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Original Article

Evaluating Adverse Events in COVID-19 Recovered Convalescent Plasma Donors: A Comprehensive Analysis

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Abstract

Background: The emergence of the COVID-19 pandemic prompted the exploration of convalescent plasma therapy (CPT) as a potential treatment modality. This study provides a comprehensive understanding of adverse events in COVID-19-recovered convalescent plasma (CP) donors for optimizing donor safety and refining donation protocols. The aim is to quantify the type and severity of adverse events associated with CP donation.

Materials and Methods: The present one-year retrospective study was undertaken in the blood center of a tertiary care hospital of Western Uttar Pradesh that was a multicentric site in the ICMR Placid trial and a dedicated COVID hospital during the first and second wave in India. Data was analyzed from donor adverse events (DARs) captured during the study period and evaluated for different parameters namely age, gender, body weight, donor status (first-time donor or previous donor), body mass index, blood volume processed, plasma volume collected and lag time between negative RT-PCR report and plasmapheresis. To determine the significance of variations in rates of DARs, Chi-square test was performed (p-value <0.05 considered significant).

Results: A total of 769 donations were performed in the study duration. The maximum donors were between the age group of 26-33 years with 301 donations were from this age group. Out of 769 donations, 648 donors (84.3%) showed no DARs, while 121 donors (15.7%) experienced adverse reactions.

Conclusion: Our findings provide essential insights into donor safety, hoping to support and plan future pandemic response strategies against novel infectious diseases.

1. INTRODUCTION

The COVID-19 pandemic, caused by the novel coronavirus SARS-CoV-2, has presented an unprecedented global health crisis, challenging healthcare systems, economies, and societies worldwide [1]. As the scientific community raced to develop effective treatments and preventive measures, convalescent plasma (CP) emerged as a potential therapeutic option, offering the passive transfer of antibodies from individuals who had recovered from COVID-19 to those battling the disease. CP, rich in neutralizing antibodies, was

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hypothesized to provide some degree of immunity and reduce the severity of illness in patients with active infections **[2].**

Numerous clinical trials were established to investigate the efficacy and safety of CPT. While initial reports showed promise, it became crucial to comprehensively evaluate and quantify any adverse events associated with this treatment **[3].** The lack of specific, proven targeted medical therapy and vaccines in the early few months generated tremendous interest in CP. CPT has been used with success in the past for the treatment of several viral diseases like Severe Acute Respiratory Syndrome Coronairus-2 (SARS-CoV-2), Middle East respiratory syndrome coronavirus (MERS-CoV), Ebola and H1N1 pandemic [4] and is based on the rationale of administering passive antibodies against a pathogen harnessed from a recently recovered patient to a susceptible individual for purpose of prevention and treatment **[5]**.

Following approval by the United States Food and Drug Administration, CP usage was designated as an "experimental therapy". At the outset, there was no definite evidence regarding its safety, efficacy, and dosing. Subsequently, trials were undertaken in nations in different parts of the world to evaluate its role in the management of COVID-19 infection [6].

The COVID-19-recovered patients became champions of this cause and the selection of donors was focused on recognizing those recovered patients who had high titers of neutralizing antibodies, with a reasonable time lag from being free of disease [5]. While many studies focussed on patient outcomes after receiving CPT hardly a few explored the consequences and tolerability of undergoing CP collection in the recovered patients turned donors.

In the era of hemovigilance, both donor and recipient safety is a priority for transfusion services. As the donor pool continues to shrink while demand for blood and its products escalates, ensuring a safe donor experience is increasingly challenging. Blood centers must focus on minimizing donor adverse reactions (DARs) to indirectly boost donor retention. Plasma donation is achieved by apheresis which is regarded as a reasonably safe though lengthy procedure [7, 8, 9]**.**

Adverse events, or untoward medical occurrences, can range from mild to severe and may be linked to various aspects of the CPT, including the donor's health, and the collection procedure. The identification, assessment, and quantification of these adverse events are pivotal in ensuring the safety of the donors in refining the CP donation protocols in the future for any similar novel infectious outbreaks.

