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Incidence and severity of SARS-CoV-2 virus post COVID-19 vaccination: A cross-sectional study in India

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ABSTRACT

Introduction: Several sociodemographic variables, including ethnic inequality, have been identified as potentially influencing the uptake of COVID-19 vaccinations. To develop herd immunity against COVID-19, at least 70–85% of the population must be vaccinated. As the situation with COVID-19 changes, the public's perception keeps fluctuating. We designed a survey to determine the prevalence of vaccinated individuals and the rate of infectivity post-vaccination. We also aimed to study the clinical manifestations and infectivity of the SARS-CoV-2 virus post-vaccination.

Materials and methods: A cross-sectional study was conducted from May 10, 2021 to July 10, 2021 across India through a pre-tested validated semi-structured self-administered electronic questionnaire, to the study subjects with objectives explained and the confidentiality of the data and results had been assured. The questionnaires were prepared using Google forms and the link was sent across social media platforms such as WhatsApp, Facebook, and various social platforms where people are actively engaged following the restrictions and protocols of social distancing. General demographic data, followed by their lifestyle and comorbid conditions, and data on their vaccination, infectivity, and side effects were collected.

Results: We included 2334 participants in the study, of which the majority of the study participants were in the age group of 25–34 years (38.6%). 1729 were vaccinated individuals of which 80.7% had received Covishield and 17.8% had received Covaxin. Around 61.1% have received both doses among 1729 vaccinated individuals and 38.9% had received only one dose of vaccine. The majority of the fully vaccinated individuals had a gap of 4–5 weeks for the second dose (37.1%) followed by 5–6 weeks (11.2%). Post-vaccination 50.8% had experienced muscle pain, 46% had experienced fatigue, 36.5% weakness, and 12.3% back pain. Among vaccinated 26% turned out to be COVID-19 positive and 44.5% non-vaccinated got infected. The odds of infection among non-vaccinated individuals was 2.27 times higher than vaccinated individuals. Individuals who encountered the viral antigen for the second time experienced either through vaccination or infection demonstrated exaggerated inflammatory response which is explained by the antibody-dependent enhancement phenomenon without life-threatening complications.

Conclusion: Although more than 50% of the vaccinated individuals experienced some form of musculoskeletal side effects, we noted a high acceptance rate (74%) of vaccination among the participants. The vaccinated individuals were two times safer from infection compared to the non-vaccinated individuals.

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1. Introduction

COVID-19 was declared a pandemic by the World Health Organization (WHO) in March 2020.[1,2] By December 5, 2021, 265 million cases had been documented globally, with 5.26 million deaths.[3] COVID-19 preventive measures were practiced ineffectively in 2020,[4] and India was hit by a second wave of the epidemic in mid-2021.[5] In these conditions, mass vaccination is the most effective way to combat the pandemic.[6] Most coastal states have achieved >50% adult vaccination since the introduction of COVID-19 vaccines, thanks to pro-immunization initiatives. The average number of daily dosages delivered declined after peaking at 6.44 million on June 26. Vaccine reluctance remained high in certain locations, with more than 60% of the adult population remaining unvaccinated (as of June 2021). Several sociodemographic variables, including ethnic inequality, have been identified as potentially influencing the uptake of COVID-19 vaccinations.[7]

Vaccine apprehension may be trending, and the WHO has listed it as one of the biggest dangers to world health.[8,9] When compared to people of other races, African Americans had a lesser acceptance of influenza and COVID-19 vaccinations. However, a larger perceived risk of COVID-19 is a novel notion that has been shown to boost COVID-19 vaccination uptake despite individual preferences.[10–12]

To develop herd immunity against COVID-19, at least 70–85% of the population must be vaccinated.[13–15] As the situation with COVID-19 changes, the public's perception keeps fluctuating. Pfizer revealed in November 2020 that its COVID-19 vaccine was 95% effective in illness prevention, and the vaccine was thereafter released.[16] Soon after, tales of negative impacts inundated social media channels.[17] As a result, individuals have become increasingly skeptical of the COVID-19 vaccination.[17,18]

We designed a survey study with the primary aim to determine the prevalence of vaccinated individuals and the rate of infectivity post-vaccination. Secondary objectives were to study the clinical manifestations and infectivity of the SARS-CoV-2 virus post-vaccination.

