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Seroprevalence of COVID-19 among voluntary blood donors

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Abstract:

CONTEXT: COVID-19 usually presents with mild symptoms. No cases of transfusion – transmission of COVID-19 had been reported. Assessing the prevalence of viral infections among blood donors is essential to frame blood safety strategies.

AIM: The main aim of this study is to assess the seroprevalence of SARS-CoV-2 antibodies among healthy and asymptomatic voluntary blood donors by enzyme-linked immunosorbent assay (ELISA).

SETTING AND DESIGN: This cross-sectional study was conducted among voluntary blood donors using a consecutive sampling technique in the Department of Transfusion Medicine, the Tamil Nadu Dr. M.G.R. Medical University, Guindy, Chennai, for 18 months.

METHODS: Adhering to COVID-19 pandemic guidelines and donor eligibility criteria, blood samples collected from 500 asymptomatic unvaccinated voluntary blood donors were tested for SARS-CoV-2 (IgG + IgM + IgA and IgG) antibodies by ELISA. Adding IgA to a conventional IgM and IgG serological test improves sensitivity.

STATISTICAL ANALYSIS USED: The collected donor data were analyzed with IBM SPSS Statistics software. Pearson's Chi-square test and Fisher's exact test were used. $P = 0.05$ was considered statistically significant.

RESULTS: IgG seropositivity among the donors was 58.8%, and IgM + IgA seropositivity was 29.6%. There was no statistically significant difference in the COVID-19 IgG/IgM + IgA seropositivity status with age, gender, blood group, occupation, or socioeconomic status. The IgG and IgM/IgA/IgG ELISA kits showed a difference of 13 cases which could be attributed to the higher sensitivity of IgG alone ELISA kit. This increased the seroprevalence by 3%.

CONCLUSION: The majority of donors were either IgG or IgM and IgA positive, despite remaining asymptomatic. The seropositivity rate coincided with the COVID-19 surge among population.

Keywords:

COVID-19, seroprevalence, voluntary blood donors

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Introduction

Assessing the prevalence of viral infections among blood donors is essential to estimate the effectiveness of blood safety strategies and to improve current strategies to increase transfusion safety. COVID-19 virus exhibits faster human-to-human transmission. The symptoms of COVID-19 are usually mild. No cases of transfusion–transmission of COVID-19 had been reported. The main aim of this study is, therefore, to assess the seroprevalence of ([IgM + IgA] and IgG) SARS-CoV-2 antibody reactivity among healthy and asymptomatic blood donors. Adding IgA to a conventional serological test containing IgM and IgG improves the sensitivity of SARS-CoV-2 diagnosis.[1]

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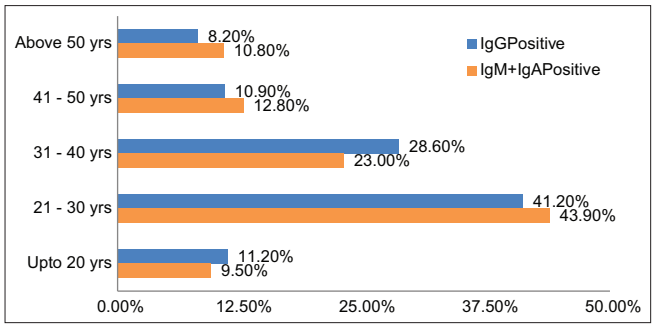

Figure 1: Age distribution in severe acute respiratory syndrome coronavirus 2 seropositive donors

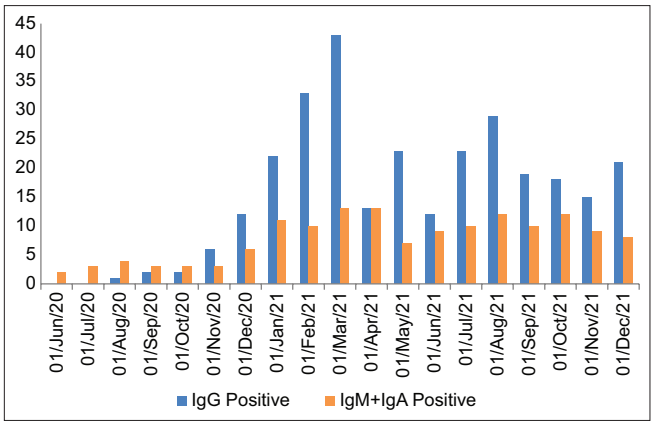

Figure 2: Month-wise distribution of Immunoglobulin (IgG)/IgM + IgA seropositivity

