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Original Research Article

Protection offered by COVID-19 vaccine against morbidity and mortality due to COVID-19 infection: a postvaccination cohort study

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ABSTRACT

Background: Many vaccines have been developed, approved and administered against the COVID-19. Phase 2 and 3 trials have proved the safety and tolerability of these. This study was conducted to assess effect of the vaccines on morbidity and mortality due to postvaccination new COVID-19 infection.
Methods: This was an observational, retrospective cohort study. The patients admitted with COVID-19 from 1st April 2021 till 30th April 2021 who were willing to participate were included. All the patients were telephonically contacted post discharge and enquired regarding history of vaccination, events during hospitalization and outcome. The data so collected was analysed to compare the morbidity (oxygen requirement, need of ICU admission and need of BiPAP or invasive ventilation) and mortality between vaccinated and nonvaccinated COVID-19 patients and relation of time elapsed post vaccination with morbidity and mortality.
Results: Total 431 patients were included. There was significant difference between the two groups in terms of need for ICU admission (OR 0.503; CI 0.30-0.82, p=0.008) as well as requirement of BiPAP or invasive ventilation (OR 0.57; CI 0.33-0.98, p=0.05). Mortality was significantly less in the vaccinated group; OR 0.48 (0.24-0.95), p=0.04). Ten patients had received both doses. Only one required ICU while none of them required invasive ventilation and none expired.
Conclusions: COVID-19 vaccine gives significant protection against COVID-19 infection related ICU admission, need of mechanical ventilation and mortality even after single dose. Two doses of vaccine may afford better protection against the disease.

Keywords: COVID-19 vaccine, Morbidity, Mortality

INTRODUCTION

COVID-19 pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has caused high morbidity and mortality.[1] Several vaccines including inactivated vaccines, live virus vaccines, recombinant protein vaccines, vector derived vaccines, and DNA or RNA vaccines have been developed.[2-5] The goal of vaccine development was to protect against severe COVID-19 disease and its complications.[6] However, data to address this endpoint could be obtained only from large phase 4 trials or epidemiological studies done after widespread deployment of a vaccine. India began its vaccination program on 16 January 2021, operating 3,006 vaccination centers on the onset.[7] Even before completion of first round of vaccines, the second wave started during which many individuals who had received one or both doses of COVID vaccine were infected. We received many such patients. Hence, we conducted this study with the hypothesis that vaccinated individuals infected with SARS

CoV2 fared well as compared to non-vaccinated individuals.

METHODS

This was an observational, retrospective cohort study, carried out at Parul institute of medical science and research (PIMSR), a tertiary care centre at western coast of India. The study started after receiving approval from institutional ethics committee. All patients admitted in our hospital with COVID-19 from 1st April 2021 till 30th April 2021 were enrolled in the study which mounted to a sample size of 1000. Those who were not willing to participate in the study were excluded. All the patients were telephonically contacted post discharge and enquired regarding history of vaccination. The questions asked included: 1. If the patients were vaccinated or not 2. How many doses of vaccine taken? 3. How many days apart were the two doses taken? 4. How many days after getting the last dose of vaccine did the symptoms of covid infection appear? 5. Did the patient required oxygen supplementation? 6. Was he/she admitted in ICU anytime during the hospital stay? 7. Did the patient receive mechanical ventilation? and 8. Was the patient discharged or expired?

Statistical analysis

The data so collected was analysed to compare the morbidity (oxygen requirement, need of ICU admission and need of BiPAP or invasive ventilation) and mortality between previously vaccinated and nonvaccinated COVID-19 patients and to see if there was any association of time elapsed post vaccination with morbidity and mortality. Results are presented as mean ± standard deviation (SD) for continuous variables and as percentages for categorical variables. Comparability of groups was analyzed by Chi-square test, student's t test or Mann-Whitney test as appropriate. IBM SPSS Statistics version 26 (IBM Corp., Armonk, NY, USA) software was used for statistical analyses.

