

A Study to Assess Symptom Profile and Break Through Infections Among Health Care Workers Post Covid Vaccination at Tertiary Care Health Facility

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Abstract

Introduction: Breakthrough infections in fully vaccinated persons pose a major challenge to the ongoing vaccine campaign against SARS-CoV-2 globally. **Objectives:** To investigate the occurrence of breakthrough infections and the association of Covid symptoms with the vaccination status of health care workers (HCWs). **Material and Methods:** Done in Government Medical College, Patiala among Covid-positive HCWs who have received one or both doses of Covid vaccine, using pretested semi-structured validated Proforma and telephonic interview from April 1, 2021 to June 15, 2021. **Results:** Among 3388 HCWs, 115 vaccinated HCWs (1st or 2nd dose) became Covid positive. Among vaccinated Covid positive HCWs, 54 received the first dose and 61 both doses. Breakthrough infections (≥ 14 days post 2nd dose) occurred in 4.6% (47 of 1021) HCWs. The vaccine is significantly protective as shown by an odds ratio of 0.27; thus, vaccinated HCWs are 73% less likely to get Covid infection as compared to non-vaccinated HCWs. There was no statistically significant difference between symptom profiles of cases whether they took one or both doses of vaccine, except headache. Only tiredness and headache were reported significantly higher in the unvaccinated group in comparison to vaccinated HCWs. **Conclusion;** Research is needed on tracking the immune response and viral genomic sequence of samples of vaccinated Covid-positive HCWs to have constant vigilance on re-emerging new strains of the SARS-CoV-2.

Keywords: Covid, HCWs, unvaccinated, vaccinated

INTRODUCTION

With the increase in Covid cases globally and in India, the Covid vaccination has become the main tool of fight against the Covid pandemic. A growing body of evidence suggests that fully vaccinated people are less likely to have asymptomatic infection and potentially less likely to transmit SARS-CoV-2, but the risk cannot be completely eliminated as long as community transmission is there.^[1] All authorized COVID-19 vaccines demonstrated high efficacy ($\geq 89\%$) against Covid-19 severe enough to require hospitalization.^[2] The effectiveness of the Covid vaccines ranges from 60% to 95% among different vaccines brands around the globe. The latest data analysis from India, from studies done in Post Graduate Institute of Medical Education and Research (PGIMER), reported breakthrough infection among 9.5% of health care workers (HCWs) post vaccination at an infection rate of 1.6%.^[3] Another study done in New Delhi reported an even higher percentage of breakthrough

infections (13.3%) post the vaccine launch on January 16, 2021 in India.^[4] The current study was done in Government Medical College and Rajindra Hospital, Patiala, one of the largest and oldest tertiary care institutes of Northern India, catering to a very high patient load of moderate to severely sick Covid patients from Punjab, Haryana, Himachal Pradesh, Uttarakhand, and Delhi. As most of the HCWs are involved in Covid Isolation facility and have long work hour duties in high-risk exposure zone, this facility is ideally suited to assess the real-time data on vaccine effectiveness, breakthrough infection rate, and symptom spectrum

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of Covid among vaccinated HCWs, particularly when there are questions of vaccine effectiveness against the Delta variant in India. The current study will add to the existing body of evidence about the effectiveness of the Covid-19 vaccine (Covishield ChAdOx1 nCoV-19) against the Delta variant, which is prominent in India and is an emerging new variant globally.

This study was undertaken to investigate the occurrence of breakthrough infection among vaccinated HCWs and find an association between Covid symptoms and vaccination status of HCWs.

MATERIAL AND METHODS

The study was done in Government Medical College in North India from January 16, 2021 till June 15, 2021, and the sampling frame was all the HCWs of the institute, including class 3, class 4, and administrative staff. As the vaccination was started in this institute on January 16, 2021, all the HCWs who have received Covid vaccination on or after January 16, 2021 and who become RT-PCR Covid positive after receiving one or two doses of Covid vaccine till June 15, 2021, that is, a follow-up period of 4 months, were included in this study. A pretested semi-structured validated proforma was used and telephonic interviews with all the post-vaccinated Covid-positive HCWs was conducted by senior faculty of the Department of Community Medicine. Verbal informed consent was taken from the HCWs after explaining to them the purpose of the study before beginning the interview. The interview includes questions on baseline characteristics such as age, sex, place of working, date of Covid-positive test report, comorbidities, symptoms of Covid infection, and date of Covid vaccination, which was then cross-checked for accuracy with the vaccination record, duly maintained at the Covid vaccination center of Rajindra hospital Patiala. All the HCWs showed keen interest to participate in the study and gave their informed consent (The study was duly approved by institute Review Board- Ethics committee vide letter no EC/NEW/.INST/2020/997/14367).

