

A Description of a Prototype Miniature Extracorporeal Membrane Oxygenation Circuit Using Current Technologies in a Sheep Model

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Abstract: In the United States, standardization of neonatal extracorporeal membrane oxygenation (ECMO) circuit was achieved during the 1980s. Since that time, the consoles and components of the ECMO circuit have remained fundamentally unchanged (bladder, roller pump, silicone membrane oxygenator). Extracorporeal technology, however, has witnessed many significant advancements in components during the past two decades. These new technologies have characteristics that may improve outcomes when applied in the ECMO arena. Understanding how these technologies perform in long-term applications is necessary. Therefore, the purpose of this project is to evaluate the performance of a miniature ECMO circuit consisting of current generation technologies in an animal model. An ECMO circuit (prime volume 145 mL) was designed that included a hollow fiber oxygenator and a remote mounted centrifugal pump. All circuit tubing and components were surface coated. Three sheep (approx 13 kg) were placed on ECMO using standard neck cannulation techniques and maintained according to

clinical protocols. Technical implementation, oxygenator function, and hematological parameters were accessed. Duration of ECMO was 20, 48, and 58 hours. There was no evidence of oxygenator failure, as measured by pressure drop and oxygen transfer, in any of the procedures. No plasma leak was observed in any oxygenators. Platelet count trended downward after 24 hours. Visual inspection after ECMO showed very little evidence of gross thrombosis. This ECMO circuit design departs dramatically from the typical North American systems. The use of this console and components facilitated a 70% reduction in priming volume over a traditional ECMO circuit. Further investigations should be conducted to determine if circuit miniaturization can reduce the morbidity associated with blood product consumption and the bloods contact with the artificial surfaces of the ECMO circuitry. **Keywords:** extracorporeal membrane oxygenation, extracorporeal life support, oxygenators, pumps, miniaturization, biocompatibility, centrifugal pump. *JECT. 2005;37:315-317*

The first successful use of ECMO was reported by Hill et al. in 1972 (1). By 1985, a standardized neonatal ECMO circuit emerged. This configuration has remained largely the same today. A 2002 survey of ELSO centers by Lawson et al. found that 97% use the Kolobow silicone membrane oxygenator that was first developed in 1972 (2,3).

The type of arterial pump used in ECMO has also remained constant with 95% using a roller pump. Biocompatible surface treatments are used by only 5-8% of the ELSO centers (3). This apparent stasis in ECMO circuitry design despite the introduction of new technologies has prompted some researchers to suggest that changes should be considered to bring ECMO technology up to date (4-6).

The critical issue of understanding how these newer devices perform in the long-term, minimally anti-coagulated environment of ECMO must be evaluated. Therefore, the purpose of this project is to test, in an animal model, prototype circuit using modern technologies in long-term ECMO applications.

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DESCRIPTION

Animals

After approval by the Committee for Humane Use of Animals, three sheep (approx. 13 kg) were prepared for veno-venous (VV) or veno-arterial (VA) ECMO through cannulation of the internal jugular placed on ECMO.

ECMO Circuit

Figure 1 shows the console and circuit configuration. A detailed view of the extracorporeal circuit is shown in Figure 2. A compact SIII 3 pump base (Cobe/Stockert, Arvada, CO) was used with a circuit consisting of a quarter-inch ID PVC "X-coated" tubing, an "X-coated" Baby Rx 05 oxygenator/heat exchanger unit (Terumo Corp, Ann Arbor, MI), and a "PC"-coated Revolution centrifugal pump (Cobe/Stockert, Arvada, CO). Tubing lengths were kept to a minimum by using a remote pump arm allowing the entire circuit to be positioned near the side of the bed. Continuous in-line blood gas measurement (arterial and venous) as well as venous saturation was accomplished using a CDI 500 device (Terumo Corp, Ann Arbor, MI).

Measurements

Typical physiologic variables for hemodynamics, hematology, and blood chemistry were recorded on a standard ECMO flow chart. Plasma-free hemoglobin and platelet count were recorded for evaluation of circuit-induced hemolysis. Oxygenator function was conducted by sequentially calculating oxygen transfer and the pressure drop across the membrane. The gas outlet of the oxygenator was monitored for indication of plasma leakage across the membrane (Table 1).

