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**Original Research Article**

# COVID-19 vaccination: disease status and outcomes of COVID-19 patients admitted in tertiary care hospital in Raigad District of Maharashtra

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## ABSTRACT

**Background:** COVID-19 pandemic had witnessed serious infections and deaths during third wave of the pandemic. This study was designed to analyse the association between severity of disease and patient outcomes with vaccination status of COVID-19 patients.
**Methods:** Retrospective record-based study was conducted among 258 COVID-19 patients from August 2021 to January 2022, during the third wave of the pandemic in a tertiary care hospital.
**Results:** Out of the 258 patients, 42% patients were above 60 years of age 19% were in the age group of 18-30 years. 58% male and 42% female patients. Overall, 50% and 36% patients above 40 years had severe and moderate disease respectively. 52% had mild disease in age group of 18-30 years and this was statistically significant with Chi-square value of 38.85 and $p<0.05$. 36%, 36% and 28% vaccinated patients had severe, moderate and mild disease respectively. 38%, 40% and 23% unvaccinated patients had severe, moderate and mild disease respectively. The mortality rate was 25%, 32% and 50% among vaccinated, unvaccinated and unknown vaccination status respectively. The mortality rate was 44% in those above 60 years. The survival rates were 90% in patients below 40 years. This difference was statistically significant with Chi-square value of 32.16, $p<0.005$. The mortality rate was 61%, 16% and 2% with severe, moderate and mild disease respectively.
**Conclusions:** The severity and mortality rate was less in vaccinated patients. This shows that vaccination might be effective in reducing the severity of disease and deaths among COVID-19 patients.

**Keywords:** COVID-19 vaccination, COVID-19 disease severity, COVID-19 pandemic

## INTRODUCTION

On March 11, 2020, the World Health Organisation declared SARS Corona Virus 2 (SARS-CoV-2), a coronavirus that causes COVID-19 infection, to be a pandemic disease. As of 23 January 2022, over 346 million confirmed COVID-19 cases and over 5.5 million deaths have been reported worldwide. The resurgence of SARS Covid 19 in the second and third waves in April 2021 and December 2022 in India has not only inflicted mortality and morbidity across the human race but has also crippled the economies of affected nations.[1] The world has witnessed significant mortality and morbidity due to the disease in the second and third waves of

infection and this has made the world realize that rapid vaccination of as many people as possible with an effective vaccine was the only lasting solution. The urgent need to control this disease worldwide has stimulated global vaccine research across nations.

The intensity of the second and third waves of disease was high in India and to control the spread of this infection two major vaccines Covishield and Covaxin were developed in India. The Covishield a monovalent vaccine made up of a single recombinant, replication-deficient chimpanzee adenovirus (ChAdOx1) vector that encodes the S-glycoprotein of SARS-CoV-2 was created by the Serum Institute of India using viral vectors in line with the vaccine created by the Jenner Institute. Covaxin, was an inactivated virus developed utilizing the Whole-Virion Inactivated Vero Cell technology vaccine was indigenously created by Bharat Biotech in collaboration with the Indian Council of Medical Research against COVID-19 disease. The efficacy of Covishield as determined by seroconversion after the first and second doses were 91% and 100% respectively and that of Covaxin was 98.3% at 56days post-vaccination.[2] The ChAdOx1 nCoV-19 strain appeared to be better tolerated in older adults than in younger adults and had similar immunogenicity across all age groups after a boost dose.[3] On 16 January 2021, the initial population to receive the vaccination against the disease in India were frontline workers, healthcare professionals, and people over 60 years old. After prioritizing vulnerable groups both vaccines were gradually made available to the general public of the nation beginning on 1st March 2021 for the elderly and people over 45 with comorbid conditions, and from 1 May 2021, it was available for all adults.[4] Most clinical trials on post-vaccination COVID-19 looked at disease severity in terms of symptomatic or asymptomatic presentation, the number of hospitalizations, ICU admissions or death events concluding that vaccinated patients had a lower severity.[5] Despite the COVID-19 vaccine's remarkable efficacy, patients who had received it got infected repeatedly, although less severely than patients who had not received it [6]

