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Seroprevalence of SARS-CoV-2 IgG antibody among healthy blood donors: a single centre study

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ABSTRACT

Background: Severe acute respiratory syndrome corona virus 2(SARS-CoV-2), the causative agent of corona virus disease-2019(COVID- 19) which has led to a global pandemic. The true extent of the burden of COVID-19 may be underestimated, and there is need to know the current prevalence of SARS-CoV-2 antibody in population.

Methods: The present study was a cross-sectional study to assess prevalence of SARS-CoV-2 IgG antibody among 586 healthy voluntary blood donors who donated whole blood between mid-December 2020 to January 2021. A chemiluminescence assay was used to detect the presence of SARS-CoV-2 IgG antibody in serum samples in addition to recommended transfusion transmitted infections tests and Signal to Cut Off (S/C) > 1 was considered as reactive for antibody as per manufacturer's instructions.

Results: In the present study, 586 healthy voluntary blood donors were enrolled and were screened for SARS-CoV-2 IgG antibody. Out of 586 donors, 52 donors had indeterminate values of SARS-CoV-2 IgG antibody. A total of 534 healthy voluntary blood donors' samples were included in the present study for analysis. Out of total 534 healthy blood donors, 42.88% (229) were found to be seropositive while 57.11% (305) were found to be seronegative.

Conclusion: A 43% positivity of SARS-CoV-2 IgG antibody among healthy blood donors was detected which is an indication of presence of infection at community level and majority of the population already has been exposed to SARS-CoV-2 infection. However, there was no statistically significant association of type of blood group and age with seropositivity.

1. INTRODUCTION

Corona virus disease 2019 (COVID-19) was first found in December 2019 and had spread all over the world and was declared as a pandemic in March 2020. As on 4 February 2021 total number of confirmed 104 million cases and 2.27 million people died resulting from acute respiratory diseases and its related complications worldwide. Rajasthan which represents north west region and largest state of India witnessed of 318 K cases and 2770 mortality [1,2].

A novel beta-coronavirus was identified as the original causative agent of SARS-CoV-2. The genome of the new virus was 70% similar to

that of severe acute respiratory syndrome corona virus, and hence it was designated SARS-CoV-2[3]. Its symptoms include fever, cough, fatigue, expectoration, shortness of breath, dyspnea and muscle soreness [4]. While the majority of patients show only mild or moderate symptoms, some progressed to viral pneumonia, acute respiratory distress syndrome (ARDS), systemic inflammatory response syndrome (SIRS), multiple organ failure (MOF) and death [5,6].

Nucleic acid testing for SARS-CoV-2 by RT-PCR (real time polymerase chain reaction) is the gold standard and helps in early recognition of confirmed COVID-19 cases but its sensitivity can be influenced by many factors like biological sampling, inadequate sample collection,

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time between sample collection and onset of symptoms and fluctuation in viral load, giving false negative results [7]. An uncertain number of asymptomatic individuals and parts of mild cases may be missed. The missing information could be obtained by screening the population for specific antibodies using validated serological assays.

Population-based serological studies as well as high-quality data on SARS-CoV-2 antibody production in healthy individuals are urgently needed to assess both the true extent of virus spread and the presence of potential antibody-mediated protection against SARS-CoV-2 at the community level. This will help in the control of transmission of the disease and ensure timely public health management. WHO has currently provided no recommendations about screening the donors for SARS-CoV-2 by RT-PCR or immunoassays, however, it recommends temporary deferral for 28 days if any symptoms (cough, fever, flu) are present, or if they have come in contact to a confirmed COVID-19 patient. WHO also recommends that the potential donors also have to inform the blood center if they develop symptoms within 28 days of donation [8,9].

However, COVID-19 virus does not transmit through blood donations and is not a blood borne disease but identification of seroprevalence among the blood donors can give an estimate of community transmission of the virus, providing actual disease burden in the population [10].

Not many studies have been done on healthy blood donors in India. Therefore, we conducted a survey to assess the seroprevalence among healthy blood donors which may give useful insight for SARS-CoV-2 infection in the population.

