

Original Research Article

Spectrum of SARSCOV2 infection with the efficacy of Covaxin and Covishield vaccines during third wave of COVID-19 pandemic: an experience of a densest state of India

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ABSTRACT

Background: Study was conducted to assess the trend or characteristic of SARSCOV2 infection during 3rd wave of pandemic and to compare the efficacy of Covaxin and Covishield Vaccines.

Methods: This descriptive cross-sectional study was conducted with a mixed-method approach (Explanatory sequential mixed method) among the SARSCOV2 infected patients of West Bengal, India on the month of January 2022. In quantitative analysis 277 SARSCOV2 infected patients who were detected as COVID positive within January, were selected randomly from the secondary data source (collected by 20 general practitioners). In qualitative analysis, 11 patients from different categories were interviewed in-depth over the telephone to explain the quantitative data. Bivariate analysis (Mann Whitney U or Kruskal Wallis test) was used as per applicability. Kaplan Meir plot compared the efficacy of Covaxin and Covishield vaccines.

Results: Most commonly presented symptom were low-grade fever (78.7%), a mild cough (41.9%), mild cold (62.4%), sore throat (41.9%), body ache (47.3%), and headache (33.2%). Few patients had experienced breathing difficulty (1.4%) and hospitalization (1.1%). Mann Whitney U test significantly ($p < 0.001$) justified that Covaxin receivers have infected in late (median 161 days) comparison to other vaccines receivers (Covishield and Sputnik V median 129 days and 115 days respectively). This finding was also demonstrated in Kaplan Meir Plot.

Conclusions: During the 3rd wave of the pandemic, SARSCOV2 infected patients commonly presented with milder symptoms, minimal hospitalization and without any case fatality. Delaying of infection has been observed more among Covaxin receivers compared to others.

Keywords: 3rd wave, Covaxin, COVID-19 pandemic, Covishield, Mixed method study

INTRODUCTION

The emergence of the COVID-19 pandemic since January 2020 has brought an imbalance in the world ecosystem to the world economy. In several countries, its impacts were various. The timing of surging of cases and severity of diseases found widely varied in different continents. Since the first reported case of COVID-19 (January 30, 2020) till now a total of 35 million cases and 486066 deaths have been reported in India.^{1,2} India witnessed a massive surge of COVID-19 cases as a

second wave since March 2021 and experienced its deadly impact.³ Increasing daily test positivity rate with steep rising of the absolute number of cases indicated that India stepped towards 3rd wave of COVID pandemic.⁴

Increasing trend of SARSCOV2 infection cases and high transmissibility of the disease in India at the end of December 2021; was indicating that India was approaching the 3rd wave of the COVID-19 pandemic. As West Bengal is the densest state of the Country and its population has the busiest national and international

travel schedule every day, it was expected that the 3rd wave would hit the state very soon. With the current trend of the high transmissibility rate of newer strain and less administrative attitude towards stringent lockdown, a massive surge of cases was experienced here. With this background, the study was conducted to assess the trend of SARSCOV2 infection and to explore the experiences of affected people. In this context, a comparative evaluation of the efficacy of different vaccines was also planned. In case of a high transmissibility rate, the epidemic curve of infectious diseases was narrowly based and it continued for 1 to 2 months. This study result or evidences would be helpful to understand the 3rd wave of pandemics and would provide baseline clinical evidence to take appropriate measures in the future to alleviate the pandemic situations.

METHODS

A descriptive cross-sectional study was conducted with mixed method approach (Explanatory sequential mixed method) among the SARSCOV2 infected patients of West Bengal during the month of January, 2022. Patients who were residing in West Bengal since last 5 years and whose samples were collected and reported as positive within 1st to 31st January 2022 were included as our study population. Patients whose data were incomplete excluded from the study. The study was planned and conducted from Bankura Sammilani medical college of Bankura, West Bengal, India.

In the first week of January total 73472 new cases were reported in West Bengal.² The proportion of new case detection among 10.14 crore West Bengal inhabitants was 0.7%.⁵ Using the formula $n = z^2 pq / e^2$ (where, n=sample size, z=value of standard normal deviate=1.96 at 95.0% confidence interval, p=proportion of new case detection, q=100-p, e=allowable error=1.0%), 277 was calculated as final sample size.

