The benefit of the Hemonetics® cell saver apparatus during cardiac surgery

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This retrospective chart review of 155 patients having coronary artery bypass graft surgery (CABG) over a two-month period determined whether the use of a cell saver apparatus (CSA) (1) reduced or increased the requirements for homologous blood; (2) increased the incidence of post-surgical bleeding; (3) was cost-effective. Two groups of patients were identified. Group 1 (n = 99) received both CSA processed red blood cells and homologous blood components. Requirement for homologous blood products was reduced in the first 24 hr after surgery (0.5 ± 1.0 vs 1.3 ± 1.8 units; $P < 0.05$) when compared with Group 2 (n = 56) in whom only homologous blood products were utilized. More patients in Group 1 had no transfusion requirements (45 vs 8; $P < 0.05$) and there was no increased risk of major haemorrhage. When the capital costs are included, utilization of the CSA was not cost-effective. We conclude that utilisation of a CSA was safe, with no increased risk of bleeding, reduced requirements for homologous blood transfusions, but added to the cost of the procedure.

Cette revue rétrospective de 150 patients ayant eu des pontages aortocoronariens (CABG) détermine si l'utilisation du "cell saver" (CSA) 1) réduit ou augmente la nécessité d'une transfusion de sang homologue; 2) augmente l'incidence de saignement postopératoire; 3) est avantageuse considérant le coût. Deux groupes de patients ont été identifiés. Le Groupe 1 (n = 99) où les patients ont reçu des unités de sang hémococoncentrés par CSA et des dérivés de sang homologues. La demande pour des produits sanguins homologues a été réduite dans les premières 24 heures après la chirurgie ($0,5 \pm 1,0$ vs $1,3 \pm 1,8$ unités; $P < 0,05$) comparativement au Groupe 2 (n = 56) chez qui uniquement des dérivés de sang homologues ont été utilisés. Plus de patients dans le Groupe 1 n'ont pas requis de transfusion (45

vs 8; $P < 0.05$) et il n'y avait pas d'augmentation du risque d'hémorragie majeure. En considérant le coût d'investissement, l'utilisation de la CSA ne présentait pas d'avantage économique. On conclut que l'utilisation de la CSA était sécuritaire, avec aucune augmentation du risque de saignement, diminuant la nécessité de transfusion de sang homologue, mais représente un coût additionnel.

Anaesthetists frequently initiate transfusion therapy during surgery. Therefore, it is necessary to be aware of alternatives to the transfusion of homologous blood products. In 1973, as a result of growing concern over the increasing use of blood and its components during surgical procedures requiring cardiopulmonary bypass (CPB), The National Institutes of Health recommended increased use of autologous blood transfusions.¹ Studies utilizing autologous blood transfusions have shown a reduced requirement for homologous blood components.^{2,3}

The safety and simplicity of autotransfusion have been further improved with the advent of the cell-saver apparatus (CSA) (Hemonetics®). However, use of the CSA results in the loss of all platelets and plasma proteins including those of the coagulation cascade,⁴ which is perhaps another reason why autologous blood transfusions continue to be underutilized.⁵ While such devices might reduce requirements for red cells, this advantage in terms of reduction of exposure to homologous blood might be offset by an increased risk of exposure to blood products because of the need to replace plasma and platelets which are removed during the washing process.

Another explanation for the relative underutilization of autologous blood transfusions may be the change in transfusion practices employed by many surgeons and anaesthetists as a result of public awareness of the risks of blood transfusions and of professional educational programs aimed at reducing donor exposure to homologous blood products.⁶⁻¹⁹ Many physicians have re-examined their transfusion practices and are more willing to accept haematocrit values of 20-30 vs 35-40 per cent to avoid further exposure to homologous blood. One consequence of the change in transfusion practices is that the use of a

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cell-saver device might be less justifiable due to its cost and the added risks of infection and altered coagulation. The results of previous studies showing that the use of a cell-saver device reduced requirements for homologous blood products may no longer be valid in light of the changes in transfusion practices.

This retrospective study of patients having coronary artery revascularization was designed to determine whether the utilization of intraoperative autologous blood transfusions with the Hemonetics® device: (1) reduced or increased the subsequent exposure to homologous blood components; (2) was associated with an increased risk of post-surgical bleeding; and, (3) was cost-effective.

