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Research Article

Assessment of Clinical and Laboratory Outcomes in Using of Albumin and Fresh Frozen Plasma as Cardiopulmonary Bypass Prime Solutions in Pediatric Arterial Switch Surgery

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ABSTRACT

Background: Cardiopulmonary bypass (CBP) prime solution in pediatric heart surgeries is critical to avoid adverse effects resulting from dilution of coagulation factors, red blood cells, and other plasma protein. This study aimed to evaluate clinical and laboratory outcomes of administration of albumin and fresh frozen plasma (FFP) in CPB prime solution in children candidates for arterial switch surgery.
Methods: This cross-sectional study was performed on 30 transposition of the great arteries (TGA) patients, candidates for the arterial switch in Tehran Children's Medical Center, Iran. As CBP prime solution, 15 patients received albumin (1 gr/kg Albumin 20%) and 15 patients received FFP (15 cc/kg). also, clinical and laboratory parameters were measured in different intervals. The statistical analysis were performed by SPSS v.20.
Results: The volume platelet infusion in the ICU was higher in FFP-received patients (40.00 ±20.70 ml) than albumin-received patients (26.67 ±25.82 ml; p-value =0.01). Upon entry into ICU, the mean of Hb and Hct in FFP-received patients (11.55 ±0.64 g/l and 34.44 ±2.44 %) was significantly higher than patients who received albumin (11.08 ±0.87 g/l and 31.44 ±3.97 %; p-value =0.04 for both). Upon entry into ICU and also 48 hours after admission into the ICU, the Cr level in the FFP-received group (median: 19 mg/dl) was significantly higher than the albumin-received group (median: 12 mg/dl; p-value =0.03).
Conclusion: FFP in CPB prime solution reduces the hemostatic complications and infusion of blood products, as well as to stabilizes Hb and Htc. Therefore, FFP is more suitable as CPB prime solution.

Transposition of the great arteries (TGA) is a congenital heart disease (CHD) manifested by the transposed main pulmonary artery and the aorta [1]. The arterial switch is the main procedure for treating TGA, which needs cardiopulmonary bypass (CPB) [2]. In heart surgeries, CBP circuits condition affects the

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physiological state of the patient, i.e., hemodynamics, hemorrhage and coagulation disorders, edema, fever, systemic inflammatory response syndrome (SIRS), and dysfunction of various organs [3].

One of the most critical points in CPB is prime solution. The prime solution can affect the physical and chemical balance of the blood and modify the body's metabolic, inflammatory, and acid-base status and reduce these side effects of CBP [4]. Due to the difference in CPB circuit sizes compared to the body size, which is larger in children than in adults, the significant dilution of coagulation factors, red blood cells, and other plasma proteins occurs in pediatric CBP [5]. Therefore, even by adding blood to the prime solution, the risks of hemodilution are always evident in pediatric CPB. Also, the decreased oncotic pressure following dilution of plasma proteins increases fluid movement into the extravascular space, tissue edema, coagulation disorders, organ dysfunction, postoperative weight gain, and increased intubation period [6].

Adding colloidal particles to the prime solution and using the colloidal solution as the main prime solution are recommended to avoid the mentioned challenges. Also, fresh frozen plasma (FFP) and albumin may be suitable for prime solutions [7]. Albumin is one of the main factors in determining oncotic blood pressure, transfer of endogenous substances such as unconjugated bilirubin and exogenous substances such as drugs, elimination of oxygen free radicals, exerting antithrombotic effects and hemodynamic stability. Acute kidney injury is common after heart surgery and is associated with an increased risk of postoperative mortality and morbidity. Administration of albumin 20% before heart surgery can increase urinary output and reduce the risk of acute postoperative renal failure [8]. The Food & Drug Administration (FDA) has approved albumin for volume enhancement and maintenance of cardiac output in patients with shock, burns, acute respiratory syndrome, and undergoing CBP [9].

Besides, FFP is a blood product containing coagulation factors, albumin, immunoglobulin, and antithrombin [7]. Although there are risks such as the transmitting allergic reactions to exogenous proteins and transmission of infections such as hepatitis B and C due to the use of FFP, in complex cases of cardiac surgery and prolongation of CPB, the level of fibrinogen and other coagulation factors is constantly decreasing [10]. Therefore, the use of FFP in pediatric heart surgery can be helpful. The administration of FFP as a prime solution for children undergoing congenital heart surgery can reduce post-CPB hemostatic disorders and reverse heparin by increasing fibrinogen levels [5]. In the last two decades, the consumption of FFP has significantly increased; the development of the hemovigilance system and allergic tests has reduced the risk of transmitting allergic reactions and infectious diseases caused by FFP [11].

