Micro-Prime Circuit Facilitating Minimal Blood Use during Infant Perfusion

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Abstract

(J. Extra-Corpor. Technol. 19[3] p. 352–357 Fall 1987, 24 ref.) There is considerable concern about the use of blood products during cardiac surgery on the part of adult patients and the parents of pediatric patients. It has been fairly easy to eliminate blood usage in most adult patients but difficult to impossible in infants and small children. Most infant perfusion circuits require a priming volume of 500–850cc which may be cut to 400cc with substantial effort. These volumes are far in excess of the blood volume of most newborns requiring cardiac surgery. We have developed and refined a circuit using commonly available components that can be primed with as little as 265cc. The circuit consists of a Capiox II 0.8m² lung, with a Terumo 100cc venous reservoir bag and ¼″ lines. It incorporates a level sensor, bubble detector, recirculation line, arterial GasSTAT™ sensor, and sampling and pressure monitoring lines. A priming volume this low facilitates minimal blood usage in even the smallest infants. This circuit is especially applicable for use with children of Jehovah’s Witness parents. It is unique from a safety standpoint in that it not only allows level sensing and bubble detection, but the lung is inverted so the inlet is at the top and the outlet is at the bottom. This configuration causes the lung to act as a bubble trap which may decrease gaseous microemboli. We will describe this “micro-prime” circuit allowing minimal or no blood usage in this age group, including a review of the literature concerning the safe limits of hemodilution.

Introduction

Recently there has been an increased concern over the use of blood products in cardiac surgery. This is a function of the growing awareness of blood transmitted diseases such as hepatitis and the universally fatal AIDS. With the increasing public hysteria regarding these diseases, clinicians are being forced to make difficult decisions in the management of patients undergoing extracorporeal circulation. The question is whether to accept a lower hematocrit or risk the consequences of blood transfusion.

Patients scheduled to undergo cardiac surgery are often requesting that donor blood not be transfused unless it is necessary to sustain their lives. Others are depositing some of their own blood into the blood bank weeks prior to surgery so that they may be transfused with their own blood and thus eliminate the risk of donor exposure. Some are requesting that autologous blood salvage systems be used during their surgery. The Jehovah’s Witness religion demands that no blood be used, even if patients die without it.1

With the advances in biomaterials, adult perfusion circuitry has become more biologically inert. This factor and the reduction of priming volume have made it relatively easy to eliminate blood usage during adult perfusion. Until recently, the miniaturization of pediatric circuits has not seen the same degree of success. Infants have small total blood volumes, with newborns generally at 200–400cc. This seems quite small when one considers that most infant circuit priming volumes range from 500–850cc.

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352

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The purpose of this paper is to introduce a "micro-prime" circuit, designed with commonly available components that provide a way to dramatically reduce blood usage in the infant undergoing extracorporeal circulation. We will compare the risks and benefits of hemodilution and the use of bank blood.

Materials and Methods

The micro-prime infant circuit was designed using commonly available components (Figure 1). The core components are the Capiox II 0.8 m² hollow fiber membrane oxygenator and the Terumo 100cc venous reservoir bag\(^a\). Additional components include the Intersept cardiotomy reservoir\(^b\), GasSTAT sensor\(^c\), and a recirculation line. It was empirically noted that the Intersept had less volume holdup and breakthrough time than did other reservoirs that had been previously used.

The circuit is constructed with ¼ inch perfusion tubing throughout. Each piece has been shortened as much as is safely possible to maximally reduce the priming volume. The lengths are: header—25 inches, arterial line—70 inches, recirculation line—7 inches, cardiotomy line—14 inches, and venous line—72 inches. When the lines are divided at the table, any extra tubing length is removed. This usually reduces the lengths another 12-24 inches. In order for the line lengths to be reduced that much, the system components were arranged so that they would be very close together and close to the Cobe-Stocket pulsatile roller pump\(^d\). The oxygenator and the venous reservoir bag brackets have been separated. Instead of a single bracket for both, a separate bracket holds the lung lower than the bag. This maneuver reduces the length of tubing necessary for the header by requiring only a few inches of tubing to extend outside the roller head on both sides. The lung is inverted so that the inlet is at the top, directly across from the positive side of the pump head. The cardiotomy reservoir is positioned so that the bottom is at the level of the top of the venous reservoir bag. This allows the shortest possible cardiotomy line to be used.

