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Various Aspects of Plateletpheresis Procedure and Uses of Single Donor Platelet at a Tertiary Care Hospital

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Abstract
Background: *Transfusion services are aimed to provide only those components which patients require and keep the rest for others. Plateletpheresis is a technique performed on donors where platelet is separated ex vivo and remainder of the blood is returned to the donor. Platelet transfusion is critical due to lack of alternative; and therefore should be used rationally.*
Aim: *Present study is designed to evaluate Plateletpheresis procedure and uses of Single Donor Platelets (SDP) at our institute.*
Materials and Methods: *A 5 years study was carried out from 1st January 2012 to 31st December 2016 at a tertiary care centre where 1120 Plateletpheresis were conducted to prepare Single Donor Platelets (SDP) and transfused to 768 patients. Data were collected, compiled and compared statistically by frequency distribution and percentage proportion. Chi-square ($\chi 2$) test was applied to know the statistically significant difference (p value) of the data.*
Results: *An 1120 SDP were transfused to 768 patients with an average of 1.46 transfusions/ patient. An average age of donors was 32.30± SD6.84 years and Male: female ratio was 98.4:1.6. The average pre and post donation platelets/cumm of donors was 289.96x103± SD13.9x103 and 244.86x103± SD10.5x103 respectively and an average yield of SDP was 3.20x1011± SD1.86. Out of 1120 SDP transfusions given, clinically belonged to; dengue 64.1%, malaria 9.0%, malignancy 7.9%, thrombocytopenia due to unknown cause 5.0%, aplastic anaemia 2.1% , ITP 1.0%, liver disorders1.0%, neurosurgical0.9%, active bleeding 0.8%, miscellaneous 0.7% and vitiligo-0.5%. An average increment of platelets in the patients was 36.13x103 ± SD9.35x103/cumm. Out of 1120 transfusions, therapeutic were 1029(85.75%) where as prophylactic were 91(14.25%) (p=0.000003). Rationality of transfusions was 84% (p=0.000003). Adverse events during the Plateletpheresis procedures was 0.8% (p=0.000004).*
Conclusions: *A better rationality of SDP 84% in the study was observed. SDP should be used rationally and scientifically as per proven criteria because it has no alternative.*
Keywords: *Plateletpheresis, Single Donor Platelets, Donor, Rationality.*

Introduction

Apheresis is a technique performed on donors or patients where by a particular component of the blood is separated ex vivo and the remainder of the blood is returned to the donors or patients [1]. This technology is based on either filtration or centrifugal systems with combination of either continuous- or intermittent-flow technology [2]. The Plateletpheresis is a method used to remove platelet from the body either from random volunteer donors, patient's family members or HLA matched donor for therapeutic/ prophylactic purposes. [3].

Plenty of knowledge has been added recently in the field of transfusion of platelet concentrates and its application in clinical practice by various studies [4,5,6]. Platelet transfusion is widely employed in modern medical practice for prevention and treatment of thrombocytopenic bleeding in patients with various clinical conditions like hematological malignancies, solid tumors, major surgical bleeding, trauma etc [5,6]. In India the demand of Platelet concentrates has been increasing, especially in the endemic regions of specific parasitic infestations like Malaria and Dengue which are known to cause thrombocyt-openia [7]. Emerging incidents of malignant disorders, aplastic anaemia and bone marrow depression caused by radiotherapy and chemot-herapy has further augmented the demand of platelet components [8]. Role of Platelets in hemostasis are well established and there are increased practices to make up the threshold thrombocytic pool before going for elective surgeries which is a recommended indications in all the authenticated agencies like British Committee for Standards in Hematology (BCSH) [9] as well as American Association of Blood Bank (AABB) [10]. Apheresis is now very well practiced in western countries and it is gaining the momentum in India also [11]. Single donor platelet (SDP) is better platelet concentrate than random donor platelets (RDP) because SDP is a simple means of reducing Septic Platelets Transfusion Reactions (SPTRs) [12] and shielding the patients from multiple immunological allogenic exposures [13].

There is no alternative treatment other than platelets in certain clinical settings; it is an essential therapy in some instances and very useful option in others [14]. Platelets are precious human resource and should be used rationally. Present study is designed to evaluate the work on Plateletpheresis and usefulness of SDP in thrombocytopenia and other clinical conditions at our institute.

