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ANALYSIS OF DONOR DEFERRAL PATTERN IN PLATELETPHERESIS ALONG WITH RECOMMENDATIONS FOR THE MODIFICATION OF THE SELECTION CRITERIA

Clinical Research

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ABSTRACT

Background: The demand of plateletpheresis has increased in the last two decades. Stringent donor selection criteria leading to higher rate of deferral are the major limitations to availability of SDP.

Aim: The aim of the present study is to analyze the reasons for the deferral of apheresis donors along with recommendations for modification of the donor selection criteria.

Materials & methods: The present study was carried for two & half years to analyze the causes, frequency and type of plateletpheresis deferred .

Results: For 193 procedures, 371 donors were screened out of which 131(35.3%) donors were deferred. The most frequent cause of deferral was poor vein access (9.5%) followed by low platelet count (6.5%).

Conclusion: As it is difficult to convince donors for plateletpheresis, screening criteria for the same should be revised especially criteria for hemoglobin & donor weight should be relaxed.

KEYWORDS

Donor deferral criteria, donor selection criteria, plateletpheresis

INTRODUCTION:

Blood transfusion service (BTS) is an integral part of the health care system which aims at providing adequate safe blood & blood components. Effective component transfusion therapy allows optimal use of blood, which is a limited natural resource. For this, the most important step is proper selection of donor by following stringent donor selection criteria. [1] Appropriate donor selection ensures safety of donor as well as recipients. Donor can donate whole blood or a particular component like platelets during apheresis procedure which is termed platelpheresis. In this procedure platelets in the donor blood are separated from blood by being passed through an apparatus and returning the remainder donor blood into the circulation.[2]

Platelet transfusions are indicated in patients who are bleeding or at an increased risk of bleeding secondary to thrombocytopenia or platelet dysfunction. The number of transfused platelet components is growing due to increasing number of patients treated with hematological malignancies, functional platelet disorders and disorders causing decreased platelet production. Single donor platelets (SDP) has numerous advantages over random donor platelets (RDP) which includes decreased risk of transfusion transmitted infections (TTIs), bacterial contamination & alloimmunization. [3,4] In addition, it also prevents the chances of refractoriness to a larger extent.[5] Over the years, the demand to SDP has increased consistently. However, plateletpheresis requires a greater dedication than the whole blood donation on the part of donor because of prolonged duration of the procedure. For adequate platelet yield (more than or equal to 3×10^{11} platelets) [6] and optimal patient & donor safety, the donor selection criteria are more stringent. Determination of reasons & rates of donor deferral during the procedure can help in planning more efficient recruitment strategies & donor selection criteria. This study aimed to define the causes, frequency & type of plateletpheresis donor deferral to plan more competent donor recruitment strategies & selection criteria.

MATERIALS & METHODS:

The present study was conducted from July 2015 to December 2017 in the Department of Transfusion Medicine, Sri Ram Chandra Bhanja (SCB) Medical college & Hospital, Cuttack, Odisha. A total of 371 donors were screened for plateletpheresis procedure during the period of two and half years.

The following donor selection criteria were followed in our institution according to the

DGHS guidelines.

(a) Age 18-50 years
(b) Weight > 60 kg
(c) Hemoglobin > 12.5gm/dL
(d) Platelet count > 1.5 lacs/ µl
(e) At least three days from last plateletpheresis / a gap of three months from the last whole blood donation
(f) No consumption of aspirin in the last three days
(g) Absence of any illness
(h) ABO identical donor for the patient
(I) Negative tests for HBs Ag, HCV, HIV, Malaria & syphilis
(j) Adequate venous status

Besides these, all other criteria for the whole blood donations were followed.

Blood samples were collected for checking the blood group which should be identical to the patient's blood group, complete blood count (CBC) & serological tests. CBC was done by Sysmex 1800i. The serological tests were done using third generation ELISA kits for HIV(Erba Lisa HIV, Transasia, Biomedicals Ltd),HBsAg (Qualisa, Qualpro diagnostic, Tulip), HCV(Erba Lisa HCV, Transasia, Biomedicals Ltd). Tests for syphilis & malaria were done by rapid card test(Advy Chemicals Pvt Ltd) , Maleriscal Bhat Bio-tech India(P) Ltd) respectively. The donors who full-filled the above criteria were called & apheresis procedure was performed using Cobe Spectra, cell separator.

