Section: Transfusion Medicine

Original Research Article

PREVALENCE OF SARS-COV-2 TOTAL AND IGG ANTIBODIES IN UNVACCINATED ASYMPTOMATIC BLOOD DONORS ATTENDING A REGIONAL BLOOD TRANSFUSION CENTRE -A CROSS SECTIONAL STUDY

Received : 05/01/2023
Received in revised form : 19/02/2023
Accepted : 01/03/2023

Keywords:
Blood donors, SARS CoV2, IgG, IgM

Corresponding Author:

Dr. Shaiji.P.S
Email:shaijimehar@gmail.com

DOI: 10.47009/jamp.2023.5.2.263

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

Int J Acad Med Pharm
2023; 5 (2); 1240-1243

Chitra James[1], M.S Suma[2], Shaiji. P.S[3]

[1]Assistant Professor, Department of Transfusion Medicine, Govt Medical College, Kottayam, India.
[2]Associate Professor, Department of Transfusion Medicine, Govt Medical College, Kottayam, India.
[3]Associate Professor, Department of Transfusion Medicine, Govt Medical College, Kollam, India.

Abstract

Background: Prevalence of SARS Cov2 have been studied widely across various countries and settings like health care workers, general population and asymptomatic blood donors. Aim of this study was to estimate the baseline seroprevalence of SARS-CoV-2 antibodies in unvaccinated asymptomatic voluntary and replacement blood donors in our institute, and to compare it with the serological and symptomatic disease prevalence in Kerala during the same period. Potential factors associated with seropositivity for SARS-CoV-2 was also assessed. **Materials and Methods:** The study was conducted in the department of Transfusion Medicine, Govt Medical College, Kottayam, Kerala, India in 696 asymptomatic unvaccinated blood donors from the period of 18/2/2021 to 27/2/2021. Blood samples collected during blood donation were screened for SARS Cov2 antibody using M/s Biorad Platelia SARS CoV-2 Total antibody (IgM+IgG) ELISA assay and SARS-CoV-2 IgG chemiluminescence assay by M/s Ortho Clinical Diagnostics. **Result:** The overall seropositivity for SARS-CoV-2 total antibodies among blood donors was 157/696(22.5%). Out of 157 donors reactive with total antibody, 32 were positive for IgM antibodies (32/696,4.59%) and 125 (17.95%) for IgG antibodies. Most of the seropositive donors were of the age group 18 – 25 years. In both groups, male donors were predominant (98%). The majority were repeat donors (80.3%) among seroreactive. **Conclusion:** The baseline seroprevalence of SARS CoV-2 IgG among blood donors is 17.95% which is higher than the general population. The socially active nature of blood donors and the increase in outdoor activity may be a possible reason. Hence It may not be prudent to always consider the prevalence of such diseases by blood donors as a reflection of prevalence in the general population.

INTRODUCTION

The prevalence of SARS Cov2 has been studied widely across various countries and various settings like health care workers, the general population, and asymptomatic blood donors.[1] The Coronavirus disease 2019 (COVID-19) pandemic has been spreading since December 2019 all over the world.[2] Like all other clinical services, blood centers also were struggling to cope up with the drastic changes in blood supply, new deferral patterns and increasing demand for convalescent plasma without robust scientific evidence.

Approximately 0.4 million donors donate blood in 175 Blood Centres across Kerala every year. These donors are subjected to medical screening according to criteria by Drugs and Cosmetics and are completely asymptomatic at donation. During the pandemic, blood banks followed NBTC guidelines for donor selection and management, released in view of the COVID-19 outbreak. Those with recent symptoms like fever, history of travel to affected areas, and contact with such people are deferred from donation.

Hence blood donors can be considered as a low-risk population for covid infection theoretically, which depends on the prevalence of asymptomatic infection in the community also in turn. Studies in China,[3] post-lockdown reported about 2% prevalence in blood donors but reports from Karachi, Pakistan,[4] had a prevalence of 37.7%. Similar or lesser prevalence than the general population was expected

ISSN (O): 2687-5365; ISSN (P): 2753-6556

to reflect in the asymptomatic blood donors who have donated blood during this period.

