

INCIDENCE OF COVID-19 DISEASE OCCURRENCE FOLLOWING VACCINATION; A CROSS-SECTIONAL ANALYTICAL STUDY

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ABSTRACT

Objective: To determine the frequency of COVID-19 disease occurrence after vaccination administration in Pakistani population.

Design: Cross-sectional (Analytical).

Place and Duration of Study: Combined Military Hospital, Quetta, 3 months (June to August 2021).

Patients and Methods: The study was carried out after the approval by the ethical review committee of this tertiary care institute of Pakistan. Inclusion criteria adhered to 18–65 years old individuals who had been vaccinated against COVID-19. American Society of Anesthesiologists status I & II, hemodynamically stable patients were recruited in the study with optimized comorbid. After making the study protocol clear to the participants, their informed, written consent was taken. Variables for analysis included demographic profile, comorbid, vaccination history, and adverse effects experienced after vaccination. Participants were inquired about the approximate duration that elapsed after vaccination if the disease occurred, total days taken for illness resolution and PCR test results to become negative, disease severity, and symptoms of COVID-19 disease experienced after vaccination.

Results: Total 256 vaccinated individuals were enrolled in this study, out of which 50% were medical professionals while the remaining half were from a non-medical background. One hundred and fifty-four (60.2%) were males and 102 (39.8%) were females. After vaccination, 36 (14.1%) experienced COVID-19 infection, half (18) of these participants, developed the disease after 2-3 months of vaccination. Medical professionals were found to be more likely to encounter COVID-19 infection after getting vaccinated, as compared to non-medical professionals ($p < 0.001$).

Conclusion: The occurrence of COVID-19 disease after vaccination was low. A bigger number from the medical profession contracted the disease, despite being vaccinated as compared to non-medical individuals. This shows that similar to other vaccinations, COVID-19 vaccination also has some failure rate but it still dispenses benefits to the maximum population. Therefore, vaccination inoculation, in addition to the precautionary measures, should be encouraged in the Pakistani population to pave the way to the middle of the road.

Key words: COVID-19, Incidence, Vaccination.

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INTRODUCTION

COVID-19 has been implicated for the enormous global loss in terms of mortality, economic recession, social life disruption, and parting ways between countries globally which

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lead to endeavours and voyages in the quest for safe vaccine development and administration^{1,2}.

World Health Organization (WHO) released the early data about COVID-19 vaccines on Nov 12, 2020. Total 212 vaccines from the following groups were under trial: the attenuated/inactivated, the traditional, genetically engineered recombinant adenovirus vectors, Ribonucleic acid (RNA) vaccines, recombinant viral vector vaccine, and Deoxyribonucleic acid (DNA) vaccines^{3,4}.

Discerning the COVID-19 genome has accelerated researchers' struggles to the evolution across 300 vaccination programs, in various phases of clinical trials. Forty are in the clinical evaluation stage, 10 are in phase III clinical trials, and 3 have been

declared successful to trans pass stage III trial evaluations^{5,6}.

Ida Mousten, a Danish epidemiologist experimented with Pfizer-BioNTech in health care workers outside clinical trials and elucidated it to be effective in 90% of participants⁷.

As per studies, reported vaccine efficacy of various brands, available in the market, are for: Moderna 94.5% after 14 or more days of 2nd dose, Pfizer 94.2% after 14 or more days of 2nd dose, AstraZeneca 81.5% after 14 or more days after 2nd dose, Johnson & Johnson one dose vaccination efficacy is 66% globally and 72% in the United States, Novavax 89.3% after seven or more days after 2nd dose, Sputnik V 91% after 21 days of 1st dose, Sinovac 50.7% without any timespan reports, and Sino pharm 78.1% with an estimated follow up of 112 days^{8,9,10}.

As yet vaccinations of Sinopharm, Sinovac, CanSino-Bio, and Sputnik companies have been administered to the Pakistani population. The 2.47 million doses of Oxford-AstraZeneca have been acquired for immunization of approximately 1.24 a million high-risk population¹¹.

This study was done with an objective to estimate the frequency of COVID-19 disease occurrence after vaccine administration and gauge vaccination failure in the population of Pakistan.