For the data collection 20 experienced busy general practitioners were selected purposively from different districts of West Bengal like Kolkata, North and South 24 Parganas, Nadia, Burdwan, Midnapore and Jalpaiguri where maximum COVID cases were reported during previous waves of the pandemic. At end of December 2021 when COVID cases were increasing, they were informed about study and willing doctors were requested to collect all necessary data meticulously. Severity or grading of symptoms was noted on the basis of patient's responses with the collaboration of clinician's findings. Before the data collection it was ensured that all doctors treated the patients as per the state guidelines. Necessary permission was obtained from institutional review board.

For quantitative analysis, 277 samples were selected by using simple random sampling method from these secondary data sources. Sampling frame had 531 patients. Secondary data were collected on March, 2022 from above mentioned sources. This data were used to analyze

the trend of current SARSCOV2 infection pattern during the 3rd wave. Data were compiled in Microsoft excel worksheet and subsequently analyzed using Microsoft excel functions and statistical package for the social sciences version 16.0 (IBM Corp, Armonk, NY, USA). Central tendency of data was represented by mean/median value. Standard deviation or Inter-quartile range was used to represent dispersion of data. Bivariate analysis (Mann Whitney U or Kruskal Wallis test as per applicability) was conducted to find out the association between patient's profile and time interval within last dose of vaccination and COVID positive report. In this study, all the cases were censored or COVID 19 positive. Probability of delaying infection after the last dose of vaccine used to measure vaccine efficacy here. Kaplan-Meir plot compared the probability of COVID-19 infection after receiving the last dose of Covaxin and Covishield vaccines.

For qualitative analysis, 11 different categories patients (5 from 52 re-infected patient, all 3 hospitalized patient and 3 out of 7 unvaccinated patients) were selected purposively from above study sample. They were interviewed in depth over telephone regarding their experiences about the course of the disease after getting remission. Before the interview the patients were ensured that their responses were recorded anonymously and informed consents were obtained subsequently. The thematic analysis was used for qualitative analysis. Responses were transcribed as it was recorded during telephonic conversation. All transcripts were read and re-read and themes were constructed. Themes were coded. Newer data were constantly compared to previous data and label of themes were refined accordingly. Ultimately developed themes were analyzed. End of Qualitative analysis data triangulation or integration done to justify or to explain the quantitative analysis findings (Figure 1).

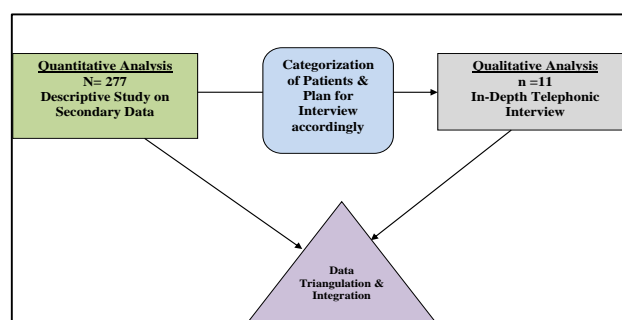


Figure 1: Schematic diagram of the study design.

RESULTS

Quantitative analysis

Median age of the study population was 36 years (interquartile range 26 years). Among the study population, 52.3% were male, and 17.7% were geriatric patients. One-third population (33.2%) had one or more

comorbidities like type 2 diabetes mellitus, hypertension, hypothyroidism, bronchial asthma, ischaemic heart disease etc. Most of the patients (97.8%) were vaccinated. Among, those mostly (97.4%) had received two doses of vaccines. In this state, maximum citizens had received the Covishield vaccine (87.5%) followed by Covaxin (9.9%) and Sputnik V (2.6%) vaccine (Table 1).

Table 1: Distribution SARSCOV2 infected patients according to their demographic, clinical and vaccination profile.