In this study, we will systematically examine the type and severity of DARs experienced by COVID-19-recovered CP donors. By doing so, we aim to contribute valuable insights that can reform donor eligibility criteria, donation protocols, and the overall safety profile of CPT. This research not only underscores the importance of donor safety but also supports future efforts to combat unforeseen pandemics with evidence-based therapies.

2. MATERIALS AND METHODS

2.1. Aims and objectives

The purpose of the study was to evaluate and quantify the type and severity of DARs occurring in the COVID-19 recovered CP donors.

2.2. Study design

The present retrospective study was undertaken between May 2020 and April 2021 in the blood center of a tertiary care teaching hospital of western Uttar Pradesh that was a multicentric site in the ICMR Placid trial and a dedicated COVID hospital during the first and second wave in 2020 and 2021

2.3. Donor Selection Criteria

Donors were recruited for harnessing CP as per the eligibility criteria enlisted in the donor protocol shared at the time of enrolment **(Table 1).** The donors could be undertaken for plasmapheresis only after they met additionally the eligibility and fitness requirements (D & C Act 1940 and rules 1945, amended till March 2020) as per the Drug Controller General of India **[10]**. Written consent was sought from all donors enrolled for plasmapheresis per ICMR protocols.

Table 1. Eligibility Criteria for plasma donation in COVID-19 recovered prospective plasma donors consenting to undergo screening for plasmapheresis (As per ICMR PLACID Trial Protocol).

Men, Nulliparous women aged 18-65 years
Weight: > 50 kilograms
RT-PCR documented positive COVID-19 report with minimum symptoms of fever and cough
Symptoms completely resolved 28 days before donation or resolution of symptoms 14 days before donation having two negative RT-PCR tests via nasopharyngeal sampling 24 hours apart on discharge
In case patient was not tested by RT-PCR on discharge, 2 nasopharyngeal samples taken 24 hours apart, negative by RT-PCR were required before being considered for plasmapheresis

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2.4. Donation Process

Plasmapheresis was performed using single needle access, intermittent flow Hemonetics Cell Separator, Model MCS+ following departmental standard operating procedures. 97CF-E closed system apheresis kits, acid citrate dextrose for anti-coagulation, and normal saline for fluid replacement were used. The target plasma yield was 400 milliliters (ml), not exceeding 450 ml since the trial protocol had set two doses of CP for each recipient, 200 ml each, 24 hours apart. Donors were asked to rest in the blood center for a minimum period of 20 minutes, given refreshments, and monitored for any adverse symptoms. Both during the procedure as well as in recovery, donor adverse events were captured in the donor records with demographic and procedural details. Post-donation instructions were given to donors with the advice of reporting immediately to the center in the event of a delayed adverse reaction namely delayed bleeding at the venepuncture site, hematoma, pain, bruising, local allergy, and loss of consciousness. A shortage of staff at the center hindered a telephonic follow-up of donors.

2.5. Donor Adverse Reactions (DARs)

The donor adverse events captured in the donor records were based on the nomenclature laid down by the Working Group of the International Society of Blood Transfusion [11]. These were broadly categorized into local, generalized (vaso-vagal), citrate toxicity-related, and other serious complications. Local adverse events included hematoma, pain at the venepuncture site, thrombophlebitis, etc while generalized or vaso-vagal reactions (VVR) were subcategorized into mild, moderate, and severe. Mild VVR included symptoms captured as weakness, dizziness, sweating, pallor, light-headedness, and hypotension. Moderate VVR donors reported symptoms listed above with transient loss of consciousness (LOC), lasting less than 60 seconds. Donors with severe VVR experienced prolonged LOC (lasting 60 seconds and more) with or without convulsions, tetany, and bladder/bowel incontinence. Citrate toxicity symptoms included numbness, tingling, nausea, and vomiting.

Data Analysis: Data was analyzed from donor adverse events captured during the study period and evaluated for different parameters namely age, gender, body weight, donor status (first-time donor or previous donor), body mass index, blood volume processed, plasma volume collected and lag time between negative RT-PCR report and plasmapheresis. Numerical data was expressed as mean and standard deviation while categorical data as frequencies and percentages. To determine the significance of variations in rates of donor adverse events a Chi-square test was performed. The data evaluated was considered statistically significant when the p-value was <0.05. The study was granted clearance by the Institutional Ethics Committee vide Ref Number GIMS/IEC/HR/2021/14.

