

Original Research Article

COVID-19 vaccine breakthrough infections among health care workers of a tertiary care center in North Kerala: a descriptive study

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ABSTRACT

Background: Vaccination against COVID-19 was started in India in January 2021 using ChAdOx1 nCoV-19 vaccine and health care workers were the first category to get vaccinated. The objective of the present study was to compare the characteristics of health care workers who had COVID-19 vaccine breakthrough infection with those who did not have breakthrough infection.

Methods: This was a descriptive study conducted among 110 health care workers in a tertiary care center in North Kerala during 1, June 2021 to 31, July 2021. An equal number of health care workers who developed breakthrough COVID infection (55) and those who did not develop breakthrough infection (55) were included in the study.

Results: The mean age of individuals who had breakthrough infection was 33.18 years (± 9.52) and those of individuals who did not develop disease was 31.2 years (± 9.57). It was also observed that 21.8% of those with breakthrough infection and 10.9% of individuals without breakthrough infection had comorbidities. The study also found that individuals who took second dose of vaccine at an interval of 28-35 days from the first dose had higher chance of developing breakthrough infection compared to those who took second dose more than 35 days after first dose.

Conclusions: The present study found that breakthrough infection was more common among those who took second dose of vaccine at an interval less than 35 days from the first dose. It was observed that numbers of individuals with comorbidities were higher among breakthrough infection group, but further studies are needed for better understanding.

Keywords: Breakthrough infection, COVID vaccine, India, Kerala

INTRODUCTION

Vaccines have a critical role in the battle against COVID-19. But being vaccinated does not mean that precautions can be left behind, because it is still not clear to what extent the vaccines protect against disease, against infection and transmission.¹

Covishield [ChAdOx1 nCoV-19 Corona virus vaccine (Recombinant)-AstraZeneca's vaccine manufactured by serum institute of India] was granted emergency use

authorization by the central drugs standard control organization (CDSCO) and vaccination of health care workers began in India on January 16, 2021. Two doses are needed to complete the vaccination schedule using ChAdOx1 nCoV-19 Corona Virus vaccine (Recombinant). The recommended time interval between two doses of the vaccine is four to twelve weeks and adequate immune response develops two-three weeks after second dose.²

No vaccine is 100% effective. The efficacy of ChAdOx1 nCoV-19 Corona virus vaccine (Recombinant) was

estimated to be between 73%-81%.³ Approximately 96.5% of individuals demonstrated seroconversion 28 days after administering first dose of ChAdOx1 nCoV-19 Corona virus vaccine (Recombinant).³ Seroconversion also depends on many factors, including intrinsic host factors, and fully vaccinated individuals may still develop disease. The objective of the present study was to compare the characteristics of fully vaccinated health care workers who developed breakthrough infection with those fully vaccinated health care workers who did not develop breakthrough infection.

METHODS

The present descriptive study was conducted in a Tertiary care center in North Kerala during 1, June 2021 to 31 July 2021. The health care workers of the institution who underwent RTPCR test for one or more reasons like: a) before joining non-COVID duty after COVID duty, b) being symptomatic (fever, headache, rhinitis, cough, or any symptom suggestive of COVID) and c) after quarantine period once they were a primary contact of COVID were selected for the study. All health care workers who have completed two doses of ChAdOx1 nCoV-19 Corona virus vaccine (Recombinant) and tested positive for COVID-19 by reverse transcriptase polymerase chain reaction (RTPCR) test during 1 March, 2021 to 31 May 2021 were contacted over telephone for describing the study and for data collection. Individuals who could not be contacted over phone even after three attempts were excluded. A total of 55 health care workers who developed breakthrough COVID-19 infection were included in the study. Systematic random sampling was used to select an equal number (55) of health care workers who have completed two doses of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) and tested negative for COVID-19 by RTPCR from the list of 204 health care workers who tested negative during the same time period.

