

Perioperative transfusions adversely affect post-operative outcomes in less than 18-year undergoing surgical repairs on cardiopulmonary bypass

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ABSTRACT


Background: Cardiopulmonary bypass (CPB) induced hemodilution and coagulopathies are important causes of perioperative bleeding following heart surgeries results both in pediatric and adult patients. However, this is more pronounced in children undergoing intracardiac repair procedures due to the weight (body mass) versus blood volume mismatch in children and inherently built-in requirement of the priming volume in the bypass circuit. **Objectives:** The objectives of the study were to observe and compare the impact of differing allogenic blood transfusion practices between the four groups of children under 18 years in the same institution. **Materials and Methods:** A total of 791 children (excluding neonates) underwent open-heart surgery in our institute by two different surgeons (A and B) during 2006–2012, each following different perioperative packed red blood cell (PRBC) or blood product transfusion protocols for their patients. Children were categorized into 2 equal and matched groups in terms of their numbers (in each category of similar type of surgery). Surgeon-A, operated all children in Group A ($n = 396$), received with hemoglobin (Hb) ≤ 7 g/dl further divided into Groups 1 and 2 while Group B ($n = 396$) operated equal numbers in empirical transfusion protocol was followed, received with Hb ≤ 10 g/dl further divided into Groups 3 and 4 based on transfusion received or not received. Restricted and targeted PRBC transfusion criteria were followed in all children. **Results:** Transfusion was required more often in critical and sick children and in those who have had longer CPB for complex repairs. 57.8% of children in Group B received either or both PRBC and blood product transfusion during its hospital stay. Logistic regression revealed that after adjusting the effect of their age, total chest, hospital stay, and ventilator time, had higher risk of mortality in the Group 1 (8.68, $P < 0.001$), Group 2 (1.38, $P = 0.458$), and Group 3 (5.17, $P < 0.001$) in contrast with Group 4 (no transfusion, Hb > 10 g/dl). **Conclusion:** PRBC or blood product transfusions in perioperative period adversely affect the post-operative outcomes; period of hospitalization, duration of recovery (morbidity), and survival (mortality) in children under 18 years.

KEY WORDS: Perioperative Bleeding; Hemodilution, Empirical; Restricted Blood Transfusion

INTRODUCTION

Pediatric patients are undergoing open-heart surgery using cardiopulmonary bypass (CPB) exhibit hemodilution,

hemolysis, and post-operative anemia at the termination of the CPB. This non-physiologic state of poor coagulability and hemodilution due to the low circulating blood volume in children is one of the primary factors that have made packed red blood cell (PRBC) or blood product transfusion after heart surgery in children more common.^[1] Blood transfusion has been the primary treatment since the early 1940s in treating postoperative coagulopathies and correcting anemia with the goal of limiting bleeding and improving oxygen-carrying capacity.^[2] However, it also carries a potential risk of infection and multiorgan failure irrespective of age,

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gender, disease-related, and type of surgery. Recently, it has been recognized as a risk factor for adverse outcomes (both morbidity and mortality) following cardiac surgeries.^[3,4]

These iatrogenic PRBC and blood product transfusions needs may also result in increased morbidity and mortality in children.^[3,4] Most children, who come to our institution, come late and in advanced heart failure or its sequelae and are often underweight, malnourished, and anemic. Perioperative blood or product transfusions are thus required in most patients going-by the customary practice of maintaining hemoglobin (Hb) levels and homeostasis for safe and satisfactory post-operative outcome.

The following study was aimed at the impact analysis of inevitable perioperative PRBC transfusion and a possible role of our interventional strategy to reduce its need, on the post-operative morbidity and mortality in children undergoing congenital heart surgeries using CPB.

Objectives

The objectives of the study were to observe and compare the impact of differing allogenic blood transfusion practices between the four groups of children under 18 years in the same institution.

