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# A PROSPECTIVE STUDY TO ASSESS THE EFFICACY OF SINGLE DONOR VS RANDOM DONOR PLATELET THERAPY IN THROMBOCYTOPENIC PATIENTS

Immunohematology

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## ABSTRACT

Platelets play a vital role in the maintenance of normal hemostatic activity. Patients with severe thrombocytopenia are presumed to be at increased risk of bleeding; consequently it has been standard practice to give allogeneic platelet transfusion to such patients as a supportive care. In the present prospective, observational study, the effectiveness of random donor and single donor platelet therapy in patients with during a period of one year was assessed. There was no statistically significant difference between SDP and RDP based on 1h CCI and 24h CCI.

## KEYWORDS

Platelet therapy, CCI, effectiveness, RDP, SDP

## 1. INTRODUCTION

The prevalent consensus supports the view that platelet transfusion plays a key role in preventing bleeding in patients with severe thrombocytopenia, however a unique definition and commonly accepted level of "adequate clinical efficacy" of platelet support are still lacking[1]. Though the risks of transfusion reactions and transmission of pathogens are minimized, platelet transfusions are not free from complications[2]. It is therefore important to continue the search for an optimal transfusion policy of platelet transfusion.

There are two different platelet concentrates available for transfusion depending upon the method of collecting platelets i.e., Single donor platelets and random donor platelets. Platelet therapy is widely employed in modern tertiary care medical practice for prevention and treatment of thrombocytopenic bleeding in patients with haematologic malignancies, major surgical bleeding, trauma and less often in patients with platelet dysfunction. Clinical anxiety derives primarily from the risk of devastating intracranial hemorrhage in such patients. Currently there are no alternatives to platelet transfusions that have been unequivocally accepted as equally efficacious and safe [3]. In view of all the above, this study was undertaken to assess the effectiveness of platelet transfusion therapy in patients with thrombocytopenia, scheduled to have platelet transfusion, in a tertiary care teaching hospital in India.

## AIM OF THE STUDY

To evaluate and compare the effectiveness of random donor platelet (RDP) and single donor platelet (SDP) transfusions in thrombocytopenic patients using post-platelet transfusion platelet count increments.

## MATERIAL AND METHODS

In the present prospective, observational study, the effectiveness of platelet therapy in patients with thrombocytopenia admitted in the medicine and surgical gastroenterology wards of Sri Venkateswara Institute of Medical Sciences, Tirupati during the period of one year from 24th February 2010 to 23rd February 2011 was assessed. Ethical Clearance has been obtained from the Institutional Ethics Committee for conducting the study. The patients were enrolled into the study based on the following inclusion and exclusion criteria.

### Inclusion criteria

1. Age between 18 to 60 years.
2. Platelet count of less than 50,000/µL

### Exclusion criteria

1. Pregnant women
2. Mentally challenged patients
3. Patients with life threatening co-morbid conditions at the time of first platelet transfusion

### Platelet Concentrates

All the platelet concentrates have been collected from donors after counseling and proper screening as per the National guidelines [4]. All the platelet concentrates transfused were tested for Transfusion transmissible infections using central drug standard control organization (CDSCO) approved test kits and were found to be nonreactive before transfusion.

The preparation method of platelet concentrates transfused, were not influenced by the investigator. Random donor platelets (RDP) have been prepared from triple bags by platelet rich plasma method (RDP-PRP) or from quadruple bags by buffy coat method (RDP-BC) respectively using automated component extractor (Terumo Automated Component Extractor, Terumo Corporation, Tokyo, Japan). The RDPs were not leukoreduced. Single donor platelets were collected by apheresis procedure to produce a leukoreduced product using an automated apheresis machine (COM.TEC Fresenius Kabi, Bad Homburg, Germany).

### Transfusion of platelet concentrates

Once issued, transfusion of platelets started immediately after reaching the ward using standard blood administration sets and finished within 30 to 60 minutes of start of transfusion for all patients.

### *Investigation of platelet concentrates*

All the platelet concentrates have been checked for quality using the parameters, macroscopic platelet swirling, platelet concentrate volume in mL, platelet count per µL using haemocytometry. Crosschecking of platelet counts of SDPs was done with automated hematology analyzer (Mindray BC-5310, Mindray Ltd, Nanshan, Shenzhen, P.R.China) and validated.

### *Investigation of patient's 1 hour, 24 hour post-platelet transfusion increment*

Under aseptic conditions, 2mL of blood sample was collected between 10 to 60 minutes and between 18 to 24 hours respectively after completion of platelet transfusion into a sterile EDTA vial. Platelet count estimation was done using an automated hematology analyzer (Mindray BC-5310, Mindray Ltd, Nanshan, Shenzhen, P.R.China). The platelet counts were crosschecked with hemocytometry and

validated. 1-hour postplatelet transfusion increment was calculated by subtracting the pre-transfusion platelet count as indicated in the blood requisition form from the 1 hour post-platelet transfusion count.