2. Materials and methods

A cross-sectional study was conducted from May 10, 2021 to July 10, 2021 across India through a pre-tested validated semi-structured self-administered electronic questionnaire, to estimate the prevalence of vaccinated individuals and the rate of infectivity post-vaccination. The questionnaires were prepared using Google forms and the link was sent across social media platforms such as WhatsApp, Facebook, and various social platforms where people are actively engaged following the restrictions and protocols of social distancing.[19] General demographic data, followed by their lifestyle and comorbid conditions, and data on their vaccination, infectivity, and side effects were collected. Informed consent was taken from the respondents before the study and an option to terminate their participation was made available anytime they desired in the form by default. The target sample size of participants was determined using the epi info sample size calculator, the vaccine acceptance rate was estimated at 21%[20] and with a 3.3% confidence limit, 99.99 confidence level, the calculated sample size is 2334, adding 2% non-response rate the final sample size is 2382. The Institutional Ethics Committee approval was obtained for the conduction of the study.

Statistical software used to analyze data were MS Excel, SPSS for Windows Inc. Version 25. Chicago, Illinois. Descriptive statistics were reported as mean and standard deviation for continuous variables, frequencies (percentage) for categorical variables. Proportions were compared using the chi-square test. Multiple logistic regression was used to find the risk of disease positivity with demographic variables. For all comparisons, the p-value of <0.05 was considered statistically significant.

Table 1
Demographic characteristics of the study participants (N = 2334).

Variable	Frequency	Percentage
Age (years)		
18–24	860	36.8
25–34	901	38.6
35–44	240	10.3
45–54	166	7.1
55–64	108	4.6
65 and above	59	2.6
Gender		
Male	1234	52.9
Female	1100	47.1
Education		
Bachelor's degree	1199	51.4
Doctorate	222	9.5
High school graduate	270	11.6
Master's degree	595	25.5
None of the above	48	2.0
Region		
Central India	200	8.6
East India	138	5.9
North India	796	34.1
North-Eastern India	67	2.9
North-Western India	29	1.2
South India	929	39.8
Western India	175	7.5

Table 2
Distribution of lifestyle risk factors among the study participants (N = 2334).

Variable	Frequency	Percentage
History of smoking		
Yes, Regular active smoker	99	4.2
Yes. occasional active smoker	215	9.2
Yes, passive smoker	102	4.4
No history of smoking	1918	82.2
History of alcohol consumption		
Yes, consume regularly	42	1.8
Yes, consume occasionally	779	33.4
No history of alcohol consumption	1513	64.8
Exercise daily		
Yes	881	37.7
No	1453	62.3
Co-morbidity		
Yes	391	16.8
No	1943	83.2
Listed co-morbidities		
Asthma	57	2.4
CVD	15	0.6
CKD	11	0.5
COPD	13	0.6
DM	45	1.9
DM & HTN	32	1.4
HTN	111	4.8
Thyroid	107	4.6
Any history of surgical intervention for any bone, joint, muscle, soft tissue or nerve related conditions		
Yes	255	10.9
No	2079	89.1
How recently were u been operated		
<1 month ago	17	0.7
>1 year ago	274	11.7
1–6 months ago	17	0.7
6–12 months ago	11	0.5
Vaccinated		
Yes	1729	74.1
No	605	25.9

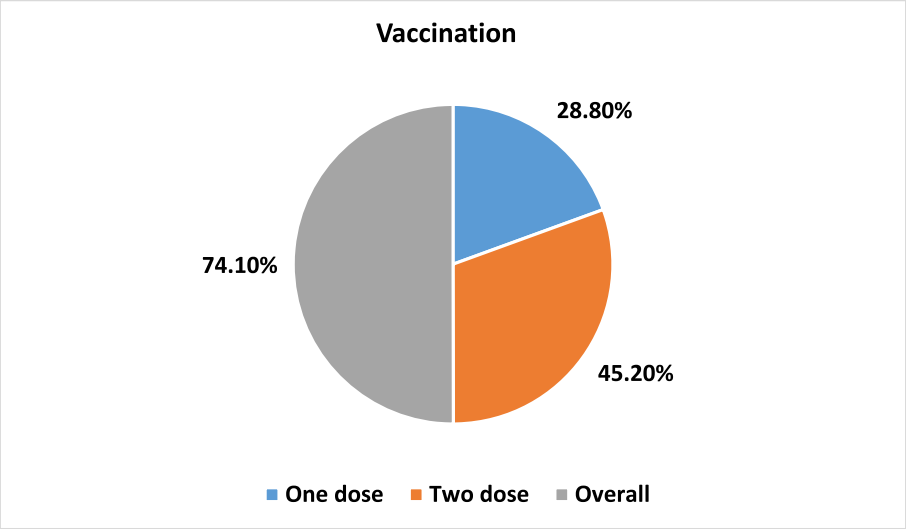

Fig. 1. Distribution of percentage of vaccinated individuals among the study participants (N = 2334).