Due to the extremely small priming volumes used with this circuit, reaction time is low. It is therefore mandatory that dependable safety devices be used. This need has been met by the Cobe AEPS system\(^e\). Simultaneous blood level and air bubble sensing are facilitated. The level sensing doppler is mounted at the appropriate level on the back of the venous reservoir bag with a modified Shiley doppler applicator\(^f\). The air bubble detector is mounted just distal to the roller pump and just proximal to the lung. Since the lung is inversely mounted with the inlet at the top, it functions as a bubble trap, allowing lower microbubble transmission.\(^3\) An additional safety device is a passive vacuum scavenge system attached to the gas outlet. This scavenge system not only eliminates the risk of inhalation of anesthetic gas, but more importantly, it is available for the active vacuuming of the lung in case of accidental air entry into the circuit.\(^3\)

Clinical Experience

We have used the micro-prime in 19 infant procedures. The patients ranged in weight from 1.94–5.2 kg., with a mean weight of 3.55 ± 0.79.* Mean red blood cell usage with the circuit was 187.37 ± 100.32 cc. Two patients were not transfused during bypass. The mean hematocrit was 22.57 ± 8.48. Flow ranged from 0–960 cc per minute. The mean maximum flow rate was 743 ± 114 cc per minute. The micro-prime circuit performed well within our protocol limits for pH, pO\(_2\), pCO\(_2\), and heat exchange.

Discussion

Blood products are chronically overused. More than 12 million blood component units are transfused to 3 million patients annually in the United States.\(^5\)

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\(^a\) Terumo, Piscataway, NJ 08854
\(^b\) J & J Cardiovascular, King of Prussia, PA 19406
\(^c\) American Bentley, Irvine, CA 92714
\(^d\) Cobe Laboratories, Lakewood, CO 80215
\(^e\) Shiley Laboratories, Irvine, CA 92714
*All means reported as mean ± standard deviation of the mean (sd)
Approximately 5%, or 150,000 patients, experience an immediate adverse reaction. An additional 7%, or 210,000 patients experience a delayed adverse reaction. Blood reaction may be as simple as a localized urticaria, or as devastating as intractable shock, hypotension, and death. Kurusz reported that 24.9% of all perfusionists responding to a survey had witnessed transfusion reactions. Three hundred nineteen (319) blood reactions were reported, with 38% described as serious, possibly resulting in death. The wrong unit of blood product being transfused was witnessed in 54 cases by 8.4% of respondents. Of the 54, there were 8 cases of permanent injury or death. The same survey revealed that 4.6% of the perfusionists responding had personally contracted hepatitis or another blood borne disease.

Between 2–10% of patients transfused develop hepatitis. Half of these patients develop chronic hepatitis. Although the incidence of AIDS transmission via blood transfusion is substantially lower than that of hepatitis, it does occur. The outcome of AIDS infection is always fatal. Blood banks have been testing donor blood for HTLV-III antibody only since Spring 1985. The period from 1978 until testing was begun is considered to have been a period of high risk to those who received blood. The true incidence of infection may be as high as 0.05% (1 in 2,000),

Observers of the Jehovah’s Witness faith demand that no blood be given, regardless of the outcome. Open heart centers often refuse surgery to these patients, as a result of the increased morbidity and mortality associated with the inability to transfuse. This increased mortality is nowhere more pronounced than with the pediatric patient. Children of Jehovah’s Witness parents pose a substantial problem for the pediatric cardiac team, for the parents’ insistence that blood not be used forces the entire team to perform without error. Any nonretrievable loss of blood is significant. Even in the face of successful surgical repair, these children often die as a result of profound anemia.

