

COVID-19 Vaccine Breakthrough Infections among Healthcare Workers in a Tertiary Care Hospital in Coastal Karnataka, India: A Prospective Cohort Study

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ABSTRACT

Background: The COVID-19 pandemic resulted in significant mortality and morbidity globally. The introduction of various COVID-19 vaccines at record time generated hope among people and doubts and apprehension regarding their safety. The study was done to estimate the incidence of COVID-19 vaccine breakthrough infections among Health Care Workers working in a tertiary care hospital and evaluate the outcome of these infections.

Methods: A prospective Cohort study was conducted among 6342 healthcare workers in a tertiary care hospital having received at least one dose of any COVID-19 vaccine. They were followed up for COVID-19 vaccine breakthrough infection for one year by epidemiological investigations. Data on COVID-19-positive healthcare workers was obtained through personal interviews and case records.

Results: 490 (7.9%) developed COVID-19 vaccine breakthrough infection during the study period. The majority of them (96.7%) were asymptomatic, and 16 (3.3%) of them developed complications needing hospitalization with 2 deaths. A statistically significant association was found in sex, healthcare worker categories, co-morbidities, and Blood groups.

Conclusion: COVID-19 vaccination among healthcare workers reduces the incidence, severity, and complications of COVID-19 vaccine breakthrough infections. The risk of acquiring COVID-19 vaccine breakthrough infections was higher among males, partially vaccinated individuals, people with co-morbidities, and those involved in the regular care of COVID-19 patients. COVID-19-appropriate behaviour and receiving all the primary doses of vaccine will be instrumental in COVID-19 control.

Keywords: COVID-19, COVID-19 vaccine breakthrough infections, Healthcare worker, COVID-19 vaccination.

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INTRODUCTION

Coronavirus disease (COVID-19) is an infectious disease caused by the SARS-CoV-2 virus.¹ Most infected people experience mild to moderate respiratory illness and recover with no specific treatment.¹ However, a small proportion of people may require intensive medical care and may die from the disease.¹ To date, India has recorded 4,50,01,421 cases and 5,33,295 deaths due to COVID-19.² Since the declaration of the COVID-19 pandemic, there have been global efforts to develop an effective vaccine against the virus and the World Health Organization strongly opined that safe and effective vaccines are a game-changing tool.³

In the past, several infectious diseases were successfully controlled with vaccines since they not only reduce transmission of infection but also reduce the incidence and severity of the disease.⁴

To commemorate the importance of healthcare workers and to highlight their role in the control of the COVID-19 pandemic, the World Health Day theme for the year 2021 was 'Nurses and Midwives – help us live in a happier, healthier world'.⁵

Vaccination against COVID-19 started in India on 16th January 2021 for healthcare workers. To date, more than 220,67,76,793 doses have been administered among healthcare workers, front-line workers, and the general public.⁶ The COVID-19 vaccines used initially were Covishield (ChAdOx 1 nCoV vaccine) and Covaxin (Inactivated virus vaccine).⁶ Later, nine more vaccines were given Emergency use authorization.⁵ Even after taking all the recommended doses, there are chances of developing breakthrough infections of COVID-19 but symptoms are more likely, and severe illness or death is rare.⁷ When someone who is vaccinated with either a primary series or primary series plus booster dose gets infected with a virus causing COVID-19, it is referred to as a 'Vaccine breakthrough infection'.⁸ It has also been proved that even after receiving primary doses of the COVID-19 vaccine, it takes around 14 days to build immunity and be fully immunized against SARS-CoV-2.⁸ Recent studies show that the efficacy of Covishield vaccine is 72% among symptomatic SARS-CoV-2 virus infection.⁹

Healthcare workers are not only at high risk of acquiring infection, but they can also transmit the infection to susceptible patients at risk of developing severe COVID-19. India has already undergone three waves of COVID-19 infections during which the healthcare workers were pivotal in its response. There is a need to evaluate the impact of the COVID-19 vaccine among healthcare workers in preventing complications and mortality. This study was done to provide evidence regarding the incidence of COVID-19 vaccine breakthrough infection among healthcare workers and evaluate the outcome the infection has on them, thereby proving the effectiveness of COVID-19 vaccines in healthcare settings.

The study was conducted to estimate the incidence of breakthrough COVID-19 infection among Health care workers working in tertiary care hospitals after COVID-19 vaccination and also to evaluate the outcome of COVID-19 infection among Health care workers after COVID-19 vaccination.

