volume measurements (slightly) more accurate, an ELSA screen asks for the volume within the tubing between the injection site and the arterial sensor. ELSA will deduct the tubing volume from the total volume, isolating the volume of the oxygenator.

ELSA's Paired FX Flow/Dilution Sensors

- Sensor size is determined by outside diameter of the tubing.
- High accuracy particularly with turbulent flows;
- Provides notifications of acoustic interruption.

ELSA HFX Flow/Dilution Sensors

Flow/ Dilution Sensor #	Tubing		Flow Range (L/min)
	ID (inches)	OD (inches)	
H6FX	1/4	3/8	0.3 - 2
H7FX	1/4	7/16	0.3 - 2
H9FX	3/8	9/16	1 - 7

ELSA's arterial and venous line Flow/dilution Sensors

III. ELSA Benefits

The ELSA Provides Vital Quantitative Data To Help Maximize ECMO Efficiency

1. Verifies Delivered Blood Flow

Pump (delivered blood) flow errors and recirculation can compromise ECMO delivery of oxygenated blood. The ELSA Monitor measures true delivered blood flow through ECMO tubing using “gold standard” transit-time ultrasound technology. By comparing actual delivered blood flow to the pump’s reading, any flow limiting cause such as incorrect cannulation placement can be identified and corrected.

Knowing Actual Delivered Flow is used to:

- Verify circuit flows;
- Determine flows in bridges or shunts;
- Determine the optimal pump flow setting with any cannula or configuration;
- Identify tubing flow restrictions that might cause hemolysis or increase pressure within the circuit.

2. Quantifies Recirculation to Optimize ECMO Delivery

With a single bolus of saline, the ELSA Monitor can detect and quantify recirculation in the ECMO circuit. Knowing recirculation helps an intensivist:

- Adjust cannula position for best treatment delivery;
- Adjust/vary pump flow for best treatment delivery;
- Identification of low CO dew to hypovolemia or hear failure;
- Identify incoming VV ECMO problems (#1, #3) with routine REC daily measurement.

III. ELSA Benefits

3. Measures Oxygenator Clotting

Clotting in the oxygenator is one of the major complications of ECMO. The challenge is to minimize oxygenator clotting while preventing bleeding in fragile ECMO patients.

With an injection of a small volume of saline the ELSA Monitor measures oxygenator blood volume to quantify early clot formation in the ECMO circuit oxygenator. Early detection and trending of clot formation in ECMO circuits allows a wider window of opportunity to perform oxygenator change-outs.

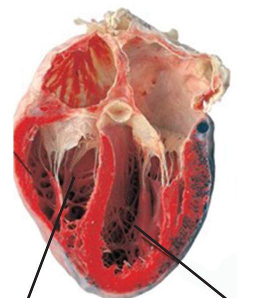
IV. ELSA Measurements

A. Optimizing ECMO Pump Flows

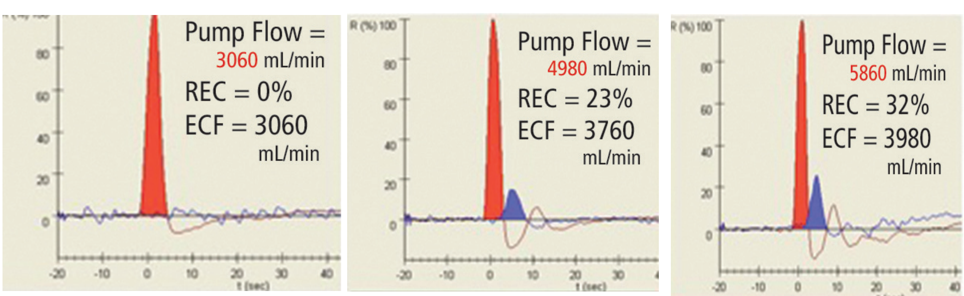
High ECMO RPMs increase the likelihood of recirculation. During VV ECMO, flow is absorbed by the patient's cardiac output (CO), but should not exceed it. Any flow exceeding the patient's CO will cause recirculation.

For example: A patient's CO is 3 L/min, but ECMO flow is set for 5 L/min. The difference of 2L/min will be recirculated. This does not improve oxygen delivery because the effective ECMO flow the patient receives does not increase proportionally to pump speed (see figures below).

It is therefore important to identify optimal RPMs to provide the most effective ECMO flow possible. High RPM's can increase hemolysis which can lead to serious complications.



The thinner walled right ventricle of the heart sustains lower pressures than does the thicker walled left ventricle. It is therefore important during ECMO to deliver enough flow to the right ventricle, but not so much that the ventricle is unduly strained.

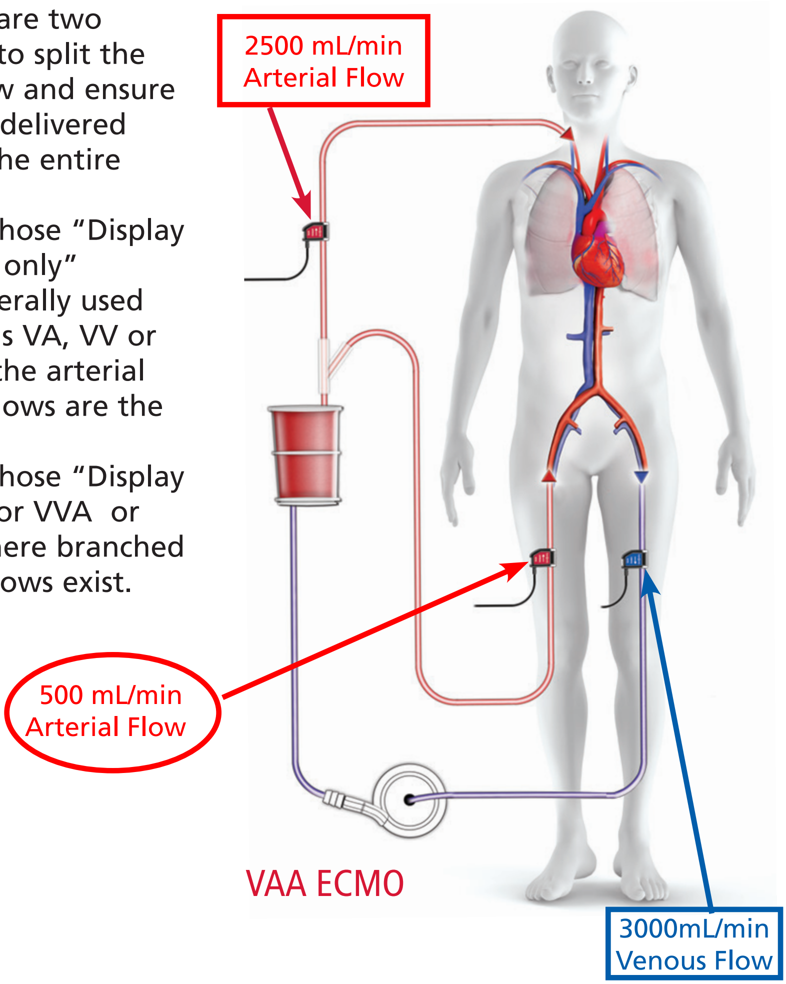


As shown by the dilution curves above, increasing pump flows from 3060 mL/min to 5860 mL/min (a 2300 mL/min increase) results in creating 32% recirculation and only increasing effective cardiac flow (ECF) from 3060 mL/min to 3980 mL/min. Thus, increasing pump speed did not proportionally increase the flow that goes to the patient because recirculation also results.