Materials & Methods

The present 5 years prospective cross-sectional study was carried out from 1st January 2012 to 31st December 2016 in the Blood Bank, Department of Pathology, a tertiary care centre in Central India. As per prior requirement of the patients, 1120 voluntary and replacement blood donors were registered for Plateletpheresis procedure, fulfilling the standard criteria of National AIDS Control Organization (NACO guidelines 2007)[15] and Plateletpheresis protocol. Donor's relevant data; age, sex, height, weight, hematocrit, pre & post donation platelet count as well as any adverse event during and after the Plateletpheresis procedure was recorded. The Single Donor Platelets (SDPs) were procured and transfused to the patients and appropriateness of its uses in our institution was assessed.

After proper cleaning of the cubital fossa, a clean venipuncture through wide-bore siliconized needles to minimize platelet and clotting factor activation was done to collect the Leukoreduced SDP by using Aphaeresis device make Haemonetics®, which is an intermittent flow device along with leukoreduced bag system. In vitro platelet quality was assessed by swirling, volume, Haemoglobin (Hb %), Platelet count, White Blood Cells (WBC) count and pH of bag. These parameters from our institute are compiled in the Table no. 1.

Table No. 1 Parameters for the Assessment of Different Platelet concentrate

S.No.	Parameter	SDP
1	Volume	200-220 ml
2	Platelet Count	3-3.8 $X10^{11}$/unit
3	Swirling	Present
4	Haemoglobin	<0.2 gm/dl
5	WBC	$4.1\pm0.8 \times 10^6$
6	ph	6.5-7.0

Units were screened for Transfusion Transmitted Infections (TTIs) i.e. Human Immunodeficiency Virus (HIV) 1 & 2, Hepatitis B Surface Antigen (HbsAg), Hepatitis C Virus (HCV), malaria and VDRL.

Prepared SDP were either issued against the requisite/ demand or stored under the optimal liquid platelet storage temperature i.e., 22^0 C with continuous gentle agitation in Platelet incubator and agitator PI200 make-Termopenpol. Storage was done for maximum 5 days. Compatibility test was done before issuing the unit. ABO compatible platelets were issued to the patients.

For each transfusion, relevant information about the patient, SDP supplied, its indication and transfusion details were noted. These information were gathered from; component demand form, issue card, transfusion notes and case sheet of the patient, which included – patient's Name, Age, Sex, Clinical Diagnosis, Indication (therapeutic/ prophylactic) of Platelet transfusion, number of transfusions, Pre & Post-transfusion Platelet count, increment in platelet count after transfusion, any adverse event etc. Rationality was screened under the guidelines of BCSH 1992 as shown in Table no.2 [9,16]. All data was collected, compiled and compared statistically by frequency distribution and percentage proportion. Chi-square ($\chi 2$) test was applied to know the statistically significant difference (*p* value) of the data. Epicalc version 2000 software was used for the same. The data was also compared with similar studies in India and abroad.

Table No.2- Recommendations For The Rational Use Of Platelet Concentrates

1.Prophylactic Causes		
Code	Platelet count	Additional features/ Clinical assessments
1A.	Less than $10x10^9$/L	Without additional risk factors
1B.	Less than $20x10^9$/L	With additional risk factors (Fever, Sepsis, Concurrent use of Antibiotics, on chemo-/radio therapy or other abnormalities of haemostasis)
1C.	Less than $50x10^9$/L	If patient is undergoing minor invasive procedure, epidural anesthesia, gastroscopy and biopsy, insersion of indwelling lines, transbronchial biopsy, liver biopsy etc.
1D.	Less than $100x10^9$/L	If patients are undergoing major surgical procedures (especially on critical site as Brain etc.)
1E.	Less than $100x10^9$/L	If Patient undergoing massive Transfusion.
2. Therapeutic cause		
In Patients with bleeds from oral cavity, mucous membranes or any other site with platelet dysfunction irrespective of platelet counts		

