Expanded Use of the VPCML Oxygenator

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Abstract

The Variable Prime Cobe Membrane Lung (VPCML) is a membrane gas exchange device originally developed for the short term cardiopulmonary support of infants and small adults. A particular advantage is its low static priming volume of 425 cc. To assess the efficacy of the VPCML in heavier patients, we used it for cardiopulmonary bypass in 123 consecutive adult patients weighing 47–120 kg (mean 78 ± 15 kg). Arterial and venous blood gases were obtained simultaneously at maximum hypothermia and during rewarming.

Venous pO_2 was used to assess the adequacy of perfusion. Mean venous pO_2 during rewarming between the 60–70 kg group (n = 22) and the 90–100 kg group (n = 17) was 38 ± 8 mmHg and 38 ± 6 mmHg respectively (p = NS). Our results, with a mean flow of 3.79 ± 0.39 LPM, showed excellent gas exchange at maximum hypothermia and during rewarming regardless of weight range.

In summary, our experience with the VPCML oxygenator demonstrates its ability to safely and efficiently oxygenate a wide range of adult patients while keeping priming volume to a minimum.

Introduction

The Variable Prime Cobe Membrane Lung was designed to address the problem of hemodilution associated with small adult and pediatric patients. Using the standard Cobe Membrane Lung (CML) as a model, the VPCML was tailored to fit the smaller weight patients.[1-4] Compartmentalization was the most significant change. With the hard shell reservoir, integrated one pump system and independent gas control, the VPCML has the set up ease of a bubbler oxygenator, while having the hematologic advantages of a membrane unit.

Our clinical experience with the VPCML began with adults in the 60–70 kg weight range.[2-4] After successful perfusion with these patients, a clinical trial was performed. The purpose of this report is to demonstrate the perfusion capacity of the VPCML oxygenator.

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Methods and Materials

Patient Population

One hundred and twenty-three patients weighing 47–120 kg having cardiopulmonary bypass comprised this study group. Body surface area ranged from 1.45 m2 to 2.4 m2 (Table 1). Perfusion pressures were maintained between 40–90 mmHg while on bypass with a calculated blood flow of 2L/m2/min. Simultaneous arterial and venous blood samples were obtained at maximum hypothermia (24°C) and during rewarming (mean 33°C). The blood gas determinations were not corrected for temperature. Mean arterial pressure, gas to blood flow ratio, serum electrolytes and Activated Clotting Time (ACT) were monitored throughout bypass.

Perfusion

Blood flow rates were established based on the patient's body surface area calculated by the Dubois nomogram. A 2L/m2/min. index was used and the oxygenating gas flow varied depending on arterial and venous blood gases. Upon commencing bypass, the gas flows were 100% oxygen in a 1:1 ratio. As hypothermia was induced, compressed air was titrated using a Cobe oxygen blender. This resulted in physiologic arterial pO_2 and pCO_2 values. Heparin was given to maintain an ACT of greater than 400 seconds.

The patients routinely had either an 8.0 mm or 24 Fr. aortic cannula inserted in the ascending aorta. Venous cannulation consisted of either a single two-stage 51–36 Fr. atrial cannula or bicaval cannulation with the cannula inserted into the superior and inferior vena cava. Left ventricular decompression was accomplished with either an atrial vent or a large needle vent in the aorta. Pericardial suction was used on all procedures. Cold potassium blood cardioplegia was infused through the aorta and a cold topical solution was also administered. All perfusions were performed using systemic hypothermia i.e., 24 degrees centi-

Table 1
Perfusion Data
n = 123

	Mean±S.D.	Range
Age (years)	63±11	16-85
Weight (Kg)	78±15	47-120
Surface Area (M^2)	1.90±0.20	1.45-2.40
Flow Rate (Liters/minute)	3.79±0.39	2.9-4.8
Bypass Time (minutes)	88±27	23-175
Rewarm Arterial PO^2 (mm Hg)	192±89	60-587
Hypothermic Arterial PO^2 (mm Hg)	291±102	100-617
Rewarm Venous PO^2 (mm Hg)	38±6	22-67
Hypothermic Venous PO^2 (mm Hg)	55±13	30-135

grade. Upon termination of bypass, protamine was administered after decannulation and the remaining perfusate collected and made available for reinfusion.

Technical Description

The VPCML is a compartmentalized gas exchange device for use in short term cardiopulmonary support during heart surgery. The oxygenation section is divided into two separate compartments of different membrane surface areas (.40 m2 + .85 m2 = 1.25 m2 total) which can be used separately as well as together.

Oxygenation is accomplished across a microporous, polypropylene, bilaminar membrane (Celgard 2402 by Celanese) which exhibits an effective pore size of 0.02 microns. The membrane is supported by a polypropylene extruded netting and is accordion-pleated producing 19 blood channels in the one-third compartment and 40 blood channels in the two-thirds compartment. It is through the micropores of the membrane that blood oxygenation and carbon dioxide removal takes place.