Infants have blood volumes between 200–400cc. This seems especially small when compared to the large priming volumes commonly used. Most published sources quote pediatric circuit priming volumes of 500–850cc. Use of such a circuit precludes the possibility of a bloodless prime unless the child is polycythemic. Additional complicating factors for the maintainence of the hematocrit are blood loss during catheterization and the amount of asanguinous volume given by anesthesia prior to going on bypass. A low prepump hematocrit compounds the already difficult problem. If a bloodless prime is used, the priming solution should not contain glucose or lactate.

Hemodilution

Some 35 years ago the first heart-lung machines required huge amounts of fresh donor blood to prime them. It was widely accepted that the hematocrits should approach normal during the perfusion. This imposed a real burden on the blood banks of open heart centers, which escalated dramatically with the advent of coronary revascularization. The early 1970s saw the widespread implementation of hemodilution, even though the feasibility had been established years before.

It has since become standard practice to prime adult circuits with only clear fluid. Animal research has demonstrated that at normothermia, a hematocrit of 20% is adequate for systemic and myocardial oxygen delivery. It is reasonable to assume that lower hematocrits are well tolerated with the reduced metabolic rate associated with hypothermia. Kawaguchi et al reported their experience with 48 pediatric patients undergoing cardiopulmonary bypass with bloodless techniques. Their experience led to the development of a sensible protocol for blood usage in the pump prime. If the estimated hematocrit of the resultant perfusate is greater than 13%, the pump will be primed with clear solution. If however, the hematocrit is predicted to fall below 13%, the pump is partially primed with blood.

Perhaps the most important consideration of severe hemodilution is that of buffering capacity. Reeves described a substantial drop in buffering capacity when the plasma proteins were diluted. This loss of buffering ability during hypothermia is not compensated for by the addition of sodium bicarbonate. Unfortunately, bicarbonate buffers are not effective during hypothermia. For this reason a nonbicarbonate buffer is most desirable. An imidazole buffer would appear to be optimal because of its buffering characteristics during hypothermia. However, a clinically approved form does not exist. Another possibility would be a nonbiologic buffer that maintains its buffering capacity linearly as the patient is cooled.

Rationale for the Micro-Prime Circuit

The micro-prime circuit was developed from necessity to meet specific objectives. Primarily, the circuit had to be primed with a small enough volume to facilitate minimal or no blood use in the infant patient. The circuit had to accept safety devices. Precise control of the blood gases for acid-base manipulation was mandatory. It had to efficiently transfer heat. Finally, it had to transmit a pulsatile waveform.

Creative positioning of the components allowed the tubing lengths to be minimized. Although ¼ inch tubing was used throughout, ½ inch might have been used for the arterial line. The small decrease in prim-
ing volume does not make up for the increased complexity of the connections. The priming volume was reduced to only 265cc, allowing asanguineous priming for even the smallest infants.

In order to be used clinically, the circuit had to be safe. This was accomplished with conventional bubble and level sensing, as well as the inversion of the lung for use as a bubble trap. The application of vacuum to the gas phase of a hollow fiber membrane oxygenator has been shown to be a very effective method for removal of air from the blood.\(^9\) The vacuum line is vented so that the gas compartment pressure is not negative. In case of inadvertent introduction of air into the lung, the patient would be clamped out of the circuit, and all air would be removed by closing the vent in the vacuum line and recirculating the blood. This creates a pressure gradient by which all air will leave the blood phase into the gas phase.\(^9\)

It is vital for the circuit to provide efficient heat exchange. All infants in the weight range for use of this circuit are rapidly cooled to 17°C and subjected to circulatory arrest.\(^22\) The use of pulsatile flow and vasodilator therapy allows cooling to 17°C in less than one minute per kilogram of body weight. We continue to cool for a total of about 10 minutes to ensure uniform body cooling. Warming times are generally longer, but are usually no more than twice the cooling time. The advantage of rapid heat exchange is substantially reduced bypass time.