Results

A total number of 1120 Plateletpheresis procedures were conducted to prepare Single Donor Platelets (SDP) and transfused to 768 patients, minimum 01 and maximum 09 with an average of 1.46 transfusions/ patient. In the study age of the donors varies from 18 to 60 years and an average age of donors was 32.30± SD 6.84 years. Male: female ratio of donors was 98.4:1.6. Pre donation platelets of donors varied from 150 x 10^3 to 400 x 10^3 / cumm. The average pre and post donation platelets/ cumm of donors was 289.96 x 10^3 ± SD 13.9 X 10^3 and 244.86 x10^3 ± SD 10.5 X10^3 respectively with an average fall of platelets /cumm was 50.10X 10^3 ± SD 11.41x10^3. Platelet yield of SDP varied from 3.0 x 10^{11} to 3.7 x 10^{11}/ unit, with an average of 3.20 x 10^{11} ± SD 1.86 in 5-6 cycles of apheresis procedure.

In the study, age of the patients varied from 3 to 78 years. Average age of the patients was 32.89 ± SD 16.14 years while male: female ratio of the patients was 65.8: 34.2. ABO blood group distribution of 768 patients was; A: 149(19.4%), B: 334(43%), O: 224(29.1%) and AB: 61(7.9%) (*p*=0.000002) (Figure No.1) while 737(95.9%)

were RhD positive and 31(4.1%) RhD Negative (p=0.000003).

A total number of 1120 SDP transfusions given in the study, clinically belonged to; dengue- 770 (64.1%), malaria-108(9.0%), malignancy- 95 (7.9%), thrombocytopenia due to unknown cause- 60 (5.0%), aplastic anaemia- 26(2.1%), ITP-13 (1.0%), liver disorders- 12(1.0%), neurosurgical- 11(0.9%), active bleeding- 10(0.8%), miscall-aneous- 09(0.7%) and vitiligo-06(0.5%) Figure No. 2.

Pre transfusion platelets of the patients varied from 4 $x10^3$ to 80 $x10^3$ /cumm. Average pre and post transfusion platelets/cumm of patients was 26.89$x10^3$ ± SD 16.08$x10^3$ and 62.02$x10^3$± SD 10.6$x10^3$ respectively, with an average increment of 36.13$x10^3$ ± SD 9.35$x10^3$/ cumm. Out of 1120 transfusions, therapeutic were 1029 (85.75%) where as prophylactic were 91(14.25%) (p=0.000003) (Figure No. 3) and as far rationality is concern 180(16%) transfusions were inappro-priate (Irrational) while 940(84%) were rational by the criteria led down by the British committee for standards in hematology (BCSH) (p=0.000003) and were statically significant Figure No. 4.

We had encountered 09 (0.8%) (p=0.000004) adverse events during the Plateletpheresis procedures; 06 belonged to the donors and 03 were due to the procedural error related with the apheresis device. Out of 06 adverse event of donor, three had symptoms of hypocalcaemia, two hypovolemic shock and one developed local hematoma around the venipuncture site. Three cases of procedural error were due to the bag tubing; 02 had kinking of tube and 01 had leakage in the tube.

