

## Association between COVID Vaccination and Disease Severity among Hospitalized Patients in a Tertiary Care Hospital: A Cross-Sectional Study

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### Abstract

**Introduction:** The ongoing COVID-19 pandemic and its unprecedented global societal and economic disruptive impact, highlight the urgent need for the development of safe, effective, affordable, and deployable vaccines against COVID-19. Among the several vaccines approved by the World Health Organization, BBV-152 (COVAXIN) and AZD1222 (COVISHIELD) are approved in India. As on 1-Apr-2021, around 9 million people were fully vaccinated and around 59 million had received one dose of vaccine in India. Hence, this study was aimed to study the association between disease severity and disease progression from mild to moderate/severity.

**Methodology:** This cross-sectional study was conducted in a private medical college at Tamil Nadu between April 2021 to May 2021 (one month period). The study included 100 participants who were aged more than 45 years admitted for COVID infection. Disease severity was assessed as per the guidelines issued by Ministry of Health and Family Welfare, and the patient vaccination status was ascertained based on the patient's testimony (also corroborated with a vaccine certificate).

**Results:** The gender ratio observed was 1.6:1. The mean age at presentation was 59 years for mild disease, 60 years for moderate disease and 61 years for severe disease. The prevalence of moderate disease was 65% among non-vaccinated, and 15% among vaccinated individuals. The prevalence of severe disease was 25% among non-vaccinated individuals, and 5% among vaccinated individuals.

**Conclusion:** Vaccination provides significant protection against moderate and severe COVID-19 disease.

**Keywords:** Covaxin, Covishield, Ministry of Health and Family Welfare, Vaccinated and Vaccinated Individuals.

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## Introduction

From the earliest stages of the pandemic, the development of safe and effective COVID-19 vaccines has been an essential component to control the virus, the disease, and its effects. COVID 19 Vaccines which have been approved by Government of India for prevention against this infection includes Covishield and Covaxin. Covishield /AZD1222 Vaccine was developed at Oxford University and consists of a replication-deficient chimpanzee adenoviral vector ChAdOx1, containing the SARSCoV-2 structural surface glycoprotein antigen (spike protein; nCoV-19) gene [1].

**Covaxin** is an inactivated Viral vaccine, developed with whole virion Inactivated Verocell derived technology. Covaxin was developed by Indian pharmaceutical company Bharat Biotech in collaboration with the Indian Council of Medical Research, a government funded biomedical research institute, and its subsidiary the National Institute of Virology [2]. The viral vector vaccines showed a vaccine efficacy of 70.4% after two doses and 64.1% of protection against symptomatic disease after at least one standard dose [3].

Studies have shown that individuals who contract COVID-19 even after vaccination are likely to have a lower viral load, experience a shorter infection time and have milder symptoms than people who are unvaccinated. Despite Covid-19 Vaccines (Covishield & Covaxin) being available for public use since January 2021, a rise in the number of n-Covid 19 infected patients was noted in the second quarter of 2021 [4].

Analysing individuals with breakthrough infections, would help to demonstrate the disease modifying efficacy of the vaccines in our study setting. In this context this study was planned with an objective to find the association between disease severity and vaccination status among patients aged more than 45 years of age and admitted with RT-

PCR positive nCovid 19 infection was studied.

## Methodology

This cross-sectional study was conducted in a private medical college at Tamil Nadu between April 2021 to May 2021 (one month period). The study included participants who were aged more than 45 years admitted for COVID infection. The study included participants with and without co-morbidities. And the study participants who had previous history of COVID infection, TB patients and immunocompromised patients were excluded from this study based on exclusion criteria.

The study was approved by institute ethical committee (TSRMMH&RC/ME-1/2021-IEC NO: 024). During the study period time, nearly 250 patients got admitted in our hospital. Based on inclusion and exclusion criteria 100 patients were selected based on universal sampling method in our study. Their vaccination history was collected - time of vaccination, the interval between the two doses (if fully vaccinated), and the type of vaccine.

All these information was ascertained from the vaccination certificate. Nasopharyngeal swabs were tested at the Molecular Biology Lab of the study institute, for SARS CoV-2 RNA by Real Time RTPCR, target sequence being RdRp gene [5]. The severity of illness was assessed according to the guidelines issued by the Government of India, Ministry of Health & Family Welfare, version 6 [6].

## Statistical Analysis

Frequency and percentage was calculated for categorical variables and chi-square test was used to find the association between the disease severity with independent risk factors. P value < 0.05 was considered significant with 96% Confidence interval. Crude's odds ratio was estimated for disease severity and vaccination status. Microsoft

Excel was used for data entry and SPSS V21 was used for data analysis.

