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Evaluation of the dose-effect association between the number of doses and duration since the last dose of COVID-19 vaccine, and its efficacy in preventing the disease and reducing disease severity: A single centre, cross-sectional analytical study from India

Aakashneel Bhattacharya^a, Piyush Ranjan^{a,*}, Tamoghna Ghosh^b, Harsh Agarwal^b, Sukriti Seth^a, Ganesh Tarachand Maher^a, Ashish Datt Upadhyay^c, Arvind Kumar^a, Upendra Baitha^a, Gaurav Gupta^a, Bindu Prakash^a, Sada Nand Dwivedi^c, Naveet Wig^a

^a Department of Medicine, All India Institute of Medical Sciences, New Delhi, India

^b All India Institute of Medical Sciences, New Delhi, India

^c Department of Biostatistics, All India Institute of Medical Sciences, New Delhi, India

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ABSTRACT

Aims: To evaluate the dose-effect association between COVID-19 vaccination and probability of turning RT-PCR positive and to assess the correlation between disease severity and vaccination status.

Methods: A single centre cross-sectional study was conducted amongst 583 individuals presenting to COVID-19 testing clinic and 55 hospitalized COVID-19 patients. Vaccination status was assessed by the number of doses and duration since the last dose. Disease severity was evaluated by the requirement of hospitalisation and ICU admission/death. The association between the vaccination status and development of disease and its severity were statistically analyzed.

Results: The mean age of the population was 36.6 years and 82.6% had no comorbidities. The odds of turning RT-PCR positive was 0.17(95% CI: 0.11–0.27) among the clinical suspects who had taken both doses of the vaccine at least 14 days before (fully vaccinated). The odds of hospitalisation was 0.12(95% CI: 0.03–0.45) and ICU admission/death was 0.07(95% CI: 0.01–0.36) among fully vaccinated individuals. The protective role of vaccination was observed to start 14 days after receiving the first dose.

Conclusions: COVID-19 vaccination provides dose-dependent protection against the development of the disease. It also lowers the risk of hospitalisation and ICU admission/death in RT-PCR positive patients in a dose-dependent manner.

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1. Introduction

COVID-19 pandemic has severely affected every aspect of human life and health, including physical, social, behavioural and psychological well-being [1–5]. In the absence of a specific therapy targeting the cure of the disease, infection prevention practices and mass vaccination remain the mainstay in controlling the disease [6]. India started the largest COVID-19 vaccination drive in the world on Jan 16, 2021. Covishield (Serum Institute, Pune, India) and

Covaxin (Bharat Biotech, Hyderabad, India) are the two major vaccines available in this country; both are given as two intramuscular injections at 4–12 weeks interval between the doses.

The phenomenon of vaccine hesitancy is universal, and even the world's most developed countries are finding it a big menace [7]. In India, despite mass campaigns regarding the vaccine, studies suggest that there is still significant hesitancy and myths regarding the vaccine among common people [8–10].

There is a lack of studies evaluating the protective efficacy of these vaccines in preventing COVID-19 in real-life scenarios. Besides, studies exploring a dose-effect association between the vaccine status (number of doses and time since the last dose of vaccine taken) and its ability to prevent the acquisition of disease and/or protection from hospitalisation, ICU admissions and/or

* Corresponding author. Department of Medicine, Third floor, Teaching block, All India Institute of Medical Sciences, New Delhi, 110029, India.

E-mail address: drpiyushdost@gmail.com (P. Ranjan).

death, is lacking. We conducted this study to evaluate the protective efficacy of COVID-19 vaccination against the development of disease among clinically suspected cases. We also analyzed the association between the number of doses and time since the last dose of vaccination with the severity of illness among the RT-PCR positive patients.

2. Materials and methods

The study was a prospective, cross-sectional, observational, analytical study conducted in a tertiary care teaching hospital in New Delhi, India. The study population consisted of adults (age more than 18 years) attending a COVID-19 testing clinic (n=583) and hospitalized (n=55) COVID-19 patients. This study was approved by the ethics committee of the institute and informed consent was obtained from the study participants or their immediate family members before enrolling them in the study.

This study included patients who attended the COVID-19 testing clinic from 1st May 2021 to 31st May 2021, during the second wave of the COVID-19 pandemic in India. This clinic serves as a testing centre for COVID-19 among the hospital staff and their family members. The diagnosis of COVID-19 was performed by RT-PCR from a combination of a nasal and a pharyngeal swabs. Patients who got hospitalized with diagnosed COVID-19 in the dedicated COVID-19 wards and two intensive care units during the second Indian COVID-19 wave, were also included in this study.