Methods

This is a cross-sectional study conducted for 18 months in the Department of Transfusion Medicine, the Tamil Nadu Dr. M.G.R. Medical University, Guindy, Chennai, among 500 unvaccinated voluntary blood donors using a consecutive sampling technique.

After considering incomprehensible trends of the COVID-19 pandemic, we decided to calculate the sample size based on the total number of donors who would donate their blood during the study period. During the study, after the implementation of COVID-19 vaccinations in January 2021, there was another limitation of finding unvaccinated donors. Accordingly, the sample size was calculated postfacto based on the formula,

$n = Z^2 \times p \times (1 - p)/\varepsilon^2$

Confidence level = 95%

Margin of error = 2%

Population size = 619 (from June 2020 to December 2021)

Based on the above formula required sample size was 493.

Selection and description of participants

Eligibility

Those voluntary blood donors who fulfill the criteria as per DGHS guidelines and guidelines for blood donation during the COVID-19 pandemic issued by the National Blood Transfusion Council, Ministry of Health and Family Welfare, Government of India.

Those blood donors who are willing and consented to participate in the study.

Exclusion criteria

Those voluntary blood donors who do not fulfill the criteria as per the DGHS guidelines.

Those blood donors who are not willing to participate in the study.

Individuals with travel history: Deferred for 28 days after the date of departure from a country with COVID-19 transmissions in the community and areas notified by the Ministry of Health and Family Welfare from time to time.

Contact history: Individuals deferred for 28 days with the last possible close contact exposure to a person who is confirmed/suspected case of COVID-19 including those under quarantine.

Confirmed case: Individuals deferred for 28 days since complete recovery from the disease including radiological and virological clearance.

Vaccinated donors.

Technical information

Five milliliters of blood from each donor meant for routine transfusion transmissible infections (TTI) screening were collected from the collection bag into a sterile capped tube. It was then centrifuged, and the serum was separated. After using the serum sample for mandatory TTI screening, the remaining serum samples were stored as two aliquots at −20°C or −80°C and were used for COVID-19 screening (IgG + IgM + IgA [J Mitra] and IgG [InBios]) by enzyme-linked immunosorbent assay (ELISA) according to the manufacturer's instruction.[2,3]

Samples were collected from June 2020 to December 2021. The sample analysis was done in two phases based on COVID-19 surges among population and lockdown strategies. Accordingly, samples collected from June 2020 to December 2020 were analyzed as Phase 1 and January 2021–December 2021 were analyzed as Phase 2.

Ethics

This study was approved by the Scientific Research Committee and Institutional Ethics Committee of the

Table 1: Immunoglobulin G/Immunoglobulin M + Immunoglobulin A seropositivity in first time and repeat donors

Number of donations and seropositivity Number of donations	IgG		IgM + IgA		χ^2	*P*
	Positive	Negative	Positive	Negative		
First time						
Count	170	94	79	185	IgG=7.225	0.007
Percentage	57.8	45.6	53.4	52.6		
Repeat						
Count	124	112	69	167	IgM and IgA=0.028	0.867
Percentage	42.2	54.4	46.56	47.4		

IgG=Immunoglobulin G, IgM=Immunoglobulin M, IgA=Immunoglobulin A

Table 2: Immunoglobulin G/Immunoglobulin M + Immunoglobulin A seroprevalence during two phases of the study

Comparison of seroprevalence of SARS-COVID-19 in two phases of study Duration	IgG		IgM and IgA		χ^2	*P*
	Positive	Negative	Positive	Negative		
Phase 2†						
Count	271	156	124	303	IgG=2.324	0.127
Percentage	92.2	75.7	83.8	86.1		
Phase 1*						
Count	23	50	24	49	IgM and IgA=0.440	0.507
Percentage	7.8	24.3	16.2	13.9		