A. Optimizing ECMO Pump Flows cont.

It is currently unknown what is being actually delivered when more than two cannulating sites are involved. Under-perfused areas can become chronically ischemic so it it helpful to know, quantitatively, what flow is being delivered where.

- . In VAA, there are two arterial lines to split the delivered flow and ensure that blood is delivered throughout the entire body.
- . The User can chose “Display Arterial Flow only” (default) generally used where there is VA, VV or CPB cases as the arterial and venous flows are the same.
- . The User can chose “Display Two Flows” for VVA or VAV cases where branched or side arm flows exist.

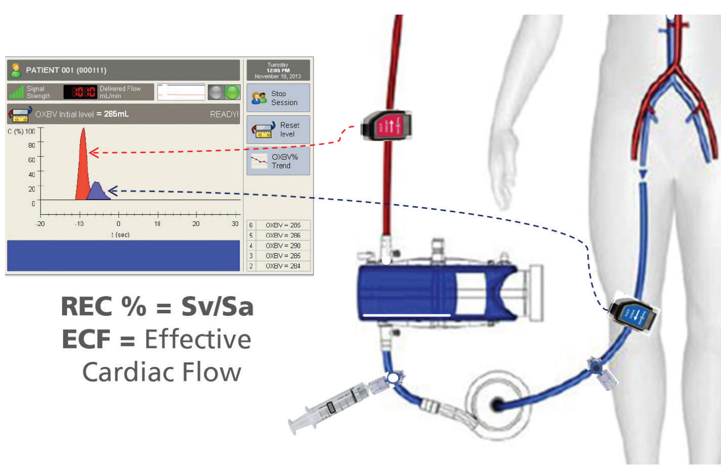


IV. ELSA Measurements

B. Quantifying VV ECMO Recirculation at the Bedside

Recirculation, a known complication of VV ECMO, occurs when oxygenated blood delivered by the cannula is not delivered to the heart but returns back into the drainage cannula/lumen. Long-lasting periods of recirculation reduce the delivery of oxygen from the ECMO circuit to the patient so that, without optimal therapy, an ECMO patient will quickly decompensate.

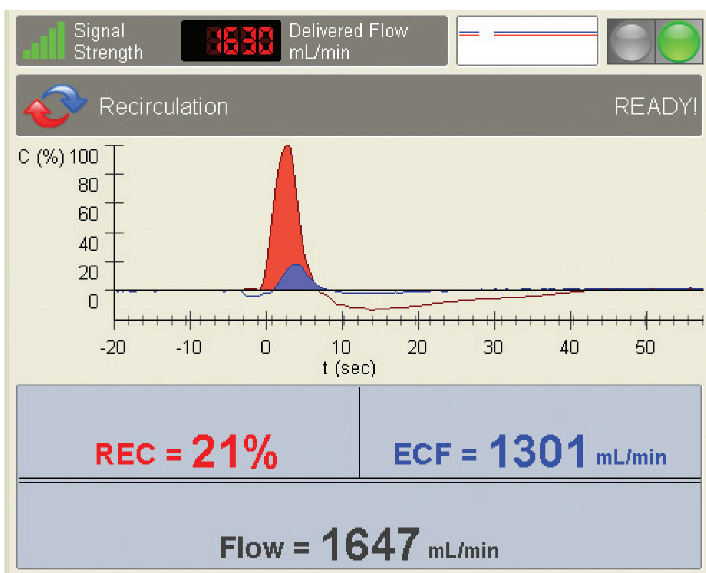
When a saline bolus is injected upstream from the arterial Flowsensor, the ELSA identifies the saline concentrations at both Flowsensors. The ratio of indicator concentrations equals recirculation. Rec= Sv/Sa*100%; where Sa and Sv are areas under the respective arterial and venous dilution curves.



B. Quantifying VV ECMO Recirculation at the Bedside cont.

Early Detection of Recirculation

Medical teams still struggle to identify how much recirculation is occurring and how seriously it is affecting the patient. Early detection can lead to faster improvement and successful weaning from ECMO. The ELSA Monitor not only confirms the presence of recirculation but also gives an actual percentage of the recirculation that is occurring. By quantifying recirculation the clinical team knows the actual oxygenated ECMO flow being delivered to the patient and can initiate measures to optimize the ECMO therapy.



ELSA Recirculation Results (21%) screen during VV ECMO. Also note the effective cardiac flow (ECF) and delivered flow (ml/min).

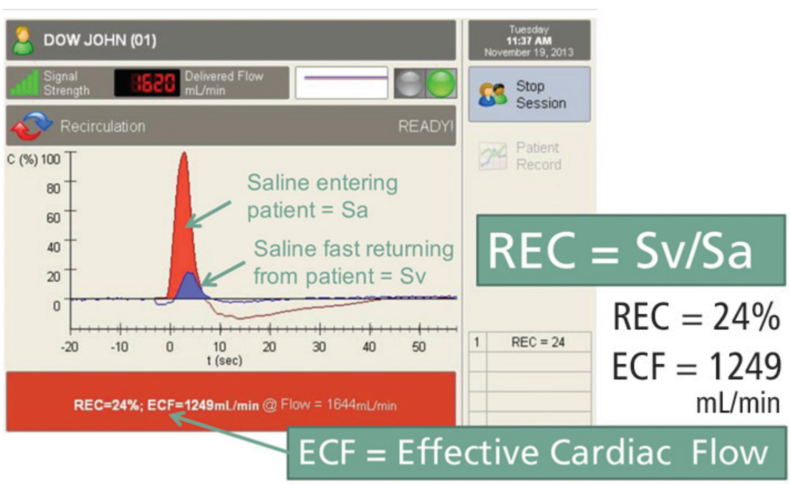
B. Quantifying VV ECMO Recirculation at the Bedside cont.

Indications of Recirculation

Until now, recirculation surveillance has relied on subjective observations, making it difficult to detect and quantify. The most obvious indication is a low arterial oxygen saturation with a high pre-oxygenator saturation.

Other subjective clinical signs include:

- low PaO2's
- increased ventilator settings
- change in vasoactive support
- suboptimal cerebral saturations using NIRS monitoring



ELSA Results screen during VV ECMO. Recirculation (REC) is 24% and effective cardiac flow (ECF) is 1249 mL/min.

B. Quantifying VV ECMO Recirculation at the Bedside cont.

Troubleshooting Recirculation

Once recirculation is identified using the ELSA Monitor, steps can be taken to eliminate or reduce recirculation and optimize treatment.

