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ASSESSMENT OF THE EFFECTS OF FREQUENT PLATELETPHERESIS DONATIONS ON HEMATOLOGIC PARAMETERS: A CLINICAL OBSERVATIONAL STUDY

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ABSTRACT

Background: There is increased concern towards subjects who are frequent donors of plateletpheresis. The present study was conducted to assess the effect of frequent plateletpheresis on the hematologic parameters in the frequent donors.

Methods: The present study included frequent donors of plateletpheresis who were the donor for 2nd time in a month. The inclusion criteria were also donors undergoing plateletpheresis for the 3rd or 4th time. The hematologic parameters were assessed and compared on recalls following plateletpheresis.

Results: For all the parameters there was a non-significant difference pre 1st duration and pre 2nd duration in the two groups of the study subjects except haemoglobin with an intergroup p-value of pre1st and pre 2nd was 0.227 and 0.882 for PDW, 0.886 and 0.368 for MOV, 0.459 and 0.084 for PCT, 0.279 and 0.004 for TPC where for TCP significant difference was seen in two groups pre 2nd donation, 0.376 and 0.438 for TLC, 0.487 and 0.333 for RDW, 0.236 and 0.434 for MCHC, 0.209 and 0.047 for MCH, 0.077 and 0.100 for MCV, 0.416 and 0.867 for HCT, 0.025 and 0.029 for RBC, and 0.285 and 0.604 for haemoglobin respective. All the parameters showed the non-significant intragroup difference

Conclusion: The present study concludes that plateletpheresis can be repeatedly done with no harmful effects on the hematologic parameters among these donors. Same follow-up results post-donation were seen concerning hematologic parameters in the donors.

Keywords: hematological parameters, haemoglobin, plateletpheresis, single donor,

INTRODUCTION

Plateletpheresis is a term used for platelet concentration donation by a single donor by apheresis which leads to a short-term fall in the platelet counts in the donors. The guidelines suggested by U.S. Food and Drug Administration (FDA) allow a donor to make a maximum of 12 donations every year not exceeding two donations a week at a minimum interval of 48 hours between consecutive donations. These guidelines were reviewed and changed to 24 donations a year which later in 2005 modified to 24 donations a year with a maximum of 3 components donated per time.[1]

However, in subjects undergoing frequent plateletpheresis, issues were raised concerning prolonged and long-term decreases in platelet counts. Previous literature data has reported that no restriction should be imposed on frequent plateletpheresis as it could negatively affect the apheresis components and their availability in the medical field. Also, literature data documented focus on the decrease in white cell count, platelet count, Hematocrit, and haemoglobin in blood samples collected 30 minutes following plateletpheresis.[2]

This decrease in the hematologic parameters does not persist for a long time as supported by documented literature data. However, this persistence is governed by materials and instruments used during the plateletpheresis procedure. However, this pattern of plateletpheresis is less studied with scarce data in the previous literature. In various Indian setups, plateletpheresis is on-demand and is conducted frequently on the regular basis. Repeated and frequent plateletpheresis is done in relatives and attendants to support the affected subjects which provide an opportunity for the researchers to assess hematologic alterations in subjects undergoing frequent plateletpheresis.[3] Hence, the present study was conducted to assess the effect of frequent plateletpheresis on the hematologic parameters in the frequent donors

MATERIAL AND METHODS

The present study was conducted to assess the effect of frequent plateletpheresis on the hematologic parameters in the frequent donors. The study was conducted at Department of General Medicine, Saraswathi Institute of Medical Sciences, Hapur, Uttar Pradesh, India after obtaining clearance from the concerned Ethical committee. The study population was comprised of the subjects undergoing frequent plateletpheresis in the Institute. The subjects who participated in the study were subjects who fulfilled the inclusion criteria and were undergoing frequent plateletpheresis in the institute were included.

After final inclusion, detailed history and general examination were done for all the subjects followed by detailed routine questionnaire filling. After explaining the detailed study design, informed consent was taken from all the subjects in both written and verbal form. All the subjects who underwent repeated plateletpheresis within the defined study period were considered a potential candidate for the study.

Counselling and screening were done for all the subjects before plateletpheresis. The blood samples were collected and assessed for blood grouping, hematologic parameters, and diseases transmitted by blood transfusion assessed with chemiluminescence immunoassay. The hematologic parameters assessed were platelet distribution width (PDW), mean platelet volume (MPV), platelet crit (PCT), total platelet count (TPC), white blood cells (WBC), mean corpuscular HB concentration (MCHC), mean corpuscular HB (MCH), mean corpuscular volume (MPV), Hematocrit, red blood cells (RBC), and haemoglobin.