The third wave arrival of COVID-19 with Omicron a new variant of SARS Corona Virus was first identified in South Africa in November 2021 having mutation in its Spike protein receptor binding domain that makes the strain antigenically different from the previous strains. Till December 2021 the number of COVID-19 cases were below 10,000 from then, India witnessed its third wave with sudden rise in incidence of COVID-19 infection with omicron variant.[7] During this period nearly 90% of Indian adult population has received at least one dose of COVID-19 vaccine but still most vaccinated individuals got re-infected with the virus. This showed that the role of vaccine in reducing the transmission of the disease was limited. Few studies were available on the incidence of COVID-19 infection after vaccination among general population.[8] Therefore, it was essential to analyse the severity of the disease and patient outcomes among the vaccinated and unvaccinated patients. Most of the COVID-19 suspect cases during the third wave were referred to this tertiary care COVID-19 hospital in Raigad District. In the present study we aimed to determine the demographic characteristics, vaccination status, severity of the disease among COVID-19 patients admitted in a tertiary care hospital in Raigad District of Maharashtra. This study has focussed on the identifying the association of vaccination status with severity of COVID-19 infection and patient outcome.

### *Objectives*

Objectives of current study were; to assess the demographic profile of COVID-19 patients admitted in a tertiary care hospital, to analyse the vaccination status and severity of disease among patients suffering from COVID-19 infection, to determine the association of age, gender and severity of disease with vaccination status of COVID-19 patients and to determine the association of patient outcomes with age, gender, vaccination status and severity of disease.

## METHODS

### *Study design, settings and duration*

This is a retrospective record-based study conducted from patients visiting fever OPD and admitted in COVID ward of a tertiary care hospital in Raigad District, Maharashtra, India. The study was conducted from August 2021 to January 2022.

### *Sample size*

Overall, 680 patients were admitted with suspected COVID-19 infection in the COVID-19 hospital between August 2021 to January 2022 during the third wave of the pandemic. Out of the 680 patients, total of 258 patients were tested positive for SARS-Co-V-2 infection. All the 258 SARS-CoV-2 positive patients were included in the study.

### *Inclusion criteria*

All Individuals above 18 years old admitted in COVID-19 ward tested positive for SARS-Co-2 infection were included in the study.

### *Exclusion criteria*

Children and individuals less than 18 years and patients tested negative for SARS-Co-2 infection were excluded from the study.

The clinical management of the patients in the COVID-19 ward was according to the ICMR COVID-19 management guidelines. The severity of the disease was classified as; Mild disease: Upper respiratory tract

symptoms and/or fever without shortness of breath or hypoxia, Admit in Ward; Moderate disease: Any one Respiratory rate >24/min, breathlessness, SpO2: 90% to ≤93% on room air, Admit in ward/ HDU and Severe Disease: Any one of: Respiratory rate >30/min, breathlessness SpO2 <90% on room air, Admit in HDU/ICU.[9]

***Data collection and statistical analysis***

The data of 258 COVID-19 positive patients was collected from the hospital records admitted in COVID-19 ward from 1 August 2021 till January 2022 during the third wave of the pandemic. Demographic characteristics such as age, gender and details such as vaccination status, severity of the disease and patient outcomes (discharged from hospital or death) were recorded from patient records and hospital patient register. Vaccination history included one or 2 doses of COVID-19 vaccination doses. Few patients could not recollect their vaccination status. The data was entered in Microsoft Excel, Percentages were calculated and graphs were plotted for descriptive statistics. Further the data was analysed using Graph Pad Prism 8 software. The statistical analysis showed the association between independent and dependant variables such as age, gender with vaccination status and the association of age, gender and vaccination status with severity of COVID-19 infection and patient outcome was analysed using Chi square test with $p<0.05$ was considered to be significant at 95% confidence interval.

## RESULTS

A total of 258 patients tested positive for COVID-19 infection and admitted to the tertiary care hospital were included in the study. Demographic characteristics such as age, gender and clinical status, vaccination status, severity of the disease (mild, moderate and severe), patient's outcome (discharge and death) was taken into account for analysis. The majority 109 (42%) patients admitted in COVID-19 ward were above 60 years of age, 19%, 12%, 12%, 15%, 42% were in the age group of 18-30 years, 31-40 years, 41-50 years and 51-60 years respectively. 150 (58%) patients were males and 108 (42%) were female patients (Table 1).