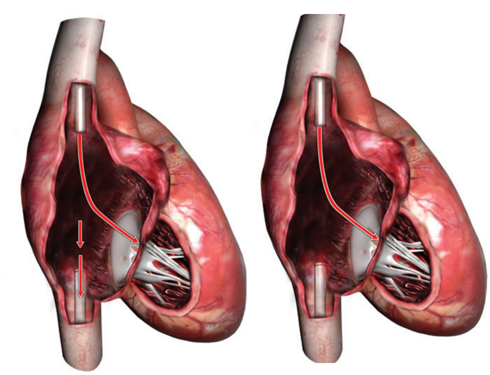
Cannula Positioning

Poor cannula position is commonly associated with recirculation. For all VV ECMO configurations, cannulas must be placed in the ideal position within the venous circulation. Each cannulation technique is susceptible to recirculation.

a) Bi-Femoral cannulations use both femoral veins to obtain ECMO support and the proximity of the cannulas to each other increase.

b) Femoro-jugular cannulations utilize a patient's femoral and right internal jugular vein to provide support. The tip of each cannula faces each other, creating high rates of recirculation if positioning is not perfected.

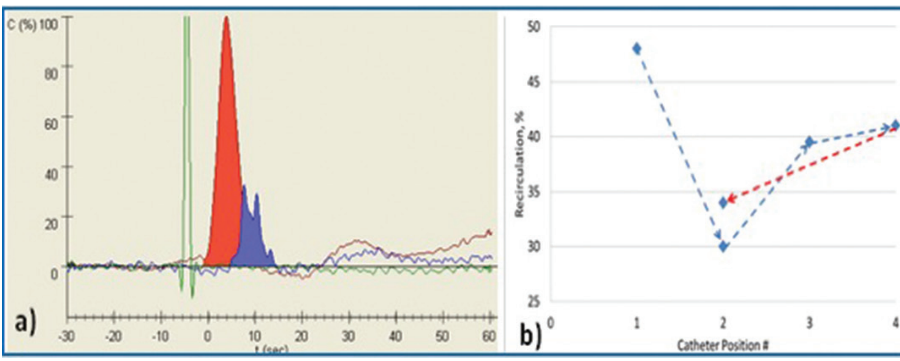
c) Double-lumen cannulas (DLB) operate with three ports; two for draining blood into the ECMO system and one for reinfusing oxygenated blood into the patient. These cannulas enter through the right internal jugular vein and continue into the right side of the heart.



Single-lumen cannula on the left, Avalon dual-lumen on the right. Red arrows show delivered blood.

B. Quantifying VV ECMO Recirculation at the Bedside cont.

Specialists can perform a recirculation measurement with the ELSA Monitor during cannulation to help surgeons locate ideal placement. They can then trend recirculation values throughout the entire ECMO case to maintain optimal cannula positioning.

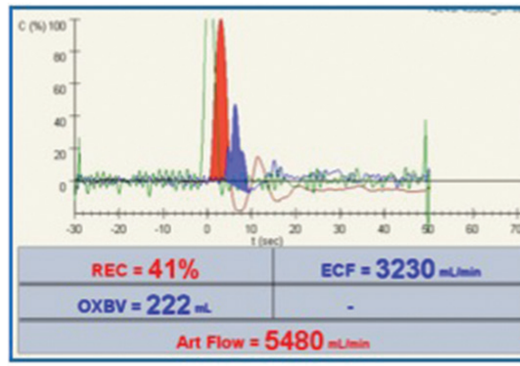


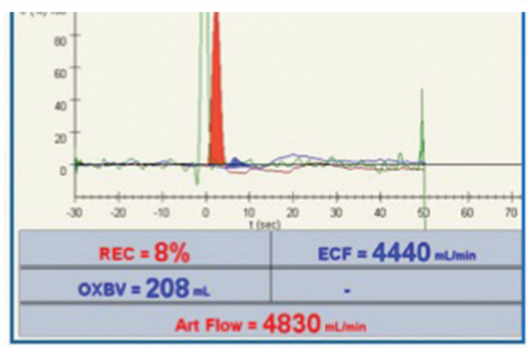
Cannula Position Optimization: Graph shows the decrease in recirculation as the cannula is repositioned. Data courtesy of Said MM, Rivera O *et al*, Children's National Medical Center, Washington, D.C.

B. Quantifying VV ECMO Recirculation at the Bedside cont.

Volume Status Optimization

When VV ECMO patients are hypovolemic, inadequate preload will increase recirculation. Providing a fluid bolus or adjusting diuretic management should help correct the lack of forward flow through a patient's native outflow tract. A recirculation measurement can be taken before and after the fluid bolus to quantify improvement and guide effective patient management.



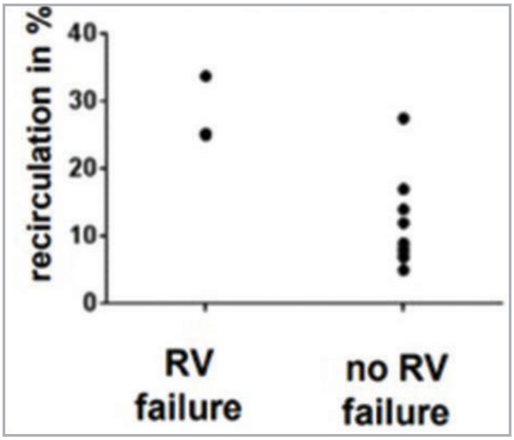


Hypovolemia leading to low CO (72 kg pt): ELSA screen shots show REC and ECF changes after fluid influsion and changes to an Avalon catheter in the OR.

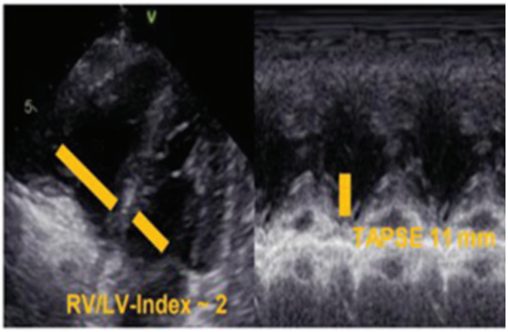
B. Quantifying VV ECMO Recirculation at the Bedside cont.

Cardiac Funtion

If previous measures have not improved recirculation, then the patient's cardiac function may be the culprit. Right ventricular dysfunction dysfunction and volume overloading can be induced by long-term VV ECMO therapy, but is difficult to detect. Evolving heart failure decreases the heart's ability to pump effectively, reducing the overall cardiac output. As cardiac output decreases, recirculation will increase. Recirculation measurements may help indicate heart failure that can then be further assessed by an echocardiogram.



Increased recirculation indicates right ventricular failure.



ECHO of ARDS patient shows enlarged right ventricle.

Summary

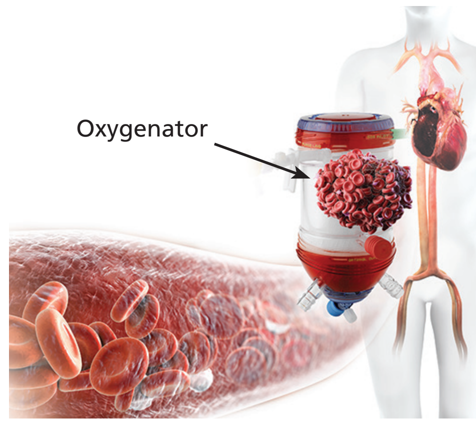
Recirculation has long been an undesirable component of VV ECMO, but has previously been hard to quantify. Transonic's ELSA Monitor is a powerful assessment tool that allows clinicians to obtain quantitative recirculation percentages which they can use to improve their patient's VV ECMO therapy.

