Original Article

Effectiveness of COVID-19 Vaccines in Preventing Severe Disease : A Retrospective Study among Patients Attending a Post COVID-19 Follow-up Clinic of a Hospital

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Abstract

Background : The vaccination campaign against COVID-19 was started on 16 January, 2021 using two of the approved vaccines namely COVISHIELD and COVAXIN. Emerging severe breakthrough infections have health authorities concerned regarding vaccine effectiveness.

Aims and Objectives : This study was done to generate evidence regarding the effectiveness of vaccines in preventing severe disease.

Materials and Methods : A case-control study was conducted among attendees of a post COVID-19 follow-up clinic of a Tertiary Care Hospital in Kolkata. Total 64 study participants (16 cases and 48 controls) were interviewed and all treatment records were reviewed. Those who had severe COVID-19 disease were taken as cases, whereas those who had mild/moderate disease (as per WHO guidelines) were taken as controls. Three controls were matched against each case.

Results : Fifty-one percent of the study participants were found to be fully vaccinated and among them only 12% had developed severe breakthrough disease. Fear of adverse effects was cited to be the commonest cause for vaccine hesitancy. Vaccine efficacy in preventing severe disease was calculated to be 78%. After adjusting for possible confounders, the adjusted vaccine efficacy was calculated to be 94%.

Conclusion : The vaccines against COVID-19 are effective and fully vaccinated individuals are less likely to develop severe disease.

Key words : COVID-19 Vaccine, Vaccine Effectiveness, Case-control Study.

On March, 2020, the World Health Organization (WHO) declared the Coronavirus disease 2019 (COVID-19) caused by the Severe Acute Respiratory Syndrome Coronavirus-2 (SARS CoV2) a pandemic. It had devastating effects in India with over 4 lac deaths (till November, 2021). A herd immunity level of 60-70% was imperative to control the spread of infections during the pandemic and vaccines remained the most crucial weapon to control the same[1].

The Government of India launched world's biggest COVID-19 vaccination campaign on 16th January 2021, with two vaccines [Covaxin (BBV152), Indigenous, Bharat Biotech Ltd; Covishield (ChAdOx1nCoV-19), Serum Institute of India with technology transfer from Oxford University and AstraZeneca][3].

Emergence of breakthrough infections concurrent to vaccination efforts, it became a global concern both clinically and epidemiologically. As per Centers for Disease Control and Prevention (CDC), a vaccine breakthrough infection is defined as the detection of SARS-CoV-2 RNA or antigen in a respiratory specimen collected from a person ≥14 days after receipt of all recommended doses of an FDA-authorized COVID-19 vaccine[4]. A vaccine effectiveness is a measure of how well vaccines work in the real World (WHO). None of the vaccines approved in India had reported 100% effectiveness and the mutant variants of SARS-CoV2 were found to evade immunity offered by vaccines in some individuals. Thus, the population remains susceptible to SARS CoV2 despite full vaccination (ie, two doses of vaccines, as recommended during the study period[4]. With this in mind, the study was done to determine the effectiveness of COVID-19 vaccines in preventing severe disease and to find the factors associated with it.

Editor's Comment :

- This study demonstrates that COVID-19 vaccination is highly effective in preventing severe disease, with markedly reduced odds of severe illness among fully vaccinated individuals, even after adjusting for confounders. However, persons with underlying comorbidities remain at higher risk of severe breakthrough infection, underscoring the need for targeted protection of vulnerable groups. Addressing vaccine hesitancy through focused health education is essential to improve coverage and further reduce severe COVID-19 outcomes.

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Received on : 09/02/2024
Accepted on : 30/06/2024

How to cite this article : Effectiveness of COVID-19 Vaccines in Preventing Severe Disease : A Retrospective Study among Patients Attending a Post COVID-19 Follow-up Clinic of a Hospital. Dey A, Bandyopadhyay S, Majumdar S, Chakrabarti S, Mondal A. *J Indian Med Assoc* 2026; **124(1):** 26-9.