3. RESULTS

A total of 769 donations were performed in the study duration. The maximum donors were between the age group of 26-33 years with 301 donations from this age group. Out of 769 donations, 648 donors (84.3%) showed no DARs, while 121 donors (15.7%) experienced adverse reactions. Maximum adverse reactions (36.4 %) were recorded in the age group of maximum donations i.e. 26-33 years **(Figure 1).** The predominant population of donors was male (95.5 %) with 80.2 % adverse reactions while the remaining 4.5 % female donors accounted for 19.8 % adverse reactions. The overall mean body weight of the donors was 76.39 ± 12.33 kg. Among the donors who had experienced DARs, the mean body weight was 74.24 kg, with a standard deviation of 12.39 kg. Notably, the highest incidence of DARs occurred in donors weighing between 60-74 kg (53 patients), followed by the 75-89 kg group (47 patients) **(Figure 2).**

In our current research, we enrolled a total of 769 donors, comprising 308 first-time donors and 461 repeat donors. Surprisingly, adverse reactions were more prevalent among the repeat donors (all being prior whole blood donors), affecting 68 individuals. Among this population, the average BMI was 26.2, with a standard deviation of 4.06. Out of the 121 individuals (15.7%) who experienced adverse reactions, the highest proportion (44.6%) fell within the BMI range of 18.5-24.9, followed closely by those with a BMI of 25-29.9 (43%).

We investigated the incidence of adverse reactions among the CP donors. The most frequently observed adverse reaction was tingling, occurring in 55 donors. Following that, dizziness was reported in 19 cases, weakness in 13 cases, numbness in limbs in 11 cases, and both chills and pain in the arms, as well as sweating, were each noted in 7 cases. Nausea was experienced by 6 donors, while vasovagal reactions occurred in 3 cases. Loss of consciousness, discomfort, and anxiety were each documented in 2 cases. Hematoma at the puncture site and vomiting were observed in one case each **(Figure 3).**

The adverse reactions were broadly classified into local complications, systemic complications; complications related to citrate, and mixed reactions. Local complications like pain occurred in 5.8 % of cases and hematoma in only 0.8 % of the cases. Systemic complications were further divided into mild, moderate, and severe reactions accounting for 30.7 %, 2.5 %, and zero cases respectively. 55.4 % of cases showed complications related to citrate use and mixed reactions were seen in 5% of the cases **(Table 2).**

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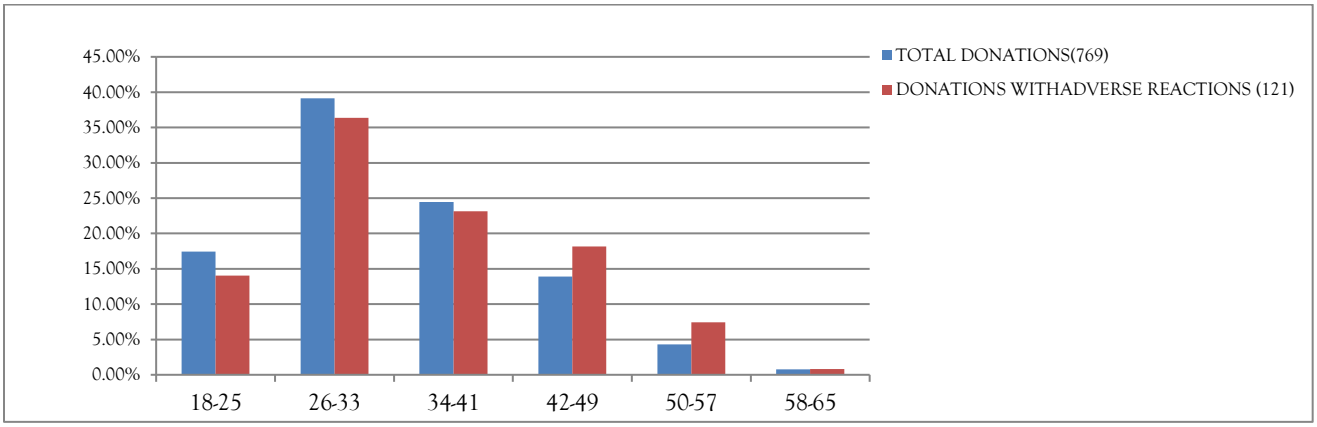