In this study, we aimed to evaluate clinical and laboratory outcomes of administration of albumin and FFP in CPB prime solution in children candidates for arterial switch surgery.

Methods

Patients and medical interfering

This cross-sectional study was performed on 30 TGA patients, candidates for the arterial switch in Tehran Children's Medical Center, Iran. As CBP prime solution, 15 patients received albumin (1 gr/kg Albumin 20%) and 15 patients received FFP (15 cc/kg). Other contents of prime solution and procedures were performed as standard protocol.

Inclusion and exclusion criteria

Inclusion criteria included weight less than 10 kg, being a candidate for arterial switch surgery, cardiac output of more than 40%, no infection or history of allergic reactions, no kidney failure or serum creatinine (Cr) concentration greater than 1.5 mg/dl, absence of coagulation disorders, and serum albumin level less than 4 gr/dl before surgery. Exclusion criteria included deep hypothermia and CPB duration less than 1 hour and more than 4 hours.

Clinical and paraclinical examinations

Clinical indexes, i.e., the vital and hemodynamic symptoms, age, height, weight, type and duration of operation, amount of chest-tube bleeding, time of spontaneous respiration and extubation, duration of ICU hospitalization, rate of the urinary outflow, and pump-driven hemofiltration, was measured. Also, laboratory parameters, i.e., hematocrit (Hct), platelet count (Plt), white blood cell count (WBC), prothrombin time (PT) and international normalized ratio (INR), partial thromboplastin time (PTT), serum albumin, blood urea nitrogen (BUN), Cr, C-reactive protein (CRP), erythrocyte sedimentation rate (ESR), and lactate were measured for all patients at the preoperative time, intraoperative time, 24 hours and 48 hours after surgery.

Statistical analysis

Qualitative data were described as relative and percentage frequencies. The frequency of qualitative data was compared between the two groups using the chi-square method. The normal distribution was determined using Kolmogorov-Smirnov or Shapiro-Wilk. Repeated-Measures ANOVA or Friedman method was used for comparing variables within a group in consecutive measurements. Also, the unpaired t-test was used to compare means between two groups, and the Mann-Whitney v-test was used to distribute non-parametric data. All statistical analyses were applied by SPSS v.20. the significance level was considered <0.05.

Results

In this study, 30 patients have been enrolled; 15 patients received FFP, and 15 patients received albumin as CPB prime solution. There was no difference between the two groups regarding age, weight, body surface area, cross-clamping time, mechanical ventilation time, and hospitalization in ICU (Table 1).

Difference of clinical parameters between FFP-received and albumin-received patients

The volume platelet infusion in the ICU was higher in FFP-received patients (40.00 ±20.70 ml) than albumin-received patients (26.67 ±25.82 ml; p-value =0.01). There was no significant difference between FFP-received and albumin-received patients in terms of arterial pressure, chest tube drainage, urinary outflow, and RBC packed cell infusion requirement in different statuses of operation and hospitalization (Table 2).

Difference of laboratory parameters between FFP-received and albumin-received patients

Upon entry into ICU, the mean of Hb in patients who received FFP (11.55 ±0.64 g/l) was significantly higher than patients who received albumin (11.08 ±0.87 g/l; p-value =0.04). Also, at the same time, the mean of Hct in patients who received albumin (31.44 ±3.97 %) was significantly lower than patients who received FFP (34.44 ±2.44 %; p-value =0.04). Upon entry into ICU and also 48 hours after admission into the ICU, the Cr level in the FFP-received group (median: 19 mg/dl) was significantly higher than the albumin-received group (median: 12 mg/dl; p-value =0.03), indicating a better renal function in the albumin group than in the FFP group. Also, there was no significant difference between FFP-received and albumin-received patients in terms of BUN, albumin, ESR, CRP, lactate in different statuses of operation and hospitalization (Table 3).