The data were analyzed, and odds ratio was used to measure the strength of associations. *P* value was calculated at 95% confidence limits to consider the results of the study to be statistically significant. Epi info version 7 of CDC and Microsoft excel were used for data analysis.

From the available literature, the infection rate among fully vaccinated individuals ≥ 14 days after the second dose ranges from 1.6%^[3] to 9.6%^[6] and 13.3%^[4] among the latest published and unpublished pre-peer reviewed stage research.

Population size (for finite population correction factor or fpc) (<i>N</i>):	1021
Hypothesized % frequency of outcome factor in the population (<i>p</i>):	13.3±6
Confidence limits as % of 100 (absolute ± %)(<i>d</i>):	6%
Design effect (for cluster surveys- <i>DEFF</i>):	

Sample size $n = \frac{DEFF * Np(1-p)}{[(d^2/Z^2_{1-\alpha/2} * (N-1) + p*(1-p))]}$ would be 110; however, to increase the power of the study and

extrapolate the results to the target population, all the HCWs vaccinated with 1st or 2nd dose of Covid vaccine who become Covid positive during the study period were taken as sample.

RESULTS

Out of 3388 HCWs, 232 HCWs became Covid positive during the study period from (April 1, 2021 to June 15, 2021) after the launch of the Covid vaccine (Covishield) on January 16, 2021 in the institute. Out of these 232 HCWs, 115 HCWs have received either one or both doses of Covishield and 117 were unvaccinated. Among these 115 HCWs, females constitute 56% (65) with mean age (SD) of 31.3 (11) years, and males were 43% (50) with a mean age of 35.7 (13.3) years. In these HCWs 25% were junior residents, interns 20%, faculty 18%, senior residents (SRs) 10%, and MBBS students 4.3%. Nursing staff and students constitute 5.2% each. The majority of HCWs (81%) were without any comorbidity, and just 11% have hypertension, CAD 2.61%, and less than 2% have COPD/asthma and diabetes [Table 1].

Among the 3388 HCWs of Government Medical College and Rajindra Hospital Patiala, 2598 (76.68%) received the first dose of ChAdOx1 n COV-19 (recombinant) vaccine, and 1042 (30.7%) subsequently received the second dose of the vaccine; 790 (23.3%) HCWs were unvaccinated. Since the start of vaccination in the institute, 232 HCWs have become Covid positive; among them, 115 (3.3%) tested positive after receiving at least one dose of Covid vaccine. In Covid-positive vaccinated HCWs, 54 received the first dose and 61 received both doses of vaccine. The median time between the receipt of the first dose and positive test was 31.5 days, with an IQR of 31.75 (17–48.75). The median time interval between receipt of 2nd dose and positive test was 39 days with an IQR of 37 (15–52). The median time interval between the first and second dose of vaccine was 39 days with an IQR of 13 (44–31). [Figure 1]. Among the HCWs who have received both doses and have completed at least 14 days of follow-up after the 2nd dose, breakthrough infection occurred in 4.6% (47 of 1021). The median time interval from receipt of second dose and breakthrough infection was 44 days with an IQR of 23 (36–59).

There was a statistically significant difference in Covid infection rate among those vaccinated with one or both doses and those who are unvaccinated. The vaccine is significantly protective as shown by an odds ratio of 0.27, suggesting that vaccination decreases the odds of Covid infection by 73% among vaccinated as compared to the non-vaccinated group [Table 2].

Table 3: Depicts the symptom spectrum of SARS coronavirus among vaccinated HCWs. Asymptomatic cases accounted for 6.96%. Among symptomatic patients, fever was a presenting symptom in 73% of cases, and the majority of them had a low-grade fever. The median number of days fever lasts was 3 days with IQR (2–4). Intermediate to high-grade fever was reported in less than one-third of cases. Cough and myalgia

