Section: Microbiology

Original Research Article

EFFECTIVENESSS OF RANDOM PLATELET CONCENTRATE IN PATIENTS WITH THROMBOCYTOPENIA, CORRELATING WITH CLINICAL IMPROVEMENT AND 24 HOURS CORRECTED COUNT INCREMENT

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ABSTRACT

Background: The platelet transfusion plays a vital role in maintaining the vascular homeostasis during active bleeding and also in clinical conditions associated with thrombocytopenia. The common transfusion-related complications, microbial screening of donor platelets, optimized storage conditions as well as the limited availability of donors, call attention to the importance of monitoring the effectiveness of platelet therapy and thereby to individualize the platelet transfusion treatment. This study explores the need for monitoring the 24 hours post transfusion platelet count by Corrected Count Increment CCI method. **Materials and Methods:** This study was designed as a cross-sectional, prospective study conducted from October 2019 to March 2020 in Government Sivagangai Medical College Hospital located in South India. The efficacy of platelet transfusion is assessed by correlating with clinical improvement and 24 hours CCI. **Results:** Among the 150 patients participated, 65 of them received single unit of Platelet concentrate while 38, 32,10 and 5 of them received, two, three, four and five units respectively. A total of 302 units of platelet transfusion were utilized. The Corrected Count Increment (CCI) for the participants documented the efficacy of Platelet concentrate as expected. Only 15.33% of them have less than 5000 raise in platelet count, and the remaining 22.67% had 5000-7500, 26% had 7500-10000 and 33.3% had more than 10000platelet raise per micro litre.85% showed clinical improvement as judged by the treating clinicians and the response given by the patients. **Conclusion:** The effectiveness of platelet transfusion should be regularly monitored by CCI and it is mandatory to verify any platelet refractoriness or allo-immmunisation.

INTRODUCTION

Blood transfusion plays a vital role in the day-to-day management of medical illness both in therapeutic and prophylactic measures. The availability of Component Separation Centrifuge in the Blood Bank paves the way for individual blood component transfusions like packed cells transfusion, fresh frozen plasma and platelet transfusions. The physiological role of platelets in the maintenance of vascular integrity, haemostasis, protective thrombosis, inflammation and the innate immune response is well known.[1] A normal platelet count in adults ranges from 150,000 to 450,000 platelets per micro litre of blood. Thrombocytopenia is defined as a platelet count of less than 150,000 per micro litre. This can lead to generalized bleeding. To avoid this endangering effect and to restore the normal physiology of vascular haemostasis, platelets can be maintained in those patients by platelet transfusion from voluntary donors. The advances in transfusion medicine paved the way for the utility of platelet concentrates (PC). PCs for transfusion can be prepared by three different methods including (i) platelet-rich plasma-platelet concentrate (PRP PC), (ii) randomly collected platelet concentrates (RPC), and (iii) aphaeresis platelet concentrates (APC). The last two preparations contain only platelets and the preferences in using this type of platelet concentrate varies across the nations, ranging from 10 to 98% use of RPC.[2] This essential platelet transfusion which is

given as an emergency therapy during life threatening active haemorrhage and as a prophylactic therapy for preventing haemorrhage is not free from adverse reactions. Non-haemolytic transfusion reactions, Allo immunisation to Human Platelet Antigen (HPA) and/or Human Leukocyte Antigen (HLA), Platelet Transfusion Reactions(PTR), viral infections, sepsis due to bacterial contamination, Post-transfusion purpura, Transfusion Related Acute Lung Injury (TRALI), transmission of other unknown or not tested pathogens are the adverse effects to be considered.[3] The cause of thrombocytopenia, existing coagulation status, and the adverse effects of platelet transfusion are all should be considered by the treating clinicians before planning for a platelet transfusion. The fact that, in certain conditions like thrombotic thrombocytopenic purpura and heparin induced thrombocytopenia, platelet transfusion will aggravate the prevailing thrombosis, should be remembered.[4,5] Further the number of units of platelets to be transfused depends upon the clinical conditions and post transfusion platelet count. According to given standards in different countries and regions of the world, single unit of platelet concentrate (PC) may contain from 2 to 8 × 10^{11} platelets.[6] Laboratory monitoring should be done to confirm the efficacy of platelet transfusion by measuring the platelet count before and after transfusion and to guide the clinicians in deciding on subsequent transfusions. The above merits of attaining the expected haemostasis by platelet transfusion and the demerits of transfusion reactions encountered during transfusion as well as the utility of available human resources , the complex process of component separation and the necessity to maintain the constant supply of platelets all should be considered and the platelet therapy should be judiciously performed. This study aims to evaluate the efficacy of platelet transfusion by clinical outcome and to correlate with the Corrected Count Increment (CCI).[7] The objectives are to find out the various clinical conditions of suspected thrombocytopenia, to calculate the pre and 24 hours post platelet transfusion platelet count, to assess the number of transfusions needed for clinical improvement and finally to work out the efficacy of platelet therapy by CCI.

