

## CONVALESCENT PLASMA DONORS DEMOGRAPHICS AND SARS-CoV-2 IgG ANTIBODY LEVELS: A STUDY AT TERTIARY CARE TEACHING INSTITUTE

Pawan Singh<sup>1</sup>, Manju Daiya<sup>2</sup>, Vikram Singh Tanwar<sup>3</sup>, Mahesh Kumar<sup>4</sup>,  
Sunita Daiya<sup>5</sup>

Received : 01/03/2024  
Received in revised form : 25/03/2024  
Accepted : 10/04/2024

**Keywords:**

COVID-19, Convalescent plasma,  
Plasma donors, IgG antibody levels,  
Demographic characteristics, SARS-  
CoV-2.

Corresponding Author:

**Dr. Pawan Singh,**  
Email: bodwalps@gmail.com

DOI: 10.47009/jamp.2024.6.2.155

Source of Support: Nil,  
Conflict of Interest: None declared

*Int J Acad Med Pharm*  
2024; 6 (2); 752-755



<sup>1</sup>Professor, Department of Pathology (Blood Bank), SHKM Govt. Medical College, Nalhar, Nuh, Haryana, India

<sup>2</sup>Blood Transfusion Officer, Sant Parmanand Hospital, Civil lines, New Delhi, India

<sup>3</sup>Associate Professor, Department of Medicine, Shaheed Hasan Khan Mewati Government Medical College Nalhar, Nuh, Haryana India

<sup>4</sup>Associate Professor, Department of Anatomy, SHKM Govt. Medical College, Nalhar, Nuh, Haryana, India

<sup>5</sup>Dental Surgeon, Sub Divisional Civil Hospital, Sohna, Gurugram, Haryana, India

### Abstract

**Background:** The COVID-19 pandemic caused by the SARS-CoV-2 virus has posed significant challenges to healthcare systems worldwide. Convalescent plasma (CP) therapy has emerged as a potential treatment option, utilizing plasma from recovered COVID-19 patients containing specific antibodies against the virus. This study aimed to investigate the demographic and clinical characteristics of plasma donors and assess the IgG antibody levels across various parameters. **Materials and Methods:** A retrospective observational study was conducted at a tertiary care hospital with dedicated COVID-19 management units. Data from 74 plasma donors who donated between 2020 and 2021 were analyzed. Donor characteristics including gender, type of donor, donor experience, age, weight, blood group, and hemoglobin levels were assessed. Additionally, IgG antibody levels were measured and analyzed based on blood group, gender, and age groups. **Result:** All the donors were male(100%), with replacement donors accounting for 81.1%. The mean age of the donors was 40.09 years. Blood group B was the most common (44.6%), followed by A (21.6%), O (24.3%), and AB (9.5%). IgG antibody levels varied across different parameters, with blood group AB donors having the highest median IgG levels (81 AU/ml), while males donors exhibited mean IgG levels of 53.2 AU/ml. The age group of 41-50 years displayed the highest median IgG level at 82.1 AU/ml. **Conclusion:** The study provides valuable insights into the demographic and clinical characteristics of plasma donors and their IgG antibody levels. The findings underscore the importance of targeted recruitment strategies and personalized donation approaches to optimize the yield and efficacy of convalescent plasma therapy.

## INTRODUCTION

The COVID-19 pandemic, caused by the novel coronavirus SARS-CoV-2, emerged as an unprecedented global health crisis in December 2019, severely straining healthcare systems worldwide.<sup>[1]</sup> With the absence of definitive standard treatment options, convalescent plasma (CP) therapy has emerged as a potential therapeutic strategy. CP, derived from individuals who have recovered from COVID-19 and developed specific antibodies against SARS-CoV-2, has been recognized as an empirical treatment with promising therapeutic potential.<sup>[2]</sup> This therapy involves the

transfusion of plasma containing virus-specific antibodies to boost the immune response of severely ill patients.<sup>[3]</sup>

