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Brief Report

Assessing the Vaccine Efficacy in Health Care Providers for Combating the COVID-19 Infection: Results from Tertiary Cancer Care Centre

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Abstract: Due to the COVID-19 pandemic's rapid expansion, the creation of vaccines is crucial for lowering disease transmission. Therefore, to determine the safety and efficacy of the vaccine against symptomatic illness and to evaluate breakthrough infections, those who received single or both the doses of vaccine against COVID-19 infection. A retrospective observational study was carried out on vaccine efficacy and the incidence of the breakthrough infections among the heath care workers, support staff and administrative staff. Out of 599 fully vaccinated health care workers, those who tested COVID-19 positive post-vaccination only 1.16% developed a severe illness that necessitates hospitalization. This study reflects a significant vaccine efficacy of 81.3% after a complete dose of vaccination and protection of 76.9% after one standard dose against symptomatic disease. The frequency of COVID-19 vaccine breakthrough is very low, which means that COVID-19 vaccines are highly effective at preventing COVID-19, particularly when it comes to severity.

Keywords: COVID-19; vaccine; vaccine efficacy; breakthrough; infection

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1. Introduction

The novel coronavirus pandemic has become a global health emergency and COVID-19 vaccines are a critical tool for controlling the ongoing global pandemic. During the COVID-19 pandemic, health care workers (HCWs) have been at a very high risk for exposure to the SARS-CoV-2 virus that causes COVID-19, through patient interactions and community exposure [1]. Apart from effective public health measures to curb this pandemic, efficacious immunization is becoming more and more crucial for preventing disease and death [2–6].

HCWs are prioritized among the high-risk group for COVID-19 vaccination to maintain the critical care services and to trim down the rate of infection in health care services [7]. This campaign coincided with a second wave of COVID-19, peaking at 0.2 million daily new cases by end of April, 2021 [8]. Vaccines may play an important role in increasing population immunity, preventing severe disease, and dipping the current health crisis.

The Indian biopharmaceutical authority approved Covishield, a recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS-CoV-2 spike glycoprotein, and Covaxin for use in an emergency (inactivated whole virions grown in Vero cells). The Covishield vaccine, which has been the only vaccination used in India to this point and is identical to Oxford-(ChAdOx1 AstraZeneca's nCoV-19) vaccine in formulation and immunogenicity [9], has composed around 88% of all doses administered in the nation [10].

Early distribution of COVID-19 vaccine (Covishield) to HCWs may possibly allow assessing vaccine efficacy (VE) in the current scenario, as they are at higher risk for exposure to SARS-CoV-2. The efficacy of COVID-19 vaccine against symptomatic illness amongst HCWs is our major area of concern? To date, a total of 2,412,226,768 vaccine doses have been administered and reported to WHO from national authorities [11]. It is documented that from March to May 2021, SARS-CoV-2 cases carrying the delta form (B.1.617.2), a variant of concern, significantly increased in India, though we do not have sufficient data to provide the exact

percentage of the HCWs who got infected by delta variant. Only one additional report from India on the protection provided by COVID-19 vaccinations has been published [12].

In a cohort study conducted in Chile between February and May of 2021, those who had received all recommended vaccinations had a VE of 65.9% (95% CI: 65.2–66.6) [13].

Our study compared the effectiveness of the Covishield vaccine in preventing laboratory-confirmed COVID-19 in those who received just one dose and in people who received the vaccine twice. Another major area of concern is to address the breakthrough infection (defined as a positive test after the health care worker was considered to be fully vaccinated (i.e., >14 days after receipt of the second dose) occurred in which who received both the doses of vaccine. According to an ICMR, the prevalence of breakthrough infections varies between two to four in 10,000 cases among the general population in India but new research from the Post Graduate Institute of Medical Education and Research, Chandigarh shows 16 in every 1000 fully vaccinated healthcare workers develop such infections [13].

In this study, our primary objective is to describe the efficacy of the vaccine against symptomatic infection and the secondary objective is to evaluate breakthrough infections, in which those who received single or both the doses of vaccine in a tertiary care hospital, Delhi, India.