RESULTS:

Over a period of two & half years from July 2015 to December 2017, 371 donors were screened for plateletpheresis for 193 procedures, out of which 131 (35.3%) deferred constituting only two female donors & the rest were being the male cases. In 43 accepted SDP donors, plateletpheresis couldn't be performed due to certain unavoidable circumstances like death of the patients, high cost of the procedure, denial of the donor to undergo the procedure (Fig 1). All the cases were deferred temporarily. As plateletpheresis procedure in our department with Cobes Spectra require dual vein access, poor vein was the commonest cause of temporary deferral followed by low platelet count 35 cases (9.5%) and 24 cases (6.5%) respectively (Fig 2). Four cases (1.1%) for being in the age group of more than 50 years were deferred, eight cases (2.2%) were not selected for having weight less than 60kg and 12 donors (3.2%) were deferred due to high hemoglobin and hematocrit counts.

DISCUSSION:

Platelet transfusions are essential in severely thrombocytopenia and at risk of spontaneous bleeding patients. Apheresis platelets are transfused to treat bleeding in critically decreased circulating platelet concentrations or functionally abnormal platelets and are used

prophylatically to prevent bleeding at low platelet concentration. Guidelines published by American Society of Anesthesiology state that prophylactic pretransfusion is rarely for concentration > 100,000/μL, is usually required for concentration < 50,000/μL and is guided by risk factors at intermediate concentration.[7] Neurological/ Ophthalmological procedures require a platelet concentration of at least 100,000/μL.[8] platelet transfusion trigger was established at 20,000/ μL. A number of randomized trials in patients with acute leukemia,hematopoitic stem cell transplantation & aplastic anemia have demonstrated the outcome equivalency of a prophylactic transfusion threshold of 10,000/ μL instead of the 20,000/ μL threshold derived from older literatures.[9] Sagmeister et al outlined a protocol of transfusing aplastic patients μL routinely at concentration < 5,000/ μL, at 6,000 to 10,000/ μL with fever or minor hemorrhage and at > 10,000/ μL when actively bleeding .[10]

The quality of SDP in terms of yield is determined by the recovery from recipient and allows prolongation of intervals between transfusions.[11] But, the significant limitation for the use of apheresis platelets is poor availability of SDP donors due to increased procedure time, causing non- cooperation by donors and increase cost of the procedure. Besides these, ineligibility of donors due to low platelet count, low hemoglobin or low weight further aggravates the problem. In the present study, 131 platelet donors were deferred due to various reasons constituting 35.3%. A deferral rate of 10.6%- 27.5% has been described by other authors. [12,13,14,15] The higher percentage of deferral in the present study may be due to the use of dual vein access for the SDP procedures & deferring 35 cases (9.5%) due to poor vein. Deferral due to poor venous access in our study was almost at par to 9.41% & 9% of Pujari et al and Kusumgar et al respectively. [12,13] Good venous access is an important criterion for successful completion of procedure. Out of 24 cases (6.5%) deferred for low platelet count 9 had platelet count in range of 1.4 lakh –1.49 lakh. As per DGHS guidelines platelet count is not required in first time donor.[16] Tendon et al found 22% decrease in platelet count after procedure. [14] Literature has documented no adverse effects in donor even at a post platelet count of 69,000/cmm. [17] Since pre procedure platelet count affect the platelet yield & we wanted to provide a yield which should have crossed 3 x 10^{11} platelets to maintain the quality, so we followed a policy to do the platelet count even in the first time donors. In case of emergency & unavailability of donors, these criteria can be relaxed to reduce family anxiety.