Figure 1. Age distribution of variables amongst COVD-19 recovered donors undergoing plasmapheresis

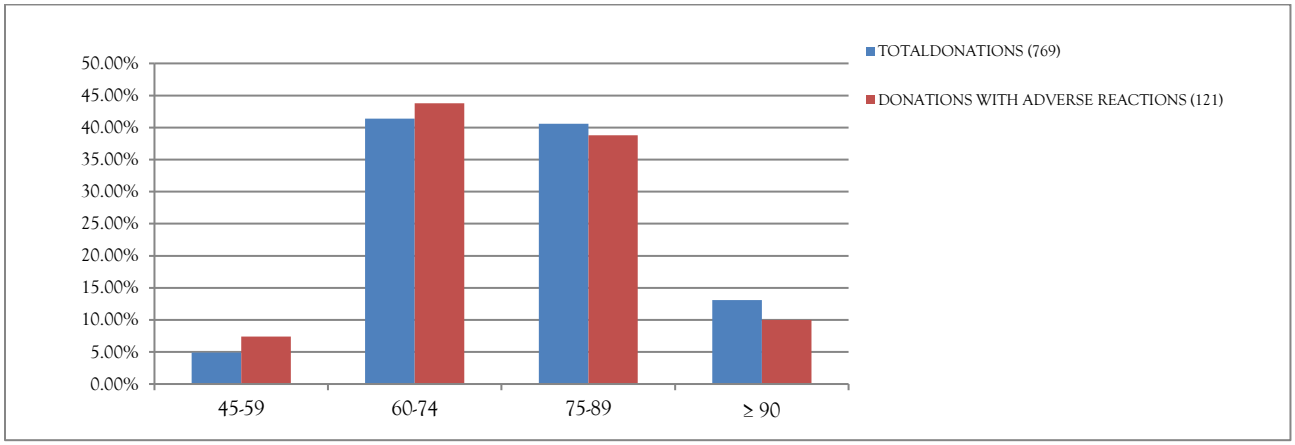

Figure 2. Weight distribution of variables amongst COVD-19 recovered donors undergoing plasmapheresis

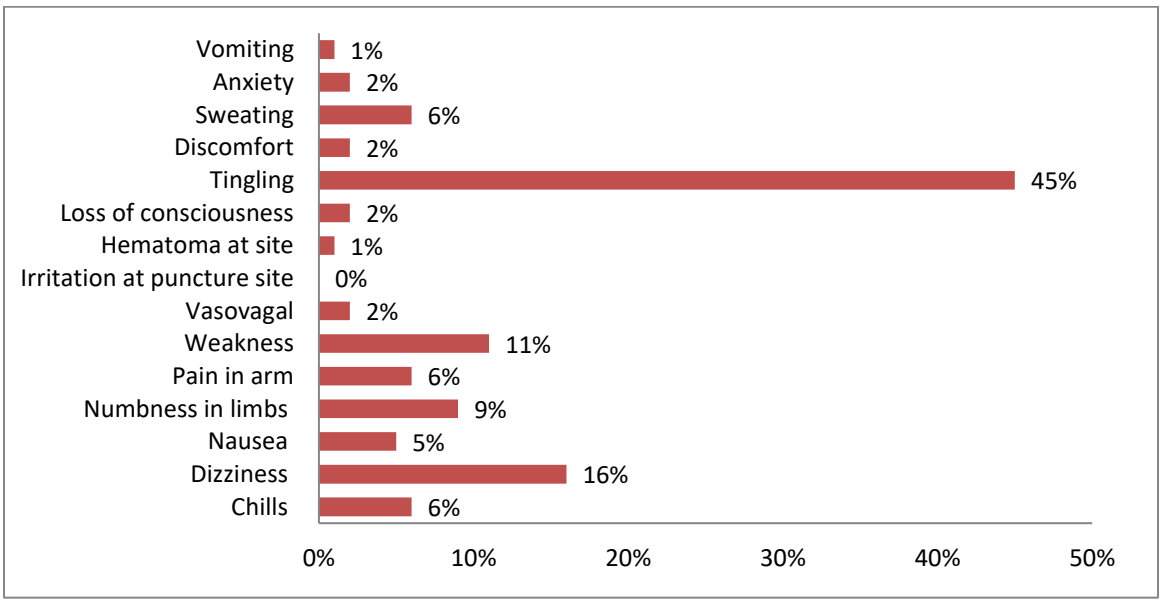

Figure 3. Frequency distribution of different types of adverse reactions experienced by the COVID-19 recovered plasmapheresis donors

