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A METHOD TO REDUCE ALLOGENEIC BLOOD EXPOSURE AND HOSPITAL COSTS WHILE PRESERVING CLOTTING FACTOR CONCENTRATION AFTER CARDIOPULMONARY BYPASS

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Global Blood Resources LLC

Introduction

Cardiovascular Surgery remains responsible for as much as 20% of all transfusions in the United States despite recent data demonstrating that transfusions are independently linked to increased short and long term morbidity and mortality. (1, 12-13)

ECC circuits have long been viewed as a contributor to hemodilution. Condensed circuitry with prime volumes of 1,000-1,500 mls are now the norm and can be RAP'd (Retrograde Auto Primed) to reduce the hemodilution even further.(15) 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. (2-5, 7)

Cell processing conserves RBC's but discards plasma proteins. (8-10) 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. (11-12)

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

Method

A new blood conservation method and technology for blood salvaging, the Hemobag® (Global Blood Resources, Somers, CT 06071) deals directly with ECC volume at aortic decannulation.

The Hemobag® recovers and concentrates essentially all autologous whole blood, platelets 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 66 patients undergoing cardiac surgery with CPB at Salem Hospital (Salem, Oregon) were randomly selected to the use of the Hemobag® Blood Salvage Device. Dependent variables and outcomes were compared between the Hemobag® treatment group and the control group.

Figure Two explains the method in more detail.

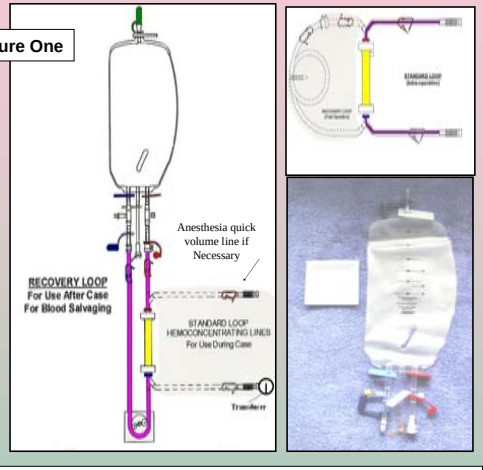
Table One

Parameter	Control Group	Hemobag® Group	p Value
Patient group size	66	66	NS
Percent male	70	74	NS
Age in years	66 +/- 11	66 +/- 13	0.300
BSA m^2	1.92 +/- 0.23	2.02 +/- 0.24	0.232
Pre-op weight kg	81 +/- 16	89 +/- 18	0.470
% Distribution of 5 surgeons	61/37/0/2/0	56/37/1/5/1	NS
% CABG surgery patients	66	65	NS
% Valve surgery patients	18	18	NS
% Valve + CABG surgery patients	16	17	NS
National Bayes risk score	5.4 +/- 6.7	5.0 +/- 6.6	0.782
LV ejection fraction %	59 +/- 16	56 +/- 22	0.456
CPB time min	131 +/- 60	131 +/- 42	0.989
Ischemic min	91 +/- 39	91 +/- 31	0.994
Pre-op HCT %	40 +/- 5	40 +/- 5	0.691
Pre-op platelet K/mm³	227 +/- 81	224 +/- 89	0.809

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 whole blood to be Salvaged, Hemoconcentrated and Infused back to the same patient quickly, safely and efficiently in the same convenient reservoir bag (Insuring ECC integrity).

Hemobag® Case Series

Salem Hospital, Salem OR

- ❑ The end-CPB circuit blood for a group of 66 patients was processed using the Hemobag® (HB) device and technique
  - HB procedures and patients were selected randomly from all comers
- ❑ The Hemobag® patient results were compared to a concurrent matched control group (NHB)
  - The control group patients were selected to match the HB group patients by procedure, surgeon, CPB 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 and outcomes between groups

Figure Two

Results

The average volume returned to the patient from the Hemobag® was **852 mL** (1 SD = 197 mL).

The average time to hemoconcentrate the Hemobag® was **just over 10 minutes**.

Total blood protein concentration in the Hemobag® contents was **8.2 +/- 1.9 gm/dL**.

Results are included in Tables One & Two and Figures Three - Five.