As discussed above, the acid-base balance is markedly disturbed by severe hemodilution. It is critical not to allow the patient to become acidic prior to circulatory arrest. Respiratory alkalosis is achieved by aggressively removing CO\(_2\). In order to maintain the pO\(_2\) at an acceptable level (\(<150\text{mmHg}\)), independent control of the pO\(_2\) and pCO\(_2\) is mandatory. This is facilitated by the Capiox II 0.8 m\(^2\) hollow fiber membrane oxygenator and the use of a gas blender.

We have presented a micro-prime circuit that facilitates minimal or no blood usage in even the smallest infants. It has proven to be a safe, reliable, and readily available circuit.

References


355
Questions from the Audience

Question: Pat Courtney, Jackson, MS: On your arterial line through your pumphead, it was 25 inches, if I remember. I know flow rates are low, but for failsafe purposes, did you consider that length of tubing as being adequate if you had a problem with the tubing in the pumphead?
Response: That’s a good point. And that’s something that could quite possibly happen. You would hope that in a short period you were cooling, and if you had a problem, you would be arrested very shortly after that. We cool these kids very rapidly. We use REGATINE and FORANE and pulsatile flow. So they cool very fast. Your point is well taken—that you would be able to walk an extra length of tubing through the rollerhead perhaps, and still be able to have some room. It was our feeling that to absolutely minimize it, we would not do that.

Question: Nancy Achorn, San Francisco, CA: I’m really interested in knowing how you accomplished this with the Cobe level sensor, the Doppler, to get it to work on the bag. We have tried and tried and tried, and all we get are constant false positives. It’s impossible to get it to work reliably for us.
Response: Shiley actually makes an applicator for its Doppler. The Doppler is smaller, and therefore, the hole is smaller. We have drilled these out to fit the Cobe level sensor so that it can snap in there, and they’re very tight. Then we apply it with a little jelly. They really work.
Comment: So what you’re saying is that you’re using the Shiley transducer with the Cobe pump.
Response: No, we’re using the Cobe-transducer with the Shiley applicator that has been modified.

Question: Pat Courtney: I am a strong advocate of reducing priming volumes in pediatrics and I applaud your efforts here. The question I have is: It seems that you have a very low reserve with 265 cc and once your vent is put in and the suckers are incorporated, you would think that some of your volume would be displaced. In what percentage of your patients would you estimate that you have to add additional volume, and approximately how much?
Response: It varies. When we primed with crystalloid solution we found that we ended up having to add some volume—more than with our old method. I shouldn’t say it’s an old method, because we still use it. We put in prime with fresh frozen plasma and red cells. Empirically, I found that we don’t add as much volume when we do that, and that’s probably an oncotic effect or something similar. We do have to add volume. And you’re absolutely right: the reserve is minimal. That’s why it’s so vital that we use safety devices that are reliable.

Question: Carl Sherman, Little Rock, AR: I see that you have no arterial filtration plan in your system. Would you address that? And do you use prebypass filtration?
Response: That’s a good point. We do not use arterial filtration. And we do not use prebypass filtration. In reality, the only filter in the circuit is that in the cardiotomy reservoir. We filter the prime, even the crystalloid prime, through a 20 micron blood filter before we put it in, and it’s filtered by the cardiotomy reservoir filter. Most of our reasoning for not using arterial filtration is our priming volume and our use of pulsatile flow. And in order to use pulsatile flow, the systolic phase of that approaches 2.3 times the flow rate of the mean flow rate. So it’s very easy to exceed the right flow of a pediatric arterial filter. If the maximum flow rate is a liter and a half for an arterial filter, and your mean flow was 800cc, you would exceed the flow rate of the arterial filter. So then you would have to go to an adult size arterial filter which would have a lot more prime volume. In fact, the arterial filter would approach the prime volume of the entire circuit. I guess the third reason would be that our surgeons have asked us not to use arterial filtration.

