

A multivariate analysis to assess the effect of packed red cell transfusion and the unit age of transfused red cells on postoperative complications in patients undergoing cardiac surgeries

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Abstract:

Background: Transfusion of blood components and age of transfused packed red cells (PRCs) are independent risk factors for morbidity and mortality in cardiac surgeries. **Materials and Methods:** We retrospectively examined data of patients undergoing cardiac surgery at our institute from January 1, 2012 to September 30, 2012. Details of transfusion (autologous and allogenic), postoperative length of stay (PLOS), postoperative complications were recorded along with other relevant details. The analysis was done in two stages, in the first both transfused and nontransfused individuals and in the second only transfused individuals were considered. Age of transfused red cells as a cause of morbidity was analyzed only in the second stage. **Results:** Of the 762 patients included in the study, 613 (80.4%) were males and 149 (19.6%) were females. Multivariate analysis revealed that factors like the number and age of transfused PRCs and age of the patient had significant bearing upon the morbidity. Morbidity was significantly higher in the patients transfused with allogenic PRCs when compared with the patients not receiving any transfusion irrespective of the age of transfused PRCs. Transfusion of PRC of over 21 days was associated with higher postoperative complications, but not with in-hospital mortality. **Conclusion:** In patients undergoing cardiac surgery, allogenic blood transfusion increases morbidity. The age of PRCs transfused has a significant bearing on morbidity, but not on in-hospital mortality. Blood transfusion services will therefore have to weigh the risks and benefits of providing blood older than 21 days in cardiac surgeries.

Key words:

Age of the packed red cell units, autologous transfusion, cardiac surgery, number of packed red cell units

Introduction

Transfusion of blood and blood components is a lifesaving intervention; however, it has been recognized that it may contribute to increased morbidity and mortality in patient populations, including critically ill, cardiac surgery, and trauma patients.^[1]

Storage of red blood cells (RBCs) results in a number of morphological and biochemical alterations, together described as the RBC storage lesions.^[2] These include a reduction in 2, 3-diphosphoglycerate, cell lysis, release of free hemoglobin (Hb), changes in nitric oxide levels, alterations in pH and increases in lipids, and cytokines. These changes are accompanied by increased membrane fragility, which can compromise microcirculatory flow and lead to increased red cell-endothelial cell interaction and inflammatory cytokine release.^[3] The clinical consequence of these storage lesions is a reduced

survival of RBC after transfusion, limiting the current storage of RBCs to 35 or 42 days, depending on the storage medium used. "Fresh blood" is a precious commodity, the provision of which produces a great burden on the inventory of any transfusion service. However, there are certain clinical conditions where clinicians prefer the use of fresh blood. These include conditions such as thalassemia, neonatal transfusions, exchange transfusions, and cardiac surgeries.

There are several reports in literature that suggest that transfusion increases the risk of serious complications and death in patients undergoing cardiac surgery.^[4-11] Transfusion of allogeneic blood (even leukoreduced)^[5] causes increased postoperative complications and mortality because of its immunomodulatory or proinflammatory (transfusion-related immunomodulation) effect^[6] on the host, possibly due to soluble mediators in the packed red cell (PRC) supernatant. There is increased incidence of complications like transfusion related

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acute lung injury in the allogeneic blood transfused individuals.^[7] At the same time, the risk of complications (renal, pulmonary, neurological, etc.) in cardiac surgeries is higher when the age of transfused blood is more.^[12] Thus, both number (dose) of the transfused PRCs^[9,10] as well as the age of transfused PRCs can cause complications.

The aim of this study was to determine whether transfusion of blood and blood components, both allogenic and autologous, and the age of transfused PRCs have an independent bearing upon morbidity and mortality in patients undergoing cardiac surgeries at our center.

Materials and Methods

We retrospectively accrued data from 937 patients who underwent the following cardiac surgeries: Coronary artery bypass graft with cardiopulmonary bypass (CABG-CPB, $n = 595$), redo CABG-CPB ($n = 4$), CABG-beating heart ($n = 10$), septal ($n = 19$), valvular ($n = 93$), redo valvular ($n = 6$), CABG + septal/valvular ($n = 35$) at the Indraprastha Apollo Hospitals, between January 1, 2012 and September 30, 2012.

