

Original Article

Effectiveness of vaccination (Sinopharm) among Covid-19 positive patients in a tertiary care hospital

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ABSTRACT

The SARS-CoV-2, has caused a pandemic of acute respiratory disease, ‘coronavirus disease 2019’ (Covid-19), posed a major threat to health and the international economy during past few years. It is believed that vaccine can stop the rapid spread of the disease. The aim of this study was to evaluate the effect of the Sinopharm vaccine in terms of mortality and severity of the disease among Covid-19 positive patients. This observational cross-sectional study was done at the Department of Medicine and Department of Pathology Shaikh Khalifa Bin Zayed Al-Nahyan/CMH Teaching Hospital (Poonch Medical College), Rawalakot AJK Pakistan from July 2021 to September 2021. Total 350 individuals with greater than or equal to 18 years of age, who were tested positive for Covid-19, were included. Patients who had received two doses of the vaccine at least 28 days apart were considered as vaccinated. The Sinopharm vaccination status was checked among patients. The severity of Covid-19 was categorized as mild, moderate and severe. A log rank regression test was applied to determine significant difference in disease severity and survival rate. The patients age range was 25-60 years (the patients mean age was 55 years). The majority of participants, 69.1% (n=242), were vaccinated by Sinopharm, and 30.9% (n=108) were non-vaccinated. Most patients had mild disease 80% (n=280) followed by moderate disease 9.7% (n=34), and severe disease 6.6% (n=23), and stratification analysis had significant ($p \leq 0.05$) association between vaccinated individuals and disease severity. The overall mortality rate was 3.7%. The mortality rate was 8% (n=9) in none vaccinated individuals, whereas 1.65% (n=4) in vaccinated individuals. The Sinopharm vaccine after both doses was found effective in reducing mortality and disease severity by 98.3% and 94.4%. The study concluded that Sinopharm vaccine after two doses at least 28 days apart given to patients, after two weeks of vaccination is highly effective in reducing the mortality, disease severity and hospital admission in Covid-19 positive patients.

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1. Introduction

Covid-19 pandemic started in China in 2019, rapidly spread throughout the world in a span of few months. This disease is a major threat to health and the international economy (1). As of August 16, 2023, 769,806,130 people have been infected with Covid-19 and 6,955,497 have died of, according to the World Health Organization (2). The four deadly waves of this pandemic disease affected many countries around the world. Vaccination has proven effective in reducing risk of infection, severity of the disease and mortality (3). As of August 19, 2023, total 13,499,767,926 vaccine doses have been administered (2). Vaccine is now considered as an important long-term solution for eradicating the SARS-CoV-2 virus (4). In countries where vaccination rate is high there is a significant decline in SARS-CoV-2 related morbidity, hospitalizations, and deaths. However, the availability of vaccines worldwide is not uniform, with percentages ranging 1%-70%, depending on wealth, and policies of a country. Consequently, a new variant of SARS-CoV-2 has emerged leading to a surge in cases, according to WHO (5). Only 25% of people in low-income developing countries have received at least a single dose of Covid-19 vaccine (6). New strains emergence of SARS-CoV-2 is a threat to global protection and the efficacy of mass vaccination efforts against Covid-19 pandemic (7). Despite the evidence of vaccine effectiveness and safety, vaccine acceptance remains controversial across cultures. Ignoring and resisting the Covid-19 vaccination has caused a major crisis for healthcare systems and the economy and threatened global health (8). Biopharmaceutical companies worldwide have developed multiple Covid-19 vaccines, including the Sinopharm vaccine, also known as BBIBP-CorV. This vaccine, along with others, has been developed to combat the Covid-19 virus. In January 2021, the Sinopharm vaccine received emergency approval from Drug Regulatory Authority of Pakistan (9). The effectiveness of two doses of Sinopharm was 79% in phase III clinical trials (10). The reality is that despite being a widely used vaccine in several countries, there is limited study data on the Sinopharm vaccine and its effectiveness, especially in our population. The aim of study was to assess the effect of Sinopharm vaccine in terms of severity of disease and mortality among patients of Covid-19.

2. Materials and Methods

This observational cross-sectional study was done at Medicine Department of Poonch Medical College, and Pathology Department of Shaikh Khalifa Bin Zayed Al Nahyan/CMH Teaching Hospital, Rawalakot AJK Pakistan from August 2021 to October 2021, after getting approval from hospital ethics committee and a written consent from individuals to participate voluntarily in this study. Total 350 individuals with greater than or equal to 18 years of age (WHO sample size calculator was used and the parameters were as follow; around 70% population of AJK had received vaccine, confidence level was 95% and alpha error