2. MATERIAL AND METHODS

2.1. Study Design

The present study was cross-sectional study consisting of serological testing on healthy blood donors who donated at Blood Center, Mahatma Gandhi Medical College, Jaipur, Rajasthan accredited by National Accreditation Board for Hospitals and Healthcare Providers (NABH), the official agency authorized to grant accreditation certificates to health care facilities in India.

Due approval was taken from Institutional Ethical Committee before undertaking the present study. A written and informed consent was taken from each study participant before enrolling him/ her in the present study.

2.2. Sample Size

Taking the prevalence of seroprevalence to be 7.1% and 2.5% as absolute error, the sample size comes out to be 430 [11]. Considering attrition of 10%, the sample size comes out to be

475. In the present study, 586 healthy voluntary blood donors were enrolled and screened for SARS-CoV-2 IgG antibody. Out of these 586 donors, 52 donors had indeterminate values of SARS-CoV-2 IgG antibody, thus were excluded from the study. A total of 534 healthy voluntary blood donors' samples were included in the present study for the seroprevalence analysis.

2.3. Study participants

All participants were healthy blood donors who visited to Blood Center, Mahatma Gandhi Medical College and Hospital, Jaipur and donated whole blood between mid-December 2020 to January 2021. Donors had to complete a written questionnaire and undergo a brief health screening. For candidates to be accepted as blood donors, they had to comply with all the donation eligibility criteria procedure on the basis of national guidelines by National Blood transfusion services (NBTC) in India [9]. Recently, some criteria regarding COVID-19 have been included: prospective donors could not have had flu like symptoms

within the 28 days before donation or had close contact with suspected or confirmed COVID-19 cases. Candidates presenting fever (forehead temperature $> 37.8^{\circ}\text{C}$) on the donation date are also deferred. Thus, individuals in the study group had no symptoms of COVID-19 and no known historical epidemiology of the disease.

Eligible participants for this study were those with no current COVID-19 symptoms and no confirmed previous SARS-CoV-2 infection or in close contact of COVID-19 confirmed cases. Blood donors were excluded if they were diagnosed with COVID-19 disease or presented with physically identifiable symptoms of any previous infection mimicking flu like infection. All individuals classified as eligible for donation during the study period participated in the study. We excluded those who refused to sign the informed consent form for blood donation and testing.

2.4. Sample Collection

The serum used for testing infectious disease markers were also used for SARS-CoV-2 antibody test and explained to donor and informed consent taken.

2.5. Serological analysis of samples for SARS-CoV-2 IgG antibody

VITROS immunodiagnostic Anti-SARS-CoV-2 IgG Assay® (Ortho Clinical Diagnostics, USA) was used as the serological immunoassay, which uses the chemiluminescence platform Eci3600 for detection for the presence of SARS-CoV-2 specific IgG antibodies as per the manufacturer's instructions [12]. This assay detects IgG antibodies against the SARS-CoV-2 spike protein (S1) and has a sensitivity of 90% and specificity of 100%, as per U.S. FDA release notification [13].

The assay was calibrated with positive and negative quality controls before analyses. Daily quality control (QC) samples were run and Levy-Jennings's graph was maintained. Assay results higher than or equal to the Signal to Cut-off ratio (S/C) of 1.0 were interpreted as reactive for SARS-CoV-2 antibodies as per manufacturer instructions while Signal to Cut-off ratio (S/C) less than <1.0 but more than > 0.1 with history of close contact positive RT-PCR for SARS-CoV-2 or had positive RT-PCR report in the past were considered as indeterminate on the basis of internal validation results.

2.6. Statistical Analysis

Data was entered in Microsoft Office Excel Worksheet. For qualitative data, chi square test was applied while for quantitative data, t test was applied. p value < 0.05 was considered statistically significant.

