

## Original Research Article

# Incidence and severity of COVID-19 infection among health care workers following vaccination: a cross sectional survey in Maharashtra

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**Received:** 19 March 2023

**Revised:** 03 April 2023

**Accepted:** 04 April 2023

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## ABSTRACT

**Background:** Despite the vaccines against COVID-19 being proven to be effective, there is the possibility of infection despite vaccination. Such risk may be potentially greater in healthcare workers (HCWs), because of enhanced rates of exposure to the virus at the workplace. The present study was executed to estimate the incidence of COVID-19 infection post vaccination as well as to assess its severity.

**Methods:** A cross-sectional study was initiated in field practice area of one of the tertiary health care institutes in Pune district of Maharashtra. All 700 HCWs were investigated through questionnaire method and detailed data was collected about their vaccination status and related details. Data analysed using Jeffreys's amazing statistics program (JASP), version 0.17.1.0.

**Results:** In the study, 29.23% of the participants showed COVID-19 infection after vaccination. The majority of clinical illnesses were of mild type. Vaccinated participants with pre-existing illnesses had more incidence of COVID-19 infection following vaccination and also the participants with complete doses had a significantly lesser rate of COVID-19 infection post vaccination compared to those with partial doses of the concerned vaccine.

**Conclusions:** Vaccinated individuals pose less risk of severe COVID-19 infections following vaccination than those who are unvaccinated against COVID-19. Pre-existing disease is one of the major risk factors for enhanced incidence and severity of breakthrough infections.

**Keywords:** Breakthrough infections, COVID-19, Severity, Risk factors, Vaccines

## INTRODUCTION

Coronavirus disease (COVID-19) is a communicable disease triggered by the SARS-CoV-2 virus. Preliminary reports of common COVID-19 symptoms encompassed fever, cough and shortness of breath.<sup>1</sup> However, the WHO guidelines include loss of smell/taste, chills, fatigue, sore throat, nasal congestion and gastrointestinal symptoms. While our understanding of COVID-19 is evolving,<sup>2</sup> most of the data used to inform its presentation are based on hospitalised patients and remain focused on those initial symptoms. However, data from broader

samples also confirm fatigue, loss of appetite and chills as predictive of a positive test for SARS-CoV-2.<sup>3-5</sup>

The approval of safe and effective COVID-19 vaccines, with extensive uptake all over the population, has enabled many nations to control the pandemic and lift maximum COVID-19 restrictions. The objectives of vaccination are to eliminate risk of infection and to diminish the severity and transmission of disease. Even though vaccines against COVID-19 are proven to be effective, there still occurs possibility of infection despite vaccination.<sup>1-5</sup> Such risk might be potentially greater in HCWs, because of increased rates of exposure to virus at workplace.<sup>1,2</sup>

In India, emergence of vaccines against COVID-19 initiated in January 2021, with healthcare professionals/providers being 1<sup>st</sup> to obtain two doses of approved vaccines i.e., Covaxin and Covishield.<sup>6</sup> Safety and effectiveness of both these vaccines are documented in literature. However, there is limited literature concerning the incidence and severity of COVID-19 infection after vaccination. The risk factors for vaccine breakthrough infections are still under research.<sup>6,7</sup>

Current study implemented to assess incidence of COVID-19 infection post vaccination with either Covishield/Covaxin/ other approved vaccine during 3<sup>rd</sup> wave of pandemic among health workers. Study also attempted to assess severity of disease among those who developed infection with COVID-19 post vaccination.

## METHODS

### *Ethical considerations*

An ethical approval was obtained from the institutional ethics committee (IEC) of the respective institute (3751) An informed consent was obtained from the study participants after providing appropriate information about the study to them.

### *Research design and settings*

A cross-sectional study was implemented between (August to September 2022) in field practice area at Sassoon general hospital, one of the tertiary health care institutes in Pune district of Maharashtra.