A formal sample size was not calculated, and purposive sampling was done. To minimise sampling bias, investigators were assigned to three different groups for a) planning the project, b) collecting the data and c) doing the statistical analysis, and none of the groups had control/influence over the other group's work. A group of seven investigators conducted a structured telephonic interview with the participants. They collected data in a pre-designed online proforma that included demographic details, comorbidities, presenting symptoms, duration of illness, number of doses of the vaccine taken, type of the vaccine and the duration since the last dose of the vaccine. The course and outcome of the disease were categorised as asymptomatic or mild disease, non-ICU hospitalisation, ICU admission and death.

Participants were categorised in RT-PCR positive and RT-PCR negative groups. RT-PCR positive patients were further categorised as patients with asymptomatic or mild disease, patients requiring non-ICU hospitalisation, ICU admission and death. The vaccination status of the participants was classified on the basis of the number of doses of the vaccine taken and duration since the last dose. They were categorised in five groups: no dose of vaccine taken at the time of RT-PCR testing, one dose taken in less than 14 days of symptoms onset, one dose taken in more than 14 days of symptoms onset, the second dose taken in less than 14 days of symptoms onset, and second dose taken in more than 14 days of symptoms onset.

2.1. Statistical analysis

The association between the vaccination status of the participants and their RT-PCR results was statistically analyzed by chi-square test. Fisher exact test was performed to evaluate the association between disease severity and vaccination status. Linear and multinomial logistic regression analysis was applied to calculate unadjusted and adjusted (adjusted to age and/or comorbidities) odds ratios to determine the probability of RT-PCR positivity and the chances of hospitalisation, ICU admission or death.

3. Results

A total of 1,193 patients were screened for possible inclusion in the study. Among them, 638 participants were enrolled. The rest were excluded from the study as 59 of them did not give consent, and 496 patients were telephonically inaccessible. Data was collected from 583 participants who attended the COVID-19 testing clinic. Fifty-five participants were enrolled from COVID-19 wards and ICUs of the same hospital. Among the 638 patients recruited in the study, 292 were detected to have SARS CoV-2 infection when tested by RT-PCR; the rest (n=346) were COVID-19 negative. The general characteristics and presenting symptoms of the participants are summarised in Table 1. The mean age of the study population was 36.6±12.4 (2SD) years and 82.6% did not have any comorbid conditions. History of vaccination was present in 474 participants. Two hundred and forty individuals were fully vaccinated (i.e. completed both doses of the vaccine at least 14 days before symptom onset), 234 were partially vaccinated and 164 participants did not receive any vaccine dose. Four hundred and forty-four participants received Covaxin (Bharat Biotech, Hyderabad, India), and the rest (n=30) were vaccinated with Covishield (Serum Institute, Pune, India).

The association between vaccination status and the chances of being RT-PCR positive is shown in Table 2. A subgroup analysis of the study population (n=638) was performed based on the number of vaccine doses received and the duration since the last dose. It was observed that there was a strong statistical correlation (p<0.001) between the vaccination status and RT-PCR positivity. Unadjusted and adjusted (adjusted to age and/or comorbidities) odds ratios were calculated to evaluate the strength of association between the RT-PCR positivity and vaccination status (Table 3). The age and comorbidity adjusted odds of turning RT-PCR positive was 0.17 (95% CI: 0.11–0.27) in fully vaccinated individuals. This indicates that the chance of acquiring COVID-19 was reduced by 83% after 14 days from receiving the second dose of the vaccine. The protective effect (p values) of vaccination was found to be incremental depending on the number of vaccine doses received and the time elapsed since the last dose. There was no role of the vaccines in preventing the disease before 14 days from receiving the first dose (p=0.687). The actual desired effect was observed to commence when 14 days had elapsed since the first dose was received (Table 3).

Another subgroup analysis was performed among the RT-PCR positive patients (n=292) based on their disease severity (Table 4). It revealed that the association between the vaccination status and the severity of COVID-19 was statistically significant (P<0.001). Unadjusted and adjusted (adjusted to age and/or comorbidities) odds ratios were calculated to observe the strength of association between disease severity and vaccination status (Table 5). The age and comorbidity adjusted odds for hospitalisation and ICU admission/death was 0.12 (95% CI: 0.03–0.45) and 0.07 (95% CI: 0.01–0.36), respectively, in fully vaccinated COVID-19 patients. It was also observed that the protective role of the vaccines in preventing severe COVID-19 began after 14 days from obtaining the first dose of vaccination. From the findings of this study, it can be commented that vaccination against COVID-19 protected against the development of the disease as well as it prevented the evolution of severe COVID-19.