**Table 1: Demographic characteristics of the COVID-19 patients admitted in a tertiary care hospital.**

| Parameters | N | % |
|---|---|---|
| **Age (years)** | | |
| 18-30 | 48 | 19 |
| 31-40 | 31 | 12 |
| 41-50 | 31 | 12 |
| 51-60 | 39 | 15 |
| >60 | 109 | 42 |
| Total | 258 | 100 |
| **Gender** | | |
| Male | 150 | 58 |
| Female | 108 | 42 |

Figure 1 shows Out of the 258 patients admitted in the COVID-19 ward, 136 (53%) patients were vaccinated with either one or two doses of COVID-19 vaccine, 106 (41%) patients were not vaccinated. 16 (6%) patients did not remember the vaccination status. Figure 2 shows the relationship between vaccination status and severity of disease, out of the 136 vaccinated patients, 36% had severe and moderate disease, 28% had mild disease. Out of 106 unvaccinated patients, 38%,40% and 23% had severe, moderate and mild disease respectively. Figure 3 shows the relationship between vaccination status and disease outcome, the mortality rate was 25% among 136 vaccinated patients, 32% among 106 unvaccinated patients and 50% in 16 patients whose vaccination status was not known.

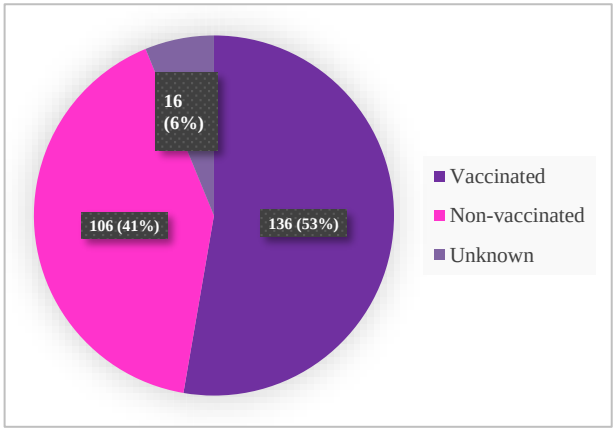


**Figure 1: COVID-19 vaccination status of patients.**

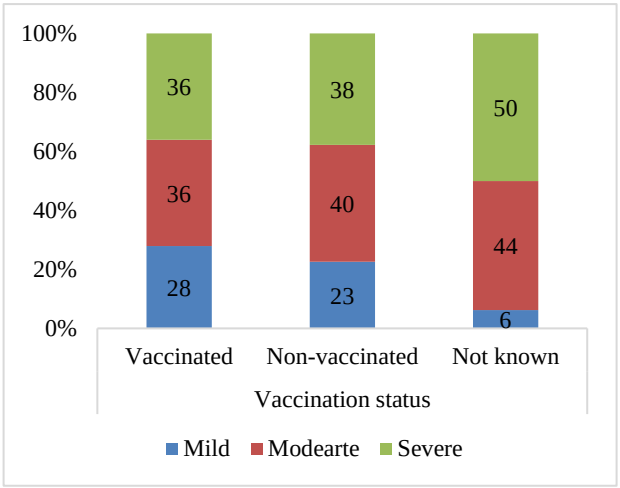


**Figure 2: Severity of disease vs. vaccination status.**

Table 2 shows the age and gender-wise percentage of vaccinated and unvaccinated SARS-CoV-2 positive patients. Out of the 258 patients, 75%, 39%, 42%, 44%, and 53% patients in the age group of 18-30 years, 31-40 years, 41-50 years, 51-60 years, above 60 years were vaccinated respectively. Around 96 (50%) patients above 30 years were unvaccinated. 16 (50%) patient's vaccination history was not known. 77 (51%) males and

59 (55%) females were vaccinated respectively, Majority of vaccinated patients were in the age group of 18-30 years and above 60 years, compared to other age groups. The Chi-square value of 30.65 and p<0.05 show that there was a significant association between age and vaccination status of the patients. The (Table 3) shows the association of age, gender and vaccination status with severity of disease. About 85 (50%) of patients above 40 years of age had severe disease 65 (52%) patients had the moderate disease above 40 years, 25 (52%) had mild disease in age group of 18-30 years. The patients with severe disease were higher in the group of 50 years and above as compared to another age group below 50 years and this was statistically significant with Chi-square value of 38.85 and p<0.05.

