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Evaluation of the Hemobag: A Novel Ultrafiltration System for Circuit Salvage

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Abstract: Following termination of bypass, the CPB circuit contains a significant volume of diluted blood. Various methods have been used to salvage this blood, including direct transfusion or centrifugation /washing of the circuit volume. These techniques produce a reinfusion product that is either dilute or free of plasma proteins. The purpose of this study is to evaluate the *Hemobag* ultrafiltration system, which may overcome these limitations. Yorkshire pigs (n = 4, ~40 kg) were placed on CPB (prime volume 1.5 L) for 60 min. Following CPB, control blood samples (Pre) were collected from the circuit. The circuit contents were then transferred into a Hemobag and processed. Blood samples (post) were then collected from the Hemobag. Pre- and post-samples were analyzed and compared using a Student's t-test. Parameters that were significantly different ($p < .05$) pre-Hemobag versus post-Hemobag were as follows: hematocrit 20.4 ± 3.4% vs. 54.1 ± 11.6%, total protein 2.4 ± 0.4 vs. 8.2 ± 2.9 gms/DL, fibrinogen 92.0 ± 20.3 vs. 305.8 ± 137.2 mg/DL. Parameters that were not significantly different but trended toward an increase post-Hemobag were platelet counts, heparin levels, white cell count, and plasma free hemoglobin. Parameters that showed no differences or trends included sodium, potassium, chloride, bicarbonate, and osmolarity. Processing times were measured at approximately 10 minutes. This device effectively concentrates post-bypass circuit volume, providing a product that is high in red blood cells and plasma proteins and may provide an alternative to current techniques for circuit volume salvage. **Keywords:** blood conservation, ultrafiltration, blood salvage, hemodilution, hemoconcentrator, Hemobag. *JECT. 2004; 36:162–165.*

The risks associated with transfusing allogenic blood have been well documented, including contraction of possible infections, transfusion reactions, and medical errors (1). Therefore, aggressive blood conservation during open-heart surgery should be used (2). It has been estimated that over 75% of the blood lost during cardiac surgery can be collected for intraoperative transfusion (3). A significant amount of recoverable blood remains in the extracoporeal circuit following the termination of cardiopulmonary bypass. A variety of methods are currently used to salvage the circuit blood for reinfusion to the patient. Common methods of salvaging the circuit contents are direct transfusion of the diluted, heparinized blood from the circuit, or centrifugation and washing of the blood and subsequent reinfusion of a packed red blood cell product. The first method salvages diluted whole blood from the circuit, including plasma proteins and clotting factors, which could play an important role in hemostasis post CPB. However, this product may have a suboptimal hematocrit, a large volume, and may contain a significant concentration of heparin. The second method, centrifugation of the circuit volume, effectively removes most of the heparin and reduces the total volume, producing a product that has a high hematocrit for transfusion post CPB. Centrifugation, however, is known to remove more than 95% of albumin and total protein from the blood (4). In addition, clotting factors are also washed away in the centrifugation process. Plasma proteins and clotting factors both help with oncotic pressures and coagulation, respectively, and removal can lead to fluid shifts and a delay in hemostasis.

Ultrafiltration and hemoconcentration of the post-CPB circuit, although less widely used, is an additional method that can be used for recovering circuit volume. This method can produce a product that is volume reduced, contains a high hematocrit, and retains plasma proteins. The ultrafiltration product also contains heparin. Comparisons of the various techniques have been performed

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outlining the advantages and disadvantages of the methods (3,5).

Historically, the ultrafiltration method of circuit salvage has involved adapting and modifying a hemoconcentrator post CPB to process the contents. The *Hemobag* is a product developed specifically for ultrafiltration circuit salvage following CPB. The purpose of this study is to evaluate the Hemobag in both function and product produced.