Table 1- Comparison of demographic and clinical data in the two groups receiving albumin and FFP

Parameters	Mean ±SD		P value
	Albumin (n =15)	FFP (n =15)	
Age (day)	6.33 ±2.28	6.27 ±2.05	0.65
Weight (kg)	3.15 ±0.302	3.21 ±0.309	0.85
Body surface area	0.29 ±0.045	0.31 ±0.039	0.57
Cardiopulmonary bypass time (minute)	200.67 ±34.9	184.47 ±31.6	0.82
Cross-clamping time (minutes)	114.73 ±26.57	121.07 ±33.17	0.32
Mechanical ventilation time (days)	2.87 ±0.64	2.73 ±0.79	0.13
Hospitalization in ICU (days)	10.05 ±2.17	10.02 ±1.41	0.09

Table 2- Investigation of parametric laboratory and clinical parameters in different status

Parameters	Intervals	Mean ±SD		t	dt	P value
		Albumin (n =15)	FFP (n =15)			
Arterial pressure (mmHg)	Preoperative	53.27 ±5.48	56.60 ±5.02	-1.736	28.00	0.54
	Inductive	52.53 ±5.75	54.60 ±5.75	-0.983	28.00	0.56
	Postoperative	49.00 ±4.64	52.27 ±6.59	-1.568	28.00	0.06
	After patient warming	51.20 ±5.03	52.60 ±6.64	-.0662	28.00	0.15
	Upon entry into ICU	54.8 ±6.27	54.47 ±5.15	0.159	28.00	0.41
	24 hours after entry into the ICU	56.53 ±6.42	56.47 ±6.32	0.029	28.00	0.73
	48 hours after entry into the ICU	54.47 ±5.75	56.20 ±5.44	-.0848	28.00	0.83
Hb (g/l)	Preoperative	12.93 ±0.95	12.86 ±0.91	0.196	28.00	0.77
	Inductive	12.40 ±0.87	12.37 ±1.02	0.095	28.00	0.38
	Postoperative	9.29 ±0.88	9.62 ±1.25	-1.009	28.00	0.17
	after patient warming	9.79 ±0.95	10.32 ±1.13	-1.394	28.00	0.27
	upon entry into ICU	11.08 ±0.87	11.55 ±0.64	-1.697	25.719	0.04*
	24 hours after entry into the ICU	11.34 ±0.99	11.69 ±0.67	-1.110	28.00	0.08
	48 hours after entry into the ICU	11.56 ±0.46	11.76 ±0.54	-1.114	28.00	0.97
Hct (%)	Preoperative	38.32 ±3.94	38.70 ±2.93	-0.300	28.00	0.60
	Inductive	37.03 ±4.17	37.18 ±4.9	-0.113	28.00	0.46
	Postoperative	28.32 ±3.32	29.55 ±3.63	-0.964	28.00	0.95
	after patient warming	29.32 ±2.93	31.17 ±3.41	-1.595	28.00	0.59
	upon entry into ICU	31.44 ±3.97	34.44 ±2.44	-1.970	26.621	0.04*

