Cross-Sectional Study

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Response to apheretic platelet transfusion in children of acute lymphoblastic leukemia receiving induction chemotherapy: a cross-sectional study from Bangladesh

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Background: Disease and therapy-related hypoproliferative thrombocytopenia is a significant barrier to managing acute lymphoblastic leukaemia (ALL) patients. To reduce the risk of haemorrhage, apheretic platelet transfusion is a modern, effective, and expensive option. Since most ALL patients in Bangladesh have financial constraints, this study can shed light on the magnitude of benefit regarding the effectiveness of apheretic platelet prophylactically and therapeutically in children of ALL receiving induction chemotherapy.

Materials and methods: This observational cross-sectional study was conducted in the department of transfusion medicine and the department of paediatric haematology and oncology at a tertiary level hospital in Bangladesh from June 2020 to June 2021. A total of 33 cases of ALL were enroled in this study according to inclusion and exclusion criteria. After receiving written informed consent, relevant data were collected using a face-to-face interview with the guardian of the patients, thorough clinical examination, and relevant investigation. After the collection of all the required data, analysis was done by Stata (v.16).

Results: Mean age of the patients was 7.39 ± 4.46 (SD), ranging from 1 to 18 years. The majority of children were aged younger than or equal to 10 years (69.70%). Male children were slightly predominant (51.5%). Significant post-transfusion platelet increment (Median pre-transfusion count 16×10^3/μl vs. Median post-transfusion count 133×10^3/μl, $P < 0.001$) was observed. WHO bleeding grades also improved after apheretic platelet transfusion ($P < 0.05$). Age was a significant factor associated with corrected count increment (CCI) in both univariate and multivariate analysis. In subgroup analysis, age and gender were significant predictors of CCI in therapeutic transfusion group but not in prophylactic transfusion group.

Conclusions: Significant improvement in bleeding status and platelet count was observed following apheretic platelet transfusion.

Keywords: Apheretic platelet, Acute Lymphoblastic Leukaemia (ALL)

Introduction

Platelet is an essential component of haemostasis because they form a platelet plug that provides a framework for forming fibrin clots and secreting cytokines and growth factors[1]. In 1910, Duke described the first successful attempt to treat thrombocytopenia by transfusing whole blood[2]. In the past, only whole blood was used as a transfusion product in all needy patients, but now we select each component according to its specific indications[3]. Cancer is one of the most common reasons for blood transfusions[4] the same is true for children with acute lymphoblastic leukaemia (ALL).

ALL is characterized malignant transformation of lymphoid progenitor cells in the bone marrow. This bone marrow dysfunction may lead to thrombocytopenia[5]. Furthermore, the

HIGHLIGHTS

- Significant improvement in bleeding status and platelet count after apheretic platelet transfusion in children with acute lymphoblastic leukaemia receiving induction chemotherapy.
- Age and sex were significant predictors of corrected count increment in therapeutic transfusion group but not in prophylactic transfusion group.
- For prophylaxis and therapeutic purposes, it can be recommended, but the substantial risk of bleeding during the intervention should be considered.

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chemotherapeutic agents used to treat ALL can also cause decreased platelet levels[6,7]. Transfusions are given to these patients either prophylactically to prevent bleeding or therapeutically to treat bleeding[8]. Prophylactic and therapeutic platelet transfusion practices have grown and continue to expand due to the increased use of high-dose chemotherapy and HSCT and as supportive care of these patients continues to improve[9].

Platelets for transfusion can be prepared either by separation of platelet units concentrates from whole blood, which is pooled before administration, or by apheresis from single donor[10]. Using apheretic platelets has a significant benefit in that an adequate number of platelets can be collected from a single donor, which can provide a suitable transfusion dose for an adult patient with thrombocytopenia. This is in contrast to the pooled platelet concentrates method, which involves pooling platelet concentrates from 4 to 6 donors to obtain the necessary number of transfused platelets[11]. Some centres report that using apheretic platelets exclusively or increasingly results in less frequent alloimmunization after transfusion compared to pooled platelet concentrates[10].

Traditionally, between 5 and 6 units of random donor platelet (RDP) are equivalent to 1 unit of apheretic platelet/single donor platelet (SDP)[12]. While in Bangladesh each unit of RDP costs on an average 550 BDT/5$ (6 units of RDP costs 2600 BDT/26$), one unit of SDP costs on an average 19 000 BDT/190$[13]. Therefore, it is important to assess the extent of effectiveness apheretic platelet provides to ensure its judicious use. The aim of this study is to shed light on the magnitude of benefit regarding the effectiveness of apheretic platelet prophylactically and therapeutically in children of ALL receiving induction chemotherapy.

