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The use of cell saver system in cardiac surgery with cardiopulmonary bypass

O uso de recuperador de sangue em cirurgia cardíaca com circulação extracorpórea

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Abstract

Introduction: **The use of cell saver (CS) in cardiac surgery is proposed to reduce the use of units of packed red blood cells stored (UPRBC), which increases morbidity, mortality and causes inflammatory reactions.**

Objective: **The objective is to evaluate whether the use of CS decreases the use UPRBC, is cost / effective and beneficial to the patient.**

Methods: **In a prospective study, between November 2009 and October 2011, 100 consecutive patients who underwent cardiovascular surgery with CPB, hemodilution and hemofiltration, were enrolled. Patients were divided into group 1 (no CS) and 2 (CS). The criteria for the replacement of RBC were hemodynamic instability and hemoglobin (Hb) <7-8g/dl. Demographic data, as well as Hb and hematocrit, mediastinal drainage, number of URBC and CPB, ICU and hospital time, were analysed.**

Results: **In groups 1 and 2 the average age was 64.1 and 60.6 years; predominantly male; the logistic EuroSCORE 10.3 and 9.4; mortality 2% and 4%. Group 2 had a higher incidence of reoperations (12% *versus* 6%), but the average of UPRBC used (4.31 *versus* 1.25) and mean length of hospital stay (10.8 *versus* 7.4 days) was lower. Univariate and multivariate analysis, were performed, which showed no statistically significant values, except in the use of UPRBC. The relationship between the CS and the cost of RBC was not cost / effective and length of stay was shorter.**

Conclusion: **The use of CS decreases the number of used UPRBC, is not cost / effective but has shown benefits for patients.**

Descriptors: **Operative blood salvage. Blood component transfusion. Cell separation.**

Resumo

Introdução: **O uso de recuperador de sangue (RS) em cirurgia cardíaca é proposto para diminuir o uso de unidades de concentrado de hemácias estocadas (UCH), que aumenta morbidade, mortalidade e reações inflamatórias.**

Objetivo: **O objetivo deste estudo é avaliar se o uso do RS diminui o emprego de UCH, é custo/efetivo e traz benefícios ao paciente.**

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Abbreviations, Acronyms & Symbols	
ANS	National Agency of Supplemental Health
CPB	Cardiopulmonary bypass
CABG	Coronary artery bypass grafting
Hb	Hemoglobin
Ht	Hematocrit
BMI	Body mass index
PO	Postoperative
BSA	Body surface area
UPRBC	Units of store packed red blood cells
ICU	Intensive care unit

Métodos: **Estudo prospectivo realizado entre novembro de 2009 e outubro de 2011, em 100 pacientes consecutivos, submetidos à cirurgia cardiovascular com circulação extracorpórea (CEC), hemodiluição mínima e hemofiltração. Os pacientes foram divididos em grupo 1 (sem RS) e 2 (com RS). Os critérios para a reposição de UCH foram instabilidade hemodinâmica e hemoglobina (Hb) <7-8g/dl. Foram analisados dados demográficos, Hb, hematócrito (Ht), drenagem mediastinal e reposição de UCH, em diversos intervalos, e tempos de CEC, UTI e hospital.**

Resultados: **Nos grupos 1 e 2, a idade média foi de 64,2 e 60,6 anos, com predominância do sexo masculino, o EuroSCORE logístico de 10,3 e 9,6 e a mortalidade de 2% e 4%, não relacionada ao estudo. O grupo 2 apresentou incidência de reoperações superior (12 x 6%), mas o número de UCH usado (4,31x1,25) e o tempo de internamento hospitalar (10,8x7,4) foram menores. Realizada análise uni e multivariada, que não demonstrou valores estatisticamente significativos, exceto no uso de UCH. A relação entre o custo do RS e das UCH foi custo/efetiva e o tempo de internamento, menor.**

Conclusão: **O uso de RS diminui o número de UCH usadas, não é custo/efetivo e mostrou benefícios ao paciente.**

Descritores: **Recuperação de sangue operatório. Transfusão de componentes sanguíneos. Separação celular.**

INTRODUCTION

Several methods have been used to decrease the use of homologous blood with the progress and increased knowledge of the pathophysiology of cardiopulmonary bypass. This has been a path, with the highest incidence of use in patients for religious reasons and those who do not wish to make use of units of stored packed red blood cells (UPRBC). The use of this strategy varies from services to services in different continents, between 15% and 60% [1].