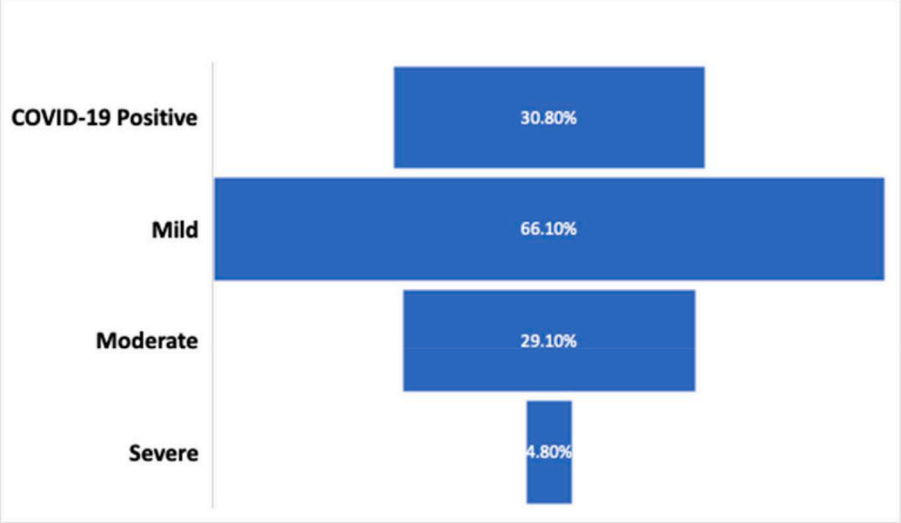

Fig. 2. Distribution of infectivity and severity among vaccinated individuals (n=1729).

3. Results

There were 2382 responses out of which 48 declined participation, hence the final sample size was 2334. Table 1 gives the demographic characteristics of the study participants. The majority of the study participants were in the age group of 25–34 years (38.6%) followed by 18–24 years (36.8%), 10.3% in 35–44 years, 7.1% 45–54 years, 4.6% 55–64 years and 2.6% 65 years and above. There was a male preponderance with 52.9% were males. The majority of them had Bachelor's degrees (51.4%) followed by master's degrees 25.5%. The majority of the respondents were South Indians (39.8%) followed by North Indians (34.1%).

In our analysis, women (1243) felt the need to vaccinate more often than men (318) ($p = 0.043$). They were more satisfied with the decision to vaccinate (women = 1251, men = 337; $p = 0.043$). People with higher education were more motivated to vaccinate themselves, having known the rationale behind vaccination ($p = 0.002$) and they would choose a vaccine based on the viral mRNA technology Pfizer (911) and Moderna (39).[21]

Lifestyle risk factors were tabulated in Table 2. There were about 17.8% smokers, 35.2% alcoholics, 37.7% of the participants who exercise daily, 16.8% having one or the other co-morbidities, 10.9% had a history of surgical intervention for any bone, joint, muscle, soft tissue, or nerve-related conditions. Overall, 74.1% were vaccinated with a minimum of one dose of vaccine (Fig. 1) (see Fig. 2).

In our study among 1729 vaccinated individuals, 80.7% had received Covishield and 17.8% have received Covaxin. Around 61.1% have received both doses among 1729 vaccinated individuals and 38.9% had received only one dose of vaccine. The majority of the fully vaccinated individuals had a gap of 4–5 weeks for the second dose (37.1%) followed by 5–6 weeks (11.2%) (Table 3). Post-vaccination 50.8% had experienced muscle pain, 46% had experienced fatigue, 36.5% weakness, and 12.3% back pain. On the second dose, 55.9% didn't experience any side effects followed by 15% muscle pain, 14% fatigue, 10.3% weakness, 3.4% joint pain, and 3.1% back pain.

Among vaccinated 26% turned out to be COVID-19 positive whereas 44.5% among non-vaccinated participants got infected. The odds of infection among non-vaccinated individuals were 2.27 times higher than vaccinated individuals (Table 4).