Based on the Director-General of Health Services guidelines, the standard operating protocol was used in all the subjects for the apheresis procedure. In the present study, ACD-A (anticoagulant citrate dextrose solution-A) was used as an anticoagulant in a 1:12 ratio to 1:7 ratio of ACD-A to the whole blood. The collection was targeted at every procedure for a dose of 3×1011 platelets in 200-250 ml plasma. No routine protein analysis was done. The exclusion criteria for the study were subjects who had their second donation more than 30 days apart. Pre-plateletpheresis samples for assessing hematologic parameters were collected 12 hours before the procedure. Follow-up data was contributed by the blood collected from the 2nd visit which was also compared with pre-plateletpheresis data.
The donors from the present study were divided into two groups where Group I comprised of subjects who underwent 2nd plateletpheresis within one week, whereas, Group II had subjects who underwent plateletpheresis within 8-30 days. These subjects were further divided into subgroups IA and IIA for platelet counts of 150,000 and 200,000/µl, subgroup IB and IIB for counts of 200,000-300,000/µl, and IC and IIC for count beyond 300,000 for the two groups.

The collected data were subjected to the statistical evaluation using SPSS software version 21 (Chicago, IL, USA) and one-way ANOVA and t-test for results formulation. The data were expressed in percentage and number, and mean and standard deviation. The level of significance was kept at $p<0.05$. Figure 1 depicts one completed case.

RESULTS

The present study included frequent donors of plateletpheresis who were the donor for 2nd time in a month. The inclusion criteria were also donors undergoing plateletpheresis for the 3rd or 4th time. The hematologic parameters were assessed and compared on recalls following plateletpheresis. There was 940 plateletpheresis performed in the institute within the defined study period were 121 subjects who were donor for a minimum of 2 times a year. There were 120 males and 1 female in the present study. The mean age of the study subjects was within the age of 18-50 years and the mean age of 28.98±8.12 years. Among 121 subjects, 88 subjects were undergoing plateletpheresis for the 2nd time and were analyzed. Assessment of hematologic parameters was done from baseline (1st donation) to 2nd visit. All the parameters were comparable with no statistical difference at two-time intervals except for MPV (Mean platelet volume) which was significantly higher at the second donation compared to the first donation with<0.05 (Table 1). It was seen that MPV at baseline was 9.82±1.98 which at 2nd donation increased significantly to 15.8±2.07 with $p <0.05$. Haemoglobin from baseline to 2nd donation decreased non-significantly from 15.06±1.13gm% to 15.02±1.07gm% as depicted in Table 1.
The donors from the present study were divided into two groups where Group I comprised of subjects who underwent 2nd plateletpheresis within one week, whereas, Group II had subjects who underwent plateletpheresis within 8-30 days. Group I had 30 subjects and Group II had 58 subjects. It was seen that for all the parameters there was a non-significant difference pre 1st duration and pre 2nd duration in the two groups of the study subjects except haemoglobin with an intergroup p-value of pre1st and pre 2nd was 0.227 and 0.882 for PDW, 0.886, and 0.368 for MOV, 0.459 and 0.084 for PCT, 0.279 and 0.004 for TPC where for TCP significant difference was seen in two groups pre 2nd donation, 0.376 and 0.438 for TLC, 0.487 and 0.333 for RDW, 0.236 and 0.434 for MCHC, 0.209 and 0.047 for MCH, 0.077 and

0.100 for MCV,0.416 and 0.867 for HCT, 0.025 and 0.029 for RBC, and 0.285 and 0.604 for haemoglobin respective. All the parameters showed non-significant intragroup differences as summarized in Table 2.

On assessing the changes following plateletpheresis in the study subjects on the platelet counts, in group I, subgroup A had 8 donors where 75% (n=6) subjects had increased count, whereas, 25% (n=2) had decreased platelet counts. The mean rise from baseline was 35650/µl and the mean decrease of 30400/µl from baseline. Subgroup B had 18 subjects where 22.22% (n=4) showed increased platelet counts, whereas, 77.77% (n=14) subjects had decreased platelet counts. The mean rise from baseline was 36000 and the mean decrease in counts was 44170 /µl. In subgroup C, the counts have decreased in 75% (n=3) subjects with a mean rise of 18320/µl from baseline and decreased in 25% (n=1) subjects where the mean decrease from baseline was 56400 /µl. In 58 subjects from Group II, subgroup A had 12 subjects where the increased count was seen in 83.33% (n=10) subjects with a mean increase of 26260 /µl from baseline and decrease in 16.66% (n=2) subjects with a mean decrease of 24820 /µl from baseline. In subgroup B, 59.45% (n=22) subjects had increased platelet counts with a mean increase of 43810 and a decrease of 40.54% (n=15) subjects with a mean decrease of 30500 /µl from baseline. In subgroup C, all subjects showed increased platelet counts with a mean increase of 17500 /µl from baseline (Table 3).