METHODOLOGY

A prospective cohort study was conducted among all the healthcare workers aged more than 18 years working in a tertiary care hospital and who had received at least one dose of any COVID-19 vaccine between Jan- Feb 2021. Ethical clearance was obtained from the institutional ethical committee. All the Healthcare workers had received the Covishield vaccine. They were followed up for COVID-19 vaccine breakthrough infection for one year between March 2021- February 2022. The study participants were informed about the study objectives, the information that would be obtained from them, and case records in the event of a breakthrough infection. Baseline information and Informed written consent were obtained from each participant while receiving their first dose of COVID-19 vaccine between January – February 2021. Consent to publish the study findings was also obtained from each participant. Using a pre-tested structured questionnaire, baseline information was collected which included age, religion, category of a health care worker, blood group, and presence of any co-morbidities like Diabetes Mellitus, Hypertension, Chronic kidney disease, Chronic lung disease, Immunosuppressive states, Cerebrovascular disease, or Cancer. Age, category of health worker, and blood grouping were cross-checked from the institution identification cards. All the healthcare workers undergo detailed health check-ups when they start working in the hospital and every year thereafter Information on co-morbidities was cross-checked with the healthcare worker's medical profile maintained and updated every year at the hospital. Healthcare workers were subjected to daily body temperature measurements using an infrared thermometer at the entry points into the hospital and the college. COVID-19 testing for symptomatic individuals and contacts of COVID-19-positive cases was done. Epidemiological investigations and contact tracing for every COVID-19-positive case and Quarantine for 7 days followed by COVID-19 testing after inter-state travels were also done. The majority of the suspect cases were tested by RTPCR which was the most sensitive and specific diagnostic tool and was recommended by prevailing guidelines.⁹ Rapid antigen tests were also used in the study even though it was considered less sensitive than RTPCR due to its inherent advantage of rapidity in detection. Symptomatic individuals who were negative by Rapid antigen tests were also subjected to RT-PCR so that we would not miss any COVID-19 cases. As the majority of the cases were either asymptomatic or had mild symptoms, home isolation was advised for

those with facilities to stay isolated after careful evaluation. Institutional isolation in COVID care centers was advised for those staff and students staying in hostels or with no facility to stay isolated in their homes to prevent further transmission. Leave records were also evaluated to look for absences due to COVID-19 during the study period. Those who subsequently developed COVID-19 breakthrough infection was personally met after recovery from the disease and details regarding hospitalization, and complications due to COVID-19 breakthrough infection along with details about COVID-19 vaccination were taken. The COVID-19 vaccination certificate downloaded from the COWIN website was used as proof of vaccination. Their health records in the hospital were also referred for cross-verification and to get any missing information. Data was analyzed using Epi Info software version 7. Data was presented using numbers, percentages, and tests of significance (Chi-square test) wherever necessary.

RESULTS

From Figure 1, 7.9% of the healthcare workers who had received both doses of the vaccine developed COVID-19 breakthrough infection. Among the infected, 36.2% did not develop any symptoms, 60.6% developed mild symptoms like mild fever, myalgia, and cough, and only 3.2% developed complications. Two COVID-19-related deaths occurred during this period, both being Doctors working in the hospital aged 64 and 67 years respectively. Both of them had Diabetes and Hypertension for several years and were fully vaccinated with the COVID-19 vaccine. The duration between COVID-19 vaccination (14 days after

the second dose) and the first symptom of COVID-19 was 30 and 176 days respectively. Follow-up of 171 participants could not be done for the study duration since they left the institution during the study.

In Table 1, we have analysed the baseline characteristics of 6342 study participants who were followed up for the entire duration of the study. The proportion of COVID-19 vaccine breakthrough infection was more among those aged between 31-40 years and was least among those aged more than 60 years. The proportion of COVID-19 vaccine breakthrough infection was higher among male sex, laboratory staff, nurses, and medical interns among the categories of healthcare workers. The proportion of COVID-19 vaccine breakthrough infection was higher among those with co-morbidities and also among those with AB-negative and O blood groups. A total of 1640 healthcare workers were tested for COVID-19 during the study period with more than two-thirds of them using RTPCR and the remainder using Rapid antigen tests.