METHODS

Animal Protocol

Four healthy, Yorkshire pigs (~40 kg) were anesthestized and instrumentated as previously described (6). Briefly, anesthesia was induced with intravenous (IV) sodium pentobarbital (50 mg/kg), and intubation was performed. Animals were ventilated using a Galileo ventilator (Hamilton Medical, Reno, NV). Continuous anesthesia with sodium pentobarbital (6 mg/kg/min) was delivered using a Harvard pump (Model 907, Harvard Apparatus, Mills, MA), while bolus infusions of pancuronium bromide was given to maintain paralysis. Electrocardiogram (ECG) monitoring was performed using a pacemaker/defibrilator system (Zoll Medical, Burlington, MA). A right carotid artery cutdown was performed and a 2 mm catheter placed to measure systemic artery pressure and for acquisition of arterial blood gas samples. A 7.5 French dual lumen catheter was placed into the adjacent internal jugular vein for maintenance of IV fluids, Pressure was measured using Argon transducers (Model 049-992-00A, CB Sciences Inc., Dover, NH) leveled at the right atrium and recorded using a 16-channel PowerLab/16s (AD Instruments Pty Ltd., Milford, MA) interfaced with a Dell Dimensions XPS R400 computer (Dell Inc., Dallas, TX).

The protocol was approved by the Committee for the Humane Use of Animals at SUNY–Upstate Medical University. All animals received care in compliance with the "Guide for the Care and Use of Laboratory Animals" (NIH Publication 85-23, revised 1985).

Cardiopulmonary Bypass

An arterial roller pump (Sarns 7000 MDX, Ann Arbor, MI) was used. The circuit was made up of an Affinity oxygenator and hard-shell venous reservoir (Medtronic, Minneapolis, MN), COBE Sentry (Cobe Cardiovascular Inc, Arvada, CO) arterial line filter, 3/8 × 3/8 inch ID. PVC tubing for the arterial–venous loop and raceway. The circuit was primed with 1200 mL lactated Ringer's, 25 mEq sodium bicarbonate, 3000 units heparin, and 0.5 gm mannitol. The right femoral artery and vein were used for cannulation. Following full dose heparinization (300 units/kg), initiation of bypass was achieved initially with gravity drainage and, once established, vacuum assisted venous drainage (VAVD) was implemented (suction regulator model 7720 Baxter, Deerfield, IL). Arterial flow rates were maintained at 75–100 mL/kg/min. ACTs were maintained >500 sec. Bypass times varied between pigs (60–200 min).

Hemobag Sysytem

The Hemobag system (Global Blood Resources, LLC, Windsor, CT) consists of the Hemobag blood collection reservoir, a hemoconcentrator (Minntech, Minneapolis, MN), and a custom tubing set for rapid integration. The Hemobag is a specially designed blood storage bag (Figure 1) with an arterial infusion port at the top and three ports at the bottom, (inlet, outlet, and transfusion). There are sampling ports on both the inlet and outlet port, and all ports on the bag have clips on them. There is a baffle just above the inlet port to prevent direct recirculation in the bottom of the bag (Figure 1). Initially, the Hemobag is at the sterile field detached from the hemoconcentrator circuit, which can be used in a conventional manner during CPB.

Following termination of CPB, the arterial cannula was removed and placed on the arterial infusion port of the Hemobag using sterile technique. The circuit volume was then pumped to the Hemobag and chased with crystalloid solution until clear. The Hemobag was then disconnected from the arterial line and passed to the perfusionist to be interfaced with the hemoconcentrator circuit via quick connectors. The Hemobag volume was the recirculated through the hemoconcentrator back to the Hemobag at a

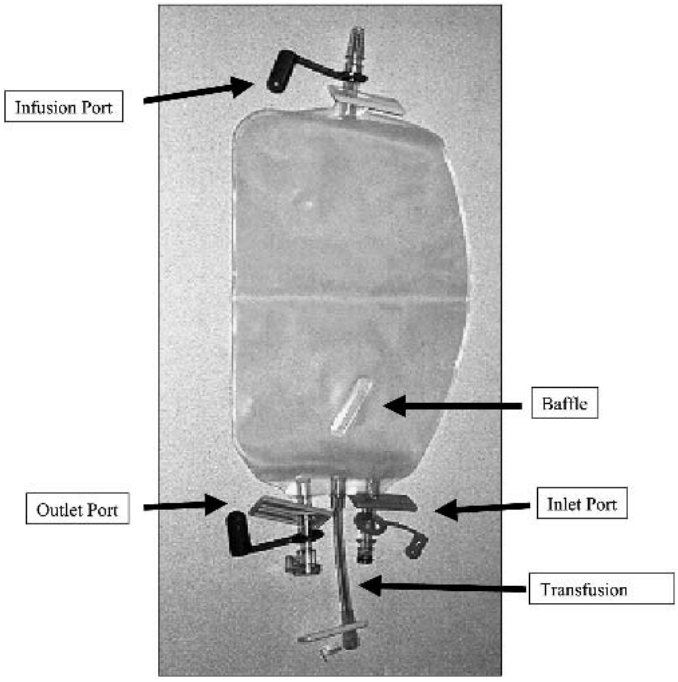

Figure 1. The Hemobag collection reservoir.