IV. ELSA Measurements

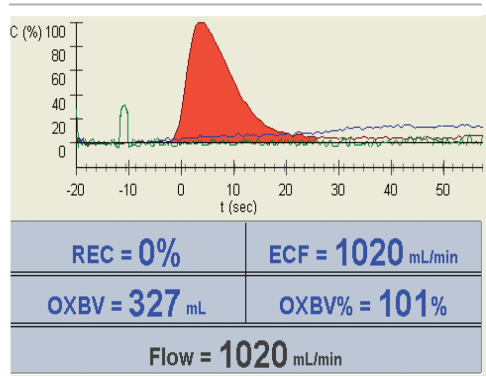
C. Oxygenator Blood Volume

Persistent clotting is among the most challenging problems encountered during ECMO runs. As blood is exposed to tubing clotting naturally occurs and activates inflammatory pathways. Clots within the ECMO circuit can have catastrophic consequences.

Anticoagulants (i.e. heparin) are used to control clotting but must be used carefully to avoid bleeding. Circuits are run with low levels of heparin to reduce the potential for clot formation while keeping bleeding (stroke) at a minimum. Since neonates have less developed clotting systems than adults, anti-coagulation strategies are even more difficult in this population Full anticoagulation requires an Activated Clotting Time (ACT) of 400 to 480 seconds, but in ECMO cases ACT levels are maintained at 180 to 200 seconds, virtually assuring clot formation.



Graphic that depicts clotting within an oxygenator,.

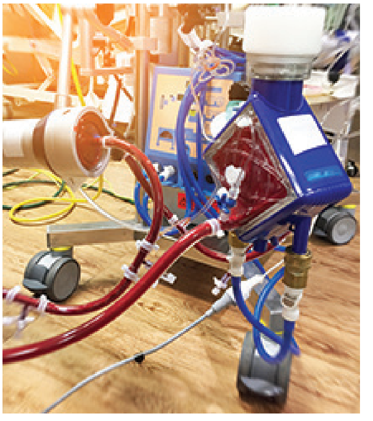


With the ELSA, a quick 1 minute measurement with non-toxic isotonic saline indicator produces a quantitative measurement of oxygenator blood volume.

C. Oxygenator Blood Volume cont.

Each ECMO patient is different with their own unique blood chemistry that requires different flows and different circuit sizes/branches and different flow rates. In some patients, a clot can begin forming within hours, in others, it might take days.

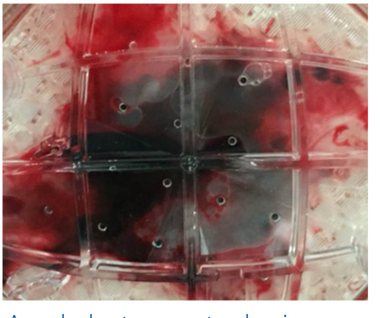
The oxygenator is at particular risk for clotting. Oxygenators are very efficient and can do their job well as long as there are clear portions. Tracking the true volume of oxygenator clots is difficult and immediate full clotting of an oxygenator can happen quickly and can be a crisis if staff are not prepared.



Flash Light Method: Non-flaking soft clots evenly spread across the fibers shown here cause a high pressure gradient. Pressure changes do not adequately access the amount of clotting within the oxygenator.

Non-Quantitative Clotting Tests

- Flashlight Method
- Laboratory Testing: can assess a patient's anti-coagulation status but does not tell if a clot is forming within the oxygenator or else in the circuit.
- Transmembrane pressure
- Diminished oxygenation



A washed out oxygenator showing a huge clot in its center.The pressures and oxygen saturation would be just fine in this instance so there is no way to predict when the oxygenator will fully clot off.

ELSA Quantitative Clotting Test

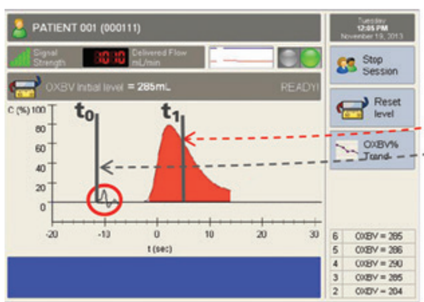
The ELSA is the only method that can trend how much the OXBV volume is decreasing over time. When room temperature saline is injected near the inlet of the oxygenator, the ELSA Monitor measures oxygenator blood volume (OXBV)

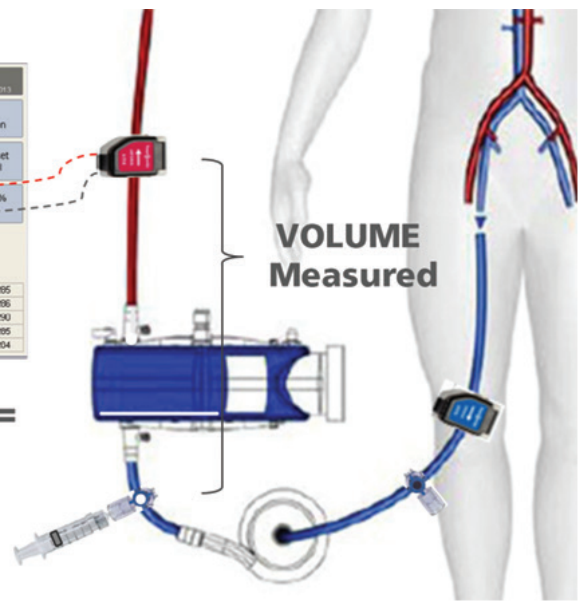
C. Oxygenator Blood Volume cont.

between the injection site and the arterial sensor and displays the result for each injection on a timeline.

OXBV decreases as clot volume increases.

Oxygenator Blood Volume (OxBV) in VV & VA ECMO





VOLUME Measured =
Q_b x $(t_1 - t_0)$ mL

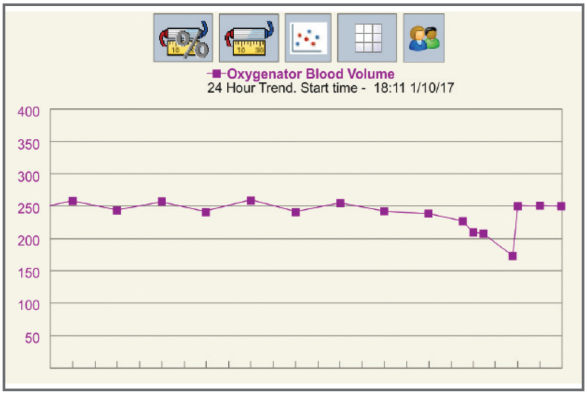
OXBV = Qb x MTT
Qb – Blood Flow
MTT – Mean transit time of saline traveling through oxygenator. Priming volume subtraction improves accuracy

The arterial sensor senses the increase in flow during the injection, and marks the time. When the saline bolus passes the sensor, the difference in wavelength is plotted in red. The flow from the injection to the center of the flow curve represents the total volume between the injection site and the sensor. As a clot increases in size, the blood volume decreases. To make oxygenator volume measurements (slightly) more accurate, an ELSA screen asks for the volume within the tubing between the injection site and the arterial sensor. ELSA will deduct the tubing volume from the total volume, isolating the volume of the oxygenator.