In Table 2, we have compared the occurrence of COVID-19 vaccine breakthrough infection among fully vaccinated healthcare workers. No statistically significant association exists between full vaccination against COVID-19 and the occurrence of COVID-19 vaccine breakthrough infections among healthcare workers of different ages and religions. Fully vaccinated Dentists (OR- 0.39, 95% CI- 0.25, 0.6), Medical / Paramedical staff (OR- 0.3, 95% CI- 0.23, 0.38), and Hospital administrative staff (OR- 0.57, 95% CI- 0.37, 0.87) had a lesser chance of developing COVID-19 vaccine breakthrough infection compared to Doctors.

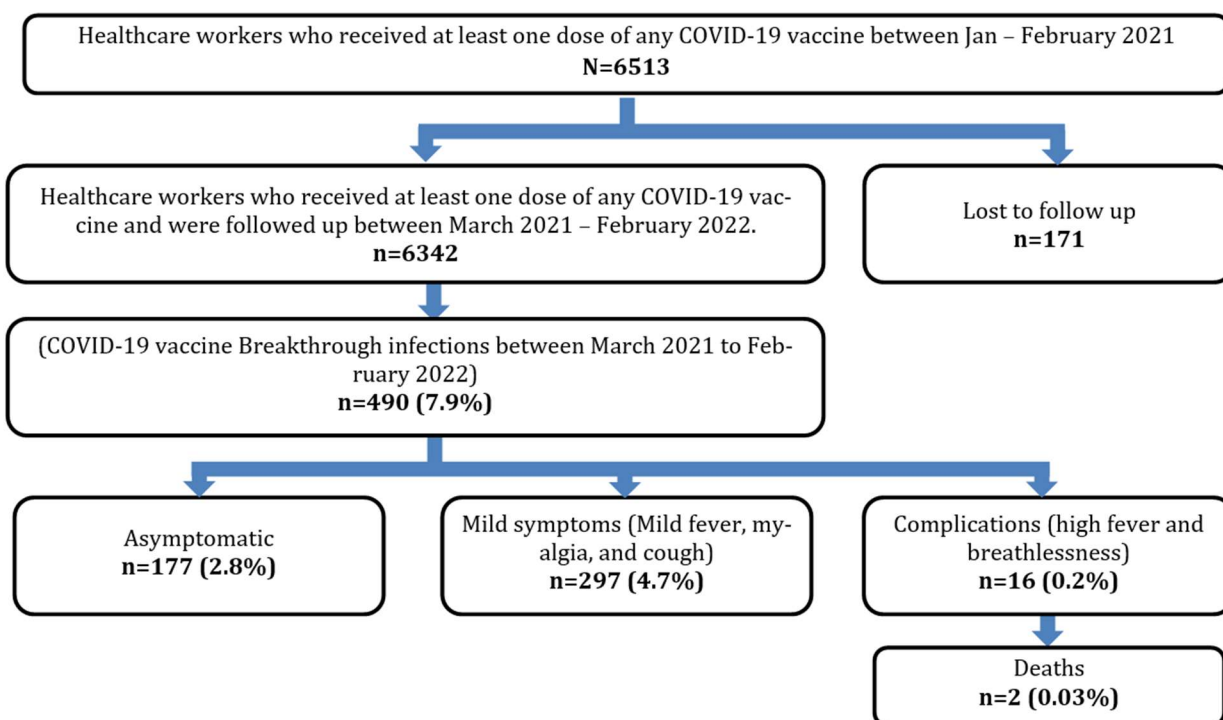


Figure 1: Summary of COVID-19 breakthrough infection among Health care workers

Table 1: Baseline characteristics (N= 6342)

Characteristic	Health care workers	COVID-19 Breakthrough Infections (%)
Age		
≤20 years	1912	148 (7.7)
21-30 years	3016	244 (8)
31-40 years	495	43 (8.7)
41-50 years	427	27 (6.3)
51-60 years	275	19 (6.9)
More than 60 years	217	9 (4.1)
Religion		
Hindu	5648	431 (7.6)
Muslim	517	47 (9)
Christian	134	6 (4.4)
Others	43	6 (13.9)
Sex		
Male	2366	215 (9)
Female	3976	275 (6.9)
Healthcare worker categories		
Doctor	756	113 (14.9)
Dentist	403	26 (6.4)
Medical Interns	138	28 (20.3)
Medical & Paramedic students	4358	214 (4.9)
Nurses	256	51 (19.9)
Hospital admin staffs	347	32 (9.2)
Laboratory staffs	84	26 (31)
Co-morbidities		
Present	421	129 (30.6)
Absent	5921	361 (6)
Blood groups		
A positive	1560	118 (7.6)
A negative	89	8 (9)
B Positive	2028	134 (6.6)
B negative	127	5 (4)
AB positive	856	25 (2.9)
AB negative	32	5 (15.6)
O positive	1522	181 (11.9)
O negative	128	14 (10.9)

