Original Article

Vaccination and COVID-19 infection among adults aged 45 years and above in a North-Eastern state of India

Vanlalduhsaki[1], Swagnik Roy[2], Gracy Laldinmawii[2], Swati M. Patki[1], Shanthosh P. Sundaram[3]

Departments of [1]Community Medicine and [2]Microbiology, Zoram Medical College, Falkawn, Mizoram, [3]Department of Community Medicine, NEIGRIHMS, Shillong, Meghalaya, India

Abstract

Background: In response to this coronavirus disease 2019 (COVID-19) pandemic, vaccines reaching the predetermined levels of safety and efficacy were rolled out for use under emergency use approval/listing (EUA/EUL). The government of India has introduced three vaccines for emergency use as of today. **Aim:** The study was conducted to evaluate the association between the Covishield vaccine and COVID-19 infection among adults (≥45 years) who undergo reverse transcription–polymerase chain reaction (RT-PCR) COVID-19 testing. **Methods:** The study was conducted in a dedicated COVID-19 hospital in a north-eastern state of India among adults aged 45 years and above, who underwent RT-PCR testing. Cases were those who tested positive for RT-PCR and controls were those who were RT-PCR negative during the same period. A structured questionnaire was used to collect relevant data pertaining to socio-demographic profile, symptoms of COVID-19, vaccination status, co-morbidities, etc. Multiple logistic regression was used to calculate the odds ratio (OR) to find the association between vaccination and COVID-19 infection. **Results:** A total of 116 participants, 45 years and above were interviewed in the study. It was found that cases were more likely to have symptoms (48% vs. 6.9%, *P* value = <0.005) and have history of positive family member (89.7% vs. 72.4%, *P* value = 0.018) than controls. The odds of having COVID-19 infection were OR 12.60 (95% confidence interval (CI) 4.03-39.34) for those that have symptoms and OR 6.07 (95% CI 1.90-19.34) for unvaccinated individuals. **Conclusions:** Covishield vaccine protected individuals against COVID-19 infection with the risk of getting the infection being significantly lower in vaccinated individuals. **Relevance for Patients:** COVID-19 vaccination prevents the infection and addresses misconceptions about the vaccine.

Keywords: COVID-19 infection, Covishield, evaluation, vaccination, vaccine-effectiveness

Introduction

In response to this coronavirus disease 2019 (COVID-19) pandemic, vaccines reaching the predetermined levels of safety and efficacy were rolled out for use under emergency use approval/listing (EUA/EUL). India's drug regulator has approved restricted emergency use of Covishield (the name employed in India for the Oxford-AstraZeneca vaccine) and Covaxin, the homegrown vaccine produced by Bharat Biotech.[1]

Free vaccination against COVID-19 commenced in India on January 16, 2021, and the government is urging all of its citizens to be immunized, in what is expected to be the largest vaccination program in the world.[1] The first phase of the vaccination drive started with health care workers (HCWs) as the beneficiaries, followed by frontline workers from February 2, 2021. The next phase of the COVID-19 vaccination commenced from March 1, 2021, for people over 60 years of age and those aged 45 and above with specified co-morbid conditions. Vaccination

Address for correspondence: Dr. Vanlalduhsaki, Department of Community Medicine, Zoram Medical College, Falkawn - 796 005, Mizoram, India.
E-mail: vanlalduhsaki07@gmail.com

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of all people aged over 45 started from April 1. The government then decided to expand the ambit of the inoculation drive by allowing everyone above 18 to be vaccinated from May 1, 2021.[2] According to the CoWIN dashboard (Ministry of Health and Family Welfare, New Delhi, India), until October 2021, just over 106 crore individuals had been vaccinated in India.[3]

Mizoram, a small north-eastern state of India, reported its first COVID-19 case on March 24, 2020, and the next case on June 1, 2020, after a long hiatus of over two months. The state witnessed a steady rise in COVID-19 cases since then but managed to not only keep the infection in check but also maintain a zero death track record for a period of seven months. However, the trend started to change by the end of 2020 when the second wave of COVID-19 hit the nation, and the state continued to report high cases of COVID-19 infection. Soon after, vaccination against COVID-19 in the form of Covishield was rolled out in the state on par with the national timeline. During the initial phase, the vaccine was under a lot of skepticism from different aspects including religious beliefs and customs. Nevertheless, with concerted efforts from the government, health department, and the community's stakeholders, Mizoram managed to achieve a high percentage of vaccine coverage.