MATERIAL AND METHODS

The present study was a cross-sectional, analytical study, done from June 2021 to August 2021 after its approval by the ethical review committee of The Tertiary Care Institute, Pakistan. The sample size calculated for this study was 255, calculated with a 95% confidence interval & 5% margin of error, with the open epi calculator. Hypothesized efficacy of Sinopharm (Majority of patients were vaccinated with Sinopharm in Pakistan) was considered to be 79% +/-5, as reported by WHO trials^{12,13}. A non-probability consecutive sampling was done. Total 256 participants comprised general population and healthcare workers who volunteered for the study, without any specific randomization. Inclusion criteria adhered to were 18–65 years old individuals; medical, and non-medical professionals, vaccinated against COVID-19, PCR negative, and American Society of Anesthesiologists status I & II, individuals with hemodynamical stability and optimized comorbid. Excluded from this study were: who did not consent, pregnant women, individuals with decompensated diabetic or hypertensive profiles, asthmatics, immunocompromised people, age > 65 years, those with axillary temperature >37°C, individuals with any drug allergies, the ones who had a contraindication to vaccination, and those with a BMI > 35 Kg/m². Moreover, exclusion criteria also adhered to individuals having a high-risk epidemiologic history within 14 days before enrolment

(e.g., travel to high-risk areas or abroad, contact history with any individual infected with SARS-CoV-2) with a negative PCR test results at the time of execution of the study.

Regarding the study protocol, all participants underwent interviews, were apprised and guided, counselled regarding the procedure, and informed, written consent from them was obtained. Vaccinated/unvaccinated status and details were confirmed by taking history, and breakthrough infection was affirmed with PCR analysis. A proforma (paper-based) was developed with the pertinent literature. Variables included demography (age, sex, profession), COVID-19 disease history before vaccination, comorbid conditions (Diabetes Mellitus, Asthma, Hypertension, Ischemic Heart Disease), vaccination history, adverse effects experienced after vaccine, injection site (redness, soreness, and swelling), in addition to other symptoms like fever or chills & rigors, fatigue/malaise, headache, gastrointestinal symptoms, and flu-like

symptoms. It was also asked whether the participants got their serum antibodies tested after the vaccine administration or not? Participants were inquired about the approximate duration that elapsed after vaccination in case the disease occurred, total days took for illness resolution and PCR test results to become negative, disease severity (mild, moderate and severe), and symptoms of COVID-19 disease experienced by them after vaccine administration (fever, chill and rigors, fatigue and malaise, headache, gastrointestinal disturbances, flu-like symptoms, shortness of breath, loss of smell and taste). The mild disease shows mild symptoms accompanied by fever, cough, and change in taste or smell. There is no dyspnea or Inflammation in the mild stage of the disease. Pneumonia can be observed in a few cases and mortality rate is low. The moderate disease includes lower respiratory tract infection (clinical and radiographic evidence) where the oxygen saturation is $\geq 94\%$. Mild Inflammation is also observed. Severe disease shows shortness of breath, respiratory rate of ≥ 30 beats/minute. Oxygen saturation at the resting state is $\leq 93\%$, and arterial partial pressure of oxygen (PaO₂)/inspired oxygen concentration is (FiO₂) ≤ 300 mmHg. Significant inflammation is observed and mortality rate is high.

Using the IBM SPSS software (version 23.0) data were entered & analyzed. The illustrative statistics of categorical data which included age groups, gender, profession, COVID-19 history, side effects after vaccination, occurrence of infection after vaccination, and symptoms were presented as frequencies and percentages. Post-vaccination occurrence of COVID-19 infection was the outcome variable, which was compared among categorical groups encompassing profession, gender and age, along with the comorbidities by utilizing the Chi-Square test. A p-value of ≤ 0.05 was taken to be statistically significant.

CAPSULE SUMMARY

A cross-sectional study was conducted to investigate the occurrence of COVID-19 disease after vaccination. The occurrence was minimal following vaccination. A higher number of medical personnel contracted the disease as compared to non-medical individuals. Like other vaccinations, COVID-19 immunization has some failure rate but still provides advantage to people at large.

RESULTS

A total count of 256 vaccinated participants engaged in this study, where half of the participants were medical professionals while the remaining half were from a non-medical background. Out of 256, 154 (60.2%) were of male gender and 102 (39.8%) were of female gender. Majority of the contributors, 142 (55.5%) fell in the age group of 36-45 years, whereas 72 (28.1%) in the age group of 25-35 years, 42 (16.4%) had the age above 45 years. It was reported that 4 (1.6%) participants suffered from COVID-19 infection before getting vaccinated. Side effects followed by COVID vaccination were experienced by 36 (14.1%) vaccine recipients. The most common side effect included soreness [28/36 (77.7%)], followed by fever [18/36 (50.0%)], and fatigue/malaise [18/36 (50.0%)]. Demographic features of the participants have been précised in Table 1.