Materials and methods

Study design, site and duration

This cross-sectional study was conducted from June 2020 to June 2021. The transfusion medicine and paediatric haematology and oncology department of a tertiary level hospital in Bangladesh were selected as the study site as it is located in the capital and receives patients from all over the country.

Study participants

The participants meeting the following criteria were included in the study (1): age younger than 18 years, (2) ALL patients (confirmed by bone marrow examination, morphology, and flow cytometry), (3) receiving induction chemotherapy and (4) parents providing informed consent. Following patients were excluded from the study (1): age older than or equal to 18 years (2), recipients of packed red cells on the same day of platelet transfusion, and (3) recipients of multiple platelet transfusions within 24 h were excluded from the study.

Sample size and sampling technique

Sample size (n) was calculated using the following formula:

$$n = \frac{\{u\sqrt{[\pi(1-\pi)]} + v\sqrt{[\pi_0(1-\pi_0)]}\}^2}{(\pi-\pi_0)^2}$$

where, n = sample size, $u = P$ value at $0.05 = 1.96$, v = power of the study at $80\% = 0.84$, $\pi = 0.94$[14] and $\pi_0 = 0.80$ (expected result). An estimated sample size of 33 patients was derived from the calculation of the formula. The participants were selected using convenience sampling since it is quick, cost-effective, and requires minimal resources.

Study procedure

After receiving informed consent, data were gathered through in-person interviews with patients and/or guardians using a pre-tested structured questionnaire. Additionally evaluated were the patient's history, prior medical records, physical examination results, and lab test results. Apheretic platelet (at least contain 3×10^{11} platelets) collection procedures were conducted on haemonetics MCS + intermittent flow cell separator (Braintree). It employed single venous access utilizing closed collection apheresis kits with efficient leukoreduction. Each apheretic platelet unit contained at least 3.0×10^{11} platelets suspended in 200–400 ml of plasma and is derived from a single donor. All the donors were screened for hepatitis B, hepatitis C, HIV, malaria, and syphilis and selected as per the donor eligibility criteria, and the procedures were performed stringently as per standard operating procedures of the department of transfusion medicine. Blood flow rates for all plateletpheresis were maintained at 45–90 ml/min with an anticoagulant (ACD-A) ratio of 9:1. A minor cross-match was performed before transfusion. The dosing of apheretic platelets was 5–10 ml/kg of body weight. The first 15 min of transfusion may begin at a rate of 3 ml/minute. Next, transfusion was given at a rate of 300 ml/ hour. Every patient received an apheretic platelet transfusion within 1 h. One hour after receiving the apheretic platelet, the study blood samples were collected from participants, and a complete blood count was done. Necessary data were collected from pre-apheretic, and post-apheretic platelet transfusion and complete blood count (CBC) reports of participants. Response to apheretic platelet transfusions was assessed by calculating the corrected count increment (CCI) using the following formula[15], CCI = Post Platelet transfusion Increment (PPI) × body surface area (m^2)/ PLT dose ($\times10^{11}$), where, PPI = post-transfusion PLT count ($\times10^9$/l) − pre-transfusion PLT count ($\times10^9$/l). Body surface area was estimated by the formula of DuBois and DuBois[16], $BSA = (W^{0.425} \times H^{0.725}) \times 0.007184$. Where W = weight is in kilograms, H = height is in centimeters. CCI at 1 h $> 7.5 \times 10^3$/μl is considered a successful transfusion[17]. The specific types and severity of bleeding of the patients before and after the apheretic platelet transfusion was assessed using WHO bleeding scale (*grade 0*: no bleeding, *grade 1*: petechiae, ecchymosis, occult blood in body secretions, mild vaginal spotting, *grade 2*: evidence of gross haemorrhage not requiring of RBC transfusion over routine transfusion needs: epistaxis, haematuria, hematemesis, *grade 3*: haemorrhage requiring transfuse of 1or more units of RBCs/day, *grade 4*: life threatening haemorrhage, defined as either massive bleeding causing hemodynamic compromise or bleeding into a vital organ (e.g. intracranial, pericardial, or pulmonary haemorrhage)[18].

Statistical analysis

After data collection, data were checked for errors and analyzed using Stata (version 16). Continuous variables were presented as mean and standard deviation and categorical variables were

presented as frequency and relative percentage. In addition, Pearson's χ^2 test, Wilcoxon signed-rank test, and Mann–Whitney U test were performed to explore a bivariate relationship. A two-tailed P value of less than 0.05 is considered statistically significant.

