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A Study on Correlation of COVID-19 Vaccination and Hospitalization among Adults Aged 45 Years and Above: A Hospital Based Case Control Study

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ABSTRACT

Introduction: Year 2020 witness emergence of a pandemic caused by a novel severe acute respiratory syndrome – coronavirus 2 (SARS-CoV-2). After the availability of the vaccine, it is important to assess its effectiveness in reducing morbidity and mortality. The study was conducted to determine the effectiveness of vaccination against severe COVID-19 disease among individuals aged 45 years and above

Methodology: The study included patients hospitalized in selected tertiary care hospital and individuals attending SARS-CoV-2 testing facility in the hospital. It was case–control study. Covid19 RTPCR positive cases admitted in hospital were taken as cases and individuals attending the COVID-19 testing facility of hospitals diagnosed **negative** for SARS-CoV-2 by rRT-PCR were taken as control. The study was done in second quarter of the year 2021.

Results: The vaccination was significantly high among controls (63.5%) in comparison to cases (14.5%). This indicates that vaccination has significantly reduces hospitalization. The vaccination has very positive effect in reducing hospitalization (OR 0.1 (0.05-0.2)).

Conclusion: Vaccine was very effective in reducing hospitalization due to Covid19. So, this study strongly support vaccination in above 45-year age people.

Keywords: Covid-19, Vaccination, Antibody, Hospitalization

INTRODUCTION

The end of 2019 saw the emergence of a novel severe acute respiratory syndrome – coronavirus 2 (SARS-CoV-2), which causes coronavirus disease 2019 (COVID-19). By mid April 2021, there were over 15.6 million cases and over 0.18 million deaths of COVID-19 reported in India.[1]

With unprecedented speed, by the end of 2020, over 200 vaccine candidates on various platforms were in development, of which 14 are in late clinical stage development, and three have received EUA/ EUL by maturity level 4 regulatory authorities and have started to be rolled out in multiple countries. Additional vaccines have received national regulatory approval and are in use in a few countries, some in advance of the results of efficacy trials or interim results.[2]

The efficacy of the ChAdOx1 nCoV-19 vaccine (COVID-19 Vaccine AstraZeneca) in a pooled interim analysis of four trials from United Kingdom, Brazil and South Africa has been reported to be 70·4% after two doses against symptomatic COVID-19, with no hospital admissions or severe cases reported in the vaccine arm.[3] Phase III trial of AZD1222 (non-replicating ChAdOx1 Vector Vaccine) in the US has confirmed 76% vaccine efficacy against symptomatic COVID-19, 100% efficacy against severe or critical disease and hospitalization and 85% efficacy against

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symptomatic COVID-19 in participants aged ≥ 65 years.[4] The vaccine is being manufactured and used in India under the brand name of Covishield.

As per interim analysis of Phase III clinical trial BBV152 vaccine (Covaxin; Bharat Biotech) demonstrated overall efficacy of 78% (95%CI: 61-88), 70% against asymptomatic infection and 100% (95%CI: 60-100) against severe COVID-19 disease after the second dose.[5]

Subsequent to emergency use authorization for the use of Covishield and Covaxin by the Drug Controller General of India in January 2021, COVID-19 vaccinations in India rolled out with two vaccines in Phase 1 on 16 January, 2021 with healthcare and frontline workers. In Phase 2 individuals above 60 years old and above 45 years old with specified comorbidities became eligible for vaccination from 1 March 2021 followed by Phase 3 for all above 45 years of age from 1 April 2021. Phase 4 for all above 18 years of age will begin on 1 May 2021.[6]

During the initial implementation phases, post-introduction evaluations are important to address many of the remaining questions about the performance of these vaccines. The real world effectiveness of Covaxin and Covishield vaccines against SARS-CoV-2 infection is not known. When a vaccine is used outside trial populations the effects of the vaccine may differ in specific geographies or subpopulations. Vaccine effectiveness (VE) might be different against various disease outcomes, against infection and infectiousness, and against newly emerging virus variant strains. From a healthcare perspective it is more important to know if the vaccine is effective against severe COVID disease and eventual hospitalization, consider the strain on health infrastructure with increasing number of cases in the country. Programmatic issues such as suboptimal cold chain capacity and off-schedule and incomplete delivery of doses could also lead to different vaccine performance. Post-introduction vaccine effectiveness evaluation can provide input into models that estimate impact of vaccines on health and economic indicators. Such evaluation provides post-authorization confirmation of effectiveness of conditionally approved products for regulatory bodies.[7]

OBJECTIVES

The study was conducted to determine the effectiveness of vaccination with either Covaxin or Covishield vaccine against severe COVID-19 disease among individuals aged 45 years and above

METHODS

The study included patients hospitalized in selected tertiary care hospital and individuals attending SARS-CoV-2 testing facility in the hospital. It was case–control study.