*Phase 1=June 2020–December 2020, †Phase 2=January 2021–December 2021. IgG=Immunoglobulin G, IgM=Immunoglobulin M, IgA=Immunoglobulin A, SARS=Severe acute respiratory syndrome

Table 3: Disparity of severe acute respiratory syndrome-COVID-19 Immunoglobulin G positivity observed between two kits

Kit manufacturer	IgG positive samples	IgG negative samples
InBios (IgG)	13**	45
J.Mitra (IgG + IgM + IgA)	0	58

**Comparative analysis of two kits showed 13 samples positive by "IgG InBios kit." Among 58 negative samples by "IgG + IgM + IgA J. Mitra kit." IgG=Immunoglobulin G, IgM=Immunoglobulin M, IgA=Immunoglobulin A

Tamil Nadu Dr. M.G.R. Medical University, Chennai. Informed written consent was obtained from the study participants.

Statistics

The collected data were analyzed with IBM SPSS Statistics for Windows, Version 23.0 (Armonk, NY, USA: IBM Corporation). To describe the data descriptive statistics, frequency analysis and percentage analysis were used for categorical variables and the mean and standard deviation were used for continuous variables. To find the significance in qualitative categorical data, the Chi-square test was used. Similarly, if the expected cell frequency is less then Fisher's exact was used. In all the above statistical tools, $P = 0.05$ is considered statistically significant level.

Results

Majority of the voluntary blood donors belonged to the age group of 21–30 years [Figure 1]. Among them, 11.4% were female and 88.6% were male. The majority of them were students (50%). About 58.8% were positive for anti-IgG COVID-19. About 29.6% were positive for IgM + IgA COVID-19 antibodies [Table 1]. There is no statistical significance between age, gender distribution, and IgG/IgM + IgA seropositivity by Pearson's Chi-square test.

Seroprevalence of IgG COVID-19 antibodies from June 2020 to December 2020 was found to be 50.7% and 60.2% from January 2021 to December 2021. About 23.3% were positive for anti-IgM + IgA from June 2020 to December 2020 and 33.7% were positive from January to December 2021 [Table 2].

The seroprevalence rate has increased by 3%, i.e., 88%–91% if postanalytical interpretations of the results of these two kits were taken into account. All blood units were screened for routine/mandatory transfusion transmittable infection and found to be negative. A total of 869 blood components were prepared and issued to various hospitals. None of the recipients reported back with COVID-19 symptoms/infection.

Discussion

The present study was undertaken to define the seroprevalence of COVID-19 (IgG and IgM + IgA antibodies by ELISA) among the voluntary blood donor population. Our blood transfusion center has 100% voluntary blood donation.

The majority (78.2%) of the donors included in the study belonged to the age group of 18–40 years and 88.6% were

Table 4: Seroprevalence of severe acute respiratory syndrome covid - 2 in various studies

Study	Place	Sample size (*n*)	IgG seropositive (%)	IgM seropositive (%)
Present study	Chennai	Phase 1: 73	Phase 1: 31.5	Phase 1: 32.8
		Phase 2: 427	Phase 2: 63.4	Phase 2: 29
Tiwari *et al*.[4] (blood donors)	Haryana	1456	60	
Das *et al*.[5] (blood donors)	West Bengal	611	4.4	
Jaiswal *et al*.[6] (blood donors)	Jaipur	586	42.8	
Kumar *et al*.[7] (blood donors)	Gujarat	4916	54.6	
Chang *et al*.[8] (blood donors)	China	38,144	1	0.68
Chandra *et al*.[9] (blood donors and health care workers)	Lucknow	2085	1.9	
Bogo *et al*.[10] (blood donors)	Southern brazil	1015	18.5	9.4
Ijeoma *et al*.[11] (blood donors)	Nigeria	113	42	41
Mokono *et al*.[12] (blood donors)	Republic of congo	2553	31.4	36.7
Selvavinayagam *et al*.[13] (general population)	Tamilnadu	Round 1: 26,135	Round 1: 31.6	
		Round 2: 21,992	Round 2: 22.9	
		Round 3: 26,592	Round 3: 67.1	
Amorim Filho *et al*.[14] (blood donors)	Rio de Janeiro	2857	11.4	23.7

IgG=Immunoglobulin G, IgM=Immunoglobulin M

male, as they comprise the main workforce and move in the community.