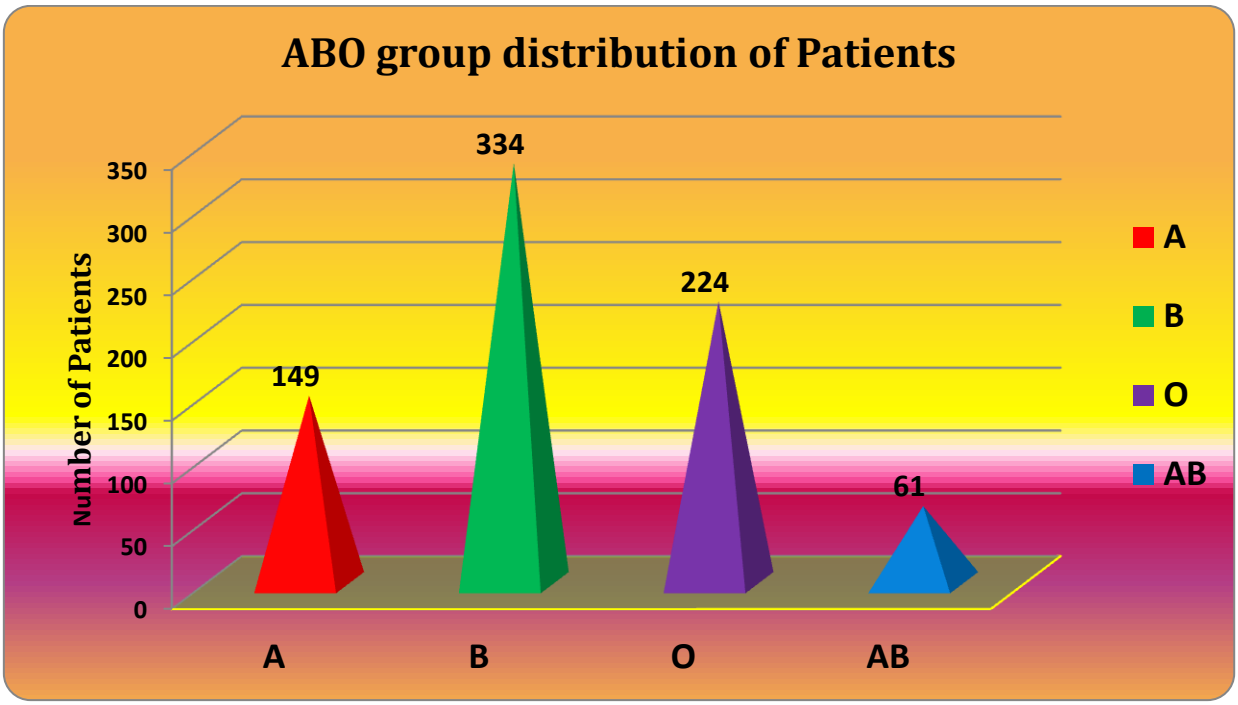

Figure No. 1 ABO group distribution of the Patients in the study

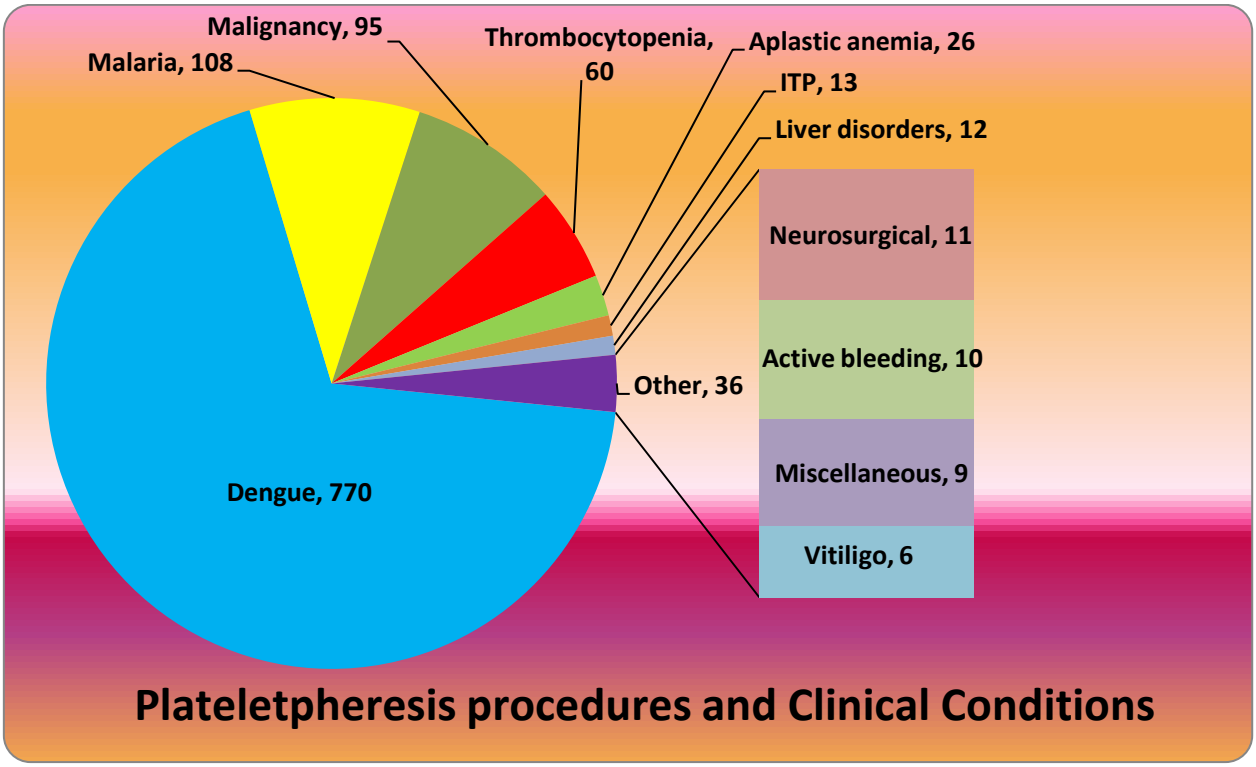

Figure No.2 Plateletpheresis procedures and clinical conditions

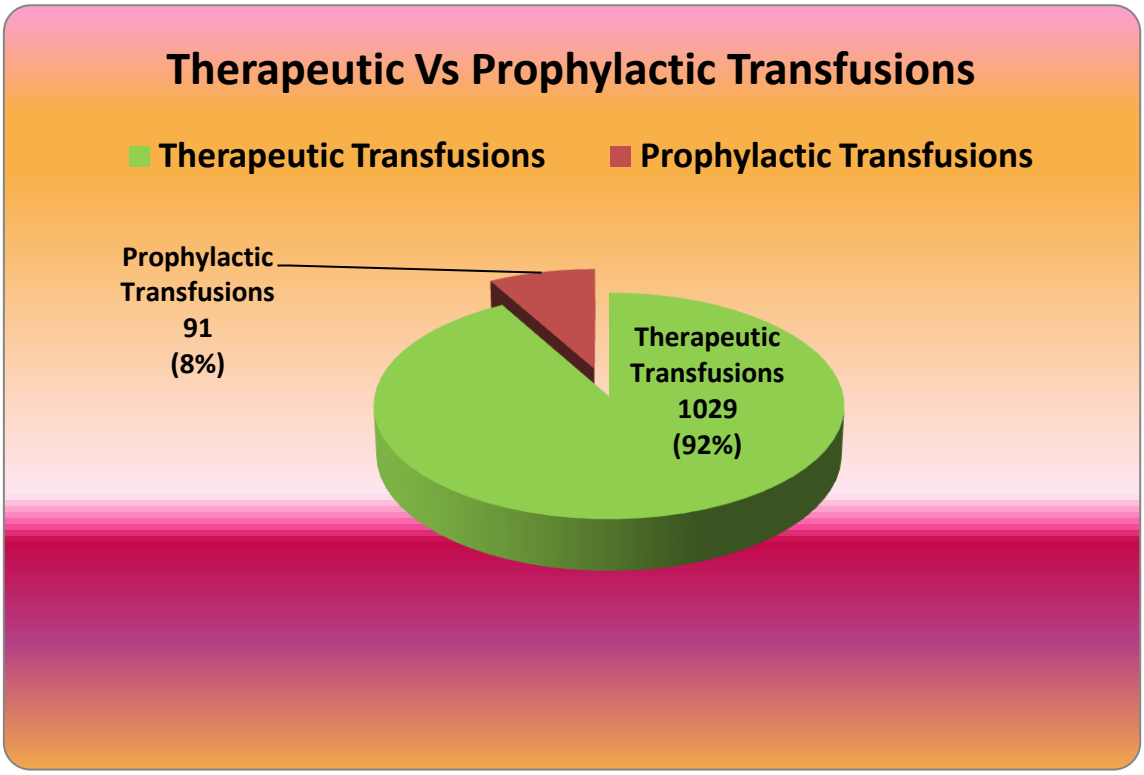

Figure No. 3 Therapeutic Vs Prophylactic Transfusions in the study

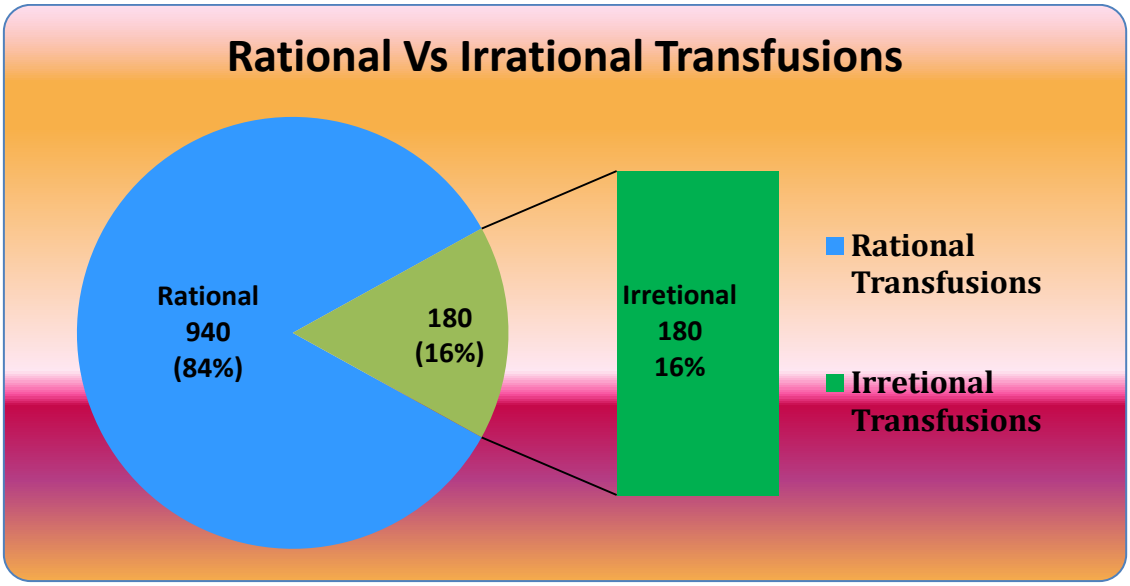

Figure No.4 Rational Vs Irrational Transfusions in the study

Discussion

Blood Banking is a rapidly progressing branch of medical science which is expanding itself to the new horizon of development. In our institute most commonly preferred platelet concentrate was Platelet Rich Plasma (PRP) 68.75% followed by Buffy Coat Platelets (BC-PC) 22.13% and SDP 9.11% [17]. Similar data for SDP was reported by Chaurasia et al. 6.88% [18] while lower preference for SDP was reported