Cases: rRT-PCR/Rapid Antigen Test **positive** (at admission or documented within 14 days prior to hospital admission) severe COVID-19 case defined as a patient hospitalised with the following signs and symptoms anytime during hospitalisation (WHO's Clinical management of COVID-19: interim guidance [8]) – clinical signs of pneumonia (fever, cough, dyspnoea, fast breathing) **plus** one of the following: respiratory rate > 30 breaths/min; severe respiratory distress; or SpO2 < 90% on room air.

Controls: Individuals attending the COVID-19 testing facility of the participating hospitals with any one of COVID-related symptoms (fever ≥37·8°C, cough, shortness of breath, anosmia, ageusia) within last 10 days with a nasal/throat swab **negative** for SARS-CoV-2 by rRT-PCR only. rRT-PCR negative individuals with high clinical/CT/laboratory results suggestive of COVID were excluded as controls.

The study was done in second quarter of the year 2021.

Operational definitions:

Hospitalised patient - Patient who has been admitted to one of the participating hospitals during the study period, and has not been discharged within 24 hours

Hospitalized with COVID-19 disease – A person hospitalized with rRT-PCR confirmed SARS-CoV-2 infection in participating hospitals for more than 24 hours

COVID-19 vaccination–Documentation of vaccination with *Covaxin* or *Covishield* from patient or Co-WIN portal. Self-reports was be considered only if documentation is not available.

Unvaccinated against COVID-19 - Patient did not receive COVID-19 vaccine or if s/he was vaccinated after onset of symptoms or hospitalisation.

Previous SARS-CoV-2 infection – Patient with documented history of past infection with SARS-CoV-2 based on rRT-PCR or RAT or those with presence of IgG antibody against SARS-CoV-2.

Exclusion criteria: The individual was not be enrolled in the study if she or he was unwilling to participate, had a contraindication for the COVID-19 vaccine, cannot be swabbed due to severe septum deviation, obstruction or other conditions that contra-indicate swabbing, or had a history of hospitalization within the 5 days immediately prior to this admission (including transfers from another hospital)

Recruitment strategies: A systematic screening of all patients admitted and individuals attending COVID-19 testing facility in the participating hospitals was be organised. This was done by sensitisation of the hospital staff at the beginning of the study, followed by the site coordinator review. Patients meeting the case definition were asked (directly or through their physician) to provide consent to participate in the study and were enrolled, if willing.

Data collection: Data was collected by trained investigators using a standardised questionnaire/data collection form. The source(s) of data included- hospital medical records, interview with patient or his/her family, interview with patient's physician, vaccination records, laboratory.

Data management: We used paper-based forms to record the data. Data-collection forms did not include any identifiable information (e.g. name) but instead use unique identifiers. A separate form was maintained that links the identifiers with participant names, and confidentiality maintained.

Data analysis plan: We did descriptive analysis to characterize the study participants. Cases and controls were first described by baseline characteristics. We compared cases and controls for background characteristics and vaccine status using chi-square for categorical variables and t-test/median test for continuous variables.

RESULTS

The study was conducted among 76 cases and 178 controls. Table 1 shows comparison of baseline characteristics of cases and control. Mean age of cases was 62.1 years and control were 55.5 years; however the deference was statistically not significant. Similarly, there was no significant difference in gender distribution among cases and controls.

Table 1: Comparison of baseline Characteristics in cases and controls

Socio-demographic Variables	Case (%) (n=76)	Control (%) (n=178)	P value
Age			
<55	19 (25)	89 (50)	-
55-64	25 (32.9)	59 (33.1)	
65-74	22 (28.9)	29 (16.3)	
>75	10 (13.2)	1 (0.6)	
Mean Age	62.1 ± 10.7	55.5 ± 7.8	>0.05
Gender			
Female	34 (44.7)	49 (27.5)	>0.05
Male	42 (55.3)	129 (72.5)	
Antibody by Qualitative Method			
Negative	4 (5.3)	40 (22.5)	<0.05
Positive	72 (94.7)	138 (77.5)	

