Original Article

Effectiveness of COVID-19 Vaccines against SARS-CoV-2 Infection among Persons Attending the RT-PCR center at a Medical College Hospital in Telangana: A Case- Control Study

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Abstract

Background: In January 2021, India's drug regulator issued restricted emergency approval for COVISHIELD and COVAXIN, which were manufactured in India. In mid-January 2021, in India, there were 10.5 million confirmed cases and 0.15 million deaths. The objectives were to evaluate vaccine effectiveness (VE) of coronavirus disease 2019 (COVID-19) vaccines made in India against severe acute respiratory syndrome coronavirus disease 2 (SARS-CoV-2) infection. **Materials and Methods:** A test-negative case-control study was conducted from May 2021 to December 2021 for a duration of 8 months among people attending a reverse transcriptase polymerase chain reaction (RT-PCR) center at a medical college hospital for RT-PCR test for SARS-CoV-2. The baseline characteristics and RT-PCR report were collected from the RT-PCR center. The exposure to COVID-19 vaccines was enquired via phone call or was checked with data available with the health authorities. **Results:** After applying inclusion and exclusion criteria and case and control definitions, a total of 380 participants (95 cases and 285 controls) were included. The adjusted VE of two doses of COVISHIED vaccine against symptomatic SARS-CoV-2 infection was 52.2% (41.7 to 62.1), and that of a single dose was 40.88% (31.26 to 51.29). The adjusted VE of two doses of COVAXIN vaccine against SARS-CoV-2 infection was 39% (29.40 to 49.27). The overall VE was 48.20% (37.90 to 58.22) for two doses of any vaccines. **Conclusions:** Vaccines made in India were nearly 50% effective. Further new studies should be conducted as new variants of SARS-CoV-2 are emerging. We do not know the VE against the variants, and whether booster doses are required or not is not yet established.

Keywords: COVAXIN, COVID-19, COVISHIELD, RT-PCR test, SARS-CoV-2 infection, vaccine effectiveness

Introduction

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by a newly discovered coronavirus.[1] The causative agent is SARS-CoV-2.[1,2] The outbreak was declared as a Public Health Emergency of International Concern on January 30, 2020.[3] World Health Organization (WHO) on March 11, 2020 declared COVID-19 a pandemic.[4]

According to the WHO situation update report on novel coronavirus disease, as of January 17, 2021, worldwide, there were 93.2 million confirmed cases and 2 million deaths. In south-east Asia region, there were 12.5 million confirmed cases and 0.19 million deaths. In India, there were 10.5 million confirmed cases and 0.15 million deaths.[5]

In January 2021, India's drug regulator issued restricted emergency approval for COVISHIELD and COVAXIN, which were manufactured in India. COVISHIELD vaccine is a Recombinant Chimpanzee Adenovirus vector vaccine and has the same formulation as Oxford/AstraZenecae (ChAdOx1 nCoV-19) vaccine.[6] Its efficacy against symptomatic SARS-CoV-2 infection after two doses was 76%.[7] COVAXIN is a whole virion inactivated coronavirus vaccine developed in collaboration with ICMR.[6] The

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Bharat Biotech BBV152 COVAXIN vaccine efficacy against COVID-19 after two doses was 78%.[8]

On January 16, 2021, India launched the largest vaccine drive against COVID-19.[9] Vaccine effectiveness (VE) is a measure of how well vaccines work in the real-world settings. On March 23, 2021, the interim WHO guidance on how to evaluate COVID-19 VE was provided based on previous guidance on VE evaluations.[10] The objectives were to evaluate effectiveness of different COVID-19 vaccines made in India (COVISHIELD and COVAXIN) and to evaluate overall effectiveness in COVID-19 vaccines made in India against symptomatic severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.