2. Methodology

This study was conducted according to strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines [14].

2.1. Study Design and Population

In this retrospective observational study VE and the incidence of the breakthrough infections among the doctors, nurses, paramedical staff, support staff (lab attendants, housekeeping) and administrative staff, the data were collected from 16 January–May 2021, of this tertiary cancer care center (RGCIRC), New Delhi. Ethical clearance has been taken from institutional ethics RGCIRC/IRB-BHR/141/2021 committee. Data were collected from the hospital information system and a questionnaire, designed in the form of a Google document, was used as a quantitative data collection tool. There was a total of 1003 healthcare workers, according to the sample size calculated.

Information on demographics (COVID-19–like illness symptoms status 14 days before and after the testing date and presence of underlying conditions and risk factors for severe COVID-19 data) was collected through telephonic interviews or self-completed surveys. Medical records were reviewed to collect data on SARS-CoV-2 test dates, type, and results and on medical care sought for COVID-19–like illness. Vaccination records, including dates and type of COVID-19 vaccine received, were obtained from occupational health or other verified sources. The questionnaire consisted about the COVID-19 infection (symptoms, and severity) and vaccination status and the severity of COVID-19 infections (mild, moderate, severe and critical) were defined as per ICMR guidelines. During the investigation period we assessed a crossed the three categorized group based on vaccination status: fully vaccinated (FV), partially vaccinated (PV) and not vaccinated (NV). A person is considered fully vaccinated after the two weeks of second dose of the vaccine is administered.

2.2. Inclusion and Exclusion Criteria

An online questionnaire was e-mailed which contained questions about HCW's COVID-19 infections (symptoms and severity) and vaccination status. Participants were excluded who tested positive after 14 days of receiving the first and second dose, and in-sufficient information was also excluded from the study (29 participants were excluded from the final analysis as their vaccination status was not confirmed).

2.3. Statistical Analysis

All continuous variables were expressed as mean ± standard deviation or median with inter-quartile range as per the distribution of data. Categorical variables were expressed

as number and their respective percentage. Categorical variables such as age, group, and sex were analyzed using cross-tabulation procedure and their association with group was analyzed by the exact chi-square test. All the reported *p*-values are two-sided and *p*-values <0.05 is considered to indicate statistical significance. All data entries and statistical analyses are performed by using SPSS® Version 23.0 software Chicago.

3. Results

The mean age of 32.34 ± 9.04 years (range: 21–72 years) Table 1 in which ratio of male and female was 1.65:1. Out of 1003 HCWs, 781 (HCWs were vaccinated in which 599 (76.69%) fully vaccinated (FV) and 182 (23.3%) were partially vaccinated (PV). In these FV 599 (76.6%) HCWs, 101 participants were tested positive for SARS-CoV-2 virus in which 75 (74.26%) had mild disease, 19 (18.8%), moderate disease and 7 (6.93%) of severe disease. In severe category out of seven, only five required hospitalization, saturation level is below 93 and their symptoms lasted for about two weeks. The mean duration between the complete dose of vaccination and infection was 54.41 ± 26.59.

Table 1. Characteristics of health care workers.

S.No.	Variables	Mean ± S.D/Percentage
1.	Age (Years)	32.34 ± 9.04
2.	Sex	
	• Male	625 (62.31%)
	• Female	378 (37.68%)
3.	Vaccination status:	
	• Fully vaccinated	599 (76.69%)
	• Partially vaccinated	182 (23.3%)
	• Not–vaccinated	193 (24.71%)
	• Not available	29 (3.71%)
	Total	1003

In partially vaccinated HCWs, 27 (64.29%) were having mild disease, 13 (30.95%) moderate and 2 (4.7%) severe disease, respectively. Two needed hospitalization with severe gastritis and their symptoms lasted about 8 to 10 days. The mean duration between the first dose of vaccination and first day of symptoms was 32.50 ± 22.18.