Question: Victor Martichenko, St. Louis, MO: At what age or kilogram weight would this circuit no longer be appropriate?
Response: We use the circuit on children, newborn as small as a 1.94 kilo child. We generally stop at 5 kilos and go a 1.6 Terumo. Although in severely hemodiluted kids—ones that we know are going to have hematocrits in the teens—then we will use a little larger one. But no more than 6 or 7 kilos.

Question: Do you use blood cardioplegia?
Response: Not in this age group. We just use profound hypothermia and arrest. We do use the blood cardioplegia on larger kids that we do not arrest.

Question: Mike Kraemer, Rochester, MI: The last time I was at the University of Denver you did a blood usage survey at Children’s Hospital. Did you do another one after this low prime circuit was instituted?
Response: We had not, but are in the process of doing that. I don't remember the numbers right off the top of my head, but for most people who would seriously look at their blood usage, we use grossly too much blood. And one of the reasons this circuit was developed was our attempt to minimize that.

Question: Do you remember any of the numbers?

Response: Honestly, I don't remember.

Question: John Handrahan, Philadelphia, PA: I noticed that you cool for five minutes. That seems a really short time. I was wondering: Is your room cold? Do you have the patient anesthetized for a good length of time before you go on bypass?

Response: The room is very cold. We try to keep it just as cold as we can get it. The patients are pre-cooled to around 32 degrees with a cooling blanket. So we're a little ahead of the game when we start. Five minutes was an example. Sometimes it's as long as 10. Especially on the long cases, even though we may reach a mean between the esophageal and rectal temperatures, say 15 degrees within as brief a time as two minutes. Generally we cool for at least for five minutes. Very often we do 10—especially on a switch procedure for transposition where the arrest period is going to be lengthy.

Question: Do you measure nasopharyngeal or tympanic membrane?

Response: Nasopharyngeal and rectal.

Question: Betty Stephens, Portland, OR: We do a great many pediatric cases. I was wondering: on your venous return, when you’re doing circulatory arrest, do you need to lower your reservoir?

Response: We have never had problems with venous return. I agree with you the bag is high. It's much higher than we formerly ran them. Remember the slide I showed, in which the circuit was to the left of the pump? It was much lower than that and we generally or traditionally use the venous reservoir at a lower level. We found through the cannulaes that we use, which are the DLP high flow metal ones. We have just not had any trouble with venous return. These kids always have a single atrial cannula put in. Generally it is a 20 french cannula, which is very adequate for a venous return.

Question: It also takes you five minutes to obtain your temperature. What temperature are you trying to get to obtain circulatory arrest?

Response: We try for a mean temperature of at least 15 degrees centigrade and a rectal temperature of less than 17.

Question: And what hematocrit are you looking for before you add blood?

Response: One rule of thumb would be to shoot for a hematocrit approaching the temperature that you're cooling to. We have two surgeons who differ in their feelings about blood usage or not. Which is nice because we can do some control studies. And we currently do that on the effects of severe hemodilutions. One would really like to, for all his patients, use no blood or the very minimal amount of blood. The other has traditionally used blood prime and we’re continuing with that regime for him. So it gives us a nice control.

Question: When you use the blood prime are you using washed red cells or what?

Response: We generally use fresh frozen plasma and then washed packed red blood cells.

Question: Frank Scalia, Monroe, LA: You’re cooling quickly. That’s something everyone has brought up. What is your normal rewarming time?

Response: It’s about twice that. It does take longer to rewarmin. However, the warming times are substantially reduced as a function of the pulsatile flow. During warming the anesthesiologist will start some Nipride to aid that as well, assuming that the pressures are adequate and we can generate a good pulse curve.