

Use of the Hemobag® for Modified Ultrafiltration in a Jehovah's Witness Patient Undergoing Cardiac Surgery

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Abstract: Modified ultrafiltration is an important technique to concentrate the patient's circulating blood volume and the residual whole blood in the extracorporeal circuit post-cardiopulmonary bypass. The Hemobag system is a device cleared by the US Food and Drug Administration and represents a novel and safe modification of traditional modified ultrafiltration systems. It is quick and easy to operate by the perfusionist during the hemoconcentration process. Hemoconcentration is accomplished by having the Hemobag "recovery loop" circuit separate from the extracorporeal circuit. This allows the sur-

geons to continue with surgery, decannulate, and administer protamine simultaneously while the Hemobag is in use. The successful use of the Hemobag in a Jehovah's Witness patient has not been previously described in the literature. This case report describes how to set up and operate the Hemobag in a Jehovah's Witness patient undergoing cardiac surgery that requires an extracorporeal circuit. **Keywords:** cardiopulmonary bypass, ultrafiltration, modified ultrafiltration, Jehovah's Witness, blood conservation, blood management, blood salvaging. *JECT. 2006;38: 265–270*

Reinfusion of residual blood from the extracorporeal circuit (ECC) has become one of the most important blood conservation techniques used during cardiac surgery today (1). The ECC is capable of containing a significant amount of diluted residual autologous whole blood (1500–2000 mL or more), which is present at the end of cardiopulmonary bypass (CPB). Commonly, this residual blood is discarded or only partially salvaged for a number of reasons including 1) the blood is excessively dilute, 2) it contains a significant amount of activated mediators, and 3) the notion that the platelets are dysfunctional and subsequently impair overall coagulation status (2,3). Published data have shown that most of the ill effects of CPB on platelets and other coagulation factors are temporary and reversible within hours post-operatively (4–6). In addition, the hemodilution encountered during cardiac surgery can be corrected through aggressive hemoconcentration (either diuresis and/or a mechanical hemoconcentrator) (7–9).

Current techniques available to concentrate and infuse the residual autologous whole blood include 1) direct infusion of diluted whole blood (either directly into the patient through an existing cannula or collected in empty bags and reinfused), 2) cell washing through the use of cell salvage device, and 3) ultrafiltration or hemoconcentration. Ultrafiltration has the advantage of removing excess non-cellular plasma water volume, which has been shown to improve systolic blood pressure, hematocrit, arterial oxygen content, and decreasing tissue edema and organ dysfunction (9). It also has been shown to reduce activated mediators and platelet inhibitors while preserving clotting factors, plasma proteins, and red cell mass (6,10–13). By concentrating the residual volume, it is possible to avoid the use of vasodilators and diuretics and the side effects caused by these agents that are variable from patient to patient.

Modified ultrafiltration (MUF) was introduced in the early 1990s as a technique to hemoconcentrate the residual blood in the ECC along with the patient's existing blood volume post-CPB (8,14,15). Several techniques have been developed to offset the difficulties associated with the original technique of MUF (16–18). The current drawbacks of MUF include 1) entraining air into the arterial cannula, 2) increasing surgical time and delaying protamine reversal because the patient remains heparin-

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ized until the MUF is completed, 3) hemodynamic instability, 4) difficulty in purging the entire ECC of blood without re-diluting the infusate, and 5) loss of residual blood that is left in the MUF system at its completion (19,20). These are some of the reasons explaining why many centers do not use MUF as a technique for blood conservation.

The Hemobag (Global Blood Resources, Somers, CT) system is a device qualified by the US Food and Drug Administration (FDA) and represents a novel and safe modification of the MUF system (18,21). This system specifically made for blood salvaging is quick and easy to operate by the perfusionist during the hemoconcentration process, and the same hemoconcentrator can be used both during the case and also at the end of the case for whole blood salvaging. Hemoconcentration is accomplished by having the Hemobag circuit separate from the ECC. This allows the surgeons to continue with surgery, decannulate, and administer protamine simultaneously while the Hemobag is in use. This progression is possible because the operation of the Hemobag is on a separate circuit from the main circuit used for CPB. The ECC remains sterile and uncompromised, allowing resumption of CBP emergently if warranted. With the Hemobag operating on a separate circuit, the contents of the ECC can be completely purged of the residual whole blood and in a timely manner. Comparatively, purging the ECC with crystalloid during classic MUF has the effect of rediluting the captured blood offsetting the original goal of hemoconcentration. Moreover, there are no risks of air embolization or dynamic shifts with systemic vascular resistance that can be associated with other techniques of MUF. The Hemobag's TS3 tubing set can also be completely purged at the end of the hemoconcentrating process for maximal autologous whole blood recovery.

