

Original Article

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Laboratory Evaluation of a Low Prime Closed-Circuit Cardiopulmonary Bypass System

Joseph J. Sistino, MPA, CCP, Robert E. Michler MD, Linda B. Mongero BS, CCP
Columbia-Presbyterian Medical Center, New York

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Abstract

We have explored the potential advantages of a low prime closed-circuit cardiopulmonary bypass (CPB) system using a non-human primate model. Although manufacturers have reduced priming volumes in individual CPB components, the standard circuit volume remains high because of the tubing diameter and length necessary for gravity drainage. By replacing gravity drainage with the negative pressure generated by a centrifugal pump, we can realize significant tubing volume reduction.

Closed-circuit bypass was conducted on 13 baboons ranging from 5-15 kg. The circuit consisted of a centrifugal pump, a hollow fiber oxygenator, and 1/4" arterial and venous tubing. The design of the circuit included the

capacity to remove a limited amount of venous air. Circulatory arrest during deep hypothermia with volume displacement into a reservoir was also accomplished with this circuit.

The potential benefits of this low prime closed-circuit bypass system include blood conservation and reduction in blood surface area contact. The future safe clinical use of this type of closed-circuit bypass for routine open heart surgery will depend upon the incorporation of a device in the venous line to remove air. This is the greatest threat to patient safety in a closed circuit system and its use for open chest surgery must wait until an efficient venous air elimination device is available.

Introduction

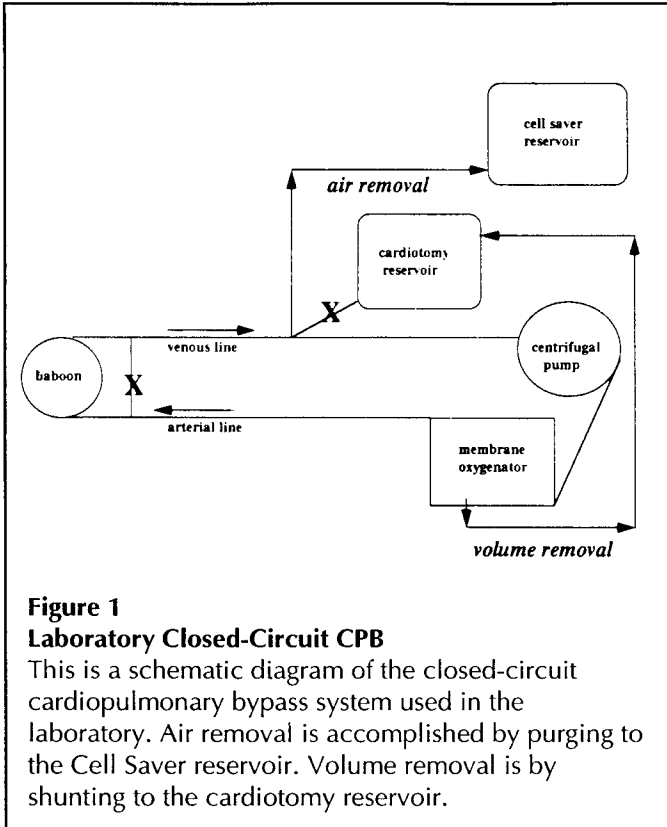
A low prime closed-circuit cardiopulmonary bypass (CPB) system for cardiac surgery may be the next major step in priming volume reduction. To reduce transfusion requirements during open heart surgery, manufacturers have directed their efforts toward reducing the priming volumes of individual CPB components. Priming volume reduction has become a major consideration in the selection of components used in the bypass circuit. Low prime membrane oxygenators, heat exchangers, venous reservoirs and cardiectomy reservoirs offer significant options for priming volume reduction.