According to the predicted serological course of SARS CoV2, there is a rise in the total antibody by the second week of infection in COVID-19 confirmed cases. IgM antibodies disappear while the IgG antibodies persist. Since symptomatic donors are identified and deferred during donor counseling and medical examination, only asymptomatic donors who were recently infected may show an IgM antibody. But those who are infected in the past may or may not carry an IgG antibody depending on the weaning off of the antibody.

The routine screening of blood donors for SARS-CoV-2 was not made mandatory as per the National Blood transfusion guidelines. Yet Various seroepidemiological studies were conducted in India at different time periods to estimate the seroprevalence of the SARS-CoV-2 antibodies among the general population.

The primary objective of this study was to study the seroprevalence of SARS-CoV-2 antibodies in asymptomatic voluntary and replacement blood donors in our institute and to compare it with the serological and symptomatic disease prevalence in Kerala during the same period which was being studied by ICMR and Government of Kerala separately. We also intended to assess potential factors associated with seropositivity for SARS-CoV-2

Rationale

Vaccination drive against COVID-19 started in Kerala on March 2021. Since the vaccination had not started at the time of our study which started in January 2021, we could obtain data on confirmed unvaccinated individuals, who have no knowledge or symptom of Covid Infection ever. It is usually assumed that the prevalence of IgG may provide a reflection of transmission in the asymptomatic individuals in the community. Hence we wanted to compare the data with the result of the seroprevalence study phase III which was ongoing simultaneously.

We also intended to assess the demographic factors associated with covid infection in blood donors. No study was done in Kerala during this pre-vaccination time period. We looked forward to knowing the need for enhancing safety measures in blood banks and also assess the need for routine screening for Covid 19 in blood banks. Also, a baseline seroprevalence in blood donors to evaluate the trend in the asymptomatic population in each area seemed useful and further 3 monthly or 6 monthly follow up could easily be done in blood bank. Moreover, a reflection of availability of convalescent plasma at any time could be obtained.

MATERIALS AND METHODS

Study Setting

The study was conducted in the department of Transfusion medicine Govt Medical College, Kottayam, Kerala, India in blood donors from the period of 18/2/2021 to 27/2/2021 . Approval from the Institutional Review Board was obtained on 16/2/2021(IRB No 22/2021). Informed Consent was taken from all participants.

Study participants

Inclusion Criteria

The donors were selected if they satisfied the eligibility criteria as per the Drug and Cosmetics Rules 1945 amended in March 2020

Exclusion Criteria

Those with a previous history of SARS-CoV-2 infection were excluded as well as apheresis/autologous/convalescent plasma donors. Also, those with repeatedly indeterminate test results or inadequate/ hemolysed samples were excluded

Method of Investigations

The sample collected for routine TTD screening was used for SARS CoV 2 antibody Test also. The test was performed using Biorad ELISA i Mark 100 and Biorad ELISA washer PW 40 installed in blood bank using Biorad platelia for IgM plus IgG antibodies. Apart from Kit control, one external control was included in each run and LJ chart was plotted for all runs. Runs that did not comply with the Westgard rules were rejected. All positive samples were frozen for future use and titer estimation. Kit was validated with convalescent samples (positive and negative, already kept in the department) tested with a validated CLIA assay.

Total antibody-positive samples were subjected to discriminatory IgG Assay on the same day. The SARS- CoV-2 IgG antibodies were measured using the enhanced chemiluminescence method (Vitros ECi, Ortho Clinical Diagnostics, New Jersey, US). This qualitative assay is based on a recombinant form of the SARS-CoV-2 spike subunit 1 protein. Results are based on the sample signal-to-cut-off (S/Co) ratio, with values <1.0 as negative and ≥ 1.00 as positive results as per the manufacturer's guide. Those who were negative for IgG were considered to be IgM.

Variables

Those who are seroreactive for SARS CoV 2 antibody (IgG /IgM) were considered as cases. Prevalence was reported out of total blood donors included in the study. The donor data collected from data entered in donor forms included age, gender, voluntary or replacement donors, number of previous donations, Occupation, Duration of outdoor activity, and Travel history. Optical density values and sample /cut-off ratios were recorded from saved data of automated analysers.