Caring for patients of the Jehovah's Witness (JW) faith has been a challenge. This challenge is more pronounced in surgery associated with large blood volume shifts such as cardiac operations. Using MUF can be an important part of the blood conservation strategy for these patients. Currently, there is no comprehensive literature on the proper use of the Hemobag in the JW patient population, although it can be used on any patient and any ECC for whole blood salvaging. We describe a case of a JW patient undergoing cardiac surgery with CPB and successful (off-line MUF) use of the Hemobag for multi-pass hemoconcentration of the residual blood in the ECC.

DESCRIPTION

The patient was a 67-year-old JW male who presented for elective coronary artery bypass surgery. His height and weight were 175 cm and 98.2 kg, respectively, with a body surface area of 2.1 m². Past medical history was significant for hypertension and peripheral vascular disease with a

remote history of smoking. Medications included an angiotensin I converting enzyme (ACE) inhibitor and a baby aspirin that was stopped >5 days before surgery. Erythropoietin was administered (40,000 units SQ weekly with iron) according to our protocol to increase hematocrit to >45% for patients who refuse allogeneic blood transfusion. The patient had a normal ejection fraction of 45% with no regional wall motion abnormalities. A total of four vessels required grafting with the use of CPB. Coagulation status was normal as shown by a normal platelet count of 254,000/mm³, with normal coagulation indices [prothrombination (PT) = 15.5 seconds, international normalized ratio (INR) = 1.2 units and activated partial thromboplastin time (PTT) = 36 seconds]. The rest of the laboratory findings along with the chest radiograph and electrocardiogram were normal. The patient consented to the blood conservation techniques used at our institution.

The standard Englewood Hospital and Medical Center multi-modality and multi-disciplinary blood conservation strategy was applied to this patient (1). These techniques include 1) pre-operative optimization of the hemoglobin, 2) intra-operative autologous donation (IAD) 3) autotransfusion, 4) tolerance of anemia, 5) meticulous surgical technique, 6) endovascular vein harvesting, 7) on-site coagulation monitoring (thromboelastograph [TEG; Haemoscope Corp., Niles, IL] and heparin concentration determination [Hepcon; HMS Plus; Medtronic, Minneapolis, MN]), and 8) targeted pharmacotherapy (anti-fibrinolytics and desmopressin acetate). Aprotinin (Trasylol; Bayer Corp., West Haven, CT) was used as a hemostatic drug for this patient and is standard for all patients who are at high risk for bleeding and all JW patients. Bovine lung heparin was administered for anticoagulation during CPB (300 IU/kg) to achieve a target ACT level > 550 seconds (kaolin activated) for this patient.

Intra-operative autologous donation was started before incision. Autologous blood (1350 mL) was removed into CPD-A anticoagulated bags (Fenwall; Baxter Healthcare, Deerfield, IL). A total of 750 mL of colloid solution (Hex-tend; Hospira, Lake Forest, IL) was used to maintain normovolemia during this time period. The hematocrit post-IAD was 31%. The patient remained hemodynamically stable throughout the pre-CPB period. An additional 1000 mL of heparinized autologous whole blood was removed and withheld (IAD) at onset of CPB, because the patient's estimated blood volume and stable hemodynamics were deemed to be more than adequate to tolerate this maneuver. The hematocrit at onset of CPB was 21%. All of the autologous whole blood was kept in continuous contact and in-line with the patient to comply with the patient's religious convictions.

The CPB circuit consisted of a hollow fiber, Trillium-coated membrane oxygenator (Medtronic), non-heparin-coated tubing (Medtronic), an arterial line filter

(Medtronic), and a roller pump for perfusion (Sarns 8000, Terumo® Medical Corporation, Somerset, NJ). The tubing length was kept to a minimum, and the circuit was primed with a total of 1000 mL Plasmalyte A (Baxter Healthcare) and 250 mL of hydroxyethyl starch in a balanced salt solution (Hextend; Hospira) for a total prime of 1250 mL.