4. Discussion

We evaluated the association between COVID-19 vaccination status (the number of vaccine shots received and time interval since the last dose) and the vaccines' clinical efficacy in India in preventing the disease and its severity. This study has several

Table 1
General characteristics and presenting symptoms of the study population (n=638).

General Characteristics		Total n=638	Non-Vaccinated n=164; (25.7%)	Partially vaccinated n=234; (36.6%)	Fully Vaccinated n=240; (37.6%)
Age (Mean ± SD)		36.6 ± 12.4	37.9 ± 14.5	36.4 ± 12.6	35.8 ± 10.4
Gender					
	Male	382 (59.8)	106 (27.7)	151 (39.5)	125 (32.7)
	Female	256 (40.1)	58 (22.6)	83 (32.4)	115 (44.9)
Symptoms					
	Asymptomatic	202 (31.6)	21 (10.4)	51 (25.2)	130 (64.3)
	Fever	127 (19.9)	40 (31.5)	48 (37.8)	39 (30.7)
	Cough	24 (3.7)	3 (12.5)	16 (66.6)	5 (20.8)
	Breathlessness	13 (2.04)	4 (30.7)	7 (53.8)	2 (15.3)
	Sore Throat	40 (6.27)	9 (22.5)	20 (50.0)	11 (27.5)
	Fever, Cough, Breathlessness and Sore throat	15 (2.3)	6 (40.0)	5 (33.4)	4 (26.6)
	Weakness	12 (1.88)	7 (58.3)	2 (16.6)	3 (25.0)
	Diarrhoea	2 (0.3)	1 (50.0)	1 (50.0)	0 (00.0)
	Fever and Cough	111 (17.4)	40 (36.0)	47 (42.3)	24 (21.6)
	Cough and Breathlessness	28 (4.3)	12 (42.8)	13 (46.4)	3 (10.7)
	Fever and Sore throat	43 (6.7)	13 (30.2)	16 (37.2)	14 (32.5)
	Cough and Sore throat	15 (2.3)	4 (26.6)	6 (40.0)	5 (33.3)
	Anosmia	6 (0.9)	4 (66.6)	2 (33.3)	0 (00.0)
Comorbidities					
	Hypertension	34 (5.3)	13 (38.2)	13 (38.2)	8 (23.5)
	Diabetes	22 (3.4)	7 (31.8)	9 (40.9)	6 (27.2)
	Asthma	14 (2.1)	7 (50.0)	6 (42.8)	1 (07.1)
	Diabetes and Hypertension	28 (4.3)	12 (42.8)	7 (25.0)	9 (32.1)
	Diabetes and Asthma	6 (0.9)	2 (33.3)	1 (16.6)	3 (50.0)
	Others	7 (1.1)	3 (42.8)	3 (42.8)	1 (14.2)
	No comorbidities	527 (82.6)	120 (22.7)	195 (37.0)	212 (40.2)

Table 2
Association between COVID-19 vaccination status and RT-PCR results among study population (n=638).

COVID-19 vaccination status (Number of doses and duration since last dose)	Total (n = 638)	RT-PCR Negative n = 346; (54.2%)	RT-PCR Positive n = 292; (45.7%)	P value
Unvaccinated	164 (25.7)	54 (32.9)	110 (67.0)	<0.001
One dose taken in less than 14 days of symptoms onset	50 (7.8)	18 (36.0)	32 (64.0)	
One dose taken in more than 14 days of symptoms onset	110 (17.2)	52 (47.2)	58 (52.7)	
Second dose taken in less than 14 days of symptoms onset	74 (11.6)	44 (59.4)	30 (40.5)	
Second dose taken in more than 14 days of symptoms onset	240 (37.6)	178 (74.1)	62 (25.8)	

Table 3
Linear logistic regression showing association between COVID-19 vaccine status and RT-PCR positivity among study population (n=638).

