ORIGINAL ARTICLE

A study on the prevalence and severity of COVID breakthrough infection at an L-3 COVID Hospital, Bareilly

Iram Shaifali, Anju Saxena, Y. Manohar, Shalini Chandra

Department of Pharmacology, RMCH, Bareilly, Uttar Pradesh, India

Corresponding Author:
Dr. Anju Saxena,
Department of Pharmacology,
RMCH, Bareilly, Uttar Pradesh,
India. Mobile: +91-8979925471.
E-mail: dranjusaxena86@gmail.com

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Background: Coronavirus disease (COVID-19) pandemic caused tremendous panic and took significant toll on the health of the people across the world. With the untiring efforts of the global scientific community, effective COVID-19 vaccines were developed to tackle this health crisis. Although vaccines proved efficacious in preventing infection, yet some cases of post-vaccination breakthrough infections (BTIs) have been reported, raising concerns about the efficacy and safety of COVID vaccines. **Aim:** This study was aimed to investigate the occurrence of BTIs among the vaccinated health care workers (HCWs) and to analyze the severity of their disease. **Materials and Methods**: This was a retrospective observational study. Data were obtained by a pre-designed questionnaire. Details of time and severity of BTIs among the vaccinated HCWs were evaluated and statistically analyzed. **Results:** A total of 616 HCWs participated in the study, out of which 553 were vaccinated and 63 of them were unvaccinated. About 15%, that is, 85/553 of the vaccinated HCWs developed BTI. Case rate was lesser (12.9%) in fully vaccinated HCWs as compared to partially vaccinated HCWs (19.5%). Most BTI cases (94%) suffered mild-to-moderate severity of symptoms and were managed in home isolation with medicines. Only five out of 85 BTI cases developed severe disease and needed hospitalization.

KEY WORDS: Coronavirus disease-19, post-vaccination, breakthrough infection, prevalence, pisease severity

INTRODUCTION

The World Health Organization on March 10, 2020, declared coronavirus disease (COVID-19) as pandemic.[1] India reported the first case of COVID-19 on January 30, 2020. By late April 2021, it became the first country to report over 400,000 new cases in a 24 h period.[2] The second wave witnessed unprecedented spike in COVID-19 cases and was much lethal than the first, with shortages of vaccines, hospital beds, oxygen cylinders, and other medicines throughout the country.[3]

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The authorization and development of COVID-19 vaccines proved a savior for controlling the ongoing pandemic. India authorized the British Oxford–AstraZeneca vaccine (CoviShield), the Indian BBV152 (Covaxin) vaccine, and the Russian Sputnik V vaccine for emergency use. India started its vaccination campaign on January 16, 2021, and prioritized the health care workers (HCW).[4] From May 1, 2020, onwards, vaccination was open to all individuals (>18 years of age) in our country. As October 1, 2021, 890,208,007 vaccine doses have been administered in India.

Despite the high efficacy of COVID vaccines, few breakthrough infections (BTIs) have been reported indicating that the mutations in the virus have been able to breach the defenses created by the vaccine. Although, very few cases of BTIs have been reported, these have raised questions about the effectiveness of the vaccines and contributed to the already prevailing vaccine hesitancy.

Aims and Objectives

This study aims to determine the burden and disease pattern of BTI among the HCWs of Rohilkhand Medical College and Hospital (RMCH).

Objectives

The objectives of the study were as follows:

1. To determine the prevalence of COVID-19 infection in post-vaccinated HCWs
2. To study rate of infection after the first and second dose of vaccination
3. To assess the severity of symptoms in breakthrough cases.

MATERIAL AND METHODS

This retrospective cross-sectional study was conducted at RMCH, a dedicated L-3 COVID-19 Hospital. Data were collected from June 1, 2021, to June 30, 2021, through pre-validated 18-item questionnaire developed by content experts. The target population consisted of all the HCWs (faculty members, students, and nursing staff) of RMCH, Bareilly. The Institutional Ethical Clearance was sought before conducting the study. Informed consent was taken from all the participants and confidentiality was maintained.

The Centers for Disease Control and Prevention (CDC) has termed the infections occurring 2 weeks after the full vaccination by an approved vaccine as "BTI".[5]

This definition was strictly adhered to, in labeling a case as BTI. Moreover, BTI was confirmed by a positive reverse transcription polymerase chain reaction and/or positive TRUE NAT test report. The HCWs were divided into two groups, namely, (*i*) fully vaccinated (FV): Those who had two doses of vaccine and (*ii*) partially vaccinated (PV): Those who had one dose of vaccine. The data were further analyzed for the symptoms of post-COVID infection, mode of treatment such as OPD-based treatment and home isolation, or requirement of hospitalization/ admission in intensive care units (ICUs).

