Study of Predonation and Post donation Haematological and Biochemical values in healthy donors undergoing Platelet Apheresis at Dhiraj Blood Bank : A Hospital based study".

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Abstract:

Background: Platelet transfusions are one of the blood components that are routinely requested by clinicians for patients undergoing cancer therapy, for those with bleeding disorders, for cardiovascular surgeries and for organ transplantation. Single donor platelets collected through apheresis technique provides adequate dose to patients without risk of alloimmunization. The present study thus aims to compare the pre and post plateletapheresis parameters of complete blood counts and biochemical parameters serum calcium and serum magnesium in healthy voluntary donors.

Materials and Methods: This study was conducted in the Department of Blood TransfusionSBKSMIRC Vadodara, over 1 year with effect from June 2018 to May 2019. clearance. The study was conducted on 60 randomly selected plateletpheresis donors. The eligibility criteria for donor selection was made as per Departmental SOPs.The details of plateletpheresis were explained to each donor before the procedure.Donor questionnaire form was filled and informed consent was taken from donor for the procedure. Plateletpheresis was done using Fresenius comtec Automated Cell Separator machine. Hematological parameters such as hemoglobin (Hb), hematocrit (Hct), platelet counts, mean platelet volume (MPV), and white blood cell (WBC) counts were analyzed both before and after plateletpheresis procedure

Results

A total of 60 donors were subjected for apheresis, all of which were males. The mean age of the plateletpheresis donors was 30 years.. The mean BMI of plateletpheresis donors belonged to "Pre-Obese" category(26.73). The mean platelet count before apheresis was 259× 10^3±31.2 /µl with the range and the mean platelet count after apheresis was 205.2× 10^3 ±8.0/µl; The mean value of platelet count dropped significantly in postdonation. siimilarly, the mean Hb level before apheresis was 14.2±1.3 g/dl and the mean Hb value after apheresis was 14.0±1.3 g/dl; the mean value of Hb dropped marginally in postdonation. The mean value of Hct concentration before apheresis was 42±3.2% and the mean value of Hct concentration after apheresis was 41.9±1.3% the mean value of Hct dropped slightly in postdonation. There were also slight changes in the WBC counts and MPV value which were not so significant. Serum calcium before procedure ws 10.80 ± 1.30 and 30 minute after procedure was 10.20±1 .28. serum magnesium b efore procedure was 2.15± 0.30 and after procedure was 2.10±0.25.

Conclusion:-

Since Donor safety was ensured throughout the procedures but to prevent any unfavorable events, and for the benefit of donors and patients, its recommended that hematological and biochemical parameters should be tested following the procedure in plateletapheresis donors. As this will help in establishing post donation reference ranges which could be utilized when suitability of donors for subsequent donations is reviewed.

Key words: Apheresis, blood donors, platelet count

Study of Predonation and Post donation Haematological and Biochemical values in healthy donors undergoing Platelet Apheresis.

Introduction:

Platelet apheresis is a process by which platelets are collected and other components are returned back to donor. The single donor platelets collection by apheresis methodology has high platelet concentration and less contamination with white and red blood cells which greatly reduces the incidence of adverse reaction to transfusion.[1]

Repeat platelet apheresis donationscan lead to a great amount of cell loss and clinically significant problems in donor, such as transient thrombocytopenia and anemia[2]

In apheresis procedures , citrate is used as an anticoagulant in the form of acid citrate dextrose(ACD) which Causes reversible chelation of circulating calcium and magnesium causing alteration of the level of total calcium which may result in donor hypocalcemia, as well as total magnesium which is involved in many metabolic process and therefore it may affect both calcium metabolism and parathormone response[3]. The ratio of whole blood to citrate anticoagulant used is 12:1 . Donors can generally tolerate upto 20% decrease in ionized calcium level but repeated and longer procedures might result in citrate accumulation and significant donor symptoms.

During apheresis procedures Magnesium level decreases upto30-50% depending on the length of procedure performed and citrate infusion rate and may also result in increased urinary excretion of magnesium which occurs during and after apheresis[4]

Material and methods:

The study is cross sectional study conducted in the department of Blood Transfusion Medicine, SBKSMIRC, Vadodara.

Study population includes SDP(single donor platelet) donors who fulfilled the eligibility criteria for Platelet apheresis donation as per guidelines of Directorate general of health services DGHS,

in the department of Blood Transfusion Medicine SBKSMIRC Vadodara from June 2018 to May 2019 [5]. Written and informed consent was obtained from all the SDP donors in either English language or in local vernacular language (which ever is preferred by donor)

Donor Selection :- Voluntary blood donors who arrive at Blood Bank are provided Predonation counseling and informed consent form is filled up . Donor fills up the single donor platelet questionnaire form and mini physical examination of the donor is performed by Medical officer.