For a comparison of associated factors, a random sample of size 471 was drawn from seronegative donors (1:3 ratio between cases and control). Age <25 year. Gender, Duration of outdoor activity as reported by donor (>8hours), Multiple previous donations (4 or more) and Voluntary donation were analysed as independent variables and dependent variable was presence or absence of seroreactivity

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Sample Size

At the time of devising this study. No previous studies were done in Kerala regarding prevalence in asymptomatic blood donors. A range of 4 to 24 percentage is reported in studies outside India. Since no previous studies were available in blood donors, a sample size of 396 is calculated assuming a prevalence of 1% and absolute precision of 1 %. As study progressed, on interim analysis prevalence of seropositivity was found to be much more and with the budget and resources allotted tests on more samples were possible. Hence sample size was revised to 720.

Sampling

On every working day, 50- 60 donor samples were randomly selected from total collection of samples from blood donors (approximately 80- 100 donors/day. Informed consent was taken from donor and all procedures were in accordance with the declaration of Helsinki.

Data Analysis

The collected data was entered in an excel spreadsheet and continuous data was expressed as mean, median, or percentage. The categorical data were analysed using Chi-Square test. Odds Ratio with 95% Confidence intervals were reported. The statistical analysis was done using SPSS software version 22.In the output produced by total antibody ELISA, samples showing very high optical density (OD) value were separately marked so those were categorised as high OD samples. In Chemiluminescence assay for IgG, high OD was defined as >9.00.

RESULTS

A total of 720 blood donors were included in the study. There was no case of inadequate sample or indeterminate result. After the samples were selected, some donors(N=10) expressed unwillingness and hence excluded. Data about some variables were missing in donor forms and 14 such donors were further excluded. Final sample size was 696.

The overall seropositivity for SARS-CoV-2 total antibodies was 157/696(22.5%) Standard Error 1.6%). Out of 157 donors reactive with total antibody 32 were positive for IgM antibodies(4.59%,SE 0.8%) and 125 (17.95%,SE 1.4%)for IgG antibodies. Seropositive donors were mostly of age group18-25%. A large proportion of donors were donors were males (98% in both groups) Majority were repeat donors among the seroreactive (80.3%). [Table 1] shows the comparison of demographic profile and [Table 2] shows the serological profile.

Analysis of factors associated with seropositivity is summarised in [Table 3]. The seroreactive group had significantly high proportion of donors with Young age<25 yrs (Odds Ratio 1,49,p 0.03), multiple previous donations (OR 2.6, p 0.0001),voluntary donors (OR 4.07,p 0.0001) and duration of outdoor activity(OR 2.17,p 0.0001). There was no significant association with Gender.

DISCUSSION

In a period between 18/2/2021 and 27/2/2021,696 blood donors were tested. 157 Were seroreactive and 539 were negative. None of the donors who recollected a symptomatic episode of covid 19 was included. Most of the donors were positive for IgG (17.95%) and 20.38% of total positive was IgM(32/157). Total prevalence of exclusive IgM antibody was 4.59% (32/696)

Majority of the donors in both seronegative and positive category were of age group 18 -25 year as generally observed in our blood centre .Most of the seropositive donors were involved in occupations involving House to house visits(. Since many educational institutions held restrictions, students were much less in number in both groups. The seroreactive donors had more of repeat donors in the range 2 to 25 times of donation. In both groups replacement donors were predominant.

ICMR, Government of India had conducted three rounds of serosurvey in Kerala during the months of May-June 2020,[7] August -September 2020,[8] and December 2020.[9] The seroprevalence was 0.3%, 0.8% and 11.6% respectively. These were serial cross-sectional surveys from three districts of Kerala. Report of the Kerala covid-19 (Sars Cov-2 IgG) serosurvey was released in March, 2021,[10] from a large sample size and this serosurvey involved samples from various sections of population, apart from blood donors. The study showed that the seroprevalence in Kerala 10.76% and at Kottayam seroprevalence was 12.50 (95% CI 9.5-15.5).

The seroprevalence of IgG observed in our study is higher than what observed in these studies. Studies in other parts of India in the pre vaccination period showed prevalences like 11.1% (Healthworkers, Mumbai,[12] Nov 2020), 12.4%,[13] (general population, bangalore rural, December), 19.1% (Healthcare workers,[14] Kerala, January 2021), 28.7% (General population, Jabalpur,[15] December 2020). 3rd Serosurveillance by ICMR at national level in 2021 January,[16] estimated a seroprevalence of 24% prevalence of IgG antibodies in general population, But by July 2021 4th ICMR serosurveillance estimated a prevalence of 67.6%,[17] among unvaccinated adults. First and second surveys had reported prevalence of 0.7% and 7.1%.[16]

Possible reasons for this higher prevalence may be related to the pattern in outdoor activity of our blood donors. Most of the seroreactive donors were repeat donors who donated >5 times and socially active. Also occupational profile involved more of outdoor activities in seroreactive donors.