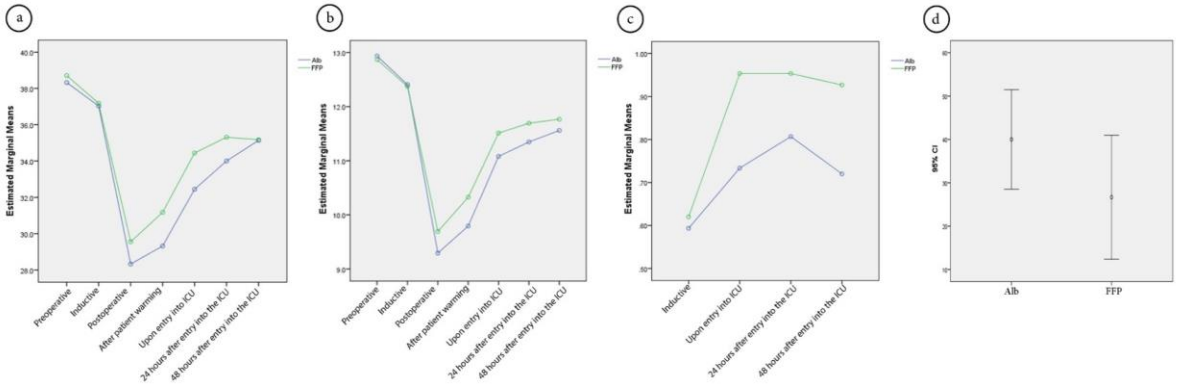
	24 hours after entry into the ICU	34.007 ±3.47	35.31 ±2.33	-1.210	28.00	0.07
	48 hours after entry into the ICU	35.14 ±1.88	35.17 ±2.21	-0.044	28.00	0.71
BUN (mg/dl)	Inductive	7.20 ±1.74	6.80 ±1.45	0.569	28.00	0.54
	upon entry into ICU	10.60 ±2.92	12.67 ±3.99	-1.617	28.00	0.14
	24 hours after entry into the ICU	11.13 ±2.92	12.8 ±3.46	-1.429	28.00	0.77
	48 hours after entry into the ICU	10.62 ±2.79	12.20 ±3.34	-1.399	28.00	0.35
Albumin (mg/dl)	Inductive	3.47 ±0.27	3.55 ±0.25	-0.827	28.00	0.47
	upon entry into ICU	3.75 ±0.28	3.40 ±0.25	3.529	28.00	0.67
	24 hours after entry into the ICU	3.70 ±0.33	3.31 ±0.22	3.317	28.00	0.06
	48 hours after entry into the ICU	3.78 ±0.32	3.36 ±0.25	3.945	28.00	0.11
ESR (mm/h)	Inductive	2.62 ±0.78	2.40 ±0.58	1.231	28.00	0.20
	upon entry into ICU	2.61 ±0.77	2.31 ±0.56	1.211	28.00	0.20
	24 hours after entry into the ICU	2.60 ±0.72	2.33 ±0.52	1.189	28.00	0.18
	48 hours after entry into the ICU	2.58 ±0.74	2.30 ±0.54	1.172	28.00	0.25
CRP (mg/dl)	Inductive	1.83 ±0.57	1.52 ±0.38	1.290	28.00	0.12
	upon entry into ICU	1.80 ±0.58	1.62 ±0.38	1.613	28.00	0.10
	24 hours after entry into the ICU	1.85 ±0.56	1.62 ±0.38	1.320	28.00	0.18
	48 hours after entry into the ICU	1.83 ±0.57	1.61 ±0.36	1.253	28.00	0.15
Chest tube drainage (ml)	Inductive	12.67 ±6.77	13.33 ±3.08	-0.347	28.00	0.07
	upon entry into ICU	16.67 ±5.56	15.67 ±3.71	0.579	28.00	0.07
	24 hours after entry into the ICU	46.67 ±14.48	47.33 ±9.97	-0.144	28.00	0.06
	48 hours after entry into the ICU	36.67 ±10.29	42.00 ±12.64	-1.267	28.00	0.73
Urinary outflow (ml)	Inductive	167.33 ±51.47	160.67 ±51.47	0.355	28.00	0.06
	upon entry into ICU	173.33 ±52.19	165.33 ±49.40	0.431	28.00	0.92
	24 hours after entry into the ICU	242.67 ±67.28	220.67 ±62.29	0.931	28.00	0.70
	48 hours after entry into the ICU	240 ±67.29	241.3 ±53.96	-0.060	28.00	0.12
RBC packed cell infusion (ml)	In operation room	123.33 ±59.36	100.00 ±53.45	1.131	28.00	0.51
	In ICU	86.67 ±71.88	63.33 ± 66.72	0.921	28.00	0.81
Platelet infusion (ml)	In operation room	73.33 ±25.82	66.00 ±25.01	0.790	28.00	0.33
	In ICU	40.00 ±20.70	26.67 ±25.82	1.560	26.736	0.01*

Table 3- Investigation of non-parametric laboratory and clinical parameters in different status

Parameters	**Intervals**	**Median**		**Mann Whitney**		**P value**
		Albumin (n =15)	**FFP (n =15)**	**U**	**Z-score**	
Cr (mg/dl)	Inductive	14.60	16.40	99	-0.603	0.59
	upon entry into ICU	12.00	19.00	60	-2.204	0.03*
	24 hours after entry into the ICU	13.20	17.80	78	-1.44	0.16
	48 hours after entry into the ICU	12.10	18.90	61.5	-2.13	0.03*
Lactate (mg/dl)	Preoperative	16.07	14.93	104	-0.356	0.74
	Inductive	12.79	11.14	56.5	-0.59	0.56
	Postoperative	14.86	14.14	93	-0.231	0.83
	after patient warming	14.89	15.10	103	-0.066	0.94

upon entry into ICU	15.87	15.13	107	-0.299	0.83
24 hours after entry into the ICU	14.89	15.10	103	0.066	0.94
48 hours after entry into the ICU	16.77	14.23	93.5	-0.789	0.43

Figure1- The Hct, Hb, Cr, and Plt infusion changes in FFP-receiving and albumin-receiving groups.



a) the mean of Hct in patients who received albumin was significantly lower than patients who received FFP upon entry to ICU (p-value =0.04); **b)** the mean of Hb in patients who received FFP was significantly higher compared to patients who received albumin (p-value =0.04); c) 48 hours after entry into the ICU, the Cr level in the FFP-received group was significantly higher than the albumin-received group (p-value =0.03); **d)** the volume of Plt infusion in ICU was higher in FFP-received patients compared to albumin-received patients (p-value =0.01).