Evaluation of the real-world effectiveness of the COVID-19 vaccine used is important to substantiate the protection offered by the vaccine and also overcome vaccination hesitancy and increase the acceptance rate. A commonly used method for evaluating the population-level effectiveness of COVID-19 vaccines has been to assess their effectiveness in preventing infection. Test negative case-control studies are probably the most efficient and least biased to evaluate vaccine effectiveness in middle and low-income countries and had already been adopted by studies from other countries to evaluate COVID-19 vaccine effectiveness.[4]

Studies relating to the COVID-19 vaccine are negligible from Mizoram in spite of being one of the states that consistently report a high number of cases of COVID-19 infection. It has been accepted that estimates of vaccine effectiveness in the prevention of COVID-19 at the population level are essential to complement the results of pre-licensing trials. Not only do these studies reflect the real-world challenges, but also involve a more diverse population than those selected in vaccine trials. With this background, this study was conducted to evaluate the association of the COVID vaccine in preventing COVID-19 infection among the Mizo population.

Materials and Methods

Participants

A case-control study was conducted to evaluate the association between the Covishield vaccine and COVID-19 infection among adults aged 45 years and above, who underwent reverse transcription–polymerase chain reaction (RT-PCR) testing in Zoram Medical College, Mizoram during October 2021. ZMC is a dedicated COVID-19 hospital and is the only facility performing RT-PCR tests in the state at the time. Individuals who had a positive RT-PCR test for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection were included as cases. Controls were individuals who tested negative by RT-PCR and were matched based on the date of testing in the ratio of 1:1. The study was approved by the institutional ethics committee. Informed verbal consent was obtained from participants who agreed to participate after explaining the purpose of the study.

Study instruments

A semi-structured questionnaire was used to collect data pertaining to socio-demographic details, history regarding vaccination, co-morbidities, family details, and symptoms (cough, fever, breathlessness, ageusia, anosmia).

Data collection

Participants who consented to participate were contacted telephonically by the investigators and data was collected using the semi-structures questionnaire via Google Form, a web based survey software developed by Google.

Statistical analysis

Data was transferred to SPSS version 21.0, for Windows (IBM Corp, 1989, 2012. Chicago, Illinois). The primary analysis included vaccination status among participants. The secondary analyses included variables that predict COVID-19 infection. Descriptive data were summarized using mean, standard deviation, frequency, and proportions. The Chi-square test was used to compare the characteristics of cases and controls. For the analysis method, multiple logistic regression was used to calculate the odds ratio (OR) and 95% confidence interval (CI) of each independent variable for the development of COVID-19 infection. A P value of < 0.05 was considered statistically significant.

Results

A total of 116 individuals were interviewed telephonically in this study. The mean age of the participants was 56.41 ± 8.36 years and 57.59 ± 10.81 years for cases and controls, respectively, and female participants were more in both groups. As presented in Table 1, both cases and controls were similar with respect to socio-demographic profiles.

As presented in Table 2, more number of cases were more likely to have symptoms compared to controls (48% vs. 6.9%, P value = <0.005). It was also found that a family member being positive was significantly associated with cases (89.7%) vs. controls (72.4%) (p-value = 0.018). 98.3% of cases and 96.6% of controls reported having a history of contact with COVID-19 positive individuals. It was also found that co-morbidities were more among the cases than controls (50% vs. 37.9%). Vaccination status does not vary significantly between both groups as a majority of the participants have received the full dose of vaccination.

The commonest symptoms reported in the cases were anosmia (24%) followed by fever (19%) and sore throat (19%). On the other hand, controls had reported only two symptoms; fever, being more common (5.2%), and sore throat (1.7%). Although there were reports of other COVID-19 symptoms like cough, shortness of breath, fatigue, dysgeusia, and headache to a lesser extent among the cases, controls reportedly did not have any other symptoms [Figure 1].