A meta-analysis on Seroprevalence of anti- SARS-CoV- 2 antibodies in Africa,[17] reported wide range of prevalence depending on the characteristics of tested population. The highest anti- SARS- CoV- 2 antibody seroprevalence was 63%,[18] in the Republic of South Africa (RSA), while the lowest anti-SARS- CoV- 2 seroprevalence recorded was 0% in

ISSN (O): 2687-5365; ISSN (P): 2753-6556

Libya.[19,20] Interestingly the study also found that the pooled prevalence of anti- SARS- CoV- 2 antibodies in blood was higher (33%, CI: 12–60) compared with health care workers (28%, CI: 10–50) and the general population. A baseline study done in Estonia,[21] using leftover laboratory samples in the same timeline showed a prevalence of 15.8% in the unvaccinated population.

In this study, we also aimed to assess the proportion of donors who may qualify for a high titer convalescent plasma donation as evidenced by the high optical density of IgG in chemiluminescence assay. There were only 6 donors who had high IgG antibody levels (4.8%).

Certain demographic factors were compared between the seroreactivity and the randomly selected controls from the nonreactive group (N=471). The seroreactive group had a significantly high proportion of donors with multiple previous donations (OR 2.6 p 0.0001) voluntary donors (OR 4.07, p 0.0001) and duration of outdoor activity (OR 2.17, p 0.0001). There was no significant association with Gender. Young age<25 yrs was also weakly associated with seropositivity (Odds Ratio 1.49. p 0.03, statistically significant). Most likely explanations in this scenario is that all these factors are related to the social behaviour of an individual namely altruistic behaviour leading to voluntary donations, regular repeat donation and more outdoor activity which may occupational and nonoccupational. Studies with further inclusion of possible confounders are necessary to arrive at the actual cause of this association.

Limitations

Periodicity observed by the IgG antibodies against SARS-COV2 is very characteristic and current seroprevalence may not be a true reflection of actual number of individuals affected.[22,23] After 3 to 6 months IgG levels may be reduced to undetectable levels. Also, limited Sample size and heterogenous nature of blood donors are limitations of the study. Also possible confounders could not be ruled out due to lack of data on such variables.

CONCLUSION

Prevalence of SARS Cov 2 antibodies found in this study are much higher than asymptomatic general population.Certain characteristics like duration of outdoor activity and social behaviour affects the prevalence of such diseases in blood donors significantly.