**Table 2: Association between age and gender with vaccination status of COVID-19 positive patients.**

| Parameters | Vaccinated | | Non-vaccinated | | Vaccination status unknown | | Chi Square value |
|---|---|---|---|---|---|---|---|
| **Age (years)** | **N** | **%** | **N** | **%** | **N** | **%** | |
| 18-30 | 36 | 75 | 10 | 21 | 2 | 4 | |
| 31-40 | 12 | 39 | 18 | 58 | 1 | 3 | |
| 41-50 | 13 | 42 | 11 | 35 | 7 | 23 | 30.65** |
| 51-60 | 17 | 44 | 20 | 51 | 2 | 5 | |
| >60 | 58 | 53 | 47 | 43 | 4 | 4 | |
| Total | 136 | 53 | 106 | 41 | 16 | 6 | |
| **Gender** | | | | | | | |
| Male | 77 | 51 | 65 | 43 | 8 | 5 | 1.006 |
| Female | 59 | 55 | 41 | 38 | 8 | 7 | |

**depicts p<0.05.

**Table 3: Association of severity status with age, gender, and vaccination status of COVID-19 positive patients.**

| Parameters | Mild | | Moderate | | Severe | | Chi Square value |
|---|---|---|---|---|---|---|---|
| **Age (years)** | **N** | **%** | **N** | **%** | **N** | **%** | |
| 18-30 | 25 | 52 | 17 | 35 | 6 | 13 | |
| 31-40 | 9 | 29 | 16 | 52 | 6 | 19 | |
| 41-50 | 6 | 19 | 12 | 39 | 13 | 42 | 38.85** |
| 51-60 | 8 | 20 | 14 | 36 | 17 | 44 | |
| >60 | 15 | 14 | 39 | 36 | 55 | 50 | |
| Total | 63 | 24 | 98 | 38 | 97 | 38 | |
| **Gender** | | | | | | | |
| Male | 33 | 22 | 56 | 37 | 61 | 41 | 1.8 |
| Female | 30 | 28 | 42 | 39 | 36 | 33 | |
| **Vaccination Status** | | | | | | | |
| Vaccinated | 38 | 28 | 49 | 36 | 49 | 36 | |
| Non-Vaccinated | 24 | 23 | 42 | 40 | 40 | 38 | 4.1 |
| Unknown | 1 | 6 | 7 | 44 | 8 | 50 | |

**depicts p<0.05

Total 61 (41%) of male patients had severe disease whereas 36 (33%) females were found to have severe disease and the relationship between gender and severity of disease was not significant. Among the vaccinated patients 49 (36%) had severe disease 49 (36%) had moderate disease. and 38 (28%) had mild disease. Amongst the unvaccinated patients, 40 (38%) had severe disease, 42 (40%) had moderate disease and 24 (23%) had mild disease. The relationship between vaccination status and severity of disease was not significant. Table 4 shows, out of the 258 patients, total 76 (71%) patients died of Covid-19 and more than 71 (93%) of COVID-19 patients died in the age group of above 40 years. Total 182 patients (70.5%) COVID-19 patients were discharged from hospital after treatment, majority (96%) were in the age group of 18- 40 years. The mortality rate for those above 60 years was 44% comparatively higher than the other age groups. The discharge rate was 90% in the age groups below 40 years as compared to 60 years and above. This difference was statistically significant with Chi-square value of 32.16, p<0.005. Among the death patients, 48 (32%) and 28 (26%) were males and females respectively. There was no significant association between the gender-wise mortality.

**Table 4: Association of COVID-19 patient outcomes with age, gender, vaccination status and severity of disease.**

| Parameters | Death | | Discharge | | Chi Square value |
|---|---|---|---|---|---|
| **Age (years)** | **N** | **%** | **N** | **%** | |
| 18-30 | 2 | 04 | 46 | 96 | |
| 31-40 | 3 | 10 | 28 | 90 | |
| 41-50 | 10 | 32 | 21 | 68 | 32.16** |
| 51-60 | 13 | 33 | 26 | 67 | |
| >60 | 48 | 44 | 61 | 56 | |
| Total | 76 | 29 | 182 | 71 | |
| **Gender** | | | | | |
| Male | 48 | 32 | 102 | 68 | 1.11 |
| Female | 28 | 26 | 80 | 74 | |
| **Vaccination Status** | | | | | |
| Vaccinated | 34 | 25 | 102 | 75 | |
| Non-vaccinated | 34 | 32 | 72 | 68 | 4.9 |
| Unknown | 8 | 50 | 8 | 50 | |
| **Severity** | | | | | |
| Mild | 1 | 2 | 62 | 98 | |
| Moderate | 16 | 16 | 82 | 86 | 82.14** |
| Severe | 59 | 61 | 38 | 39 | |

**depicts p<0.05.

The mortality rate among the vaccinated patients was 25% (34), among unvaccinated patients was 32% (34) and among unknown vaccinated status it was 50% (8), There was no statistical significance between mortality rates in the three groups.

