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A study to analyze the changes in clinically significant serum cation levels during plateletpheresis in healthy donors

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Abstract

Background: Plateletpheresis is used to gather platelets for transfusion, but there are worries about how it might affect serum cation levels, which are crucial for biological functions. The objective of this research is to examine changes in clinically significant serum cation levels in healthy donors during plateletpheresis**.**

Methods: 130 healthy subjects participated in a prospective interventional research at a hospital. We examined changes in serum cation levels in healthy donors undergoing plateletpheresis. Our study showed a minimum detectable difference in mean and standard deviation for calcium and magnesium levels served as the basis for determining the sample size. In order to boost the study's power and reduce alpha error, we raised the sample size from the necessary minimum of 130 donors to 137 donors.

Results: Serum calcium and magnesium levels decreased during plateletpheresis in healthy donors and then started to improve after 30 minutes, with 14.60% of donors experiencing adverse reactions but responding well to prophylactic oral calcium supplements**.**

Conclusion: In conclusion, weanalyzed changes in clinically significant serum cation levels during plateletpheresis in healthy donors. The findings suggest that there were statistically significant decreases in calcium and magnesium levels during the procedure, although these changes were transient and returned to baseline levels within 24 hours. Overall, plateletpheresis appears to be a safe procedure for healthy donors with minimal impact on serum cation levels**.**

Keywords: Plateletpheresis, Serum cation levels, Healthy donors, Calcium and magnesium levels,

Introduction

Apheresis is a process of separating cellular and soluble components of blood for transfusion purposes(1). Plateletpheresis is a type of apheresis procedure that requires an anticoagulant infusion to prevent blood clotting in the apheresis circuit. Citrate is the most commonly used anticoagulant for this procedure.(2) Citrate chelates cations, particularly the free bioactive blood calcium, which is required by coagulation factors.(3) Reduced calcium and magnesium levels in donors are considered physiological and of little

consequence.(4-7) However, citrate accumulation may outpace metabolism during longer and repeated procedures, resulting in markedly decreased ionized calcium levels and significant donor symptoms.(8)

The most common observed apheresis-related complication is hypocalcemia due to chelation of free calcium by citrate. Hypocalcemia may lead to more severe complications,such as frank tetany with spasm in other muscle groups, including life-threatening laryngospasm, Q-T prolongation, and fatal arrhythmias(9-11). Repeated plateletpheresis donations may lead to a great amount of cell loss and clinically significant problems in donors, such as transient thrombocytopenia and anemia.

Plateletpheresis is a significant advance in transfusion medicine, with the administration of these platelets significantly reducing the risk of alloimmunization.(12) The higher yield is reached if the donor has a higher initial platelet count and shorter separation duration. To ensure donor safety, the U.S. Food and Drug Administration has laid down guidelines, allowing 24 donations per year, with not more than three components per procedure being allowed. (13)Apheresis technology, even though known as safe and efficient, carries some additional risks to the donors.

Apheresis procedures, including plateletpheresis, are essential in transfusion medicine. However, they are not without risks, with hypocalcemia being the most common complication due to chelation of free calcium by citrate. Therefore, proper monitoring and management of the donor's electrolyte balance are crucial to avoid severe complications. The guidelines laid down by the U.S. Food and Drug Administration should be followed to ensure donor safety.(13)

Material and Methods

We conducted this research in the Department of Immunohematology and Transfusion Medicine at SMS Hospital in Jaipur, Rajasthan. It was a hospital-based prospective observational research that aimed to determine the changes in serum calcium and magnesium levels in healthy single donor platelet (SDP) voluntary donors during the apheresis procedure. Our research included all healthy SDP donors who gave written informed consent. This research was conducted after approval from the research review board of SMS Medical College, Jaipur. The procedure was performed using closed system Plateletpheresis kits and acid, citrate and dextrose-A (ACD-A) as an anticoagulant. Samples were collected at various time points and serum calcium and serum magnesium levels were evaluated by coloric spectrophotometric method in SMS hospital central lab. During our research, no oral calcium supplement was given to the donors, but in the event of any adverse reactions due to hypocalcemia/hypomagnesemia, calcium supplement was provided to the donor (oral/IV) and Serum Cation levels were measured separately. The data collected was recorded in tables, and any adverse reactions observed were also noted.

Results

Table 1: Comparison between Serum Calcium Levels at different time intervals

Time Interval	Mean ±SD		P value
	Serum calcium level (mg/dl)	Difference from baseline	
Baseline	9.78±0.21	-	-
30 min	9.33±0.24	0.45±0.11	<0.0001(HS)
60 min	8.99±0.21	0.78±0.15	<0.0001(HS)

End of Procedure	8.82±0.25	0.95±0.18	<0.0001(HS)
30 min after Procedure	9.63±0.21	0.14±0.12	<0.0001(HS)

Serum calcium levels slowly decreased from baseline to the end of the procedure and again they started improving after 30 min of the procedure. There are highly significant differences in mean calcium levels.

Table 2: Comparison between Serum Magnesium Levels at different time intervals

Time Interval	Mean ±SD		P value
	Serum Magnesium level (mg/dl)	Difference from baseline	
Baseline	2.47±0.25	-	-
30 min	2.09±0.21	0.39±0.13	<0.0001(HS)
60 min	1.83±0.28	0.65±0.20	<0.0001(HS)
End of Procedure	1.70±0.32	0.78±0.25	<0.0001(HS)
30 min after Procedure	2.36±0.30	0.11±0.09	<0.0001(HS)

Serum magnesium levels slowly decreased from baseline to the end of the procedure and again they started improving after 30 min of the procedure. There are highly significant differences in mean magnesium levels.