### *Sample size estimation*

After having preliminary consultation with biostatistician, the required sample size for present study was calculated considering three factors namely 95% confidence level, prevalence of COVID-19 infection post vaccination and the allowable level of margin of error. The sample size was determined by using following formula.

$$n = Z_{(1-\alpha/2)}^2 p(1-p)/d^2$$

Where,  $Z_{1-\alpha/2}$  = it is standard normal variate (at 5% type 1 error ( $p < 0.05$ ) it is 1.96 and at 1% type 1 error ( $p < 0.01$ ) it is 2.58). As in most studies p value is considered significant below 0.05 hence 1.96 is used in formula.  $p = \text{COVID-19 infection post vaccination} = 31.07\%$ ; therefore  $p = 68.93\%$  (according to previous study).

Absolute error or precision = 5%,  $n = (1.96)^2 \times 0.31(1 - 0.31) / (0.05)^2 = 329$

The estimated sample size in the present study was 329. However, considering an interest of additional number of health care workers to actively participate in the study on voluntary basis, the total sample size of 700 was considered for the study.

### *Study population and sampling procedures*

Through universal sampling method, all 700 health care workers including medical teachers, medical students, paramedical staff and people with clerical positions employed at the respective institute were considered as study participants.

### *Inclusion criteria*

Health care workers including mentioned category from the respective institute only and who could provide an informed consent were permitted to participate in study.

### *Exclusion criteria*

Participants who had taken vaccines other than Covaxin/ Covishield/ Sputnik V against COVID-19 were excluded.

The present study implemented an online survey through 'Google form' where a pre-designed, pilot-tested, validated semi-structured questionnaire was provided to the participants who were asked to fill up questionnaire. The questionnaire consisted of 20 open and close ended questions regarding vaccination status, COVID-19 infection and its symptoms post vaccination, and quarantine status, disclosure of any personal information was voluntary. Data was entered into Microsoft office excel sheet and statistical analysis was performed. Relationship of different variables with incidence of COVID-19 infection following vaccination evaluated. Correlation of these variables with the severity of COVID infection following vaccination was then measured through considering necessity for hospitalisation, use of steroids, Remdesivir, and ventilation support.

### *Statistical analysis*

After collection and editing of data, classification and tabulation was done under appropriate heading to obtain the summary values for further statistical treatment. The data values were summarized as medians and interquartile ranges for continuous variables and as frequencies and percentages for categorical variables. Evaluation of the association between categorical variables was performed using the Fisher's exact test. Odds ratios with 95% confidence intervals were reported. P values less than 0.05 were considered statistically significant. All hypotheses were formulated using two-tailed alternatives against each null hypothesis. Data was analysed using JASP, version 0.17.1.0.

## RESULTS

Out of 700, the data analysis could be done only for 667 participants. Among 667 registered participants, 366 (54.87%) were males and 301 (45.13%) were female participants. The mean age of participants was  $28.638 \pm 6.52$ . These participants comprised of medical teachers and students (56.75), paramedical staff (37.7%)

and clerks (5.55%). Table 1 shows the description about the type of vaccine and vaccination status of participants. In the study, 643 (96.40%) participants received vaccine while 24 (3.60%) were unvaccinated for COVID-19. Forty-one (6.15%) received Covaxin, 2 (0.30%) took Sputnik whereas 600 (89.96%) participants were vaccinated with Covishield. Out of 667 participants who tested positive for COVID-19, 549 (54.9%) were home quarantined while 118 (11.8%) were hospitalized for further management. Of these 118 in hospital participants, only 105 (88.9%) were vaccinated against COVID-19 and remaining were unvaccinated.

In present study, out of 643 vaccinated participants, only 188 (29.23%) developed COVID-19 infection post-vaccination. Most of them acquired infection 2 weeks from 2<sup>nd</sup>/ last dose of the corresponding vaccine. Of 188, only 21 (11.17%) participants needed hospitalization, 14 (7.44%) required steroids and only 2 (1.06%) participants were assisted with ventilation support (Table 2).