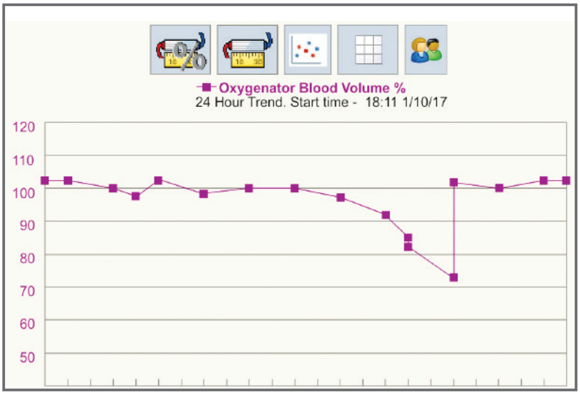
C. Oxygenator Blood Volume cont.

Measurements are trended over time to quantify clotting independent of oxygenator type. This trending is the most important for they will help predict when an oxygenator change-out will be necessary. Such foreshadowing of clot formation in ECMO circuits can allow for device change outs, before clotting becomes a serious clinical risk.

Oxygenator blood volume trending is available in 4 hours, 24 hours, or total-case-time screens.



Each injection is plotted. Here you can see where the volume decreased (as clot volume increased), and returns to baseline when the oxygenator is changed out.



Oxygenator Blood Volume trended as a percentage.

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In Vitro and *In Vivo* Assessment of Oxygenator Blood Volume for the Prediction of Clot Formation in an ECMO Circuit (Theory and Validation)

Children's National Medical Center & George Washington University School of Medicine, Washington, DC

INTRODUCTION

Clotting and bleeding are major causes of mortality and morbidity during extracorporeal membrane oxygenation (ECMO). Oxygenator blood volume (OXBV) is the total amount of blood that flows through the oxygenator. As a clot develops, OXBV decreases. As clots form in the oxygenator, as an oxygenator blood volume (OXBV) decreases over time, OXBV becomes a direct measure of the volume of clots formed in the oxygenator. A pressure gradient, currently used to predict clot formation, is unreliable because its relative changes are not always proportional to a clot's size. An uneven clotting pattern leaves some areas of the fibers open which allows the pressure gradient to remain deceptively small.

OBJECTIVE

The objective of this study was to develop and validate measurements of OXBV by ultrasound dilution technology as a quantitative assessment of oxygenator clotting.

METHOD

Bench Test: Validation of the accuracy of OXBV was measured using the ELSA Monitor (Transonic Systems Inc., Ithaca, NY, USA) by measuring the transit time of a bolus of saline passing through the oxygenator recorded by a Flow/Dilution Sensor placed on the ECMO circuit after the oxygenator.

In Vivo Animal Experiment: The accuracy and reproducibility (coefficient of variation [CV]) of OXBV measurement and its independence from ECMO flow, was assessed *in vivo* by a total of 88 ultrasound dilution measurements in 6 newborn lambs undergoing ECMO. A bolus of 3-5 mL of isotonic saline into the ECMO circuit was used to measure OXBV and recirculation. Ultrasound dilution results were compared with actual volume changes from the injection of fixed known volumes (from 5 to 40 mL) of petroleum jelly (Vaseline) into oxygenators to mimic the formation of clots of varying sizes. To assess the reproducibility of the data, archived clinical data were analyzed to calculate the coefficient of variation (CV) of consecutive measurements.

RESULTS

In vivo accuracy compared with volumetric measurements of OXBV of 22-134 mL at flows of 300-700 mL/min was -0.8±6.6%. OXBV measured at different pump flows showed a variation of 0.11±2.86% from the mean flow of 400 mL/min. The *in vivo* animal experiment demonstrated a strong relationship (R^2= 0.85) between the volume of petroleum jelly injected into the oxygenators and the percentage decrease of the oxygenator blood volume measured by ultrasound dilution. OXBV ranged from 42- 387 mL; ECMO flow ranged from 210-5960 mL/min; the coefficient of variation was 3.20±2.44 %. For an OXBV of 355 mL at flows of 1020-7000 mL/min, accuracy was -0.4±1.6%.

CONCLUSION

Ultrasound dilution technology can accurately and reproducibly assess the clotting process in an oxygenator. Larger studies are needed to establish guidelines for the prediction of imminent clotting to help to avoid unnecessary ECMO circuit changes.

REFERENCE: Krivitski N, Galyanov G, Cooper D, Said MM, Rivera O, Mikesell GT, Rais-Bahrami K, "*In vitro* and *in vivo* assessment of oxygenator blood volume for the prediction of clot formation in an ECMO circuit (theory and validation)," Perfusion. 2018 May; 33(1 suppl): 51-56. (Transonic Reference # ELS11317V)

Optimization of V-V ECMO circuit determined by blood recirculation measurements improved systemic oxygenation in a 10-year-old patient

Ruß M *et al,* Berlin University of Medicine, & Institute of Health, Germany

During veno-venous extracorporeal membrane oxygenation (V-V ECMO) used to treat life threatening acute respiratory distress syndrome (ARDS), the fraction of ECMO blood flow (Q_{EC}) that recirculates directly into the drainage cannula does not support systemic oxygenation. Therefore, measurement of recirculation is critical in identifying effective ECMO blood flow (Q_{EFF}).

CASE REPORT

- A 10-year-old patient weighing 44 kg and 132 cm tall suffering from extra-pulmonary ARDS caused by postoperative sepsis and massive transfusion was placed on V-V ECMO in the hospital's pediatric ICU.
- After femoro-jugular cannulas were inserted and ECMO was initiated, pulmonary arterial oxygen levels only increased from 44 mmHg to only 66 mmHg.
- The child was then transferred to Charité's intensive care unit. There, recirculation was measured with the Extracorporeal Life Support Assurance (ELSA) Monitor using saline dilution ultrasound technique.
- The position of the two cannulas was also visualized by CT-scans.
- Together, the high recirculation fraction (Rf = 78%, 65%) with corresponding low effective ECMO blood flows (Q_{EFF} = 680 mL/min, 1260 mL/min) results with the visualization of the cannulas, lead the clinicians to postulate that the depth of the drainage cannula's insertion caused direct jetting of blood towards the inferior vena cava which cause high recirculation.
- In response, they pulled the cannula back approximately 2 cm in an attempt to reduce recirculation.
- Recirculation dropped dramatically to 25% and effective ECMO blood flow increased to 1800 mL/min.

CONCLUSION

When high flow V-V ECMO did not sufficiently support systemic oxygenation in the child, measurements of recirculation, imaging techniques and applied ECMO physiology did lead to optimization of systemic oxygenation and protective lung ventilation.