3. RESULT

In the present study, 586 healthy voluntary blood donors were enrolled and were screened for SARS-CoV-2 IgG antibody. Out of these 586 donors, 52 donors had indeterminate values of SARS-CoV-2 IgG antibody, thus were excluded from the study. A total of 534 healthy voluntary blood donors' samples were included in the present study for analysis.

As shown in Fig. 1, out of total 534 healthy blood donors, 42.88% (229) were found to be seropositive while 57.11% (305) were found to be seronegative.

As shown in Table 1, among all seropositive, maximum was found to be B Positive (33.18%) followed by O Positive (25.76%), A Positive (21.83%), AB Positive (8.73%). On applying Chi square test, the difference was not found to be statistically significant.

Among seropositive, 82 cases were found to have blood group B while 68 cases had blood group O while 58 cases and 21 cases had blood group A and AB respectively. Among seronegative, 110 had blood group B while 100 cases, 79 cases and 16 cases had blood group O, A and AB respectively. (Fig. 2)

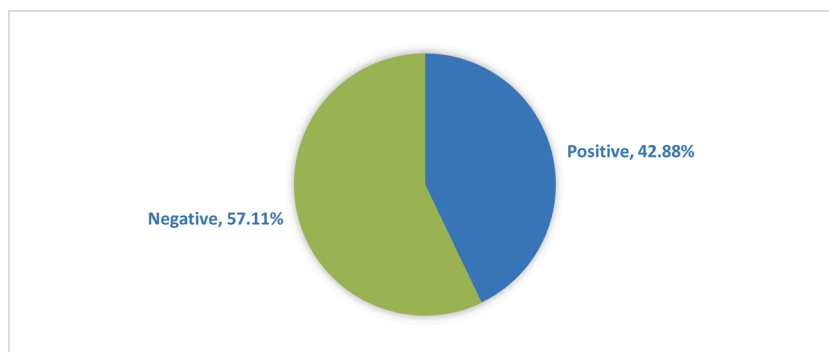


Fig. 1. Pie chart showing the seropositive and seronegative in the healthy blood donors.

Table 1

Distribution of seropositive and seronegative healthy blood donors according to their blood group

Blood group		Positive N (%)	Negative N (%)	Chi square (df)	p value
ABO	RhD				
A	Positive	50 (21.83)	69 (22.62)	3.551 (7)	0.940
A	Negative	8 (3.49)	10 (3.27)		
AB	Positive	20 (8.73)	15 (4.91)		
AB	Negative	1 (0.43)	1 (0.32)		
B	Positive	76 (33.18)	101 (33.11)		
B	Negative	6 (2.62)	9 (2.95)		
O	Positive	59 (25.76)	85 (27.86)		
O	Negative	9 (3.93)	15 (4.91)		
Total		229 (100)	305 (100)		

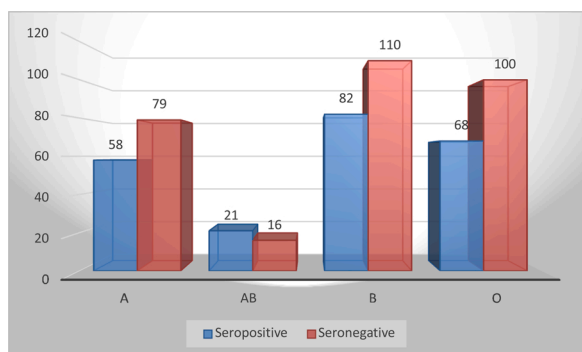


Fig. 2. Bar diagram showing distribution of seropositive and seronegative according to blood group.

Among all seropositive, 89.51% were found to be Rh Positives while 10.48% were found to be Rh Negative. Among all seronegative, 88.52% were found to be Rh Positive while 11.47% were found to be Rh Negative.

4. DISCUSSION

Serosurvey helps in identifying the fraction of asymptomatic or subclinical infection in the population and is likely to offer useful information regarding the true magnitude of infection in the community. Thus, defining the seroprevalence of SARS CoV-2 among blood donors will give useful insight for COVID19 infection in otherwise healthy population.