DISCUSSION

The present study assessed frequent donors of plateletpheresis who were the donor for 2nd time in a month. The inclusion criteria were also donors undergoing plateletpheresis for the 3rd or 4th time. The hematologic parameters were assessed and compared on recalls following plateletpheresis. There was 940 plateletpheresis performed in the institute within the defined study period were 121 subjects who were donor for a minimum of 2 times a year. There were 120 males and 1 female in the present study. The mean age of the study subjects was within the age of 18-50 years and the mean age of 28.98±8.12 years. Among 121 subjects, 88 subjects were undergoing plateletpheresis for the 2nd time and were analyzed. Assessment of hematologic parameters was done from baseline (1st donation) to 2nd visit. All the parameters were comparable with no statistical difference at two-time intervals except for MPV (Mean platelet volume) which was significantly higher at the second donation compared to the first donation with $p<0.05$. It was seen that MPV at baseline was 9.82±1.98 which at 2nd donation increased significantly to 15.8±2.07 with $p <0.05$. Haemoglobin from baseline to 2nd donation decreased non-significantly from 15.06±1.13gm% to 15.02±1.07gm%. These results were comparable to the results of Duggan F et al[4] in 2016 and de Aguilar-Nascimento et al[5] in 2012 where authors reported non-significant changes in hematologic parameters following plateletpheresis.

The donors from the present study were divided into two groups where Group I comprised of subjects who underwent 2nd plateletpheresis within one week, whereas, Group II had subjects who underwent plateletpheresis within 8-30 days. Group I had 30 subjects and Group II had 58 subjects. It was seen that for all the parameters there was a non-significant difference pre 1st duration and pre 2nd duration in the two groups of the study subjects except haemoglobin with an intergroup p-value of pre1st and pre 2nd was 0.227 and 0.882 for PDW, 0.886, and 0.368 for MOV, 0.459 and 0.084 for PCT, 0.279 and 0.004 for TPC where for TCP significant difference was seen in two groups pre 2nd donation, 0.376 and 0.438 for TLC,

0.487 and 0.333 for RDW, 0.236 and 0.434 for MCHC, 0.209 and 0.047 for MCH, 0.077 and 0.100 for MCV, 0.416 and 0.867 for HCT, 0.025 and 0.029 for RBC, and 0.285 and 0.604 for haemoglobin respective. All the parameters showed a non-significant intragroup difference. These results were in agreement with the results of Sachdev R et al[6] in 2014 and Budak YU et al[7] in 2016 where authors reported results as of the present study where hematologic parameters did not change significantly following plateletpheresis donation.

Concerning the changes following plateletpheresis in the study subjects on the platelet counts, in group I, subgroup A had 8 donors where 75% (n=6) subjects had increased count, whereas, 25% (n=2) had decreased platelet counts. The mean rise from baseline was 35650/µl and the mean decrease of 30400/µl from baseline. Subgroup B had 18 subjects where 22.22% (n=4) showed increased platelet counts, whereas, 77.77% (n=14) subjects had decreased platelet counts. The mean rise from baseline was 36000 and the mean decrease in counts was 44170 /µl. In subgroup C, the counts have decreased in 75% (n=3) subjects with a mean rise of 18320/µl from baseline and decreased in 25% (n=1) subjects where the mean decrease from baseline was 56400 /µl. In 58 subjects from Group II, subgroup A had 12 subjects where the increased count was seen in 83.33% (n=10) subjects with a mean increase of 26260 /µl from baseline and decrease in 16.66% (n=2) subjects with a mean decrease of 24820 /µl from baseline. In subgroup B, 59.45% (n=22) subjects had increased platelet counts with a mean increase of 43810 and a decrease of 40.54% (n=15) subjects with a mean decrease of 30500 /µl from baseline. In subgroup C, all subjects showed increased platelet counts with a mean increase of 17500 /µl from baseline. These results were consistent with the results of Lippi G et al[8] in 2014 and Thokala RP et al[9] in 2016 where authors showed similar raise and drop in platelet levels the following plateletpheresis from baseline values as in the present study.

CONCLUSION

Within its limitations, the present study concludes that plateletpheresis can be repeatedly done with no harmful effects on the hematologic parameters among these donors. Same follow-up results post-donation were seen concerning hematologic parameters in the donors. However, the present study had a few limitations including small sample size, short monitoring period, use of IOPAR, and geographical area biases. Hence, more longitudinal studies with a larger sample size and longer monitoring period will help reach a definitive conclusion.

