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COVID-19 seroprevalence study of an Indian Diagnostic Laboratory - Report on gender and age analysis

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ABSTRACT

In COVID-19 the extent of the impact on exposure, symptoms, recovery remains minimally explored as the spectrum is challenging to study across geographies. The aim of our study report was to explore seroprevalence in a pan-India cohort of Asian Indians across different age groups. Covid-19 antibodies were tested from a total of 1,36,210 Asian Indians inclusive of 97,124 males and 39,086 females, respectively. Testing for covid-19 antibodies was done by electrochemiluminescence immunoassay (ECLIA) and enzyme-linked immunosorbent assay (ELISA). Analysis for seroprevalence found the frequency to be 19%. The percent positives were higher among females at 21%, compared to males at 19%, and the difference was found to be statistically significant at p < 0.0001. Further, age group-wise analysis found seroprevalence between age groups of 21 - 80 years to be significant at p < 0.0001. Our study found higher seroprevalence among females, which is in line with many small cohort studies published online.

Key words: Antibody, Coronavirus, COVID-19, Females, India, Males, Pandemic

INTRODUCTION

The coronavirus disease of 2019 (COVID-19) caused by the SARS-CoV-2 has had an enormous impact on global healthcare infrastructure. The social impact of the pandemic include, loss of livelihood for many, apart from anxiety around the cause for fatality. Apart from understanding the mechanism of infection, determining risk factors on the cause, and the spread of the pandemic has generated heterogeneous information deluge. The delay in making available testing kits, variations in diagnosis criteria, the inherent risk around sample collection for reverse transcriptasepolymerase chain reaction test (RT-PCR), and implementation of different intervention strategies at different stages of the pandemic has made epidemiological data comparison even within the country, a difficult task. Answers to a lot of questions around the spectrum of disease severity ranging from asymptomatic to a mild symptomatic, severe disease requiring hospitalization and fatality are critical¹. The recurring incidences of coronavirus infection first in the year 2003, and then 2012, and the current 2019, has been overwhelming both in terms of healthcare management, through its mode of transmission, higher risk of death among the vulnerable, increased risk for healthcare workers, and the significant number of deaths². In the case of India, one report by the Indian Council of Medical Research (ICMR) highlighted the age group of 60 - 79 years to be the most vulnerable, with 51.2% having succumbed to covid-19 being over 60 years of age³. Another following report from New Delhi detected 43% of the covid-19 deaths to have taken place in the younger age groups of between 30 - 44 years and 45 - 59 years, respectively⁴. The wide spectrum in the age group around the fatality of covid-19 in the country does add to a lot of epidemiological dilemma wherein risk stratification becomes difficult.

In the case of diagnosis of covid-19, RT-PCR has been recommended, and many comparison studies have detected molecular analysis to be better in terms of sensitivity and specificity. The type of specimen tested and the time period has been shown to impact diagnosis with RT-PCR, as early period serum samples were detected to be negative, while the respiratory specimen was positive⁵. Pre-analytical and analytical variables have been shown to highly impact diagnostic accuracy of RT-PCR, including quality of the sample, wherein sputum has been detected to be better than oropharynx, which is superior to the nasopharynx⁶. Testing for total (IgG and IgM) covid-19 antibodies adds convenience to the sampling process and feasibility to use for large scale population monitoring. The added advantage of studying covid-19 antibodies lies in the general efficacy of the serological assays among late presenting patients and those with low viral load⁷. Antibody tests have been viewed as an

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excellent companion for RT-PCR tests in SARS-CoV-2 as they aid in identifying asymptomatic individuals. Though the window period for antibody testing in covid-19 is debated to lie between 10 - 14 days after symptom onset, they are important for epidemiological investigations to monitor the extent and prevalence of infection ⁸.

The aim of the present study was to assess the seroprevalence for the covid-19 antibody in a pan-India cohort of Asian Indians across different age groups. This is crucial for risk stratification and designing public health measures. A nationwide serosurvey that is targeting specific strata, including different age groups and gender, will aid in determining the impact of containment measures, as well as behavioral changes. An age group serosurvey analysis also aids in determining the high-risk category and identifying the mode of transmission across different subsections of society.