Table 5 shows the association of clinical parameters and disease infectivity among vaccinated individuals. The IL-6 count (pg/ml) during the active infective phase including home-based care, ferritin level (ng/

Table 3
Distribution of parameters on vaccine among the study participants (n = 1729).

Variable	Frequency	Percentage
Type of vaccine		
AstraZeneca	1	0.06
Coronavac	3	0.2
Covaxin	308	17.8
Covishield	1395	80.7
Moderna	5	0.3
Pfizer 13	13	0.75
Sputnik V	4	0.23
Are you full vaccinated (both dosages of covishield, covaxin, sputnik V)		
Yes	1056	61.1
No	673	38.9
What was the period of difference for taking the second dosage of the COVID-19 vaccine?		
4–5 weeks	642	37.1
5–6 weeks	196	11.3
6–7 weeks	140	8.1
7–8 weeks	130	7.5
8–12 weeks	166	9.6
More than 12 weeks	91	5.3
Did you experience any musculoskeletal pain after the first dose of the COVID-19 vaccination?		
Backpain	213	12.3
Weakness	631	36.5
Fatigue	796	46.0
Joint pain	232	13.4
Muscle pain	878	50.8
None	421	24.3
Did you experience any musculoskeletal pain after the second dose of the COVID-19 vaccination?		
Backpain	53	3.1
Weakness	178	10.3
Fatigue	243	14.1
Joint pain	59	3.4
Muscle pain	260	15.0
None	968	55.9

Table 4
Association of vaccine and severity of the disease (N = 2334).

Variable	Vaccinated (n = 1729)	Non-vaccinated (n = 605)	Chi-square (df) p	OR (95% CI)
COVID-19 positive				
Yes	450 (26%)	269 (44.5%)	71.45 (1)	1
No	1279 (74%)	336 (55.5%)	<0.001	2.27 (1.87–2.76)
Severity of infection				
Mild	309 (17.9%)	166 (27.4%)	80.640 (3) <0.001	2.045 (1.635–2.557)
Moderate	126 (7.3%)	83 (13.7%)		2.507 (1.854–3.392
Severe	15 (0.9%)	20 (3.3%)		5.075 (2.571–10.020)
No infection	1279 (74%)	336 (55.5%)		1

ml), and LDH level (U/L) were clinically raised among vaccinated individuals compared to non-vaccinated individuals.

4. Discussion

The obtained research results indicate, the lack of reporting of side effects after the administration of the COVID-19 vaccine by people. The COVID-19 vaccines can induce moderate side effects after the first or second dose such as pain, redness, or swelling at the site of vaccination along with fever, exhaustion, headache, nausea, vomiting, itching, chills, and can infrequently cause anaphylactic shock.[22] Quality documentation of the side effects of vaccine is essential as it encourages

Table 5
Association of clinical parameters and disease infectivity among vaccinated individuals (n=719).

Variable	Vaccinated (n = 450)	Non-vaccinated (n = 269)	Chi-square (df) p
What was your treatment plan?			
Both home-based + ICU	35 (7.8)	24 (8.9)	
Home isolation	352 (78.2)	204(75.8)	0.81
Hospital-based care with ICU	26 (5.8)	15 (5.6)	(3)
Hospital-based care with oxygen support	37 (8.2)	26 (9.7)	0.84
If hospital-based care what was the duration for the same?			
>6 weeks	37 (8.2)	23 (8.6)	
1–2 weeks	47 (10.4)	26 (9.7)	3.69
2–4 weeks	11 (2.4)	14 (5.2)	(3)
4–6 weeks	5 (1.1)	2 (0.7)	0.29
Maximum CRP count (mg/dl) during the active infective phase including home-based care			
0-6 (normal)	101 (22.4)	60 (22.3)	
<26 (mild)	106 (23.6)	56 (20.8)	2.378
26-100 (moderate)	56 (12.4)	33(12.3)	(4)
>100 (severe)	13 (2.9)	13 (4.8)	0.67
Not aware	174 (38.7)	107 (39.8)	
What was the maximum reported range of IL-6 count (pg/ml) during the active infective phase including home-based care			
0-7 (normal)	106 (23.6)	48 (17.8)	
<15 (mild)	52 (11.6)	21 (7.8)	8.88 (5)
15-100 (moderate)	42 (9.3)	27 (10)	0.07
100-500 (severe)	6 (1.3)	3 (1.1)	
>500 (critical)	0	1 (0.4)	
Not aware	244 (54.2)	169 (62.8)	
Maximum reported range of D-dimer level (mcg/ml) during the active infective phase including home-based care			
<0.5 (normal)	144 (32)	78 (29)	4.478 (3)
<1 (mild)	61 (13.6)	32 (11.9)	0.21
>1 (moderate-severe)	43 (9.6)	18 (6.7)	
Not aware	202 (44.9)	141 (52.4)	
Maximum reported range of ferritin level (ng/ml) during the active infective phase including home-based care			
<13	55 (12.2)	30 (11.2)	9.768 (3)
13–150	56 (12.4)	24 (8.9)	0.02
>150	73 (16.2)	27 (10)	
Not aware	266 (59.1)	188 (69.9)	
Maximum reported range of your LDH level (U/L) during the active infective phase including home-based care			
0–250	61 (13.6)	25 (9.3)	12.434 (2)
>250	95 (21.1)	35 (13)	0.002
Not aware	294 (65.3)	209 (77.7)	
Maximum reported range of your ESR count (mm/hr) during the active infective phase including home-based care			
0–22	95 (21.1)	48 (17.8)	1.934 (2)
>22	70 (15.6)	37 (13.8)	0.38
Not aware	285 (63.3)	184 (68.4)	