## Results

Nearly 45% of the study participants were known case of hypertension or diabetes mellitus or both SHT and DM. And there was only one patient with hypothyroidism. In Table 1,2.1 and 2.2 association between disease severity and demographic variables

and vaccination status was analysed used chi-square test. It is evident that from the table that there was no statistical association between disease severity and demographic variables. But there was association between vaccine status and disease severity. We found that patients who were unvaccinated had 38.70 times more risk of developing moderate to severe disease when compared to vaccinated patients.

**Table 1: Association between demographic variables and Disease severity**

	Disease severity			P value
	Mild	Moderate	Severe	
<b>Gender</b>				
Female	11(28.9)	18(47.4)	9(23.7)	0.43
Male	12(19.4)	37(59.7)	13(21.0)	
<b>Age category</b>				
<60 years	11(22.0)	29(58.0)	10(20.0)	0.83
61-70 years	10(28.6)	16(45.7)	9(25.7)	
71-80 years	2(16.7)	8(66.7)	2(16.7)	
>81 years	0(0.0)	2(66.7)	1(33.3)	
<b>Co-morbidity</b>				
Present	8 (17.0)	23 (48.9)	16 (34.0)	0.20
Absent	15 (28.3)	32 (60.4)	6 (11.3)	
Total	23 (23.0)	55 (55.0)	22 (22.0)	

In Table 1, association between disease severity and demographic variables such as gender, age category and co-morbidity status was analysed used chi-square test. It is evident that from the above table there was no statistical association between disease severity and demographic variables.

**Table 2:**

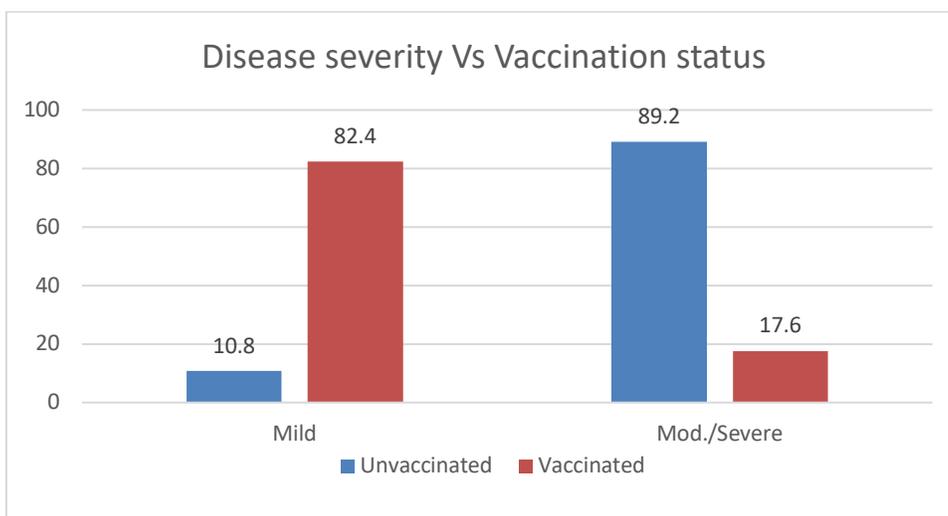
	Disease severity			P value
	Mild	Moderate	Severe	
<b>VACCINE STATUS</b>				
Unvaccinated	9(10.8)	53(63.9)	21(25.3)	0.001
Vaccinated	14(82.4)	2(11.8)	1(5.9)	
<b>VACCINE STATUS</b>				
UNVACCINATED	9(10.8)	53(63.9)	21(25.3)	0.001
1COVISHLD	4(100.0)	0(0.0)	0(0.0)	
2COVISHLD	4(100.0)	0(0.0)	0(0.0)	
1 <sup>st</sup> COVAXIN	3(75.0)	0(0.0)	1(25.0)	
2 <sup>nd</sup> COVAXIN	3(60.0)	2(40.0)	0(0.0)	

In Table 2.1, Association between disease severity with vaccine status was analysed using chi-square test and it is evident that there is statistical association between vaccine status and disease severity