MATERIALS - METHODS

This observational report includes data from samples processed in a reference laboratory and not a hospitalbased setting. No patient identifiers have been used in any part of this report, and hence the need for informed consent and review board approval does not fit as a necessity. Data from a total of 136,210 samples tested for the covid-19 antibody assay have been used for this analysis.

Total covid-19 antibody testing was done by the technology of electrochemiluminescence immunoassay (ECLIA), and that for IgG was done by enzyme-linked immunosorbent assay (ELISA). The approved commercial kits for ECLIA include the Cobas[®] Elecsys Anti-SARS-CoV-2 (Roche Diagnostics, GmbH) and the SARS-CoV-2 Total (COV2T, Siemens Healthcare Diagnostics Inc., USA). The approved commercial kits for ELISA include the COVID-19 IgG ELISA Kit (Omega Diagnostics, UK) and ErbaLisa[®] COVID-19 IgG (Calbiotech Inc. USA). The ECLIA assay involved the use of a recombinant protein representing the nucleocapsid (N) antigen to detect antibodies against the SARS-CoV-2, and also a sandwich immunoassay using acridinium ester chemiluminescent technology. In the case of ELISA, the principle was a semi-quantitative plate-based assay to detect COVID-19 IgG antibodies. Result interpretation was made using the cutoff index (COI) as specified by the manufacturer.

RESULTS

A total of 136,210 serum samples were assessed for the covid-19 antibody, including 97,124 males and 39,086

females. The seroprevalence found in our analysis was 19%. In case of females the percent positive was found to be higher at 21%, compared to males at 19%, and the difference was statistically significant at p < 0.0001. Further, age group analysis was also done to understand if there was any difference in seroprevalence, impacting age-related susceptibility. The results have been summarized in **Table 1**.

Analysis of significance in seroprevalence between different age groups found the difference in percent positive between age groups of 21 - 80 years to be significant at p < 0.0001. The seroprevalence of above 20% was found in the age group of > 40 years. Our analysis also found the age group of between 61 – 80 years to exhibit maximum exposure.

Further analysis of gender among different age groups found the percent positive difference between males and females to be significant up till 60 years of age at p = 0.0025 among children and adolescents, while at p < 0.0001 for the adults. Maximum exposure among both males and females was detected in the age group of between 61 – 80 years. The seroprevalence was found to be consistently high among adult females in the cohort.

DISCUSSION

The covid-19 pandemic continues to evolve in terms of disease severity, recovery, and fatality rates. The developed nations of the world are challenged by high death per million (DPM), while the economically weaker geographies are under pressure to tackle the high volume of testing, to effectively control infection spread. The pandemic has posed many challenges, from the need to identify the spectrum of disease severity to studying transmission and rates, and lastly, the factors that promote the risk of fatality from severe illness stage¹. Age has been classified as one of the risk factors for infection, and many studies have identified the risk of infection among the elderly to be affected by other age groups^{9,10}. Studies on contact rate, and infection transmission across different age groups, have detected the old age group to be susceptible, and the impact of social distancing on pandemic control to depend on the role of different age groups in transmission⁹.

Age group analysis becomes a crucial factor in many epidemiological aspects of covid-19, right from charting exposure to susceptibility, contact tracing, and rate of transmission. Adaptive immunity, which determines exposure as well as susceptibility index in a population, also becomes a crucial factor to study pandemic control. India has vast geography, and a few metro cities have contributed to over 50% of

Table 1. Age group analysis for corra 19 analody prevalence in Asian malans			
Age group (Years)	Total %P	Males Positive	Females Positive
< 20	18% (1643)	18% (1057)	16% (586)
21 - 40	17% (12790)	16% (9070)	19% (3720)
41 - 60	22% (8969)	21% (6151)	24% (2818)
61 - 80	26% (2472)	26% (1612)	25% (860)
> 80	25% (158)	25% (87)	25% (71)