The health care workers competent enough to answer self-administered questionnaire were provided with a Google form questionnaire to fill in with appropriate answers. Those individuals who did not have access to Google forms or not competent enough, were interviewed over telephone and data entered to Google form. The persons interviewing health care workers were given orientation regarding the questionnaire and data collection. The study tool included questions on basic demographic details like age, gender, designation, clinical details like presence of comorbidities and treatment, history of COVID-19 in the past, vaccination details like date of first dose and second dose, details of COVID-19 infection after vaccination, details of COVID duty and change in safety precautions after being vaccinated.

The data was entered in Google forms and analyzed using SPSS version 16. Quantitative variables were expressed as mean with standard deviation and qualitative variables were expressed as frequencies with percentages. Chi-

square test and student t test were used for testing statistical significance.

Ethical considerations

The study was conducted after obtaining permission from institutional research committee and ethics committee. The study did not lead to additional expenditure (in terms of time/ money) to the participant as only those who had already done RTPCR test was included. Anonymity and confidentiality was maintained.

Operational definitions

Health care workers: Individuals working or studying in the tertiary health care center. Fully vaccinated against COVID-19: Health care workers who have taken two doses of ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant) as per Government of India vaccination guidelines and completed two weeks since the second dose will be considered to be fully vaccinated against COVID-19.⁴ Breakthrough COVID-19: Fully vaccinated individuals who test positive for COVID-19 by RTPCR will be considered to have breakthrough COVID-19.⁵ Health care workers who did not develop COVID-19: Fully vaccinated health care workers who tested negative for COVID -19 in RTPCR test.

RESULTS

The present study was conducted among 110 health care workers in a tertiary care center in North Kerala. All the study participants were vaccinated with two doses of COVID vaccine Covishield [ChAdOx1 nCoV-19 Corona virus vaccine (Recombinant)-AstraZeneca's vaccine manufactured by serum institute of India] and had completed 14 days since their second dose of COVID vaccine.

Of the total 62 health care workers who had developed breakthrough COVID infection (positive by RTPCR) during the study period, 7 excluded as they could not be contacted over phone even after three attempts. So, total of 55 health care workers who had developed breakthrough COVID infection were included in the study.

From the list of fully vaccinated health care workers who had tested negative with RTPCR (204), an equal number of health care workers (55) were selected by systematic random sampling method. So, the study population constituted 55 health care workers who had breakthrough COVID-19 infection and 55 health care workers who did not develop breakthrough COVID-19.

Among the study population, 19 (17.3%) were males and rest 91 (82.7%), females. Table 1 shows comparison of baseline characteristics between the two groups of study population. The study participants included doctors

(21.8%), staff nurse (22.7%), students (21.8%), other hospital staff (30.1%) and office staff (3.6%).

Table 1: Distribution of study population by baseline characteristics.

Variables	Group with breakthrough infection, (n=55) (%)	Group without breakthrough infection, (n=55) (%)	Total
Mean age (In years)	33.18 ($\pm$ 9.52 SD)	31.2 ($\pm$ 9.57 SD)	
Sex distribution			
Males	9 (16.4)	10 (18.2)	19
Females	46 (83.6)	45 (81.8)	91
Comorbidities			
Present	12 (21.8)	6 (10.9)	18
Absent	43 (78.2)	49 (89.1)	92
Interval between two doses of vaccine (Days)			
28-35	51 (92.7)	39 (70.9)	90
More than 35	4 (7.3)	16 (29.1)	20
History of COVID infection before COVID vaccination			
Yes	3 (5.5)	5 (9.1)	8
No	52 (94.5)	50 (90.9)	102
Local/systemic side effects following COVID vaccination			
Present	41 (74.5)	36 (65.5)	77
Absent	14 (25.5)	19 (34.5)	33

The mean age of individuals who had breakthrough infection was 33.18 years [$\pm$ 9.52 (standard deviation)] and those of individuals who did not develop disease was 31.2years [$\pm$ 9.57 (standard deviation)]. This difference was not statistically significant. It was observed that among those with breakthrough infection 83.6% (46 out of 55) were females and in the group without breakthrough infection, 81.8% (45 out of 55) were females. This difference was not statistically significant ($p=0.5$, Chi square test).