REFERENCES

1. Zhu N.Zhang D.Wang W.Li X.Yang B.Song J.et al.A novel coronavirus from patients with pneumonia in China, 2019. N Engl J Med. 2020; 382: 727-733
2. Rostami A, Sepidarkish M, Leeflang MMG, et al. SARS-CoV-2 seroprevalence worldwide: a systematic review and meta-analysis. Clin Microbiol Infect. 2021;27:331-340.
3. Chang L, Hou W, Zhao L, et al. The prevalence of antibodies to SARS-CoV-2 among blood donors in China. Nat Commun. 2021;12:1383
4. Amber Younas, Samra Waheed, Shabnum Khawaja, Mehjabeen Imam, Munira Borhany, Tahir Shamsi,Seroprevalence of SARS-CoV-2 antibodies among healthy blood donors in Karachi, Pakistan,Transfusion and Apheresis Science.2020;59:6
5. Amorim Filho L,Szwarcwald CL, Mateos S, Ponce de Léon ACM, Medronho RA,Veloso VG, et al. Seroprevalenceof Ig G and IgM anti-SARS-CoV-2among blood donors in Rio de Janeiro, Brazil. Rev Saude Publica.2020;54:69.
6. Fischer Bastian , Knabbe Cornelius , Vollmer Tanja . SARS-CoV-2 IgG seroprevalence in blood donors located in three different federal states, Germany, March toJune 2020. Euro Surveill. 2020;25;28
7. Murhekar MV, Bhatnagar T, Selvaraju S, Rade K, Saravanakumar V, Vivian Thangaraj JW, 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.
8. Murhekar MV, Bhatnagar T, Thangaraj JWV, Saravanakumar V, Santhosh Kumar M, Selvaraju S, et al. (2021) Seroprevalence of IgG antibodies against SARS-CoV-2 among the general population and healthcare workers in India, June–July 2021:
9. .Murhekar MV, Bhatnagar T, Selvaraju S, Saravanakumar V, Thangaraj JWV, Shah N, et al. SARS-CoV-2 antibody seroprevalence in India, August–September, 2020: findings from the second nationwide household serosurvey. Lancet Glob Health. 2021;9:e257–66. https://doi.org/10.1016/S2214-109X(20)30544-1 pmid:33515512
10. Murhekar MV, Bhatnagar T, Thangaraj JWV, Saravanakumar V, Kumar MS, Selvaraju S, et al. SARS-CoV-2 seroprevalence among the general population and healthcare workers in India, December 2020–January 2021. Int J Infect Dis. 2021;108:145–55.
11. Technical paper COVID 19 ICMR – Serological Surveillance Report Round 3 available from https://dhs.kerala.gov.in/wp-content/uploads/2021/02/Technical-paper-COVID-19-Sero-Surveillance-Round-3-ICMR.pdf
12. Kumar N, Bhartiya S, Desai S, Mutha A, Beldar A, Singh T. Seroprevalence of Antibodies Against SARS-CoV-2 Among Health Care Workers in Mumbai, India. Asia Pac J Public Health. 2021;33(1):126-128. doi:10.1177/1010539520977307,
13. Inbaraj LR, George CE, Chandrasingh S. Seroprevalence of COVID-19 infection in a rural district of South India: A population-based seroepidemiological study. PLoS One. 2021 Mar 31;16(3):e0249247
14. Jessy SJ, Beegum S, Genga S, Bindu G, Chintha S, Sasidharan S, Tonio A, Reghukumar A.Prevalence of SARS-CoV-2 Infection among Health Care Workers of a Hybrid Tertiary COVID-19 Hospital in Kerala, India [Internet].2022 July [Cited November 15, 2022];11(3):BO13-BO18.
15. Ramaswamy S, Athotra A, Kasar PK, Tiwari R, Tomar SP, Kuraria R et al. Cross-sectional Study on Sero-Prevalence of SARS-CoV-2 Infection in Jabalpur, Madhya Pradesh, India. J Commun Dis 2021; 53(1): 82-88
16. 4th National Serosurvey: 67.6% of Population Has Antibodies, Says ICMR 2022 July[cited 2022 17 nov];102(6):[about 3 p.]. Available from:https://www.thequint.com/news/india/serosurvey-national-fourth-round-covid-19-coronavirus-india-icmr-findings
17. Chisale MRO, Ramazanu S, Mwale SE, et al. Seroprevalence of anti-SARS-CoV-2 antibodies in Africa: A systematic review and meta-analysis. Rev Med Virol. 2022;32:e2271
18. Sykes W, Mhlanga L, Swanevelder R, et al. Prevalence of anti-SARS- CoV- 2 antibodies among blood donors in Northern Cape, KwaZulu- Natal, Eastern Cape, and Free State Provinces of South Africa in January 2021. Preprint. 2021:9-11
19. Kammon AM, El- arabi AA, Erhouma EA, Mehemed TM, Mohamed OA. Seroprevalence of antibodies against SARS-CoV- 2 among public community and health- care workers in Alzintan City of Libya. Preprint. 2020:1–8.
20. Kagucia EW, Karani A, Gitonga JN, et al. Seroprevalence of anti- SARS- CoV- 2 IgG antibodies among truck drivers and assistants in Kenya. Preprint. 2021:1–11.
21. Soeorg H, Jõgi P, Naaber P, Ottas A, Toompere K, Lutsar I. Seroprevalence and levels of IgG antibodies after COVID-19 infection or vaccination. Infect Dis (Lond). 2022;54:63-71
22. Abbasi J. The flawed science of antibody testing for SARS-CoV-2 immunity. 2021.JAMA;326:1781-2
23. Kumar N, Bhartiya S, Singh T. Duration of anti-SARS-CoV-2 antibodies much shorter in India. Vaccine. 2021;39:886-888

ISSN (O): 2687-5365; ISSN (P): 2753-6556