Hypothermic perfusion to 24°C was maintained during the period of myocardial ischemia. Myocardial arrest was achieved with a single dose of potassium-rich blood in the aortic root during the initiation of CPB. Myocardial protection consisted of systemic and topical hypothermia. Total CPB time was 140 minutes, of which 117 minutes were with the aortic cross-clamped. At termination of CPB, the hematocrit was 25%, the bladder temperature was 35°C, and the patient was hemodynamically stable. A total of 1400 mL of ultrafiltrate volume was removed during CPB, preventing the hematocrit from dropping below the initial 21% seen at onset of CPB. No crystalloid or colloid was added to the ECC during CPB. Only the 1000 mL of the IAD blood was returned to the circuit intermittently throughout CPB. At the end of CPB, the TEG showed a very slight coagulopathy consistent with a factor deficiency.

HEMOBAG PROTOCOL

A total volume of >2000 mL of autologous whole blood remained in the ECC at the end of CPB. The hematocrit of the blood was 25%. It was decided to hemoconcentrate the final volume while off CPB. The Hemobag was used to attain this goal. Modifications to the standard Hemobag protocol were made to comply with the religious beliefs of this JW patient.

A sterile Hemobag was accepted onto the surgical field. A small-bore non-compliant 84-in male–male pressure tubing was connected sterily to a three-way stopcock that was placed on the “luer port” of the inlet line at the bottom of the Hemobag (Figure 1). The non-compliant line was primed with sterile saline using a syringe attached to the stopcock. The tubing was handed to the anesthesiologist and connected to the patient's central line, creating a continuous connection with the patient (Figure 2). The Hemobag was now ready to collect blood from the ECC. To salvage all of the patient's blood from the ECC, the blood-filled lines (i.e., cardioplegia lines, manifold, and sampling lines) were drained back to the venous reservoir. The aortic cannula was first removed from the patient. The scrub technician separated the aortic cannula from the 3/8-in arterial line and immediately connected the latter to the Hemobag (by a 1/4- to 3/8-in stepped Universal Arterial Infusion adaptor on top of the Hemobag). The contents of the venous reservoir and ECC could now be transfused forward into the Hemobag in the surgical field. Other variations of filling the Hemobag in the field or off the field at the level of the pump using a forward flow line like an unused 1/4-in line are possible. Protamine sulfate



Figure 1. Set up of the Hemobag for a JW patient.

(278 mg) was administered during aortic decannulation without incident. Decannulation of the right atrium occurred next. Blood in the venous line was re-captured by having the scrub technician use 0.9% normal saline to drain the line back to the ECC and keep it primed.

The residual blood in the venous reservoir and ECC was totally purged forward into the Hemobag using 0.9% normal saline. A total volume of >2000 mL was collected into the Hemobag, which was clamped, disconnected from the ECC, and capped. The Hemobag remained in a continuous circuit with the patient by the previously established connection of the pressure tubing connected to the Hemobag and the central line. The Hemobag was carefully handed over from the surgical field to the perfusionist for hemoconcentration. This process was accomplished using the TS3 tubing sets “recovery loop,” which consisted of the Hemobag, the TS3 tubing set (Global Blood Resources), the same pressure manometer and hemoconcentrator used during the case (Minntech HPH 1400; Minneapolis, MN), and a roller pump (Sarns 8000, Terumo® Medical Corporation, Somerset, NJ) that was not in use after discontinuing CPB (Figure 3). The “recovery loop” created a safe, sterile, and isolated circuit that concentrated the whole blood into the Hemobag using a multi-pass ultrafiltration technique to a final volume of 750 mL with a hematocrit of 52%. Average flows were maintained around 450 mL/min, with a maximum transducer pressure of 325 mmHg. Periodic agitation was performed by squeezing the Hemobag to enhance the blood mixing, which lessened the hemoconcentrating pressures. No suction was required to facilitate effluent removal. Only siphon drainage was used. This method of filling the Hemobag allowed us to keep the ECC sterile and primed throughout the entire process in case CPB needed to be re-instituted. The total time needed to hemoconcentrate