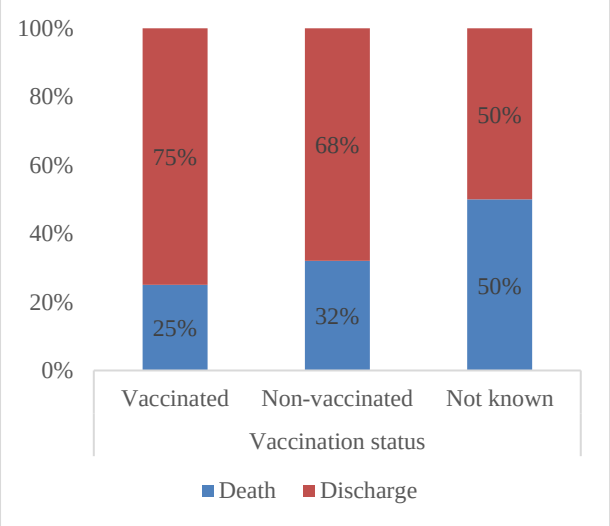


**Figure 3: Vaccinations status vs. disease outcome.**

Total 59 (61%), 16 (16.3%) and 1 (2%) mortality was seen in patients suffering from severe, moderate and mild disease respectively. 38 (39%), 82 (86%) 62 (98%) patients suffering from severe, moderate and mild disease were discharged from the hospital respectively. The severity of the disease was higher in the death cases as compared to the patients who had survived and this difference was statistically significant with Chi-square value 82.14, p<0.005 The mortality rate was higher among severe cases as compared to mild and moderate cases.

## DISCUSSION

In this study the association between Covid-19 vaccination with demographic profile, severity of disease and patient outcome was analysed. This study showed that the majority (42%) of the patients admitted with COVID-19 infection were above 60 years of age in comparison to other age groups. Almost half of them were males and half were females. More than 50% elderly patients were vaccinated against SARS-CoV-2. This shows that after taking vaccination majority of the elderly persons suffered from infection due to waning immunity against COVID-19 infection. A significant number of vaccinated patients in the age group of 18-30 years also suffered mild disease. When compared with other studies conducted by Arora et al observed 7.91% of vaccinated individuals had breakthrough infection. Amongst them were 57.96% males and 42.04% females, with the older age group, 61 years and above, males were found to be at higher risk.[10] Chandan et al conducted a meta-analysis and found that among the partially vaccinated, fully vaccinated and unvaccinated HCWs, the pooled proportion of COVID-19 infections was 2.3% 1.3%, and10.1% respectively. The study showed the risk of COVID-19 infection in both partially and fully vaccinated HCWs remains exceedingly low when compared to unvaccinated individuals.[11] Newman et al found declining neutralising antibody responses to wild-type SARS-CoV-2 for individuals aged 70-89 years, vaccinated with two doses of BNT162b2 (Pfizer–BioNTech) 3 weeks apart, between 3 and 20 weeks after the second vaccine dose, neutralising antibody titres fell 4.9-fold to a median titre of 21.3 with 21.6% of

individuals had no detectable neutralising antibodies at the later time point.[12] Wright et al showed that vaccine effectiveness declined over time, from 94·0% to 80·4% by days 200-250 after vaccination. After 250 days, vaccine effectiveness declines were even more notable. The risk of severe breakthrough infection was most strongly associated with age older than 80 years.[13] The present study showed the majority of patients admitted with severe infections were 60 years. Cucunawangsiha et al found through active and passive surveillance that 1.25% healthcare workers tested positive for COVID-19 infection after vaccination.[14] Nordström et al studied the outcome of severe COVID-19, vaccine effectiveness waned in older individuals than in younger individuals. They found progressively waning vaccine effectiveness against SARS-CoV-2 infection of any severity across all subgroups.[15]

This study showed that the majority of moderate and severe COVID-19 cases among all age groups above 40 years were admitted in the hospital. Mild cases were admitted mostly for observation and treatment, as the majority of mild cases were managed at home during the third wave of the pandemic. This data was analysed from August 2021 to February 2022 after almost a year of vaccination commencement, therefore we see more vaccinated cases than non-vaccinated, as the majority of the adult Indian population had received at least one dose of vaccination within 6 months of vaccine approval.