Patient and public involvement

Members of the public were involved in several stages of the study including design and conduct. We received input from children and their parents and implemented them in our study design. We intend to disseminate the main results to study participants and will seek public involvement in the development of an appropriate method of dissemination.

Ethical approval and registration

This study was approved by the institutional review board of the respective hospital (Approval No. BSMMU/19/13343). The 1964 Declaration of Helsinki and later modifications and comparable ethical standards were followed wherever feasible. Informed consent has been obtained from the guardian of each participant. The study has been retrospectively registered in the Research Registry (www.researchregistry.com) with the unique identifying number: researchregistry9362[19]. The study has been reported in line with the Strengthening The Reporting Of Cohort, Cross-Sectional And Case-Control Studies In Surgery (STROCSS) criteria[20].

Result

The mean age of the participants was 7.39 ± 4.46 years, with the maximum being between younger than or equal to 10 years of age (69.7%). There was a male (51.52%) preponderance with a male-to-female ratio of 1.06:1. [Table 1].

Among all patients, the median pre-transfusion count of platelet was 16×10^9/l, which increased statistically significantly to 133×10^9/l after platelet transfusion ($P < 0.001$). A significant increase in platelet count was noted in both prophylactic (12.5×10^9–135×10^9/l) and therapeutic (16×10^9–133×10^9/L) treatment groups [Fig. 1].

Among children who were given platelet transfusion for therapeutic purposes, the WHO bleeding grades improved from pre-transfusion levels to post-transfusion levels statistically significantly ($P = 0.014$) (Fig. 2). At the pre-transfusion stage, 6 out of 11 children had grade 2, and 5 out of 11 children had grade 1 bleeding. While after transfusion, respectively, 3, 6, and 2 out of 11 children had grade 2, 1, and 0 bleeding [Tables 2 and 3].

Table 1

Background information of study participants ($n = 33$)

Characteristics	Entire study cohort ($n = 33$)
Age (in years), mean ± SD	7.39 ± 4.46
≤ 10	23 (69.7)
> 10	10 (30.3)
Sex, *n* (%)	
Male	17 (51.52)
Female	16 (48.48)
Residence, *n* (%)	
Rural	27 (54)
Urban	23 (46)

Values are expressed as *n* (%) unless otherwise mentioned.

Discussion

Bone marrow failure in acute leukaemia might lead to fatal haemorrhages. Routine use of prophylactic and therapeutic platelet transfusion greatly reduces the risks and episodes of haemorrhage in these patients[21]. Induction of remission in acute leukaemia frequently requires platelet support because of myelosuppression on top of already dysfunctional marrow[22]. Platelet concentrates are obtained either from whole blood or by apheresis from healthy donors[23]. Apheretic platelet transfusion has been shown to increase platelet count more than random donor platelet transfusion[24]. Hence, this study aimed to see the effectiveness of apheretic platelet transfusion in children of acute lymphoblastic leukaemia receiving induction chemotherapy.

A total of 33 children with ALL were included in the study. All of them were undergoing induction chemotherapy. Therefore, apheretic platelet was given to all of them to reduce bleeding events and episodes. The average age of the included children was 7.39 ± 4.46 years. The majority (69.70%) had an age of younger than or equal to 10 years. One previous study found a similar age profile among acute lymphoblastic leukaemia children[25]. Out of 142 children with ALL, 91 (64.08%) had an age younger than 10 years. Saikia *et al.*[26] studied 52 childhood ALL patients and reported a mean age of 7.1 (±4.7) years (SD), which is concordant with that of the present study.

We found a slightly higher proportion of males (51.5%) than females (48.5%) in this study. This is lower than that found by Saikia and colleagues (2019). They noted that 69% were male and 31% were female in the study. Alkaid and colleagues also found a male prevalence of 59% among childhood ALL patients[27]. Mallard and Mohty, in their review of ALL, noted that the usual ratio of male to female in ALL is 1.2:1, indicating a slightly higher prevalence of ALL in males[28] which we also noted in our study.

Apheretic platelet can be given both prophylactically and therapeutically in ALL. In this study, 66.7% of children got platelet transfusion prophylactically and 33.3% therapeutically. Clinical studies started during the last half of the twentieth century have shown that prophylactic platelet transfusion reduces episodes of bleeding, and therapeutic transfusion reduces fatal haemorrhages[29]. From then on, these treatments have been used widely.