Table 1: Profile of post vaccinated Covid positive HCWS (n=115)		
HCW Category	Frequency	Percent
Faculty	21	18.26%
SR	11	9.57%
JR	28	24.35%
Interns	22	19.13%
MBBS students	5	4.35%
Dental college faculty and staff	1	0.87%
Nursing students	6	5.22%
other students (MSC/pharmacy etc.)	2	1.74%
Staff Nurse	5	4.35%
Clerical staff	5	4.35%
Class 3	6	5.22%
Class 4	3	2.61%
Comorbidities		
Comorbidities absent	93	80.87%
Hypertension	12	10.43%
Hypothyroidism	4	3.48%
CAD	3	2.61%
COPD/Asthma	2	1.74%
Diabetes	2	1.74%
Neurological disorder	1	0.87%

were reported in half of the cases. Sore throat was reported in 40% cases; loss of sense of smell and taste in 28%; and headache, cold, and running nose in one-fourth of cases each. Diarrhea was reported in 17% of cases, and less than 2% reported other symptoms such as conjunctivitis, skin rash, and dysgeusia. Among vaccinated Covid-positive cases, 90% have no breathing difficulty, and chest heaviness was reported in just 3.5% of cases. There was no statistically significant difference between symptom profiles of cases whether they took one or both doses of vaccine, except headache, whereas HCWs who took both doses reported significantly less headache.

Table 4: Shows the comparison of symptoms among fully vaccinated and unvaccinated HCWs. Fever was present in 75% of vaccinated and 67.5% of unvaccinated participants, although intermediate to high-grade fever was reported more among unvaccinated HCWs. There was no statistically significant difference among the symptoms of fully vaccinated and unvaccinated HCWs, except tiredness and headache, which was reported significantly less among fully vaccinated HCWs

DISCUSSION

Breakthrough infections among vaccinated persons is a major concern with the emergence of delta and delta plus variants as dominant strains, even more in HCWs as they are constantly working in high-exposure zones, particularly in tertiary-level health facilities. In the latest data analysis done in PGIMER, the incidence of infection among those who have received one dose was 2.6% and in those who took both doses and completed at least 14 days was 1.6%. The study done in Chandigarh reported 9.5% breakthrough infections

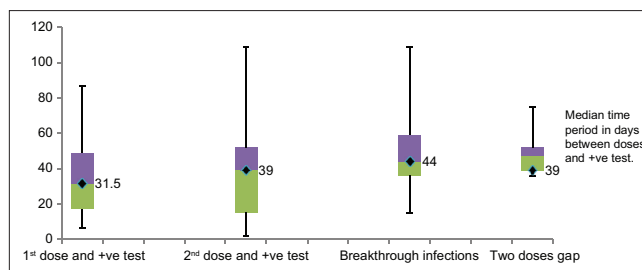


Figure 1: Median time period between doses and +ve test and dose gap in days

among vaccinated Covid-positive HCWs post the vaccine launch. Another study done in New Delhi by Tyagi K *et al.*^[4] in non-Covid care center of Excellence of diabetes reported 13.3% breakthrough infections among vaccinated staff. In the current study, breakthrough infections occurred in 4.4% (47 of 1021 HCWs). A study done by Bouton *et al.* reported a prevalence of 1.3% (96/7109) among HCWs who received at least one dose and 0.3% (17/5913) among HCWs who received both doses. Another study done by Amit *et al.* reported an infection prevalence of 0.54% in vaccinated HCWs. Findings very similar to our findings were reported by Thompson *et al.* study with a prevalence of 5.2% (205/3950).^[5-7]

A study done in Indraprastha Apollo Hospitals, New Delhi, India reported infection in 2.65% of fully vaccinated HCWs and hospitalization in just 0.06%. Indian Council of Medical Research (ICMR) reported re-infection in just 0.02%–0.04% of individuals vaccinated with ChAdOx1 nCoV-19 (recombinant) and BBV152 vaccines.^[8,9]

In a study in a tertiary care hospital of Mumbai, where retrospective analysis was done, breakthrough infection was reported in 10.1% of HCWs and a significant reduction in the likelihood of infection among vaccinated HCWs in comparison to unvaccinated HCWs was reported, with an odds ratio of 0.34 and confidence limits of 0.16–0.70, which corroborated the findings of the current study, which reported an odds ratio of 0.36 (0.24–0.56).^[10] Another study done in Fortis healthcare reported breakthrough infections in 6% of the vaccinated HCWs.^[11]

Since the start of vaccination, 232 HCWs have tested positive; among them, 47 (20.2%) have breakthrough infections. A higher incidence of breakthrough infections was reported by Tyagi *et al.*^[4] who had done the study in a non-Covid care facility, indicating that variants such as Delta and Delta Plus have higher chances of causing breakthrough infections, a possibility also reported by Hacisuleyman, Hale, Saito, *et al.*^[12] Another study done in Government Medical College Hospital, Kozhikode reported breakthrough infection among 16% of vaccinated HCWs.^[13]

In our study, the majority of infected HCWs were JRs, faculty, interns, and SRs; however, Patil *et al.*^[10] reported high prevalence of infection among LTs and radiographers. Rajindra hospital being a tertiary-level health facility, most of the Covid-related work was done by a team of HCWs, which might be the reason for higher infection in these HCWs.