To adjust for differences in platelet dose and blood volume of patient, the corrected count increment (CCI) was calculated by using the formula (86).

CCI= [API × body surface area (BSA) in $m^2 \times 10^{11}$]/ number of platelets transfused.

For all measures, BSA was calculated by using the following Dubois and Dubois formula (87).

$BSA\,(m2) = 0.007184 \times Height\,(cm)^{0.725} \times Weight\,(Kg)^{0.425}$

The BSA obtained after above calculation has been rounded off to three decimals.

**Statistical Analysis**

The various factors analyzed included quantitative variables such as age, height, weight, body surface area, dose of platelets, pre-transfusion platelet count, 1 hour and 24 hour post-transfusion platelet counts, 1h API, 1h CCI, 24h API, 24h CCI and qualitative variables such as sex, bleeding at time of admission, success of increments (1h CCI, 24h CCI), etc., Data were recorded on a predesigned proforma and managed using Microsoft Excel 2007 (Microsoft Corp, Redmond, WA). All the entries were double checked for any possible error. Descriptive and analytical statistics were performed using computer software (PASW version 18.0 for Windows, SPSS, Chicago, IL). A p-value of less than 0.05 was considered statistically significant.

## RESULTS

During the study period, 223 requests were received seeking platelet transfusion for 130 patients from the Departments of Medicine and Surgical Gastroenterology. Of these 110 transfusions given to 61 patients were considered for analysis in the present study.

**Demographic characteristics**

Sixty one patients with a mean age of 36.1±12.5 years (range: 18-60 years) were included in the study. Of these 36 (59%) were males. A history of multiple transfusions were present in 2 (3%) of the patients and they were both males. Fifty (82%) and 11 (18%) patients were admitted under the care of Departments of Medicine and Surgical Gastroenterology respectively. Of the 50 patients admitted under care of Department of Medicine, 29 (58%) were males; similarly 7 (64%) of the 11 patients admitted under care of Department of Surgical Gastroenterology were males.

**Clinical details**

Fever, splenomegaly, hepatomegaly, sepsis, uremia were present in 48 (78%), 22 (36%), 20 (32%), 11 (18%), 9 (14%) patients respectively. Twenty six (42%) patients had a history or an episode of bleeding prior to admission into respective wards. Fifty four (88%) patients had no bleeding at the time of admission. Seven (11%) patients had bleeding episodes at the time of admission into the hospital. The mean duration of hospital stay of the patients was 10.4±8.6 days (range 2-41 days). The mean height, weight and body surface area of the patients were 162.2±7.9 cm (range 145 to 176 cm), 55.2±9.8 Kg (range 33 to 82 Kg), 1.577±0.156 $m^2$ (range 1.201 to 1.985 $m^2$) respectively. Most of the patients were not having hematological malignancies. Depending on varying severity of underlying illness, patients received platelet transfusions at different transfusion thresholds for each type of disease.

**Platelet concentrates**

A total of 258 platelet concentrates were transfused during the present study to 61 patients. Of these, 23 (9%) units were single donor platelets and the rest, 235 (91%) were random donor platelets (RDP). Of the 217 RDPs, 180 (70%) were RDP-BC and 55 (21%) were RDP-PRP. The mean volume of SDP, RDP-PRP and RDP-BC were 281 ± 67mL (range 64mL - 350mL), 52 ± 3mL (range 45mL- 59mL) and 74 ± 3mL (range 66mL - 81mL) respectively. The mean platelet count per µL of SDP, RDP-PRP and RDP-BC were 10,55,957 ± 1,66,110 (range 7,05,000-14,33,000), 11,27,745 ± 75,303 (range 9,88,000 - 13,24,000) and 8,21,556 ± 36,826 (range 6,80,000 - 9,98,000) respectively. The mean platelet content of SDP, RDP-PRP and RDP-BC were $3 \pm 0.8 \times 10^{11}$ (range $8 \times 10^{10}$ - $4 \times 10^{11}$), $5.85 \pm 0.34 \times 10^{10}$ (range $5.5 \times 10^{10}$ - $7.3 \times 10^{10}$) and $6.05 \pm 0.32 \times 10^{10}$ (range $4.9 \times 10^{10}$ - $7.4 \times 10^{10}$) platelets respectively.

**Platelet transfusions**

A total of 110 transfusions have been administered to 61 patients. The dose of the platelets transfused was $1.9 \pm 0.92 \times 10^{11}$. Twenty two (20%) transfusions were only single donor platelets, and the rest 88 (80%) were random donor platelets. The mean 1 hour corrected count increment was 21,545 ±9,159 (range 2,210 to 59,292) platelets/m2 (BSA)/µL. The mean 24h CCI was 21,380 ±32,834 (range -24,191 to 2,03,659) platelets/m2 (BSA)/µL. No adverse reactions, due to platelet transfusion were observed during the 110 study transfusions.