Materials and Methods

This observational, analytical study of case- control study design was conducted in the post-COVID-19 follow-up clinic of Infectious Disease & Beleghata General Hospital in Kolkata from 1st October, 2021 to 30th November, 2021 among clinic attendees aged ≥45 years.

The total sample size of 64 was obtained (taking the Confidence Interval - 95%, power- 80%, ratio of controls to cases: 3 and odds ratio 0.184, as obtained from a pilot study) out of which there were 16 cases and 48 controls.

All patients aged ≥45 years (as this age group was eligible for vaccination during the period) who attended the clinic during the reference period and had recovered from COVID-19 in the preceding 3 months were included in the study. Whereas, those who were infected within 14 days of vaccination or were partially vaccinated (received less than two doses) were excluded.

Selection of Cases and Controls :

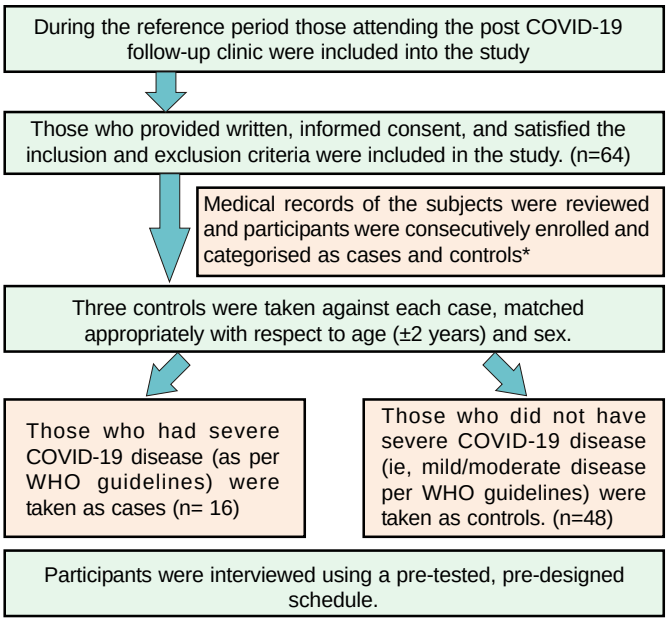
Cases : Patients who had severe COVID-19 disease (as per WHO guidelines) were taken as cases[5].

Controls: Patients who did not have severe COVID-19 disease (mild/moderate disease, as per WHO guidelines[5] were taken as controls. Three controls were taken against each case, matched appropriately with respect to age (±2 years) and sex.

Hospital records such as admission certificate, treatment records, bed head tickets were reviewed for the purpose of selection of cases and controls (Fig 1).

With due clearance from the Institutional Ethics Committee (Memo no: IDBGH/Ethics/344) and hospital authorities, participants were enrolled into the study after obtaining a written informed consent, consecutively and categorised as cases and controls. Three controls were matched against each case till desired sample size achieved. to avoid duplication of data, OPD registration number was taken into consideration. Participants were interviewed using a pre-tested, pre-designed schedule and were assured about the confidentiality and anonymity of their information.

Data was analysed for consistency and completeness and entered in Microsoft Excel datasheet. IBM SPSS software version 23 was used to analyse the data. Mean (±Standard Deviation) and percentages were used to present the summary measures. Pearson's Chi square test was use to elicit association between categorical variables. The protective effect of vaccine in preventing severe disease was statistically tested using univariate logistic regression and was expressed in Odds Ratio (OR). Vaccine Effectiveness (VE) was calculated using the following formula: VE = [(1-OR) X 100 %]. Univariate analysis followed by binomial logistic regression analysis were performed to find out the factors associated with breakthrough COVID-19 disease severity. A P-value of <0.05 was considered significant.