The present study noted a significant improvement in platelet count after apheretic platelet transfusion. Platelet count increased from a median value of 16 to 133×10^9/l ($P < 0.001$). Significant improvements were noted in both the prophylactic and therapeutic groups. In the prophylactic group, the median platelet count improved from 12.5 to 135×10^9/l ($P < 0.001$). The therapeutic group's median platelet count improved from 28 to 114×10^9/l ($P = 0.003$). Similar improvements were noted and repeated in previous studies. Chen *et al.*[30] gave apheretic platelet to 49 patients and found a significant improvement in platelet count after transfusion. Gudeloglu and Albayrak gave prophylactic apheretic platelet infusion among children with ALL and reported a significant improvement in

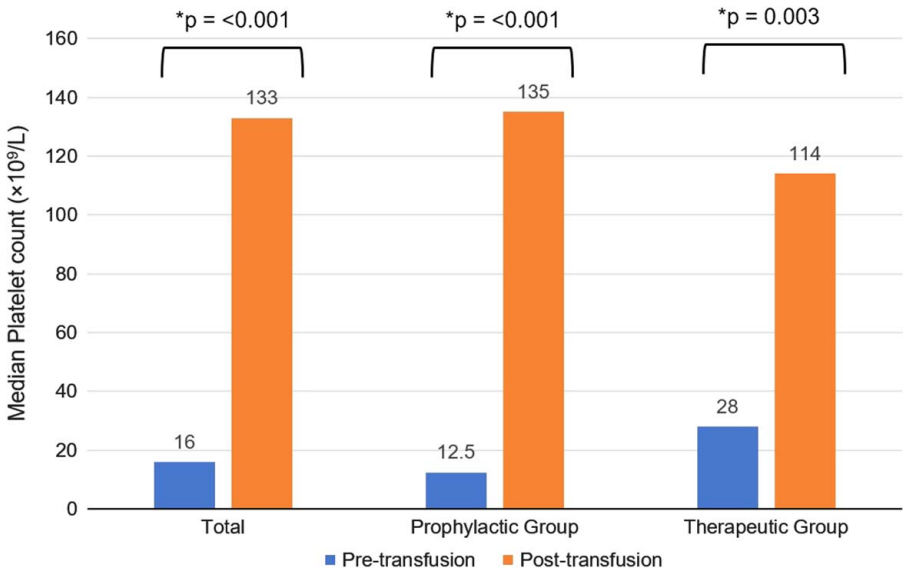

Figure 1. Pre-transfusion and post-transfusion platelet count among children ($n = 33$). *P* value determined by Wilcoxon Signed-Rank test.

platelet count, which was even higher than that of random platelet infusion[24].

The effectiveness of apheretic platelet was also confirmed by a reduction in the grades of bleeding in the therapeutic transfusion group. Out of 11 children, respectively, 5 and 6 had grade 1 and 2 bleeding before transfusion. While after transfusion, the bleeding qualities become respectively 2, 1, and 0 in 3, 6, and 2 children. The difference was significant ($P = 0.014$). This result is supported by Higby and colleagues, who noted a similar improvement in the bleeding profile of ALL cases after platelet-rich plasma transfusion[21].

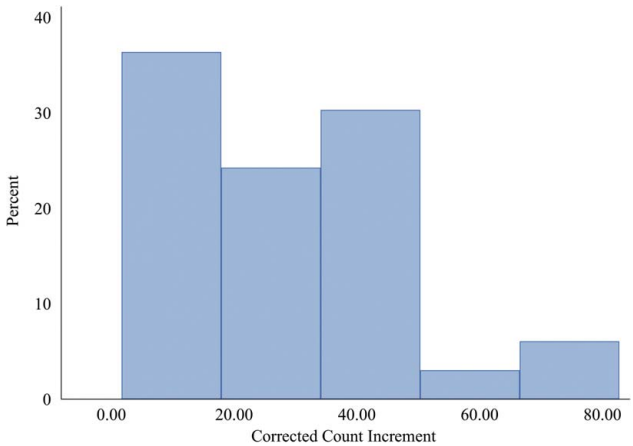

Figure 2. The distribution of the 1-h post-transfusion corrected count increments. The median corrected count increment (CCI) in the platelet was 27.57×10^3/μl ranging from 1.68–82.72 ($\times 10^3$/μl). Age was a significant factor associated with CCI in both univariate and multivariate analysis. There was no significant difference in CCI between prophylactic and therapeutic transfusion group. In subgroup analysis, age and sex were significant predictors of CCI in therapeutic transfusion group but not in prophylactic transfusion group.