In recent years, efforts have been made to decrease more and more the use of homologous blood, with recovery of autologous blood during surgery and sometimes even in the postoperative period [2], along with a more hemostasis strict protocols throughout the surgical procedures. Cell savers machines (CS) have been used [3] in adult patients with high risk of bleeding, due to the fact that they decrease the inflammatory response to cardiopulmonary bypass. The Society of Thoracic Surgeons and the Society of Cardiovascular Anesthesiologists [4], in its guidelines for 2007, considered as class I the use of CS. However, several authors have shown that the use of CS is not as beneficial as stated [5,6] and is not cost-effective [7-9].

In order to clarify this issue, the authors devised this work, which aims to verify that the primary use of CS in cardiovascular surgery with cardiopulmonary bypass (CPB), is cost-effective. As a secondary objective, we sought to identify a reduction in the use of units of UPRBC in patients who used CS, and morbidity resulting from the use of this protocol.

METHODS

This is a non-randomized prospective cohort study that was held at the Institute of Cardiovascular Surgery of Paraná, in a group of 100 consecutive patients operated on by the same surgeon (RMSA) from November 2009 to October 2011 .

All patients undergoing cardiovascular surgery with CPB were included, without any established exclusion criteria. The patients were divided into two groups of 50 patients: Group A - without using CS, Group B - with

the use of CS. Both groups made use of the CPB, partial hemodilution and hemofiltration. The criterion for the use of UPRBC was hemoglobin (Hb) below 7 or 8 g/100 ml, with hemodynamic instability. The number of units of plasma, platelets and cryoprecipitate used was not taken into consideration, for not being the objective of this study.

All patients underwent induction of anesthesia with the use of midazolam and remifentanil and its maintenance was carried out with servoflurano. After median sternotomy and manufacturing of cannulation pouches, the patients were heparinized with a dose of 300 U / kg in order to obtain activated clotting time exceeding 400 seconds; controls were performed every 60 minutes. In all cases, an adult membrane oxygenator was used (Braile Biomedica®, São José do Rio Preto, SP, Brazil) with a total of 500 ml filling volume. Blood and antegrade infusions were used. In Group B, the CS used was autolog Autotransfusion System (Medtronic, Minnesota, USA), throughout the surgery, with the CPB blood being pumped and processed by the CS system at the end of the surgery. Hb and hematocrit (Ht) were obtained on the day of hospital admission, upon arrival to the intensive care unit (ICU), on the first postoperative day and on the day of discharge, the volume aspirated and infused by CS were also recorded, as well as Hb and Ht of infused blood. The number of UPRBC used was recorded. The package prices of disposables CS and UPRBC were obtained for the purchase by a company belonging to the National Health Agency (ANS). At current prices, UPRBC was R$ 400.00 and the package of disposable CS was R$ 1,650.00. The study was approved by Assis Gurgacz Ethics Committee under the protocol number 154/2012.

The continuous variables are statistically represented by their mean and standard deviation and median. Student's t-test, Mann Whitney test and Fisher's exact test were used to analyze the variables in this study. We used statistics for the variables in the preoperative period (age, gender, weight, type of surgery, CPB and aortic clamping time and packed cell volume), to verify whether the sample of the two groups was comparable or not.

RESULTS

The patients' ages ranged from 26 to 84 years old, and the average age of patients in Group A was 64.15 ± 9.99 years and 60.55 ± 12.01 in Group B. There was a predominance of males in both groups. The demographic data are shown in Table 1.

In Group A, 60% of patients underwent coronary artery bypass grafting, while in Group B 68%; the logistic EuroSCORE was similar in both groups, as well as the additive EuroSCORE, by subgroups (Table 2). Age, weight, gender, type of surgery (in two subgroups with larger number of patients), CPB and aortic clamping time, and Hb and preoperative PCV were statistically analyzed to see if the two groups were comparable. There was no statistical difference between the two groups except in the variable weight (Table 3). Two patients in Group B were reoperations (4%), and a fifth surgery, and one in Group A (2%). The CPB, aortic clamping time and the various stages of hospitalization are shown in Table 4. The incidence of reoperation for bleeding was 6% in Group A and 12% in Group B.

Table 1. Both groups clinical characteristics.

			Group A	Group B
	Age	Mean ±	64.15 ± 9.99	60.55 ± 12.01
		Median SD	65	63
	Gender	Male	56%	84%
EuroSCORE	Additive	0 a 2	9	10
		2 a 5	19	21
		> 5	22	19
		Logistic	10.28	9.55
	Weight	kg	75.61 ± 14.85	78.36 ± 16.59
	Height	cm	166.31 ± 9.35	169. 92 ± 8.48
	Body Surface	cm^2	185.86 ± 23.75	187.48 ± 20.02
	Body Index Mass		27.25 ± 3.86	26.72 ± 4.26
	CPB	min	73.06 ± 20.97	66.62 ± 15.69
	Aortic clamping time	min	38.70 ± 13.91	37.43 ± 9.73

Table 2. Type of surgery.