Table 2: COVID vaccination status and breakthrough infection

Covid vaccination status	Frequency	Percent	Becomes covid + ve <14 days after vaccination	Becomes covid + ve ≥14 days after vaccination	Chi-square	P
1st dose taken	54	46.96%	9	45	0.707	0.4005
Both doses Taken	61	53.04%	14	47		
TOTAL	115	100.00%	23	92		

Association of vaccination and Covid infection among HCWs

	Vaccinated with one or both doses (n=2598)	%	Unvaccinated (n=790)	%	Chi square	P
Covid positive	115	4.4%	117	14.8%	100.8	0.0000001
Covid negative	2483	95.38	673	85.1%		Odds ratio 0.26 (0.20-0.34)

Vaccination taken >14 days before + ve test

	1st dose (n=2566)	%	2nd dose (n=1021)	%	Chi square	P
Covid positive	45	1.7%	47	4.6%	22.61	0.0000009
Covid negative	2521	98.24	974	95.39		Odds ratio 0.36 (0.24-0.56)

Risk reduction in fully Vaccinated HCWs (≥14 days post vaccination)

	Covid +ve	Covid -ve	Odds Ratio	Chi-square	P
Fully vaccinated	47	974	0.27 CL (0.195- 0.39)	55.11	0.0000001
unvaccinated	117	673			

Table 3: Covid symptoms and its association with covid vaccination (n=115)

Symptoms of Covid Present	Frequency	Percent	First dose of vaccine taken (n=54)	Both doses taken (n=61)	Odds Ratio	P
Fever	84	73%	38	46	0.77 (0.3-1.76)	0.6912
Low-grade fever	51	44.30%	23	28	0.87 (0.4-1.82)	0.866
Intermediate to high fever	33	28.60%	15	18	0.91 (0.40-2.06)	0.99
Dry Cough	57	49.57%	32	25	2.09 (0.99-4.4)	0.07
Myalgia	56	48.70%	25	31	0.83 (0.4-1.7)	0.7
Sore throat	46	40.00%	18	28	0.58 (0.27-1.2)	0.23
Tiredness	43	37.39%	23	20	1.5 (0.7-3.2)	0.37
Malaise	36	31.30%	20	16	1.65 (0.7-3.6)	0.23
Loss of sense of smell and taste	32	27.83%	12	20	0.58 (0.2-1.35)	0.21
Headache	30	26.09%	20	10	3 (1.25-7.19)	0.018
Cold and running nose	29	25.22%	15	14	1.29 (0.5-3)	0.6
Diarrhea	19	16.52%	9	10	1 (0.38-2.73)	0.83
Difficulty in breathing	12	10.43%	7	5	1.66 (0.49-5.6)	0.59
Asymptomatic	8	6.96%	3	5	0.65 (0.14-2.8)	0.85
Sinusitis and nasal blockage	6	5.22%	1	5	0.2 (0.02-1.86)	0.26
Chest congestion	4	3.48%	1	3	0.3 (0.03-3.6)	0.69
Cough with expectoration	2	1.74%	1	1	1.13 (0.069-18.5)	0.53
Conjunctivitis	2	1.74%	0	2	0	0.5
Skin rash	2	1.74%	0	2	0	0.53
Dysgeusia	1	0.87%	0	1	0	0.95
Vomiting	1	0.87%	1	0	0	0.95

Total vaccinated (1st or 2nd) = 115

Another latest study done in CMC Vellore by Dr. Joy J. Mammen and still in preprint pre-peer-reviewed stage reported infection in 9.6% of fully vaccinated HCWs (n = 7080), 47 days (34–58) after the second dose,

which is more than double the rate reported by our study. The mean age was 31.5 years, similar to our study, where the mean age was 33.3 years and the female: male ratio was 3:2. The study also corroborated the findings done in our study

Table 4: Comparison of Covid symptoms among fully vaccinated and unvaccinated HCWs