MATERIALS AND METHODS

Study Population

This hospital based retrospective study was conducted at a tertiary care postgraduate teaching institute in Northern India. Surgical and perfusion related data were obtained from the institutional hospital information system database. Institutional ethical policies of observations were followed. The study included 792 children (<18 years) weighing between <5 and 30 kg who underwent open-heart surgeries between 2006 and 2012.

Patients in both the groups “were matched for their diagnosis and were operated by different surgeons, who followed nearly similar operative techniques and environment but different PRBC transfusion practices.

All children were divided into two equal groups. Children in Group A ($n = 396$) operated by Surgeon A, where $Hb \leq 7$ g/dl was used as trigger criteria for RBC transfusion. In contrast, an equal number of children ($n = 396$) in-Group B, operated by Surgeon B used $Hb \leq 10$ g/dl as the PRBC or blood product transfusion as the trigger.

Group A, further divided into Group 1 ($n = 33$, $Hb \leq 7$ g/dl was used as trigger criteria for RBC transfusion) and Group 2 ($n = 263$, $Hb > 7$ g/dl was not received RBC transfusion). Those 33 ($n = 33$) children in Group A, who required PRBC

transfusions during their hospital stay were classed as “crossover.”

Similarly, Group B was further divided in Group 3 ($n = 229$, $Hb \leq 10$ g/dl as received PRBC or blood product transfusion) and Group 4 ($n = 167$, $Hb > 10$ g/dl did not receive blood product transfusion).

These groups were compared and contrasted with each other in terms of adverse post-operative outcomes. The risk adjustment for congenital heart surgery (RACHS-1) method was created to refine the differences in the mortality among the children undergoing congenital heart surgery within pediatric population. These data included, gender, age at surgical repair, type of surgery, and the RACHS-1.^[5]

Types of surgeries were: Atrial septal defect ($n = 158$), ventricular septal defect ($n = 114$), tetralogy of Fallot ($n = 85$), total anomalous pulmonary venous connection ($n = 12$), right ventricular outflow tract RVOT reconstructions ($n = 5$), bidirectional BD-Glenn/Fontan ($n = 12$), and others ($n = 10$) [Table 1].

Technique

Surgeon A, who operated all 396 children (Group A) used retrograde autologous blood priming (RAP) of the pump circuit to reduce the impact of hemodilution. Surgeon B, (Group B), who operated an equal number of 396 children, in contrast, practiced bloodless priming. Both surgeons were used pH-stat blood gas management strategy during CPB.

All these children were operated through median sternotomy using CPB under high-flow (75–150 ml/kg/min) mild hypothermia (32°C) using intermittent cold blood cardioplegia (St. Thomas cardioplegia, 10 ml/kg) at every 20 min interval through aortic root along with topical cooling. After termination of the CPB, heparinization was neutralized by standard dosing schedules of protamine sulfate until the

Table 1: Distribution of surgery types (RACHS-1 category)

Type of surgery	Group A	Group B
ASD	158 (39.9)	158 (39.9)
VSD	114 (28.7)	114 (28.8)
TOF	85 (21.4)	85 (21.5)
TAPVC	12 (3.0)	12 (3.0)
RVOT reconstruction	5 (1.3)	5 (1.3)
BD Glenn/Fontan	12 (3.0)	12 (3.0)
Others	10 (2.5)	10 (2.5)
Total	396 (100.0)	396 (100.0)

RACHS-1: Risk adjustment for congenital heart surgery, ASD: Atrial septal defect, VSD: Ventricular septal defect, TOF: Tetralogy of Fallot, TAPVC: Total anomalous pulmonary venous connection, RVOT: Right ventricular outflow tract, BD: Bidirectional

activated coagulation time had normalized and the remaining heparinized blood in the CPB circuit was returned to the patient within the same operative day.

Measuring Units

Hb measurement was in grams per deciliter, CPB circuit prime volume in milliliters, total CPB time in minutes, body core temperature in °C, CPB circuit flow rate in milliliter/kilogram/minute, hospital stay in days, intensive care unit (ICU) stay in hours, and short-term hospital mortality in days.

Inclusion criteria

Children with congenital anomalies below 18 years were included in this study.