by Saluja K, et al. 1.18% [16]. Despite of a better component, SDP is less commonly preferred in India because of unavailability of facilities and unawareness.

In the study, average age of Apheresis donors was 32.30± SD 6.84 years while it was 28.56 ± 5.77 years in Pakistani study [19]. Male: female ratio of donors was 98.4:1.6 while in the study of Amanat ST *et al* there was 100% male donors [19].

The average pre and post donation platelets/ cumm of donors was 289.96 x 10^3 ± SD 13.9 X 10^3 and 244.86 x10^3 ± SD 10.5 X10^3 respectively in the present study while in the study of Amanat ST *et al* it was 268 x 10^3/µL and 200 x 10^3 /µL. An average fall of platelets /cumm in the donor in our study was 50.10X 10^3 ± SD 11.41x10^3 while it was 68,000/µL in the study of Amanat ST *et al.* Platelet yield of SDP varied from 3.0 x 10^{11} to 3.7 x 10^{11} platelets/ unit, with an average of 3.20 x 10^{11} ± SD 1.86 platelets/ unit in 5-6 cycles of apheresis procedure which was at par of quality parameters of 3 x 10^{11} platelets/ unit [20].

In the study, age of the patients varied from 3 to 78 years. An average age of the patients was 32.89 ± SD 16.14 years while male: female ratio of the patients was 65.8: 34.2. Male: female ratio in the study of Amanat ST *et al* was 43.2: 56.8 out of 125 cases [19]. ABO blood group distribution among 768 patients in our study was; A: 149 (19.4%), B: 334(43%), O: 224(29.1%) and AB: 61(7.9%) while 737(95.9%) were RhD positive and 31(4.1%) were RhD Negative which was in accordance's with the geographical distribution of this region [21]. Distribution of ABO and Rh blood group varies widely geographically and racially.