The VPCML incorporates both an integral cardiotomy reservoir and heat exchanger. The integral cardiotomy reservoir is a two-stage filter with one layer being a Reemay non-woven polyester fiber mat and the other being a 20 micron nylon woven mesh. It effectively filters 90% of particles above 25 microns. The integral heat exchanger is three coils of convoluted tubing (304 stainless steel) with a wall thickness of twelve thousandths of an inch. The coils have an outside diameter of 0.75 inches which are then compressed to 0.45 inch and exhibit a surface area of approximately 175 sq. in. The heat exchanger is pressure tested to 80 p.s.i.

The external housing of the VPCML is clear and composed of a polycarbonate material. Three-eighths inch inlet and (2) outlet blood ports are located at the ends of the device with three-eighths inch outlet from the venous reservoir and (2) three-eighths inlets to the membrane compartments located on the medial surface. A single one-half inch gas port and (2) one-half inch ports for the water source are located on the lateral surface. On the top of the unit is located (3) quarter-inch ports to the integral cardiotomy, a three-eighths inch filter bypass port, a quarter-inch filter bypass port, and (3) luer ports. It is ethylene oxide sterilized and disposable.

The perfusion circuit consisted of the VPCML's 1800 ml hard shell, integrated venous reservoir and cardiotomy, a Cobe-Stockert roller pump, the VPCML's membrane compartment, and a Healthdyne extracorporeal bubble trap. Currently the custom tubing pack is manufactured by Cobe using Tygon tubing and Cobe connectors. Although not required in the instructions for use, the entire system is CO_2 flushed ensuring rapid, easy debubbling and recirculation. The total priming volume of the extra-corporeal circuit is 1620 ml prior to the removal of the prebypass filter. The circuit was primed with Normosol-R electrolyte solution with the addition of 7500 units of porcine heparin and 12.5 gm mannitol. The water source for the heat exchanger was the Sarns heater/cooler.

Table 2
Operative Procedure

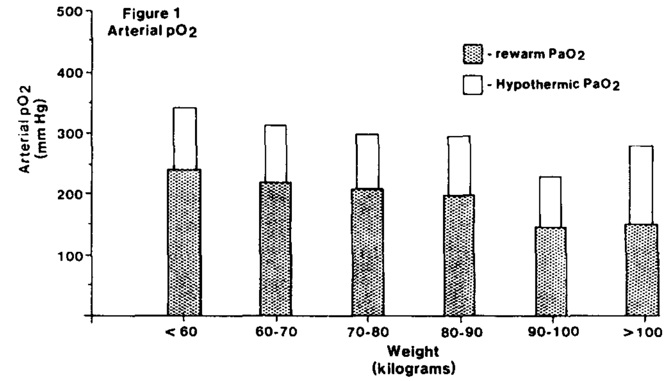
CABS	96
REDO CABS	6
CABS + AVR	4
CABS + MVR	2
CABS + VSD	1
AVR	6
MVR	4
MVR + TVR	1
ASD	1
VSD	1
MITRAL COMMISSUROTOMY	1
---TOTAL---	123

CABS= Coronary Artery Bypass Surgery,
AVR= Aortic Valve Replacement
MVR= Mitral Valve Replacement
VSD= Ventricular Septal Defect Repair
ASD= Atrial Septal Defect Repair
TVR= Tricuspid Valve Repair

Table 3
Comparison of Weight Extremes

	47 Kg.	120 Kg.
Surface Area	1.45 M^2	2.4 M^2
Blood Flow	2.96 L/min	4.8 L/min
Bypass Time	87 min	68 min
Operation	CABS x2	CABS x2
Priming Volume	1500 ml	1700 ml
Hemodilution	2800 ml	2900 ml
Rewarm PaO_2	261 mmHg	176 mmHg
Rewarm PvO_2	33 mmHg	43 mmHg
Hypothermic PaO_2	336 mmHg	112 mmHg
Hypothermic PvO_2	73 mmHg	55 mmHg
pH	7.34	7.34

M^2 = Meters squared, L/min = Liters per minute, CABS x2 = 2 Vessel Coronary Bypass Graft Surgery, PaO_2 = Arterial pressure, pvO_2 = Venous pressure