COVID-19 vaccination status (Number of doses and duration since last dose)	Unadjusted OR ^a (95% CI)	P-Value	Adjusted for age OR ^a (95% CI)	P-Value	Adjusted for comorbidities OR ^a (95% CI)	P-Value	Adjusted for age and comorbidities OR ^a (95% CI)	P-Value
Unvaccinated	1		1		1		1	
One dose taken in less than 14 days of symptoms onset	0.87 (0.45–1.69)	0.687	0.83 (0.44–1.70)	0.593	0.88 (0.45–1.73)	0.720	0.85 (0.43–1.68)	0.649
One dose taken in more than 14 days of symptoms onset	0.55 (0.33–0.89)	0.017	0.58 (0.34–0.94)	0.027	0.54 (0.33–0.88)	0.015	0.56 (0.34–0.93)	0.025
Second dose taken in less than 14 days of symptoms onset	0.33 (0.19–0.59)	<0.001	0.35 (0.19–0.61)	<0.001	0.32 (0.18–0.57)	<0.001	0.34 (0.19–0.66)	<0.001
Second dose taken in more than 14 days of symptoms onset	0.17 (0.11–0.26)	<0.001	0.17 (0.11–0.27)	<0.001	0.17 (0.11–0.27)	<0.001	0.17 (0.11–0.27)	<0.001

^a OR: odds ratio.

Table 4
Association between COVID-19 vaccination status and severity of disease among RT-PCR positive COVID-19 patients (n=292).

COVID-19 vaccination status (Number of doses and duration since last dose)	Total n=292	Asymptomatic & Mild disease n=211; (72.2%)	Non-ICU Hospitalisation n=38; (13.0%)	ICU n=20; (6.8%)	Death n=23; (7.8%)	p-value
Unvaccinated	110 (37.6)	61 (55.4)	23 (20.9)	14 (12.7)	12 (10.9)	<0.001
One dose taken in less than 14 days of symptoms onset	32 (10.9)	21 (65.6)	6 (18.7)	2 (6.2)	3 (9.3)	
One dose taken in more than 14 days of symptoms onset	58 (19.8)	45 (77.5)	4 (6.9)	3 (5.1)	6 (10.3)	
Second dose taken in less than 14 days of symptoms onset	30 (10.2)	27 (90.0)	2 (6.6)	0 (0.0)	1 (3.3)	
Second dose taken in more than 14 days of symptoms onset	62 (21.2)	57 (91.9)	3 (4.8)	1 (1.6)	1 (1.6)	

Table 5
Multinomial logistic regression showing association between COVID-19 vaccination status and severity of disease among RT-PCR positive COVID-19 patients (n=292).

COVID-19 vaccine status (Number of doses and duration since last dose)	Unadjusted OR ^a (95% CI)	P-Value	Adjusted for age OR ^a (95% CI)	P-Value	Adjusted for comorbidities OR ^a (95% CI)	P-Value	Adjusted for Age and comorbidities OR ^a (95% CI)	P-Value
Asymptomatic vs Hospitalisation								
Unvaccinated	1.0		1.0		1.0		1.0	
One dose taken in less than 14 days of symptoms onset	0.76 (0.27–2.11)	0.596	0.57 (0.19–1.68)	0.307	0.74 (0.26–2.08)	0.571	0.57 (0.19–1.68)	0.310
One dose taken in more than 14 days of symptoms onset	0.24 (0.08–0.73)	0.012	0.25 (0.08–0.79)	0.018	0.24 (0.08–0.73)	0.012	0.24 (0.08–0.79)	0.019
Second dose taken in less than 14 days of symptoms onset	0.19 (0.04–0.89)	0.035	0.18 (0.04–0.86)	0.031	0.19 (0.04–0.85)	0.030	0.17 (0.04–0.83)	0.029
Second dose taken in more than 14 days of symptoms onset	0.14 (0.04–0.49)	0.002	0.13 (0.03–0.46)	0.002	0.13 (0.04–0.47)	0.002	0.12 (0.03–0.45)	0.002
Asymptomatic vs ICU/Death								
Unvaccinated	1.0		1.0		1.0		1.0	
One dose taken in less than 14 days of symptoms onset	0.56 (0.19–1.64)	0.290	0.37 (0.11–1.26)	0.113	0.56 (0.19–1.63)	0.282	0.38 (0.11–1.27)	0.282
One dose taken in more than 14 days of symptoms onset	0.47 (0.20–1.10)	0.081	0.46 (0.17–1.29)	0.141	0.47 (0.19–1.09)	0.080	0.47 (0.17–1.29)	0.080
Second dose taken in less than 14 days of symptoms onset	0.09 (0.01–0.67)	0.019	0.07 (0.01–0.64)	0.019	0.08 (0.01–0.65)	0.018	0.07 (0.01–0.65)	0.020
Second dose taken in more than 14 days of symptoms onset	0.08 (0.02–0.36)	0.001	0.07 (0.01–0.35)	0.001	0.08 (0.02–0.35)	0.001	0.07 (0.01–0.36)	0.001