Data were sourced from three sources

1. Our blood bank records for the details pertaining to the unit transfused to the patient viz. the date of the collection, date of transfusion, date of expiry, number of units of blood components that is, PRCs, fresh frozen plasma (FFPs), and random donor platelets (RDPs) transfused per patient (intra and postoperatively) and the number of autologous units collected, intraoperatively if any for acute normovolemic hemodilution.
2. The surgical notes for the type of cardiac surgery, whether planned or emergency and the surgical and anesthetic teams involved.
3. The discharge summaries of patients for demographic details, postoperative length of stay (PLOS), complications, deaths, and biochemical and pathological parameters.

Patients who underwent the above-mentioned cardiac surgeries successfully were included in the study. Patients with comorbid conditions (cirrhosis, chronic obstructive pulmonary disease, malignancy, coarctation of the aorta, and aortic aneurysm), those who underwent emergency surgeries, belonged to pediatric age groups, cases where adequate data were unavailable, death during the surgery were excluded from the study.

Data were categorized into age, and sex, type of surgery (procedure), surgical teams (including the anesthetists), type of transfusion (autologous/allogenic), component transfused, number of units transfused, unit age of red cells, PLOS and complications such as renal, pulmonary, neurological, and hepatic. PLOS is the duration for which the patient stays in the hospital postoperatively. For the purpose of this study, increased PLOS was defined as a hospital stay of more than 8 days. Serum creatinine >2 mg% or a rise of >0.7 mg% from the baseline values within 2 weeks of surgery or a need for dialysis were considered as indicators of renal dysfunction. Pulmonary complications considered were postoperative pneumonia, pleural effusion, increased dependence on ventilator (>3 days) or persistent chest tube drainage. Deranged liver function tests were indicators of hepatic complications,

whereas fresh neurological deficit or central nervous system infections were considered as neurological complications.

The PRC units issued were further categorized based on their dates of collection <7 days, 8-14 days, 15-21 days and >21 days old. Patients were categorized based on the age of the oldest unit transfused irrespective of the volume or age of the remaining transfused units, as even a single unit of long stored blood transfused can lead to adverse effects.^[3]

Statistical analysis

Data analysis was carried out in two stages [Figure 1]. Stage 1 included both transfused as well as nontransfused individuals. Univariate analysis of variance (ANOVA) was carried out making increased PLOS and complications as dependents on different variables such as age, gender, type of procedure, surgical teams, type of transfusion (autologous/allogenic), component transfused, and number of units transfused. Age of the PRCs unit was not considered as a factor for analysis in the Stage 1. All the factors found significant ($P < 0.05$) by the univariate ANOVA were further analyzed using the multivariate step-wise regression. Stage 2 included only the transfused individuals. In this stage, univariate ANOVA included age of the PRCs (as a continuous variable) for analysis. Rest of the steps was similar to that of Stage 1. Receiver operating characteristic (ROC) curve analysis was done keeping unit age of PRCs as a continuous variable. Odds ratio (OR) was calculated to decipher the increase in risk factor with the increase in the volume and unit age of the PRCs. During the analysis of OR, the unit age was divided into categories (said above).

Results

After consideration of the exclusion criteria, 175 of the total 937 patients were excluded from the study. Of the remaining 762 patients, 613 (80.4%) were males and 168 (19.6%) were females. They were all between 14 and 84 years of age with the mean age of 56.6 years.

One or more allogenic PRCs were transfused in 383 patients. All the PRC units were 3-4 log leukoreduced. The mean number of PRC units transfused was 2.66 units with the mean age of the unit being 13.2 days. The volume of each PRC unit was around