MATERIALS AND METHODS

Study Design: This study was designed as a cross-sectional, prospective study to assess the efficacy of platelet transfusion by correlating with clinical improvement and 24 hours CCI.

Ethical Considerations: The study was conducted in accordance with ethical guidelines for research involving human participants. Prior approval was obtained from the Institutional Ethics Committee, Government Sivagangai Medical College (IEC approval number: 1402/ME1/2018). Confidentiality and anonymity of the participants were maintained throughout the study.

Study Setting: The study was conducted in a Government Sivagangai Medical College Hospital located in South India.

Sample Size and Participants: A total of 150 participants who received platelet transfusion for thrombocytopenia as per the clinician's advice were evaluated

Study Period: The study was carried out over a six-month period, from October 2019 to March 2020

Inclusion and Exclusion Criteria

- Patient who received platelet transfusion in the form Random platelet concentrate (RPC) only, for thrombocytopenic conditions were included.
- All other modes of platelet transfusion like platelet rich plasma (PRP) were excluded.
- All other patients who have not received Random platelet concentrate (RPC) were excluded.

Method of study:

Random donor platelet concentrates were prepared by the centrifugation of Whole Blood collected in triple bags from voluntary donors, in a Blood component separator within 8 hours of collection. The separated platelets were then placed in a Platelet Agitator, for constant agitation at room temperature, which is necessary for the maintenance of platelet viability and stored there for only 5 days.[6]

Pre and 24 hours post transfusion platelet count were estimated to assess the efficacy of transfusion. Height and weight parameters of the recipients were retrieved from case sheets to calculate their Body Surface Area

To assess the efficacy of platelet transfusion, the platelet count is measured before platelet transfusion and 24 hours after the platelet transfusion for calculating the so-called Corrected Count Increment (CCI) [7] The CCI for each patient was calculated to assess the effectiveness of transfusion using the following formula.

$$CCI = \frac{(PC\text{-}POST) - (PC\text{-}PRE)}{\text{No. of Platelets transfused (x } 10^{11})} \times BSA$$

PC-POST: platelet count post-transfusion (PLT/μ L)
PC-PRE: platelet count pre-transfusion (PLT/ μL)
CCI: corrected count increment
BSA: body surface area in m^2
The CCI should be > 7,500 at 1 hour and 4,500 at 24 hours.

RESULTS

The total number of thrombocytopenia patients who received random platelet concentrate transfusion across the wards in the medical institute was 150. Among the recipients, sixty six were males and 84 were females including 8 male children and 6 female children respectively. They were admitted in various wards including the early neonatal ward to the geriatric ward (Figure 1).

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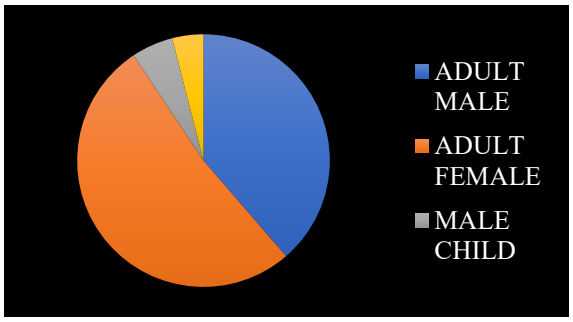

Figure 1: Gender distribution

Among the 150 patients who received platelet transfusion, the majority of them had medical illness (90), followed by haemato-pathology (24), paediatric illness (14), obstetrics complications (13) and surgical emergencies (9) (Figure 2).