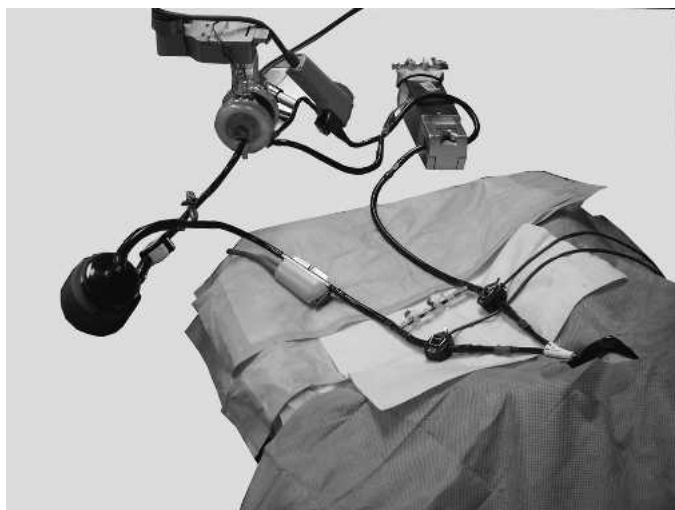


Figure 1. View of ECMO circuit and console.



Figure 2. The extracorporeal circuit.

DISCUSSION

Numerous ECMO equipment surveys indicate that there has been little change in the basic ECMO circuit design during the last two decades in the United States (2,7,8). The backbone of this standard ECMO system is the silicone membrane oxygenator, roller pump, and venous line bladder. Alternative devices such as hollow fiber membrane oxygenators, centrifugal pumps, and surface treatments have been suggested as technologies appropriate for ECMO (2,4-6,9,10). In the United States, however, the silicone membrane is currently the only oxygenator that is approved for long-term applications by the FDA. This certainly has contributed to the lack of proliferation of modern technologies to ECMO.

Although the prototype circuit presented here is atypical in the United States, overseas, this type of ECMO circuit paradigm is hardly unique. Horton et al. reports extensive clinical applications using hollow fiber oxygenators and centrifugal pumps for ECMO applications with excellent outcomes in the neonate (11). In their report, the Quadrox_D diffusion membrane hollow fiber was used (Jostra Medizintechnik AG, Hirrlingen, Germany). This oxygenator (currently not available in the United States)

Table 1. ECMO Data.

Animal	Hours on ECMO	Plasma Leak?	Oxygenator Performance				Pump Flow (mL/min)	Comments
			Pressure Drop (mmHg)		pCO ₂ (mmHg)			
			Start	End	Start	End		
Sheep 1 (14 kg)	48	No	32	38	36	39	500	Started VV and converted to VA
Sheep 2 (14 kg)	58	No	41	79	38	46	500	Excess bleeding from nose. Heparin stopped 12 h
Sheep 3 (11 kg)	20	No	32	33	33	30	500	Sheep's bowel bloated impeding venous drainage

is a low-resistance true membrane that is free from the problems of plasma leak. In the United Kingdom, the performance of a small hollow fiber polymethyl pentene oxygenator (Medos Hilite 800 LT, Medos Medizintechnik, Frankfurt, Germany) was compared to the silicone oxygenator (Medtronic 0800, Minneapolis, MN) a clinical ECMO study (12). The authors report significant reductions in resistance in the hollow fiber oxygenator when compared to the silicone oxygenator. They also note the benefits of a smaller priming volume, less surface area, and quicker priming characteristics of the hollow fiber ECMO circuit. Until the polymethyl pentene hollow fiber oxygenators become available in the United States, ECMO practitioners wishing to apply the benefits of a hollow fiber oxygenator ECMO system need to incorporate existing CPB technologies.

This article demonstrates that the application of these technologies to ECMO facilitates the ability to dramatically redesign the ECMO circuit. The compact Cobe SIII console with servo-regulation and remote centrifugal pump arm allowed one to bring the entire circuit to bed level resulting in a 70% reduction in prime volume when compared with our conventional circuit. The use of the centrifugal pump with the low resistance hollow fiber oxygenator did not appear to cause hemolysis in the first 24 hours, although collection was incomplete and this issue should be more rigorously examined. Despite minimal anticoagulation, the circuits showed very little signs of thrombosis or fibrin upon flush and visual inspection after each trial. The PC coated Cobe Revolution™ centrifugal pump was free from visible deposits on the fins. There was a minor drop in platelet count during the first 24 hours. The Terumo Baby Rx™ oxygenator showed no evidence of failure by oxygen transfer and pressure drop for up to 58 hours. Using the same oxygenator, a recent publication by Deptula et al., reports a use of 17.5 hours during a period of post-CPB cardiac support with good results (13). The appeal of using a low-prime, small surface area hollow fiber membrane oxygenator must be weighed against potential pitfalls. For example, the compact nature of these devices comes with a trade-off in a decrease in gas exchange (12). In addition, the design of the small hollow fiber oxygenators may be more susceptible to catastrophic failure by clot embolism (14).

This prototype circuit demonstrates that ECMO systems can be dramatically reconfigured using current CPB technologies. The animal trials using this prototype here are preliminary and limited. Rigorous evaluation and data collection should be carried out to validate the performance of these technologies when applied to long-term applications,

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