^a OR: odds ratio.

noteworthy findings. Firstly, both the Indian vaccines provided a significant protective role in preventing the disease among people who had a clinical suspicion of COVID-19. Secondly, These vaccines protected from progression to a severe form of the disease among the patients who turned RT-PCR positive despite getting vaccinated. The probability of hospitalisation was about eight times less, and ICU admission/death was about fourteen times lesser among fully vaccinated patients in comparison to unvaccinated RT-PCR positive patients (Table 5). Thirdly, the protective efficacy of the vaccines had a dose-dependent effect. The effectiveness is maximum among individuals who received both doses of vaccination at least two weeks before the onset of their symptoms. However, significant protective effects were also observed among individuals who received the first dose at least 14 days before symptoms onset. The level of protection increased subsequently, reaching its maximum after two weeks from the second dose.

During the second wave of the pandemic, many people in India were exposed to the risk of COVID-19. During this time, there was a surge of the newer delta variant (B.1.617.2) of SARS CoV-2 which was accounted for around 87% COVID-19 cases in Delhi and North India in May 2021. B.1.1.7 (alpha), B.1.351 (beta), P.1 (gamma) and some other lineages were responsible for the rest of the infections [11,12]. Many people had developed the disease despite being vaccinated, either partially or fully. This raised a question on the efficacy and protection of the vaccines available in India against this new strain. In the United States, BNT162b2 (Pfizer) and mRNA1273 (Moderna) are two mRNA vaccines that are majorly being used in their vaccination programme. Clinical trials have already demonstrated considerably high vaccine efficacy rates (95% and 94.1% for BNT162b2 and mRNA1273, respectively) in the American population [13]. The vaccination drive in India started primarily with two vaccines; Covishield and Covaxin. Both of them are administered as two intramuscular injections in an interval of 4–12 weeks. Covishield (ChAdOx1 nCoV-19, AZD1222) has been shown to provide an efficacy rate of 70.4% (95.8% CI: 54.8–80.6) [14]. Covaxin (BBV152) efficacy has been analyzed by *in vitro* neutralisation studies against different variants of SARS CoV-2 [15,16]. Currently, 6.2% of the Indian population have received two doses, whereas 24.1% are yet to receive the second shot [17]. In an unpublished trial conducted by the Indian Council of Medical Research (ICMR), it was

revealed that two doses of COVID-19 vaccines were able to prevent 95% of COVID-19 related deaths in Indian police personnel [18]. As these vaccines will be administered to another one billion people, clinical studies must determine the actual protection conferred by them.

There is no published data till date, to endorse the beneficial role of the Indian vaccines in the real-world scenario in preventing the disease or its severity. There is still significant vaccine hesitancy in the Indian population, possibly due to the scarcity of data demonstrating the effectiveness of the vaccines currently used in this country. This study reveals that both the vaccines are significantly effective in preventing COVID-19 and reducing disease severity (hospitalisation, ICU admission/death), even in patients who were infected with the newly emerged delta variant. This data will provide another scientific basis to encourage the general population of India to get fully vaccinated at the earliest.

The major strength of this study is its objective approach in analyzing the protective effect of the vaccines in a real-world situation. Studies have already proven the immunogenicity or antibody response elicited by the vaccines currently being administered in India. Our research findings have established their clinical efficacy. However, one should interpret the results of this study with caution as the study population was relatively young with fewer comorbidities, and thus, this study does not fully establish its applicability in the older and comorbid population. Besides, this study relied on the responses obtained from telephonic interviews or online surveys and is therefore liable to recall bias. Also, this study does not report the COVID-19 virus strain data of individual patients, but takes into account the prevalence of the circulating strains of the virus in the region at that time.

5. Conclusion

Vaccine hesitancy is still prevailing in India regarding COVID-19 vaccination. It is the need of the hour to generate reliable data on the clinical efficacies of the vaccines currently used in this country. This study has revealed that the probability of contracting COVID-19 after 14 days from the second dose was 83% lower while compared with the unvaccinated individuals. The risks of hospitalisation and ICU admission/death were reduced by 88% and 93%,

respectively, in patients who developed COVID-19 after 14 days from receiving the second dose. The protective effects were observed to start after 14 days from the first dose, and it increased incrementally with the subsequent dose to reach its peak after 14 days from the second dose of vaccination. Therefore, vaccination was found to be highly beneficial in preventing COVID-19, even in patients who were infected with the delta variant. Furthermore, it effectively reduced the chance of progression to severe disease.

Declaration of competing interest

There is no conflicts of interest between the authors.

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