We also found that co-morbidities pre-existed in both groups [Figure 2]. The most common co-morbidity was found to be hypertension (22.4%) among cases and diabetes mellitus (22.4%) among the controls. Other co-morbidities existed across both the groups including cardio-vascular diseases, coronary artery disease, chronic obstructive pulmonary diseases (COPD), thyroid disorder, and chronic liver diseases.

Table 1: Socio-demographic variables of the participants (*n*=116)

Variables	Cases *n* %	Controls *n* %	*P* (Chi-square)
Age in years (Mean±SD)	56.41±8.36	57.59±10.81	0.515*
Gender			
Male	26 (44.8)	25 (43.1)	0.852
Female	32 (55.2)	33 (56.9)	
Employment status			
Employed	25 (43.1)	18 (31.0)	0.178
Unemployed	73 (56.9)	40 (69.0)	
Educational qualification			
Uneducated	1 (1.7)	1 (1.7)	0.162
Primary	28 (48.3)	18 (31.0)	
Secondary	29 (50.0)	37 (63.8)	
Graduate and above	0	2 (3.4)	
Type of family			
Nuclear	24 (41.4)	23 (39.7)	0.850
Joint	34 (58.6)	35 (60.3)	

Table 2: Characteristics of participants based on COVID-19 history

Variables	Cases *n* (%)	Controls *n* (%)	*P* (Chi-square)
COVID-19 symptoms			
Yes	28 (48.3)	4 (6.9)	<0.005
No	30 (51.7)	54 (93.1)	
Family member positive			
Yes	52 (89.7)	42 (72.4)	0.018
No	6 (10.3)	16 (27.6)	
Previous COVID-19 history			
Yes	3 (5.2)	1 (1.7)	0.309
No	55 (94.8)	57 (98.3)	
History of contact			
Yes	57 (98.3)	56 (96.6)	0.559
No	1 (1.7)	2 (3.4)	
Co-morbidities			
Yes	29 (50.0)	29 (50.0)	0.190
No	22 (37.9)	36 (62.1)	
Vaccination status			
Unvaccinated	6 (10.3)	4 (6.9)	0.209
Partially vaccinated	12 (20.7)	6 (10.3)	
Fully vaccinated	40 (69.0)	48 (75.9)	

Table 3 shows the unadjusted and adjusted OR and 95% CI for the association between the variable of interest and COVID-19 infection. The odds of having COVID-19 infection was OR 0.93 (95% CI 0.44-1.94) in females, OR 1.00 (95% CI 0.61-16.37) for those who are uneducated, OR 12.60 (95% CI 4.03-39.34) for those that have symptoms, OR 6.07 (95% CI 1.90-19.34) for unvaccinated individuals, and OR 1.63 (95% CI 0.78-3.42) for those that have co-morbidities. After adjusting for possible confounders such as age, gender, educational status, vaccination status, and co-morbidities, the multivariable analysis showed an adjusted OR of 1.14 (95% CI 0.45-2.84) in females, 2.75 (95% CI 0.15-50.02) for those who are uneducated, 16.10 (95% CI 4.83-53.60) for those that have symptoms, 7.27 (95% CI 2.05-25.79) for unvaccinated individuals, and 1.97 (95% CI 0.77-5.01) for those that have co-morbidities.