The questionnaire was distributed on Google Forms platform. The data were collected and assessed using suitable statistical tests.

RESULTS

A total of 616 HCWs participated in the study, out of which 553 were vaccinated and 63 of them were unvaccinated. Of the 553 vaccinated study participants, 205 had received only the first dose of CoviShield vaccine, that is, 37% (n = 205) were PV and the rest 63% (n = 348) were FV with both the doses of CoviShield [Figure 1].

Our study findings revealed that 15%, that is, 85/553 of the vaccinated HCWs developed BTI [Figure 2]. From 63 unvaccinated study subjects, 25 people developed COVID symptoms whereas 38 of them did not suffer from any COVID related symptoms. Hence, the calculation of odds ratio shows that the vaccinated HCWs were 0.27 times less likely to develop BTI as compared to unvaccinated individuals.

Moreover, we observed that out of the 85 BTI cases, 40 were PV and 45 were FV. Hence, the case rate in HCWs who were PV was 19.5% (40/205) whereas it was decreased to 12.9% (45/348) in those HCWs who were FV [Figure 3].

In terms of severity of BTI, out of 85 BTI cases, 12 of them remained totally asymptomatic. Sixty-eight BTI cases developed symptomatic disease with low-grade fever, cough, malaise, and anosmia. Few of them also reported diarrhea, conjunctivitis, and mild breathlessness. Only five cases developed serious disease with breathlessness and fall in SpO_2. All those HCWs who developed mild-to-moderate infection (asymptomatic and symptomatic cases) were given OPD-based treatment in home isolation with/without oxygen therapy. However, five people who developed serious disease with fall in SpO_2 were hospitalized [Figure 4].