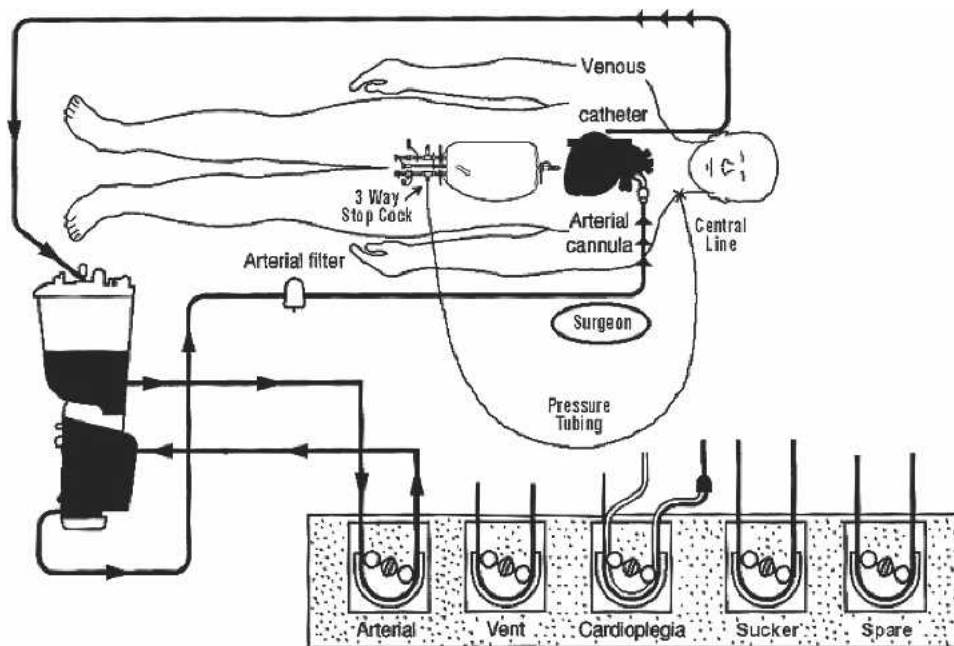


Figure 2. Diagram showing the set up of the Hemobag for a JW patient undergoing cardiac surgery with a primed non-compliant line connecting the Hemobag to the central line.

this blood with the Hemobag system was <12 minutes. While this Hemobag process was ongoing, the surgeons were able to continue the procedure without interruption or delay.

Neither inotropic nor vasoactive supports were required after CPB. There was minimal bleeding as evidenced by the lack of red blood cells processed for the cell salvage system (Fresenius CATS, Redmond, WA), which was equal to only 100 mL. Total fluids infused during the case were 1900 mL of crystalloids, 750 mL of colloids, and 2350 mL of IAD, of which 1000 mL was given back to the patient on CPB.

The patient was transferred to the intensive care unit in stable condition. The first set of tests drawn showed a hematocrit of 34%, platelet count of 123,000/mm³, fibrinogen of 296 mg/dL, INR of 1.5, and PTT of 55 seconds. The arterial blood gas was 7.44/36/166 on 50% O₂. The mixed venous blood gas showed a PvO₂ of 41 mmHg with a 77% O₂ saturation of hemoglobin. The patient was extubated in 6 hours. Total 24-hour chest tube drainage was 335 mL. The patient was discharged from the intensive care unit on the first post-operative day with a hematocrit of 36%. There were no post-operative complications, and the patient was discharged on the fifth post-operative day.

COMMENT

At Englewood Hospital and Medical Center, the cardiac surgery department has adopted a successful multi-

modality, multi-disciplinary perioperative approach to blood conservation (1). Part of this multi-modality approach is to hemoconcentrate the residual whole blood in the ECC post-CPB. This avoids the discard of plasma proteins, coagulation factors, and platelets (as seen with cell washing techniques). Established MUF techniques are cumbersome and time consuming, requiring the cannulae to remain in the patient during the entire process, thereby prolonging surgical time and thus delaying the reversal of heparinization. An alternative technique is direct infusion of the residual contents of the ECC into the patient. This has the potential to cause hemodilution and volume overload, contributing to organ edema and organ dysfunction during one of the most critical time periods of a cardiac surgical procedure. To counter these negative effects that can last 4–8 hours postoperatively, vasodilation and diuretic therapy can be given. Subsequently, this can create further hemodynamic instability and electrolyte imbalance. Frequently, the effects of the diuretics and vasodilators persist well into the postoperative period. With the Hemobag, the same goals can be accomplished in ~10 minutes.

The Hemobag is a quick and easy alternative method to salvage and concentrate the autologous whole blood post-operatively from any ECC. The Hemobag system is designed to allow surgery to continue uninterrupted while the hemoconcentration process is ongoing, unlike other techniques of ultrafiltration. The system was designed to easily and sterily purge the contents of the ECC into a large reservoir bag. In a separate circuit using the TS3