Symptoms of Covid Present	Fully vaccinated (n=61)	%	Unvaccinated (n=117)	%	Odds Ratio	P
Fever	46	75.4	79	67.5	1.4 (0.7-2.9)	0.17
Low-grade fever	28	45.9	41	35.0	1.57 (0.8-2.9)	0.10
Intermediate to high fever	18	29.5	38	32.5	0.8 (0.44-1.7)	0.40
Dry Cough	25	41.0	48	41.0	0.99 (0.53-1.87)	0.4
Myalgia	31	50.8	55	47.0	1.16 (0.62-2.16)	0.37
Sore throat	28	45.9	38	32.5	1.76 (0.93-3.3)	0.055
Tiredness	20	32.8	59	50.4	0.47 (0.25-0.91)	0.018
Malaise	16	26.2	30	25.6	1.031 (0.50-2.088)	0.46
Loss of sense of smell and taste	20	32.8	25	21.4	1.79 (0.8-3.5)	0.06
Headache	10	16.4	36	30.8	0.44 (0.20-0.96)	0.02
Cold and running nose	14	23.0	29	24.8	0.9 (0.4-1.87)	0.46
Diarrhea	10	16.4	11	9.4	1.88 (0.75-4.7)	0.13
Difficulty in breathing	5	8.2	16	13.7	0.56 (0.19-1.62)	0.68
Asymptomatic	5	8.2	12	10.3	0.78 (0.2-2.3)	0.43
Sinusitis and nasal blockage	5	8.2	3	2.6	3.3 (0.7-14)	0.09
Chest congestion	3	4.9	5	4.3	1.15 (0.2-5)	0.42
Cough with expectoration	1	1.6	5	4.3	0.3 (0.04-3.2)	0.3
Conjunctivitis	2	3.3	1	0.9	3.9 (0.34-44)	0.2
Skin rash	2	3.3	0	0.0	0	0.1
Dysgeusia	1	1.6	8	6.8	0.2 (0.027-1.8)	1.3
Vomiting	0	0.0	3	2.6	0	0.25

that vaccinated HCWs required less hospitalization, oxygen therapy, and even ICU admission. In our study, just one HCW needed hospitalization,^[14] In our study, the median time period between receipt of first dose and development of infection was 31.5 days, similar to the study done in PGIMER, which reported 44 days.^[3] A higher median time period of 77 days was reported by a study done in CMC Vellore. In our study, the odds ratio is 0.27; thus, fully vaccinated HCWs are 73% less likely to get infected than unvaccinated HCWs, similar to the study done in CMC Vellore where RR was 0.35 (0.32–0.39).^[14]

In a study done in the United Kingdom on a cohort of 23,324 participants with vaccine coverage of 89%, 977 (38%) of unvaccinated participants developed Covid infection and 71 (3.4%) of vaccinated developed the infection. In our study, 15% of unvaccinated developed infection in comparison to just 4.45 among vaccinated HCWs who have received at least one dose of vaccine.^[15] Another multicenter trial of ChAdOx1 nCoV-19 vaccine efficacy done in the UK, Brazil, and South Africa reported an overall vaccine efficacy of 70.4%, which is in concordance with our study results.^[16]

In our study, the majority of vaccinated HCWs had mild symptoms presenting with mild to moderate fever, and half of them had cough and sore throat. There was no mortality and no need for ICU care and oxygen. All vaccinated HCWs were managed by home isolation treatment. Hospitalization was done in only one HCW for 1–2 days who had received just one dose of vaccine. Similar findings were reported in a study done by Tyagi *et al.* and study done in Vellore.^[4,6] In our study, 7% of vaccinated HCWs who tested positive were totally

asymptomatic; these were interns who got themselves tested for home visit, with a mean age of 23 years, and had taken one dose of vaccine, in comparison to SIREN study done in the UK, which reported 19% asymptomatic infections among the vaccinated group as they have done the study on BNT162b2 mRNA vaccine, which has higher efficacy.^[15] A retrospective study done in Mumbai reported asymptomatic infection among 15% of vaccinated HCWs.^[10]

Limitations

The study is not a typical efficacy study; however, odds ratio was used to assess the likelihood of infection among vaccinated HCWs, moreover, the study was done in just one tertiary level health care facility, and the results of only one vaccine type were analyzed (Covishield vaccine); thus, efficacy cannot be compared with other vaccine types.

CONCLUSION

The higher incidence of breakthrough infections among HCWs in tertiary-level health care facilities is a matter of concern, particularly with the emergence of Delta and Delta Plus strains. Further research is needed on tracking the immune response and viral genomic sequence of samples of vaccinated Covid-positive HCWs to have constant vigilance on reemerging new strains of SARS-CoV-2.

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Conflicts of interest

There are no conflicts of interest.

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