Material and Methods

A test-negative case-control study was conducted from May 2021 to December 2021 for a duration of 8 months among people attending a reverse transcriptase polymerase chain reaction (RT-PCR) center at a medical college Hospital in Khammam, Telangana, for RT-PCR test for SARS-CoV-2. The persons who were 18 years and above age and who gave informed oral consent were included in the study. Consent was according to WHO interim guidance on how to assess COVID-19 vaccine effectiveness.[10] The persons who were not able co-operate, those who were not willing to participate, pregnant women, and those who were administered with other COVID-19 vaccines were excluded from the study.

In a test-negative case-control study, persons or patients seeking care for a defined set of symptoms and signs were enrolled in the evaluation and tested for SARS-CoV-2.[10] Cases were defined as persons who were RT-PCR test-positive for SARS-CoV-2 infection and had at least one COVID-19 symptom. The symptoms were fever, cough, shortness of breath, fatigue, body aches, headache, new loss of taste or smell, sore throat, runny nose, vomiting, and diarrhea.[11] Controls were defined as persons who were RT-PCR test-negative for SARS-CoV-2 infection and had no symptoms of COVID-19 and were seeking the test for other purposes such as admission to medical and surgical wards, college admissions, and travel. In a week, for every 4–5 cases, 12 to 15 controls were chosen, and age group matching was performed for the data collection period (24 weeks). The case to control ratio was 1:3.

The baseline characteristics and RT-PCR laboratory report were collected from the RT-PCR center. The exposure to COVID-19 vaccines was noted from the data available with the district health authorities or enquired via phone call. Data-collection forms were assessable only to the principal investigators, and confidentiality was maintained.

The vaccination status was taken on the day of RT-PCR testing. A person was considered as vaccinated with the first dose after 14 days of vaccination, and a person was considered as vaccinated with the second dose after 7 days of vaccination. A person who received only a single dose (1 dose) was considered as partially vaccinated, and a person who received a second dose (2 doses) was considered as a completely vaccinated person. Ethical clearance was obtained from the Institutional Ethics committee.

Statistical analysis

First, the data were entered in Microsoft Excel and then transformed into R software version 4.1.2 and analyzed. The data were represented by frequency, percentage, mean, and standard deviation. Conditional logistic regression was utilized to find VE and 1 minus odds ratio (×100) for complete and partial vaccination compared against no vaccination in vaccines made in India. The VE was calculated at 95% confidence interval. The final model was adjusted for age and gender. The adjusted VE was calculated based on adjusted odds ratios in the final model.

Results

After applying the inclusion and exclusion criteria and case and control definitions, a total of 380 participants (95 cases and 285 controls) were included. Out of 380 participants, 194 (51.1%) were males and 186 (48.9%) were females. All participants' age was in the range of 18 years to 92 years with the mean age of 41.98 ± 16.88.

The unadjusted VE of a single dose and two doses of COVISHIED vaccine against symptomatic SARS-CoV-2 infection was 40.88% (31.26 to 51.29) and 62.64% (52.76 to 72.44), respectively. The adjusted VE for a single dose and two doses of COVISHIELD was 31.1% (22.10 to 41.03) and 52.2% (41.7 to 62.1), respectively. The unadjusted and adjusted VE for two doses of COVAXIN was 50% (39.83 to 60.17) and 39% (29.40 to 49.27), respectively. The overall unadjusted and adjusted VE in vaccines made in India was 58.81% (48.70 to 68.70) and 48.20% (37.90 to 58.22), respectively. The VE among completely vaccinated and partial vaccinated participants was more as compared to unvaccinated participants [Table 1].

The overall adjusted VE of the participants for two doses in the age group of 41–64 years [57.7% (47.71 to 67.8)] was more than that of the other age groups, 18–40 years [45.5% (35.03 to 55.27)] and ≥65 years [13.4% (7.11 to 21.2)]. The COVISHIELD VE of the participants for two doses in the age group ≥65 years [69.1% (58.92 to 77.87)] was more than those of the other age groups, 41–64 years [58.3% (47.72 to 67.8)] and 18–40 years [43.2% (33.1 to 53.2)] [Tables 2 and 3].