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TABLES

Parameter	Baseline	2nd donation	p-value
PDW (platelet distribution width)	15.54±2.03	15.83±2.06	>0.05
MPV (Mean platelet volume)	9.82±1.98	15.8±2.07	**<0.05**
PCT (Plateletcrit)	0.24±0.07	0.23±0.07	>0.05
TPC (Total platelet count)	242.58±56.68	242.76±57.69	>0.05
TLC (Total leukocyte count)	7.46±1.56	7.46±1.53	>0.05
RDW (Red cell distribution width)	14.13±1.38	13.98±1.39	>0.05
MCHC (mean corpuscular haemoglobin concentration)	33.97±1.48	33.77±1.57	>0.05
MCH (mean corpuscular haemoglobin)	30.02±3.06	29.78±2.98	>0.05
MCV (Mean corpuscular volume)	88.77±6.58	88.63±6.38	>0.05
HCT (Hematocrit)	44.53±3.25	44.19±5.13	>0.05
RBC (Red blood cell)	5.05±0.45	5.04±0.45	>0.05
Hb (Haemoglobin)	15.06±1.13	15.02±1.07	>0.05

Table 1: Changes in hematologic parameters at baseline and 2nd donation in the study subjects

Parameter	Subgroup	Pre 1st donation	Pre 2nd donation	p-value
PDW (platelet distribution width)	**Group I**	15.16±2.39	15.82±1.82	0.204
	Group II	15.66±1.75	15.84±2.07	0.619
	p-value	0.227	0.882	
MPV (Mean platelet volume)	**Group I**	10.08±1.47	9.48±2.07	0.077
	Group II	9.66±9.62	9.05±1.94	0.158
	p-value	0.886	0.368	
PCT (Plateletcrit)	**Group I**	0.24±0.07	0.22±0.06	0.036
	Group II	0.25±0.07	0.24±0.08	0.812
	p-value	0.459	0.084	
TPC (Total platelet count)	**Group I**	234.4±53.68	220.68±54.37	0.096
	Group II	247.26±58.18	255.04±56.22	0.203
	p-value	0.279	0.004	
TLC (Total leukocyte count)	**Group I**	7.65±1.59	7.66±1.44	0.946
	Group II	7.36±1.55	7.36±1.63	0.955
	p-value	0.376	0.438	

RDW (Red cell distribution width)	**Group I**	14.22±1.54	14.17±1.36	0.348
	Group II	14.02±1.27	13.88±1.32	0.228
	p-value	0.487	0.333	
MCHC (mean corpuscular haemoglobin concentration)	**Group I**	33.83±1.54	33.97±1.94	0.606
	Group II	34.17±1.46	33.66±1.36	0.082
	p-value	0.236	0.434	
MCH (mean corpuscular haemoglobin)	**Group I**	30.57±2.48	30.57±2.27	0.812
	Group II	29.75±3.27	29.37±3.17	0.006
	p-value	0.209	0.047	
MCV (Mean corpuscular volume)	**Group I**	90.36±5.97	90.18±5.72	0.729
	Group II	87.85±6.76	87.97±6.62	0.739
	p-value	0.077	0.100	
HCT (Hematocrit)	**Group I**	44.16±2.56	44.07±3.06	0.893
	Group II	44.71±3.51	44.26±5.95	0.454
	p-value	0.416	0.867	
RBC (Red blood cell)	**Group I**	4.93±0.38	4.87±0.37	0.914
	Group II	5.13±0.48	5.07±0.42	0.717
	p-value	0.025	0.029	
Hb (Haemoglobin)	**Group I**	14.94±1.16	14.95±1.02	0.962
	Group II	15.16±1.07	15.07±1.07	0.277
	p-value	0.285	0.604	

Table 2: Change in hematologic parameters pre 1st donation and pre 2nd donation in the two groups of the study subjects

Groups	**Total donors**	**Donor number with counts increased from baseline=n (%)**	**Mean rise from baseline (/µl)**	**Donor number with counts decreased from baseline =n (%)**	**Mean drop from baseline (/µl)**
I					
Subgroup A	8	6 (75)	35650	2 (25)	30400
Subgroup B	18	4 (22.22)	36000	14 (77.77)	44170
Subgroup C	4	3 (75)	18320	1 (25)	56400
II					
Subgroup A	12	10 (83.33)	26260	2 (16.66)	24820
Subgroup B	37	22 (59.45)	43810	15 (40.54)	305000
Subgroup C	4	4 (100)	17500	0	0

Table 3: Effect of plateletpheresis on platelet counts in the study subjects