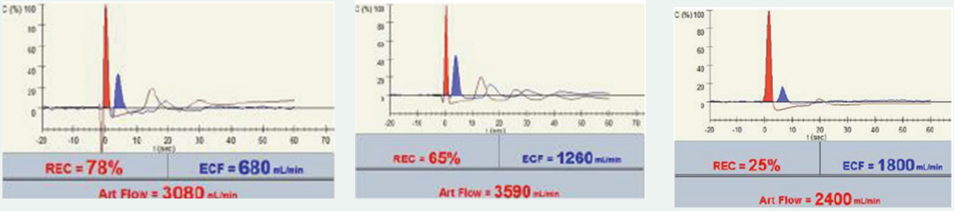

Fig. 1a, 1b, 1C: Two recirculation measurements after ECMO was initiated. Recirculation was 78% and 65% respectively. Effective flow was 680 mL/min and 1260/min. After the outflow cannula was repositioned recirculation dropped to 25% and effective flow increased to 1800 mL/min.

REFERENCE: Ruß M, Weber-Carstens S, Skrypnikov V, Taher M, Francis RCE, BoemkeW, Pickerodt PA, "Optimization of V-V ECMO circuit determined by blood recirculation measurements improved systemic oxygenation in a 10-year-old patient," 5th Annual Symposium on ARDS, Berlin, Germany, June 2019 (Transonic Reference: ELS10569A)

Precision and Accuracy of the New Transonic ELSA Monitor to Quantify Oxygenator Blood Volume (*in-vivo* and *in-vitro* studies)

Said MM *et al,* Children's National Med Ctr, & George Washington Univ. School of Medicine Washington, DC.

BACKGROUND

Major complications of ECMO are bleeding and clotting in the circuit. The challenge of heparin therapy during ECMO is to keep the ECMO circuits (mostly the oxygenator) from clotting while preventing patient bleeding. Recently, the ELSA monitor (Transonic Systems Inc. Ithaca NY) was introduced that measures clot formation in the oxygenator by recording oxygenator blood volume (OXBV) using a dilution method.

OBJECTIVE

Too evaluate the reproducibility *(in-vivo)* and absolute accuracy *(in-vitro)* of ELSA Monitor OXBV measurements.

METHOD

- During VV ECMO, OXBV was measured in seven newborn lambs (1- 5 days old, wgts. 4.2+0.5 kg).
- The ECMO circuit included a Jostra Rotoflow centrifugal pump and Quadrox-iD pediatric oxygenator with the circuits primed with heparinized ovine blood.
- ELSA flow-dilution sensors were attached to the blood lines.
- Isotonic saline was injected to measure OXBV.
- After completion of the animal experiments of each ECMO run, the lamb was removed from circuit.
- The circuit was transitioned to a recirculating loop and fixed volumes of Vaseline were injected into the oxygenators to mimic clot formation of varying size.

RESULTS

- A total of 88 OXBV measurements were taken.
- The coefficient of variation(1.49±1.12%) demonstrated high precision.
- OXBV measured at different pump flows (200-600 mL/min) showed a variation of 0.11±2.86% from the mean flow of 400mL/min.
- The *in vitro* arm of the study showed a strong inverse relationship (R^2= 0.85) between the volume of Vaseline injected into the oxygenators, and the percent decrease in oxygenator blood volume (Figure 1).

CONCLUSION

- The ELSA Monitor demonstrated high precision in measuring decrease in oxygenator volume in the ECMO circuit using the injection of a small volume of saline.
- The ELSA monitor would be a valuable tool to identify early clot formation in ECMO circuits and allow device change outs before they become clinically emergent.

REFERENCE: Said MM, Mikesell GT, Rivera O, Khodayar Rais-Bahrami K, "Precision and Accuracy of the New Transonic ELSA Monitor to Quantify Oxygenator Blood Volume (in-vivo and in-vitro studies)." 2015 PAS Annual Meeting and Eastern SPR Annual Meeting (Transonic Reference: ELS10230V)

Influence of Central Hemodynamics on VV ECMO Oxygen Delivery in Neonatal Animal Model

Said MM *et al,* Children's National Med Ctr, & George Washington Univ. School of Medicine Washington, DC.

BACKGROUND

Venovenous (VV) ECMO has become more widespread in the treatment of neonates and other patient populations with respiratory failure. Its goal is to provide respiratory support to the patient. However, recirculation of oxygenated blood in venovenous extracorporeal membrane oxygenation (VV ECMO) can decrease the oxygen delivery provided by the ECMO support and reduces the efficiency of the system and can cause severe hypoxemia.

OBJECTIVE

To investigate the influence of central hemodynamics and catheter position on the amount of recirculation and oxygen delivery in lambs during VV ECMO. Also to compare results of recirculation measured by the ELSA Monitor with those obtained using blood sampling of oxygen saturations from the central venous line (CVL Method).

METHOD

- Subject: Seven newborn lambs (mean weight 4.7kg);
- Initial hemodynamic status including cardiac output and blood volume parameters was measured with the Transonic COstatus Monitor.
- The ECMO pump was set at a prescribed flow rate of 110-120 mL/kg/min for a targeted oxygen delivery rate of 6cc/kg/min without recirculation;
- Recirculation was measured by the Transonic ELSA Monitor and the CVL methods (blood samples from the SVC, IVC, and locations before and after membrane oxygenation) at varying ECMO pump flows from 200–600 mL/min.

RESULTS

- Lambs with a higher cardiac index (>160 mL/min/kg) tended to have a higher percentage of oxygen delivery (65-94%, at prescribed flows);
- Lambs with lower cardiac index (<150mL/min/kg) tended to have a lower percentage of oxygen delivery (39-62%, at prescribed flows);
- At the prescribed pump flow of 110–120 mL 231 /min/kg, an optimal catheter position with the lowest percentage of recirculation was established;
- REecirculation percentage measurements between the ELSA Monitor and the CVL Method were in agreement.

CONCLUSION

The ELSA monitor provides an easy to use, non-invasive method to measure recirculation in VV ECMO without blood sampling. The data also suggests that cardiac function may play an important prognostic role in achieving effective VV ECMO support.

REFERENCE: Said MM, Rivera O, Mikesell GT, Rais-Bahrami K,"Influence of central hemodynamics on VV ECMO oxygen delivery in neonatal animal model," J Neonatal Perinatal Med. 2017 Apr 8. (Transonic Reference # ELS11180AH)

Cannula Design and Recirculation During VV Extracorporeal Membrane Oxygenation.

Palmér O *et al*, ECMO Centre Karolinska, Karolinska University Hospital, Stockholm, Sweden.

BACKGROUND

Extracorporeal membrane oxygenation (ECMO) is a lifesaving respiratory or cardiac failure treatment. During venovenous (VV) ECMO, recirculation occurs, but how much is not known and actions to minimize recirculation after measurement are not routine.

OBJECTIVE

To investigate the effect of draining cannula design on recirculation fraction (Rf) during VV ECMO using the ELSA Monitor and ultrasound dilution technology (UDT).

STUDY

- Fourteen patients admitted to ECMO Centre Karolinska between October 2014 and July 2015 who were catheterized by the atrio-femoral single lumen method were included in the study.
- A total of 108 measurements were conducted to compare a conventional mesh cannula (n = 31) with a multistage cannula (n = 77).
- The effect of adjusting cannula position was also studied.
- Ultrasound dilution technique was used to measure recirculation at different ECMO flows and after cannula repositioning.

RESULTS

- The multistage cannula showed significantly less recirculation (19.0 ± 12.2%) compared with the conventional design cannula (38.0 ± 13.7).
- Adjustment of cannulas reduced Rf by 7%.

