Reducing Allogeneic Blood Exposure and Preserving Blood Cell, Protein and Clotting Factor Concentration During Cardiac Surgery: Update on the Hemobag®

Keith A. Samolyk CCP, LCP, Global Blood Resources LLC, Somers, CT USA 06071 and Scott R. Beckmann CCP, Salem Hospital, Salem, OR.97306 USA

www.MyBloodFirst.com

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Introduction

Cardiovascular Surgery still remains responsible for approximately 10-20% of all transfusions in the United States despite recent evidence demonstrating that transfusions are independently linked to increased short and long term morbidity and mortality. (1-3)

ECC circuits have long been viewed as a contributor to hemodilution but now condensed circuitry with prime volumes of 1,000-1,500 mls are the norm and can be RAP'd (Retrograde Auto Primed) to reduce the hemodilution even further. Blood volume remaining in the ECC at aortic decannulation has been traditionally salvaged by either processing with a "Cell Saver" or "chasing the ECC volume into the patient. (4-7) Returning this blood remaining in the ECC is proving to be one of the most important steps in a total blood conservation strategy in cardiac surgery today.

Cell processing conserves RBC's but discards plasma proteins. (4-6) Chasing the pump contents into transfer bags for infusion or directly into the patient stresses the kidneys to process extra fluid in a patient that is already volume overloaded. This stress may contribute to further organ dysfunction compared to maintaining normovolemic homeostasis. (9)

Observational data and descriptive statistics from a case series is presented to illustrate the use of the Hemobag® system. [See Figure One]

Method

The Hemobag® technique is a new blood conservation method and technology that is FDA cleared for blood salvaging that deals directly with ECC volume at aortic decannulation. It recovers and concentrates essentially all autologous whole blood and proteins from the ECC in a timely fashion for infusion, while maintaining the integrity and security of a safe primed circuit at all times. Use of the Hemobag® circuit allows for conventional ECC ultrafiltration during the procedure and works with any commercial Hemoconcentrator.

After IRB approval a total of 204 patients undergoing cardiac surgery with CPB at Salem Hospital (Salem, Oregon) were arbitrarily assigned the use of the Hemobag® Blood Salvage Device (Global Blood Resources, Somers, CT 06071).

Data was analyzed using SPSS 13.0 (SPSS Inc., Chicago, IL 60606). Five patient outliers from each group in regard to blood product usage were removed prior to group comparisons.

Figure Two explains the method in more detail.

Table One

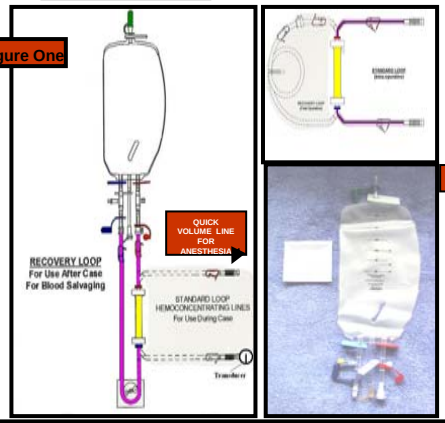
Parameter	Control Group	Hemobag® Group	p Value
Patient group size	102	102	NS
Percent male	75	76	NS
Age in years	65 +/- 11	64 +/- 13	NS
BSA m²	2.0 +/- 0.24	2.0 +/- 0.22	NS
Pre-op weight kg	86 +/- 17	89 +/- 18	NS
% CABG surgery patients	63	61	NS
% Valve surgery patients	18	19	NS
% Valve + CABG patients	19	20	NS
National Bayes risk score	5.2 +/- 7.4	5.0 +/- 6.4	NS
CPB time min	138 +/- 55	137 +/- 52	NS
Ischemic min	94 +/- 34	93 +/- 38	NS

Mean +/- 1 stdev. Nominal data evaluated by chi-square analysis; Other data analyzed by independent sample t-test.

Hemobag® Whole Blood "Recovery Loop"

TS3 Tubing Set "Standard Loop"

Figure One



The HEMOBAG® Blood Salvage Device is a reservoir system that allows the patient's own whole blood to be salvaged, hemoconcentrated, and infused back to the same patient quickly, safely and efficiently in the same convenient reservoir bag while insuring ECC integrity for safety and security.

Hemobag® Case Series

Methodology

Figure Two

- The end-CPB circuit blood for a group of 102 patients was processed using the Hemobag® (HB) device and technique
  - HB procedures and patients were selected arbitrarily from all comers in community-based medical center
- A concurrent, matched patient group (n = 102; non-HemoBag®; NHB) was selected to compare to the Hemobag® patient group
  - The control group patients were selected to match the HB group patients by procedure, surgeon, CPB time, Clamp time, age and BSA
  - The control group end-CPB circuit blood was processed by the Cell Saver®
- Compared pre-op, operative, ICU and post-op parameters, outcomes and blood product usage and cost between HB and NHB groups

Results

Results

There were no significant differences between the two groups in regard to patient morphology and demographics. There was similar use of intraoperative ATS and preoperative ANH in both groups to enhance blood conservation.

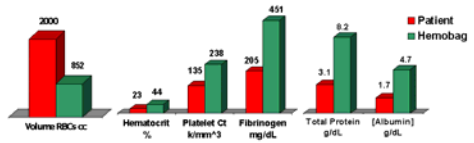
The average volume returned to the patient from the Hemobag® was 852 mls (1 SD = 197 mls). The average time to fully hemoconcentrate the Hemobag® was 11 minutes. **All blood fractions showed a statistically significant improvement from the baseline when concentrated with the Hemobag®** [See Figure Three].

