

# Effect of COVID-19 vaccination status on outcome of adult patients admitted at a tertiary care centre in India

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## Abstract

COVID-19 vaccination was initially started in India on  $16^{\rm th}$  January 2021 after approval from national authorities. This

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This article is distributed under the terms of the Creative Commons Attribution-NonCommercial International License (CC BY-NC 4.0) which permits any noncommercial use, distribution, and reproduction in any medium, provided the original author(s) and source are credited. study was carried out to assess the effect of vaccination status on the severity and clinical outcome among patients infected with COVID-19. The study included all adult COVID-19 patients admitted to our hospital from 1<sup>st</sup> April to 30<sup>th</sup> June 2021. A total of 819 patients were enrolled in the study out of which only 183 (22.3%) were vaccinated. The study documented a statistically significant reduction in the severity of illness among the vaccinated (single/double dose) (33% severe COVID-19) against the unvaccinated (43% severe COVID-19) groups; along with a reduction in mortality. On univariate and multivariate analysis, age, severity of illness and lack of COVID-19 vaccination status were associated with a statistically significant increased mortality. To conclude, this study demonstrates the role of vaccination in decreasing the severity and mortality of COVID-19 infection.

## Introduction

COVID-19 vaccination was initially started in India on 16th January 2021 for health care workers, followed by Frontline workers and elderly population (60 year plus), middle-aged population with comorbidities (45 to 60 years) and eventually to all middle-aged population and young adults (18 to 45 years). The national protocol was providing two doses one month apart. Two vaccines COVAXIN (inactivated vaccine made indigenously by Bharat Biotech) and COVISHIELD (carrier vaccine made by AstraZeneca) were approved and the world's largest vaccination drive was launched [1]. COVID-19 vaccination can help in decreasing risk of infection and transmission thereby helping in attaining herd immunity [2]. Even though both the vaccines had a proven efficacy of over 50% in phase II/III trials, as desired by the World Health Organization (WHO), real world data from India only can help understand the benefits of vaccination in a holistic perspective. This retrospective study was carried out to assess the effect of vaccination status on the severity and clinical outcome among patients infected with COVID-19.

## Methods

The study included all adult COVID-19 patients admitted in our hospital from 1<sup>st</sup> April to 30<sup>th</sup> June 2021. Demographic and clinical outcome records were retrospectively tabulated and analysed. Data was analysed using Stata 11 (Stata Corp, College Station, TX, USA).



#### Table 1. Baseline characteristics of the study population.

Variable	n (%)
Gender Male Female	513 (63) 306 (37)
Age in years, mean (SD)	52 (16)
Age in years <40 40-60 >60	207 (25.3) 362 (44.2) 250 (30.5)
Co-morbidities Present Absent	349 (42.6) 470 (57.4)
Vaccinated One dose Two doses Not vaccinated	183 (22.3) 147 (17.9) 36 (4.4) 636 (77.7)
Type of vaccine COVAXIN COVISHIELD	114 (62.3) 69 (37.7)
Disease severity Mild Moderate Severe	$\begin{array}{c} 142 \ (17.3) \\ 341 \ (41.6) \\ 336 \ (41) \end{array}$
Outcome Discharge Death Still admitted	615 (75.1) 189 (23.1) 15 (1.8)
ICU requirement	334 (40.8)

## Results

There were 819 patients in the study period out of which only 183 (22.3%) were vaccinated with a single (147 patients) /double dose (36 patients) of either vaccine approved in India. Notably, the majority of the hospital admission population [636 (77.7%)] was not vaccinated. It was a predominantly male (63%) middle-aged (mean age of 52 years) population with 42.6% having comorbid illnesses (most common being Diabetes and hypertension). The demographic and clinical profile of the patients is summarised in Table 1.

As per Indian national guidelines [3], patients with COVID-19 are classified as mild, moderate and severe. Moderate COVID-19 has been defined as a respiratory rate (RR) of 24-30/minute with saturation of oxygen (sO2) in the range of 90-94% requiring oxygen support. Severe disease is classified if patients have tachypnoea (RR>30/min) or sO2 <90% or shock or acute respiratory distress syndrome (ARDS). Of 819 patients, 677 were moderate (41.6%) and severe (41%); 334 (40.8%) required intensive unit care (ICU). At the end of the study period, 615 (75%) patients were discharged, 189 (23%) deceased and 15 were still admitted. The median duration of hospital stay was 8 days. The study documented statistically significant differences in severity of illness among the vaccinated (single/double dose) (33% severe COVID-19) and unvaccinated (43% severe COVID-19) groups (Table 2). Moreover, mortality was reduced in the vaccinated group (13.5%) as compared to those not vaccinated (26%). On univariate analysis (Table 3); age, presence of comorbidities, severity of illness and unvaccinated status were associated with an increased risk of mortality. However, on multivariate

Table 2. Severity of disease and outcomes in vaccinated and unvaccinated.