Consider a typical circuit, 40% of the priming volume may be used to fill tubing. The large diameter and the length required for gravity drainage of the venous tubing is standard regardless of the other system components. To reduce blood flow resistance, the patient-pump height difference (typically 20-40 cm) requires that the venous tubing often be larger than the arterial and reach the oxygenator that is placed near the floor. This dependence on gravity drainage severely limits the reduction in system priming volume. Substitution of gravity drainage by centrifugal pump suction would allow the system to be placed closer to the patient.

By minimizing the priming volume of the CPB circuit, red blood cells, plasma proteins, and platelets are less diluted, preserving oxygen carrying capacity, oncotic pressure, and coagulation. This is extremely important in neonatal and pediatric cardiac surgery where the priming volume of the CPB circuit often exceeds the patient's blood volume. Although

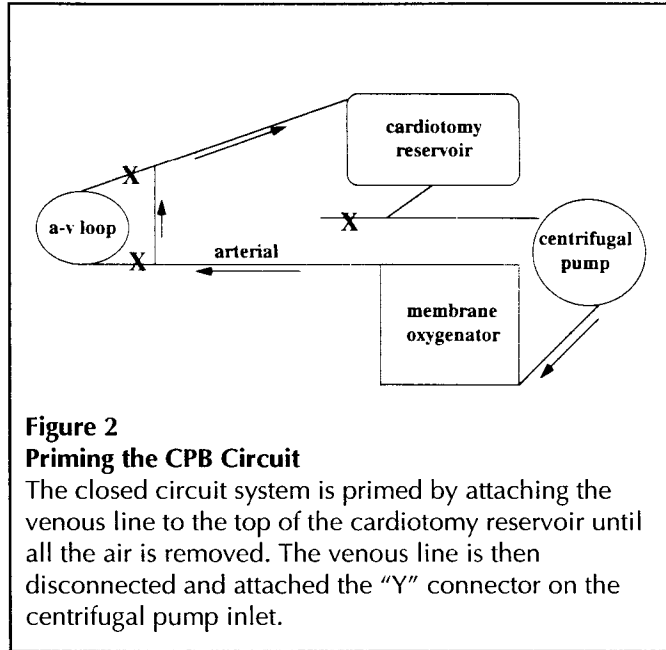
Address correspondence to:

Joseph J. Sistino
Columbia-Presbyterian Medical Center, N.Y.
MHB 4-350
New York, N.Y. 10032



smaller tubing diameters are used in pediatric surgery, the resistance to blood flow increases as the radius of the tubing decreases, severely limiting reduction in priming volume proportional to the patient size.

Suction for venous drainage was part of the design of the heart-lung machine developed by John Gibbon (1). This was abandoned for the simpler technique of gravity drainage which is now the method used clinically for open heart surgery. However, the centrifugal pumps for ventricular support use the negative pressure produced by the non-occlusive centrifugal pump to generate venous return. The use of a closed-circuit system with a single centrifugal pump for both venous return and as the arterial pump in conjunction with an oxygenator has been successfully used for emergency support bypass. Further modifications would have to be developed to adapt the system for open heart surgery. These modifications include the addition of cardiomy suction, elimination of venous air, storage of blood volume, and limiting excessive negative pressure.



Materials and Methods

A laboratory experiment using Papio anubus baboons (5-15kg) (n=13) was designed to test this circuit as a model for the pediatric patient. All animals received humane care in compliance with the "Guide for the Care and Use of Laboratory Animals" published by the National Institutes of Health (NIH Publication No. 85-23, revised 1985). A Medtronic Minimax^a hollow fiber membrane oxygenator and a BP-50 Bio-Medicus^b pump were connected to a 1/4" tubing circuit (Figure 1) for cardiopulmonary bypass during deep hypothermia with either circulatory arrest or low flow (0.5L/min/m²). The total system priming volume was 350 ml. with a maximum blood flow rate of 1.5 L/min. Suctioned blood was collected in the cardiomy reservoir^c and returned into the venous line through a "Y" connector. This "Y" connector incorporated a luer lock fitting to which was attached a one-way purge line, and this was connected to the Cell Saver^d for intermittent evacuation of venous line air if it occurred during the procedure. Venous line pressure was monitored by a DLP^e pressure display.