Discussion

In response to the pandemic, the global efforts to develop multiple vaccines to protect against COVID-19 disease were underway. By the end of 2020, three COVID-19 vaccines have received EUA/EUL by maturity level 4 regulatory authorities, based on reaching predefined criteria for safety and efficacy, and at least several dozen more are in clinical trials. Post-introduction evaluations are of utmost importance to understand the vaccine's effect on reducing infections and disease in real-world conditions and address many of the questions about the performance of these vaccines.[5,6]

Epidemiological studies on vaccine effectiveness had been carried out in various countries as it is necessary to complement the results of pre-licensing trials to estimate the efficacy of these vaccines at the population level in real-world conditions and had offered best practice guidance on how to undertake post-introduction evaluations of the effectiveness of COVID-19 vaccines.[7,8] Observational studies conducted in different countries indicated the high effectiveness of the vaccine in preventing severe outcomes.[9,10]

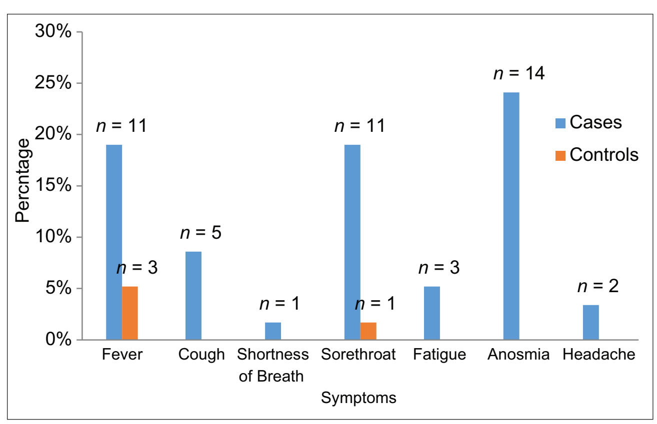

Figure 1: Distribution of COVID-19 symptoms (*n* = 116)

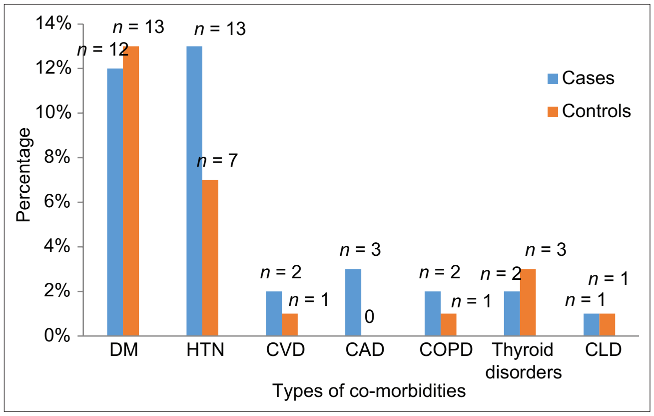

Figure 2: Graphical representation of pre-existing co-morbidities

Table 3: Regression analysis of COVID-19 infection with selected predictors

Variables	COVID-19 Infection			
	COR	*P*	AOR*	*P*
Age	0.98 (0.95-1.02)	0.512	0.99 (0.95-1.04)	0.831
Gender				
Male	Reference	0.852	Reference	
Female	0.93 (0.44-1.94)		1.14 (0.45-2.84)	0.775
Educational status				
Educated	Reference	1.000	Reference	
Uneducated	1.00 (0.61-16.37)		2.75 (0.15-50.02)	0.417
Symptoms				
Yes	Reference	<0.005	Reference	<0.005
No	12.60 (4.03--39.34)		16.10 (4.83-53.60)	
Vaccination status				
Vaccinated	Reference		Reference	
Unvaccinated	6.07 (1.90-19.34)	0.022	7.27 (2.05-25.79)	0.002
Presence of co-morbidities				
Yes	Reference	0.192	Reference	0.154
No	1.63 (0.78-3.42)		1.97 (0.77-5.01)	

* Adjusted for age, gender, and educational status, presence of symptoms, vaccination status, and presence of co-morbidities

This case-control study was undertaken to assess the association between vaccination and COVID-19 infection. Cases and controls were comparable with respect to socio-demographic characteristics [Table 1]. The study also showed that two variables viz., manifesting the symptoms of COVID-19 and having a positive family member significantly predicted the infection among the participants [Table 2]. It was found that cases manifested a wide variety of symptoms, including fever, which is the commonest, cough, shortness of breath, sore throat, fatigue, anosmia, and headache [Figure 1]. Several studies have also reported fever to be the commonest symptom of COVID-19 cases,[11-13] while other studies reported cough as the commonest symptom in COVID-19 patients.[14-16]

In the present study, the most common pre-existing co-morbidity among cases was hypertension (13%) followed by diabetes (12%). On the other hand, the most common co-morbidity reported by controls was diabetes (13%) and only 7% of controls reported having hypertension [Figure 2]. Pre-existing co-morbidities have been correlated with increased disease severity and adverse outcomes. A systemic review and meta-analysis consisting of 4266 articles, carried out by Wern Hann Ng *et al.*[17] showed that hypertension, obesity, and diabetes mellitus were identified to be the most prevalent co-morbidities in COVID-19 patients.