In present study, 586 donors healthy blood donors were enrolled for SARSCoV-2 IgG antibody tested by CLIA on ECI VITROS (OCD,US) from December 2020 to January 2021.

In the present study, 43% seropositivity was seen among healthy blood donors. This is higher than seroprevalence study recently done by

Murhekar MV, Bhatnagar T, Selvaraju S, et al in second nationwide household serosurvey and Sharma et al in Delhi which showed the seroprevalence to be 7% & 24.71% respectively [11,14]. Similar studies done in Al-Madinah and other part of Saudi Arabia showed the SARSCoV-2 seroprevalence among blood donors to be 19.31% and 1.7% respectively in May to July 2020[15,16]. In other studies, were done in United States and Kenya in March which showed seroprevalence of 1.82% in 42 states and 5.6% respectively [17,18]. Since the above study was done in early phase of the pandemic, the seroprevalence was much less.

In the present study, among seropositive, 99.12% were males while only 0.87% were females. Among seronegative, 98.03% were males while 1.96% were females. There was no significant association of gender with seropositivity. Similar results of no association of gender with seropositivity was seen in a study done in Al-Madinah, Saudi Arabia.[15] As blood donors enrolled in the present study were predominantly males, the association of gender with seropositivity could not be assessed due to few female donors.

The range of age in completed years in seropositive samples was 18-57 years while that in seronegative samples was 18-59 years. The mean age of seropositive and seronegative samples in our study was found to be 30.16 & 30.37 years respectively. The difference in mean age of seropositive and seronegative was not found to be statistically significant. However, a similar study done by Natalia Martinez Acuna et al showed that donors aged 18- 49 years were more likely to be seropositive compared to 50 years or above age group.[19]

In the present study, among all seropositive, maximum was found to be B Positive (33.18%) followed by O Positive (25.76%), A Positive (21.83%), AB Positive (8.73%). A Negative, AB Negative, B Negative and O Negative were 3.49%, 0.43%, 2.62% and 3.93% respectively. Among all seronegative, maximum was found to be B Positive (33.11%) followed by O Positive (27.86%), A Positive (22.62%), AB Positive (4.91%). A Negative, AB Negative, B Negative and O Negative were 3.27%, 0.32%, 2.95% and 4.91% respectively. However, there was no statistical association of type of blood group with seropositivity. This doesn't coincide with the result shown in other study that individuals with blood group A have been found to be more at risk as compared to those with blood group O [20,21].

5. Limitation of the study

The participants enrolled in the present study were only from single blood center in the north west region of India to assess the seroprevalence among healthy blood donors and its association with blood group and age. We need more serosurvey studies to strengthen present findings in near future to assess herd immunity and future recommendations for social guidance.

6. Conclusion

To conclude 43% positivity of SARS-CoV-2 IgG among healthy blood donors was detected which is an indication of presence of infection at community level that is majority of the population has already been exposed to SARS-CoV-2 infection. However, there was no statistically significant association of type of blood group and age with seropositivity.

CRedit authorship contribution statement

RMJ,SS,AS : Conceptualized the study
 ND: helps in investigation and data collection
 RV,MK: helps in statistics and analysis
 PR and RKS : reviewing and supervising.

Declaration of Competing Interest

The authors declare no conflict of interest.