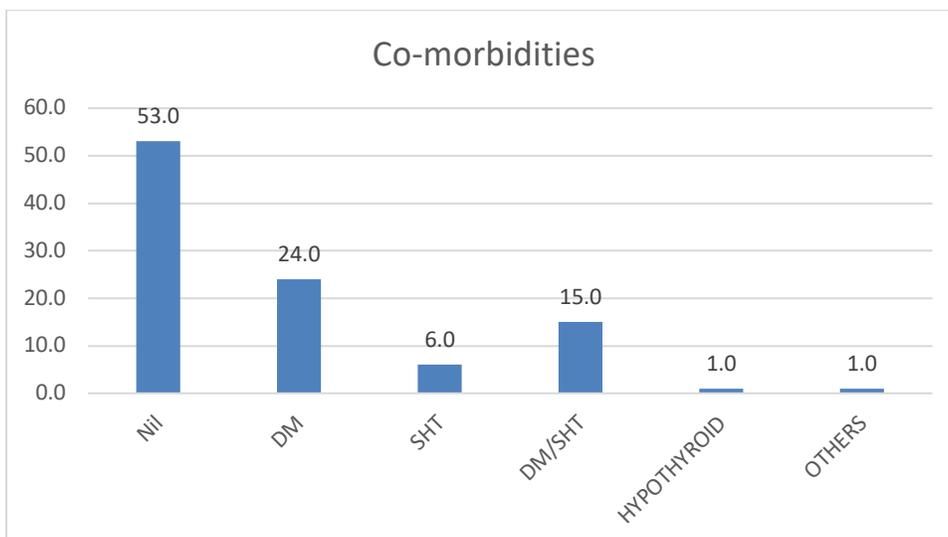
**Table 3:**

COVID-Vaccination	Disease severity		Odds ratio	P value
	Mild	Mod/severe		
Unvaccinated	9(10.8)	74(89.2)	38.70 (9.2-159.72)	0.001
Vaccinated	14(82.4)	3(17.6)		
Total	23(23.0)	77(77.0)		

In Table 2.2, Association between vaccination status and Disease severity was analysed to find the odds ratio. We found that patients who were unvaccinated had 38.70 times more risk of developing moderate to severe disease when compared to vaccinated patients.



**Figure 1: Disease severity Vs Vaccination status**



**Figure 2: Distribution of co-morbidities among the study participants**

## Discussion

Novel coronavirus infection caused by SARS CoV 2 had a great impact on its first wave in 2020. Vaccines were introduced as early as possible to sustain immunity and control the pandemic. But vaccine hesitancy remained a major problem. Though the Government of India announced the vaccines for people more than 60 years of age from 16th January 2021 and more than 45 years of age from 1st March 2021, a lot of misinformation and misconception led to a poor compliance.

A surge in the newly infected patients was observed in April 2021 (the second wave). A cross section of patients (100), who tested positive for COVID 19 for the first time, admitted in this period, aged more than 45 years were analysed for their vaccination status and the severity of illness they developed. Among the hundred patients analysed, 62% were males, which showed a male preponderance. Biological, psychological, behavioural and social factors may put men at a greater risk. This may also be attributed to the high expression of ACE2 receptors in men, higher incidence of smoking and drinking among men and a more responsible attitude towards the COVID-19 pandemic among women [7]. By categorizing these hundred patients according to the severity of illness, 22 (22%) patients had severe disease, 55 (55%) patients had moderate disease and 23 (23%) patients had mild disease. In the study only patients aged more than 45 years were included which may explain the higher incidence of moderate disease. 20% of the study patients had got vaccinated for covid-19 infection (partially or fully vaccinated).

Out of the 20% of vaccinated individuals who developed covid-19 infection, 80% (16 patients) were having only mild infection and 15% (3 patients) developed moderate disease. Only one of the vaccinated individuals developed a severe infection,

which was a partially vaccinated status, the vaccine shot being only 10 days prior to the onset of illness. According to WHO's newsroom on Vaccine effectiveness, all approved COVID 19 vaccines provide a high degree of protection against getting seriously ill and dying from the disease [8].

The prevalence of moderate disease among vaccinated individuals was only 15% as compared to 65% among non-vaccinated individuals. Similarly, the prevalence of severe disease among vaccinated individuals was 5% while among non-vaccinated individuals was 25%. This vaccination trend among the various category of patients was statistically significant as p value was less than 0.05.

By calculating the prevalence ratio, it has been inferred that non vaccinated individuals have a 38.70 times more risk of developing moderate/severe disease. Our study finding was in concordance with studies conducted by A Bhattacharya *et al*, Mark WT *et al* and C singh *et al* [9-12]. Vaccine hesitancy is one of the major hindrances in achieving herd immunity. Addressing any misinformation remains essential. "Misinformation feeds on people's fears and anxieties about the pandemic to promote anti-vaccination conspiracy theories."

"An excessive amount of information, rapid changes in COVID-19 information and guidance, and lack of certainty has caused misinformation to spread faster than the infection, thus creating general distrust and confusion [12-15]. This requires a meticulous, structured, informative and clear communication strategy to create adequate awareness, ensure accurate knowledge, generate and manage adequate demand, facilitate eagerness and address vaccine hesitancy and confidence, and mitigate for unintended situations to ensure the smooth

introduction and roll-out of COVID-19 vaccine(s).

### Conclusion

Covid 19 Vaccination provides protection by preventing the progression from mild infection to moderate/ severe infection. Complete vaccination reduces the chances of oxygen and ICU requirement to almost zero. Convenience, effective communication and avoiding mis-information are the key concepts to break vaccine hesitancy

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