Our study also showed that unvaccinated individuals had a higher risk of getting COVID-19 infection (OR 6.07 (95% CI 1.90-19.34)) than vaccinated individuals, indicating that vaccination had significantly protected against COVID-19 infection [Table 3]. A study assessing the effectiveness of vaccines from Scotland found that both Oxford-AstraZeneca and Pfizer-BioNTech COVID-19 vaccines were effective in reducing the risk of SARS-CoV-2 infection and COVID-19 hospitalization in people with the COVID-19 infection.[18] Our study corroborates the finding that vaccination is protective.

A study assessing the protective effect of COVID-19 infection in Tamil Nadu found that the risk of infection among fully vaccinated HCWs was substantially lower when compared with unvaccinated HCWs (relative risk [RR], 0.35; 95% CI, 0.32 to 0.39).[7] Another study from Tamil Nadu assessing the effectiveness of the vaccine in preventing Covid-19 deaths among high-risk groups showed that compared to unvaccinated individuals, the relative risk of COVID-19 deaths among those receiving one and two doses was 0.18 (95% CI: 0.08-0.43) and 0.05 (95% CI: 0.02-0.15), respectively. The vaccine effectiveness in preventing COVID-19 deaths with one and two doses was 82% (95% CI: 57–92%) and 95% (95% CI: 85–98%), respectively.[19]

In a previous study from the UK, it was found that the first dose of the BNT162b2 messenger RNA (mRNA) vaccine was associated with a vaccine effect of 91% (95% CI 85–94) for reduced COVID-19 hospital admission at 28–34 days post-vaccination. The vaccine effect at the same time interval for the ChAdOx1 vaccine was 88% (95% CI 75–94).[20] Another vaccine study from Chile found that, among persons who were fully immunized with CoronaVac, the adjusted vaccine effectiveness was 65.9% (95% confidence interval [CI], 65.2 to 66.6) for the prevention of COVID-19 and 87.5% (95% CI, 86.7 to 88.2) for the prevention of hospitalization, 90.3% (95% CI, 89.1 to 91.4) for the prevention of intensive care unit (ICU) admission, and 86.3% (95% CI, 84.5 to 87.9) for the prevention of COVID-19-related death.[8]

Conclusion

To our knowledge, this is probably the first study that assessed the effectiveness of the COVID-19 vaccine from Mizoram. The results of our study are consistent with published studies showing effectiveness against COVID-19 infection. This is an important finding not only because data on the vaccine's effect is very scarce from this part of the country, but could also address certain issues relating to vaccine uptake such as vaccine hesitancy due to religious beliefs and customs and also the effectiveness among the local population. However, the study has its own limitations. This study enrolled only adults aged more than 45 years and above who had their swab sample tested by RT-PCR during October 2021, during which cases were more common among young adults. Additionally, vaccination roll-out was already extended to cover the whole population from 18 years and above. Nevertheless, this data on vaccine effectiveness substantiates the importance of COVID-19 vaccination in preventing the infection and keeping the pandemic in control.

In conclusion, our study indicated that Covishield is effective in preventing COVID-19 infection. This finding affirms that vaccination still remains the single, most cost-effective measure to prevent infection. Increasing the coverage of vaccination would significantly reduce the number of cases and ultimately put the pandemic at bay. For the benefit of the public, vaccination should be advocated by HCWs and any misinformation regarding vaccination, which could lead to public distrust of vaccine, should be clarified both scientifically and generally.

Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form, the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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