**Platelet transfusion effectiveness**

***1 hour corrected count increment (1h CCI)***

A 1h CCI of more than 7,500 platelets/$m^2$ BSA/µL was considered successful. One hundred and seven (97%) transfusions were successful and had a 1h CCI of more than 7,500 platelets/$m^2$ BSA/µL. Three (3%) transfusions to three different patients had 1h CCI less than 7,500 platelets/$m^2$ BSA/µL. Two patients who had a 1h CCI less than 7,500 did not have repeatedly low 1h CCI while, 1 patient did not need further transfusions. Two patients had a 1h CCI of less than 5,000 platelets/$m^2$ BSA/µL. In one patient low 1h CCI was not observed during later transfusions.

***24 hour corrected count increment (24h CCI)***

A 24 hour corrected count increment of more than 4,500 platelets/$m^2$ BSA/µL was considered successful in the present study. Seventeen (16%) transfusions had a 24h CCI of less than 4,500 platelets/$m^2$ BSA/µL, while the rest 93(84%) were successful.

***Type of platelets concentrates transfused and corrected count increments***

Type of platelet concentrates transfused and its effect on successful platelet transfusion based on corrected count increments have been analyzed (Table 1). There was no statistically significant difference between SDP and RDP based on 1h CCI and 24h CCI.

**Table 1: Comparison of prevalence of successful outcome of single donor platelets and random donor platelets**

| CCI (platelets/$m^2$ BSA/µL) | | 1hr CCI | | | 24hr CCI | | |
|---|---|---|---|---|---|---|---|
| | | <7500 | ≥7500 | p-value | <4500 | ≥4500 | p-value |
| Type of platelet concentrate | SDP | 0 | 22 | | 3 | 19 | |
| | RDP | 3 | 85 | | 14 | 74 | |
| Total | | 3 | 107 | 1.000 | 17 | 93 | 1.000 |

SDP=Single donor platelets; RDP=Random donor platelets; BSA=Body surface area; CCI=Corrected count increment.

## DISCUSSION

In this prospective observational study, the effectiveness of platelet transfusions in patients with thrombocytopenia was evaluated. This study was undertaken as only few clinical trials have been conducted to investigate the effectiveness of platelet therapy in controlling and preventing thrombocytopenic bleeding in non hematooncology patients.

In the present study, a total of 74 (67%) transfusions were given to patients prophylactically and the rest, 36 (32%) were given to patients with intraoperative bleeding or in patients with persistent bleeding. This was comparable with the survey of Transfusion Practice Committee of the American Association of Blood Banks in 1992 which showed that 70 percent of hospitals transfuse platelets primarily for prophylaxis[5].

**Efficacy of platelet transfusions**

Based on 1h CCI, 24h CCI, 97.3 percent, 84.5 percent transfusions were effective respectively. There were no studies assessing efficacy of platelet transfusions in non-hematooncology patients. Hence it was difficult to compare results obtained in hematooncology patient group in other studies with that of the present study. However the mean 1h API of the study transfusions in the present study was $25.16 \pm 15.41 \times 10^9$ platelets/L which was comparable with that of a study by Slichter et al, 2005[6] ($24.9 \pm 17.0 \times 10^9$ platelets/L) in acute leukemia patients.

**Role of type of platelets transfused**

On statistical analysis, there was no statistically significant difference between SDP and RDP transfusions in terms of successful platelet transfusion based on corrected count increments. Randomized trials have demonstrated the equivalence of apheresis and whole blood

derived platelet concentrates in terms of efficacy in hematooncology patients [3]. Similar results were available from one Indian study [7]. Randomized trials have proved that leukoreduced and ABO identical platelet transfusions (SDP/RDP) have reduced the risk of HLA alloimmunization, platelet refractoriness, transfusion reactions and CMV transmission in oncology patients [8]. However it has to be known that apheresis platelets present a lower risk of infectious agent transmission indirectly by decreasing the number of donors to whom the recipient might be exposed [3].

## LIMITATIONS OF THE STUDY

1. A heterogeneous population with different categories of illnesses were studied in the present study.
2. The sample size was small (110 transfusions)
3. Patients were not randomized to receive SDPs or RDPs. The clinicians choice of SDP or RDP transfusion was individualized taking into account among other things, the expenditure or the cost factor

## CONCLUSION

There was no statistically significant difference between single donor and random donor platelets in terms of platelet corrected count increments at both 1 hour and 24 hour ($p = 1.000$) in non-hematooncology patients. However in view of the advantages documented for single donor platelet transfusion in the published literature such as reduction in risk of alloimmunization and transfusion transmissible viral infections, SDPs may be preferable to RDPs.

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