Methods

Patient population and sources of data

For the months of February and March 1987, the medical records of all patients who had undergone cardiac surgery were reviewed and the following information abstracted: patient identification number, name, sex, body surface area (BSA), surgeon, anaesthetist, operative procedure, operative time (time from skin incision until transportation to the surgical intensive care unit), duration of cardiopulmonary bypass (CPB), and total number of hospital days.

Haematocrit values were recorded: (1) prior to induction of anaesthesia, (2) before CPB, (3) just after initiation of CPB, (4) during the phase of maximum hypothermia, (5) prior to discontinuing CPB, and (6) prior to transfer to the intensive care unit. The administration of component blood products was determined by a review of the signed blood administration records and by analysis of the laboratory record of blood products issued for any particular patient. Any discrepancy between the two sources was resolved by taking the maximum number of units as the true value.

The number of units of autologous blood transfused was determined by reviewing the Hemonetics® blood administration record maintained by the perfusionist responsible for the use of the apparatus during surgery. Use of the Hemonetics® device was at the discretion of the attending surgeon. Blood component administration in the operating room was supervised by the attending anaesthetists; in the ICU by the Critical Care staff from the Department of Anesthesiology; and, after transfer to the floor, by the surgery and cardiology teams. Transfusion of packed red blood cells was based on the level of the patient's haematocrit (maintained within the range 20–30 per cent during the surgical procedure). Transfusion of plasma, platelets, or cryoprecipitate was based on clinical signs of a coagulopathy; determination of the PT, PTT, and platelet count; and evidence of ongoing surgical

bleeding, e.g., chest tube drainage above $200 \text{ ml} \cdot \text{hr}^{-1}$. In all cases the decision to initiate transfusion of blood products intraoperatively and in the ICU was made by the attending anaesthetist in consultation with the surgeon. In cases where the CSA was not employed, the contents of the oxygenator were transfused into the patient before the end of surgery. Where the CSA device was employed, the contents of the oxygenator were added to scavenged blood from the operative field, spun down in the CSA and the cell fraction was re-infused to the patient.

Excessive bleeding was defined as the requirement for more than ten component blood products within the 24 hr following initiation of the operative procedure. A single donor exposure was defined as administration of a unit of packed cells, whole blood, platelets, plasma, or cryoprecipitate.

Conduct of cardiac surgery

Five cardiac surgeons and eight anaesthetists were involved with cardiac surgery. The anaesthetic management was primarily narcotic based with the use of other CNS depressants (e.g., volatile anaesthetics, benzodiazepines, thiopentone) when appropriate. Hypothermic cardiopulmonary bypass ($25\text{--}28^\circ$ at flows of $50\text{--}75 \text{ ml} \cdot \text{kg}^{-1} \cdot \text{min}^{-1}$ with a membrane oxygenator) was used routinely. The surgical assistants and perfusionists were shared by all surgeons.

Exclusions

Patients having surgery other than coronary artery bypass surgery or having emergency coronary artery bypass surgery were excluded from the analysis. Patients who died were also excluded from the data analysis.

Cost analysis

The costs for the utilization of the CSA were determined by taking the cost of the disposable materials used. Professional fees were excluded as the personnel required (perfusionists) were required to be present for the surgical procedure. Fixed costs for the routine blood grouping and provision of cross-matched blood for all patients were provided by the Red Cross. Costs for transfusion of a single unit of packed cells including disposables were provided by the Hematology Laboratory. Amortization estimates were based on the approximate purchase cost of the equipment amortized over five years.

Statistical methodology

T tests with Bonferroni correction, or a one-way analysis of variance with Scheffe's *post hoc* analysis determined the difference ($P < 0.05$) among groups for continuous data while a Chi-square test was utilized for categorical data.