Table 2: Comparison of vaccination status in cases and controls

Vaccination	Case (n=76) (%)	Control (n=178) (%)	Odds Ratio	95% CI	P value
Not Received Vaccine	65 (85.5)	65 (36.5)	Ref		
Vaccine Received	11 (14.5)	113 (63.5)	0.1	0.05-0.2	<0.01
Doses					
Single Dose	10 (13.2)	63 (35.4)	0.16	0.07-0.34	<0.01
Two Doses	1 (1.3)	50 (28.1)	0.02	0.00-0.15	<0.01

Table 2 indicates that the vaccination was significantly high among controls (63.5%) in comparison to cases (14.5%). This indicates that vaccination has significantly reduces hospitalization. The vaccination has very positive effect in reducing hospitalization (OR 0.1 (0.05-0.2)).

DISCUSSION

In this analysis of 76 laboratory-confirmed COVID-19– associated cases among hospitalized adults aged >45 years, all COVID-19 vaccine products currently authorized for use in India had high effectiveness in preventing laboratory-confirmed COVID-19 associated hospitalizations. These findings are consistent with estimates from other observational studies of the vaccines and provide an early estimate of the effectiveness in preventing COVID-19–associated hospitalization.[1–3,5] Although the method used in this analysis does not account for many important potential confounders and results should be interpreted with caution, taken together, these findings provide additional evidence that available vaccines are highly effective in preventing COVID-19–associated hospitalizations and demonstrate that performance of COVID-19 vaccines can be assessed using existing disease surveillance and immunization data.

This analysis provides an early estimate of the vaccine effectiveness in preventing hospitalization in older adults, adding to the limited observational data available assessing vaccine effectiveness in India. These findings are consistent with other clinical trial efficacy data, which found an efficacy of 76.7% for prevention of moderate to severe disease ≥14 days after vaccination[8]. The relatively few cases and low population vaccination coverage with in this analysis likely contributed to the wide CIs for the vaccine effectiveness estimate. In addition, given vaccine prioritization for populations at high risk, older adults receiving the product were more likely to be at lower

risk and differ substantially from those receiving vaccine available earlier in the vaccine rollout. Other observational studies have demonstrated variability in the effectiveness of partial vaccination in preventing hospitalization, with point estimates of effectiveness of 64% to 91%.[9,10] Variation in estimates of effectiveness of partial vaccination between Covishield and Covaccine in this analysis might represent confounding from differences among the persons receiving these products. Elderly population was prioritized early in the vaccine rollout and were more likely to receive Covishield than Covaccine. The underlying risk for severe illness from COVID-19 in this medically fragile population could contribute to lower vaccine effectiveness among elderly than among the general population of adults and to an apparently lower effectiveness of Covishield. Moreover, if partial protection increases between the third and fourth week after receipt of the first dose, it is possible that the timing of the second Covishield and Covaccine doses (28 days after the first dose) could affect the observed effectiveness of partial vaccination. Therefore, these results should not be interpreted as definitive evidence of a difference in the effectiveness of partial vaccination between the two vaccines, but rather as an indication that further evaluation is warranted.

The findings in this report are subject to at least four limitations. First, although adjustments were made for time, the analysis did not adjust for other potential confounders, such as chronic conditions, because person-level data were not available for the catchment population. In addition, although the analysis was stratified by age, the heterogeneity of disease risk, vaccination coverage, and differences in the populations who received different vaccine products might confound estimates of vaccine effectiveness. Second, changes in circulating SARS-CoV-2 variants might affect vaccine effectiveness when assessed over time. Third, persons choosing to receive vaccine later in the rollout might have different risk characteristics than do those vaccinated earlier and might have experienced differences in access to vaccine products by time. Finally, this analysis was limited to adults aged >45 years, and the results are not generalizable to younger age groups.

This analysis found that all COVID-19 vaccines currently authorized in India are highly effective in preventing COVID-19–associated hospitalizations in older adults and also demonstrates the utility of this method in generating a relatively rapid assessment of vaccine performance in the setting of high-quality surveillance and vaccine registry data. Efforts to increase vaccination coverage are critical to reducing the risk for COVID-19–related hospitalization, particularly in older adults.

Limitation

Being a hospital-based study, the results have all limitation which is applicable to a hospital-based study.

CONCLUSION

From this study we conclude that vaccine was very effective in reducing hospitalization due to Covid19. This ultimately led to reduction in health care expenditure and better outcome. So, this study strongly support vaccination in above 45-year age people.

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