Variables		Number (%)
Age, (Years) (n=277)	<60	229 (82.7)
	≥ 60	48 (17.3)
Gender, (n=277)	Male	145 (52.3)
	Female	132 (47.7)
Co-morbidity, (n=277)	Yes	92 (33.2)
	No	185 (66.8)
Vaccination, (n=277)	Yes	271 (97.8)
	No	6 (2.2)
Fully vaccinated, (n=271)	Yes	264 (97.4)
	No	7 (2.6)
Type of vaccine received, (n=271)	Covishield	237 (87.5)
	Covaxin	27 (9.9)
	Sputnik V	7 (2.6)
Re-infection of COVID, (n=277)	Yes	52 (18.8)
	No	225 (81.2)
Median (IQR)		
Time interval between last dose of vaccination and COVID positive report, (n=271)	Covishield	129 (68)
	Covaxin	161 (59)
	Sputnik V	115 (11)

The average [Median (IQR)] time interval between the last dose of vaccination and COVID positive report was 130 days (67 days). The shortest interval was 40 days, and the longest was 265 days. Histogram with distribution curve, Skewness (0.505) and Kurtosis (0.216) value indicates that data distribution was not normal. The median value of time interval was long among Covaxin receivers (161 days) followed by Covishield (129 days) and Sputnik V receivers (115 days).

In bivariate analysis (Mann Whitney U test), it was justified significantly (p<0.001) that Covaxin receivers were infected by SARSCOV2 after a long gap, from the last dose of vaccine in comparison to other vaccines receiver. (Table 2). Kaplan Meier plot also showed that the probability of COVID-19 infection after receiving the last dose of Covaxin was delayed than Covishield and this difference was statistically significant in Log rank (Mantel-Cox) test [$\chi^2= 8.392$, df=1, p=0.004] (Figure 2).

About one-fifth population had a history of re-infection of COVID (18.8%). All of them had received two doses of vaccines. Among them, 71.2% received Covishield, 15.2% Covaxin and 13.5% received Sputnik V. One fifth

(21.2%) of re-infected patients had co-morbidity history. In the case of re-infected patients, the median time interval between the last dose of vaccination and COVID positive report was 111 days for Covishield, 135 days for Covaxin and 115 days for Sputnik V. But, the Kaplan Meir plot found no significant difference in probability of preventing re-infection among all vaccines [Log rank (Mantel-Cox) test: $\chi^2= 208$, df= 1, p=0.648] (Table 1).

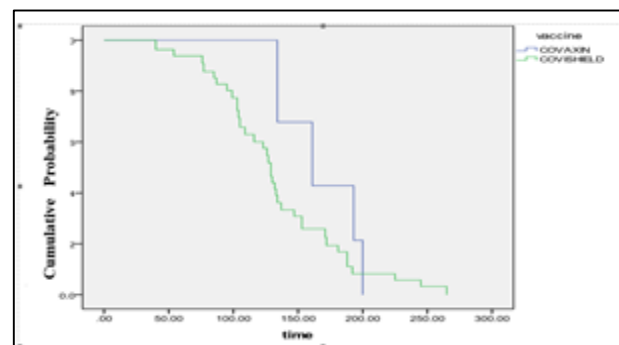


Figure 2: Kaplan Meir plot of probability of COVID-19 infection after receiving last dose of Covishield and Covaxin.

*Log rank (Mantel-Cox) test: $\chi^2= 8.392$, df= 1, p=0.004.

A pattern of clinical symptoms

It clinic-based data, most of them found symptomatic, only 4.3% asymptomatic. Most commonly presented symptoms were low-grade fever (78.7%), mild cough (41.9%), mild cold (62.4%), sore throat (41.9%), body ache (47.3%) and headache (33.2%). Shivering reported by 11.6% patients. Fewer patients had experienced weakness (14.1%), loose motion (2.5%), altered taste (2.5%), breathing difficulty (1.4%) (Table 3).

Table 2: Relationship between patient’s profile and time interval within last dose of vaccination and COVID positive report, (n=271).

Variables		Mean rank	
Age (Years)	<60	135.07	Mann Whitney U test, U=5144.5, p=0.673
	≥ 60	140.32	
Gender	Male	134.69	Mann Whitney U test, U=8980.5, p=0.775
	Female	137.42	
Type of vaccine	Covishield	129.21	Kruskal Wallis test, $\chi^2=19.085$, df=2, p=0.001*
	Covaxin	198.46	
	Sputnik	125.00	
Comorbidity	Present	128.76	Mann Whitney U test, U=7455.00, p=0.288
	Absent	139.54	

*P<0.005 statistically significant.

