

## ORIGINAL ARTICLE

# Study of COVID-19 Infection, its Severity and Outcome in COVID-19 Vaccinated People at Tertiary Health Care Center, North West Rajasthan

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## Abstract

**Objective:** Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), the causative agent of corona virus-induced disease 19 (COVID-19) that was declared as a global pandemic in March 2020 by the world health organization (WHO). Two vaccines were granted for emergency use by the Central Drugs Standard Control Organization (CDSCO) in India, Covishield® (AstraZeneca's vaccine manufactured by Serum Institute of India) and Covaxin® (manufactured by Bharat Biotech Limited). Sputnik - V has been granted EUA in the month of April 2021. The purpose of this study is to determine the association of COVID-19 infection, its severity and outcome in COVID-19 vaccinated people.

**Methods:** This was a hospital based prospective cohort study done between March to June 2021 at PBM & Associated Group of Hospitals (AGH), Bikaner, Raj. Total 1028 COVID suspected cases consulted in COVID OPD or hospitalized under department of medicine, out of which 146 satisfied the inclusion and exclusion criteria, out of these 146, first 100 cases who gave consent for part of study were selected.

**Results:** Among 100 COVID-19 infected cases, 49 received first dose while rest got both doses. After first dose of vaccination 42.86% had mild and 32.65% had severe clinical infection while after both doses 80.39% had mild and 11.76% had severe clinical infection. On evaluation of HRCT Chest, after first dose 8.16% had normal & 40.82% were in severe category while those who got both doses it was 52.82% & 3.92% respectively. Among 49 who got first dose, 10.20% recovered on just home based treatment without any need of hospitalization, while 89.8% got admitted in dedicated COVID hospital out of which 73.47% got recovered and 16.33% died. Among 51 who got both the doses, 66.67% recovered on just home based treatment, while 33.33% required hospitalization out of which 25.49% got recovered and 7.84% died.

**Conclusion:** After 2nd dose of vaccine there is a significant risk reduction in need of hospitalization and getting severe infection and mortality when compared with first dose only.

(ICU) treatment.<sup>3</sup>

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The purpose of this study is to determine the association of COVID 19 infection, its severity and outcome in COVID 19 vaccinated people at tertiary healthcare center, Bikaner, Rajasthan.

## Material and Methods

This was a hospital based prospective cohort study carried out between March to June 2021 at P.B.M. & Associated Group of Hospitals, Bikaner, Rajasthan, with sample size of 100 selected via convenient sampling. Total 1028 cases consulted in COVID OPD or hospitalized under department of medicine, out of which only 146 satisfied the inclusion and exclusion criteria & among them first 100 cases who gave consent for being part of study were selected.

In this study, exposure is taken as COVID-19 infection after first or both doses of COVID-19 vaccine and outcome is taken as recovery at home based treatment or need of hospitalization leading to recovery or death of participant.

## Inclusion Criteria

1. Patient should be vaccinated by first or both dose of COVID-19 vaccine.

## Introduction

Severe acute respiratory syndrome Coronavirus 2 (SARS-CoV-2), the causative agent of corona virus-induced disease 19 (COVID-19) was first reported in December 2019, in Hubei Province, China, from where it spread rapidly to all over the globe. COVID-19 was declared as a global pandemic in March 2020 by the world health organization (WHO).<sup>1</sup> In India first case of COVID-19 infection was

reported from Kerala, on January 30, 2020.<sup>2</sup> Most people with COVID-19 have mild illnesses or asymptomatic, while approximately 14% develop severe disease that requires hospital admission and oxygen therapy, and 5% patients need an Intensive Care Unit

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2. Patient should be RTPCR COVID-19 positive or clinical suspicion and radiological evidence of COVID-19 infection.

3. No history of COVID-19 infection in past.

#### Exclusion Criteria

1. Age less than 18 years.
2. Those who refused to give consent.

#### Primary predictors

Severity is defined on the basis of clinical status of patients (Table 1) and radiological HRCT Chest SCORE (Table 2) of COVID-19 infection.

#### Statistical analysis

Differences in COVID-19 infection and its severity following first and second dose of COVID-19 vaccination was compared, using chi square test for categorical variables and ANOVA for continuous variables. The level of significance was kept at 95% for all statistical analysis, p value <0.05 was taken as statistically significant. It was then exported into SPSS 17.0 software.