The COVISHIELD VE of the participants for two doses among males [55.7% (45.72 to 65.92)] was more than that of females [48.3% (37.90 to 58.22)] [Tables 2 and 3]. COVAXIN VE according to age and gender was not quantified because of a small sample size.

Discussion and Conclusions

In our study, the overall VE of vaccines made in India was nearly 50%. The VE (two doses) of COVISHIELD was more than that of COVAXIN by 13.2%. Studies at Faridabad and CMC Vellore in India showed that the VE for a single dose (46·2% and 61%, respectively) and two doses (63·1% and

Table 1: Evaluation of Overall VE and COVISHIELD and COVAXIN VE among the participants attending the RT-PCR center at a medical college hospital, Telangana

Overall Vaccine status	Cases *n*=95 (%)	Controls *n*=285 (%)	Unadjusted VE (95% CI)	Adjusted VE (95% CI)
Unvaccinated	38 (40)	71 (24.9)	.	.
Any vaccine - Single dose	29 (30.5)	87 (30.5)	37.71 (28.48 to 48.21)	28.30 (19.48 to 37.87)
Any vaccine - Two doses	28 (29.5)	127 (44.6)	58.81 (48.70 to 68.70)	48.20 (37.9 to 58.22)
COVISHIELD Vaccine status	**Cases *n*=81 (%)**	**Controls *n*=240 (%)**	**Unadjusted VE (95% CI)**	**Adjusted VE (95% CI)**
Unvaccinated	38 (46.9)	71 (29.9)	.	.
Single dose	25 (30.9)	79 (32.9)	41 (31.26 to 51.29)	31.1 (22.10 to 41.03)
Two doses	18 (22.2)	90 (37.5)	63 (52.76 to 72.44)	52.2 (41.7 to 62.1)
COVAXIN Vaccine status	**Cases *n*=52 (%)**	**Controls *n*=116 (%)**	**Unadjusted VE (95% CI)**	**Adjusted VE (95% CI)**
Unvaccinated	38 (73)	71 (61.2)	.	.
Single dose	4 (7.7)	8 (6.9)	7 (2.86 to 13.89)	4.4 (1.10 to 9.93)
Two doses	10 (19.3)	37 (31.9)	50 (39.83 to 60.17)	39 (29.40 to 49.27)

VE was calculated as 1 minus odds ratio for a single dose and two doses, as compared with no vaccination n=Number, % - percentage

Table 2: Evaluation of overall VE among participants attending the RT-PCR center according to age and gender

Matched Age groups (years)	Cases *n*=95 (%)	Controls *n*=285 (%)	Unadjusted VE (95% CI)	Adjusted VE (95% CI)
18-40				
Unvaccinated	19 (20)	35 (12.3)	.	.
Any vaccine - Single dose	15 (15.8)	50 (17.5)	44.8 (34.08 to 54.28)	34.5 (24.82 to 44.15)
Any vaccine - Two doses	14 (14.7)	59 (20.7)	56.3 (45.72 to 65.92)	45.5 (35.03 to 55.27)
41-64				
Unvaccinated	16 (16.9)	26 (9.1)	.	.
Any vaccine - Single dose	10 (10.5)	30 (10.5)	45.9 (35.98 to 56.26)	34.4 (24.82 to 44.15)
Any vaccine - Two doses	10 (10.5)	52 (18.3)	68.8 (58.97 to 77.87)	57.7 (47.71 to 67.8)
≥ 65				
Unvaccinated	3 (3.2)	10 (3.5)	.	.
Any vaccine - Single dose	4 (4.2)	7 (2.5)	NE	NE
Any vaccine - Two doses	4 (4.2)	16 (5.6)	16.7 (10.23 to 25.82)	13.4 (7.11 to 21.2)
Gender	**Cases *n*=95 (%)**	**Controls *n*=285 (%)**	**Unadjusted VE (95% CI)**	**Adjusted VE (95% CI)**
Males				
Unvaccinated	21 (22.1)	33 (11.6)	.	.
Any vaccine - Single dose	10 (10.5)	44 (15.4)	64.3 (53.79 to 73.36)	52.4 (41.78 to 62.1)
Any vaccine - Two doses	15 (15.8)	71 (24.9)	66.8 (55.85 to 75.18)	55.2 (44.73 to 64.97)
Females				
Unvaccinated	17 (17.9)	38 (13.3)	.	.
Any vaccine - Single dose	19 (20)	43 (15.1)	1.3 (0.02 to 5.4)	0.9 (0.40 to 1.64)
Any vaccine - Two doses	13 (13.7)	56 (19.7)	48.2 (37.9 to 58.22)	39.1 (29.4 to 49.27)