The system was primed by attaching the venous line to the inlet at the top of the cardiomy reservoir (Figure 2). Following removal of air from the circuit, the venous line was disconnected from the top of the cardiomy reservoir and attached to the "Y" connector in the Biopump inlet line. Recirculation of the prime was carried out in a closed arterio-venous (A-V) loop and the cardiomy inlet line remained unclamped to avoid drawing air into the circuit through the microporous membrane oxygenator. As soon as the A-V loop was divided for connection to the arterial and venous cannulas, the cardiomy line was clamped to maintain a closed circuit.

Either single atrial or bicaval venous cannulation was

a Medtronic Cardiopulmonary Division, Anaheim, CA 92807
 b Medtronic BioMedicus Inc., Eden Prairie, MN 55344
 c Bentley Laboratories, Irvine, CA 92714
 d Haemonetics Inc., Braintree, MA 02184
 e DLP Inc., Grand Rapids, MI 49504

	<u>OPEN CIRCUIT</u>	<u>CLOSED CIRCUIT</u>
oxygenator	220	220
venous reservoir	360	0
arterial filter	220	220
tubing	600	280
<u>pump</u>	<u>100</u>	<u>80</u>
Total	1500 ml	800 ml

Table 1
Comparison of Priming Volume for Adult CPB Circuits
 Comparison of priming volume for open and closed bypass circuits for adults. The elimination of the venous reservoir and the reduction in tubing volume with a closed-circuit system significantly lowers the priming volume compared to the standard open circuit.

utilized. When bicaval cannulation was used, cardioplegia was discarded from the right atrium.

Results

The sequence for initiation of bypass was analogous to that of closed cardiopulmonary bypass angioplasty support; the pump flow rate is determined by the venous return and patient volume status (2,3). Venous line pressure was kept in the range of negative 50-70 mmHg which produced maximum flow. When this flow was achieved, further increases in revolutions per minute (RPM) resulted in excessive negative venous pressure and abrupt decreases in blood flow rate. Additional volume was added to the circuit if a higher flow rate was desired.

Following the initiation of bypass, the animals were cooled to 18 C. followed by either 1 hour of circulatory arrest or low flow CPB (cardiac index of 0.5 L/min/m²). During this period of time, volume had to be removed from the closed circuit to prevent ventricular distension. This was accomplished by attaching a purge line from the oxygenator arterial sampling port to the top of the cardiotomy reservoir. Volume was collected in the reservoir until the venous pressure was reduced to the desired level.

Occasionally, air was entrained into the venous line during catheter positioning. Air was then eliminated by opening the purge line on the venous inlet side of the centrifugal pump. The arterial line (Biopump outlet) was clamped and the pump had to be turned off during this maneuver which usually took less than 10 seconds.

Weaning from cardiopulmonary bypass was accomplished by first reducing centrifugal pump RPM to decrease blood flow and increase the central venous pressure. This was