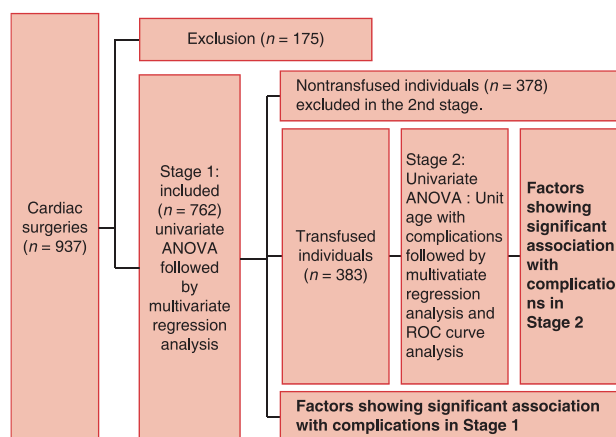


Figure 1: Two staged model of the analyses

260-290 ml. FFPs (200 ml each) were transfused in 240 patients with a mean of 2.67 units transfused per patient, and 133 patients were transfused with one or more RDPs with a mean of 4.23 units transfused per patient. One or more units of autologous blood were transfused in 129 patients. The PLOS ranged from 1 day (case of death) to 40 days with a mean PLOS of 8.1 days.

The pretransfusion Hb varied widely from 6.1 to 13 g% with a mean of 8.4 g% for PRC transfusion, from 0.9 to 6.9 with a mean INR of 1.9 for FFP transfusion and from 28,000 plt/ul to 320,000/ul with a mean of 110,000/ul for RDP transfusion. The upper ends (Hb = 13 g%, plt = 320,000/ul, INR = 0.9) of the ranges were seen in a total of 12 cases probably indicated on table complication.

The consumption of PRCs ranged from 0 to 16 units, with maximum blood being consumed for redo-CABGs ($n=4.9$) and minimum usage seen in CABG-beating heart ($n=0.7$) surgeries. The details of volume and age of PRC units transfused are provided in Table 1.

Pulmonary complications were the most frequent ($n = 60$) followed closely by renal complications ($n = 51$). Hepatic

complications were seen in 22 patients and neurological in 2 patients. More than 2 organ systems were involved in 29 patients and multiple organ dysfunction syndromes in 2 patients. There were in total 10 deaths during the in-hospital stay.

Univariate ANOVA in Stage 1 of the analysis [Table 2] showed age of the patient, number of PRCs, number of FFPs, number of RDPs had a significant association with both increased PLOS and complication. Rest of the factors (gender, type of procedure, surgical teams, and RDPs) didn't show significance with either of them. The significant factors were then put to multivariate stepwise regression [Table 3, Stage 1], which excluded RDPs. The number of PRC units, number of FFPs and age of the individual were the predictors of complications. There was a significant positive correlation ($P=0.003$, $r=0.720$) between the number of PRC units and number of FFPs transfused.

Increased PLOS and complications showed significant associations with each other in univariate ANOVA [Table 2]. Therefore, during further analyses only complications were used as a representative of morbidity.

Odds ratio analysis showed every unit of transfused PRC increases the risk of postoperative complications 2.9 times over the non transfused individual [Table 4]. When compared with individuals transfused with 1 unit of PRC, the risk of complications was not significant up to 4 units. A significant increase in risk was seen when 5 or greater units of PRCs were transfused to the patient [Table 4].

In the Stage 2 of the analysis, unit age of the PRCs was included. Univariate ANOVA showed that unit age was a significant factor in causing postoperative complications. It was put into multivariate stepwise regression along with the other significant factors [Table 3, Stage 2]. Multivariate stepwise regression showed that age of the unit PRCs transfused, number of PRC units transfused and age of the patient were predictors in the model while FFP and the RDP volume were not. There was no significant correlation (Pearson's $r = 0.033$, $P = 0.517$) between the number of PRC units and unit PRCs age, indicating that they acted independently, while causing complications.

Receiver operating characteristic curve analysis was done on the sample. In the model, number of PRCs and the age of the PRCs transfused predicted the occurrence of postoperative complications with 73.5 and 73.2% accuracy (area under the curve), respectively. Analysis of the coordinates of the curve revealed that the 20.5 days old units (sensitivity = 0.65, specificity = 0.63) and 4.5 units of PRCs (sensitivity = 0.7, specificity = 0.76) were reasonable cut-offs for the age and number of the PRCs transfused to the patients [Figure 2].