Table 1: Summary of demographic characteristics of study participants (n=256)

Demographics	Profession	
	Medical n=128 (%)	Non-medical n=128 (%)
Age group		
• 26-35 years	38 (29.7)	34 (26.6)
• 36-45 years	70 (54.7)	72 (56.3)
• >45 years	20 (15.6)	22 (17.2)
Gender		
• Male	80 (62.5)	74 (57.8)
• Female	48 (37.5)	54 (42.2)
History of comorbid		
• Hypertension	0 (0)	2 (1.6)
• Asthma	4 (3.1)	0 (0)
History of COVID-19 before vaccination		
• Yes	4 (3.1)	0 (0)
• No	124 (96.9)	128 (100)
Experienced side effects after vaccination		
• Yes	32 (25.0)	4 (3.1)
• No	96 (75.0)	124 (96.9)
Type of side effect (n=36)		
• Soreness	24/32 (66.6)	4/4 (100)
• Fever	18/32 (56.2)	0 (0)
• Chills / Rigors	4/32 (12.5)	0 (0)
• Fatigue / Malaise	18/32 (56.2)	0 (0)
• Headache	12/32 (33.3)	0 (0)
• Flu-like symptoms	2/32 (6.2)	0 (0)

None of the participants reported having checked the antibody titer following the COVID vaccination. After vaccination, 36 (14.1%) experienced COVID-19 infection, where the majority of the participants, 18/36 (50.0%) developed the disease after 2-3 months of vaccination. The disease lasted for 7-14 days in most of the cases, 24/36 (66.6%), who suffered from COVID-19 after vaccination and experienced mild/moderate symptoms. Moderate-Severe symptoms were experienced by 4/36 (11.1%) of the infected participants as given in Table 2. Fever [34/36 (94.4%)] was the most common symptom experienced by infected participants, followed by fatigue/malaise [32/36 (88.8%)], headache [24/36 (66.6%)] and gastrointestinal disturbance [24/36 (66.6%)] as shown in Table 2.

A remarkable association was observed between the occurrence of post-vaccination COVID-19 infection and profession. Medical professionals were observed to have been more likely to develop COVID-19 infection after getting vaccinated as compared to non-medical professionals (p<0.001). The majority of medical professionals had COVID-19 infection after 2-3 months of vaccine administration as compared to their counterparts (p=0.004). Moderate-severe symptoms were also more likely to be experienced by medical professionals as compared to non-medical professionals (p=0.001). Other comparisons are depicted in Table 2 in detail.

Table 3 shows that no significant association was found between the occurrence of post-vaccination COVID-19 and age group or gender. Whereas the history of co-occurring conditions was tracked to be correlated with the occurrence of infection. Participants with comorbidities such as hypertension and asthma were more likely to develop COVID-19 infection post-vaccination (p<0.001). Similarly, those who had a history of COVID-19 infection previously were more likely to develop COVID-19 infection again after vaccination (p=0.037). Last but not the least, those who were found to have experienced side effects after vaccination were also more prone to develop post-vaccination COVID-19 infection (p<0.01) as given in Table 3.

DISCUSSION

The spate of COVID-19 led to global challenges resulting in a surge of emerging vaccines in order to mitigate the effects¹⁴. The vaccine is of utmost importance for the front liners and is effective in 95% of cases either limiting the disease progression or even eliminating it, as quoted by Moghadas et al¹⁵. Our study proposes a decreased disease occurrence post-vaccination thus a reduction in hospital admissions and morbidity with other safety methods under consideration is achieved.

The B.1.617.2 (delta) variant, initially dredged out in India in December 2019, was the most common variant in patients with SARS-COV-2 in April 2020, with a worldwide spread. Meagre information is yet available about the effectiveness of the COVID-19 vaccine on delta variants¹⁶. In our study, disease prevalence after vaccination was observed more in healthcare workers. Angel et al organized a study at Tel Aviv Sourasky Medical Center where a reduction of 85% of cases was detected

Table 2: Occurrence of COVID-19 infection among vaccinated study participants

	Overall n=256 (%)	Profession		p-value
		Medical n=128 (%)	Non-medical n=128 (%)	
Occurrence of COVID-19 infection	36 (14.1)	28 (21.9)	8 (6.3)	<0.001
Duration after infection occurred				
• <1 month	8 (22.2)	6 (21.4)	2 (25.0)	0.004
• 1-2 months	4 (11.1)	2 (7.1)	2(25.0)	
• >2-3 months	18 (50.0)	16 (57.1)	2(25.0)	
• >3 months	6 (16.6)	4 (14.2)	2 (25.0)	
Duration of the infection period(days)				
• 1-7	4 (11.1)	4 (14.2)	0 (0)	0.001
• >7-14	24 (66.6)	16 (57.1)	8 (100)	
• >14	8 (22.2)	8 (28.5)	0 (0)	
Severity of illness				
• Mild	8 (22.2)	4 (14.2)	4 (50.0)	0.001
• Moderate	24 (66.6)	20 (71.4)	4 (50.0)	
• Severe	4 (11.1)	4 (14.2)	0 (0)	
Symptoms				
• Fever	34 (94.4)	28 (100.0)	6 (75.0)	<0.001
• Chills / Rigors	24 (66.6)	22 (78.5)	2 (25.0)	<0.001
• Fatigue / Malaise	32 (88.8)	24 (85.7)	8 (100)	0.001
• Headache	24 (66.6)	22 (78.5)	2 (25.0)	<0.001
• GI disturbance	24 (66.6)	24 (85.7)	0 (0)	<0.001
• Flu-like symptoms	8 (22.2)	8 (28.5)	0 (0)	0.001
• Breathlessness	8 (22.2)	6 (21.4)	2 (25.0)	0.002
• Anosmia	6 (16.6)	4 (14.2)	2 (25.0)	0.001
• Ageusia	14 (38.8)	12 (42.8)	2 (25.0)	0.001