RESULTS

A total of 1000 patients were contacted, from which 568 patients were excluded in view of unwillingness to provide information or non-reachability. A total of 431 patients were included in the study following exclusion. Out of these, 267 were males and 164 were females.

The 249 patients were non-vaccinated (males-153, females-96) while 182 were vaccinated (males-114, females-68). In the vaccinated group, 172 were vaccinated with single dose and 10 with both doses of vaccine. A total of 47 patients died, of which 34 were non-vaccinated (20 males and 14 females) while 13 (10 males and 3 females) had received single dose of vaccine (Table 1).

The mean age of the vaccinated group was 56.95±13.37 years, while that of the non-vaccinated group was 50.68±15.70 years. More than 50% of the vaccinated belonged to the 51-70 years age group (51-60 years, 23.62% and 61-70 years, 32.41%) while 20-30 years, 31-40 years and 41-50 years accounted for 5.49%, 6.59% and 17.58% respectively. The 71-80 years and 81-90 years age group made 12.09% and 2.19% of the vaccinated group. More than 50% of the nonvaccinated belonged to the 41-70 years age group (41-50 years, 23.69%, 51-60 years, 22.48% and 61-70 years, 18.47%) while 20-30 years and 31-40 years accounted for 6.42% and 18.07% respectively. The 71-80 years and 81-90 years age group made 7.63% and 3.21% of the non-vaccinated group (Table 1).

Among the 182 vaccinated participants, 108 (59.34%) had no comorbidity, 37 (20.32%) had hypertension, 17 (9.34%) had diabetes mellitus, 12 (6.59%) had CV stroke, 5 (2.74%) had cardiac disease and 1 (0.54%) each had renal involvement, thyroid disorder and malignancy. In the nonvaccinated group, 158 (63.54%) had no comorbidity, 25 (10.04%) had hypertension, 23 (9.23%) had diabetes mellitus, 21 (8.43%) had CV stroke, 11 (4.41%) had cardiac disease and 4 (1.61%), 5(2.01%) and 1 (0.4%) had renal involvement, thyroid disorder and malignancy respectively. Only 1 patient in nonvaccinated group had cirrhosis of liver (Table 1).

Table 1: Basic characteristics of the two groups.

Variables	Vaccinated	Non-vaccinated
Total	182	249
Males	114	153
Females	68	96
Mean age (Years)	56.95±13.37	50.68±15.70
Age category (Years)		
20-30	10 (5.49)	16 (6.42)
31-40	12 (6.59)	45 (18.07)
41-50	32 (17.58)	59 (23.69)
51-60	43 (23.62)	56 (22.48)
61-70	59 (32.41)	46 (18.47)
71-80	22 (12.08)	19 (7.63)
81-90	04 (2.19)	8 (3.21)
Comorbidity		
None	108 (59.34)	158 (63.45)
Hypertension	37 (20.32)	25 (10.04)
Diabetes mellitus	17 (9.34)	23 (9.23)
Cardiac disease	5 (2.74)	11 (4.41)
Renal involvement	1 (0.54)	4 (1.61)
Thyroid disorder	1 (0.54)	5 (2.01)
Malignancy	1 (0.54)	1 (0.4)
Cerebrovascular stroke	12 (6.59)	21(8.43)
Cirrhosis liver	0	1 (0.4)

Oxygen requirement was not significantly different in vaccinated group (103 patients out of 182) as compared to the non-vaccinated group (154 patients out of 249 patients); OR 0.804 (0.54-1.18), p=0.27. However, there was significant difference among the two groups in terms

of need for ICU admission (OR 0.503; CI 0.30-0.82, p=0.008) as well as requirement of BiPAP or invasive ventilation (OR 0.57; CI 0.33-0.98, p=0.05). Similarly, mortality was also significantly less in the vaccinated group as compared to the nonvaccinated group; OR 0.48 (0.24-0.95), p=0.04) (Table 2).