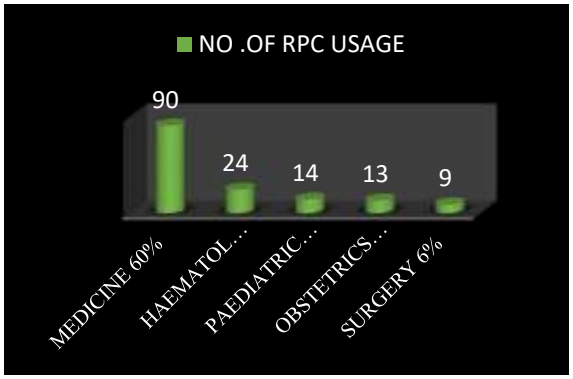

Figure 2: Distribution of Recipients

The distribution of medical diseases was shown in Figure 3.

The medical conditions for which Random Platelet Concentrate were transfused comprises of tropical infections, pyrexia of unknown origin (PUO), and liver diseases.

Among the (90) patients in medicine ward, infections (76) were the most common reason for thrombocytopenia, dengue haemorrhagic fever were present in 55,viral hemorrhagic fever in 21 and sepsis in 7 were noted. 4 patients with Liver disorder and 3 patient with Pyrexia of unknown origin also received platelet transfusion as a prophylactic measure (Figure 3).

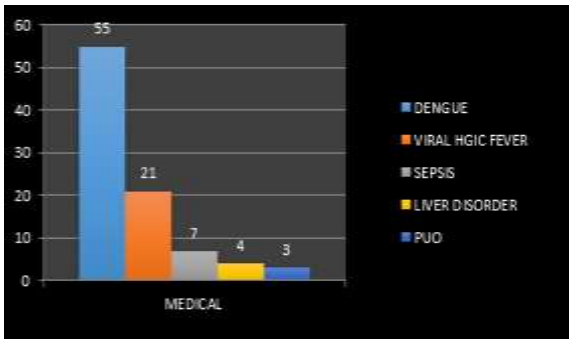

Figure 3: Distribution of Medical Diseases

Haematological causes (14) like anaemia along with thrombocytopenia between 100000-150000, petechiae, pancytopenia and haemato-oncology like acute leukemia patients in the wards also received RPC's. In addition, other oncology patients on chemotherapy who suffered low platelet count (10), utilized RPC during the study period. 14 units were utilized in paediatric wards for cases diagnosed as neonatal sepsis (10) and tropical infections (4).13 patients in obstetrics ward had low platelet counts during their antenatal and post natal period and essentially were in need of transfusion of platelets. Obstetric cases were of anemia and gestational thrombocytopenia(5),followed by pre-eclampsia, and eclampsia(3),intra-uterine death(1), HELLP syndrome(2), post-partum hemorrhage(1) and vaginal bleeding(1) (Figure 4).

In surgical wards, post operative bleeding demanded platelet transfusion for 7 cases whereas 2 cases were of acute abdomen with hematemesis received the same. The 1 hour pre transfusion platelet count was evaluated from clinical pathology laboratory. Table1 shows the percentage of pre transfusion platelet count of the recipients.

Table 1: Pre- Transfusion Platelet Counts

SL NO	PRE-TRANSFUSION PLATELET COUNT (PER μl)	NO. OF PLATELET RECIPIENTS	PERENTAGE %
1	<10,000	14	9.3
2	10000-25000	30	20%
3	25000-50000	35	23.3
4	50000-100000	70	46.7
5	100000-150000	1	0.7

Among the 55 dengue fever cases and 21 viral haemorrhagic fever cases, 50 % of them had platelet count of 40,000-100,000 per micro litre. Nearly 60% of the total recipients had clinical improvement with raised platelet count either after one or two units of platelet concentrate. Table 2 declares the number of units utilized by the patients.