## Results

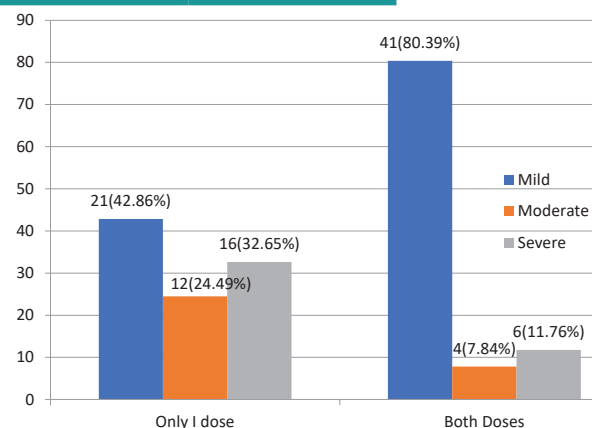
Among 100 cases, 49 cases were

**Table 1: Severity according to clinical status<sup>5</sup>**

Severity	Clinical status
Mild	Respiratory rate <24/min & SPO2 >94% room air
Moderate	Respiratory rate 20-30/min or SPO2 90-94% room air
Severe	Respiratory rate >30/min or spo2 <90% room air or less than <94% with oxygen or ARDS or septic shock

**Table 2: Severity according to HRCT Chest Score<sup>6,7</sup>**

Severity	HRCT chest score
Mild	1-8
Moderate	9-15
Severe	More than 15



**Fig. 3: Distribution of cases according to clinical severity**

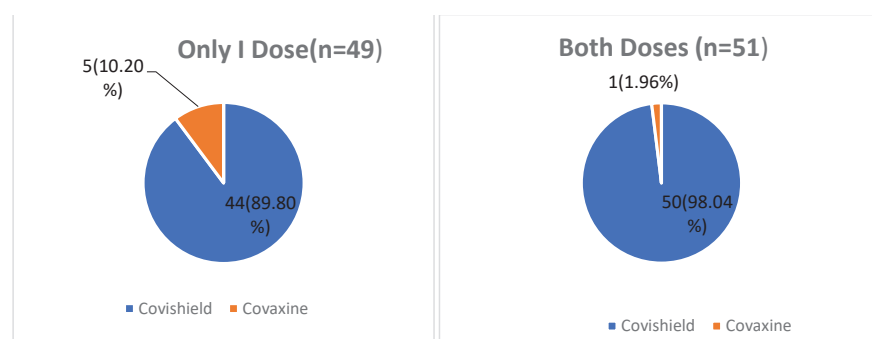
vaccinated for first dose only while 51 cases for both the doses. 44(89.80%) out of 49 cases who got only first dose were vaccinated with Covishield while 5(10.20%) got Covaxine. Similarly for both doses, 50(98.04%) out of 51 got Covishield while only 1(1.96%) got Covaxine (Figures 1, 2).

Among 100 cases, 63 were males and rest females. In our sample of 100 cases, 38 were health care workers while rests were general population. Out of 100 cases tested for RTPCR 73 turned out Positive of which 30 (41%) got one dose while 43 (58.9%) got both doses of vaccine. Rest 27 cases were negative on RTPCR but HRCT Chest strongly suggestive of COVID-19 infection. Patients were categorized based on their clinical status. In 49 patients who got only first dose, 21 (42.86%) had mild infection, 12 (24.49%) had moderate and 16 (32.65%) landed up with severe infection. In 51 cases who got both doses, 41 (80.39%) had mild infection, 4 (7.84%) had moderate while 6 (11.76%) had severe COVID-19 infection (Figure 3). On the basis of HRCT Chest Scoring, 49 patients who got only first dose 4

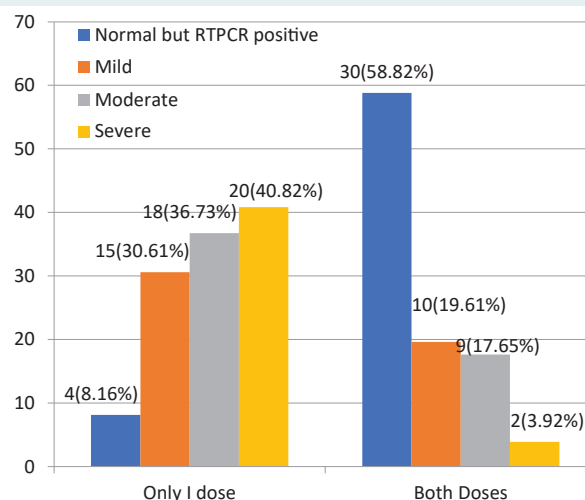
(8.16%) had normal HRCT Chest but confirmed RT-PCR positive, while 15 (30.61%), 18(36.73%), and 20(40.82%) cases were categorized into mild, moderate and severe respectively. Among 51 who received both doses of vaccine, 30(58.82%) had a normal HRCT Chest, while 10(19.61%), 9(17.65%) and 2(3.92%) cases were categorized into Mild, Moderate and severe respectively (Figure 4 and Table 3).