Exclusion criteria

The following criteria were excluded from the study:

1. Neonates
2. Infants below 5 kg
3. Emergency surgery and
4. Reoperation.

Statistical Analysis

Normality of the continuous variable was tested, and a variable was considered normal when standard deviation was below of half mean value. Normally distributed data were analyzed using One-Way ANOVA test to compare the means among the four groups while non-normal data by Kruskal–Wallis H test followed by multiple comparisons if the common $P < 0.05$. Independent samples *t*-test was used to compare the means between Groups A and B while for non-normal data, the distribution between the groups was compared using Mann–Whitney U-test. Two proportions Z-test/Chi-square test were used to compare the proportions between the groups as appropriate. To test the effect of the factors on the outcomes of the patients, binary logistic regression analysis was used. All the significant factors ($P < 0.05$) found in univariate analysis were included in multivariate analysis to compute adjusted odds ratio (AOR) and 95% confidence interval (CI). $P < 0.05$ has been considered as statistical significant. All the statistical analyses were performed using SPSS-23 software (Statistical package for the social sciences, IBM, Chicago, USA).

RESULT

The rate of PRBC or blood product transfusion as indicated by numbers who crossed over to either PRBC or blood product transfusion in the perioperative period was significantly lesser in Group A (33/396) when compared with Group B (229/396), (8.3% vs. 57.8%, $P < 0.001$, two proportions Z-test). Further based on PRBC or blood product transfusion given, we divided the Group A (Group 1 [≤ 7 g/dl]: Blood product transfusion given; $n = 33$ and Group 2 [> 7 g/dl]:

Blood product transfusion was not given; $n = 363$) and Group B (Group 3 [≤ 10 g/dl]: Blood product transfusion given; $n = 229$ and Group 4 [> 10 g/dl]: Blood product transfusion was not given; $n = 167$).

In 792 study patients, median age was 9 years with age range was 1 month–18 years. Kruskal–Wallis H test applied on patients' information's to compare the baseline data (age, total chest, ICU stay hours, and ventilator hours) among the four groups, was statistically significant ($P < 0.05$). Multiple comparisons showed that median age were different between Groups 2 and 3 as well as Groups 2 and 4 but not significant between rest groups. One-way ANOVA test used to compare the mean value of hospital stay, BMI, CPB time and blood loss during surgery, among four patient groups. Result showed that mean value of hospital stay, CPB time, and blood loss during surgery was statistically significant ($P < 0.05$) while BMI was not significant ($P > 0.05$). As most of the variable's values were significantly different between the groups, an indication that these variations might be influence the outcome of the patients [Table 2].

For total patients, highest proportion of casualty occurred in the Group 1 (60.6%) followed by Group 3 (34.8%), Group 2 (7.2%), and Group 4 (4.8%) ($P < 0.05$). Similar trend of proportions of death was observed in the patients those ventilator time was ≤ 30 h ($P < 0.05$) while in patients > 30 h in ventilators, proportions of death was almost same ($P > 0.05$). Overall in the Group A, proportion of death was lesser than Group B (11.6% vs. 21.9%, $P < 0.001$).

In total patients, patients with ≤ 30 ventilator hours have lesser proportion of death as compared to > 30 h (13.5% and 45.7%, $P < 0.05$) irrespective of their treatment groups. Similarly, highest proportions of sick, as well as infection rate, were observed in the Group 1 followed by Group 4, which was statistically significant ($P < 0.05$) [Table 3].

In Table 4, binary logistic regression analysis used to identify the factors for the outcome (dead/survive) of the patients. In the univariate analysis, variable's: Age, total chest, hospital stay, ventilator hours, groups, CPB time, sick, blood loss during surgery, and gender were found significant factors for the outcome ($P < 0.05$) while BMI, ICU stay time, and infection rate was not significantly associated with the outcomes ($P > 0.05$).