Table 2 describes the pattern of comorbidities that were present among the study population.

It was observed that 21.8% (12 out of 55) of those with breakthrough infection had one or other comorbidity and only 10.9% (6 out of 55) of those without breakthrough infection had comorbidities. This observation was, however not statistically significant ($p=0.098$, Chi square test).

Among the study population (110), eight (7.3%) had past history of COVID infection before COVID vaccination. It was observed that 5.5% (3 out of 55) of individuals with breakthrough infection had history of COVID infection before vaccination and 9.1% (5 out of 55) of those without breakthrough infection had COVID infection in

the past. This observation was not statistically significant. ($p=0.358$, Fisher's exact test).

Table 2: Type of comorbidities among the study population with comorbidity (n=18) (not mutually exclusive).

Comorbidity	Group with breakthrough infection, (n=12)	Group without breakthrough infection, (n=6)
Diabetes	3	1
Hypertension	1	0
Thyroid disorder	5	2
Bronchial asthma	2	1
Coronary artery disease	1	0
On treatment for malignancy	0	1
Arthritis	0	1
Total	12	6

The present study found that 56.7% (51 out of 90) of those who had taken second dose of vaccine 28-35 days after first dose developed breakthrough infection, whereas only 20% (4 out of 20) of those who took second dose after an interval of more than 35 days developed breakthrough infection. This finding was statistically significant. (Chi-square test, $p=0.003$).

The present study observed that 70% of participants had local/systemic side effects following vaccination. Among those who developed local/systemic symptoms after COVID vaccination, 53.2% (41 out of 77) developed breakthrough infection, while 42.4% (14 out of 33) of those who did not have side effects developed breakthrough infection. This finding was not statistically significant ($p=0.203$, Chi square test).

Table 3 depicts the symptom profile of breakthrough COVID infection. Among the 55 persons who developed breakthrough COVID-19 infection, 49 (89.1%) were symptomatic, but none of them were critical and didn't require admission to intensive care unit (ICU).

Among those with breakthrough COVID-19 infection, 20% (11 out of 55) were on COVID duty at the time of testing and among those who did not develop breakthrough infection, 7.3% (7 out of 55) were on COVID duty at the time of testing. It was also found that among those with breakthrough infection, 29.1% (16 out of 55) were on COVID duty two weeks prior to testing and among those without breakthrough infection, 16.4% (9 out of 55) were on COVID duty two weeks prior to testing. These two findings were, however not statistically significant ($p=0.052$ and $p=0.111$ respectively by Pearson Chi-square test).

Table 3: Symptom profile of breakthrough COVID-19 infection (n=55) (symptoms not mutually exclusive).

Symptoms	Frequency of individuals who had this symptom	Percentage of individuals who had this symptom (%)
Fever	27	49.1
Myalgia	13	23.6
Cough	15	27.3
Nasal discharge	11	20
Sorethroat	12	21.8
Fatigue	14	25.5
Loose stools	9	16.4
Breathlessness	8	14.5
Headache	5	9.1
Vomiting	3	5.5
Anosmia	4	7.3
Nausea	1	1.8
Aguesia	3	5.5
Conjunctival congestion	1	1.8
No symptoms	6	10.9

The present study also observed that among those who developed breakthrough infection, 61.8% (34 out of 55) and among those without breakthrough infection, 21.8% (12 out of 55) had history of close contact with COVID patient in their family/community. This observation was found to be statistically significant (Chi-square test, $p < 0.0001$).

It was also observed that 20% (11 out of 55) of those who developed breakthrough infection said that they were not strictly following safety precautions after the completion of vaccination. Only one person among those who did not develop breakthrough infection (1 out of 55, 1.8%) said that there was laxity in following safety precautions after vaccination. This was also found to be statistically significant (Chi-square test, $p = 0.002$).