Table 3: Pattern of clinical symptoms of SARSCOV2 infection during 3rd wave of COVID pandemic, (n=277).

Symptoms	N	Percentage (%)
Fever	No	39 14.1
	Low grade (<100F)	218 78.7
	Moderate grade (100-102 F)	14 5
	High grade (>102 F)	6 2.2
Body ache	No	146 52.7
	Mild	56 20.2
	Moderate	44 15.9
	Severe	31 11.2
Head ache	No	185 66.8
	Mild	59 21.3
	Moderate	33 11.9
Cough	No	118 42.6
	Mild	119 41.9
	Moderate	34 12.3
	Severe	6 2.2
Cold	No	72 26
	Mild	173 62.4
	Moderate	32 11.6
Shivering	Present	32 11.6
	Absent	245 88.4
Sore throat	Present	116 41.9
	Absent	161 58.1
Nausea/vomiting	Present	6 2.2
	Absent	271 97.8
Weakness	Present	39 14.1
	Absent	238 85.9
Altered taste	Present	7 2.5
	Absent	270 97.5
Loose motion	Present	7 2.5
	Absent	270 97.5
Breathing difficulty	Present	4 1.4
	Absent	273 98.6

Outcome

Only three patients (1.1%), was admitted to the hospital, and their median hospital stay was seven days. One of them was admitted to the intensive care unit (ICU), and the rest were treated in a high dependency unit (HDU). All hospitalized patients received two doses of Covishield at least 68 days before infection. They had some co-morbidity like type 2 diabetes mellitus, hypertension, chronic kidney disease or bronchial asthma. Two of them were geriatric patients, and 1 was a middle-aged patient. The mortality rate was zero. Maximum patients (98.9%) cured in home-based care. Their median day of suffering was four days. In case of the unvaccinated patients' median day of suffering was longer (9 days).

Qualitative analysis

Theme 1

Re-infected patient's experience

"9 months before I had COVID again I have been infected now despite all precautionary measures. I had already received two doses of Covishield also."

"Last time symptoms were more severe, had severe weakness, severe decreasing of appetite, in the last time, it took 17 days to recover completely. This time it was like just a common cold. This time symptoms persisted hardly for three days"

Theme 2

Unvaccinated patient's experience

"Due to fear of side-effects I did not receive COVID vaccine yet. I had severe body ache, weakness, loss of appetite. It takes 14 days to recover. But my friends who were vaccinated had minimal symptoms and were cured within 4 to 5 days."

"Symptoms were mild, but it takes ten days to cure."

Theme 3

Hospitalized patient's experience

"I felt shortness of breath on 3rd day of fever, SpO₂ was dropping below 91%. I have type 2 diabetes mellitus and hypertension; I had admitted to HDU of hospital on day six I got discharged."

"I had a history of severe bronchial asthma. Last year I was admitted for an asthmatic attack. This time I was admitted with similar symptoms and diagnosed as COVID positive after admission. I was treated in ICU and discharged on the 13th day."

The quantitative analysis findings matched with unvaccinated patients' experiences. Re-infected and hospitalized patients' experiences explained quantitatively analyzed data elaborately in detail.

DISCUSSION

To explore the trend or pattern of clinical symptoms and severity of the SARSCOV2, among inhabitants of West Bengal, India, during the 3rd wave of the pandemic, this descriptive cross-sectional study was conducted with an explanatory sequential mixed-method approach. Comparative evaluation of vaccine efficacy was also done.

During the 2nd wave, maximum catastrophes were throughout the world including India.⁶ Mortality rate was also very high in India.⁷ From the beginning of the 3rd wave, mortality was less, but high transmissibility of the disease is noticed.⁸ Probably, it was due to the characteristics of newer mutant strains and the effect of the successful vaccination program. The picture was not different here also. Vaccination coverage among SARSCOV2 infected patients of this state of India was found quite well (97.8%). Most of the patients (87.5%) received Covishield vaccine which was found efficacious against moderate to severe COVID-19.⁹ In this research, bivariate analysis has found that Covaxin receivers had infected in delay compared to Covishield and Sputnik V and Kaplan Meir plot also supported this difference. Efficacy of Covaxin has proved in phase 3 trial.¹⁰ Though it does not prove Covaxin as more efficacious than the other two vaccines, the observation is needed to clarify by further experimental study. This quantitative analysis revealed that 97.8% got infection despite vaccination. It is very premature to comment that less hospitalization or less severity of the disease outcome was the success of the vaccination program or due to the characteristic of the mutant strain. The shorter median day (4 days) of suffering indicates the disease as characteristically milder this time. The recovery is less eventful also. Median hospital stays (7 days) during the 3rd wave remain the same as the 1st (8 days) and 2nd wave (7 days) of the pandemic.⁷