The clinical condition where SDP was transfused is summarized in Figure no. 2. Most common clinical condition was dengue (64.1%) fallowed by Malaria (9.0%) because our area is endemic for these conditions. Malignancy- 95(7.9%), thrombo-cytopenia due to unknown cause- 60(5.0%), aplastic anaemia- 26(2.1%), ITP-13(1.0%), are the emerging conditions of thrombocytopenia in India [8]. Liver disorders- 12(1.0%), neurosurgical-11 (0.9%), active bleeding- 10(0.8%), miscellaneous-09(0.7%) are the other conditions can cause the thrombocytopenia. In 6(0.5%) cases of vitiligo SDP was used in our study as a regenerative medicine [22].

In our study, an average increment of Platelets after one hour of SDP transfusion in the patients was $36.13x10^3 \pm$ SD $9.35x10^3$/ cumm while it was $43.1+24.2 \times 10^3$ /µl reported by Singh R P et al in his study [23]. One unit SDP expected to raise the platelet count by 30,000-60,000/ul in a 70 kg patient [24]. In the present study out of 1120 transfusions, therapeutic were 1029 (85.75%) and 91(14.25%) were prophylactic (p=0.000003) as per guidelines of BCSH 1992 which is comparable with study of Chaurasia R et al 2015 while high proportion of prophylactic transfusion of platelet concentrates was reported by Buhrkuhl DC et al 2012 (77%), Davidson A 2014 (73%) and Qureshi H. et al 2003(55%) in their reports as recapped in table no 3.

Table 3: Therapeutic verses Prophylactic transfusions

S. No	Studies	Therapeutic (%)	Prophylactic (%)
1	Buhrkuhl DC et al 2012 [24]	23%	77%
2	Davidson A 2014 [25]	27%	73%
3	Qureshi H. et al 2003 [26]	45%	55%
4	Chaurasia R et al 2015 [18]	65.35%	34.65%
5	Present Study	85.75%	14.25%

As far rationality of SDP transfusion was concern, 180(16%) transfusions were inappropriate (Irrational) and 940 (84%) are rational by the criteria led down by the British committee for standards in hematology (BCSH) (p=0.000003) and were comparable with the audit studies on platelets transfusions in India and abroad as shown in table no 4. High rationality in the present and studies from the other part of India is at par with developed countries indicates the development of health services in India especially in the field of transfusion medicine.

Table 4: Rationality of Platelet Transfusions

S.No.	Study	Rational Transfusions (%)	Irrational Transfusions (%)
01.	Saluja K 2007 [16]	88%	12%
02	Hui CH et al 2005 [27]	79%	21%
03	Minal Wade 2009 [28]	93%	07%
04	Charle wood R 2007 [29]	87%	13%
05	Present study	84 %	16%

We have encountered 09 (0.8%) adverse events during the Plateletpheresis procedures, similarly low incidence 0.68% (18/2,641) is reported by Pietro Bonomo et al [30] while higher incidence was reported by Barbosa M H et al 4.4% [31] and much higher incidence 18% (n=90) was reported by Patidar G K et al in their study [32]. Commonly encountered adverse events were hypocalcaemia, hypovolemic shock, local hematoma around the venipuncture site and events related to device. No serious event was encountered during Plateletp-heresis procedure in the present study.

Conclusion

In developing countries like India, lower preference for SDP is because of its high cost and selective availability, but due to its effectiveness, it is getting momentum in the present days. In our institute, therapeutic use of SDP is more common than the prophylactic use. Better rationality of SDP (84%) in the present study was observed due to coordinated and updated approach between clinicians and transfusion specialist. Platelets should be used rationally and scientifically as per proven criteria because it has no alternative.

Ethical Approval

All author(s) hereby declare that all procedure have been examined and approved by the appropriate ethics committee of Gajra Raja Medical College, Gwalior. Research has therefore been performed in accordance with the ethical standards laid down in the 1964 declaration of Helsinki.

Patient's and Donor's consent

Informed written consent has been taken from the patient in whom SDP has been transfused as well from the donor selected for Apheresis procedure in the study.

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Competing Interests

Authors have declared that there are no competing interests.

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