DISCUSSION

The present study included 55 health care workers who had developed breakthrough COVID infection and 55 health care workers who did not develop breakthrough COVID infection. Among the persons who developed breakthrough COVID-19 infection, 89.1% were symptomatic, but none of them developed serious disease and did not require admission to ICU. In a study by Tyagi et al among 113 health care workers in New Delhi it was observed that 13.3% of vaccinated individuals developed breakthrough infection. Among those who developed disease, majority had mild disease, except one person who required hospitalization.⁶ The surveillance by centers for disease control and prevention had found that among 10, 262 breakthrough infections reported in United States of America, 27% were asymptomatic, 61% had mild disease, 10% required hospitalization and 2% died.⁷ In

the genomic surveillance of six COVID breakthrough infections in Kerala by Beena Philomina J et al, it was found that none of the patients developed serious illness or required hospitalization. All of them were vaccinated at interval of 4-6 weeks between the two doses.⁸

The mean age of individuals who had breakthrough infection was 33.18 years (± 9.52) and those of individuals who did not develop disease was 31.2 years (± 9.57) (Table 1). This difference was however, not statistically significant. It was also found that 66.7% of individuals with comorbidities and 46.7% of individuals without comorbidities had breakthrough COVID-19, but this finding was not statistically significant. The present study also observed that among those who had breakthrough infection, 83.6% were females and rest males (Table 1). This was not statistically significant. A prospective observational study in United Kingdom by Menni et al had observed that the risk of infection after vaccination was higher among females and among those with one or more comorbidities compared to their counterparts.⁹ The investigation by centers for disease Control and prevention (CDC) among covid vaccinated individuals to study breakthrough infection found that among those who had breakthrough infection, 63% were females.⁷

It was observed that 56.7% of those who had taken second dose of vaccine 28-35 days after first dose developed breakthrough infection, whereas only 20% of those who took second dose after an interval of more than 35 days developed breakthrough infection (Pearson chi-square test, $p = 0.006$). The present study found that individuals who took second dose of vaccine at an interval of 28-35 days from the first dose had higher chance of developing breakthrough infection compared to those who took second dose more than 35 days after first dose. In the study by Menni et al it was found that the risk of infection was significantly lower among vaccinated group 12-21 days after first dose [Relative risk (-39%)] and 21-44 days after first dose [Relative risk (-60%)] compared to unvaccinated individuals.⁹ Vaccine efficacy increases with longer dose intervals of 8 to 12 weeks.¹⁰

It was also observed that among the study participants, 70% developed local/systemic side effects after COVID vaccination (Table 1). The study by Menni et al observed that systemic side effects were reported by 33.7% and local side effects were reported by 58.7% after first dose of COVID vaccine.⁹

It was also observed that 20% (11 out of 55) of those who developed breakthrough infection said that they were not strictly following safety precautions after the completion of vaccination. Only one person among those who did not develop breakthrough infection (1 out of 55, 1.8%) said that safety precautions were not strictly followed after completion of vaccination. This was also found to be statistically significant (Pearson-Chi-square test, $p = 0.002$). The laxity in following COVID precautions

following vaccination has to be addressed in order to avoid infections which could be prevented.

Limitations

The number of individuals included in the study was limited (110), and that might have influenced the statistical significance of a few parameters. The study period was three months because of feasibility issues. If the period was longer, it might have been possible to catch more breakthrough infections. Further studies with more subjects and longer study period are needed for obtaining further clarity about the topic.

CONCLUSION

The present study found that breakthrough infection was more common among those who took second dose of vaccine at an interval less than 35 days from the first dose. It was observed that numbers of individuals with comorbidities were higher among breakthrough infection, but more studies are needed for a better understanding. It was noticed that measures have to be taken to reinforce the importance of following COVID precautions even after getting vaccinated.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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