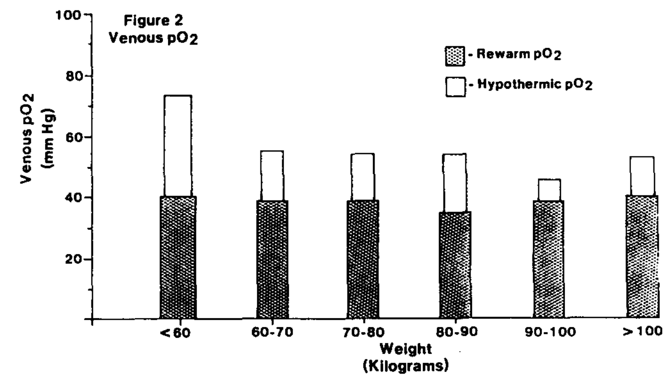
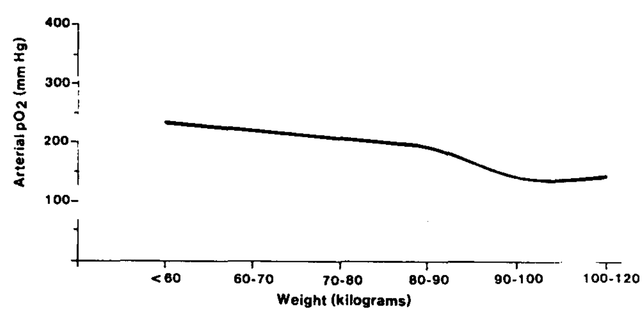


Figure 3
Relationship between body weight and euthermic oxygenation



Results

The VPCML performed satisfactorily for 123 consecutive patients with 70% of patients weighing greater than 70 kg. Operative procedures are listed in Table 2. The average time on bypass was 88 ± 27 minutes (range 23–175 min.), Table 1. Mean arterial pO_2 at maximum hypothermia was 291 ± 102 mmHg (range 100–617 mmHg) and 192 ± 89 mmHg (range 60–587 mmHg) during rewarming. Venous pO_2 averaged 55 ± 13 mmHg (range 30–135 mmHg) at maximum hypothermia and 38 ± 6 mmHg (range 22–67 mmHg) during rewarming. No acid base problems were encountered with a mean pH of 7.41 during rewarming and 7.39 at maximum hypothermia (Table 1).

Perfusion and bypass parameters between the two weight extremes are shown in Table 3. Both underwent a 2 vessel bypass operation with similar perfusion times. Arterial and venous pO_2 values were acceptable in both with the mean values decreasing with increasing weight. Figures 1 and 2 are graphs of the mean ± standard deviation of blood gas values as a function of weight. By using Pearson's Correlation Coefficients for the group as a whole, weight was found to have a significant inverse correlation with arterial and venous pO_2 but not with time on bypass. Theoretically, a maximum weight could be extrapolated to give a weight at which the mean pO_2 would fall below 100 mmHg (Figure 3).

Eleven of 123 patients transiently were exposed to arterial pO_2 values between 60 and 90 mmHg during rewarming. To avoid extended periods of time with arterial oxygen tensions at the low end of normal parameters, we now use the CDI 300 monitoring system to continuously monitor arterial and venous blood gas parameters during bypass.

Discussion

Cardiothoracic surgeons are faced with the choice of several good available oxygenators. Current usage seems biased toward membrane oxygenators[5,6,7]. Attractive characteristics of a product include low priming volume, ability to employ the device over a large weight range, high flow to membrane surface

Table 4
Comparison of Membrane Oxygenators

Oxygenator	Size (m^2)	Static Priming Volume (cc)
VPCML	1.25	425
CML-2	3.0	780
Bently	5.8	730
Capiox II	5.4	700
Sci Med	3.5	920
Maximum	2.0	480

area, reliable oxygenation both in the hypothermic and euthermic phases, and ease of set up. This report of our experience with the Cobe VPCML oxygenator shows it performs well in all aspects studied.

The VPCML with an average total circuit priming volume of 1620 cc has a lower priming volume than most adult membrane oxygenators. The capacity of the venous reservoir with a size of 1800 ml was a concern initially for the larger size patients. A Y-connector off of the arterial line, routinely used to access cardioplegia, was available for the potential problem of excess venous return. The problem did not arise with any of the 123 patients perfused with the VPCML.

Although marketed for use in pediatric patients, the demonstrated efficiency of gas exchange with the VPCML oxygenator has been documented in all weight categories up to 120 kg. We continue to be enthusiastic about its routine use in extra-corporeal circulation cases.

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Questions from the Audience

Gloria Mitten, St. Louis, MO: Question: I was curious how far do you cool your patients and if you had any trouble rewarming the larger patients?
Answer: We cool them to 24 degrees centigrade and encountered no delay with rewarming.
Beverly Parault, Shreveport, LA: Question: On your larger patients, what was your average FiO_2 level required to maintain adequate arterial gases?
Answer: At maximum hypothermia, we were able to routinely go to 40% FiO_2, gradually working up to 100% during rewarming.
Question: For full rewarm, you had to go to 100% on your large patient?
Answer: On the extremely heavy patients.
Tom Utsey, Charleston, SC: Question: What was your largest patient that you did in this study?
Answer: 120 Kilograms.
Question: Did you take any measures to see if you had some sort of consistency with your level of anesthesia which would have had, I think, a big effect on your ability to do this?
Answer: We do have a consistent group of anesthesiologists, with similar techniques, that use a heavy narcotic anesthesia. They make a strong effort to keep them under heavy anesthesia especially during rewarming so that you do avoid increased metabolic rate during that period of time.