In response to the urgent need for effective treatments, the US-FDA authorized the use of convalescent plasma as an investigational drug on April 13, 2020.<sup>[4]</sup> Subsequently, the Ministry of Health and Family Welfare, Government of India, endorsed the off-label use of CP for COVID-19 patients with moderate disease not responding to standard treatments in their "Clinical Management Guidelines: COVID-19, Version 3" released on 13th June 2020.<sup>[5]</sup> Despite the ongoing research and endorsements, the effective collection of high-titer

CP from qualified donors remains a significant challenge for blood transfusion services globally, including India.<sup>[6]</sup>

Recent interim recommendations by the Association for the Advancement of Blood & Biotherapies (AABB) emphasize the safety and efficacy of high-titer CP, suggesting that the timing of donation in relation to symptom onset is crucial for its effectiveness.<sup>[7]</sup> However, there is a lack of comprehensive studies from India analyzing major donor characteristics and SARS-CoV-2 antibody response in CP collections. Understanding these demographics and collection characteristics is essential for maintaining a viable inventory of high-titer CP products, especially in acute crisis settings.<sup>[8]</sup>

Therefore, this study aims to investigate the clinical and serological characteristics of voluntary and replacement donors visiting blood centers for CP donation in the Indian context. This research will contribute to the existing body of knowledge and potentially enhance the effectiveness of CP therapy by identifying donor characteristics correlating with higher functional antibody activity.

## MATERIALS AND METHODS

This observational, retrospective study analyzed 74 records from 2020 and 2021 at a tertiary care hospital with dedicated COVID-19 management units. Donor data were obtained from the blood bank donor management database.

Donor selection followed the Drugs and Cosmetics Second Amendment Rules, 2020, and the emergency release authorization by the Ministry of Health and Family Welfare (MOHFW), Government of India, for off-label use of convalescent plasma for moderate COVID-19. Inclusion criteria encompassed men or nulliparous women aged 18-60 years, body weight >55 kg, and a confirmed diagnosis of COVID-19 via rRT-PCR or Rapid antigen test using ICMR approved assays. Donors were required to be symptom-free for 28 consecutive days or 14 days with negative rRT-PCR test results. Repeat CP donors had a minimum interval of 2 weeks from the first donation.

Donors underwent a medical interview, routine medical examination, and were screened for symptoms and blood parameters. ABO blood grouping, Rhesus phenotype, complete blood counts, and antibody screening were conducted. Donors meeting the criteria were accepted after negative screenings for HIV, hepatitis B or C, syphilis, and malaria. Donors were tested for Anti-SARS-CoV-2 IgG (S1) antibodies using Electrochemiluminescence on Roche-USFDA Approved range 0.000-1.000; >1: Positive for SARS CoV2 antibodies, <1: Negative, Chemiluminescent

Micro particle Immuno Assay(CMIA); < 1.4 Negative Index, >1.4 positive Index (S/C) and Diasorin SARS Cov-2 S1/S2 Ig Test(Indirect Chemiluminescence Immuno Specific Recombinant S1 & S2 Antigen ) etc.

Statistical analysis: It was conducted using IBM SPSS Statistics for Windows, Version 26.0, with P values < 0.05 considered significant and P values < 0.0001 highly significant. Ethical clearance was taken from institutional ethical committee.

## RESULTS

A total of 74 plasma donors were evaluated to understand the demographic and clinical characteristics in the study. The gender distribution revealed that all the donors were male, constituting 100% (n=74) of the donors. In terms of the type of donors, the majority were replacement donors, making up 81.1% (n=60), while voluntary donors constituted 18.9% (n=14). When examining the donor experience, 51.4% (n=38) were first-time donors, and 48.6% (n=36) were repeat donors.

The age distribution of the donors indicated an overall mean age of 40.09 years with a standard deviation (SD) of 8.7, ranging from 20 to 60 years. The weight of the donors was also analyzed, showing an overall mean weight of 68.32 kg (SD=14.10).