Out of 9 individual variables found significant in univariate analysis, 5 variables, namely: Age (AOR = 0.93, $P < 0.001$), total chest (AOR = 1.001, $P = 0.001$), hospital stay (AOR = 1.55, $P < 0.001$), > 30 h ventilator time (AOR = 2.29, $P = 0.006$), and patients groups as per transfusion criteria ($P < 0.001$) were significant in multivariate analysis which indicated that younger age, higher total chest, more time in hospital stay days, and > 30 h ventilator time were increasing risk in the patients. In the patient Group 1 (AOR = 8.68, $P < 0.001$)

Table 2: Distribution of demographic and clinical property in the patients groups

Variable's	Group A		Group B		P	Median (IQR)	Total Min-Max
	Transfusion (1)	No transfusion (2)	Transfusion (3)	No transfusion (4)			
	Median (IQR)	Median (IQR)	Median (IQR)	Median (IQR)			
Age (year's)	8 (1–15)	6 (2–13)	12 (4–15)	11 (3–15)	<0.001	9 (3–15)	0.1–18
Total chest	610 (560–670)	150 (71–290)	620 (580–680)	200 (100–370)	<0.001	314 (115–610)	2–3973
ICU stay	86 (78–104)	47 (28–82)	72 (44–92)	54 (40–90)	<0.001	65 (36–89)	2–288
Ventilator hours	6.3 (4.1–31.0)	4.4 (3.0–7.3)	6.0 (4.2–13.1)	5.3 (4.0–8.0)	<0.001	5.2 (3.4–9.0)	0.2–589
*Hospital stay	11.9±1.0	9.5±1.6	10.5±2.3	9.4±1.8	<0.001	9.9±1.9	1–16
*BMI	14.9±3.2	14.5±2.9	14.5±2.9	15.3±3.3	0.095	14.6±3.1	2–25
*CPB time	97.3±5.9	56.2±18.3	111.3±15.3	93.6±23.4	<0.001	81.7±30.5	34–234
*Blood loss during surgery	229±15	122±13	227±17	133±17	<0.001	159±50	100–250

*Data presented in mean±SD and one-way ANOVA test used to compare means. Data presented in median (Interquartile range) and Kruskal–Wallis H test used, $P < 0.05$ significant. CPB: Cardiopulmonary bypass, ICU: Intensive care unit, SD: Standard deviation

Table 3: Distribution of morbidity and mortality in the patient's groups

Variable's	Group A		Group B		P
	Transfusion (1)	No transfusion (2)	Transfusion (3)	No transfusion (4)	
	n=33 (%)	n=363 (%)	n=229 (%)	n=167 (%)	
Dead total (133/792)	20 (60.6)	26 (7.2)	79 (34.5)	8 (4.8)	<0.001
Dead as per ventilators hours					
≤30 h (96/711)	14 (58.3)	17 (4.9)	59 (32.8)	6 (3.7)	<0.001
>30 h (37/81)	6 (66.7)	9 (47.4)	20 (40.8)	2 (50.0)	0.565
Infection	12 (36.4)	0 (0.0)	25 (10.9)	0 (0.0)	<0.001
Sick	33 (100.0)	51 (14.0)	60 (26.2)	31 (18.6)	<0.001

*Chi-square test/Fisher exact test used, $P < 0.05$ significant

showing 8.7 times more risk as compared to Group 4. Similarly for the Group 2 (AOR = 1.38, $P > 0.005$) and Group 3 (AOR = 5.17, $P < 0.001$) had 1.38 and 5.17 times more risk as compared to Group 4 [Table 4].