Out of 70 not vaccinated (NV) cases, 41 (58.57%) were mild, 23 (32.8%) moderate and 5 (7.12%) severe disease, whereas 1 (1.42%) were in critical condition. The oxygen saturation level was below 70 went on ventilator and death occurred that was considered unrelated to the vaccine, with the cause of death assessed as immune-compromised (Table 2). No death case was reported in full, as well as partially vaccinated, HCWs.

Table 2. COVID-19 vaccine effectiveness among HCWs by number of COVID-19 vaccine doses received before SARS-CoV-2 test date.

Vaccination	Degree of COVID-19 Infection				*p*-Value	Admission Status		Mean ± S.D	*p*-Value
	Mild	Moderate	Severe	Critical		Home Isolation	Admitted		
Not Vaccinated (70/193)	41 (58.57)	23 (32.86)	5 (7.14)	1(1.43)		66 (94.29)	4 (5.71)		0.967
Partially Vaccinated (42/182)	27 (64.29)	13 (30.95)	2 (4.76)	0(0)	0.207	40 (95.24)	2 (4.76)	32.50 ± 22.18	<0.001
Fully Vaccinated (101/599)	75 (74.26)	19 (18.81)	7 (6.93)	0(0)		96 (95.05)	5 (4.95)	54.41 ± 26.59	
Total	213								

We found five breakthrough infections in those who were less than 50 years of age, who were symptomatic and had infection (two had loose motions and loss of smell and taste, three of them had sore throat, cough, fever, congestion and one had severe gastritis). They got infected after 14 days, (Figure 1) and 11 became infected after receiving the first dose of vaccination. However, their symptoms were moderate.

