

Review Article

COVID-19 Infection Rate following COVID-19 Vaccination among Healthcare Professionals at a Tertiary Care Public Hospital in City of Mumbai

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Background : India launched COVID-19 mass Vaccination campaign after regulatory approval of Covishield & Covaxin vaccines. However, inspite of Vaccination, cases of COVID-19 infection are being reported. Hence, this study is aimed to assess the COVID-19 infection and/or re-infection rate, including breakthrough infections, following vaccination among Health Care Workers at a Tertiary Care Dedicated COVID Hospital. This questionnaire-based survey was initiated following Institutional Ethics Committee approval. We also looked at reasons for Vaccine hesitancy and occurrence of adverse reactions following vaccination, their management and duration amongst the Healthcare Workers.

Results : Of 564 Healthcare Workers (HCWs) who consented to participate, only 503 filled in the questionnaire completely. Majority of the HCWs received Covishield vaccine (78.56%). The infection rate postvaccination was 8.28% (with a median of 22 days and IQR of 8-43 days). This infection rate was significantly higher in those who were not vaccinated as compared to the Vaccinated HCWs (OR = 0.10, 95 CI% = 0.05–0.22, p <0.0001). Breakthrough infection rate was 2.42. Although 58.39% of the participants suffered adverse reactions after vaccination, like myalgia, Fever, Headache, these were mild in nature lasting for an average of 3-4 days. The vaccine hesitancy rate at our hospital HCWs was 6.36%, the main issue being the concerns regarding safety and effectiveness of the vaccines against the COVID-19 infection.

Discussion/Conclusion : The infection and Breakthrough infection rates in our study were low and severity of COVID infection post vaccination was mild, not requiring hospitalisation.

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Key words : COVID-19, Healthcare Workers, Infection rate, Breakthrough infection, Vaccination, Vaccine hesitancy, Adverse reactions.

The COVID-19 pandemic has affected most Countries Globally and is showing minimal signs of abating. there have been 216,303,376 confirmed cases of COVID-19, including 4,498,451 deaths reported as of 30 August 2021, Globally. In India there have been 32,737,939 confirmed cases with 4,38,210 deaths¹.

COVID-19 safety measures and use of masks are the backbone of the management protocol to prevent spread of the COVID-19 infection. Various vaccine platform have been created to fight this pandemic. In current situation, COVID-19 vaccines are being

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Editor's Comment :

- Vaccination and Booster are a must irrespective of said complication.
- Vaccination is a must not only for HCW but also community at large.

considered as the main stay to halt the progression of the pandemic.

India launched COVID-19 Mass Vaccination campaign from January 2021, in a phased manner beginning with Health Care Workers, essential frontline workers, followed by Geriatric population, people with comorbidities, those aged more than 45 years later the entire adult population².

Two vaccines were approved and deployed in India. AZD1222 - ChAdOx1-S (Covishield), was manufactured in India by Serum Institute of India through license from AstraZeneca-Oxford. BBV152 (Covaxin), indigenous Vaccine developed by Bharat Biotech in collaboration with the Indian Council of Medical Research (ICMR)^{3,4}.

The Covishield (ChAdOx1-S/nCoV-19) recombinant vaccine that expresses the SARS-CoV-2 spike protein gene⁵. while Covaxin is a whole-virion inactivated

SARS-CoV-2 adjuvanted Algel-IMDG vaccine.

The efficacy of Covishield (ChAdOx1-S) after administration of two doses of the Vaccines irrespective of interval is 62.1%, with possibly higher efficacy with longer intervals is 78%⁶.

There have been reports of COVID-19 infection in vaccinated individuals especially amongst the Healthcare Workers (HCWs)⁷. Among the total number of Healthcare Workers Vaccinated In USA between December to February 2021, 71% tested positive within the first 2 weeks after the first dose. The number of Health Worker testing positive within 7 days was more compared to after 7 days to 15 days. These findings correspond to a positivity rate of 0.05%.

In the study cohort of University of California, San Diego (UCSD) and the University of California, Los Angeles (UCLA), the absolute risk of testing positive for SARS-CoV-2 after Vaccination was 1.19% among Health Care Workers at UCSD and 0.97% among those at UCLA⁸.

A CDC report dated 29th March 2021 provides strong evidence that mRNA COVID-19 Vaccines are highly effective in preventing SARS-CoV-2 infections in real-world conditions among Healthcare personnel, first responders, and other essential workers. Results showed that following the second dose of Vaccine (the recommended number of doses), the risk of infection was reduced by 90 percent two or more weeks after Vaccination. Following a single dose of either vaccine, the participants' risk of infection with SARS-CoV-2 was reduced by 80 percent two or more weeks after Vaccination⁹.