was 5%), who were tested positive for Covid-19 PCR at pathology department of same setting hospital were included. The patient's vaccine status of Sinopharm was checked by the vaccine certificate issued by National Database and Registration Authority (NADRA) Pakistan, patients who received two doses of vaccine at least 28 days apart were considered as vaccinated, with one dose or second dose before 28 days were considered as partially vaccinated and those who did not receive any dose were considered as non-vaccinated. Patients who had been vaccinated partially, having duration of less than or equal to 2 weeks between two doses and positive Covid-19 PCR, vaccinated by any other vaccine besides Sinopharm and having booster dose were excluded. A structured proforma was used to record the study outcomes. The proforma contained four sections of questions. First section included demographic details i.e., age and gender. Second section included Covid-19 history and disease severity which was considered as mild, moderate and severe disease. Severity of disease was defined as; Mild category (mild clinical signs, no need for oxygen, no pneumonia on X-ray chest or High-resolution computed tomography or HRCT), Moderate category (fever, cough and pneumonia with CT lung (< 40% penetration), Oxygen saturation (SpO₂) may be greater than or equal to 93% of need oxygen, and Severe category (respiratory distress, resting SpO₂ > 30/min and/or Pa ratio of arterial O₂, fractional inspired O₂ > 300 mmHg (PaO₂/FiO₂), or need O₂ via non-rebreathing mask (NRM), high concentration O₂ non-invasive or invasive via venturi, shock or ARDS) (11). The third part was regarding details of vaccine of Covid-19. The fourth section was about comorbidities, individual required antibiotics, supplementary O₂ given, duration of hospital stay, and mortality. The questions were closed except for those asking about the history, details of positive tests by number of days, or disease severity requiring hospitalization. Statistical analysis was done by using SPSS 25 to see the effect of vaccine on patient's outcome by comparing the vaccinated and non-vaccinated individuals. Descriptive data was measured in the form of frequencies and percentages to describe vaccination rates and mortality rate. Next, association of variables with mortality rate was measured and cross tabulation with the chi-square method with relative risk ratio was used. A log rank regression test was performed to see the significant difference in disease severity, hospital admissions and survival rate among vaccinated and non-vaccinated patients.

3. Results

350 Covid-19 positive patients were included in present study. Majority of whom, 69.1% (n=242), were vaccinated by Sinopharm, and 30.9% (n=108) were non-vaccinated. The majority participants were males 57.1% (n=200), and 42.9% (n=150) were females. The patients age range was 25-60 years. Out of 350 patients, 74% (n=259) had no comorbidity. The most reported comorbidity was multiple type 11.4% (n=40) followed by hypertension (HTN) 7.1%

(n=25). diabetes mellitus (DM) 3.7% (n=13), chronic obstructed pulmonary disease (COPD) 2% (n=7). Ischemic heart disease (IHD) and chronic kidney disease (CKD) ratio were same 0.9% (n=3). The participants socio-demographic data is summarized in Table 1. Majority of the patients, 80% (n=280), presented with mild disease followed by moderate disease 9.7% (n=34), and severe disease 6.6% (n=23). Whereas, 3.7% (n=13) patients had positive PCR for Covid-19 disease without any symptoms. When stratification analysis (Fisher's Exact test) was performed, it revealed a significant association ($p < 0.05$) between vaccination and disease severity, more patients were found to have moderate to severe disease who were not vaccinated (Table 2). Maximum patients 83.7% (n=293) did not require hospital admission, the duration of hospital stay was from 1 to 15 days in admitted patients. A significant association ($p \leq 0.05$) was found between vaccination and hospital admission in Covid-19 positive individuals, hospital admission rate was much lower in vaccinated individuals (Table 3). The relative risk ratio was determined between vaccinated and non-vaccinated groups, the results revealed a significant difference in terms of hospital admission (RR: 0.33, CI 95%; 0.18 – 0.58) among vaccinated and non-vaccinated groups, and supplementary

O₂ (RR: 0.26, CI 95%: 0.14 – 0.48), and insignificant difference in terms of antibiotic given (RR: 0.69, CI 95%: 0.44 – 1.08) in Covid-19 positive patients (Table 4 & 5). The overall mortality rate was 3.7%, 8% (n=9) in non-vaccinated and 1.65% (n=4) in vaccinated individuals. There was a significant association ($p \leq 0.05$) between vaccination and mortality caused by covid-19, mortality was higher in non-vaccinated individuals (Table 6). The correlation between vaccination status and disease severity was analyzed (Table 7). The hazard ratio of disease severity and vaccination status were 0.42 (95% CI: 0.33 – 0.52), and 0.69 (95% CI: 0.47 – 0.66), respectively in vaccinated and non-vaccinated groups. The test revealed that a significant correlation presents between vaccine status and disease severity ($p \leq 0.05$). There was significant difference in survival curve and mean hospital stay (in days) among vaccinated and non-vaccinated individuals, log rank (Mantel-Cox) test was applied (Figure 1). The chi square value was 7.27, and $p = 0.007$. The non-vaccinated mortality rate was high and number at risk was 0.19. The Sinopharm vaccine after both doses was effective in reducing mortality, severity of the disease and hospital admission by 98.3%, 94.4% and 88.8%, respectively at least 2 weeks after second dose.