Table 1: Number and age distribution of PRC units transfused

PRC: Number of units	Number of patients transfused	Unit age wise	Number patients transfused
0	379	<7 days	86
1	116	8-14 days	216
2	104	15-21 days	61
3	66	22-28 days	6
4	52	29-35 days	8
5	18	36-42 days	6
6	18		
7 and above	9		

PRC: Packed red cell

Table 2: Stage 1 — Univariate ANOVA: PLOS and complications as dependent variables

Factors	PLOS significance	Complications significance
Surgeon	0.813	0.486
Age of the individual	0.000	0.003
Gender	0.696	0.055
Procedure type	0.182	0.164
PRC	0.000	0.000
FFP	0.000	0.000
RDP	0.000	0.000
Autologous blood	0.473	0.755
PLOS	—	0.000
Complication	0.000	—

PRC: Packed red cell; ANOVA: Analysis of variance; PLOS: Postoperative length of stay; FFP: Fresh frozen plasma; RDP: Random donor platelet

Table 3: Multivariate stepwise regression analysis - Stage 1 and 2

Stage	Steps	Predictors	Excluded variables	Significance
Stage 1	1	PRC	FFP, age of individual, RDP	0.000
	2	PRC, age of individual	FFP, RDP	0.000
	3	PRC, age of the individual, FFP	RDP	0.000
Stage 2	1	PRC	Unit age, FFP, age of individual, RDP	0.000
	2	PRC, age of the individual	FFP, unit age, RDP	0.000
	3	PRC, age of the individual unit age	FFP, RDP	0.000

PRC: Packed red cell; FFP: Fresh frozen plasma; RDP: Random donor platelet

Odds ratio analysis showed risk of the complications increased significantly when transfused with unit >21 days when compared with unit PRC <7 days old [Table 5].

The mortality during the hospital stay was 1.3% (n = 10). Compared to individuals transfused with units ≤21 days old, there was no significant rise in mortality in those transfused with units >21 days old (P = 0.42) [Table 6].

Table 4: OR analysis comparing the risk of complications between non transfused and patients transfused with 1 or more units (y compared with x)

x	y	OR	CI (95%)	P value
No transfusion	1 unit	2.92	1.68-5.08	0.000
1 unit	2 units	1.112	0.59-2.09	0.764
	3 units	1.371	0.6-2.78	0.394
	4 units	1.332	0.6-2.87	0.429
	5 units	4.3	1.3-1.37	0.003
	6 units	8.9	2.4-35.3	0.000
	7 units and above	∞	4.3-∞	0.000

PRCs: Packed red cells; OR: Odds ratio; CI: Confidence interval

Table 5: OR analysis: Risk of complications and the age of PRCs transfused (y compared with x)

x	y	OR	CI (95%)	P value
<7 days old PRCs	8-14 days	1.116	0.632-1.975	0.689
	15-21 days	1.24	0.627-2.792	0.421
	>21 days	2.62	0.894-8.068	0.04

PRCs: Packed red cells; OR: Odds ratio; CI: Confidence interval

Table 6: OR analysis of deaths versus age of PRCs transfused

Deaths	OR	CI (95%)	P value
Deaths in patient transfused with PRC unit age >21 days compared with <21 days	0.49	0.059-10.9	0.42

PRCs: Packed red cells; OR: Odds ratio; CI: Confidence interval

Discussion

Worldwide approximately 1,000,000 patients undergo cardiac surgery annually.^[13] Although several blood conservation strategies are now being employed, allogenic blood transfusions play a crucial role in these advanced surgical procedures. Patients undergoing cardiac surgeries consume a large proportion of RBC units, estimated at approximately 20% of the total blood supply.^[14] The transfusion rates for CABG show great variability between hospitals with a mean number of transfused units varying between 0.4 and 6.3 units per patient.^[15] The mean PRC consumption in our study was 2.66 units per patient depending upon the nature of surgery.

In the study of this kind where multiple factors (surgical complications, transfusion related complications, age and gender of the individual, etc.) play a role in the outcome of the surgery, it is difficult to arrive at a conclusion on the definitive role of a particular factor, only a statistical approximation in the form of multivariate analysis can be done. In this study, analysis was done with a two stage model. The first stage of the model gave an opportunity to analyze the risk of morbidity due to the transfusion of blood and blood components in comparison to no transfusion and other factors such as age, and gender, type of surgery (procedure), surgical teams on a larger number of individuals. In the first stage of the model, we could rule out the factors that could exclude surgical complications due to type of surgery (procedure) and surgical teams, gender, autologous blood and RDPs as the causes of complications. The second stage provided us to analyze the impact of unit age of PRCs alongside with other factors of significance. Thus, second stage helped us to analyze all factors related to cardiac surgery under one model of study.