TABLE I Comparison of transfusion requirements in two groups of patients having coronary artery bypass graft surgery. Group 1 ($n = 99$) received blood processed using a cell saver apparatus (CSA) intraoperatively and autologous blood products as necessary. Group 2 ($n = 56$) received only autologous blood products. (All results mean $\pm$ SD)

	Group 1	Group 2
Sex (M/F)	77/22	43/13
Age (yr)	62 $\pm$ 9	61 $\pm$ 9
BSA (m ²)	1.91 $\pm$ 0.28	1.99 $\pm$ 0.20*
Operative time (min)	252 $\pm$ 53	214 $\pm$ 43*
Time on CPB (min)	101 $\pm$ 34	82 $\pm$ 18*
First HCT (%)	39 $\pm$ 5	39 $\pm$ 4
Last OR HCT (%)	26 $\pm$ 4	25 $\pm$ 3*
CSA units received	3.8 $\pm$ 1.3	0*
Units red cells in first 24 hr	0.5 $\pm$ 1.0	1.3 $\pm$ 1.8*
Total units autologous blood products received	3.3 $\pm$ 7.3	4.0 $\pm$ 8.6
Hospital days	12.5 $\pm$ 6.9	9.3 $\pm$ 3.4*

* $P < 0.05$ vs Group 1.

Results

For the two-month period 230 patients underwent cardiopulmonary bypass. Of the total population, 155 patients underwent elective coronary artery bypass graft surgery (CABG) and met the criteria for inclusion in this study (Table I). Two groups were identified based on the use of the CSA apparatus. Group 1 ($n = 99$) received red blood cells processed intraoperatively utilizing the CSA and such other homologous blood products as were deemed necessary. Group 2 ($n = 56$) received only homologous blood. Forty-five patients in Group 1 and eight patients in Group 2 received no autologous blood products ($P < 0.05$). Seven patients from Group 1 and one patient from Group 2 required more than ten units of blood products in the first 24 hours following surgery ($P = \text{NSD}$).

Based on these initial observations, patients having revascularization procedures but whose duration of hospitalization was less than 15 days were examined. Our

rationale was that hospitalizations beyond 15 days did not reflect the usual course of uncomplicated coronary artery revascularization, and represented some complication such as respiratory failure, intraoperative myocardial infarction with resultant heart failure, or sepsis. This would adversely bias the results against the CSA group since there was only one opportunity to utilize the CSA (during surgery) whereas, with prolonged hospitalization, there was increased incidence of phlebotomy and subsequent requirements for autologous blood products.

When examined in this fashion, 134 patients in three distinct groups were identified based upon their transfusion requirements. Group 1 (no Hemonetics®) (Table II) consisted of 54 patients in whom there was no use of the CSA. Group 2 (Hemonetics®, $n = 47$) were transfused with autologous blood only scavenged from the operative field and cardiectomy reservoir utilizing the CSA. Group 3 (PC + Hemonetics®, $n = 33$) received both homologous and autologous blood products during the course of their operative procedure.

Patients in Group 2 (Hemonetics®) were younger than those in Group 3 (PC + Hemonetics®) ($P < 0.05$) (Table II). The group in which it was necessary to administer homologous blood in addition to utilizing the cell-saver apparatus had significantly more females (Group 3 – PC + Hemonetics®), a lower body surface area, and their initial haematocrit values were significantly lower than the other two groups. However, when the mean pooled number of exposures to homologous blood products was compared for a sex difference, none was found (4.0 ± 4.1 vs 3.5 ± 2.9 units, males vs females, $P > 0.05$). There was an over-representation of males in the group in which the CSA alone was used and their initial haematocrits were higher than the other two groups (Table II, Figure). There were no differences among the groups with respect to the number of vessels grafted. Patients in whom the cell-saver apparatus was not utilized (Group 1 – no Hemonetics®) had a significantly shorter duration of

TABLE II Patient demographics in a subpopulation of patients having coronary artery bypass graft surgery whose duration of hospitalisation was less than 15 days. (All results mean $\pm$ SD)

	No Hemonetics	Hemonetics	PC + Hemonetics
Number of patients	54	47	33
Age (yr)	61 $\pm$ 9	59 $\pm$ 10*	64 $\pm$ 8
Male/female	41/13	44/3†	17/16†
Body surface area (m ²)	1.99 $\pm$ 0.20*	1.99 $\pm$ 0.19*	1.83 $\pm$ 0.18
Grafts (n)	3.6 $\pm$ 1.3	3.1 $\pm$ 1.1	3.2 $\pm$ 1.0
First hematocrit (%)	39 $\pm$ 4*	41 $\pm$ 5*†	37 $\pm$ 3
Duration of CPB (min)	82 $\pm$ 18	98 $\pm$ 33†	103 $\pm$ 26†
Operative time (min)	213 $\pm$ 43	244 $\pm$ 48†	251 $\pm$ 52†
Total hospital days	8.8 $\pm$ 1.7	9.7 $\pm$ 2.1	10.2 $\pm$ 1.9†

* $P < 0.05$ vs PC + Hemonetics.