Hemobag® Case Series

Salem Hospital, Salem OR

HB vs. NHB group comparison:

- No significant difference in distribution of surgeons, procedures, patient age, BSA or gender between groups
- No significant difference in CPB and ischemic (clamp) times between groups
- No significant difference in National Bayes Risk Scores
- Same volume of pre-CPB autologous blood drawn (ANH)
- Same 100% use of cell-processor in both groups except the use of the HemoBag® to process the end-CPB circuit volume in the HB group

Figure Three

Hemobag® Case Series

Salem Hospital, Salem OR

HB vs. NHB group comparison:

- There were no significant difference in operative hematocrit nadir, post-op HCT or chest tube drainage volume
- Though not statistically significant there were strong tendencies toward clinically significant differences with sizeable financial consequences:
  - More Hemobag® patients received no blood products
  - Hemobag® patients received about 1/3 less total donor exposures on the average compared to control group
  - Average RBC transfusion rates per patient were lower (>50%) in the HB group (p = 0.053) compared to the control patients
  - Hemobag® patients blood costs were about 50% of control group blood costs per patient (p = 0.058): $41,650. difference

Figure Four

Parameter	Control Group	Hemobag® Group	p Value
Hemobag® processed cc	NA	852+/- 197	NA
Post-op bleeding cc/kg	9.4 +/- 6.5	7.9 +/- 7.2	0.191
FFP units per patient	1.1 +/- 2.4	0.9 +/- 1.5	0.546
Platelet pheresis units per patient	0.7 +/- 1.6	0.5 +/- 0.8	0.410
RBC transfusions per patient	1.8 +/- 2.9	1.0 +/- 1.6	0.053
Donor exposures per patient*	4.3 +/- 8.1	2.5 +/- 3.4	0.097
% Patients with no transfusions	41	50	
Cost blood products $ per patient	1,417 +/- 2,487	777 +/- 1,055	0.058
Cost of blood products $ for group	92,166	50,516	NA
Discharge % HCT	32 +/- 4	31 +/- 7	0.523
Pre-op creatinine mg/dl	1.4 +/- 2.2	1.1 +/- 0.4	0.222
Post-op creatinine mg/dl	1.6 +/- 1.0	1.8 +/- 1.9	0.524
Weight kg in ICU	NR	95.0 +/- 19.5	NR
ICU - pre-op weight change kg	NR	4.2 +/- 2.7	NR
Ventilator hours**	33 +/- 80	13 +/- 15	0.053
ICU hours**	72 +/- 98	53 +/- 53	0.161
Total hospital days*	11 +/- 12	9 +/- 4	0.153

*Nominal data evaluated by chi-square analysis; other data analyzed by ANOVA. [ ] and NS are not significant at p < 0.05, NM is not measured, NR is not recorded and NA is not applicable. *One outlier (>M + 2.5 SD) in each treatment group was removed before analysis. **Three outliers were removed from each treatment group before analysis.*

Table Two

Parameter	Control Group	Hemobag® Group	p Value
Pre-op HCT %	40 +/- 5	40 +/- 5	0.691
Pre-op platelet K/mm³	227 +/- 81	224 +/- 89	0.809
Hemobag® content platelet K/mm³	NM	238 +/- 73	NM
Post-CPB platelet K/mm³	NM	121 +/- 46	NM
Post-op platelet K/mm³	93 +/- 30	108 +/- 43	0.022
% of baseline post-op platelet count	-55 +/- 15	-51 +/- 16	0.079
Hemobag® content fibrinogen mg/dl	NA	451 +/- 174	NA
Post-CPB fibrinogen gm/dl	NM	206 +/- 89	NA
Low CPB °C	31 +/- 5	31 +/- 7	0.796
Pre-CPB autologous blood draw cc/kg	4.0 +/- 2.4	4.3 +/- 2.3	0.594
Total heparin dose K IU /kg	831 +/- 260	831 +/- 267	0.991
Hemobag® content HCT %	NA	44 +/- 6	NA
Low operative HCT %	23 +/- 3	24 +/- 3	0.031
% of baseline drop to low HCT	-41 +- 10	-40 +/- 9	0.270

Nominal data evaluated by chi-square analysis; other data analyzed by ANOVA. [ ] 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 appears to safely recover proteins, clotting factor and cell volume 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) **Factor VII levels in three Hemobag® contents averaged a 259% increase.** (14)

The Hemobag® offers a new way to safely and efficiently manage and salvage autologous extracorporeal (ECC) whole blood for patients. 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)

Prospective clinical studies are being conducted to assess the advantages in patient outcomes and potential reduction of allogeneic blood product use during cardiac surgery with the Hemobag® Blood Salvage Device end-CPB technique.

Total cost of blood products was reduced in the HemoBag® group

All blood products for the 33 of 66 HemoBag® patients receiving blood cost about $50,516 versus the $92,166 for the 39 of 66 control group patients who received a blood product

$41,650. Difference!

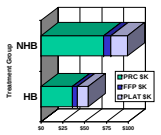


Figure Five

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