Table 1: Age group analysis for covid-19 antibody prevalence in Asian Indians

Note: %P - Percent positive for covid-19 antibody

the total caseload in the country, including Mumbai, and Pune from Maharashtra, Delhi, Ahmedabad from Gujarat, and Jaipur from Rajasthan and Chennai from Tamil Nadu¹¹. Seroprevalence analysis in a countrywide aspect can play a crucial role in identifying the success of existing pandemic control measures. Our study's aim was to assess the seroprevalence of covid-19 antibodies across different age groups in a pan-India population. The samples included those from the general population, including working professionals, and the total percent positive found in our study was 19%. In comparison, a study on 60,000 participants from Spain detected seroprevalence to be low at 5%, while a Swiss study which assessed 2766 specimens found the same to be around 10.8%^{12,13}. The earliest seroprevalence study which was done in the epicenter of covid-19; Wuhan, after 4 - 8 weeks of peak infection, found the frequency to be low at 3.8%¹⁴. Similar seroprevalence reports from 10 sites in the United States detected the prevalence to range between 1% to 6.9%¹⁵. The seroprevalence detected by our study in India is higher in comparison to many other countries, and this can also be the attributable factor for the low DPM¹⁶.

A seropositive survey across different age groups, including young children to adults, and older population, was also included. Our study detected the seroprevalence to be significant between age groups of 21 - 80 years at p < 0.0001. Government data indicated 85% of covid-19 deaths to occur among the 45-plus years age population¹⁷. Published reports highlight an association between fatality rates, and age-associated susceptibility, though our seroprevalence study indicates good percent positives in all the age groups studied. Our findings can also be compared with another Indian report on seroprevalence from Mumbai and Delhi done in early July 2020. This report, which studied IgG prevalence, detected the positive to be 23% in Delhi, while in Mumbai, the frequency was higher at 57% in the slum areas and 16% in the non-slum localities. Assuming 40% of the city's population in Mumbai to reside in slum areas, a prevalence of roughly 33% was cited as of the time of the survey¹⁸. A recent serosurvey report by ICMR has estimated 1 in 15 above the age of 10 years to have been exposed to the SARS-CoV-2 by August 2020. This report also highlighted an increasing trend noted in seropositive from 23.5 % in July to 29.1 % in August¹⁹. A recent serosurvey report by the Bombay Municipal Corporation, Tata Institute of Fundamental Research, and Niti Aayog identified the age group of between 41-60 years to be the most exposed in Mumbai²⁰.

Gender analysis was also done to identify seroprevalence differences, if any, across males and females. Our study detected the difference in percent positive between males and females to be significant between 21 - 60 years of age at p < 0.0001. The frequency of seropositive was higher among females. An Indian report on the lines of stating covid infection to double among males over females further stated age group of between 19 – 35 years to be more affected. The data further indicated the death rate to be 68% among males and 32% among females²¹.

CONCLUSIONS

Under-reporting of data across age groups can greatly impact the outcome of social distancing and other pandemic control measures. A seroprevalence study to a great extent can aid in assessing epidemiology surveillance, and when data across different age group is made available, informed choices behind easing lockdown strategies becomes easier. The data utilized for this report though, has a pan-India representation; there have been no statistical calculations around determining the right cohort size or population selection. Since the purpose of this report revolves around highlighting the findings of a national diagnostic laboratory, the concerns around sample bias have not been met adequately. The study we believe is one of the first few large scale Indian reports to focus on covid-19 seroprevalence across different age groups, and we detected females to be higher in percent positive than males, and the prevalence to be comparable across different age groups.

LIST OF ABBREVIATIONS

COI - Cutoff Index COVID-19 - Coronavirus disease of 2019 DPM - Death Per Million ECLIA - Electrochemiluminescence Immunoassay ELISA - Enzyme-Linked Immunosorbent Assay ICMR - Indian Council of Medical Research RT-PCR - Reverse Transcriptase - Polymerase Chain Reaction

CONFLICT OF INTEREST

All authors are employees of Thyrocare Technologies Limited. However, no compensation has been received for this study, and hence no aspect that can be construed as a potential conflict of interest exists.

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