Table 2: Number of Platelet Units Utilized

NO. OF UNITS TRANSFUSED TO AN INDIVIDUAL PATIENT	NO. OF PLATELET RECIPIENTS	TOTAL NO. OF PLATLET UNITS UTILIZED
1	65	65

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2	38	76
3	32	96
4	10	40
5	5	25
TOTAL	150	302

Table 3: 24-Hours Corrected Count Increment After Platelet Transfusion

24-HOUR CCI (per μl)	NO. OF PLATELET RECIPIENTS	PERCENTAGE %
<5000	23	15.33%
5000-7500	34	22.67%
7500-10000	39	26%
>10000	50	33.3%
NO improvement	4	2.67%
TOTAL	150	100%

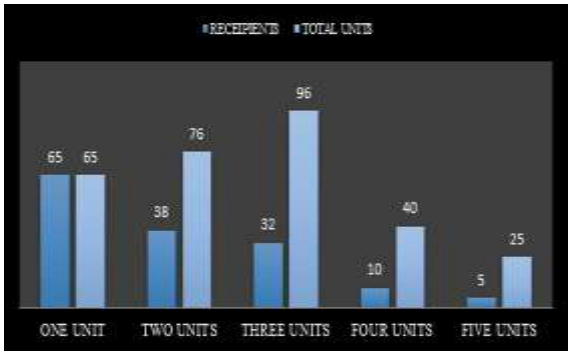

Figure 4: Number of Patients Vs RPC Usage

DISCUSSION

In our study a total of 66 males and 84 females received platelet transfusion; the male to female ratio was 1:1.3. The distribution of platelet transfusion among the different clinical conditions revealed that 60%, 16%, 9.3%,8.7%and 6% had occurred in specialities like Internal Medicine, Haematology, Paediatrics, Obstetrics and Surgery respectively. The RPC usage is nearly similar to an Indian study by Supriya et al,[8] where 53.57% of platelet recipients were from medicine ward and to an observational audit conducted by Deepika Chenna et al,[9] where 42.5 %, from medicine wards 7% from surgical wards used RPC's. The present study reveals the most common indications for platelet transfusion were from medicine ward and among those patients, tropical infections were the main reason for thrombocytopenia. Dengue fever tops the platelet therapy by 36.6% followed by viral haemorrhagic fever by 14%. In tropical countries like India, fever with thrombocytopenia were more common and the similar scenario exists in our study and also in another study by Naik et al.[10] The seasonal, regional variation and the existence of vectors may be considered for the high prevalence of these infections necessitating the increased usage of RPC's. The second most common condition that required platelet transfusions was haemato-oncological (16%) which is slightly lower with international studies (29.7%) done by Charlewood etal,[11] In an another study done in eastern Ontario Canada by Silver et al,[12] the second most common cause for platelet transfusion is haemato-oncology . Bayer WL et al, study concludes that the essential role of platelet concentrates is highest for hematologic malignancies and other oncology. In India, a study conducted in a Himalayan institute by Gaur et al,[13] showed that the need for requirement of blood and its components arises due to anaemia secondary to anorexia, cancer cachexia, bone marrow suppression in cases of leukaemia or for patients on chemotherapy. These studied mirrored the prevalence of malignancy and the need for blood and its products such as RPC's in our country also.

Cancer patients can recurrently develop thrombocytopenia, either from the malignancy itself or cancer chemotherapy. Hence, the 2020 revised version 5.0 of the US National Institute of Health Common Terminology Criteria for Adverse Events (CTCAE) classified thrombocytopenia associated with cancer treatment as follows:

grade 1, 75–150 $\times 10^9$/L;
grade 2, 50–75 $\times 10^9$/L;
grade 3, 25–50 $\times 10^9$/L;
grade 4, <25 $\times 10^9$/L.

This shows the promising role of platelet therapy in these situations. [5, 14]

All these studies confirmed that the most common compelling cause of RPC's include tropical infections followed by malignancies itself and chemotherapy induced thrombocytopenia(CIT) and our study also parallel these studies. The same scenario is shared by Hemavathi et al,[15] in a hospital based study. The other haematological disorders include bleeding manifestations such as epistaxis and petechiae, anaemia with thrombocytopenia and panctyopenia in our study matches with the study done by Naik et al,[10] and Hemavathi et al.[15] Among the 14 units issued to paediatric population, 8units were utilized to treat neonatal sepsis and 6 units for maintaining haemostasis in dengue infection is in comparison with Indian studies by Supriya et al.[8] The most common diagnosis among Obstetric cases were anaemia, and gestational thrombocytopenia followed by of pre-eclampsia, and eclampsia, intra-uterine death, HELLP syndrome, post-partum haemorrhage and vaginal bleeding and this accounts for 8.7% of our total study. This proportion is similar to an Indian study conducted by Padmavar et al,[16]