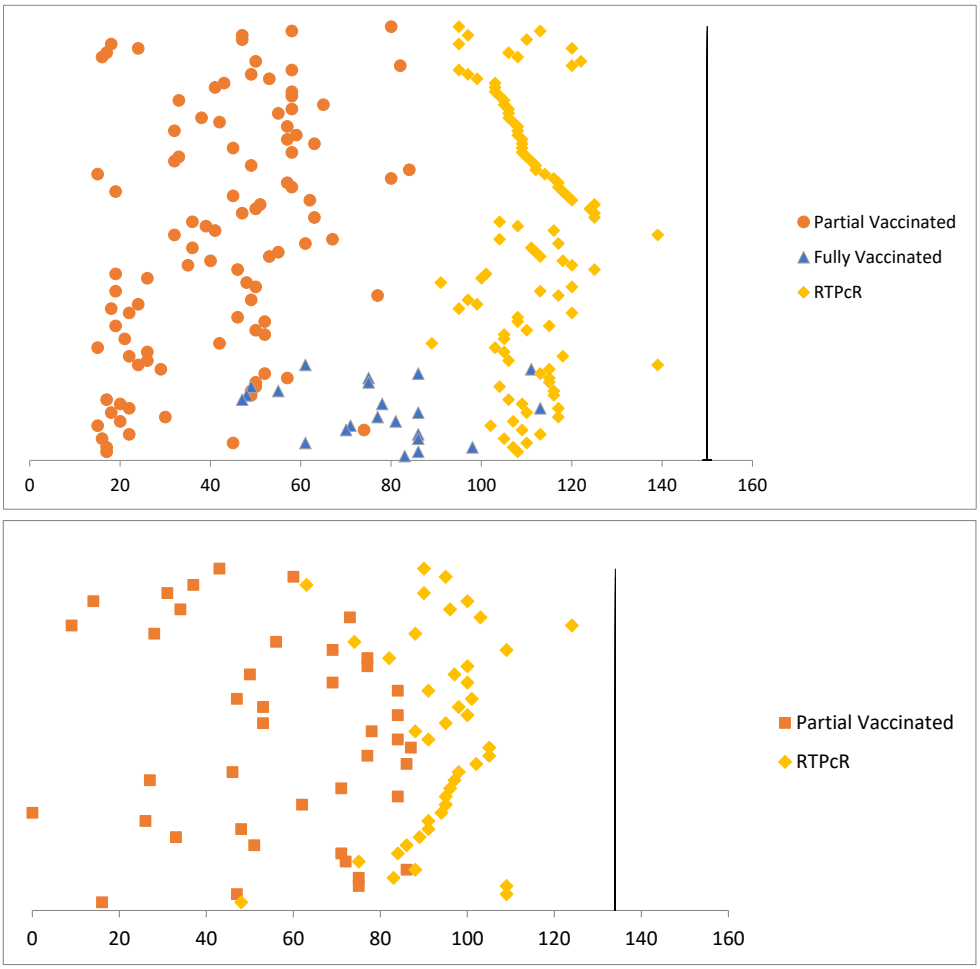

Figure 1. (**top** and **bottom**) depicts clinical chronology of the study's samples in relation to rtPCR and immunization.

4. Discussion

The current COVID-19 upsurge across India has been catastrophic in terms of its high transmissibility, pathogenicity, and strain on health care resources. In this study, we assess the effectiveness and safety of the vaccination (Covishield) administered in our hospital. Our data show significant vaccine efficacy of 81.3% after two doses (FV) and protection of 76.9% after at least one standard dose against symptomatic disease, with no safety apprehensions. Similar results have been seen as per Merryn Voysey et al. In 2021, ChAdOx1 nCoV-19 vaccine from four ongoing blinded, randomized, controlled clinical trials carried out crossways three countries (COV001 (phase 1/2; UK), COV002 (phase 2/3; UK), COV003 (phase 3; Brazil), and COV005 (phase 1/2; South Africa), presented noteworthy vaccine efficacy of 70·4% after two doses and protection of 64·1% after at least one standard dose, against symptomatic disease [15].

In the context of HCWs, no previous study has been published in the Indian context on the efficacy of a viral-vectored coronavirus vaccine so far. This study provides the first evidence that induction of immune responses against spike protein using viral vectors provides protection against the disease.

Emerging variants of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) are of clinical concern. As per the survey carried out by other three hospitals of Delhi, 6–8% of healthcare workers [16] became infected with COVID-19 post-vaccination. However, in our study we also found the SARS-CoV-2 infection rate was 14.2% out of 1500 HCWs during second wave.

Fully vaccinated persons developed only mild COVID-19 infection, largely recovering under home care and only 9 cases had severe illness that require hospitalization. No death occurred in FV and PV HCWs as compare to non-vaccinated HCWs despite a surge in serious infections during the second wave of the pandemic. The mean duration between the vaccination and COVID-19 infection is 54.41 $\pm$ 26.59 days (p = 0.001), which shows that vaccine can help in reducing the transmission of COVID-19 infection.

In our findings, complete doses of COVID-19 vaccines are highly effective in preventing symptomatic COVID-19 and may decrease the risk of acquiring COVID-19 infections by 70–90%. This may help by reducing the rate of severe to fatal disease.

Immune escape variants of SARS-CoV-2 may contribute to an increased rate of infections and potentially have an adverse effect on the efficacy of vaccines that leads to breakthrough infections. Our data show that there is an enhanced fraction of vaccine breakthrough infections that occurs within two specific windows of time.

HCWs who received both the doses and became positive after 14 days subsequent to receiving the second dose the incidence of breakthrough infections was 2% and those who received single dose were 6.04% Figure 2. However, the infection was mild in nature and none of the patient in either category needs hospitalization. Similar studies from AIIMs (unpublished study) health care workers who received both doses and were completed after 14 days and followed up after the second dose. The incidence of breakthrough infection was 1.16% (48 of the 3000 health care workers) and the median time from receipt of the second dose to breakthrough infection was 29.5 days [17].