Only 83 patients could recall the exact duration from vaccination to onset of symptoms. Out of these, 43 got vaccinated ≥15 days prior while 40 got vaccinated <15 days before onset of the symptoms. On analysing for the difference in morbidity between these two groups, statistically significant difference was observed in need of ventilation (BiPAP or invasive) (OR 0.270; CI 0.078-0.935, p=0.045). However, oxygen requirement OR (0.541; CI 0.218-1.33, p=0.182) and need of ICU admission (OR 0.346; CI 0.108-1.109, p=0.067) were not significantly different (Table 3).

Ten patients had received both doses. Out of them only one required ICU while none of them required invasive ventilation and none expired.

Table 2: Odds of morbidity and mortality in vaccinated as compared to nonvaccinated.

Variables	Vaccinated	Non-vaccinated	OR (CI)	P value
Oxygen requirement				
Yes	103	154	0.804 (0.54-1.18)	0.27
No	79	95		
ICU admission				
Yes	27	64	0.503 (0.30-0.82)	0.008
No	155	185		
Ventilator requirement				
Yes	23	47	0.57 (0.33-0.98)	0.05
No	159	202		
Mortality	13	34	0.48 (0.24-0.95)	0.04

Table 3: Odds of morbidity and mortality according to number of days lapsed after vaccination to new infection (≥15 days vs<15 days).

Variables	≥15 days	<15 days	OR (CI)	P value
Oxygen requirement				
Yes	24	28	0.541 (0.218-1.33)	0.182
No	19	12		
ICU admission				
Yes	05	11	0.346 (0.108-1.109)	0.067
No	38	29		
Ventilator requirement				
Yes	04	11	0.270 (0.078-0.935)	0.045
No	39	29		

DISCUSSION

The on-going COVID-19 pandemic caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), has led to high morbidity and mortality worldwide.[1] Many vaccines have been approved now for vaccination against the disease. The safety and tolerability of the vaccines has been proved through phase 2 and 3 clinical trials, however assessing efficacy of the vaccines needed epidemiological studies in post vaccinated individuals.[8,12] In the second wave of the pandemic, besides unvaccinated individuals, we saw many vaccinated people presenting with acute COVID-19, hence this study was carried out to assess effect of vaccine on morbidity and mortality due to fresh COVID-19 infection.

Our findings show that COVID vaccines significantly reduced admission to ICU, need of BiPAP/invasive ventilation as well as mortality. These findings are encouraging because this was an epidemiological study done after vaccination.

We also observed that the patients who had received the vaccine >15 days before contracting infection fared much better than those who contracted infection within 15 days of receiving vaccine, although the difference was not statistically significant in terms of ICU admission and ventilator requirement. This may be because only 83 people could recollect exact time elapsed between vaccination and symptom onset.

The study population mainly included individuals >40 years of age as the vaccination campaign in India was done in phases and initially included all people who were more than 60 years of age and those >45 years old who had some comorbidity as during the first wave of pandemic, greater

casualty was noted amongst elderly and those with comorbidities. This study gives some evidence of protection offered by COVID vaccine against progression to severe disease and death in COVID-19 infection.

However, although much reduced, some morbidity and mortality were seen in the vaccinated group also. This may be because of the fact that most of the participants had received a single dose of vaccine. Many of them were infected within two weeks after receiving the first dose, which may be due to them falling out of window of protection induced by the vaccine.

Although, there were only ten participants who had received both doses, none of them required any intervention more than minimal oxygen supplementation and all survived. This may suggest that much better protection can be anticipated after administration of two doses as compared to a single dose as was reported in the phase 2 and 3 trials. We couldn't find any similar post vaccination study to compare the results.

Small sample size, most participants receiving single dose of vaccine and retrospective design are limitations of this study. In addition, we could not obtain data on the type of vaccine administered and thus could not compare different vaccines in terms of their effectivity. Larger studies need to be conducted that includes participants with complete vaccination along with the type of vaccine administered in order to extrapolate the findings at population level.

CONCLUSION

COVID vaccine gives significant protection against COVID-19 infection related ICU admission, need of mechanical ventilation and mortality even after single dose. Two doses of vaccine may afford better protection against the disease.

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