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Table 2. Frequency (and %) distribution of the adverse reactions experienced by the COVID-19 recovered plasmapheresis donors based on the nomenclature laid down by the Working Group of the International Society of Blood Transfusion.

		Number of cases	Percentage
Local complications	Pain	7	5.8
	Hematoma	1	0.8
Systemic complications	Mild	37	30.6
	Moderate	3	2.5
	Severe	0	0.0
Complications related to citrate used		67	55.4
Mixed reactions (citrate, local & systemic)		6	5.0
Total		121	100

On average, the mean hemoglobin (Hb) level in the donors was approximately 14.69 ± 1.14 grams per decilitre (g/dL). Donors with Hb levels less than 12 g/dL were deferred as per guidelines, hence no recorded adverse reactions in this category. Donors with Hb levels between 12 and 13.5 g/dL had a relatively low percentage of adverse reactions (27.3%). Donors with Hb levels between 13.6 and 15 g/dL had a moderate percentage of adverse reactions (52.9%) while those with Hb greater than 15 g/dL had the lowest percentage of adverse reactions (19.8%) **(Table 3).**

The mean hematocrit (HCT) level in the donor's blood was approximately 41.84 ±4.16 %. Donors with HCT levels between 40.1% and 45.0% had the highest percentage of adverse reactions (50.4%), followed by donors with HCT levels between 35.1% and 40.0% (34.7%). There was no recorded adverse reaction in the donors with HCT levels > 50 % **(Table 3).**

The mean blood volume processed during donations was approximately 1716.02 ml, with a standard deviation of 185.48 ml. The range of blood volume processed in donations varied from a minimum of 532 ml to a maximum of 2800 ml, with an average range of 2268 ml. In the majority of plasmapheresis procedures, the blood volume processed was between 1501 and 2000 ml (n=663). This subset showed the highest percentage of adverse reactions (90.9%) **(Table 3).**

The mean plasma volume collected from the donations was approximately 426.17 ± 36.64 ml. Donations with volumes between 401 and 450 ml had a moderate percentage of adverse reactions (58.7%), followed by donations with volumes ranging between 451 and 500 ml (24.0%) **(Table 3).**

The mean lag time between receiving a negative RT-PCR report and undergoing plasma donation was approximately 65.87 ± 57.9 days. Donations made within 31 to 60 days of a negative report also had a moderate percentage of adverse reactions (36.4%). Donor reactions were seen with nearly similar frequency whether donations were made within 31 to 60 days or 14 to 30 days post negative RT-PCR report (36.4 % and 35.5% respectively) **(Table 3).**

A significance test was conducted to examine the relationship between donor adverse events and various demographic parameters, including gender, age, weight, donation status, BMI, Hb, HCT, blood volume, plasma volume collected, and the difference in days since the negative RT-PCR test. The results revealed significant p-values for gender (0.00), weight (0.00), Hb (0.00), HCT (0.00), plasma volume (0.023), and the date difference between negative RT-PCR (0.035). In contrast, no statistical significance was observed for age (0.259), donation status (0.359), BMI (0.085), and blood volume (0.12).

4. DISCUSSION

Among 769 post-COVID-19 recovered patients who were recruited as plasma donors, the majority were in the 26-33 years age group, accounting for 301 donations. Out of the total donations, 648 donors (84.3%) experienced no DAR, while 121 donors (15.7%) reported adverse reactions. Our study revealed a higher percentage of DARs compared to other studies, such as *Narayan et al; 2021* and *He et al; 2021,* where DAR rates were 12.1 % and 8.73 % respectively [12, 13]. This variation may be attributed to different geography and smaller sample sizes**.** The mean age of the donors was 33± 8 years, with the highest number of donations coming from the 26-33 age group. A significant portion of DARs (36.4 %) also occurred within this age range **(Figure 1).** However, the study by *Cho et al; 2021* revealed that the highest numbers of donors were in the 45- 64 age group but maximum numbers of DARs were observed in the age group of 16-20 years. This difference in findings may be due to different age group brackets and large sample sizes [14].