flow rate of 500 mL/min. An effluent line from the hemofilter passively drained ultrafiltrate into a 1 L graduated cylinder. The process continued until the Hemobag was approximately half of its original volume.

Sampling/Measurements

Blood samples were removed from the Hemobag's sampling port before processing (pre-Hemobag) and then again after processing (post-Hemobag). Both "pre" and "post" samples were placed on ice and sent to the lab for analysis. Blood sample measurements included hemoglobin/hematocrit and platelet count (Abbott Cell-Dyn 4000, Abbott Park, IL), fibrinogen and heparin levels (Diagnostica Stago STA Coagulation Analyzer, Parsippany, NJ), total serum protein and electrolytes (Ortho-Clinical Diagnostics VITROS 950 AT, Raritan, NJ), and osmolarity (Advanced Micro Osmometer Model 3MO Plus, Norwood, MA). Plasma free hemoglobin levels were obtained by spectrophotometric determination (Beckman Model DU640B, Fullerton, CA).

Timing of Processing

Functional aspects of the device were also measured, such as processing time.

Statistical Analysis

Data are expressed as mean ± standard deviation. Data were compared between groups using an unpaired *t*-test. A *p*-value less than .05 was considered significant.

RESULTS

Processing Time

The time that the Hemobag was connected to the arterial line, processed, and ready for reinfusion took approximately 10 minutes.

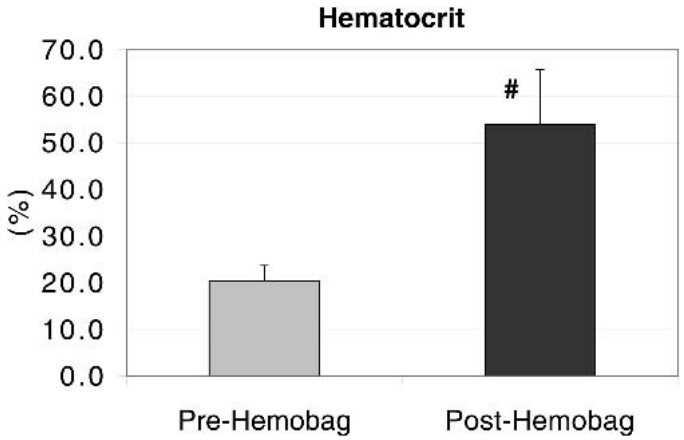

Figure 2. Hematocrit (%) pre- and post-Hemobag. # Denotes $p < .05$ compared to pre-Hemobag sample.

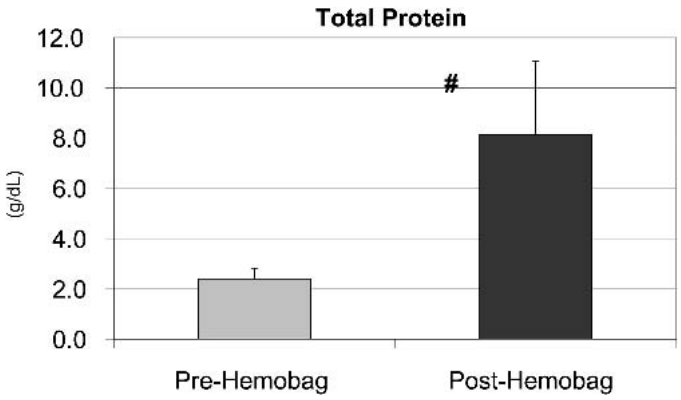

Figure 3. Total protein (gm/dL) pre- and post-Hemobag. # Denotes $p < .05$ compared to pre-Hemobag sample.