**Medical records included admission certificate, discharge certificate, treatment records, bed head tickets.*

Fig 1 — Chart showing the selection of cases and controls

Results

Among the attendees of the post COVID-19 clinic, a total of 64 individuals (comprising of 16 cases and 48 controls) were interviewed during the study period. In this study the mean age of the study participants was 59.3 (±8.8) years and comprised of 56% females and 44% males among both cases and controls. Fifty-one percent of the study participants were found to be fully vaccinated out of which only 12% had developed severe breakthrough disease. Majority (75%) of the cases and 40% of the controls were not vaccinated. Sixty-nine percent of the cases and 29% of controls had at least one chronic comorbidity. Thirty-one percent of the cases and 63% of the controls had been infected more than once (Table 1). Fear of adverse effect was cited as the predominant cause for vaccine hesitancy. Vaccination status was found to be significantly associated with disease severity (P= 0.019, OR= 0.22) and vaccine efficacy in preventing severe disease was calculated to be 78% (Table 2). After adjusting for factors such as age, practice of the recommended COVID-19 appropriate behaviour, presence of comorbidities and history of previous COVID-19 infection, the adjusted vaccine efficacy {(1-aOR) X 100} was found to be 94% (aOR= 0.06)

On Univariate analysis breakthrough COVID-19 disease severity was found to be significantly associated with the presence of comorbidities (p= 0.11, OR= 14.4) and previous

Table 1 — *Background characteristics of the study participants (n=64)*

Variables		Cases N(%)	Control N(%)	p-value
Age (years)	<60 years	1 (5.8)	16 (94.2)	0.376[a]
	≥60 years	3 (16.7)	15 (83.3)	
Vaccinated	Yes	4 (12.1)	29(87.9)	0.019[b]
	No	12 (38.7)	19 (61.3)	
Comorbidities	Present	3 (37.5)	5 (62.5)	0.011[b]
	Absent	1 (4)	24 (96)	
COVID-19 appropriate behaviour	Practiced	2 (18)	9 (82)	0.450[b]
	Not practiced	2 (9)	20 (91)	

a= unpaired t-test ; b= χ^2 test

COVID-19 infection (p=0.04, OR= 0.09) (Table 3). On binary logistic regression after adjusting for possible confounders such as Age and Practice of Covid appropriate behaviour and previous COVID-19 infection, individuals with comorbidities were found more likely to develop severe breakthrough COVID-19 disease (p= 0.011, aOR= 3.8, 95% CI : 1.38-9.13).

Discussion

The Government of India has rolled out a rigorous vaccination campaign with two effective vaccines to curb the ongoing pandemic. Currently the vaccines are being administered on persons aged ≥45 years and has contributed significantly in reducing morbidity and mortality[5]. Although there is evidence suggestive of immunity obtained from SARS-CoV2 infection have protective role against reinfection but the waning nature of this natural immunity is evident as reinfections continue to occur, thus vaccines are imperative, even for those who have been already infected[5]. In this study the overall unadjusted effectiveness of vaccines against COVID-19 among completely vaccinated individuals (two doses) was found to be 78% and the adjusted vaccine effectiveness was found to be 94%. Those with chronic comorbidities were more likely to develop severe breakthrough COVID-19 disease.

Multiple large-scale studies have been done to assess the effectiveness of the various approved vaccines Worldwide. The VIVALDI cohort study conducted in the United Kingdom among older adults aged ≥65 years reported 68% effectiveness (adjusted HR-0.32, 95% CI-0.15-0.66) of the Oxford-AstraZeneca ChAdOx1in vaccine in preventing SARS-CoV-2 infection at 35-48 days of vaccination[6]. In a test negative case-control study done in England among older adults reported an effectiveness of the Oxford-AstraZeneca vaccine to be 60% (41% to 73%) from 28 to 34 days postvaccination, which was found to increase to 73% (27% to 90%) after 35 days[7].

In a comprehensive systematic review and meta-analysis of the efficacy and effectiveness of COVID-19 vaccines done in China showed a cumulative effectiveness of 79.5% (95% CI: 73.9%, 83.8%), 80.2% (95% CI: 74.1%, 84.9%), 95.1% (95% CI: 93.1%, 96.5%), and 92.4% (95% CI: 88.6, 94.9) to prevent Delta variant infection, COVID-19, severe COVID-19, and COVID-19-related death, respectively[8]. A meta-analysis of large observational studies done to determine the real- world effectiveness of the BNT162b2 mRNA vaccine reported an effectiveness of 53% (95% CI 32-68%) after 1 dose and 96% (95% CI 95-97%) after two doses[9].