Percent platelet recovery is commonly used for assessing the improvement in cell count after transfusion. It depends on the pre-transfusion platelet, the dose of platelets transfused, and other factors that affect recovery[29]. But one-third of the circulating platelet is reversibly pooled by the spleen, and two-thirds remain in circulation. Hence, a formula for adjusting the platelet count was made to find out the true proportion of the rise in the platelet count after transfusion. Corrected count increment, or CCI, is widely used in clinical settings for post-transfusion platelet count measurements. In this study, the median CCI after transfusion was 27.57×10^3/μl. Out of 33 children, only 4 (12.1%) did not achieve an adequate increase in CCI level 1-h after transfusion. They had a CCI level below 7.5×10^3/μl. However, the overall CCI was good and didn't differ significantly across gender, and different treatment protocol. Like our study, Chen *et al.*[30] reported a significant CCI increase after transfusion of apheretic platelet.

It is important to note some of the limitations of the study. We had to employ cross-sectional design, convenience sampling and relatively small sample size in this study due to time, resource constraints, and the ongoing COVID-19 pandemic at that time. Due to the cross-sectional nature of the study, we cannot infer causality for the associations presented. Since convenience sampling was applied, it may introduce bias and

Table 2

Pre- and post-transfusion WHO bleeding grades among children (n = 11)

Pre-transfusion WHO bleeding grades	Post-transfusion WHO bleeding grades			
	Grade 0, *n* (%)	Grade 1, *n* (%)	Grade 2, *n* (%)	*P*
Grade 1 ($n = 5$)	2 (40)	3 (60)	—	**0.014**[a]
Grade 2 ($n = 6$)	—	3 (50)	3 (50)	

[a]*P*-value determined by Wilcoxon signed-rank test.
Bold values are statistical significance $p < 0.05$.

Table 3

Factors affecting corrected count increment (CCI) in children receiving apheretic platelet

		Univariate analysis				Multivariate analysis			
	Variables	**Coefficient (β)**	***P***	**95% CI**		**Coefficient (β)**	***P***	**95% CI**	
Overall	Age (in years)	1.26	0.02	0.19	2.33	1.21	0.03	0.11	2.30
	Sex								
	Male	Reference				Reference			
	Female	− 8.84	0.07	− 18.43	0.75	− 8.12	0.097	− 17.75	1.50
	Type of transfusion								
	Prophylactic	Reference				Reference			
	Therapeutic	− 2.48	0.64	− 12.89	7.93	1.72	0.74	− 8.66	12.11
Prophylactic transfusion	Age (in years)	− 0.11	0.88	− 1.60	1.37	− 0.130	0.86	− 1.64	1.38
	Sex								
	Male	Reference				Reference			
	Female	1.21	0.84	− 10.50	12.93	1.331	0.82	− 10.60	13.26
Therapeutic transfusion	Age (in years)	2.89	0.001	1.38	4.39	2.202	0.002	0.92	3.48
	Sex								
	Male	Reference				Reference			
	Female	− 29.55	0.001	− 45.54	− 13.56	− 22.075	0.003	− 35.50	− 8.65

limit the generalizability of the findings. Also, the relatively small sampling size may impact the statistical power of the study. Further longitudinal studies with a larger sample size and more robust sampling method, that is random sampling might be necessary to provide better recommendations for patients.

Conclusion

This study observed a significant improvement in bleeding status and platelet count after apheretic platelet transfusion in children with acute lymphoblastic leukaemia receiving induction chemotherapy. So, for prophylaxis and therapeutic purposes, it can be recommended, but the substantial risk of bleeding during the intervention should be considered.

Ethical approval

This study was approved by the institutional review board of the respective hospital (Approval No. BSMMU/19/13343). The 1964 Declaration of Helsinki and later modifications and comparable ethical standards were followed wherever feasible.

Patient consent

Informed consent has been obtained from the guardian of each participant.

Sources of funding

No funding was received for conducting the study.

Author contribution

Study conception and design: S.K.B. and M.A.I.; data collection: R.C. and A.K.; analysis and interpretation of results: S.S.M., S.S.I.S. and S.M.; draft manuscript preparation: S.K.B., M.A.I., R.C., S.S.I.S. and S.M. All authors reviewed the results and approved the final version of the manuscript.

Conflicts of interest disclosure

The authors have declared that they have no competing interests.

Research registration unique identifying number (UIN)

Not applicable.

Guarantor

Not applicable.

Availability of data and materials

The dataset used and/or analyzed during the current study are available from the corresponding author Dr Mohammad Azmain Iktidar on reasonable request.

Provenance and peer review

Not commissioned, externally peer-reviewed.

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