In this study, comparatively less number of patients had severe and moderate disease in the vaccinated group than in the unvaccinated group, this shows that vaccination had a protective effect on the severity of the disease. Bajpai et al found 43.7% were aged above 60 years, 26% of the vaccinated group experienced severe illness compared to 71.5% in the unvaccinated group. The all-cause 30-day mortality in the non-vaccinated population was higher than that in the vaccinated population [16] Singh et al showed that the severity of the disease was 30.3%, 51.3%, 54.1% among fully, partially vaccinated and unvaccinated individuals.

Vaccination lowers the chances of the development of severe disease.[6] Our study showed that although there was no significant difference in the severity of infection between vaccinated (38%) and unvaccinated (36%) patients. The survival rates were better in vaccinated group than the unvaccinated group. Kataria et al concluded that 29.23% of the health care workers, showed COVID-19 infection after vaccination. The majority of clinical illness were of mild type. Vaccinated individuals pose less risk of severe COVID-19 infections following vaccination than those who are unvaccinated against COVID-19.[17]

The discharge rates were higher in the younger age groups as compared to 60 years and above. This difference was statistically significant with a Chi-square value of 32.16, $p<0.005$. The severity of the disease was higher in the death cases as compared to the patients who had survived and this difference was statistically significant with 82.14 ($p<0.005$) This could be due to advanced age and co-morbidities. When compared with other research studies for severity of infection and mortality among the patients Verma et al showed more males were affected than females. Vaccinated patients were significantly found to have less probability of needing hospitalization, less duration of stay in hospital and less chances of needing Intensive Care Unit support.[18] Takke et al found mild clinical symptoms in vaccinated COVID positive patients. Vaccines might not be effective against re-infection but can attenuate disease severity and mortality, as evident by high coverage of vaccination in the country.[7]

Unvaccinated elderly patients were more affected and had poor outcomes than younger population to support this finding, a study conducted by Sara et al concluded that Coronavirus disease 2019 (COVID-19) caused by the virus is particularly severe in older individuals because they are more likely to have an impaired immune response. Older adults have benefitted the most, in terms of reduced morbidity and mortality, from vaccination.[19] Parameswaran et al concluded that COVID-19 vaccination confer immunity against severe forms of COVID-19 infections.

Presence of pre-existing medical comorbidities is associated with increased incidence and severity of breakthrough infections.[20] Watson et al used mathematical model of COVID-19 transmission and vaccination to report COVID-19 mortality and all-cause excess mortality in 185 countries and territories. It was estimated that vaccinations prevented 14·4 million deaths from COVID-19 in 185 countries and territories between 8 December 2020, and 8 December 2021. A global reduction of 63% in total deaths. they estimated that 41% of excess mortality of 17.9 million deaths were averted with vaccination.[21]

Rossi et al concluded that vaccination was associated with a 36% and 90% reduction in the risk of infection and hospitalization, respectively. Vaccination remains an essential public health tool for preventing severe forms of COVID-19.[22] COVID-19 vaccination had reduced the severity of infection among those affected by it, but breakthrough infections continue to occur among the population by new virus strains. The severity of infection and mortality rate was lower in vaccinated patients as compared to unvaccinated and unknown vaccination status patients.

### *Limitations*

The data was analysed based on available information collected from the patients and their relatives during the third wave of COVID-19 pandemic. The records were deficient in capturing number of vaccination doses of the

patients, so it was not possible to analyse the relationship between number of vaccine doses and outcome.

## CONCLUSION

The study showed that vaccination might have had some protective effect on reducing the severity of the disease and the mortality. Although vaccinated, patients suffered from COVID-19 infection indicates that vaccination does not necessarily prevent infection in individuals. This recommends the need for regular booster doses of vaccination. However, it is proposed that further multi-centric research studies should be conducted to assess the efficacy of vaccination to prevent breakthrough infection, reduce severity of disease and mortality associated with it.

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