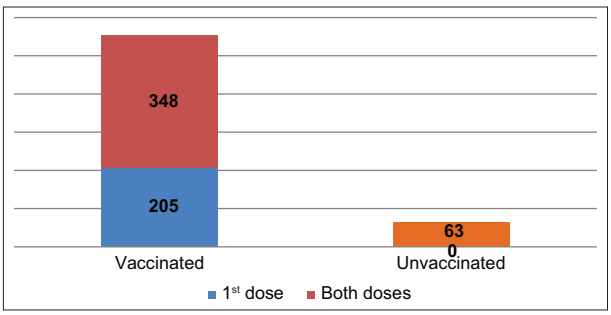

Figure 1: Status of vaccination

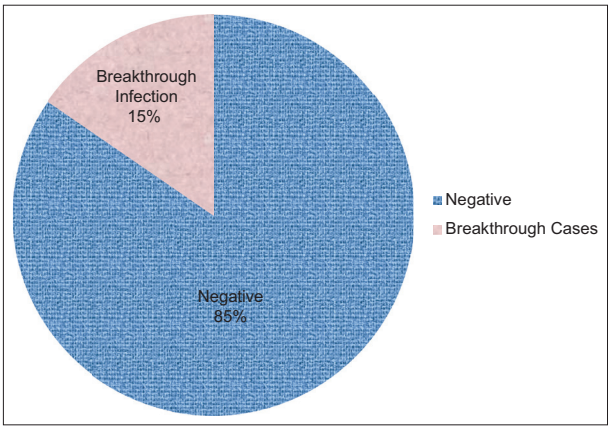

Figure 2: Total number of breakthrough infection cases

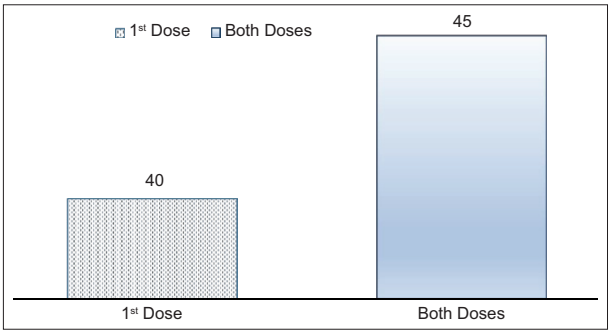

Figure 3: Status of vaccination doses in breakthrough cases

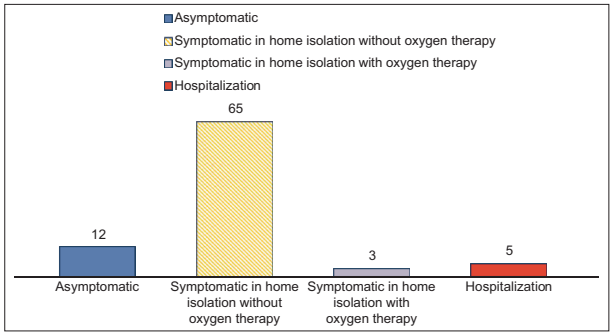

Figure 4: Severity of breakthrough infections

DISCUSSION

The development of COVID-19 vaccines emerged as the life savior for controlling the ongoing devastating pandemic. The Food and Drug Administration gave a nod for the Emergency Use Authorizations for three COVID-19 vaccines for use in the United States.[6] The vaccination campaign for COVID-19 in India was started on January 16, 2021, using two vaccines; CoviShield (AstraZeneca's vaccine manufactured by Serum Institute of India) and Covaxin (manufactured by Bharat Biotech Limited). CoviShield vaccine is a viral vector-based technology. Covaxin is a Whole-Virion Inactivated Corona Virus Vaccine. Both these vaccines have been granted emergency use authorization by the Central Drugs Standard Control Organization in India.[7] Although COVID vaccines emerged as the most potent tools in the pharmaceutical armamentarium to control the ongoing pandemic, yet there have been some concerns raised over the vaccine's efficacy with the emergence of BTIs.[8]

Our study findings of 15% BTI and a higher percentage of case rate among PV-HCWs as compared to FV-HCWs (12.9%) are in concordance with the results observed by Tyagi *et al.*[9] and by Patil *et al.*[10] who also observed 15% and 10% prevalence of BTI cases at Fortis Hospital, New Delhi, and at Jagjivan Ram Hospital, Mumbai Central, respectively. The study jointly conducted by the Institute of Genomics and Integrative Biology and Max Hospitals in Delhi-NCR, also reported similar figure of 25% of HCWs having BTI despite getting fully jabbed.[11]

We noted a higher case rate of BTI among PV-HCWS as compared to FV-HCWs. Similarly, Polack *et al*., Lumley *et al*., and Thompson *et al.*[12-14] also observed lesser incidence of BTI cases after two vaccine doses compared with one dose. This is also in agreement with preliminary results from a large UK surveillance study which indicated that infections of SARS-CoV-2 fell by 65% after a first dose and by 70% after a second dose of the Pfizer vaccine.[15]

The Indian Council of Medical Research (ICMR) in collaboration with Viral Research and Diagnostic Laboratories tracked 677 BTI-positive samples from 17 states of India between April and June 2021. After telephonically interviewing these subjects and analyzing the clinical data, ICMR reported that 71% of BTI cases were symptomatic with one or more symptoms, while 29% were asymptomatic, out of which only 9.8% of cases required hospitalization while fatality was observed in only 0.4%. This study reinforced the fact that the vaccination is effective and does provide reduction in hospital admission and mortality.[16]

In the present study also, 90% of the BTI cases suffered mild-to-moderate disease and were given OPD-based treatment in home isolation with/without oxygen therapy. Only 6% developed severe BTI and required hospitalization. Our findings have also been supported by Tyagi *et al.*[10] and Patil *et al.*[11] who also observed similar trends in BTI severity. A similar study carried out at Indraprastha Apollo Hospitals, New Delhi, by Vaishya *et al.*[17] also noticed mild disease in majority of BTI cases. Out of all the 3235 vaccinated HCWs in their study, only 2 (0.06%) required hospital admissions due to BTI and none of them required an ICU admission.

CDC COVID-19 Vaccine Breakthrough Case Investigations Team[18] also released a statement that the number of COVID-19 cases, hospitalizations, and deaths that will be prevented among vaccinated persons will far exceed the number of vaccine breakthrough cases.

CONCLUSION

The large vaccination drive following the roll out of COVID vaccines has significantly reduced the incidence of COVID-19 cases globally. COVID vaccines have provided hope that the pandemic will soon be mitigated, despite the eruption of few BTI cases which are a potential threat to vaccine efficacy. Hence, more research work on BTIs as well as long-term effects of post-COVID vaccination should be focused. Hence to completely eradicate the pandemic, mass vaccination should be promoted and people should continue using masks and maintain social distancing in public places even after full vaccination as advised by the Ministry of Health and Family Welfare, Government of India, and the CDC.[19,20]

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