DISCUSSION

The society of thoracic surgeons and society of cardiovascular anesthesiologists, blood conservative clinical practice (2011) guidelines were based on adult cardiac surgery patients and therefore, its application on pediatric population remains unclear.^[6]

Cardiac surgery remains one of the highest consumers of blood and blood products^[7] due to need for replacement of significant perioperative blood losses in children undergoing open heart repairs. Some of the several reasons, in these patients are;

1. Perioperative anemia caused due to the “extreme hemodilution” by the mandated use of CPB circuit priming in patients with smaller blood volume^[8]
2. Major post-operative blood losses caused by

coagulopathies with the use CPB with its own implications in the post-operative recovery.^[9]

It is a well-established fact that, blood transfusion itself can be a significant cause of mortality and morbidity in critically ill children undergoing pediatric cardiac surgery. Although “the immediate benefits” of blood and blood product transfusion are sometimes dramatic, they are known to cause and increase the long-term mortality.^[10]

Several methods are employed to balance these competing inevitable cause and effects with a single objective to achieve the best outcome for the patient. Whole blood and RAP of the CPB circuit are two commonly used techniques to limit perioperative anemia caused by hemodilution. Both the methods have their own limitations. On the one hand, whole blood priming of the CPB circuit may counter the intraoperative anemia but requires the use of banked blood. RAP method, on the other hand, is a technique that effectively limits perioperative hemodilution and reduces transfusion requirements.^[9] However, RAP may not be, always feasible in smaller, already anemic or children with unstable

Table 4: Predictors of the outcomes of the study patients

Variables	Univariate binary Logistic regression				Multivariate binary Logistic regression			
	OR	LL	UL	P	AOR	LL	UL	P
Age	0.97	0.94	1.00	0.048	0.93	0.90	0.97	<0.001
Total chest	1.002	1.001	1.002	<0.001	1.001	1.000	1.002	0.001
Hospital stay	1.76	1.56	1.99	<0.001	1.55	1.36	1.77	<0.001
Ventilator hours (>30 h)	5.39	3.31	8.77	<0.001	2.29	1.27	4.14	0.006
Group				<0.001				<0.001
Group1 (≤ 7)_T	30.57	11.29	82.78	<0.001	8.68	3.01	25.04	<0.001
Group 2 (>7)_NT	1.53	0.68	3.46	0.304	1.38	0.59	3.23	0.458
Group 3 (≤ 10)_T	10.47	4.89	22.40	<0.001	5.17	2.30	11.66	<0.001
Group 4 (>10)_NT	Ref.				Ref.			
CPB time (>90)	4.39	2.75	7.01	<0.001	-	-	-	-
*Blood loss during surgery	1.019	1.015	1.023	<0.001	-	-	-	-
Sick	2.57	1.72	3.84	<0.001	-	-	-	-
Male sex	1.7	1.1	2.6	0.024	-	-	-	-
BMI	0.96	0.89	1.03	0.217	-	-	-	-
ICU stay	1.003	1.000	1.007	0.054	-	-	-	-
Infection	1.90	0.90	4.03	0.093	-	-	-	-

All the significant ($P < 0.05$) variables of univariate analysis included multivariate analysis. In the final model, 5 variables came out as statistically significant. AOR: Adjusted odds ratio, OR: Odds ratio

hemodynamics. Whole blood priming was not used in both the groups. Clear prime was used in all (396/396, 100%) patients in Group A in contrast, wherever feasible RAP was employed in Group A patients. Although several factors can influence post-operative transfusion need, use of RAP (289/396, 72.97%) in Group A and clear prime in all (396/396, 100%) Group B patients must have had a clear impact on the post-operative transfusion rate and thus outcome parameters. This is evident by the marked difference in rate of transfusions in Group B patients, (229/396, 57.8%) compared with Group A (33/396, 8.3%). Surgeon B did not practice and therefore no patient in Group B were subjected to RAP. This difference should have an important implication on the post-operative anemia and thus blood transfusion requirements in both the groups ultimately affecting the difference in the mortality risk (OR) and post-operative morbidity.