† $P < 0.05$ vs No Hemonetics.

FIGURE Change in haematocrit in three groups of patients having uncomplicated coronary artery bypass graft surgery. The no Hemonetics® group received homologous blood products only; the Hemonetics® group received only autologous blood; and the PC + Hemonetics® group received both autologous and homologous blood products. The PC + Hemonetics® group consisted of more females, had a lower mean body surface area, a lower initial haematocrit and received twice as many blood products as either of the other two groups.

cardiopulmonary bypass, operative time, and total duration of hospitalization.

Comparison of the group receiving only homologous blood (Group 1 – no Hemonetics®) with the group receiving only autologous blood products (Group 2 – Hemonetics®) during the operative procedure revealed that use of the CSA resulted in fewer subsequent donor exposures (3.7 ± 8.3 vs 0.6 ± 1.8 units, $P < 0.05$, Table III). This difference persisted when the data were corrected for one patient in the no Hemonetics group who had a postoperative bleeding episode (2.6 ± 1.9 vs 0.6 ± 1.8 units). No patient in whom the cell saver device alone was

used had any postoperative bleeding complications. In the two groups receiving blood scavenged and transfused using the CSA, the number of units scavenged during the operative procedure did not differ (3.6 ± 1.2 vs 3.8 ± 1.4 units, Table III). Nearly all transfusion requirements were met within the first 24 hr following initiation of surgery (Table III).

The cost of the disposable parts for use of the Hemonetics® CSA was \$150. The cross-match fee was \$48.70 (common for all patients irrespective of transfusion requirements). The fee for each unit of cross-matched packed cells provided was \$54.10.

Discussion

The major finding from this retrospective analysis of transfusion requirements in patients having CABG surgery is of a reduced requirement for homologous blood products during the first 24 hr following surgery when a cell saver apparatus (CSA) is employed (0.5 (Group 1; CSA + homologous blood) vs 1.3 units (Group 2; homologous blood only); $P < 0.05$, Table I). Use of the CSA was not associated with an increased risk of bleeding. Significantly more patients in whom the CSA was employed had no additional requirements for homologous blood ($45/99$, Group 1 vs $8/56$, Group 2; $P < 0.05$). However, use of the CSA was associated with an increased duration of cardiopulmonary bypass (101 vs 82 min; $P < 0.05$), operative time (252 vs 214 min; $P < 0.05$) and duration of hospitalization (12.5 vs 9.3 days; $P < 0.05$).

Similar results were found when a subgroup of patients whose duration of hospitalization was less than 15 days was examined (Tables II, III). Although an arbitrary cut-off point, we reasoned that duration of hospitalization of greater than 15 days reflected a complication of surgery, e.g., respiratory failure, perioperative myocardi-

TABLE III Blood donor exposure in three subgroups of patients having coronary artery graft surgery whose duration of hospitalization was less than 15 days

	No Hemonetics®	Hemonetics®	PC + Hemonetics
During OR	$1.2 \pm 1.4^{*†}$	0 ± 0	$2.5 \pm 3.0^{*}$
First 24 hr	2.2 ± 7.8	0.2 ± 0.7	0.7 ± 1.3
25–72 hr	0.2 ± 0.6	0.3 ± 1.5	0.1 ± 0.4
4–10 days	0.1 ± 0.3	0.0 ± 0.1	0.1 ± 0.3
Total donor Exposure	$3.7 \pm 8.3^{*}$ ($2.6 \pm 1.9^{*†}$)	0.6 ± 1.8	3.7 ± 3.5
Total no. autologous units	0	$3.6 \pm 1.2^{\ddagger}$	$3.8 \pm 1.4^{\ddagger}$

(All results mean $\pm$ SD)

[†]Values excluding those for one patient with a postoperative bleeding episode.

* $P < 0.05$ vs Hemonetics®.

[†] $P < 0.05$ vs PC + Hemonetics®.