Regarding blood group distribution, the most common blood group among the donors was B, accounting for 44.6% (n=33), followed by A at 21.6% (n=16), O at 24.3% (n=18), and AB at 9.5% (n=7). The hemoglobin levels were consistent among the donors with a mean of 14.92 g/dl and a standard deviation of 1.42.

The IgG antibody levels, measured in arbitrary units per milliliter (AU/ml), were examined across different parameters among the plasma donors. When considering blood group, individuals with blood group AB exhibited the highest median IgG levels at 81 AU/ml, followed by blood group B at 70.1 AU/ml, blood group A at 52.1 AU/ml, and blood group O at 42.34 AU/ml. Male donors had median IgG level of 53.2 AU/ml.

Age-related variations in IgG levels were also observed among the donors. The age group of 41-50 years displayed the highest median IgG level at 82.1 AU/ml, followed by the age group of 31-40 years at 59.9 AU/ml. The youngest age group, 20-30 years, had a median IgG level of 44.9 AU/ml, and the oldest age group, 51-60 years, had a median IgG level of 54.85 AU/ml. However, the correlation between age and IgG antibody levels was found to be weak, with a coefficient of linear regression between donor age and SARS-CoV-2 antibody level ( $r^2 = 0.0245$ , correlation coefficient = 0.49).

**Table 1: Demographic and Clinical Characteristics of Plasma Donors (N=74)**

	N	%
Gender		
Male	74	100
Type of Donor		
Voluntary	14	18.9
Replacement	60	81.1
Donor Experience		
First time	38	51.4
Repeat	36	48.6
Age (years)	Mean (SD)	
Overall	40.09 ± 8.7 (20-60)	
Weight (kg)	Mean (SD)	
Male	68.32 ± 14.10	
Blood Group		
A	16	21.6
B	33	44.6
AB	7	9.5
O	18	24.3
Hemoglobin (g/dl)	14.92 ± 1.42	

**Table 2: IgG Antibody Levels (AU/ml) Among Plasma Donors by Blood Group, Gender, and Age Group**

Parameter	IgG level (AU/ml)
Blood Group	
AB	81
B	70.1
A	52.1
O	42.34
Gender	
Male	53.2
Age Group (years)	
20-30	44.9
31-40	59.9
41-50	82.1
51-60	54.85

## DISCUSSION

The present study examined the demographic and clinical characteristics of plasma donors, focusing on gender, type of donor, donor experience, age, weight, blood group, and hemoglobin levels. Additionally, IgG antibody levels were evaluated across different parameters including blood group, gender, and age groups.

Our findings revealed a predominance of male donors, constituting 100% of the study population. This gender bias in blood donation is consistent with previous research that suggests males are more likely to donate blood than females.<sup>[9]</sup> The majority of donors were replacement donors (81.1%), a trend observed in various studies that highlight the reliance on replacement donors due to the specific requirements of the recipients.<sup>[10]</sup>

Regarding the donor experience, almost half of the donors were repeat donors (48.6%), emphasizing the importance of continuous donor engagement and retention strategies in blood donation programs.<sup>[11]</sup> The age distribution of the donors in our study showed an interesting trend. The mean age of the donors was 40.09 years. These findings are consistent with previous studies which reported that younger individuals are more likely to donate blood.<sup>[12]</sup>

The weight and blood group distribution of the donors in our study were also noteworthy. The mean

weight of the donors was 68.32 kg. In terms of blood groups, blood group B was the most common, followed by A, O, and AB. These findings are consistent with the distribution patterns reported in the Indian population.<sup>[13]</sup>

Furthermore, the IgG antibody levels in our study demonstrated variations across different parameters. Donors with blood group AB had the highest median IgG levels, followed by blood group B, A, and O. Age-related variations were also observed, with the 41-50 years age group showing the highest median IgG levels. However, it is essential to note that the correlation between age and IgG antibody levels was weak, which could be attributed to various factors such as previous exposure to the virus and individual immune responses.<sup>[14]</sup>

The strengths of our study include a comprehensive evaluation of donor characteristics and antibody levels in a significant sample size. However, the study is not without limitations. The retrospective nature of the study and the lack of information on the time since recovery from COVID-19 among the donors may influence the IgG antibody levels.