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done to assess the maternal and foetal outcomes among 1470 pregnant women attending the obstetric ward. Their data showed 100 women, had platelet count less than 150,000/micro litre, which is 6.8%. Surgical speciality needs this therapy for cases of post operative bleeding and in haematemesis. The pre platelet count were between 50000 to 100000 /µl for around 46.7% of them, 23.3 % between 25000/µl to 50000/µl and 29.3% % below 25000/µl. Naik et al,[10] observed the same range of thrombocytopenia among different dengue patients. Septicaemia was noted in seven cases of fever-associated thrombocytopenia and they suffered various bleeding manifestations necessitating more than a unit. A total of 302 units of platelet transfusion were utilized. Among the 150 participants 65 received single unit while 38, 32,10 and 5 of them received, two, three, four and five units respectively. The Corrected Count Increment (CCI) recorded in our study participants is as follows- for less than 5000, 5000-7500, 7500-10000 and more than 10000 per micro litre were 15.33%, 22.67 %, 26%and 33.3% respectively. This data shows variation in percentage with study done by Hemavathy,[15] et al.

Out of the 150 recipients, 80% showed clinical improvement as judged by the treating clinicians and the response given by the patients. Four of our patients did not show any increase in platelet count. Patients with a low CCI on two or more occasions is due to immunological related refractoriness to platelet transfusions. A low CCI in the first hour (< 7,500) and in 24 hours (< 4,500) is often associated with Allo-immunisation to leucocyte and platelet antigens. This type of refractoriness can be caused by antibodies against HLA class I antigens (A and B) or against platelet-specific antigens in particular HPA-1a.[17] In a study conducted by Xiaoye Sun,[18] et al, a total of 364 patients received 1,060 platelet transfusion and the study concluded that the increase in the number of Platelet transfusions is directly proportion to the increases in Platelet Transfusion Refractoriness. Platelet antibodies were detected for all the 364 patients and 67 of them turned to be positive. Among them, 63 cases (94.02%) were positive for HLA class I antibody. Platelet antibody is the main immune factor causing Platelet Transfusion Reactions (PTR). The judicial use of optimal platelet dose in thrombocytopenic patients is important. Transfusing platelets in correct doses and comparing their post transfusion response should be regularly performed. The efficacy of transfusion can be assessed by Platelet response indicators like Corrected Count Increment (CCI) and also by Platelet Recovery Time (PRT).[19] The increasing demand for platelet products is to be met with the available resources. The limited storage time of platelets outpaces the availability of donors. The possibility of potential transmission of viruses and bacteria, transfusion related allergic and febrile reactions and, Allo immunization after repetitive platelet transfusion resulting in platelet refractoriness should be considered before transfusion. Platelet response indicators should be monitored frequently. Eventhough platelets devoid of HLA Class I molecules are promising in preventing alloimmunization, and in reducing the risk of refractoriness ,they alone can't meet the increasing needs of platelet transfusions. Hence it may be sensible to find substitutes for platelets.[20] A number of promising approaches are under process to find safe and effective alternatives to platelet transfusions. This includes auxiliary therapeutic strategies to support plasma coagulation, and also by employing thrombopoietin mimetics, "Thromboerythrocytes,[21]", "Plateletsomes", "Infusible Platelet Membranes", "Thrombosomes", in vitro production of thrombocytes.[22]

CONCLUSION

In developing countries like India, where the demand for platelet transfusion outstrips the limited availability of resources, the sensible and cautious use of platelets is to be followed strictly. Assessment of platelet response indicators such as Corrected Count Increment (CCI) and Percentage Platelet Recovery (PPR) before deciding on subsequent platelet transfusions can minimize the drawbacks of repeated transfusions and help maintain a steady platelet supply for emergency needs. This approach also reduces the risk of alloimmunization and platelet refractoriness caused by the formation of platelet antibodies. Several promising strategies are currently being explored to develop safer and more effective alternatives to platelet transfusion, though these have yet to become widely available across transfusion facilities in India. Until then, regular monitoring of CCI should be considered a valuable tool for evaluating the efficacy of platelet transfusions.

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