On analyzing age groups we observed that 80% of cases <45 years age, 7% of 45-60 years and none of age >60 years recovered on just home based treatment. While only 20% of <45 years needed hospitalization but the number grew to 66.67% and 70% in ages 45-60 years and >60 years respectively. There was no mortality noted in cases <45 years of age which grew exponentially to 10% in 45-60 years and 30% in >60 years. This gives a clue that the effectiveness of vaccine is more in younger population as compared to older age groups (Table 4).

This is also suggestive from data that out of 38 HCWs, 92.1% recovered on just home based treatment and 7.90%



**Figs. 1, 2: Representing distribution of cases according to vaccination status**



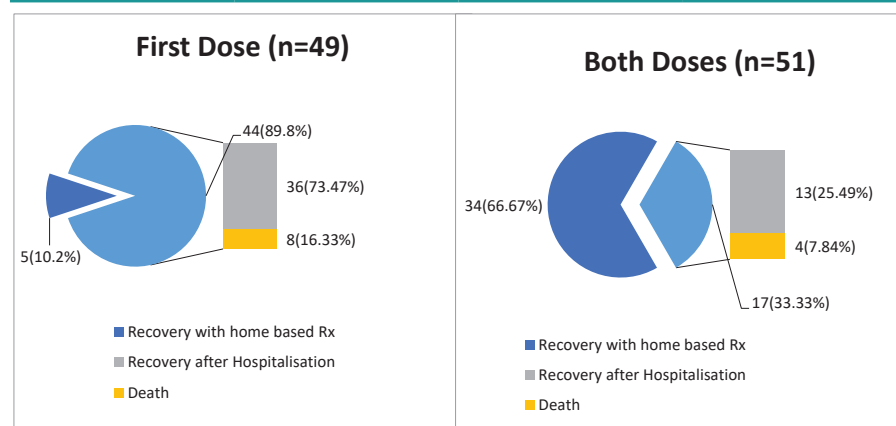
**Fig. 4: Distribution of cases according to HRCT severity criteria**

**Table 3: Correlation of various parameters with vaccine doses**

Variable		First Dose (n=49)	Both Doses (n=51)	p-Value
Age(in years)	<45	7(17.5%)	33 (82.5%)	0.001
	45-60	21 (70%)	9(30.0%)	
	>60	21 (70%)	9(30.0%)	
Sex	Males	30(47.62%)	33(52.38%)	0.878*
	Females	19(51.35%)	18(48.65%)	
RTPCR	Positive	30 (61.22%)	43 (84.34%)	0.018
	Negative (HRCT Suggestive)	19 (38.78%)	8 (15.69%)	
Clinical Criteria	Mild	21 (42.86%)	41 (80.39%)	0.001
	Moderate	12 (24.49%)	4 (7.84%)	
	Severe	16 (32.65%)	6 (11.76%)	
HRCT Criteria	Normal	4 (8.16%)	30 (58.82%)	0.001
	Mild	15 (30.61%)	10 (19.61%)	
	Moderate	18 (36.73%)	9 (17.65%)	
Occupation	Severe	20 (40.82%)	2 (3.92%)	0.001
	HCW	5(13.16%)	33(86.84%)	
	General population	44(70.97%)	18(29.03%)	
Co morbidities	Present	28(57.14%)	16(31.37%)	0.017
	Absent	21(42.86%)	35(68.63%)	
Outcome	Home Based Rx	5 (10.20%)	34 (66.67%)	0.001
	Hospitalised	44(89.20%)	17 (33.33%)	
	-Recovery	36 (73.47%)	13 (25.49%)	
	-Died	8 (16.33%)	4 (7.84%)	

**Table 4: Correlation of age of participants on composite outcome**

	Age (<45 years) (n=40)	Age (45–60 years) (n=30)	Age (>60 years) (n=30)
Only I dose	7 (17.5%)	21 (70%)	21 (70%)
Both I & II dose	33 (82.5%)	9 (30%)	9 (30%)
Outcome			
Home Based Treatment	32 (80%)	7 (23.33%)	–
Recovered			
Recovered (Hospitalized)	8 (20.0%)	20 (66.67%)	21 (70%)
Died	0	3 (10%)	9 (30%)

**Figs. 5, 6: Distribution of outcome of cases correlated with vaccine doses**

needed hospitalization without need of Intensive care facilities and recovered without any mortality.

Among 49 cases who got first dose, 5 (10.20%) recovered on just home based treatment without any need of hospitalization, while 44 (89.8%) got admitted in dedicated COVID hospital, out of which 36 (73.47%) got recovered and 8 (16.33%) died (Figure 5).