Table 1. Details of socio-demographic data of study participants, n=350

		Frequency	%
Gender	Male	200	57.1
	Female	150	42.9
Comorbidities	None	259	74.0
	HTN	25	7.1
	DM	13	3.7
	COPD	7	2.0
	IHD	3	0.9
	CKD	3	0.9
	HTN/DM/IHD/COPD	40	11.4
	Sinopharm vaccinated	Yes	242
	No	108	30.9

Table 2. Stratification analysis between Sinopharm vaccination and disease severity, n=350

		Disease severity				Total	Fisher's value	p-value
		No symptoms	Mild	Moderate	Severe			
Sinopharm vaccination	No	0	78 (72.2%)	21 (19.4%)	9 (8.3%)	108 (100%)	22.944	.0001
	Yes	13 (3.7%)	202 (83.4%)	13 (5.3%)	14 (5.7%)	242 (100%)		
Grand Total		13 (3.7%)	280 (80.0%)	34 (9.7%)	23 (6.6%)	350 (100%)		

Table 3. Stratification of Sinopharm vaccination with hospital admission, n=350

		Hospital admission		Total	Chi-square	p-value	Risk ratio (CI: 95%)
		Not required	Required				
Sinopharm vaccination	No	78 (72%)	30 (28%)	108	15.131	.0001	0.33 (0.18 – 0.58)
	Yes	215 (89%)	27 (11%)	242			
Total		293 (83.7%)	57 (16.3%)	350			

Table 4. Antibiotics given in patients, n=350

		Antibiotics given		Chi-square	p-value	Risk ratio (CI: 95%)
		No	Yes			
Sinopharm vaccination	No	51 (47%)	57 (53%)	2.644	.104	0.69 (0.44 – 1.08)
	Yes	137 (56.6%)	105 (43.4%)			

Table 5. Requirement of supplementary oxygen, n=350

		Supplementary oxygen		Chi-square	p-value	Risk ratio (CI: 95%)
		Not required	Required			
Sinopharm vaccination	No	78 (72%)	30 (28%)	20.614	.0001	0.26 (0.14 – 0.48)
	Yes	220 (90.9%)	22 (9.1%)			

Table 6. Stratification of Sinopharm vaccination with mortality, n=350

		Mortality		Total	Chi-square	p-value
		Alive	Death			
Sinopharm vaccination	No	99 (91.6%)	9 (8.4%)	108 (100%)	9.318	.002
	Yes	238 (98.4%)	4 (1.6%)	242 (100%)		
Grand Total		337 (96.3%)	13 (3.7%)	350 (100%)		

Table 7. Cox regression between vaccine status and disease severity

	B	SE	Wald	df	Sig.	Exp(B)	95% CI for Exp(B)	
							Lower	Upper
Severity of the disease	-.879	.116	57.91	1	.0001	.415	.331	.520
Vaccination status	-.713	.125	52.01	1	.0001	.687	.473	.660

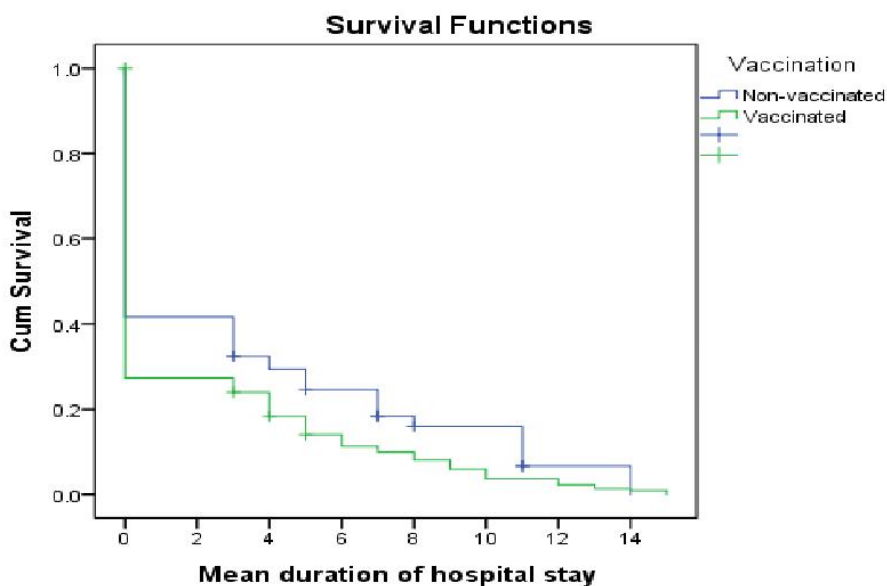


Figure 1. Survival curve of vaccination status with mortality.