Sample collection and testing:

- Sample for analysis was collected from the arm not to beused for plateletapheresis procedure.
- 5 ml of whole blood from each donor was collected . 2 ml transferred to EDTA contained Lavender coloured vacutainer tubes and 3 ml of whole blood to plain red topped vacutainer tubes.
- Samples are to be taken just before and 30 minutes after the completion of plateletapheresis procedure.
- ABO Typing and Rh typing of donor sample was done.
- Screening for transfusion transmissible infections was done on donors sample using rapid screening kits prior to donation and later (post donation), the sample was tested by Elisa technique.
- Haematological parameters of the donors were analyzed using calibrated automated cell counter and biochemical parameters analyzed using calibrated automated biochemical analyzer.
- Donors negative for TTIs fulfill eligibility criteria's according to guidelines issued under DGHS standards technical Manual 2003, the donor is subjected to plateletapheresis procedure.
- All Plateletapheresis procedures were performed using Fresenius comtec apheresis machine using single needle procedure .
- After completion of priming sequence in machine haemocalculator page is displayed and sex, height, hematocrit, and preplatelet count are added .
- The end point for the product collected was fixed with target yield of $3x10^{11}$ platelets /unit.
- Following haematological parameters namely

  Hemoglobin

  Hematocrit

  RBC Count

  WBC Count

Platelet count

Mean platelet volume

- Platelet Distribution Width are measured both before and after Plateletapheresis procedure. Results recorded and correlated with citrate toxicity.

The following biochemical parameters, namely, viz., serum calcium, serum ionized calcium and serum magnesium levels are measured, both before and after the plateletpheresis procedures, their results recorded and changes analyzed with normal reference range for serum calcium (8.9 – 10.1mg/dL) serum ionized calcium (1.14- 1.38 mmol/L) serum magnesium (1.7- 2.3 mg/dL)90 and correlated with citrate toxicity.[6]

Actual platelet yield was calculated by using the following formula

Actual Platelet = Volume of x PLT count of x Conversion factor

Yield product PC sample (x $10^3/\mu L$)

- The following procedural parameters namely, viz., number of cycles,

  Duration, blood volume processed, platelet yield, product platelet volume,

  return rate , saline used, ACD-A used are recorded at the end of the

  procedure.

Sample size was calculated :-

Sample size was calculated using n Master software.

Statistical Analysis:-

Data was entered in MS-Excel and statistically analyzed using SPSS software. Demographic detail will be given in descriptive statistics. Pre and post procedure parameters analysis using paired t test. Differences were considered to be statistically significant when the P value was less than 0.05.

Aims And Objectives

The present study aims to compare the pre- and post- plateletpheresis values of hematological and biochemical parameters on single donor platelet donors.

Results:-

The plateletapheresis procedures at our centre were done on 60 healthy donors. The age range of healthy donors in our study population was 18-50 years. All donors who donated SDP were

males. The weight varied from 50-90 kgs (mean 72± 9.3). The mean BMI of plateletpheresis donors belonged to "Pre-Obese" category(26.73).The mean height of SDP donors was 178.5±6.2 cms(160-192 cms). The donors who donated for first time were 53 and repeat apheresis donors were 5.

The mean blood volume processed was 2580.52ml over a mean duration of 90.28 minutes by using 290.80 ml of ACD during procedures.

After plateletapheresis it was found that Hb concentration , Hematocrit , platelet count and WBC count were highly significantly reduced ($p < 0.05$).

There was increase in MPV Post donation and it was Statistically significant ($p < 0.05$) .

Table 2 :- Shows drop in mean total calcium levels of donors at the end of procedure with mean difference of about 10.20±1.28 and for magnesium it was 2.10±0.25.

Discussion:-

Table no 4:-

Mean Comparison of pre and post donation hematological parameters of Plateletapheresis donors with other studies.