The association of multiple variables with need for ventilation, steroids, remdesivir and hospitalisation were tabulated in Table 2. For the majority of markers, the

study revealed statistically significant association (Table 2). However, for few variables, the positive association could not be found (Table 2).

Table 3 illustrates symptomatology related to COVID-19 infection among vaccinated group who developed clinical illness after vaccination. The majority of signs/symptoms were of mild type and resolved with symptomatic treatment and basic medical support. However, very few participants (<4%) required additional medical support in the form of steroids, remdesivir and ventilation.

**Table 1: Distribution of parameters on vaccine among the study participants, (n=667).**

Variables	Frequency	Percentage (%)
<b>Type of vaccine</b>		
Covishield	600	89.96
Covaxin	41	6.15
Sputnik V	02	0.30
<b>Vaccination status (643)</b>		
Complete	601	93.46
Partial	42	6.53

**Table 2: Correlation between gender, vaccine doses, pre-existing illness, past COVID-19 infection with markers for severity of infection.**

Variables	Hospitalization	Steroid use	Remdesivir	Ventilation support
<b>Gender</b>				
Male	16 (8.51%)	12 (6.38%)	04 (2.12%)	02 (1.06%)
Female	05 (2.65%)	02 (1.06%)	01 (0.53%)	0
P value	<0.05	<0.05	<0.05	>0.05
<b>Pre-existing medical comorbid conditions</b>				
	18 (9.57%)	13 (6.915)	05 (2.65%)	02 (1.06%)
P value	<0.05	<0.05	<0.05	>0.05
<b>Previous COVID-19 infection</b>				
	12 (6.38%)	08 (4.25%)	07 (3.72%)	01 (0.53%)
P value	<0.05	<0.05	<0.05	>0.05
<b>Doses of vaccine (643)</b>				
One dose (42)	16 (2.48%)	09 (1.39%)	04 (0.62%)	02 (0.31%)
Two doses (601)	05 (0.77%)	05 (0.77%)	01 (0.15%)	0
P value	<0.05	<0.05	<0.05	>0.05

P<0.05=statistically significant.

**Table 3: Various clinical signs and symptoms of breakthrough infections among symptomatic participants after vaccination, (n=188).**

Sign/symptom	N	Percentage (%)
Cough	58	30.85
Fever	152	80.85
Myalgia	88	46.80
Headache	47	25
Loss of taste	32	17.02
Loss of smell	17	9.04
Tiredness or fatigue	125	66.48
Breathing difficulty	14	7.44
Chills	08	4.25
Sore throat	58	30.85
Pale grey or blue skin	07	3.72
Chest pain when breathing	11	5.85
Confusion or difficulty in waking up	21	11.17

## DISCUSSION

In the current study, 29.23% of the participants showed COVID-19 infection after vaccination. In the study, male participants were more infected with COVID-19 than females and even males had acquired more COVID-19 infection following vaccination when compared to female participants. These findings were in concurrence with the findings of the study conducted by Parmeshwaran et al.<sup>8</sup> In the present study, vaccinated participants with pre-existing illnesses reported greater incidence of COVID-19 infection following vaccination and also the participants with recommended complete doses had a significantly lesser rate of COVID-19 infection post vaccination compared to those with partial doses of the respective vaccine. These results were similar to the study of Parmeshwaran et al.<sup>8</sup>

The present study also revealed reduced incidence ( $p < 0.05$ ) of COVID-19 infection post vaccination among participants who had history of past COVID-19 infection before the receipt of vaccine. This might be attributed to the role of natural immunity due to infection. In this context, one of the interesting findings reported by Letizia et al.<sup>9</sup> that, even though antibodies produced by initial infection are hugely protective, it may not ensure effective COVID-19 virus neutralization or immunity against subsequent infection. It reiterates the need of COVID-19 vaccination even in previously infected individuals specially to control pandemic.<sup>9-14</sup>

As per the results of present study, growing age, male gender, existence of medical comorbidities and repeated exposure to COVID-19 infected patients were connected with an augmented severity of COVID-19 infection even following vaccination. Completed recommended vaccine schedule (rather than partial) was related with lowered severity of the infection post vaccination. These facts are supported in multiple studies.<sup>15-17</sup> These emerging inferences may be helpful in planning of control measures for COVID-19 particularly in high risk areas.