Tiwari *et al*.[4] concluded 60 % seropositivity of SARS-CoV-2 IgG antibody among healthy blood donors which is an indication of persistence of infection at community level and that majority of the population has been exposed already to SARS-CoV-2 infection [Table 4]. Similar findings were observed by Jaiswal *et al*.[6] (43% seropositivity) and Kumar *et al*.[7] (54.6 % seropositivity) of SARS-CoV-2 IgG antibody, Ijeoma *et al*.[11] (42% seropositivity), Mokono *et al*.[12] (31.4% seropositivity) and Bogo *et al*.[10] (18.5%seropositivity) [Table 4]. Chandra *et al*.[9] reported 1.9 % seropositivity of SARS-CoV-2 IgG antibody among blood donors and health care workers [Table 4].

In the first phase of the study (June 2020–December 2020), the seroprevalence of IgM + IgA (32.8%) COVID-19 was high compared to the IgG (31.5%) seropositivity. In the second phase of the study (January 2021–December 2021), the seroprevalence of IgG (63.5%) COVID-19 was high compared to IgM + IgA (29%) seropositivity. This correlates with the study findings by Selvavinayagam *et al*. [Figure 2].[13] Das *et al*.[5], Amorim Filho *et al*.[14] and Chang *et al*.[8] have reported SARS-CoV-2 IgG seropositivity of 4.4% , 11.4% and 1% respectively among blood donors.

There was no statistically significant difference ($P > 0.05$) in the COVID-19 status in the above said different periods. There was no statistically significant difference in the COVID-19 IgG/IgM + IgA seropositivity status with age, gender, blood group, occupation, or socioeconomic status.

The research kits for IgG and IgM/IgA/IgG ELISA approved by US FDA and ICMR showed a difference of 13 cases. This variability between the test kits could be attributed to the sensitivity and specificity of each kit [Table 3].

The seropositivity difference between the two kits in our study could be explained by the sensitivity claimed by the manufacturers (J. Mitra 96.72%, InBios 100%). Kulkarni *et al*.,[15] in their study observed that InBios showed the highest sensitivity and negative predictive value for COVID-19 IgG detection in comparison to other kits, namely, IRSHA, Euroimmun, Erbalisa, Kavach. In our study, also, the higher sensitivity of "IgG InBios kit" resulted in 3% increase in seroprevalence rate, i.e., 88%–91% in comparison to IgG + IgM + IgA J. Mitra Kit.[2,3]

Conclusion

In the era of globalization, pandemic diseases are inevitable. To understand, the pattern of such emerging diseases is essential for health-care professional to enable uninterrupted services to mankind. Blood transfusion service is one of the essential services that need to be rendered even during similar disastrous conditions. The present study revealed the reality of exposure to COVID-19 infections among asymptomatic voluntary blood donors.

The majority of them were either IgG or IgM and IgA positive, despite remaining asymptomatic. The IgM and IgA and IgG seroprevalence matched with the surges of COVID-19 among population.

Further, this study iterates the importance of continuing blood transfusion services by removing apprehensions among voluntary blood donors and service providers. However, appropriate health-care behavior needs to be adhered to in such pandemics.

Several literature revealed respiratory viruses such as the Middle East respiratory syndrome and severe

acute respiratory syndrome will not be transmitted through blood transfusion. In our study too, none of the patients reported either COVID-19 symptoms or infection following transfusion. The nature of the disease compelled the approving authorities to issue at least the Emergency Use Authorization label for several diagnostic kits. This has resulted in varying abilities to identify COVID-19 infections among several manufacturers and the same has also been observed in our study.

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Conflicts of interest

There are no conflicts of interest.

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