

Argument for the Hemobag® for Autotransfusion: Blood, Ethics and Common Sense Best-Practices in Cardiac Surgery

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Introduction

Blood conservation and management is now the most important issue surrounding cardiac surgery today! With the recent removal from the market of one of its tools (Aprotinin®), the blood conservation tool box has gotten smaller. The Hemobag® has now become a much more important tool for blood conservation in invasive surgical procedures in Cardiac, Vascular and Thoracic Surgery.

The Hemobag® (HB, www.mybloodfirst.com) is an autologous whole blood salvaging device and technique designed by a perfusionist for perfusionists for blood conservation both during and at the end of the case. The HB safely recovers autologous whole blood from any extracorporeal circuit (ECC) with all the cells and proteins still intact. The HB protocol concentrates the residual ECC volume quickly with multipass hemoconcentration so it may be reinfused to the patient.¹ With the HB, the perfusionist always keeps the circuit safely primed and ready to immediately go back on bypass if there is an emergency. The HB may be conveniently filled either in or off the surgical field, and it has ports for quality control sampling and pressure monitoring. The Hemobag® reclaims all of the blood from the circuit quickly and

offers benefits to the surgical patient by reducing blood use, overall costs and improving patient outcomes, not just with the Jehovah's Witness community, but for any patient needing autotransfusion.^{2,3} The HB is employed in the critical window of time, directly after the separation from ECC support, where the benefits are extended into the following "Golden Hours."⁴ A recent review of RBC transfusion in the ICU and during Cardiac Surgery expounds on its deleterious effects^{5,21} The first hours after CPB are the most susceptible period for blood product administration and the opportunity to improve patient outcomes.

Team Effort

It is a multidisciplinary - multimodality team effort that works best to not lose the patient's blood in the first place.^{6,7} Blood components are preserved with meticulous surgical techniques, and by not diluting the patient's blood volume to the point of a dilutional coagulopathy. It is important not to be washing away all the viable plasma cell and protein fractions to a waste bag on the side of a cell processor. It is disturbing to calculate the daily wasted platelets and proteins from saline red cell washing. An on-line ATS waste calculator is available to the public for free to estimate the replacement cost of clotting factors and proteins wasted during cell washing (www.mybloodfirst.com/downloads/calc/gbr-waste-calc.html).

Processing cardiac surgery patients' whole blood to wash away the plasma, platelets and proteins to the point that you have to transfuse allogeneic blood products is a little bit insane.²⁰ There are ethical issues related to getting into this situation when the clinician can likely predict the outcome of transfusion.⁸ It makes no sense to throw away viable autologous cells and proteins to a cell washer waste bag everyday. You might agree that, "If that blood was good enough to systemically circulate through the patient moments before on bypass," it should still be

good to give back to the patient quickly after bypass. Only now the concentrated residual circuit blood becomes a powerful unit of autologous whole blood that aids in increasing viscosity, oncotic pressure, and red cell mass. The increased plasma protein concentrations really enhance coagulation and overall volume management.^{1, 4} I always found it interesting that people would add Albumin to the CPB circuit during the case to increase the COP, only to wash it all away at the end during blood salvaging with a cell washer.

Targeted Hemoconcentration

The Hemobag® is able to accomplish for patients in eight to ten minutes what it takes four to six hours or more to do with diuretics, but the benefits last a lifetime. The HB is used to simulate off-line modified ultrafiltration (MUF). The fallacy of diuretics often leads to chasing volume into a dilated patient placed in the Trendelenburg position. The extra volume dilutes the patient and quickly migrates into the interstitium causing organ edema. Edema may lead to lactic acidosis and organ dysfunction at arguably the most critical time in that patient's life.^{3, 9} Chasing volume, reacting to hypotension, and promoting edema is tantamount to substandard care. When the excess water load is minimized, the team will not have to treat the clinical abnormalities of potassium and magnesium electrolyte imbalances that occur with aggressive diuretic therapy.⁴

There are people who say that if you aggressively hemoconcentrate then the patient will have oliguria postoperatively. But if you think about it, most people have a hematocrit in the 40% plus range and they have no problem making urine. Recently a prospective randomized trial by Kuntz, et al.¹⁰ revealed that aggressive ultrafiltration is not only beneficial for raising the hematocrit and removing excess fluids and mediators, but it does not effect native urine production.

Changing Behaviors

Many perfusionists have contemplated the Hemobag® method in various forms.

Consequently, there are perfusionists who say that they can do something similar on their own by hemoconcentrating at the end of the case with a homemade or jerry-rigged method to accomplish this goal.¹¹ But when you ask if they are doing their method routinely, most say “No”. Why not? The usual responses are: “Because then I have to cut this and get that, and it’s a little messy.” or ”I don’t get all the blood back from the circuit.” or “ I am not sure if I am over concentrating the volume causing hemolysis and activating platelets without monitoring and sampling.” or “ I have to stop concentrating when I get to the bottom of the reservoir. ” or ”I have to find a way to get the blood into a sterile bag for anesthesia.” or “ It gets re-diluted when I chase it out.” or “Then I have to commit the circuit to be unprimed.” or “It takes too long and it’s just a hassle.” These are just some of the answers. The Hemobag® was brought to market by a perfusionist specifically for perfusionists to make it quick, easy and reproducible to salvage any extracorporeal blood. The simplicity of the Hemobag® system comes from its design, sterility, ease to connect and disconnect, monitoring capabilities, reproducibility and speed of use. Few other techniques allow the same degree of safety and efficiency for speedy reinfusion of the extracorporeal circuit contents. Lastly, the Hemobag® is defendable (as an FDA-cleared device) with the Joint Commission that will soon be looking at approved methods of blood conservation in hospitals, especially cardiac surgery, which uses as much as 20%. The Hemobag® makes the team focus on blood conservation together, and that is a good thing.