## CONCLUSION

In conclusion, our study provides valuable insights into the demographic and clinical characteristics of convalescent plasma donors and their IgG antibody levels. The findings underscore the importance of

targeted recruitment strategies and personalized donation approaches to optimize the yield and efficacy of convalescent plasma therapy.

## REFERENCES

1. Pollard CA, Morran MP, Nestor-Kalinoski AL. The COVID-19 pandemic: a global health crisis. *Physiol Genomics*. 2020 Nov 1;52(11):549–57.
2. Verma HK, Farran B, Bhaskar LVKS. Convalescent plasma transfusion a promising therapy for coronavirus diseases 2019 (COVID-19): current updates. *AntibTher*. 2020 May 27;3(2):115–25.
3. Convalescent plasma therapy against the emerging SARS-CoV-2 variants: Delineation of the potentialities and risks - PMC [Internet]. [cited 2024 Apr 6]. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8717699/>
4. Commissioner O of the. FDA Issues Emergency Use Authorization for Convalescent Plasma as Potential Promising COVID–19 Treatment, Another Achievement in Administration’s Fight Against Pandemic [Internet]. FDA. FDA; 2020 [cited 2024 Apr 6]. Available from: <https://www.fda.gov/news-events/press-announcements/fda-issues-emergency-use-authorization-convalescent-plasma-potential-promising-covid-19-treatment>
5. Research C for BE and. Investigational COVID-19 Convalescent Plasma [Internet]. FDA; 2023 [cited 2024 Apr 6]. Available from: <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/investigational-covid-19-convalescent-plasma>
6. Datta SS, Sil S, Mandal S. Rare blood group registry in India-current challenges and future perspectives. *Front Genet*. 2023 Sep 11;14:1264853.
7. Estcourt LJ, Cohn CS, Pagano MB, Iannizzi C, Kreuzberger N, Skoetz N, et al. Clinical Practice Guidelines From the Association for the Advancement of Blood and Biotherapies (AABB): COVID-19 Convalescent Plasma. *Ann Intern Med*. 2022 Sep;175(9):1310–21.
8. Use of convalescent plasma for COVID-19 in India: A review & practical guidelines - PMC [Internet]. [cited 2024 Apr 6]. Available from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8184072/>
9. Davis AR, Elbers SK, Kenworthy N. Racial and gender disparities among highly successful medical crowdfunding campaigns. *Soc Sci Med*. 2023 May 1;324:115852.
10. Demographic Patterns of Blood Donors and Donations in a Large Metropolitan Area - ScienceDirect [Internet]. [cited 2024 Apr 6]. Available from: <https://www.sciencedirect.com/science/article/abs/pii/S0027968415303163>
11. Motivations to donate blood: demographic comparisons - Glynn - 2002 - Transfusion - Wiley Online Library [Internet]. [cited 2024 Apr 6]. Available from: <https://onlinelibrary.wiley.com/doi/abs/10.1046/j.1537-2995.2002.00008.x>
12. Glynn SA, Wright DJ, Kleinman SH, Smith JW, Schreiber GB, Nass CC, et al. Trends in Incidence and Prevalence of Major Transfusion-Transmissible Viral Infections in US Blood Donors, 1991-1996.
13. Agrawal A, Tiwari AK, Mehta N, Bhattacharya P, Wankhede R, Tulsiani S, et al. ABO and Rh (D) group distribution and gene frequency; the first multicentric study in India. *Asian J Transfus Sci*. 2014;8(2):121–5.
14. Seow J, Graham C, Merrick B, Acors S, Pickering S, Steel KJA, et al. Longitudinal evaluation and decline of antibody responses in SARS-CoV-2 infection. *Nat Microbiol*. 2020 Dec 1;5(12):1598–607.