In India, there is incidence of COVID infection amongst Healthcare Worker following Vaccination¹⁰⁻¹³. Hence the aim of this study was to measure the occurrence of COVID-19 infection, re-infection and breakthrough infections following vaccination in the past, also Vaccine hesitancy and adverse reactions post vaccination and its management were also assessed.

METHODOLOGY

An observational Study was conducted among Healthcare Workers working in a tertiary care hospital in Mumbai, a dedicated COVID Hospital during the pandemic. From January 2021, following Emergency Use Authorisation (EUA) of the two COVID-19 Vaccines, as per the Government of India policy, two doses of either Covaxin or Covishield Vaccine at least 4 weeks apart were available for Administration to all HCWs. The primary outcome of our study was to calculate the incidence of COVID-19 infection/re-infection following vaccination with a COVID-19

Vaccine among Healthcare Workers. The secondary outcome was to assess Vaccine hesitancy amongst healthcare workers and reasons for the same, and to assess adverse reactions post vaccination. Healthcare workers who gave consent were included in the study and they were asked to complete a pre-tested google questionnaire. The questionnaire covered issues regarding COVID-19 infection in the past, COVID-19 infection postvaccination, vaccination details, Vaccine hesitancy prior or post 1st dose of Vaccine, adverse reactions if any post vaccination with treatment and duration of these reactions

Those who had suffered COVID-19 infection in the previous year (2020) before the vaccines were available and then Post Vaccination (first or second dose) were considered as 'Reinfection'. The Infection was considered as a 'Breakthrough infection' when a participant got infected after the 14-day gap following both doses of the vaccine¹⁴. Information about vaccine hesitancy with reasons for the same were documented. The questionnaire was completed either physically or through an online Google form by the participants.

Although the reported percentage of individuals getting infected post vaccination was less than 0.5%⁸, we proposed to enrol all Healthcare Workers at our Institute who consented to participate in the study. The data was collected over a period of 4 months after receiving Institutional Ethics Committee approval.

Statistical Analysis :

Sample size calculation : The sample size was calculated using the reported prevalence of Breakthrough Infections among HCWs in India as 13.3%¹⁰. At 95% confidence level & 5% precision, the sample size was 185. Assuming 20% non-response, the sample size was estimated as 250.

Statistical analysis : Results are expressed in frequency and proportions for categorical variables and mean and standard deviation for continuous variables. Difference between proportions was assessed using Chi-square test. A p-value <0.05 was considered statistically significant.

RESULTS

In 564 Healthcare Workers (HCWs) consented to participate in the study and filled in the questionnaire. However, a review of the filled questionnaires showed that 503 of the 564 (89.18%) were complete and hence only this data was considered for analysis. The 503 HCWs whose data was considered included 246 doctors, 117 Nurses, 13 Occupational and Physiotherapy Doctors, 54 Ward Boys and 5 Ayahs and 68 Healthcare Workers not directly interacting with

patients but working in the hospital (Administrative staff).

The mean (SD) age of the participants was 34.69 (± 11.7) years including 282 (56.06%) men and 221 (43.94%) women. 453 (90.06%) of the enrolled participants had received both doses of the COVID vaccine while 18 had taken only one dose of a COVID-19 Vaccine during the study period and 32 had not yet been vaccinated. There were 370 (78.56 %) Covishield recipients and 101 (21.44 %) Covaxin recipients. The interval between the 2 doses of the Vaccine was 41.58 (± 16.93) days for the Covishield recipients and 38.05 (± 9.03) days for the Covaxin recipients.

Out of 503 participants, 135 were infected with COVID-19. Of these, 96 participants were infected prior to the availability of the COVID-19 vaccines while 39 participants got infected after being vaccinated. Of the 135 participants, 2 participants suffered from COVID-19 Pre- and Post Vaccination and 1 participant who had not taken either vaccine was also infected. The details are summarised in Table 1.

Of the 39 participants who had COVID-19 infection post vaccination, 29 had received Covishield while 10 had received Covaxin. Of the 29 who received Covishield, 15 got infected after receiving the 1st dose while 14 got infected after receiving the 2nd dose. In case of Covaxin, 8 got infected after the 1st dose while 2 got infected after the 2nd dose. This has been summarised in Table 2. Thus, the infection rate was significantly higher in those who were not Vaccinated as compared to the Vaccinated HCWs (OR = 0.10, 95 CI% = 0.05–0.22, $p < 0.0001$)².

Of these, 11 HCWs got Breakthrough Infections as they were infected after the 14-day gap following the 2nd dose of the vaccine (range- 18-60 days). All 11 participants had received 2 doses of Covishield Vaccine. All 11 participants however, only had a mild episode of COVID-19 infection and were quarantined for the same. None of them required hospitalization and recovered over a period of 5-7 days.