The majority of donors were male (95.5 %) with 80.2 % adverse reactions, rest of the 4.5 % female donors experienced 19.8 % DARs, this observation aligns with study by *Crocco et al; 2007* where male donors predominated, with higher DAR rates while *Cho et al; 2021* demonstrated higher numbers of female donors (51.9 %) resulting in higher rated of DARs in female donors (0.05 %) compared to male donors [15, 14]. Since, the majority of population of India is male, therefore, maximum DARs were seen in male population in our study as well. The mean body weight of all the donors was 76.39 ± 12.33 kg, while donors with adverse reactions had a mean body weight of74.24 ± 12.39 kg,

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Table 3. Frequency distribution of variables amongst COVD-19 recovered donors undergoing plasmapheresis with adverse events.

	Total donations (N = 769)	Donation with adverse reactions (N = 121)	Donation with adverse reactions (%)
Hemoglobin (g/dl)			
Mean ± SD	14.69 ± 1.14	14.23 ± 1.11	
<12	0	0	
12 - 13.5	138	33	27.3
13.6 - 15	325	64	52.9
>15	306	24	19.8
Hematocrit (HCT) (%)			
Mean ± SD	41.84 ± 4.16	40.88 ± 3.44	
≤ 35	71	6	5.0
35.1 - 40.0	156	42	34.7
40.1 - 45.0	377	61	50.4
45.1 - 50.0	158	12	9.9
>50	7	0	0.0
Blood volume processed (ml)			
Mean ± SD	1716.02 ± 185.48	1749.21 ± 184.95	
≤1000	3	1	0.8
1001 - 1500	94	9	7.4
1501 - 2000	663	110	90.9
> 2000	9	1	0.8
Plasma volume collected (ml)			
Mean ± SD	426.17 ± 36.64	433.21 ± 49.24	
≤400	198	20	16.5
401 - 450	438	71	58.7
451 - 500	128	29	24.0
> 500	5	1	0.8
Date difference between negative rtpcr report and donation (days)			
Mean ± SD	65.87 ± 57.9	45.38 ± 24.66	
14 - 30 DAYS	246	43	35.5
31 - 60 DAYS	228	44	36.4
> 60 DAYS	295	34	28.1

which was in line with the findings of *He et al ; 2021* in which mean weight was 69±13 kg [13] **(Figure 2).**

The adverse reactions were more commonly seen in the repeat donors (68 patients). This finding was dissimilar to study by *Narayan et al; 2021* and *He et al; 2021* whereas higher rate of reactions was observed in first time donors (7 % and 58.6 %) [12, 13]. This difference in data can be due to the fact that may be donors of our study underwent plasmapheresis at a different stage of recovery or had different levels of residual antibodies. The mean BMI of the patients was 26.2 ± 4.06, which was similar to *Fante et al; **2020*** who observed a mean BMI of 26.9 ± 5.5 [16].

The study explored the frequency of adverse reactions among COVID-19 recovered plasmapheresis donors, with tingling being the most common reaction. Hematoma at the puncture site and vomiting occurred in only one case each,

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and irritation at the puncture site was not reported (**Figure 3**), differing from the findings of *McLeod et al; 2003*, in which pain and hematoma was the most common reaction followed by nausea, vomiting and vasovagal symptoms [17]. The early signs of citrate toxicity are perioral paraesthesia, tingling, shivering, light-headedness, twitching, and tremors, numbness. Further nausea and vomiting can also occur in these patients. This condition can progress to tetany or seizure as the ionized calcium levels fall further. In our study the symtoms related to the citrate toxicity were highest resulting into 55.4 % cases as the citrate is used as the most common anticoagulant in donor apheresis procedures (**Table 2**). Citrate acts by chelating calcium ions resulting into unavailability of calcium ions to participate in biological reactions such as the coagulation cascade. This was the reason tingling, was the most common reaction observed in our study which is in concordance to the study done by *Philip et al ;2013* [18].