In this study, different variables namely gender, presence of COVID-19 infection before vaccination, pre-existing health co-morbid conditions and vaccine doses could not show statistically significant relationship with need for ventilation among participants who reported COVID-19 infection as a result of vaccination (Table 2). One of the possible reasons for lack of positive association may be the lesser number of participants who needed ventilator support.

The current study selected HCWs as participants for some specific reasons. They were the first population group who obtained vaccination in India. Furthermore, they could give relevant, reliable and specific information essential for the research, as during early pandemic period, the level of uncertainty was comparatively high regarding information about clinical features, diagnosis, prevention including vaccination aspects related to

COVID-19 infection. In addition, HCWs particularly doctors have easy access to diagnostic and treatment services. They are one of the high-risk groups for COVID-19 infection. The emerging data on incidence and severity of COVID-19 infection among HCWs might provide in-depth understanding of efficacy of multiple approved vaccines.

The present research had some limitations. The restricted sample size with single centric study may be the first limitation as the emerging results cannot be generalized. The Information given by study participants might have limitations in the form of selection bias, data accuracy and depth of information. The whole data was collected only through 'online survey' as the precision to each question could not be verified through face-to-face mode due to social distancing measures during pandemic. Another limitation of this study was that prolonged follow-up of the participants post vaccination and detailed exploration of all possible risk factors could not be implemented. In our study, the source of laboratory (to confirm COVID-19 infection) could not be ascertained.

In spite of these challenges, the study had numerous strengths. Though the safety and efficacy of vaccines (Covishield, Covaxin and Sputnik V) are well documented in the general population, there is sparse literature on the incidence as well as severity of vaccine breakthrough infections specifically in health care workers, who are prone for acquiring COVID-19 infection. The results of the study would be beneficial for policy makers, administrators and planners who have a key role in control of COVID-19 in the communities. This study was not funded by any organization or agency, and the authors do not have any conflict of interest, which provides credibility to the study.

### Limitations

The present research had some limitations. The restricted sample size with a single centric study may be the first limitation as the emerging results cannot be generalized. The information given by study participants might have limitations in the form of selection bias, data accuracy and depth of information. The whole data was collected only through an 'online survey' and the precision of each question could not be verified through face-to-face interview due to social distancing measures during the pandemic. Another limitation of this study was that prolonged follow-up of the participants post-vaccination and detailed exploration of all possible risk factors could not be implemented. In our study, the source of the laboratory (to confirm COVID-19 infection) could not be ascertained.

## CONCLUSION

Complete recommended vaccine schedule not only significantly lessens the incidence and severity of COVID-19 infection compared to partial dosage but also

ensures considerable level of immunity against lethal form of COVID-19 infection. Vaccinated HCWs even though being exposed frequently to COVID-19 infected patients show a significantly low incidence of COVID-19 infection following vaccination. Pre-existing disease is one of the major risk factors for enhanced incidence and severity of breakthrough infections. Multicentric studies with large sample size are needed to assess and validate the efficacy of COVID-19 vaccines among vulnerable and general population.

*Funding: No funding sources*

*Conflict of interest: None declared*

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

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**Cite this article as:** Kataria A, Kataria P, Suryawanshi P. Incidence and severity of COVID-19 infection among health care workers following vaccination: a cross sectional survey in Maharashtra. *Int J Community Med Public Health* 2023;10:1726-30.