CONCLUSION

- The choice of cannula matters.
- Adjustment of the draining cannula position during atrio-femoral VV ECMO also matters.
- By utilizing the ultrasound dilution technique to measure Rf before and after repositioning, effective ECMO flow can be improved for a more effective ECMO treatment.

REFERENCE: Palmér O, Palmér K, Hultman J, Broman M, "Cannula Design and Recirculation During Venovenous Extracorporeal Membrane Oxygenation," ASAIO J. 2016; 62(6): 737-742. (Transonic Reference # EC11034AH)

Quantification of Recirculation as an Adjuvant to Transthoracic Echocardiography for Optimization of Dual-lumen Extracorporeal Life Support

Körver EP *et al,* University of Maastricht, The Netherlands

OBJECTIVE

To present three representative cases with which to illustrate the benefits of ultrasound dilution technique to quantify recirculation in addition to transthoracic echocardiography during venovenous extracorporeal life support (VV-ECLS).

STUDY

- Transthoracic echocardiography images were taken of cannula positioning in three VV-ECLS patients.
- One flow/dilution sensor was placed on the arterial inlet of a double-lumen catheter, the second on the venous outlet of the catheter.
- Recirculation was measured in three patients by a 10 mL saline bolus into the outlet port of the oxygenator. Ultrasound velocity changes were detected by the flow/dilution sensors and were displayed as a dilution curve and percent recirculation.

RESULTS

- In the first case a 2% recirculation by ultrasound dilution confirmed proper cannula positioning as displayed on the transthoracic echocardiography screen.
- In the second case a 45% recirculation by ultrasound dilution confirmed a suboptimal cannula positioning as displayed on the transthoracic echocardiography screen.
- In the third case, ultrasound dilution registered a 38% recirculation, although the transthoracic echocardiography images showed good positioning of the cannula. The ultrasound dilution recirculation prompted repositioning of the cannula that permitted a decrease in mechanical ventilation and increased arterial saturation.nts (24.9 ml/kg) and controls with no cardiac shunts (18.2 ml/kg; P< 0.05).

STUDY'S CONCLUSIONS

Cannula migration can cause suboptimal VV-ECLS, but resultant recirculation may remain undetected using transthoracic echocardiography alone. Ultrasound dilution proved to be a valuable tool to monitor dual-lumen cannula position during VV-ECLS. We therefore suggest quantification of recirculation in addition to image guidance to prompt interventions that improve oxygenation and decapneization, and provide optimal VV-ECLS.

DISCUSSION

Although transesophageal echocardiography can verify cannula positioning during dual-lumen VV-ELS, recirculation and resultant inadequate lung assist may still occur due to cannula migration. The ultrasound dilution technique's ability to quantify recirculation may be crucial in correctly (re)positioning a double-lumen cannula for maintaining optimal VV-ECLS.

REFERENCE: Körver EP, Ganushchak YM, Simons AP, Donker DW, Maessen JG, Weerwind PW. "Quantification of recirculation as an adjuvant to transthoracic echocardiography for optimization of dual-lumen extracorporeal life support." Intensive Care Med. 2012; 38(5): 906-9. (Transonic Reference # ELS9679AH)

Measurements of Recirculation during Neonatal Veno-venous Extracorporeal Membrane Oxygenation: Clinical Application of the Ultrasound Dilution Technique.

Clements D *et al*, State Univ of NY Upstate Medical Center, Syracuse, NY

OBJECTIVE

To report the first clinical application of ultrasound dilution technology's capability to quantify recirculation during neonatal venovenous extracorporeal membrane oxygenation (VV ECMO) and to study various aspects of using ultrasound dilution to quantify recirculation.

METHOD

- A 2.8 kg male neonate born with congenital diaphragmatic hernia was placed on VV ECMO using a single 12 Fr. dual lumen cannula inserted into the right atrium through the internal jugular vein.
- Utrasound dilution sensors were applied to the arterial and venous lines of the ECMO circuit near the dual lumen cannula.
- A 3-5 ml bolus injection of room temperature normal saline was injected into the extracorporeal circuit.
- During the 12-day VV ECMO run, 86 recirculation measurements were performed under a variety of conditions.
- Measurements using injections of platelet concentrates were compared with those made with saline.

RESULTS

- The average recirculation measurement was 34.3% and ranged from 15-57%.
- The reproducibility of recirculation measurements performed within five minutes of one another was within 5.6% of each other.
- Changes in patient positioning resulted in significant changes in recirculation.
- Measurements of platelet injection correlated closely with saline injections (mean difference, .25% +/- 2.8%).

CONCLUSION

In this initial case experience, ultrasound dilution technique provided quick, reproducible beside results that showed changes in recirculation associated with VV ECMO therapy. Application of this technique could provide early data that will assist the clinician in guiding interventions to minimize recirculation.

DISCUSSION

VV ECMO recirculation occurs when a portion of the oxygenated blood that is delivered to the patient through a double-lumen catheter's arterial lumen immediately flows back into the venous lumen and, therefore, doesn't circulate within the patient. Excessive recirculation will result in suboptimal oxygen delivery to the patient. This paper shows that ultrasound dilution technology can be used to quantify recirculation in neonates on VV ECMO.

REFERENCE: Clements D, Primmer J, Ryman P, Marr B, Searles B, Darling E. "Measurements of recirculation during neonatal veno-venous extracorporeal membrane oxygenation: clinical application of the ultrasound dilution technique." J Extra Corpor Technol. 2008;40(3):184-7. Transonic Reference: ELS9680AH

Appendix

Minimizing Infection Risk

Sierra Coyle MS, RRT-NPS

We recognize the importance and diligence required to minimize infection risks for ECMO patients. That is why we have established a way to obtain measurements with the ELSA Monitor while keeping infection control a priority. Using a closed system within the pre-membrane transducer site allows clinicians to give the saline bolus without accessing the circuit every time.

To maintain a closed system, connect a three way stop-cock to a syringe, IV tubing and a bag of saline (see figure below). Then configure this to join the pre-membrane transducer site. The specialists can then use the stopcock to fill the syringe and give the saline flush when performing a REC and OXBV measurement with the ELSA.

Key Points

- Use a 10mL syringe for neonatal/pediatric patients and 30mL syringe for adult patients.
- Be aware of pre-membrane pressure alarm, as it may be activated during flush depending on set-up.
- Diligence is required to eliminate bubbles within the line while giving the bolus. This is not likely to activate a bubble alarm. However, caution is advised.

Infection Control(ELS-320-tn)RevA2019

Appendix cont.

Extracorporeal Life Support (ELS) Glossary

ARDS (Acute Respiratory Disease Syndrome) is a severe, life-threatening medical condition characterized by widespread inflammation in the lungs. Occurs when fluid builds up in the tiny, elastic air sacs (alveoli) in the lungs that deprives the body of oxygen. It is often fatal.

Blender: A device that mixes room air with oxygen to create the desirable composition of sweep gas to be delivered to the gas side of the oxygenator. (see oxygenator)

Blood Gas: Test that measures levels of venous and arterial oxygen, cabon dioxide, hematocrit, pH, bicarbonate, calcium, sodium, potassium, glucose, creatinine, and lactate. These are drawn usually every hour, and help guide the flow rate of the pump and gas settings on the oxygenator.