Study	Predonation mean Hb(gm/dl)	Post donation mean Hb gm/dl)	Predonation Hct(%)	Post donation hct(%)	Predonation Platelet count(Nx10^{11})	Post donation platelet count Nx10^{11})	Predonation WBC count Nx10^{11})	Post donation WBC count . Nx10^{11})
Rajaddhyaksha, 2009[8]	12.5-17.3	8.9-16.6	34.0-54.2	26.3-49.7	150-438	80-385	3.3-12.1	2.7-10.8
Das et al ,2009[9]	12.2-17.2	10.5-16.3	31.8-54.1	28.5-49.2	150-467	79-413	3.8-15.1	2.5-14.6
Khurshid I et al, 2019 [14]	12.3-18.2	11.2-16.7	36.1-55.1	37.375 2.47	161-330	113-278	4.0-11.9	2.6-9.7
Present study	15.5-12.9	15.3-12.7	45.2-38.8	45.1-38.7	290.2-227.8	213.2-204.4	9.9-4.9	9.6-5.0

Table no. 5

Comparison of Procedural Parameters across various studies:-

Procedural parameters	Present study	Solanki A et al10 (n=60)	Barbosa MH et al56 (n=316)	Bueno JL et al23 (n=51)	Col Swarup D et al22 (n=80)	Das SS et al33 (n=20)
Duration [min]	90.28	-	73	74.3	71.47	93.9
Blood volume processed	2580.52	3490	2829.8	3072	2501.97	2930
Platelet yield [x 1011/unit]	3.22	-	3.47	-	3.33	2.88
Platelet volume [ml]	310.85	-	-	-	-	-
Return rate [ml/min]	85.60	-	-	-	-	-
Saline used [ml]	250.62	-	-	-	-	-
ACD-A used [ml]	290.80	307.6	360	271	-	275

In this study a total of 60 plateletapheresis donors were recruited into the study. The study showed a significant reduction in the platelet count of donors after plateletapheresis. This finding is similar to earlier studies on Plateletapheresis elsewhere.(7)(8)(9)

In present study donor safety issues were assessed by studying the changes in the hematological , biochemical, procedural parameters. In present study a statistically significant decline in hemoglobin level and platelet count was observed but none of donors experienced any clinical evidence of anemia or thrombocytopenia.

In the present study, there were a significant decrease in the post procedure levels of haematocrit (42 +/- 3.2vs 41.9 +/- 3.2) and WBC count (7.4±2.5 vs 7.3±2.3). However, in a study conducted by Das SS et al. there was a statistically significant decrease in post procedure haematocrit, WBC count as compared to the pre-procedure levels (10)

The possible reasons for the decrease in post procedure haemoglobin and haematocrit are as a result of haemodilution due to infusions of citrate solutions and saline; blood loss in the void volume of apheresis kit, technique applied and mechanical haemolysis by the pressure pumps. A significant and sustained decrease in post procedure platelet count is expected following plateletpheresis but without clinical manifestations of anaemia or thrombocytopenia. However, low or borderline pre-donation platelet count 259±31.2 /µL) and haemoglobin (14.2±1.3 g/dL) need to be assessed and monitored after the procedure for any decrement in haematological parameters.(9) (10)

In the present study, a significant decrease was observed in S.Calcium (10.80 ± 1.30 vs 10.20 ± 1.28), S.Ionised calcium (1.15 ± 0.18 vs 1.10 ± 0.10) and S.Magnesium (2.15 ± 0.30 vs 2.10 ± 0.25) levels, but was not statistically significant. However, studies conducted by Solanki A et al.; Das SS et al.; VB et al. reported a statistically significant reduction in post procedure levels of S.Calcium, S.Ionised calcium and S.Magnesium. This variation is attributed to the prophylactic intervention in the form of oral calcium and intravenous calcium infusion drip with normal saline, provided to the plateletpheresis donors(11, 12)

The possible reasons for the decrease in the post procedure level of serum ionised calcium in the oral Ca2+ group and a corresponding increase in the IV Ca2+ group might be attributed to the level and mode of calcium supplementation which are dose limited, and a better bioavailability of IV calcium infusion drip with normal saline as compared to the oral calcium supplements.(13)

Conclusion :-

In our study, we observed better bioavailability of serum ionised calcium among Plateletpheresis donors who had been administered prophylactic IV calcium compared to oral calcium supplementation. This fact has further been reiterated by absence of adverse reactions in this group. However, if oral prophylactic calcium supplementation is preferred, administration of 2 – 3 tablets of calcium (0.969 g of total Ca2+ / 375 mg of elemental Ca2+) most often prevents manifestations of mild citrate toxicity. This enables frequent, smooth and comfortable collection of higher concentration of platelets from a single donor and reduces patient's exposure to multiple donors. However, it is imperative to conduct more studies with larger number of donors to observe donor adverse reactions specific to our population.

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