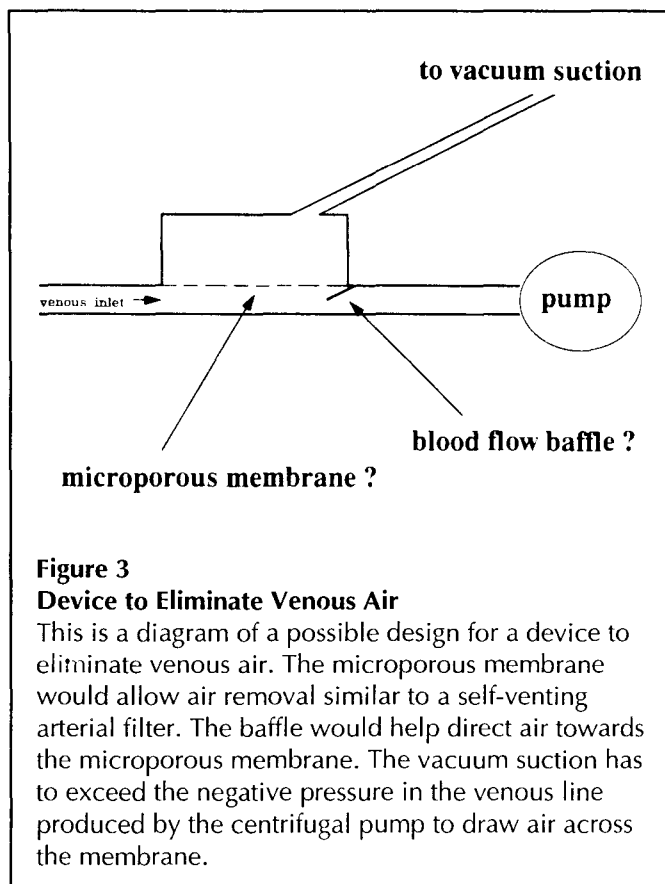


Figure 3
Device to Eliminate Venous Air

This is a diagram of a possible design for a device to eliminate venous air. The microporous membrane would allow air removal similar to a self-venting arterial filter. The baffle would help direct air towards the microporous membrane. The vacuum suction has to exceed the negative pressure in the venous line produced by the centrifugal pump to draw air across the membrane.

followed by additional volume administration through the cardiotomy "Y" line until the desired ventricular filling pressures were achieved. Bypass was terminated by first clamping the outlet line from the Biopump, and then the venous line from the patient. Additional transfusions were made by unclamping the cardiotomy line and transfusing through the arterial line.

Discussion

The potential for a low prime closed-circuit bypass system appears greatest in the adult patient where a perfusion circuit of a similar design could reduce the prime to 800 ml from the usual 1500 ml (Table 1). This includes 220 ml for the oxygenator, 220 ml for the arterial filter, 80 ml for the centrifugal pump and 280 ml for the 3/8" tubing. This would reduce hemodilution by more than 40% and have a significant impact on blood conservation. If additional hemodilution is required, then a large prebypass autologous collection of whole blood could be salvaged for post bypass transfusion.

The number of supported angioplasties (4) and emergency CPB procedures is increasing and this circuit offers the patient two potential benefits. First, cardiac surgery could be carried out without the need for transfer to another bypass circuit and second, the potential untoward effects of additional

hemodilution can be avoided (5).

The described circuit possesses some desirable features, but the limitations and risks must be recognized. An arterial filter must be used to remove air that passes through the centrifugal pump. In addition, meticulous care must be taken to avoid introduction of air into the venous side of the circuit. Careful observation of the venous line pressure and of the intracardiac pressures is necessary to avoid any ventricular distention.

The key to the future use of this type of circuit for bypass lies in the design of a device for efficient air removal from the venous line (Figure 3). The difficulty lies in the fact that negative pressure in the range of 60-100 mmHg is present in the venous line due to the pressure generated by the centrifugal pump. In this circuit, the negative pressure in the Cell Saver cardiotomy reservoir exceeded this amount and facilitated some air removal. The design of a device for 100% air removal under these circumstances without interruption of bypass provides a true challenge, and the future widespread implementation of a closed circuit system will probably depend on the development of such a device.

The unification of all the extracorporeal devices, i.e., pump, oxygenator, heat exchanger and arterial filter, into a single heparin-coated device (6) with the appropriate monitoring attachments would further simplify the circuit, and be the next step in the evolution of cardiopulmonary bypass technology.

The potential benefits of a low prime closed-circuit bypass system include blood conservation and reduction in foreign surface area contact. This may be possible in the future by modifying a closed-circuit bypass system to safely manage venous air and blood volume during CPB as well as circulatory arrest.

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