4. Discussion

Vaccine played a vital role in reducing the severity and mortality of Covid-19 disease during global spread of Covid-19 pandemic (12). Our study demonstrated the effectiveness of vaccination against Covid-19 disease in our population. In our study Sinopharm vaccine was found effective in reducing the mortality rate and the severity of disease by 98.3% and by 94.4% respectively, after two doses with at least 28 days apart, four weeks post vaccination. It also reduced the hospital admission rate and duration of hospital stay among vaccinated patients. Our findings are in accordance with the phase III clinical trials of Sinopharm vaccine and few other studies after clinical trials (13). The parameters of our study were severe disease, mortality and hospital admission among Covid-19 positive patients. These are the most important parameters as for as the burden of Covid-19 pandemic is concerned on the health care system and economy of a country. Reducing mortality, reducing the severity of the disease and reducing the hospitalization rate are the main goals of the Covid-19 vaccination. Our study clearly provided the evidence that Sinopharm vaccine reduced the mortality, severity of disease and hospital stay in our population. Previous studies also show that vaccination reduces the mortality in Covid-19 disease, Sinopharm reduced the mortality by 88% in a study conducted in Hungary (13), these finding are consistent with our results. Results of Nadeem et al study revealed reduction of mortality by 98.6% in Covid-19 positive patients (14), almost same as in our study. Mortality was found as 8.7% in non-vaccinated patients as compared to 4.3% in vaccinated patients in another study by Holt et al (15). Studies have shown that other vaccines also reduced the mortality, in Canada, Pfizer's mRNA vaccine was effective in reducing the mortality and hospital admission by 98% in a Canadian study (16). We also found that Sinopharm vaccine reduced symptomatic as well as severity of Covid-19. Vaccination reduced severity of disease by 94.4% in our study. Effectiveness of Sinopharm was 92% in preventing intensive care admission with severe disease in a cohort study conducted in United Arab Emirates (UAE) (17), these results from UAE support our findings. A study from Faisalabad Pakistan also reported the decrease in symptomatic and severe Covid-19 disease by 94.3% (14). Two doses of Pfizer-BioNTech and Moderna's mRNA were also highly effective in reducing the severe Covid-19. Pfizer's vaccine effectiveness was 97% in a study conducted in Israel (18). These findings suggest that all vaccines have almost similar efficacy in reducing the severity of the disease in Covid-19 disease. Hospital admission rate and duration of hospital stay was significantly lower in vaccinated patients as compared to non-vaccinated individuals (p -value ≤ 0.0001) in our study. Other studies also revealed that Covid-19 vaccines reduce the hospitalization in Covid-19 disease. Sinopharm was found 90% effective against Covid-19 related hospitalization in Morocco (19), and about 89% in UAE (17), consistent with our results. Vaccine effectiveness was

89% after two doses and 99% after three doses in preventing hospitalization in a study conducted in Germany (20). A meta-analysis also concluded that vaccines are effective in reducing the hospital admission in different populations (21).

Strength and Limitations

Our study shows that Sinopharm is highly effective in our population without booster dose, this is main strength of our study. The effectiveness of Sinopharm was much better in our study as compared to phase III clinical trials where it was found 79%. This difference may be due to different strains of Corona virus during the trials and our study. Due to limitation of resources, we did not perform gene sequence to find out the variant, it was one of the limitations of our study. Many studies conducted around the world have shown that protective effect of vaccines against mortality, severe disease and hospital admission wanes slowly over the time in Covid-19 disease (22). We did not check the status of Covid-19 exposure before vaccination. We were unable to see to whether efficacy of Sinopharm decreases over time or remains same, this is another limitation of our study. The study concluded that Sinopharm vaccine given both doses to Covid-19 positive patients at does reduce the mortality, disease severity and hospital admission rate among Covid-19 positive patients. It also reduces the hospital stay in admitted patients and decreases the requirement of supplementary oxygen. Sinopharm vaccine is highly effective in our population even without booster dose.

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None

Authors' Contribution

Provided concept/research design and did data collection: MN. & SS.

Did statistical analysis and manuscript writing: NA. and MN.

Did edit of manuscript and project management. MN. & SM.

Did critical revision of the manuscript for important intellectual content. MAZ. & JZ.

Takes the responsibility and is accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved: NA. & MN.

Ethics

On behalf of all co-authors, I hereby confirm that I have reviewed and complied with the relevant Instructions to Authors, the Ethics in Publishing policy, and Conflicts of Interest disclosure.

Conflict of Interest

The authors declare that they have no conflict of interest.

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Data Availability

The data that support the findings of this study are available on request from the corresponding author.

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