We deferred 12 cases (3.2%) with hemoglobin count more than 16.5 gm% & hematocrit count with more than 49% who are said to be polycythemic according to WHO guideline. [18] Our deferred percentage was lower in this case in comparison to other authors who had deferred the donors when Hb% was above 12.5 gm%. [14] Only 9 cases were not selected in our case due to low Hb% below 12.5 gm%. Fraser et al found lowering the cut-off value of Hb% upto 11.5 gm% has no deleterious effect on apheresis donors. [19] Because only 20-40 ml of blood (PRBC) is lost if procedure is performed properly. The rationale for hemoglobin testing & setting the cut-off at > 12.5 g/dL for donor acceptance is justified in whole blood donation with decrese of one g/dl in hemoglobin level, but not in case of plateletpheresis. We deferred 8 donors due to hypertension from which 2 donors had raised hemoglobin & hematocrit counts in addition to raised blood pressure.[9]

In our study, we deferred 8 cases (2,2%) having weight less than 60 kg which included 4 donors having weight between 50-60 kg. M Pujari et al & Kusumgar et al followed a cut off value of 60 kg & 50 kg and deferred 4.7% & 5% donors for low weight respectively. [12,13]

Kusumgar et al did not report any adverse effect in weight ranging between 50-60 kg. Buchhotz et al did not find any adverse effects in plateletpheresis donors of 45-49 kg of weight. [20] In the present study we could have included these 6 cases basing on the modified NACO guideline.[21]

11 cases were deferred for the cause of medication. Four donors were deferred because they were more than 50 years age group which is considered to be the upper limit of age consideration as per DGHS guidelines. But, all of the authors in previous publications have taken the upper limit of age to be 60 years & have not reported any deferral/ adverse events in this context. Thus, recently the donor selection ncriteria have been modified in the NACO guidelines regarding the age limit. [21] Considering these modifications we could have accepted these six deferral cases whose age was between 50-60 years.

Nine donors (2.4%) were deferred as they were the first degree relatives of the patients. These cases could have been considered if we had the facility of irradiating the blood components in our center.

CONCLUSION:

The demand of plateletpheresis is increasing with the shortage of apheresis donors. Selection of plateletpheresis donors follows the stringency of whole blood donation criteria along with certain additional criteria. Taking into account these factors, we would like to recommend that the selection criteria for the plateletpheresis donors should be revised. The critereia regarding the pre- procedure platelet count (above 1.5 lac/μL) & hemoglobin (above 12.5g/dL) need to be lowered to suit the Indian scenario. Donors being deferred for low platelet count should be followed up and repeat platelet count should be performed to reduce the deferral rates. With slight revision of the SDP donor selection criteria, deferral rate for apheresis can be drastically lowered as temporary deferrals account for the majority of the causes of deferral.

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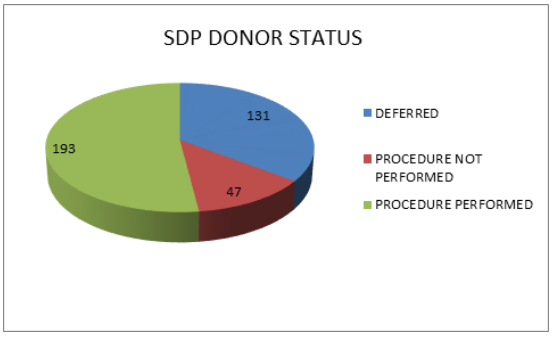

Figure 1: Status of donor deferral and accepted

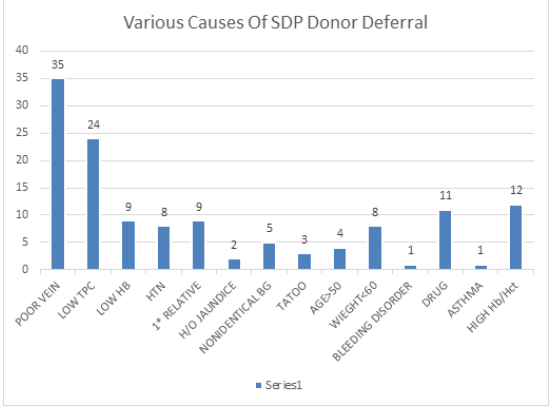

Figure 2: Various causes of SDP donor deferral

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