Regarding vaccine hesitancy, the most common reasons given by the HCWs are listed below:

- No benefit from the vaccine.
- There is not enough data on safety/efficacy of the vaccine. Also the virus is continuously mutating so there is no evidence that any of the vaccines will actually be effective. COVID-19 precautions are anyway

Table 2 — Breakup of COVID-19 infection as per the vaccine received

| Vaccine | After 1 st dose | After 2 nd dose | Total | Breakthrough Infections n [%] | Severity of the COVID-19 infection |
|------------|----------------------------|----------------------------|-------|-------------------------------|------------------------------------|
| Covishield | 15 | 14 | 29 | 11 [2.42] | Mild |
| Covaxin | 8 | 2 | 10 | 0 | |
| Total | 23 | 16 | 39 | 11 | |

to be followed irrespective of vaccination status.

- I have autoimmune and/or allergic or other medical disorders, so prefer not to take the Vaccine.
- Not interested in taking the Vaccine
- Had got COVID-19 infection previously hence no need for Vaccination
- Fear of injections

In 224 of the 471 (47.56%) participants who received the COVID-19 vaccine suffered one or more mild adverse reactions after the 1st and/or 2nd dose like myalgia, fever, headache, which lasted for average of 3-4 days. The only medications taken for these adverse reactions was Paracetamol thrice a day till the adverse reaction lasted. The most common adverse reactions reported by the participants is summarised in Fig 1.

DISCUSSION

This study mainly aimed to assess the rate of COVID-19 infection, re-infection and Breakthrough infections among vaccinated Health care workers working at a dedicated COVID Tertiary Care Hospital in Mumbai. The data of 503 HCWs who participated in the study was analysed and it was seen that 453 (90%) HCWs were vaccinated with both doses of the COVID Vaccine while 18 had taken only one dose of a COVID-19 vaccine at the time of the survey. There were 81.67%

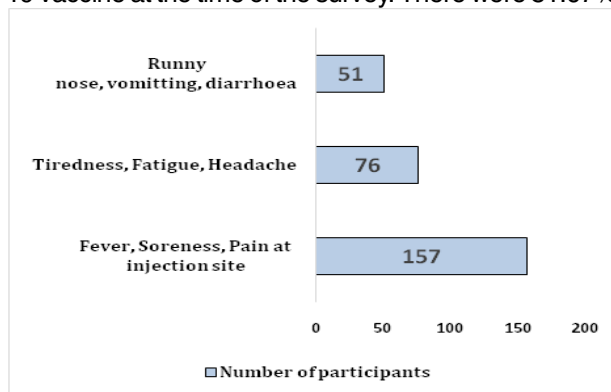


Fig 1 — Details of the adverse reactions experienced by the HCWs post vaccination

Table 1 — Summary of vaccinations and breakthrough infections

| Total number of participants | Vaccinated | Not vaccinated | Vaccination dosing | | Type of Vaccination | | Number Infected | | |
|------------------------------|------------|----------------|----------------------|----------------------|---------------------|---------|----------------------|----------------------|----------------------|
| | | | 1 st dose | 2 nd dose | Covishield | Covaxin | Prior to vaccination | 1 st dose | 2 nd dose |
| 503 | 471 | 32 | 18 | 453 | 370 | 101 | 96 | 23 | 16 |

Covishield recipients and 22.29% Covaxin recipients. Out of 503 participants, 135 were infected with COVID-19. Of these, 97 (20.59%) participants were infected prior to the availability of the COVID-19 Vaccines while 39 (7.75%) participants got infected after being Vaccinated. Breakthrough infections occurred in 11 participants Post Vaccination.

Thus, the rate of infection with COVID-19 in our HCWs post vaccination at our hospital was 8.28% (with a median of 22 days and IQR of 8-43 days) and the re-infection rate was 0.42%. The infection rates were higher in the Covishield recipients as compared to the Covaxin recipients, however, this is acceptable as the number of Healthcare Workers who received the Covishield Vaccine was 3 times that of Covaxin recipients. However, the difference in the infection rate in the Covishield group as compared to the Covaxin group was not statistically significant. The COVID infection rate after receiving the 1st dose of vaccination was 4.88% (with a median of 18 days and IQR of 8-44 days) and 3.40% (with a median of 27 days and IQR of 8-42 days) after complete vaccination, As per Dr Balram Bhargava, Secretary, Department of Health Research (DHR) and Director-General, ICMR, the infection rate was 0.04% after the first dose and 0.04% after the second dose of Covaxin & 0.02% after the first dose 0.03% after the second dose of Covishield respectively¹⁵. The Breakthrough infection rate at our hospital was lower than that reported from 3 studies done on HCWs, 2 in New Delhi - 11.3% at MAMC, New Delhi¹⁰ and 13.2% at a Chronic Care Facility in Delhi¹¹ and 1 in Kerala (8.17%)¹². It was however, higher than that reported from PGIMER (1.6%)¹³.