Factors VII, IX and X levels measured in several HB contents averaged a greater than 260% increase.

More detailed results are presented in Table Two and Figures Three and Four.

Average change in blood parameters with Hemobag®

Figure Three



2000 ml of autologous residual pump blood is concentrated to 870 ml. The total protein and albumin concentration increased significantly ($p < 0.05$). Hematocrit, platelet count and fibrinogen concentration increased significantly ($p < 0.05$) with hemoconcentration.

Figure Four

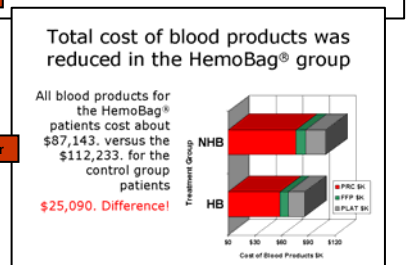


Table Two

Parameter	Control Group	Hemobag® Group	p Value
Pre-op HCT %	39.7 +/- 5.0	39.9 +/- 5.0	NS
Hemobag® ml processed	NA	852 +/- 197	NA
Hemobag® content platelet K/mm³	NM	238 +/- 73	NM
Post-op platelet K/mm³	100 +/- 39	109 +/- 39	NS
Hemobag® content fibrinogen mg/dl	NA	451 +/- 174	NA
Hemobag® total protein gm/dl	NA	8.2 +/- 1.9	NA
Hemobag® albumin	NA	4.7 +/- 1.1	NA
Pre-CPB autologous blood draw (ANH) ml/kg	5.0 +/- 3.3	5.5 +/- 2.8	NS
Hemobag® content HCT %	NA	44 +/- 6	NA
Low operative HCT %	23.1 +/- 3.5	23.9 +/- 2.6	NS
Hemobag® F VII, IX, X	NA	> 260%	NA
FFP units per patient	1.2 +/- 2.3	1.03 +/- 1.0	[0.191]
Platelet pheresis packs per patient	0.6 +/- 1.0	0.5 +/- 0.8	[0.124]
% Patients transfusion-free	27 %	47 %	0.008
RBC transfusions per patient	1.6 +/- 1.8	1.2 +/- 1.8	NS
Post-op bleeding cc/kg	9.0 +/- 5.9	7.6 +/- 6.3	NS
Donor exposures per patient	3.7 +/- 4.9	2.9 +/- 3.9	NS
Cost blood products $ per patient	1,157 +/- 1,317	898 +/- 1189	[0.074]
Total blood product $ per group	112,233	87,143	NA
Discharge HCT	31.5 +/- 3.5	31.8 +/- 3.6	NS
% Patients with pulmonary complications	46 +/- 50	37 +/- 48	NS
Total hospital days	13.6 +/- 7.8	8.7 +/- 4.6	0.039

Mean +/- 1 stdev. Nominal data evaluated by chi-square analysis; Other data analyzed by independent sample t-test. [ ] and NS are not significant at $p < 0.05$, NM is not measured, NR is not recorded and NA is not applicable.

Discussion

Infusion of the CPB circuit residual blood concentrate with the Hemobag® safely recovers proteins, clotting factors and cell volumes for all types of cardiac procedures which leads to reduced patient donor exposures, improved outcomes and reduction in the related costs.

Use of the Hemobag® allowed the clinicians to capture blood platelets and proteins that would have been normally discarded. (2, 5, 8-9) Factors VII, IX, X levels in the Hemobag® contents averaged more than a 260% increase. Saving autologous factors is critical & economical today (12).

Use of this new technique offers advantages over the current technologies of salvaging blood from ECCs while offering the potential to improve patient outcomes. (2, 5-10) The Hemobag® is used successfully with Jehovah Witness patients. (12)

The Hemobag® is gaining ground successfully in cardiothoracic and vascular programs throughout the USA. Prospective clinical studies are ongoing focusing on blood avoidance, outcomes and costs when salvaging autologous whole blood with the use of the Hemobag®. So far the results show a strong causal-comparative relationship when using the Hemobag® where patients do much better when their blood is more concentrated perioperatively and less diluted by any kind of IV Intra-vascular volume replacement. (13)

Hemobag® Case Series Conclusions

Figure Five

HB vs. NHB group comparison:

- Significantly more Hemobag® patients received no blood products
- HB patients experienced substantailly less chest tube drainage
- HB patients received about 1/4 less total donor exposures on the average compared to control group
- HB patients had fewer exposures to FFP, platelet packs, cryoprecipitate and RBC transfusions
- HB patients experienced substantially lower pulmonary complications
- HB patients tended to have higher hematocrit nadirs and higher post-operative platelet counts
- Use of the Hemobag® is safe and effective, even when employed in conjunction with multiple blood conservation techniques

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Hemobag® Case Series Conclusions

HB vs. NHB group comparison:

- Significantly more Hemobag® patients received no blood products and experienced substantially less chest tube drainage
- HB patients received about 1/4 less total donor exposures compared to control group, and had fewer average exposures to FFP, platelet packs, cryoprecipitate and RBC transfusions
- HB patients experienced substantially lower pulmonary complications and significantly shorter hospital lengths of stay
- HB patients tended to have higher hematocrit nadirs and higher post-operative platelet counts
- HB technique retrieved and concentrated blood proteins including fibrinogen and precious clotting Factors VII, IX and X
- The Hemobag® is an efficient technique in the treatment of Jehovah's Witness patient’s wishes & guidelines
- Use of the Hemobag® is safe and effective, even when employed in conjunction with multiple blood conservation techniques