healthcare providers to communicate in a systematic, consistent, and effective manner.[23] In a study by Jęśkowiak et al.[24] statistically significant side effects after receiving the vaccine were noted which include pain at the injection site (1275; $p < 0.0001$), redness at the injection site (696; $p < 0.0001$), and pain in the limb (766; $p < 0.0001$) after the first dose of the vaccine, and after the second dose of the vaccine, a temperature above 38 °C (226; $p = 0.04$).

There was significant correlation between first dose of vaccine shot and side effects of the vaccine along with occurrence of covid 19 infection. Among those non infected with covid 19, stronger side effects were reported after the second dose of the vaccine ($p < 0.001$). In our study, post-second dose of vaccine, although around 55.9% didn't experience any side effects, 15% experienced muscle pain, 14% had fatigue, 10.3% with weakness, 3.4% had joint pain, and 3.1% with back pain which is significantly high ($p < 0.001$) compared to the reported

side effects after the first dose of the vaccine in non-infected individuals.

In our study, association of clinical parameters and disease infectivity among vaccinated individuals were assessed. The IL-6 count (pg/ml) during the active infective phase including home-based care, ferritin level (ng/ml), and LDH level (U/L) were clinically raised among vaccinated individuals significantly ($p < 0.001$) compared to non-vaccinated individuals.

In a study by Jęśkowiak et al.,[24] T-cell and antibody responses correlate with the severity of COVID-19 clinical disease. Among those previously infected with covid 19, the adverse effects reported after the first dose of vaccine may be because of antibody-dependent enhancement (ADE). ADE refers to a situation in which antibodies that would normally lessen the consequences of a viral infection end up doing the opposite: they fail to control the virus' pathogenicity, or even enhance its virulence by facilitating its entry into the cell, or by triggering an extensive reaction, causing damage to the host organs through hyper-inflammation (cytokine storm).[25] In comparison to patients with severe disease, patients with milder disease have more clonal expansion and less active proliferation in CD8 T-cells in the bronchial fluid, as well as lower blood cytokine levels.[26]

Our study has certain limitations. We could not achieve an overall representative data across all the age groups subjected for vaccination. Secondly, the cross-sectional observational nature of our study and the chosen sampling method may limit the validity of the results obtained. On the other hand, the strengths of our work include the novelty of the topic, the large sample size, and identification of the under-reported problem pertinent to the population subjected to vaccination. It also clearly exposes the lack of awareness of the people to report side effects for any health-related intervention being administered on large scale. In addition, the study identified the most frequent side effects associated with vaccination, such as fatigue and weakness.

5. Conclusion

Although more than 50% of the vaccinated individuals experienced some form of musculoskeletal side effects such as muscle pain, and fatigue following first dose of vaccination, we noted a high acceptance rate (74%) of vaccination among the participants. We did not note such high prevalence of adverse events following second dose of vaccination. The vaccinated individuals were 2.27 times safer from infection compared to the non-vaccinated individuals.

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Declaration of competing interest

Nil.

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Nil.

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