Transfusion of allogenic PRCs in patients undergoing cardiac surgery is associated with increased risk of mortality and morbidity.^[4,16] Our study identified significantly higher risk of postoperative complications in allogenic PRC transfused patients

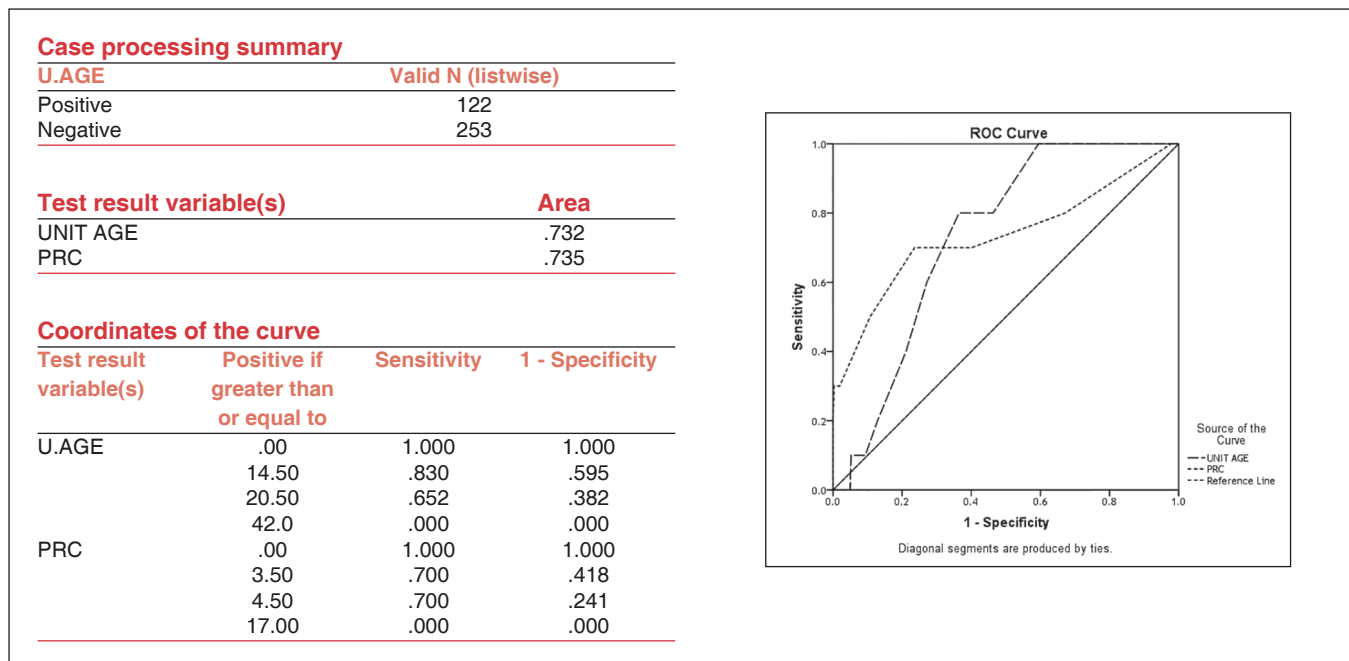


Figure 2: Receiver operating characteristic curve analysis

when compared with the non transfused patients. The risk of postoperative complications also increased with the increase in number of PRC units transfused. Risk was significant in individuals transfused with more than 4 units of PRCs. Both ROC curve and OR analysis emphasized this fact.

Fixing the cut-offs for continuous variables is always a trade-off between sensitivity and specificity. In our case, while fixing the age limit for PRC units we noticed that keeping high sensitivity and low specificity definitely benefit the patients, but at the cost of blood inventory. On the contrary, more specificity means the patient suffers at the benefit of inventory. We therefore fixed the cut-off as 21 days, which had reasonable sensitivity (65%) and specificity (62%).