[‡] $P < 0.05$ vs No Hemonetics®.

al infarction, sepsis. Examination of the results in Tables I and III indicate that the majority of transfusions occur within the first 24 hr postoperatively and utilization of the CSA has its greatest impact on transfusion requirements within that period of time, irrespective of whether a complication subsequently develops or not. Use of the CSA significantly reduced the total transfusion requirements for a group of patients characterised as predominantly males with a large body surface area and an initial haematocrit of greater than 41 per cent (Table II, Hemonetics® group). In addition, for a group of patients characterised by a larger proportion of females with a small body surface area and initial haematocrit of 37 per cent (PC + Hemonetics®), use of the CSA reduced the total transfusion requirements to a level comparable with the no Hemonetics® group, even though the intraoperative requirements for homologous blood were twice that of the no Hemonetics® group (Table III).

Kaplan *et al.*⁹ reported in 1977 that the average amount of blood transfused at this institution for patients having cardiac surgery was reduced by utilizing autologous blood withdrawn prior to surgery. At that time the average amount of blood transfused to their patients (75 per cent of whom had coronary artery bypass surgery) was 2300 ml (compared with approximately 1000 ml in the present study (Table I)). However, acute preoperative phlebotomy is limited in scope due to the development of myocardial ischaemia secondary to anaemia with a reduced oxygen carrying capacity. The reduced amounts of blood transfused in the present study (Table I, Group 2) when compared with the previous study likely reflect the changing attitudes among physicians about the hazards of homologous blood transfusions. Use of the CSA was associated with a further reduction in transfusion requirements (Table I, Group 1).

With respect to complications due to use of the CSA, utilization of the CSA during the study period was not associated with episodes of air embolism or excessive postoperative bleeding. Whether infection due to utilization of the CSA might be responsible for complications leading to a prolonged hospitalization (Table I) could not be evaluated in this report but has been examined prospectively. In that study, use of the CSA did not lead to an increased incidence of infection.¹⁹ Although seven patients in whom the CSA device was employed had a requirement for greater than ten blood products in the first 24 hr (vs one in the group in which the CSA was not employed), this difference was not statistically significant nor were the overall transfusion requirements higher in the CSA group suggesting that increased bleeding is not a feature of use of the CSA. Indeed, more patients in the CSA group received no homologous transfusions in the first 24 hr following surgery (45/99 vs 8/56). Bleeding

was a complication in 2/21 patients with a prolonged hospital stay (i.e., greater than 15 days) in whom the CSA was employed. In one case a coagulopathy developed during the course of a prolonged surgical procedure with difficulty terminating CPB. In the second case, the patient returned to the operating room for surgical bleeding. In neither case, therefore, is it likely that use of the CSA was responsible for the increased requirements for homologous blood products.

In this study, 93 per cent of the blood products transfused were initiated by an anaesthetist. While surgical preferences for transfusion of blood products may have played a role in the decision to use the CSA device, the fact that only seven per cent of the transfusions were initiated by non-anaesthetists suggests that CSA use did not play a major role in the overall decision to initiate transfusions. Such decisions were more likely based on haematocrit values determined perioperatively.

The cost of the provision of autologous blood scavenging and retransfusion utilizing the CSA must also be considered. Excluding the initial capital and professional fees associated with use of the device, the cost of the disposable apparatus is approximately \$150. The cost of transfusing one unit of packed cells is \$54. Since utilization of the CSA results in a savings of approximately three units of homologous blood, there is no increased cost for the use of autologous blood. The amortization fees for the equipment are extra, approximately \$9500 p.a. for five years, and add to the cost of the procedure. However, the savings associated with the prevention of transfusion-associated accidents and infection must also be considered. Currently, there is little information about these benefits but the potential savings could be very large.

In conclusion, this retrospective study has demonstrated that the intraoperative scavenging of blood during cardiac surgery utilizing the Hemonetics® cell-saver device resulted in a reduction in transfusion requirements for homologous blood products from 1.3 ± 1.8 to 0.5 ± 1.0 units within the first 24 hr. More patients in whom the device was employed received no additional homologous blood products. There was no increased risk of postoperative bleeding and no major complications associated with its use were identified. Utilization of the device was cost-effective if the capital costs of the equipment are excluded. Prospective studies designed to assess further the risks of complications such as infection and the prevention of transfusion-related incidents and blood-borne infection seem warranted.

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