	Group A	Arterial Graft	APS	Metal Prosthesis	Biological Prosthesis	Group B	Arterial Graft	APS	Metal Prosthesis
CABG	30	34	67			34	43	71	
Associated CABG									
Aortic Valve Replacement						3	3	4	
Mitral Valve Replacement	1	1			1	1		1	1
Aortic Valve Plasty	1	1	2						
Mitral Valve Plasty	2	2	4						
Ascending Aortic Aneurysm						1		2	
Myxoma	2		4			5			2
LV Aneurysm	1	1							
Aortic Valve Replacement	4			1	3	3			2
Mitral Valve Replacement	3				3	1			
Aortic Valve Plasty	1								
Mitral Valve Plasty									
Ascend. Aor. Aneur.	2			1	1	1			
Mixoma						1			
Atrial Septal Defect	2								
Ventricular Septal Defect	1								

Table 3. Table of comparative variables.

Variables	With Cell Saver (n=50)	Without Cell Saver (n=50)	*P*-Value
Age(years)	63.72±12.21	60.56±9.90	*P*=0.1587
Weight(Kg)	79.58±16.43	76.10±15.04	*P*=0.2722
Male/Female	38/12	27/23	*P*=0.0233
Type of Surgery			
(Aortic/non-aortic)	6/44	9/41	*P*=0.4195
(Coronary x non-coronary)	41/9	36/14	*P*=0.2476
CPB time (minutes)	67.10±20.05	73.10±21.23	*P*=0.1517
Clamping time (minutes)	38.28±13.82	38.36±13.82	*P*=0.9787
Preoperative Hb	13.70±3.67	12.80±1.69	*P*=0.1397
Preoperative PCV (%)	41.10	38.40	*P*=0.1397

The hospital mortality was 2% in group A (patient who underwent CABG with mitral valve replacement for multiple organ failure), and 4% in group B (patient who undewent CABG with aortic valve replacement and porcelain aorta due to cerebrovscular accident, and patient with CABG with ventricular septal defect because of multiple organ failure). No deaths occurred during the follow-up period. The daily bleeding during postoperative days, and the use of UPRBC are shown in Table 3. The mean total volume of aspirated fluid was 1657.00 ± 2309.65 ml, in which 474.58 ± 160.66 ml were used for infusion, with a mean Hb and Ht of 18.58 ± 4.51 g/100 ml and 52.31 ± 11.28%, respectively.

Bleeding average was 642.51 ± 193.30 ml in group A, and 685.65 ± 210.36 mL in Group B. Body surface area (BSA) and body mass index (BMI) were, respectively, 3.46 and 3.66 ml/cm^2 and 23.58 and 25.66 ml/cm^2 in Groups A and B, with no significant difference. A total of 194 UPRBC was used for Group A and 62 in Group B. The average use of RBC in Group A was 2.42 ± 1.37, and 0.70 ± 0.93 in Group B. On 0° postoperative day, 123 and 29 UPRBC

Table 4. CPB, aortic clamping time e other times.

Time	CPB	min	73.06 ± 20.97	66.62 ± 15.69
	Aortic clamping time	min	38.70 ± 13.91	37.43 ± 9.73
Time	Preoperative	Mean ± SD	2.98 ± 2.86	2.37 ± 1.73
		Median	2	2
	ICU	Mean ± SD	4.24 ± 5.87	3.66 ± 5.36
		Median	2	2
	Postoperative	Mean ± SD	10.79 ± 14.70	7.43 ± 6.97
		Median	7	6
	Hospital Stay	Mean ± SD	13.77 ± 15.23	9.80 ± 7.33
		Median	9	8
1st Postoperative Period	Hb	g/100 ml	9.41 ± 1.09	9.85 ± 1.27
	Ht	%	28.27 ± 5.33	29.64 ± 3.86
Hospital Discharge	Hb	g/100 ml	10.10 ± 1.32	9.48 ± 1.20
	Ht	%	30.41 ± 4.16	28.71 ± 3.65
Bleeding	0 Postoperative Period	ml	428.57 ± 214.10	443.20 ± 271.65
	1st Postoperative Period	ml	175.51 ± 134.64	231.84 ± 190.47
	2nd Postoperative Period	ml	25.67 ± 77.33	10.61 ± 64.19
	After	ml	12.77 ± 133.76	0.00 ± 0.00
	0 Postoperative Period			
uPRBC	1st Postoperative Period	n°	2.51 ± 1.20	0.58 ± 1.48
	2nd Postoperative Period	n°	1.05 ± 1.00	0.39 ± 0.92
	After	n°	0.37 ± 0.78	0.27 ± 0.63
		n°	0.38 ± 1.07	0.02 ± 0.14

Table 5. Table analysis of statistically significant variables.