Among 51 who got both the doses,

34 (66.67%) recovered on just home based treatment without any need of hospitalization, while 17 (33.33%) got admitted in dedicated COVID hospital, out of which 13 (25.49%) got recovered and 4 (7.84%) died (Figure 6).

Mean age of all the patients who died is 68.08 years with male to female ratio of 5:1. Out of 12 died, 8 (66.66%) had received only first dose of vaccine, while 4 (33.33%) died even after receiving both doses of

vaccine. Mean duration of onset of symptoms after last dose of vaccination was 22 days. 8 (66.66%) had RTPCR positive report, while 4 (33.33%) had RTPCR negative report but HRCT Chest suggestive of COVID-19 infection. Of 12 patient, 7 (58.33%) had co-morbidities like asthma, diabetes, hypertension, COPD, etc., rest 5 (41.66%) had no co-morbidities. On the basis of clinical parameters, 2 (16.66%) had moderate infection while 10 (83.33%) were categorized as severe. On basis of HRCT Chest, 5 (41.66%) and 7 (58.33%) were categorized as moderate and severe respectively (Table 5).

## Discussion

Currently, the vaccine development efforts have started to come to fruition as some of the leading vaccine candidates have shown positive results in the prevention of clinical disease.<sup>8-10</sup>

In this study we observed that, there is a risk of COVID-19 infection even after vaccination & clinicians should have high level of suspicion of reported symptoms and avoid dismissing complaints as vaccine related until true infection is ruled out.

When we compared clinical severity in COVID 19 infected patients we observed that after single dose 42.86% had mild infection, 24.49% had moderate and 32.65% had severe infection while after both doses 80.39% had mild infection, 7.84% had moderate and just 11.6% had severe infection.

On comparing outcome, we observed that after first dose, only 10.20% patients recovered on Home based treatment and 89.33% needed hospitalization out of which 16.33% died, while after both the doses 66.67% patients recovered without need of hospitalization, and 33.33% needed admission out of which only 7.84% died. This data is not in concordance with the study done in AIIMS, New Delhi which reported no deaths in post vaccination COVID-19 infected cases<sup>11</sup> but other study carried out in PGIMER Chandigarh reported deaths per thousand with a single dose was 0.25 and with both doses, it was 0.05<sup>12</sup> signifying less mortality after both dose as in concordance with our study.

This whole data emphasizes that there is a significant reduction in morbidity as well as mortality after both doses as compared to only first

**Table 5: Distribution of deaths according to different variables**

Patient No.	Age	Gender	Vaccination Status	Duration*	RT PCR Report	Co Morbidities	Severity†	Category on HRCT Chest	Outcome
1	69	Male	First Dose	30	Positive	HTN	Severe	Severe	Died
2	45	Male	First Dose	1	Positive	None	Severe	Moderate	Died
3	85	Male	First Dose	18	Positive	None	Severe	Severe	Died
4	66	Male	First Dose	44	Positive	HTN	Severe	Severe	Died
5	73	Male	First Dose	41	Negative	None	Severe	Moderate	Died
6	57	Male	First Dose	2	Negative	COPD	Severe	Severe	Died
7	62	Female	First Dose	23	Positive	Diabetes	Moderate	Severe	Died
8	65	Male	First Dose	7	Positive	Asthma	Severe	Severe	Died
9	76	Male	Both Doses	28	Positive	Hypertension, Diabetes, Chronic liver disease	Severe	Severe	Died
10	77	Male	Both Doses	9	Negative	Hypertension, Diabetes	Moderate	Moderate	Died
11	56	Female	Both Doses	22	Negative	None	Severe	Moderate	Died
12	86	Male	Both Doses	41	Positive	None	Severe	Moderate	Died

\*Duration of onset of symptoms after last dose of COVID-19 vaccination (days); †Severity based on clinical parameters

dose as observed in other studies<sup>13,14</sup> also, so there is a need for boosting up vaccination programme for both the doses so as to reduce the burden on already overwhelmed health system as well as to reduce the treatment expenses.

On analyzing effect of co morbidities on outcome it was observed that out of 12 deaths, 58.33% had associated co morbidities, maximum of Hypertension and Diabetes, and 41.66% had no associated co morbidity. Along with the need for reduction of modifiable risk factors, people with no co morbidities should stay vigilant as they are also at a significant risk of getting severe infection and even death.

Despite sufficient evidences available that vaccination prevents from getting severe infection and

hospitalization, there are still risk of getting COVID-19 infection and even hospitalization emphasizing the need of following universal health precautions even after vaccination.

This study enjoys the benefit of being carried out in the period of peak of second wave of COVID-19 and limitation of being a single center study so it is difficult to generalise the result on population.

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