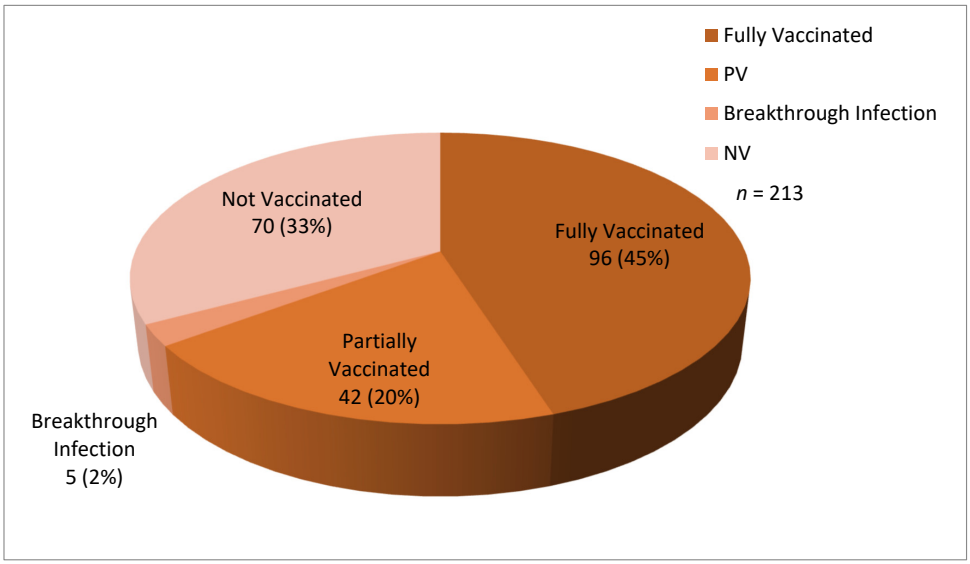

Figure 2. Vaccination status, breakthrough infection and timing of positive test result among 213 health care workers who tested positive for SARS-CoV-2, 16 January to 30 May 2021.

Teran et al. 2021 reported that, out of 627 participants, 22 participants were infected with COVID-19. Two thirds (14 of 22; 64%) of participants with breakthrough infections were asymptomatic [17]. In one of the other studies, Tyagi et al. also conducted a similar study and observed that most of these breakthrough infections are either asymptomatic or mild in nature, as only one person required hospitalization for COVID-19 pneumonia [18].

This was also confirmed by Center for Disease Control (https://www.cdc.gov) that the breakthrough infection is rare, but not serious in nature. In the current scenario, after adequate vaccination, breakthrough infections are a matter of concern, but sufficient data

regarding these infections are not on hand, so according to Hacisuleyman E et al. 2021, breakthrough infections could be attributed to COVID-19 variants which may possibly evade vaccine-induced immunity [19]. The biology behind the explanation of breakthrough infection rates at different time window period for FV and PV as was observed in this study might be due to immune evasion, mediated by particular alterations present in the mutated strains [20–25].

Though FDA-authorized vaccines are extremely efficient, breakthrough cases are expected, especially before population immunity reaches sufficient levels to further decline transmission. Conversely, vaccine breakthrough infections occur only in a small fraction of all vaccinated persons and account for a small percentage of all COVID-19 cases [26–29].

5. Limitations of the Study

The limitations of this study are that we did not test asymptomatic individual who might harbor COVID-19 infection, as well as the absence of data on co-morbid diseases, which are an important aspect to assess the severity of COVID-19 infection.

6. Conclusions

Vaccination against COVID-19 infection has a significant impact on the pandemic, if used in populations at risk of severe disease. In the current scenario, it has been found that vaccination (Covishield) is effective and has contributed to controlling the severity of infection in this COVID-19 pandemic. The frequency of COVID-19 vaccine breakthrough is very low, which means that COVID-19 vaccines are highly effective at preventing COVID-19, particularly when it comes to severe disease.

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Institutional Review Board Statement: IRB-BHR has decided to approve the study to be conducted in its presented form and has granted a waiver from consenting process.

Informed Consent Statement: The study RGCIRC/IRB-BHR/141/2021 submitted in Institutional Review Board and got waiver from consenting process as there is no invasive procedure involve in the entire study as well as it is just as an observational retrospective study.

Data Availability Statement: Data available on request due to restrictions eg privacy or ethical. The data presented in this study are available on request from the corresponding author. The data are not publicly available due to ethical aspect of confidentiality.

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