During the last wave, the most common presenting symptoms were fever (71.7%), shortness of breath (48.6%), dry cough (39.8%), sore throat (13.8%), headache (11.3%), fatigue (12.3%), etc. in India. In Myanmar, common presenting symptoms were fever 54.1%, loss of smell 50.3%, and cough 30.9% during the last wave.¹¹ In this wave, most commonly presented symptoms are low-grade fever (78.7%), a mild cough (41.9%), mild cold (62.4%), sore throat (41.9%), body ache (47.3%) and headache (33.2%). Only 1.4% of patients had reported shortness of breath. Loss of taste and loss of smell was fewer reported symptoms in both the second and third waves. Milder symptoms have been reported more during this wave in comparison to the 2nd wave.⁷ Proportion of COVID-19 patients with co-morbidities (33.2%) remained same as 2nd wave of pandemic (37.8%).¹¹ Unvaccinated patients had a longer duration of the course of the disease. They reported varied (both mild and moderate) symptoms but had no hospitalization history. The differences in symptoms and duration of disease among vaccinated and unvaccinated patients may reflect the vaccine's success. This finding is collaborating with the Mielke et al study where different aspects of COVID vaccines' success had observed.¹²

Despite full vaccination development of re-infection might raise the question about the extent of vaccine efficacy. Nothing can state as confirmed without any experimental study design and sufficient biological plausibility. All hospitalized patients had one or more co-

morbidities. In the 1st and 2nd wave, 55.9% and 45.9% of hospitalized patients had a history of Co-morbidities respectively.⁷ Present studies found that all hospitalized patients had co-morbidities during this wave. Only one Bronchial asthma patient was admitted to ICU and had a longer hospital stay. Rest was discharged within 1 week from HDU. During the 1st and 2nd wave, 4.7% and 8.0% of hospitalized patients required mechanical ventilation respectively,⁷ but this research had found that mechanical ventilation had used in 33.3% of cases during the 3rd wave. This reflects that the maximum hospitalized patients were critically ill this time though they were very few in numbers (1.1%). In this study, the average hospital stays in the case of non-ICU admitted patients was 6.5 days, and in ICU, it was 13 days. But in Vekaria et al study, non-ICU hospital stays were longer, and ICU hospital stay was the same.¹³ In both types of hospital admitted patients, median hospital stay was less, in Rees systemic review.¹⁴

Qualitative analysis revealed that re-infected patients were experienced less severe symptoms. It was also supported by Soriano et al. They found less clinical severity among re-infected patients during the second wave than during the first wave.¹⁵

Third-phase experiment showed that Covishield (90%) was more effective than Covaxin (80%). But this study's finding was reverse. Das et al study predicted that the efficacy of Covishield might reduce in the future with the trend of dramatically changing spike (S) protein structure.¹⁶ Changing spike proteins of newer strains during the 3rd wave of the COVID-19 pandemic might be the reason for the lesser efficacy of the Covishield vaccine.

As all the study participants were SARSCOV2 positive and had no SARSCOV2 free compare group, vaccine efficacy could not be assessed here directly by observing the disease preventing ability of the vaccines. Indirect method was used here for the assessment of vaccine efficacy like delaying of disease occurrence.

CONCLUSION

During the 3rd wave of the pandemic, commonly presented symptoms of SARSCOV2 infected patients were low-grade fever, mild cough, cold, sore throat, and body ache. This time hospitalization rate was very minimal. Covaxin receivers got the infection after taking last dose of vaccine in longer duration gap in comparison to other vaccine users. This hypothesis has been generated and has tested in this research. Experimental studies should conduct further to prove vaccine efficacy.

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