same as Table 1, NE=Not effective

65%, respectively) of COVISHIELD was more than that of our study.[12,13] However, a study conducted at Gangaram Hospital, New Delhi, showed that during surge of infection, the VE for a single dose (18%) and two doses (28%) of COVISHIELD was less than that of our study.[14] In a study conducted at Sao Paul, Brazil, among older adults, the VE for a single dose (33.4%) of COVISHILED was close to that of our study.[15]

The VE for a single dose of COVAXIN was not effective, similar to AIIMS Delhi study. The VE for two doses of COVAXIN (39%) was less than that of AIIMS study (46%). The overall VE among males (55.2%) was more than that of females (39.1%), but in AIIMS study, the VE for COVAXIN among females (66%) was more than that of males (38%).[16]

There were several limitations such as a small sample size, and some factors such as COVID appropriate behavior, socio-economic status, and occupation were not considered. Furthermore, more studies should be conducted as new variants of SARS-CoV-2 such as Omicron are emerging. We do not know the VE against the variants, and whether booster doses are required or not is not yet established.

Key messages

COVID-19 VE quantifies the protection afforded by the vaccine against the COVID-19 infection in the real-world situation. The vaccine effectiveness data will be useful for the policy makers in the development of vaccine policy.

Table 3: Evaluation of COVISHIELD VE among participants attending the RT-PCR center according to age and gender

Matched Age groups (years)	Cases *n*=81 (%)	Controls *n*=240 (%)	Unadjusted VE (95% CI)	Adjusted VE (95% CI)
18-40				
Unvaccinated	19 (23.5)	35 (14.6)	.	.
Single dose	13 (16)	45 (18.8)	46.8 (36.92 to 57.24)	36.3 (26.6 to 46.21)
Two doses	10 (12.5)	40 (16.7)	54 (43.72 to 64.0)	43.2 (33.1 to 53.2)
41-64				
Unvaccinated	16 (19.8)	26 (10.8)	.	.
Single dose	9 (11)	27 (11.3)	45.9 (35.98 to 56.26)	34.4 (24.82 to 44.15)
Two doses	7 (8.6)	37 (15.4)	69.3 (58.92 to 77.8)	58.3 (47.72 to 67.8)
≥ 65				
Unvaccinated	3 (3.7)	10 (4.2)	.	.
Single dose	3 (3.7)	7 (2.9)	NE	NE
Two doses	1 (1.2)	13 (5.3)	74.4 (64.27 to 82.26)	69.1 (58.92 to 77.87)
Gender	**Cases *n*=81**	**Controls *n*=240**	**Unadjusted VE (95% CI)**	**Adjusted VE (95% CI)**
Males				
Unvaccinated	21 (25.9)	33 (13.8)	.	.
Single dose	9 (11.1)	39 (16.3)	63.8 (53.72 to 73.36)	51.8 (41.78 to 62.10)
Two doses	10 (12.3)	48 (20)	67.3 (56.88 to 76.08)	55.7 (45.72 to 65.92)
Females				
Unvaccinated	17 (21)	38 (15.8)	.	.
Single dose	16 (19.8)	40 (16.6)	10.6 (5.62 to 18.83)	7.6 (3.52 to 15.16)
Two doses	8 (9.9)	42 (17.5)	57.5 (46.71 to 66.86)	48.3 (37.90 to 58.22)

same as Table 1, NE=Not effective

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Conflicts of interest

There are no conflicts of interest.

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