Cannula (cannulas): A plastic tube that allows the drainage of blood from, or return to, the body. Also known as a catheter.

Cannulate/Cannulation: Placing cannulas or tubes into the blood vessel. This will be performed surgically or by percutaneous method

Cavitation: high negative pressure can pull air out of solution, and the bubbles will travel through the circuit and patient until they lodge in small passages, such as the oxygenator, or patient capillary beds.

Carotid Artery: large artery in the neck. In infant VA ECMO, oxygenated blood from the circuit returns through the cannula placed in this vessel.

Chest Tube: A tube that is placed through the chest wall into the space between the lung and chest wall to drain air or fluid. Used to reinflate a collapsed lung (pneumothorax) or to drain fluid.

Congenital diaphragmatic hernia (CDH): In newborns, the abdominal contents herniate through the diaphragm into the heart and lung space, limiting breathing and cardiac output.

Decannulate/Decannulation: The process of removing cannulas from the blood vessels. If the cannulas were placed by percutaneous method, they will be pulled out like an IV and pressure held for at least 20 to 30 minutes. Cannulas that were placed surgically will require a small operation to remove them. This can be performed at the bedside.

Delivered Blood Flow: Volume flow in mL/min that is acutally delivered to a patient as measured by the ELSA Monitor.

Dobhoff Tube: Feeding tube placed through the nose onto the stomach (intestines) to deliver food and nutrition to the patient.

ECHO: Echocardiogram, a probe that emits ultrasonic waves, and measures the amount of signal returning (the ëechoí) to create images of anatomic structures. The probe is inserted into an unconscious patientís esophagus, and immediately behind the heart. From that position, clear views can be obtained of the valves, myocardium, and great vessels. (See TEE).

ECF (Effective Cardiac Flow): Flow that is pumped from the heart during ECMO.

ECLS: Extracorporeal Life Support: A common alternative term for ECMO, intended to differentiate a circuit with an oxygenator to a circuit without one. While ECLS is more descriptive,

ELS Glossary cont.

ECMO is still the most common collective term for both types of support.

ECMO: traditional term associated with use of prolonged extracorporeal cardiopulmonary bypass, usually via extrathoracic cannulation, in patients with acute, reversible cardiac or respiratory failure who are unresponsive to conventional medical or pharmacologic management.

- Extracorporeal: outside the body
- Membrane: a type of artificial lung
- Oxygenation: the process of getting oxygen into the blood

ELSA (Extracorporeal Life Support Assurance) **Monitor:** Flowmeter developed, manufactured and marketing by Transonic that measures delivered blood flow, recirculation and oxygenator blood volumes during ECMO.

ECMO Flow: The amount of blood traveling through the ECMO circuit each minute. This flow is measured in cc per minute. This relates to how much support the patient is receiving.

EEG: Electroencephalogram, a tracing of the electrical activity of the brain. Electrodes (wires) are placed on the scalp in several locations. Used to determine brain death.

Edema: Swelling of tissues due to excess fluid.

Head Ultrasound: (for infants) A painless procedure that uses sound waves to look at brain tissue. Gel is placed on the top of the head and a special wand is passed slowly over the soft spot on top of the head (fontanelle). This test cannot be done once the soft spot closes. It is performed to check for bleeding.

Hemofiltration: A hemoconcentrator, identical to a hemodialysis filter, used to remove extra fluid that a patientís own kidneys canít remove. It is inserted into the ECMO circuit.
Intracanial or Intraventricular Hemorrhage: Abnormal bleeding in the brain or head. Detected by ultrasound.
Jugular Vein: A large blood vessel in the neck. The ECMO cannula that drains blood into the circuit is often placed in this vein.

Lines: Arterial line: the line from the oxygenator to the patient. Venous line - the line from the patient to the ECMO circuit.

Meconium Aspiration: Before or shortly after birth, a baby may inspire meconium, which is very detrimental to the lungs, reducing oxygen exchange, and is often fatal. ECMO is useful in its treatment.

Membrane Oxygenator: An artificial lung. Carbon dioxide is removed and oxygen is added.

MRI: Magnetic Resonance Imaging, a test that uses a magnetic field to obtain pictures of the brain or body. Sedation may be required if movement interferes with the test.
Oxygenate: To combine or supply with oxygen. When oxygen enters the blood, as in the lungs, it becomes oxygenated. This is known as arterial blood.

Oxygenator: An artificial lung that adds oxygen and removes carbon dioxide from the blood as it passes through. The oxygenator is divided into two separate chambers by a semipermeable membrane. The venous blood enters the oxygenator and travels along one side of the membrane termed the BLOOD SIDE. Fresh SWEEP GAS is delivered to the other side termed

ELS Glossary cont.

the GAS SIDE. Gas exchange (oxygen uptake and carbon dioxide elimination) takes place across the membrane.

Oxygenator Blood Volume: Volume of flow through an oxygenator in an ECMO circuit, as measured by the ELSA Monitor

Percutaneous: ECMO cannulae are placed like an IV. The other option is to surgically place the cannulas. The surgeon will decide which method is best for each individual case.

Persistent fetal circulation **or persistent pulmonary hypertension of the newborn, or PPHN:** an advanced level of difficulty in breathing and circulation what often develops when the lungs cannot maintain respiratory needs; often the beginning of a vicious downward spiral. In the womb, the child is supplied with oxygen by the mother through the umbilical cord. The lungs are not used until the child is born. At this time, the circulation must change from fetal to newborn circulation, allowing the blood to pass through the lungs to be oxygenated. If this fails to occur, the blood continues to circulate as it did in the fetal state, and the childís body does not get enough oxygen.

Proning: Placement on the stomach to help recruit (open up) different areas of the lungs.

Platelets: Cells in the blood that help in the clotting ability of the blood.

Pneumothorax: An accumulation of air between the lung and the chest wall that causes the lung to collapse.

Recirculation: Percentage of oxygenated flow that returns to the the drainage cannula before traversing a patient's circulation, measured by the ELSA Monitor

Respiratory Distress: At birth, or shortly after, a child may encounter difficulty breathing. This may be caused by immature lungs or foreign material present in the lungs.

Servo-regulation: an electronic pump-speed controller that slows and speeds the pump to match the venous return.

Surfactant: slippery fluid that lines the lungs, and keeps the sticky surface from adhering to itself, and making the alveoli unreachable during breathing. Premature babies often do have enough of this to keep their lungs from collapsing.

Transesophageal ECHO (TEE): A probe placed in the esoghagus to look at heart function using ultrasound.
Trial-off: Temporary clamping of the ECMO circuit, to determine the underlying effort the patient is able to maintain. When the patient can sustain their own cadiopulmonary needs, ECMO is discontinued.

Unoxygenated blood: Blood that has delivered most of its oxygen to the tissues of the body and is lower in oxygen. Also called venous (blue) blood.

Ventilator: A breathing machine that delivers oxygen, pressure and a rate of breathing to the patient by a breathing tube. Also known as a respirator.

Weaning: ECMO blood flow rate being decreased gradually as the patient improves, and is able to maintain adequate blood flow and oxygenation, without assistance

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