Fully vaccinated laboratory staff (OR- 2.53, 95% CI- 1.53,4.2) had higher chances of developing COVID-19 vaccine breakthrough infection compared to doctors. Fully vaccinated healthcare workers with co-morbidities (OR- 7.03, 95% CI- 5.56, 8.89) had a higher chance of developing COVID-19 vaccine breakthrough infection compared to fully vaccinated healthcare workers with no co-morbidities. Fully vaccinated healthcare workers with the O-positive blood group (OR- 1.64, 95% CI- 1.28, 2.09) had higher chances, and fully vaccinated healthcare workers with the AB-positive blood group (OR- 0.36, 95% CI- 0.23, 0.57) had lower chances of developing COVID-19 vaccine breakthrough infection.

From Table 3, Among those with COVID-19 vaccine breakthrough infection, the incidence increased with increasing duration since vaccination.

In Table 4, we can see that the proportion of COVID-19 vaccine breakthrough infection was higher among the partially vaccinated individuals in comparison to

those who received their primary series of vaccinations and this was found to be statistically significant further emphasising the importance of full vaccination in conferring complete protection from COVID-19.

DISCUSSION

In our study, it was observed that the incidence and severity of COVID-19 was reduced among the fully vaccinated healthcare workers even during rising cases of Delta and Omicron variants in the district and this finding was similar to most of the contemporary and recent studies.¹⁰⁻²⁵

The Incidence of COVID-19 vaccine breakthrough infection among healthcare workers in our study was 7.9% in a year observation period which was similar to a study done by Paris et al with 4.4% over six months, Rahi et al at 8.7% and De Maria et al at 9.7% over one year and 20.2% over 2 years.^{17,19,26,27} In studies done by Gurung et al and Bhavya et al, there was a significantly higher incidence of COVID-19 vaccine breakthrough infections among healthcare workers compared to our study which could be partly explained by increased awareness, better adherence to COVID-19 appropriate behaviour in our study and possibility of highly transmissible variants circulating among the participants of their study.^{16,18} On the contrary, several studies showed a lesser incidence of COVID-19 vaccine breakthrough infection among healthcare workers when compared with our study.^{15,21,22,23,24,25,28} This apparent increase in incidence in our study could be due to a surge in COVID-19 cases in the district between March to May 2021. Most of the cases with lesser incidence were conducted for a shorter duration of observation ranging between two to 6 months and studies have shown that the frequency of infection increases with increasing duration from vaccination.^{7,29} We should also note that these studies were done with different vaccines with different effectiveness depending on circulating strains in the community. Even though results confirm that SARS-CoV-2 infection can break vaccine protection but clinical course is favourable.

The majority of the healthcare workers with COVID-19 vaccine breakthrough infections in our study were either asymptomatic or suffered from mild symptoms which is similar to the observations seen in contemporary studies.^{15,16,17,18,19,21,23,24,25} Hospitalization and death occurred in only 2 fully vaccinated healthcare workers in our study. Similar observations of reduced hospitalization and fatality were noticed in several studies further strengthening the effectiveness of vaccines in reducing the frequency and severity of infection.^{16,17,18,23,24,25,28} In a study done by Luigi De Maria et al, COVID-19 vaccine breakthrough infections were proportionately higher among doctors and nurses which was similar to the findings in our study.²⁸