Post-operative transfusions in cardiac surgery are often based on clinical judgment rather than objective data.^[10] This was one of the most important criteria in the creation of two groups in this observation to study the impact on the post-operative outcomes. Transfusion need was continuously evaluated in all 396 patients in Group A based on the defined trigger criteria ($Hb \leq 7$ g/dl) and careful clinical evaluation of the child. In contrast, Group B children were subjected to commonly practice empirical transfusion criteria ($Hb \leq 10$ g/dl). This has resulted in significant higher rate of transfusions in Group B compared with Group A (229/396, 57.8% vs. 33/392, 8.3%). Longer CPB duration is known to cause more damage to blood cells and coagulation proteins and thus may also have contributed to increased post-operative blood loss in Group B

compared with Group A patients, transfusions rates. Despite both groups were case matched yet more patients in Group B remained on CPB for longer duration as well as higher proportions of CPB time >90 min (mean 60.2 min, 20.2% vs. 103.7 min, 91.9% [$P < 0.001$]). Average mediastinal blood shedding in Group A patients was 129.5 ml versus 191.8 ml in Group B ($P < 0.001$) [Figures 1 and 2].

ICU length of stay is an important clinical parameter of post-operative morbidity. In this study, the median ICU length of stay in Group A (48 h) was significantly lesser compared with children in Group B (70 h) (Mann-Whitney U-test, $P = 0.001$). Early discharge from ICU also affects hospitalization period. This was more in patients receiving blood or PRBC transfusions [Figure 3].

Similarly, increased morbidity in terms of median duration of post-operative ventilation as well as >30 h (4.8 h vs. 6.0 h, $P < 0.001$ and 2.3% vs. 12.4%, $P < 0.001$), mean hospital stay (9.7 vs. 10.1 days, $P = 0.013$), and even higher mortality (11.6% vs. 22.0%, $P < 0.001$) was observed in Group B patients [Figures 1-3]. Risk of death in the Group B (OR = 2.14, 95% CI = 1.45–3.16, $P < 0.001$) was 2.14 times more in univariate analysis and 1.59 times (AOR = 1.59, 95% CI = 1.00–2.54, $P = 0.050$) in multivariate analysis as compared to Group A (after adjusting the effect of age, total chest, hospital stay, ventilator time, and sick staus).

Similar, observation was reported by Salvin *et al.* in their retrospective study of 802 pediatric cardiac surgery patients, where they had found a high PRBC transfusion

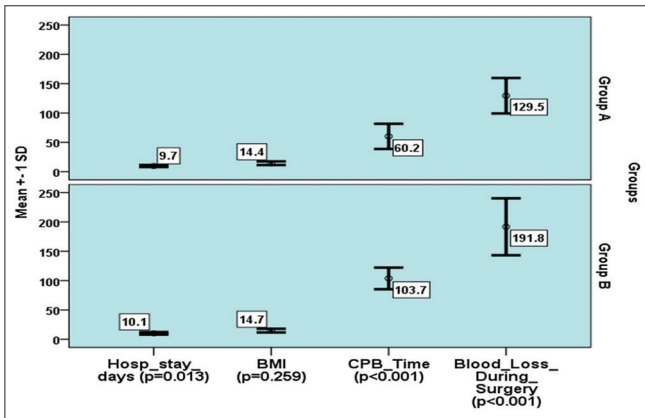


Figure 1: Comparison of the mean value of demographic and clinical property in Group A versus Group B

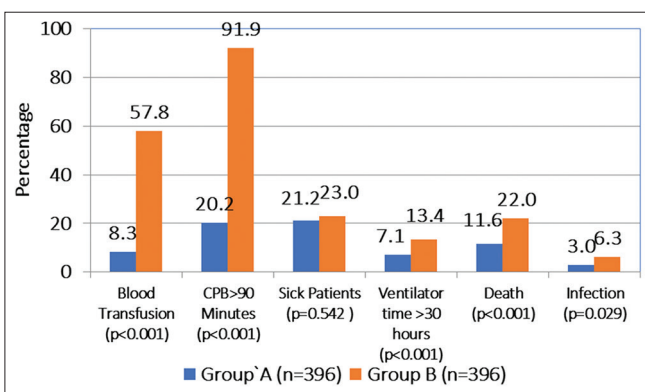


Figure 2: Comparison of the proportion of clinical property in Group A versus Group B