Table 3: Association of occurrence of COVID-19 infection after vaccination with other demographic and clinical characteristics

	Occurrence of infection		p-value
	Yes n=36 (%)	No n=220 (%)	
Age group (Years)			
• 26-35	10 (27.8)	62 (28.2)	0.998
• 36-45	20 (55.6)	122 (55.5)	
• >45	6 (16.7)	36 (16.4)	
Gender			
• Male	22 (61.1)	132 (60.0)	0.900
• Female	14 (38.9)	88 (40.0)	
History of comorbid			
• Hypertension	2 (5.6)	0 (0)	<0.001
• Asthma	4 (11.1)	0 (0)	
History of COVID-19 before vaccination			
• Yes	2 (5.6)	2 (0.9)	0.037
• No	34 (94.4)	218 (99.1)	
Experienced side effects after COVID vaccination			
• Yes	28 (77.8)	8 (3.6)	<0.001
• No	8 (22.2)	212 (96.4)	

post-vaccination ¹⁷. In our study, antibody titers were not performed in any of the participants, this is a pondering moment that depicts the effectiveness of vaccine therapeutically¹⁸. In a study by Thompson et al performed during the initial stages of vaccination strategy in 8 different locations concluded a lowering of risk for infection communicability due to mild symptoms post-vaccination. We were also of the opinion at the end of our study that the communicability risk lowered post-vaccination in both, asymptomatic or late symptomatic people, which is important for healthcare workers' (HCWs) protection ¹⁹.

Another emerging confusion post-vaccination is COVID-19 like symptoms which at times are considered post-vaccine side effects but should not be disregarded by the clinicians and the

affected should be tested for COVID-19. This was also depicted by a study conducted in Sheba Medical Center by Amit et al where co-occurrence along with re-occurrence was observed in HCWs²⁰.

The study of Amit and Regev-Yochay et al. emphasized that in mass vaccination programs, the second dose can be slowed down when faced with a shortage of vaccines. This strategy could help in the acceleration of the national vaccination program²¹. In general, the slope of COVID-19 incidence generally in the population and specifically in healthcare workers went downwards post-immunization. This was also supported by a study conducted by Domi and Leitson et al. in NHS at a vaccine clinic where supporting staff and resident hospital workers presented in low numbers with the disease ²².

Results of this study have elucidated that frequency of disease occurrence was greater in medical professionals despite being vaccinated, therefore exposure is still considered to be the most important factor. Getting vaccination and being immunized is no doubt the need of the hour, but unfortunately, this has transmitted a wave of incautious attitudes among the population therefore it is mandatory for the government to propagate information and knowledge among the masses. Moreover, emphasis on taking precautionary measures such as wearing masks, and avoiding overcrowding should not be denied.

CONCLUSION

The occurrence of COVID-19 disease after vaccination was low. Medical professionals were more prone to this disease despite being vaccinated as compared to non-medical individuals. This shows that similar to other vaccinations COVID-19 vaccination also has some failure rate, still providing benefits to the maximum population. Therefore vaccine inoculation, in addition to precautionary measures, should be encouraged in the Pakistani population to pave the way to the middle of the road.

RECOMMENDATIONS

The government should make endeavours to make availability of other brands of vaccination as well and vaccines should be available easily in the market for the acquisition of every individual. Moreover, since the virus has shown rapid mutations in different communities and parts of the world, we should make sincere efforts to develop our own vaccination, based on strains in the Pakistani population.

AUTHORS' CONTRIBUTION

Beenish Abbas	Conception and design, Drafting the Article, Critical revision
Sana Abbas	Conception and design
Nasar Um Min Allah	Analysis and interpretation of data, Drafting the Article
Hina Ishaq	Acquisition of data, Critical revision
Khadija Tahira	Acquisition of data
Fahmeed Akhtar	Conception and design, Critical revision

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