Laboratory Data

Comparision of pre- to post-Hemobag showed a significant increase in hematocrit, 20.4 ± 3.4 vs. 54.1 ± 11.6% (Figure 2), total protein: 2.4 ± 0.4 vs. 8.2 ± 2.9 gm/dL (Figure 3), and fibrinogen level: 92 ± 20.3 vs. 305.8 ± 137.2 mg/dL (Figure 4).

There were no significant differences between pre- and post-Hemobag platelet count, osmolarity, potassium, heparin levels, white cell counts, and plasma free hemoglobin. (Table 1)

DISCUSSION

Identification of the superior method of circuit blood salvage following CPB has been illusive. Comparative clinical studies of centrifugation and ultrafiltration have yielded mixed results. Several investigators have found increases in total protein, albumin, or fibrinogen in the ultrafiltration group when compared to the centrifugation group (3,7–12). A number of these studies have also shown an increased platelet count when ultrafiltration is used to salvage residual circuit volume (5,9–11) However, this does not seem to translate into reduced blood loss

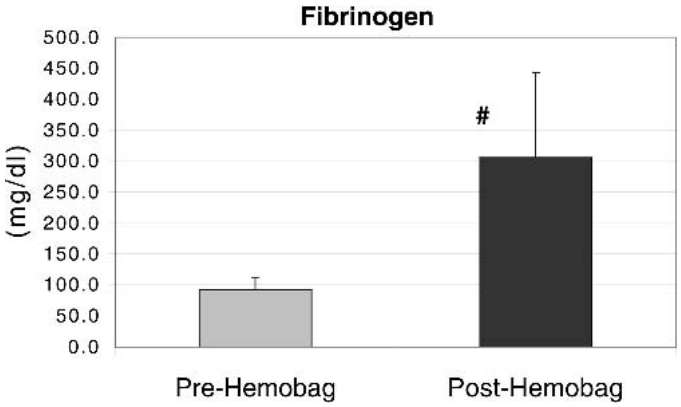

Figure 4. Fibrinogen(mg/dL) pre- and post-Hemobag. # Denotes $p < .05$ compared to pre-Hemobag sample.

Table 1. Hematologic changes following Hemobag processing.

Parameter	Pre-Hemobag	Post-Hemobag	*p*-Value
Platelet count (K/mL)	186 ± 106.2	256.8 ± 129.4	0.16
Potassium (mmole/L)	4.5 ± 0.8	4.6 ± 0.9	0.19
Osmolarity (mosm/kg)	292.0 ± 7.4	294.0 ± 4.4	0.24
Heparin levels (U/mL)	1.6 ± 0.3	3.5 ± 2.1	0.08
Plasma-free hemoglobin (mg/dL)	11.8 ± 10.6	49.5 ± 42.5	0.06
White blood count (K/ml)	3.0 ± 1.8	6.3 ± 2.3	0.11

postoperatively. Eichert et al. (10), found no differences in blood loss when comparing direct infusion, centrifugation, and ultrafiltration blood conservation methods. Johnson et al. (9) also did not see a difference in post-operative bleeding when comparing ultrafiltration with centrifugation salvage techniques.

Some technical limitations with studies that compare post-CPB centrifugation versus ultrafiltration should be considered. Centrifugation systems are specifically designed to facilitate blood conservation and are consistently used in a similar manner from institution to institution. On the other hand, ultrafiltration circuit salvage is usually accomplished using a "home-made" modification to the extracorporeal system and may have a highly variable processing scheme. This lack of a standarized ultrafiltration system makes interpretation of the literature difficult.

The Hemobag is a product that may overcome this deficiency in current ultrafiltration salvage methods. The present study evaluates this ultrafiltration system. It was found that the system allows for conventional ultrafiltration during CPB, which is easily converted to a standalone cell salvage system following CPB. This study found the system accommodated a near complete blood salvage without compromising the integrity or sterility of the bypass circuit. The Hemobag effectively produced an end product that has a high concentration of red cells, total protein and fibrinogen. Investigators found the processing time of approximately 10 minutes to be acceptable. The Hemobag allowed for easy quality control sampling following processing.

A limitation of this small, nonclinical study is that it simply evaluates the integration of the device with the CPB circuit and the parameters of the end product produced by circuit processing by the Hemobag. Future clinical studies should be conducted that compare patient parameters following centrifugation, direct infusion, and Hemobag ultrafiltration circuit salvage methods. The cost effectiveness of this product should also be evaluated.

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