Table 2: COVID-19 breakthrough infections among fully vaccinated individuals

Characteristic	Fully vaccinated individuals with COVID-19 Vaccine breakthrough infection (n=490) (%)	Fully vaccinated individuals without COVID-19 Vaccine breakthrough Infection (n=5727) (%)	OR	95% CI	p-value
Age					
≤ 50 years	462 (94.3)	5295 (92.4)	1		
More than 50 years	28 (5.7)	432 (7.6)	0.74	0.5-1.10	0.13
Religion					
Hindu	431 (88)	5049 (88.2)	1		
Muslim	47 (9.6)	524 (9.1)	1.05	0.76, 1.43	0.75
Christian	6 (1.2)	120 (2)	0.58	0.25, 1.22	0.2
Others	6 (1.2)	34 (0.7)	2.06	0.86, 4.85	0.1
Sex					
Male	215 (43.8)	2090 (36.5)	1		
Female	275 (56.2)	3637 (63.5)	0.73	0.61, 0.88	0.0012
Health care workers categories					
Doctor	113 (23)	640 (11.1)	1		
Dentist	26 (5.4)	377 (6.6)	0.39	0.25, 0.6	<0.0001
Medical intern	28 (5.7)	110 (2)	1.44	0.9, 2.28	0.11
Medical and Paramedical staff	214 (43.7)	4022 (70.2)	0.3	0.23, 0.38	<0.0001
Nurses	51 (10.4)	205 (3.6)	1.4	0.97, 2.03	0.06
Hospital admin staffs	32 (6.5)	315 (5.5)	0.57	0.37, 0.87	0.009
Laboratory staffs	26 (5.3)	58 (1)	2.53	1.53, 4.2	0.0003
Co-morbidities					
Present	129 (26.4)	271 (4.7)	7.03	5.56, 8.89	<0.0001
Absent	361 (73.7)	5456 (95.3)	1		
Blood groups					
A positive	118 (24)	1406 (24.5)	1		
A negative	8 (1.7)	80 (1.4)	1.19	0.56, 2.52	0.64
B Positive	134 (27.4)	1863 (32.6)	0.85	0.66, 1.10	0.23
B negative	5 (1)	119 (2)	0.5	0.2, 1.2	0.13
AB positive	25 (5)	809 (14.2)	0.36	0.23, 0.57	<0.0001
AB negative	5 (1)	23 (0.4)	2.59	0.96, 6.93	0.06
O positive	181 (37.1)	1313 (22.9)	1.64	1.28, 2.09	0.0001
O negative	14 (2.8)	114 (2)	1.46	0.81, 2.6	0.2

OR – Odds Ratio, CI- Confidence Interval

Table 3: Duration of COVID-19 break through infection following COVID-19 vaccination

Status of COVID-19 vaccination	COVID-19 infections (N=541) (COVID-19 among partially vaccinated + COVID-19 vaccine breakthrough infection)
Partial vaccination (between 14 days from the First dose to 14 days after the second dose)	51 (9.4%)
Full vaccination (after 14 days of second dose)	
First month	36 (6.7%)
Second month	44 (8.2%)
Third month	46 (8.5%)
Fourth month	48 (8.8%)
Fifth month	64 (11.8%)
Sixth month	66 (12.1%)
More than 6 months	186 (34.5%)

Table 4: COVID-19 vaccine breakthrough infection and vaccination status of healthcare workers

COVID-19 vaccination status	COVID-19 infection during the study period		Total	OR	95% CI	p-value
	Yes (%)	No (%)				
Not fully vaccinated	51 (9.42)	74 (1.27)	125	1		<0.0001
Fully vaccinated	490 (90.58)	5727 (98.73)	6217	0.12	0.08, 0.17	
Total	541	5801	6342			

The incidence of COVID-19 breakthrough infections increased following six months post-vaccination in our study and it has also been corroborated by systematic reviews giving evidence of reducing vaccine effectiveness by 20-30 points.^{29,30} In a study done by

Contractor et al, the incidence of COVID-19 vaccine breakthrough infection was higher among partially vaccinated in comparison to fully vaccinated healthcare workers, similar to what we observed in our study. In a study done by Ray et al, the incidence

of COVID-19 vaccine breakthrough infection was not affected by the vaccine type or blood group but increased among partially vaccinated than fully vaccinated individuals.¹¹

LIMITATIONS

Healthcare workers have an increased exposure to COVID-19 and it is difficult to determine immunity conferred by natural infection.

CONCLUSION

COVID-19 vaccination among fully vaccinated healthcare workers reduces the incidence, severity, and complications of COVID-19 vaccine breakthrough infections compared to their partially vaccinated counterparts. The risk of acquiring COVID-19 vaccine breakthrough infections was higher among males, partially vaccinated individuals, people with co-morbidities, and those involved in the regular care of COVID-19 patients. Receiving all the primary doses of the vaccine will be instrumental in COVID-19 control.

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