While concentrating the circuit contents with the Hemobag®, it is easy to know when to stop at a hematocrit of approximately 50% by visualizing the bag volume decreasing to about half of the starting volume and monitoring the limits with a pressure transducer. You may always shuttle a portion of the HB contents away from the main “recovery loop” to the impatient anesthesiologist, if needed. The CPB circuit will always remain uncompromised, bubble free and primed with chased crystalloid volume ready to crash back on bypass, and you can always reinfuse the concentrated Hemobag® contents back into the circuit as well.

Who is responsible?

It is not just perfusion, but the entire surgical experience itself that causes hemodilution and the resultant coagulopathy in the perioperative time period.⁶ Recent discussions on reducing primes to enhance hematocrit and oncotic pressure obviously help to improve patient outcomes and avoid allogeneic blood products – but it is a trade-off and a fine line that we walk to decrease ECC volumes and maintain safety economically.¹² We do not want to fail to protect our patients (and ourselves) by pushing the line of safety too far. In our efforts to reduce prime volumes we should not lose sight of the cardinal rules of perfusion to keep it simple and avoid systemic micro-air embolism.¹³

We already have the CPB procedure honed to a fairly safe and trusted science without going to more expense and further out on a limb to try to reduce priming volumes and jeopardize patient safety, especially when we can auto-prime the circuit economically. Improvement and change are important, but where is the risk / benefit limit?

Avoiding dilution is not just a "one discipline" effort; the responsibility *cannot* be placed only on Perfusion to carry the burden. Blood management should be multidisciplinary and can only be successful with effective communication.^{7,14} Anesthesia and other members of the team as well as ICU care givers contribute much to the dilution of patients and need to be held accountable.⁹ They should employ techniques that maximize the patient's red cell mass, such as Epopen® and iron, and safely increase the vascular resistance while monitoring cardiac output, and, of course, judicious microsampling.⁶ We need to work meticulously on not losing blood and avoiding hemodilution to the point that the patient requires allogeneic blood products.

Transfusion triggers should also be reevaluated. Current reviews of the literature suggest that a nadir hematocrit on CPB of 22% in cardiac surgery is safe and effective in preventing morbidity and mortality^{15,16} and that a restrictive transfusion trigger (hemoglobin = 8 gm/dL) is comparable to a liberal transfusion trigger (hemoglobin = 10 gm/dL) with regard to patient outcomes.¹⁷

Challenging the Paradigm

The washing away of viable platelets and plasma proteins must be reevaluated, as washing blood components to waste is counter intuitive to sound ethical and medical practices. The long-embraced paradigm stating that the infusion of unwashed salvaged or residual circuit blood contains immunologic-active chemicals (that evoke the systemic inflammatory response) does not appear to be associated with increased patient complications or morbidity.¹⁸ This is evidenced by the bagging of diluted residual blood or shed blood, and infusion, which is still a mainstay in many programs. Likewise, the argument about plasma free hemoglobin can be laid to rest by our randomly measured samples of the Hemobag® product that average between 20–

45 mg/dL maximum.¹ This is low compared to a unit of packed red blood cells released that can average between 150 mg/dL fresh and 450 mg/dL in older stored blood.

The Hemobag® technique may not remove all of the potentially harmful contaminants that may be washed away by most red blood cell-washers, however, these contaminants are transient and reversible in-vivo with patient blood levels returning to baseline within hours.¹⁸ The balancing factor and key to success is that coagulation and homeostasis appear to be immediately improved with the infusion of the patient's concentrated autologous whole blood. This gives perfusionists a new role and procedure that benefits the patient for hours after the termination of surgery, well into the ICU "golden hours." Both surgeons and intensive care nurses have commented that since starting the use of the HB technique for autotransfusion, patients seem to have eliminated that first hour or two of instability compared to the old standard, and patients are hours ahead in terms of recovery.⁴

Conforming to Guidelines

The recently updated, evidence-based American Society of Anesthesiology (ASA) perioperative blood transfusion guidelines¹⁹ were written to benefit patients. The ASA recommendations emphasize avoiding allogeneic transfusion and the use of methods to preserve the patient's own blood components. The use of the Hemobag® conforms to the ASA guidelines and may soon become a best practice standard of care in cardiac surgery for many reasons, but primarily because of the low supply and high demand issues for allogeneic blood, the associated costs, and the uncertainty of morbidity associated with allogeneic transfusions. There is nothing better for a patient than to receive their own warm fresh autologous whole blood when they need it the most in the surgical setting.¹⁷

Perfusionists are a crucial link in direct patient outcome, but knowingly discarding vital platelets and plasma proteins necessary to the stabilize patients constitutes not only an ethical issue and concern, but one of oversight, even neglect, when allogeneic blood products are administered as a result. There is a saying that goes, “You can’t start saving blood Until you actually start saving blood!”

It is far better and easier to save more of the patient’s own fresh whole blood in the first place and return it concentrated quickly, than to discard functional blood cells and fractions. Autologous blood has increasingly become the most precious substance on the planet. Wasting cells and proteins causes impaired homeostasis that has to be stabilized with precarious and, in some cases, lethal allogeneic blood products. And realizing this ahead of time, that it may soon become a legal issue of negligence is only common sense for today’s Best Practices.

The Hemobag is just one tool for blood conservation, but it’s a good one. The Hemobag® just *makes it easy to make blood better* and improve patient care. “With regards to life, It’s all in the bag, the Hemobag.”

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