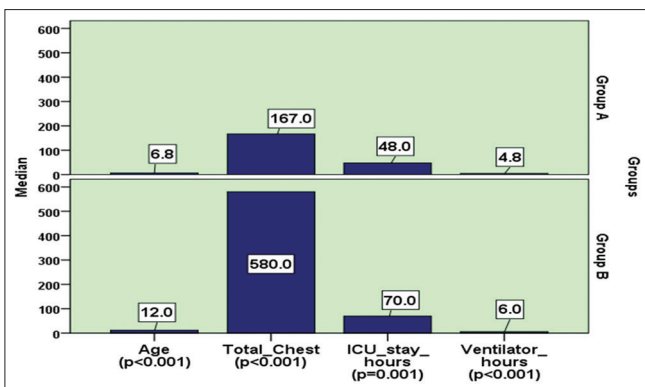


Figure 3: Comparison of the median value of demographic and clinical property in Group A versus Group B

group had double of the median ICU length of stay of 11 days compared with the patients who received no blood transfusion ($P < 0.01$) and also significantly higher rates of post-operative infections (14%).^[11] Although not in cardiac surgery patients similar observation of prolonged hospital stay was reported in a randomized, controlled trial examining “critically ill children” ($n = 637$) admitted to the pediatric ICU that examined restrictive and liberal transfusion strategies (thresholds of 7 g/dL and 9.5 g/dL, respectively).^[12] Similarly, two other randomized studies in carried out in pediatric intensive care patients by Hébert *et al.* and Lacroix

et al. reported the potential benefits of restricted transfusion elucidating the harmful effects of liberal transfusion.^[12,13]

With these clear observations in a large number of case-matched pediatric population subjected to two contrasting blood transfusion protocols undergoing elective open-heart surgeries authors feel confident to attest the need for actively practicing targeted and restrictive trigger protocol for blood transfusion. This study underscores that the combined use of two strategies; use of RAP in selective patients and restricted transfusions along with careful clinical evaluation of pediatric patients as an adjunct was certainly helpful without compromising the safety of the patients and yet gaining advantages of restricted transfusions as observed in this study resulting into better post-operative outcomes.

Despite the availability of very small size priming circuits now available there are situations where one must make use of one or more of, some commonly employed strategies to counter the deleterious effects hemodilution. These are;

- Priming the bypass circuit with banked whole blood,
- Addition of calculated volume of PRBC to prevent perioperative anemia,
- Pre-donation in toddler cyanotic children,
- Addition of PRBC during bypass whenever hematocrit falls below a certain level,
- Some manage intraoperative hemodilution using ultrafiltration during and later in the post-operative period to “reduce” the use of autologous blood,
- Almost every unit, accepts the need for post-operative blood transfusion whenever, Hb or protein levels fall to certain level according to the surgeon’s protocol.

The fact is, all above strategies require transfusion of either whole or blood product transfusion at some stage during the perioperative period.

Strength

Since all case-matched patients in either group came from a single geographical and social background, operated with nearly identical techniques and recovered in similar environment, we believe that the impact analysis of the only variable, namely, blood and product transfusion on morbidity and mortality would exhibit strong correlation.

Limitations

It is a single center institutional study in a tertiary pediatric cardiac centre, children operated by two surgeons practicing two different allogenic transfusion protocols thus these results may not be generalized to all the centres. The current study determined the effect of PRBC transfusion on post-operative outcome; therefore, postoperatively number of blood product usage was not analyzed. The effect of PRBC storage time was also not analyzed in the current study as its effect

also has an impact on morbidity and mortality on pediatric cardiac patients. Erythropoietin was not used preoperatively or postoperatively. Intraoperative no cell salvage device was used as a method of blood conservation.

CONCLUSIONS

Unrestricted blood transfusion in post-operative period adversely affects the hospital recovery and survival using differing allogenic transfusion protocols although following similar operative and recovery environment. The use of selective RAP and Hb ≤ 7 g/dl can be safely employed in pediatric patients to achieve improved outcomes in pediatric patients without compromising their safety and obvious additional indirect benefit of reduced hospitalization cost for patients, significantly relevant in low-income countries like India.

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