Similar studies done in India have also generated evidence regarding vaccine effectiveness, one such being a study done in eastern India, where the adjusted vaccine effectiveness was reported to be 52.0% (95% CI 39.0–63.0%) and 83.0% (95% CI 73.0–89.0%), after partial and

Table 3 — *Binary logistic regression analysis for association of different factors with breakthrough COVID-19 disease*

Variables	Severe COVID-19		p-value	OR (95% CI)	aOR (95% CI)
	Yes, N (%)	No, N(%)			
Age (years) :					
<60 years	1 (5.8)	16 (94.2)	0.376	0.3	0.26 (0.01-5.05)
≥60 years	3 (16.7)	15 (83.3)		1	1
Comorbidities :					
Present	3 (37.5)	5 (62.5)	0.011	14.4	30.88 (13.8-58.3)
Absent	1 (4)	24 (96)		1	1
COVID-19 appropriate behaviour :					
Practiced	2 (18)	9 (82)	0.450	2.2	0.38 (0.02-6.54)
Not practiced	2 (9)	20 (91)		1	1

Table 2 — *Effectiveness of vaccines in preventing severe COVID-19 disease (n=64)*

Variables		Cases N= 16(%)	Control N=48(%)	OR	aOR	VE (%)	Adjusted VE(%)
Age in completed years	<60	10 (62.5)	25 (52)	1.53(0.48-4.89)	3.64(0.63-21.21)		
	≥60	6 (37.5)	23 (48)	1	1		
Vaccinated	Yes	4 (25)	30(62.5)	0.22(0.06-0.78)	0.06 (0.09-0.37)	78	94
	No	12 (75)	18 (38.5)	1	1		
Comorbidities	Present	11 (69)	14(29)	5.343(1.57-18.22)	7.19(1.38-37.03)		
	Absent	5 (31)	34 (71)	1	1		
COVID-19 appropriate behaviour	Practiced	9 (56.3)	31(64.6)	1.42(0.45-4.49)	1.17(0.27-5.07)		
	Not practiced	7 (43.7)	17(35.4)	1	1		
Previous COVID-19 infection	Yes	11 (68.7)	18 (37.5)	3.67(1.09-12.27)	0.19(0.04-0.93)		
	No	5 (31.3)	30 (62.5)	1	1		

complete vaccination respectively. They have also stressed on the most common reason for not receiving the vaccine to be inaccessibility to vaccination centres compared to this study where fear of adverse effects was the most cited cause[10]. In another study done in Mumbai, the effectiveness of COVID-19 vaccines was found to be 70% among completely vaccinated individuals and 88% among those with a history of previous infection[11].

There were some limitations in our study. The combined effectiveness of both Covaxin (BBV152) and Covishield (ChAdOx1nCoV-19) vaccines was determined. The individual effectiveness could not be determined. Also, the vaccine was approved for usage among those aged 45 years and above, thus its effectiveness among the younger age group was beyond the scope of this research.

Nevertheless, the study has generated useful information on the effectiveness of COVID-19 vaccines which can further contribute in fortifying the indisputable role of vaccines in combatting the pandemic that currently has the World in its grips. The information is also expected to appease the hesitancy and combined with a more vigorous vaccination campaign help improve vaccination coverage.

Conclusion

In this study it was found that the approved vaccines against COVID-19 were effective and those vaccinated, were less likely to develop severe disease. The vaccine effectiveness was found to be significantly higher among individuals who were younger, without any chronic comorbidity, practiced the recommended COVID-19 appropriate behaviour and had history of previous infection. However, vaccine hesitancy was a considerable problem during the study period which was reflected in the vaccine coverage among the study participants, also the practice of precautions necessary after vaccination were found to be unsatisfactory. A rigorous vaccination campaign combined with health education to target populations is recommended to combat vaccine hesitancy. A study on a larger scale is recommended to further explore the vaccine effectiveness against disease caused in the younger age group and that by the newer variants of the virus.

Financial support : This research received no specific grant from any funding agency in the public, commercial, or not-for-profit sectors.

Conflict of interest : None.

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