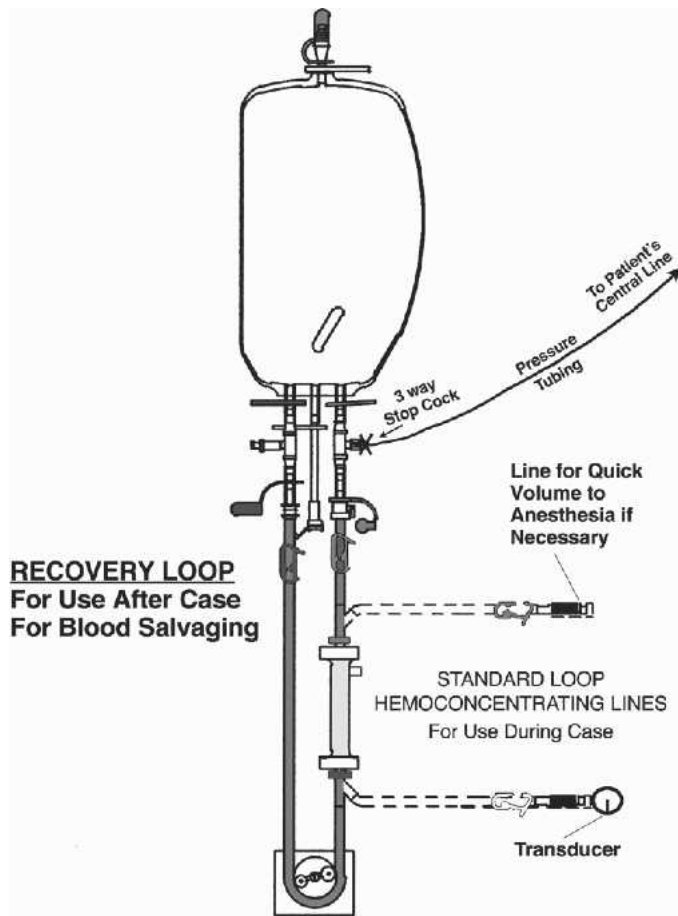


Figure 3. Diagram of the sterile and isolated circuit for hemoconcentrating the whole blood in the Hemobag using a multi-pass ultrafiltration technique. This is referred to as the "recovery loop" by the manufacturer, which consists of the Hemobag, the TS3 tubing set (Global Blood Resources), the same pressure manometer and hemoconcentrator used during the case, and a roller pump that was not in use at the end of the case after discontinuing CPB.

Tubing Set, the perfusionist can safely hemoconcentrate the residual autologous blood with multi-pass ultrafiltration quickly and have the ability for sampling quality assurance and quality control samples. The aortic and venous cannulae can be removed from the patient, and protamine can be administered, thus preserving the integrity and the sterility of the ECC: keeping it primed and uncompromised to resume CPB emergently if warranted. The correct and routine use of the Hemobag has been described (21), and patient results have been reported (18) in earlier publications. The adaptations made for this JW patient were simple to make and did not contradict the manufacturer's instructions for use.

Approximately 8% of our cases are JW patients. One of the challenges we faced was how to incorporate the Hemobag technology into our blood conservation strategy during cardiac surgery. The method described above provided a continuous circuit that conforms to the beliefs of

the JW community. The small-bore, non-compliant tubing connected to the "luer port" on the inlet line by a stopcock at the bottom of the Hemobag and to the patient's central line was primed with sterile saline to avoid air and to create a continuous pathway. This kept the Hemobag in continuous contact with the patient during transfer of the Hemobag to the perfusionist for hemoconcentration and eventually to the patient for re-infusion.

We now routinely incorporate the Hemobag system with our JW patients at Englewood Hospital and Medical Center. The Hemobag technique is rapid and easy to assemble. By avoiding direct infusion of large volumes of unfiltered autologous whole blood from the ECC, we can avoid the use of diuretics to offset the excess volume infused, and there is no hemodynamic instability encountered during the process. In addition, there is no need to replace the potassium that would have been lost through diuresis. The hemoconcentrating occurs separately from the ECC. Therefore, the surgeons can continue with the surgery, and protamine can be systematically administered while the ECC remains primed and ready for emergent reinstitution of CPB if necessary.

This case report describes the successful use of the Hemobag in a JW patient. The use of the Hemobag facilitates hemostasis and homeostasis by re-infusing the patient's own plasma proteins and platelets from the residual blood in the ECC that would normally be discarded and minimizes hemodilution, leading to iatrogenic anemia and edema with concomitant organ dysfunction, all in a timely manner when the patient's cardiovascular status is at a critical stage. Although this case shows how to set up and operate the Hemobag in a JW patient, it has been adopted into our blood conservation strategy and is routinely considered for whole blood salvaging in any of the cases where our patients require ECC use.

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