Table 3: Relation between Adverse Reaction and Type of Machine used

Machine Type	Adverse Reaction	
	Yes	No
AMICUS	2	24
COMTEC	2	27
MCS+	15	39
OPTIA	1	27
Total	20	117

Perioral tingling was seen in 20 donors and no reactions were seen in 117 donors.

Table 4: Type of Adverse Reaction Noted

Type of Adverse Reaction	Number of Samples	Percentage
Perioral Tingling	20	14.60%
No Reaction	117	85.40%
Total	137	100%

A prophylactic oral calcium supplement was given for 20 donors in the current study. No Therapeutic dose was required.

Table 5: Treatment given for Adverse Reaction

Treatment given for Adverse Reaction	Number of Samples	Percentage
Prophylactic Oral Calcium Supplement	20	14.60%
Therapeutic	0	0
No Reaction	117	85.40%
Total	137	100%

All 20 patients who received prophylactic oral calcium supplement were relieved afterwards from suffering.

Discussion

In the present study, samples from 137 plateletpheresis donors in North India were analysed between 2021 and 2022.

In 2015 in North India, the research by Solanki A and Agarwal P(1) analysed 60 samples from 60 healthy donors. Similar to the present research, 5 ml samples were taken in this study at various intervals throughout each procedure and 30 minutes after the procedure ended. Like Solanki A. and Agarwal P., we tested the levels of serum calcium and magnesium.

The mean serum levels of calcium and magnesium showed a continuous decline from baseline levels to the procedure's conclusion, but after 30 minutes, levels returned to being close to their baseline levels, similar to the present study between 2021 and 2022, samples from 137 plateletpheresis donors in North India were examined for the current research.

The study conducted in 2015 by Solanki A and Agarwal P(1) in North India analysed 60 samples from 60 healthy volunteers. Similar to the current study, 5 ml samples were taken in this study 30 minutes after each procedure concluded and at different intervals during each procedure. We measured the serum calcium and magnesium amounts, just like Solanki A. and Agarwal P when compared to the current study, the mean serum levels of calcium and magnesium showed a continuous decline from baseline levels to the end of the procedure but then returned to near baseline levels after 30 minutes..

During the majority of the process, the average serum concentrations of total and ionised calcium and protein levels decreased. The significant increases in citrate levels were ascribed to a rise in complexed calcium. Calcium amounts in proteins were decreased more than calcium in other forms. His research demonstrated that calcium citrate does not affect parathyroid hormone production.

At a citrate rate of 1.6 mg per kg per minute, ionised calcium and magnesium concentrations dropped by 33 and 39 percent below baseline, respectively. However, the research by Bolan found that urine pH levels were correlated with an increase in the excretion of citrate, calcium, magnesium, sodium, and potassium. (10)

These findings suggest that the use of citrate may have contributed to the hypocalcemia and hypomagnesemia. It produces a soluble compound by chelating calcium and magnesium ions, which leads to a decrease in ionised calcium and an increase in the excitability of nerve membranes, which results in spontaneous depolarization and perioral paraesthesia or tingling. The adverse outcomes only perioral tingling was observed in this research. Other side effects were not noticed. In the Strauss trial (3), some donors reported shaking, nausea, chills, abdominal pain, dizziness, trembling, and cramps.

Frank tetany and laryngospasm may result from severe hypocalcemia. Alkalosis brought on by excessive breathing can lessen these symptoms and indications. (14)

Plateletpheresis procedures are extremely safe for donors, and in the study by Tomita(15), study which examined vasovagal reactions, only a very small proportion of donors experienced severe adverse reactions. Incidence of vasovagal reactions was higher in women than in men, and prevalence fell with advancing age. In this study, pulse variations were also observed. There were no pulse fluctuations in the present study.

In the current research, different types of machines were used at various intervals, and there are highly significant differences in the serum levels of calcium and magnesium.

In the research by Farrokhi (6), the CS machine's and the Cobe machine's levels of ionised calcium decreased by 18% and 18.4%, respectively. Ca2+ and citrate levels did not alter during the second hour.In 22% and 28% of donors with Cobe and CS, Farrokhi found flimsy indications of muscle hyperexcitability.In the current research, prophylactic calcium completely eliminated all perioral tingling symptoms.

It is now well known that acute hypocalcemia and hypomagnesemia both happen during platelet pheresis; therefore, during citrate anticoagulated platelet pheresis, both of these cationsshould be watched.The simultaneous

detection of the ionic activity of calcium and magnesium in the blood may be possible with new technology. (16)To increase safety, more research should be conducted to pinpoint the danger signs and root reasons of different donor reactions.

Conclusion

The study aimed to analyze changes in serum cation levels during plateletpheresis in healthy donors. A total of 137 healthy SDP voluntary donors were included in the study, and their age ranged from 18 to 50 years. All donors were male, and their pre-transfusion hematological parameters were analyzed. Most samples were processed in the machine MCS, followed by COMTEC. The study observed a slow decrease in serum calcium and magnesium levels from baseline to the end of the procedure, followed by improvement after 30 minutes. Highly significant differences were observed in mean calcium and magnesium levels at various time intervals on all the machines used. Twenty donors experienced adverse reactions, with perioral tingling being the most common symptom. Prophylactic oral calcium supplements were given to these donors, and therapeutic doses were not required. The study concluded that serum calcium and magnesium levels decreased during plateletpheresis in healthy donors, but adverse reactions could be managed with prophylactic oral calcium supplementation.

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