Variables	With Cell Saver (n=50)	Without Cell Saver (n=50)	*P*-Value
Hb after CPB (g/dl)	10.55±1.80	10.29±1.48	*P*=0.4645
Hb in the 1° Postoperative Period (g/dl)	9.85±1.28	9.40±1.09	*P*=0.0846
Hb during Hospital Discharge (g/dl)	9.47±1.21	10.09±1.33	*P*=0.0247
Bleeding (ml)	443.2±274	431.6±216	*P*=0.8149
Transfusion (ml)	174±449	526±468	*P*=0.002

were used, on the 1st postoperative day, 42 and 19, on the 2nd postoperative day, 14 and 13, until hospital discharge 15 and 1 in Groups A and B, respectively (Table 3). All patients from Group A were infused with at least two UPRBC (2-13) during hospitalization, 28 patients in group B received no UPRBC, while the rest of them used 2.81.

In the analysis of variables between the two groups that were statistically significant, we observed that hemoglobin at hospital discharge and the number of UPRBC transfused were the only statistically significant differences (Table 5).

Regarding the cost, taking into account only the price of all UPRBC in Group A, and in Group B, the RBC added to the material cost of CS system, we can conclude that in the first group there was a cost / patient of R$ 1,552.00 and in the second one, R$ 1,946.00.

DISCUSSION

Studies have shown that the use of homologous blood in cardiovascular surgery increases not only mortality but also morbidity [10-12] The use of cell saver machines began in the 1970s, due to an increasing demand by patients not to use blood. These requests were prompted by a religious group, which did not allow the use of stored blood to be infused into their worshipers. According to the guidelines used by the National Health Service, the use of CS in

cardiovascular surgery with CPB, should be performed at the surgeon's discretion and can be cost-effective [13]. The main objective in using CS is to have the ability to decrease the use of UPRBC in patients and thereby reduce inflammatory reactions and morbimortality. This care must be taken simultaneously with perfect hemostasis in both initial dieresis and before synthesis in cardiovascular surgeries. In the early 1980s, some authors already had their opinion against the indiscriminate use of CS, because it would neither decrease the costs nor the necessity of homologous blood [14]. However, several studies have shown advantages in the use of CS, as an increase in hemoglobin concentration and less time in ICU [15], less use of UPRBC, as long as the blood lost during surgery be reused [16], and poor results with low Ht in postoperative period of cardiovascular surgery [17]. Data from this study show shorter hospitalization time in ICU, one day less and less use of UPRBC during the hospital stay. There was no difference regarding postoperative complications between the two groups, since they were not related to the use of RBC, but the underlying disease and its treatment methods.

A major difference in this study in relation to Reyes et al. [18], one of the last articles published in the literature, is that they considered consecutive patients, without any exclusion (real life study), and on the other, the authors excluded patients with: concomitant surgeries, aortic surgery, reoperations, emergencies, high levels of creatinine, and patients with anemia BS<1.6 m^2, as well as patients with a EuroSCORE> 10% and high risk of bleeding. This study showed 21% of patients with a EuroSCORE above that percentage, and the group that made use of CS, 6% of patients were operated on duration while using clopidogrel and a patient was being subjected to a fourth reoperation (fifth procedure). Still comparing criteria, the combination of procedures performed in 90% of patients (6% in Group B), and 55.6% of them underwent surgical exploration for bleeding, which corresponds to 5% of the entire group.

Attaran et al. [19], in a group of 1871 patients using CS, obtained percentage of re-exploration for bleeding that varied with the type of surgery, similar to that shown previously. These authors also concluded that regular use of CS does not bring any benefit to the patient, and this decision should be made individually.

We can see that there was no economic advantage when comparing the cost of the amount of RBC used per patient in Group A, with the amount of disposable material of CS in Group B. The higher cost was observed in Group B, R$ 394.00 more. Several authors have also come to this conclusion [7- 9,11] and, therefore, its indication has been made for specific cases in which bleeding is above normal [10]. However, we must take into consideration that the group using CS, 28 patients did not have UPRBC infusionn infusion, the total of 1.25 RBC / patient / hospitalization, and in Group A, 4.31. Several authors have demonstrated that the non-use RBC in the postoperative period decreases not only the morbidity but also trans and postoperative mortality [4,5].

This device has the advantage of reducing the use of UPRBC in cardiac surgery, but only in selected cases, therefore, its benefits are not the same for all patients. More studies should be conducted so that we can have a response in relation to inflammatory markers and advantages of its use in daily practice.

CONCLUSION

This study demonstrated that the use of CS is not cost-effective, which decreased the number of UPRBC in the group using CS and there was no morbidity related to this protocol implementation.

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