The adverse reactions were broadly classified into local complications, systemic complications; complication related to citrate toxicity and mixed reactions. Our study showed maximum donors with citrate toxicity followed by systemic complications, local complications and mixed reactions. Systemic complications were further divided into mild, moderate and severe on the basis of intensity of symptoms similar to the criteria by *Arora et al; 2061* as below [19]:

Mild systemic complications: Syncope, malaise, dizziness, sweating, paraesthesia, headache and palpitation

Moderate systemic complications- Nausea, vomiting, hypotension and arrhythmia

Severe systemic complications: Hyperventilation, tetany, apnea, loss of consciousness, convulsive crises, systemic hematoma. However, their study showed very less no. of donors with mild (2.33 %), moderate (0.58 %) systemic reactions in comparison to our study i.e. 30.7 %, 2.5 % respectively. Also, a significant no. of patients showed severe systemic complications (1.16 %), while in our study no severe systemic complication recorded [19] (**Table 2**).

On average, the mean Hb level in the donor's blood was approximately 14.69 ± 1.14 grams per deciliter (g/dL). Similar findings were noted in the study by *He et al*; 2021, where mean Hb level of donor was 14.2± 1.2 g/dl. Both the studies showed that donors with Hb levels less than 12 g/dL had no recorded adverse reactions (0.0%). While our study showed maximum DARs with Hb levels between 13.6 and 15 g/dL (52.9%), *He et al*; 2021 had the highest DARs between 12.0- 13.4 g/dl Hb [13] (**Table 3**). Hb is a protein in red blood cells responsible for carrying oxygen throughout the body. It is essential for maintaining oxygen levels and overall health. COVID-19 can have various effects on the body, including potential impacts on the haematological system, but the relationship between Hb levels in plasma donors who have recovered from COVID-19 and the occurrence of adverse reactions is not a well-documented or widely studied area.

The mean HCT level in the donor's blood was approximately 41.84 ±4.16 %, this finding was almost similar to *Khade et al; 2022* who documented 43.15± 3.54 % mean HCT. The mean blood volume processed was 1716.02 ± 185.48 ml which was similar to the finding of *Khade et al*; 2022 where 1882.16±390.09 ml blood volume processed was documented [20] (**Table 3**).

The mean plasma volume collected from the donations was approximately 426.17 ± 36.64 units. Donations with volumes between 401 and 450 units had a high percentage of DARs (58.7%), which was in discordance with the findings of *He et al*; 2021 who showed that DARs were significantly higher for volume ≥600 mL [13] (Table 3). Larger volumes of plasma may lead to a higher likelihood of reactions, as it can temporarily reduce the donor's blood volume and affect blood pressure but in the present study the DARs in the donors where volume of plasma collected ≥ 600 ml was only 0.8 %. The reason is still unknown to us and requires a research into the matter.

The mean lag time between receiving a negative RT-PCR report and making a plasma donation was approximately 65.87 ± 57.9 days. Donations made within 31 to 60 days of a negative report also had maximum DARs which was in concordance with study conducted by *He et al*; 2021 where 96.8 % donors had developed DARs after 28 days of development of disease [13] (**Table 3**). This may be due to the fact that Donors may be taking medications or have underlying health conditions that can increase the risk of adverse reactions. It's important for donors to disclose their medical history and medications to healthcare professionals overseeing the donation process.

After the test for significance was applied, it was observed that there was positive correlation between gender (male donors), weight (75-89 kg), normal Hb (13.6- 15 g/dl), HCT (40.1-45 %), plasma volume collected (401-450 ml) and difference of date between negative RT-PCR report(31-60 days) with DARs recorded. There was no correlation noted between age, donation status (first or repeat), BMI and blood volume processed with DARs recorded.

5. CONCLUSION

Apheresis donation is a relatively safe procedure where adverse reactions requiring major intervention or hospitalisation are infrequent. This study offers a valuable contribution to our understanding of the safety profile of

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convalescent plasma donation among COVID-19 recovered individuals. By evaluating and quantifying adverse events in theses donors, we aim to enhance donor safety and donation protocols where CP may be considered as a valuable tool for patient management in future novel infectious disease pandemics.

Acknowledgment

None.

Conflict of interest

The authors declare that they have no conflict of interests.

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