A study assessing Vaccine effectiveness among US Veterans who had received 2 doses of either Pfizer-BNT-162b2 or Moderna-mRNA-1273 vaccine between December 15, 2020 and March 30, 2021, showed that the breakthrough infection rate was 0.1% among vaccinated persons compared to 6.4% among the unvaccinated matched controls¹⁶. A retrospective cohort study looking at the association between receipt of the Pfizer-BioNTech BNT162b2 vaccine and the incidence of symptomatic and asymptomatic SARS-CoV-2 infection among Health Care Workers in Tel Aviv, Israel showed that vaccination with the BNT162b2 vaccine was associated with an adjusted incidence rate ratio of 0.03 for symptomatic infection and 0.14 for asymptomatic infection more than 7 days after the second dose^{17,18}.

Vaccine hesitancy was another issue that we have addressed in this paper. The hesitancy rate at our hospital HCWs was 6.36%, the main issue being the

concerns regarding safety and effectiveness of the vaccines against the COVID-19 infection. Analysis showed that the infection rate was significantly higher in the unvaccinated as compared to vaccinated HCWs. 'The Covid Symptom Survey' (CSS) is a survey being conducted by Facebook in partnership with the University of Maryland, in 200 Countries, including India. The survey findings reveal that a significant proportion of the population across states are Vaccine-hesitant. The proportion of the population hesitant to COVID vaccines is highest in Tamil Nadu (40%), Punjab (33%), Haryana (30%), Gujarat (29%) and Andhra Pradesh (29%) while it is lowest in Uttarakhand (14%), Assam (15%), Jharkhand (19%), Kerala (19%) & Odisha (19%). The top five reasons for not taking Vaccine included "waiting for others to get it first" (42%), "other people need it more than me" (35%), "fear of any side-effects" (34%), "vaccines won't work" (21%) and "don't believe in the vaccine" (11%). Contrary to popular perception, the proportion of people choosing "high price of vaccines" and "religious belief" as reasons to opt-out remains minuscule¹⁹. A similar response was noted by Taman El Elimat *et al* following a survey conducted in Jordan regarding acceptance and attitudes toward COVID-19 vaccines wherein the public acceptability of COVID-19 vaccines was fairly low (37.4%). Many participants believed that there was a conspiracy behind COVID-19 (OR = 0.502, 95CI% = 0.356-0.709, p<0.001) and they did not trust any source of information on COVID-19 vaccines (OR = 0.271, 95CI% = 0.183-0.400, p<0.001)².

Most of our study participants reported mild to moderate adverse reactions post vaccination lasting for 3 to 4 days with the most common symptoms being fever, headache, pain at injection site, soreness, fatigue, tiredness, diarrhea, runny nose & vomiting. These symptoms were similar to those reported in the study done by Jayde *et al*/however, the percentage of participants who reported these symptoms was higher²¹.

Healthcare Workers do have a high risk of getting infected due to sustained occupational exposure to SARS-CoV-2. Vaccination is one of the main resources to fight against the virus as it decreases the severity of the illness and mortality. It is a known fact the no vaccine provides 100% protection against any disease, and variants will evolve with mechanisms to bypass the Vaccine induced antibody response. However, even if infected with the highly infectious delta variant of the SARS-CoV-2 virus, the severity and mortality has been shown to be less in those vaccinated compared to the unvaccinated^{22,23}.

The positive outcome from our study is that although our hospital was a Dedicated COVID Hospital in both the first & second waves of the pandemic and our Health care Workers worked diligently to manage COVID patients, the infection as well as re-infection rate was low indicating that proper precautions were being followed inspite of being overwhelmed by the number of admitted patients.

Our study does have its limitations. Firstly, due to paucity of funds, we were not able to assess the Vaccine induced Antibody response. Also, data analysis with respect to the infection rate in HCWs suffering from comorbidities such as Diabetes Mellitus, hypertension and other Cardiac and Respiratory Disorders has not been done. Thirdly, although the sample size in our study was 503, this was a single center study and multicentric studies in HCWs in various Mumbai hospitals would be required to get the bigger picture of the infection rates in our city.

Thus to summarize, both the infection and Breakthrough infection rates in our study were low and severity of COVID infection post vaccination was mild, not requiring hospitalisation.

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