References

- [1] Government of India. COVID-19 dashboard. 2021. Feb 3, 2021. <https://www.mygov.in/covid-19> (accessed Feb 3, 2021).
- [2] John Hopkins University, <https://github.com/CSSEGISandData/COVID-19>, last assessed on February 3, 2021.
- [3] WHO. A coordinated global research roadmap: 2019 novel coronavirus; March 2020. Geneva: World Health Organization; 2020.
- [4] Chen N, Zhou M, Dong X, Qu J, Gong F, Han Y, et al. Epidemiological and clinical characteristics of 99 cases of 2019 novel coronavirus pneumonia in Wuhan, China: a descriptive study. *Lancet* 2020;395:507–13.
- [5] Huang C, Wang Y, Li X, Ren L, Zhao J, Hu Y, et al. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. *Lancet* 2020;395(10223): 497–506.
- [6] Zhu N, Zhang D, Wang W, et al. A Novel Coronavirus from Patients with Pneumonia in China. *N Engl J Med* 2019;2020. <https://doi.org/10.1056/NEJMoa2001017>.
- [7] Wang W, XU V, Gao R, Lu R, et al. Detection of SARS-CoV 2 in different types of clinical specimens. *JAMA* 2020;323(18):1843–4.
- [8] WHO interim guidance for maintaining a safe and adequate blood supply during the pandemic outbreak of coronavirus disease(COVID-19), 20 March 2020.
- [9] National Guidance to Blood Transfusion Services in India in light of COVID 19 Pandemic Council; National Blood Transfusion Council; Ministry of Health and Family Welfare; Government of India Vide D.O No.: S-12016/99/2019- NACO (NBTC). (accessed on 2021 Feb 03), Available from: <https://mohfw.gov.in/pdf/2ndNBTCGuidanceinLightofCOVID19Pandemic.pdf>.
- [10] AABB Interorganizational taskforce statement on Corona virus and Blood Donation; <https://www.aabb.org/advocacy/regulatorygovernment/Pages/Statement-on-Coronavirus-and-Blood-Donation.aspx>.
- [11] Murhekar MV, Bhatnagar T, Selvaraju S, et al. Prevalence of SARS-CoV-2 infection in India: findings from the national serosurvey, May–June 2020. *Indian J Med Res* 2020;152:48–60.
- [12] Anti-SARS-Cov-2 IgG Assay kit IFU, manufactured by Ortho Clinical Diagnostics.
- [13] EUA Authorized Serology Test Performance (<https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/eua-authorized-serology-test-performance>).
- [14] Nandini Sharma, Pragya Sharma, et al. The seroprevalence and trends of SARS-CoV-2 in Delhi, India. A repeated population based seroepidemiological study. *BMJ Yale* 2021. <https://doi.org/10.1101/2020.12.13.20248123>.
- [15] Mahallawi Waleed H, Al-Zalabani Abdulmohsen H. The seroprevalence of SARS-CoV-2 IgG antibodies among asymptomatic blood donors in Saudi Arabia. *Saudi Journal of Biological Sciences* 2021. <https://doi.org/10.1016/j.sjbs.2020.12.009>.
- [16] Banjar Ayman, Al-Tawfiq Jaffar A, et al. Seroprevalence of antibodies to SARS-CoV-2 among blood donors in the early month of the pandemic in Saudi Arabia. *International Journal of Infectious Diseases*. 2021. <https://doi.org/10.1016/j.ijid.2021.01.028>.
- [17] Dodd Roger Y, Xu Meng, Stramer Susan L. Change in donor characteristics and antibodies to SARS-Cov-2 in donated blood in US, June-August 2020. *JAMA* 2020; 324(16):1677–9.
- [18] Uyoga Sophie, Adetifa Ifedayo MO, et al. Seroprevalence of anti-SARS-CoV-2 IgG antibodies in Kenyan blood donors. *Uyoga et al. Science* 2021;371:79–82.
- [19] Martinez-Acuña1 Natalia, Avalos-Nolazco Diana, et al. Seroprevalence of anti-SARS-COV-2 antibodies in blood donors from Nuevo Leon state, Mexico, during the beginning of the COVID-19 pandemic. *MedRxiv* 2021. <https://doi.org/10.1101/2020.11.28.20240325>. preprint doi:.
- [20] Fontanet A, Tondeur L, Madec Y, et al. Cluster of COVID-19 in northern France: a retrospective closed cohort study. *MedRxiv* 2020. published online April 23.
- [21] Valenti L, Bergna A, Pelusi S, et al. SARS-CoV-2 seroprevalence trends in healthy blood donors during the COVID-19 Milan outbreak. *MedRxiv* 2020. Published online May 31.