Variables	Vaccinated (n=183)	Not vaccinated (n=636)	n-value
Mild disease Moderate disease Severe disease	40 (22%) 82 (45%) 61 (33%)	102 (16%) 259 (41%) 275 (43%)	0.034
Outcome Discharge Death Still admitted	157 (86%) 25 (13.5%) 1 (0.5%)	458 (72%) 164 (26%) 14 (2%)	0.001

#### Table 3. Factors affecting mortality in the study population.

Variable	Death (n=189)	Discharged (n=615)	p-value						
Univariate analysis of factors affecting outcome in study population									
Male gender	110 (58%)	393 (64%)	0.15						
Age category (years) <40 40-60 >60	16 (8%) 83 (44%) 90 (48%)	186 (30%) 272 (44%) 157 (26%)	<0.0001						
Severity of disease (severe)	132 (70%)	189 (31%)	< 0.0001						
Presence of comorbidities	94 (50%)	248 (40%)	0.022						
Vaccinated	25 (13%)	157 (26%)	< 0.0001						
Variable	Death (n=189)	Discharged (n=615)	p-value	Adjusted odds ratio					
			Multivariate analysis of factors affecting outcome in study population						
	Multivariate analy	rsis of factors affecting outcom	e in study population						
Male gender	Multivariate analy 110 (58%)	visis of factors affecting outcome 393 (64%)	e in study population 0.35	1.2 (0.82, 1.75)					
Male gender Age category (years) <40 40-60 >60	Multivariate analy 110 (58%) 16 (8%) 83 (44%) 90 (48%)	sis of factors affecting outcom 393 (64%) 186 (30%) 272 (44%) 157 (26%)	e in study population 0.35 <0.0001	1.2 (0.82, 1.75) 2.27 (1.7, 3.01)					
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Male gender Age category (years) <40 40-60 >60 Severity of disease (severe) Comorbidities	Multivariate analy 110 (58%) 16 (8%) 83 (44%) 90 (48%) 132 (70%) 94 (50%)	rsis of factors affecting outcom 393 (64%) 186 (30%) 272 (44%) 157 (26%) 189 (31%) 248 (40%)	e in study population 0.35 <0.0001 <0.0001 0.56	1.2 (0.82, 1.75) 2.27 (1.7, 3.01) 4.2 (3.01, 5.8) 1.11 (0.76, 1.63)					

analysis (Table 3); only age, severity of illness and lack of COVID-19 vaccination status were associated with a statistically significant increased mortality.

## Discussion

These results are of immense public health importance. Severity classification of COVID-19 and effective triage [4] of patients can help in judicious utilisation of healthcare resources and reducing mortality. However, in the absence of definite treatment and limited tertiary care hospitals, the strongest weapon against COVID-19 is mass vaccination as it can help decrease the severity along with mortality of the illness [5].

Phase II/III trials demonstrate efficacy by showing risk reduction in COVID-19 infection. However, the benefits of mortality and severity reduction cannot be undermined. This study is one of the initial data from India demonstrating this key role of vaccination.

Recent evidence from the United States using an agent-based model of SARS-CoV-2 transmission has found reduced infection, severity, ICU admission and deaths, especially among the elderly age-groups after vaccination [6]. Similarly, a susceptible-exposedinfectious-recovered (SEIR) model-based study has found reduced transmission, hospitalisation and deaths. It was concluded that early vaccination is the key to increased efficacy and benefit [7]. Thus, it is imperative to carry out large scale vaccination in India along with following COVID-19 appropriate behaviour to prevent, mitigate and effectively manage subsequent COVID-19 waves [8].

## Limitations

This was a single-centre retrospective study conducted over a small period of time amongst hospitalised patients infected with COVID-19. While the study demonstrated mortality and severe reduction amongst infected patients, further large-scale multicentre studies are required to assess the impact of vaccination on infectivity, severity and mortality. Significant mutations in the SARS-CoV-2 genome have led to multiple surges in case load globally, over the past 12 months [2]. This poses another challenge to the development of effective vaccines. Our study did not include genomic sequencing of the SARS-CoV-2 virus isolated from our



patient population. Thus, it limits our knowledge on these vaccines' efficacy against various known mutants.

#### Conclusions

This study demonstrates the efficiency of COVID-19 vaccination in prevention against the development of severe disease and mortality. With significant differences in prognosis of the disease between vaccinated and unvaccinated populations in our study, it is need of the hour to accelerate vaccination drive to combat this pandemic.

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