We observed that transfusion of PRCs older than 21 days significantly increased risk of postoperative complications. As evident by the increasing OR, the postoperative complications tripled on transfusion of blood of over 21 days. As in our study, several authors have identified age of the transfused PRC units (some quote 14 days and some as 21 days) as an important factor contributing to morbidity and mortality.^[12,17] However, contradictory results were reported by McKenny *et al.*, who evaluated 1153 patients undergoing cardiac surgeries concluded that storage age of RBC transfusion up to 35 days was not associated with increased postoperative adverse outcome after cardiac surgery.^[18] These discrepancies among the studies may be due to the methodology of the analysis. For example, Koch *et al.*^[19] in their study noted that the units older than 14 days caused increased morbidity and mortality, which is a contrary result to our study. They studied the patient population, which was divided into two groups <14 days and >14 days. This strategy introduced the bias in the beginning itself. To fix a cut-off point, we have to analyze age of PRCs as a continuous variable. Once the cut-off point is fixed, based on it the impact has to be deciphered. Second, Koch *et al.* used exclusively <14 and >14 days old units transfused, which is impracticable in any observational set-up. This is because, most blood banks try to provide the freshest possible blood in cardiac surgeries and the provision of units is always a mixture of units of various ages (depending on their availability). In this study, we hypothesized that even a single old unit can cause harm if age of the unit was a cause of morbidity. Therefore, whatever is transfused to our patient population is a mixture of units of variable ages. Whether this causes a dilution effect or not is a matter of debate.

In this study, we found that there was no significant correlation between the number of PRC transfused and its age. Therefore, we could confidently state that they acted independently in causing complications.

Though, theoretically, any transfusion can cause increase in complications, we did not observe any significant increase in postoperative complications or PLOS in patients transfused with only autologous blood or platelets. This finding was noted in both the stages of our study. In a similar study Welsby *et al.* concluded that PLT storage age was not associated with infections, adverse short-term outcomes or decreased long-term survival after cardiac surgery.^[20] The number of FFP showed significant association with complication in the first stage, but failed to do so in the second. This may be due to the strong correlation of the FFPs volume with that of PRCs so that they moved together in the first stage and in

the second stage since non transfused individuals were removed from the model, its association with complications might have faded away. Further detailed studies are required to accept or reject this association. There are several other studies supporting our findings that platelet and FFP transfusions do not confer an increased risk of morbidity or mortality.^[21,22]

Although several studies^[8,10] have shown that age of the PRC transfused has a direct bearing on the long as well as short-term survival, we did not find a significant difference in the in-hospital mortality rates among patient's being transfused with older PRC units. However, transfusion of allogenic PRCs *per se* had a significant bearing on mortality when compared with non transfused individuals (OR = ∞, confidence interval [95%] = 1.87-∞, P = 0.002).

Our study however had certain limitations. First, we could not definitely determine the impact of the number of transfused FFPs on complications independently. Second, there was the lack of patient follow-up to assess long-term mortality. Since, the patients were followed-up only until the time of discharge from the hospital; the study was more or less a morbidity study. However, there were also certain strengths in our study. First, we could establish firmly that the number and age of the PRCs transfused have independent bearing on morbidity. Second, since the type of the procedure and surgical teams didn't show any significant association with the postoperative complications, the confounding caused because of intra-operation theater factors was eliminated.

In this study, the OR given are the univariate ones. They should be interpreted with caution. They can be used for comparative purposes rather than in absolute terms.

Conclusion

In patients undergoing cardiac surgery allogenic blood transfusion increases morbidity. The age of PRCs transfused has a significant bearing on morbidity, but not on in-hospital mortality. The number of PRC units transfused also has a significant bearing on morbidity. For transfusion purposes, use of blood ≤21 days is preferable in cardiac surgeries. In case of emergencies, however, >21 days old PRCs may be transfused since there is no significant rise in in-hospital mortality with the same as a lifesaving measure. Autologous transfusion is associated with least complications and should be practiced whenever possible. Further studies are required to enquire the role of FFPs in causing complications.

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