Discussion

Without cardiopulmonary bypass (CPB), various heart surgeries in children, i.e., arterial switch, are not possible [12]. Due to the lack of development of organs in infants such as the brain, lungs, coagulation system, and endocrine system and their higher metabolic needs, CPB in children is associated with more adverse effects than adults [3-4]. A suitable CPB prime solution straightly affects the results of pediatric heart surgeries. A suitable prime solution can reduce complications such as postoperative weight gain, pulmonary problems, coagulation disorders, the need for blood transfusion, prolongation of intubation and hospitalization in the ICU, metabolic and inflammatory disorders, and acid-base disorders [13]. In this study, we used albumin (1 gr/kg albumin 20%) and FFP (15 cc/kg) in the prime solution of CPB in pediatric arterial switch surgery.

Regarding renal status in CPB, our results showed that Cr levels varied between the two groups 48 hours after entry to ICU, increasing Cr levels in the FFP group compared to the albumin group. Although the urinary outflow rate was not significantly different in the groups, the study of a renal parameter, Cr, showed better renal function in the albumin group. In a 2016 prospective study, Lee et al. examined using albumin 20% on acute postoperative renal failure incidence in patients undergoing the off-pump coronary artery bypass grafting (CABG) [13]. They found that administration of albumin 20% immediately before surgical incision could increase the rate of urinary outflow and reduce the risk of acute renal failure after off-pump CABG surgery. Patel et al. studied the role of CPB prime solution in renal function of patients undergoing surgery. They concluded that using albumin in CPB prime solution in <1-year-old children can increase urinary outflow and decrease serum Cr and BUN in patients by maintaining colloidal pressure [14]. Also, in a cohort study conducted by Lee et al. on patients undergoing congenital heart surgery, preoperative albumin deficiency was identified as the most important cause of acute postoperative renal failure [15].

The CPB prime solution is critical in allergic reactions. A meta-analysis study by Van Der Linde et al. examined allergic reactions due to blood and blood products in Prime solution [16]. A result was a further increase in inflammatory factors and allergic reactions in the use of FFP compared to other blood products in the prime solution. Due to the importance of inflammatory and anti-inflammatory immune responses, it seems that the albumin solution is more suitable than FFP. Still, in our study, there was no evidence of increased inflammatory factors, i.e., ESR and CRP, in the studied groups.

As described above, a suitable CPB prime solution is critical to reducing coagulating disorders. Lee et al. used FFP in CPB prime solution and examined its effect on coagulation factors in 1 month-to-16-year-old of congenital heart surgery-candidate patients. they concluded that the addition of FFP to prime solution in pediatric congenital heart surgery reduces the hemostatic complications due to hemodilution immediately after CPB and improves clot formation [17]. In our study, although there was no significant difference in terms of the amount of drainage of chest tubes and the need for blood transfusion in patients of the two groups, patients in the FFP-receiving group had significantly higher

serum levels of Hb and Htc and fewer platelet infusion compared to the albumin-receiving group after entering the ICU.

Based on the findings of the present study, during congenital heart surgery, a more appropriate prime solution can be selected due to the risks for children, which reduces treatment complications as well as patient costs and increases the surgeon and patient satisfaction with the outcome of the operation. Although patients did not differ much in terms of clinical outcomes during surgery and the first 48 hours thereafter, changes in their hemostatic and renal markers were observed in the present study. Also, it is recommended to study long-term clinical and paraclinical outcomes and investigate more inflammatory markers to investigate the inflammatory consequences in patients more accurately.

Conclusion

Although FFP appears to be superior to albumin in reducing the hemostatic effects of hemodilution after heparin reversal, the Cr levels in the serum of patients who received albumin in CPB prime solution were lower, which indicates a more appropriate renal status in albumin-receiving patients compared to FFP-receiving group. Since no significant difference was observed in the clinical outcomes of patients in the two groups, it is recommended to use FFP colloidal solution in CPB prime solution of TGA patient candidate for pediatric arterial switch surgery to reduce the hemostatic complications and infusion of blood products, as well as to stabilize Hb and Htc of patients after CPB. Also, albumin is preferable to FFP if there is evidence of postoperative renal impairment in patients.

Ethical statement

This study was confirmed by the Ethical Committee of Mashhad University of Medical Sciences [IR.MUMS.MEDICAL.REC.1400.200].

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