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Vaccine

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Impact of the Sinopharm's BBIBP-CorV vaccine in preventing hospital admissions and death in infected vaccinees: Results from a retrospective study in the emirate of Abu Dhabi, United Arab Emirates (UAE)



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ARTICLE INFO

Article history:

Received 6 November 2021

Received in revised form 7 February 2022

Accepted 8 February 2022

Available online 19 February 2022

Keywords:

COVID-19

SARS-CoV-2

Inactivated viral vaccine

Sinopharm BBIBP-CorV vaccine

Real-world vaccine effectiveness study

United Arab Emirates (UAE)

ABSTRACT

Background: This is a community-based, retrospective, observational study conducted to determine effectiveness of the BBIBP-CorV inactivated vaccine in the real-world setting against hospital admissions and death.

Study Design: Study participants were selected from 214,940 PCR-positive cases of COVID-19 reported to the Department of Health, Abu Dhabi Emirate, United Arab Emirates (UAE) between September 01, 2020 and May 1, 2021. Of these, 176,640 individuals were included in the study who were aged ≥ 15 years with confirmed COVID-19 positive status who had records linked to their vaccination status. Those with incomplete or missing records were excluded ($n = 38,300$). Study participants were divided into three groups depending upon their vaccination status: fully vaccinated (two doses), partially vaccinated (single dose), and non-vaccinated. Study outcomes included COVID-19-related admissions to hospital general and critical care wards and death. Vaccine effectiveness for each outcome was based on the incidence density per 1000 person-years.

Results: The fully-, partially- and non-vaccinated groups included 62,931, 21,768 and 91,941 individuals, respectively. Based on the incidence rate ratios, the vaccine effectiveness in fully vaccinated individuals was 80%, 92%, and 97% in preventing COVID-19-related hospital admissions, critical care admissions, and death, respectively, when compared to the non-vaccinated group. No protection was observed for critical and non-critical care hospital admissions for the partially vaccinated group, while some protection against death was apparent, although statistically insignificant.

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Conclusions: In a COVID-19 pandemic, use of the Sinopharm BBIBP-CorV inactivated vaccine is effective in preventing severe disease and death in a two-dose regimen. Lack of protection with the single dose may be explained by insufficient seroconversion and/or neutralizing antibody responses, behavioral factors (i.e., false sense of protection), and/or other biological factors (emergence of variants, possibility of reinfection, duration of vaccine protection, etc.).

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1. Introduction

The severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and the resulting coronavirus disease 2019 (COVID-19) have afflicted > 400 million people in a worldwide pandemic, leading to the deaths of over 5.8 million people so far [1]. To thwart its spread, over 300 vaccines have so far been developed at an unprecedented rate using various vaccine platforms, ranging from the classical inactivated virus to the more innovative adenoviral-vectored, DNA, and mRNA-based vaccines [2]. Of these, 33 vaccines have been approved by at least one country, while 10 vaccines have obtained Emergency Use Listing (EUL) status from the World Health Organization (WHO), including Pfizer-BioNTech, Moderna, Oxford-AstraZeneca/Covishield, Janssen/Johnson & Johnson [3]. The China-based pharmaceutical company, Sinopharm's inactivated whole virus vaccine, BBIBP-CorV [4] is the first Chinese vaccine that was granted Emergency Use Authorization (EUA) in May 2021 by WHO as the fifth such vaccine [5]. It is also the first inactivated vaccine approved for phase 1 and 2 clinical trials in the world that began in April 12, 2020, just 4–5 months into the start of the pandemic [6,7]. Now, CoronaVac developed by another China-based pharmaceutical company, Sinovac, and Covaxin developed by Bharat Biotech has joined this growing list of WHO-approved inactivated vaccines for emergency use [3].

By June 2020, Sinopharm had initiated phase 3 clinical trials of its BBIBP-CorV vaccine in seven countries, including United Arab Emirates (UAE), Bahrain, Jordan, Egypt, Morocco, Peru, and Argentina consisting of 45,000 volunteers [8]. In the UAE, the phase 3 clinical trial encompassed ~ 31,000 individuals, with 15,000 volunteers only in the Emirates of Abu Dhabi, its largest emirate [9]. Initial results of the trial across the UAE and Bahrain with 40,411 participants that received inactivated vaccines from two different viral strains (HB02 (i.e., BBIBP-CorV) and WIV04 strains) has shown vaccine efficacy of 78.1% (for BBIBP-CorV) and 72.8% (for WIV04) against symptomatic cases, 100% protection against severe disease, and 99% rate of seroconversion [9]. As of October 2021, the BBIBP-CorV vaccine has been approved in 66 countries with over 1.5 billion doses delivered worldwide [3,10].

Data evaluating post-vaccine effectiveness in the real-world scenario are available for either high risk groups (such as the healthcare workers or the elderly) or other COVID-19 vaccine platforms, such as mRNA or adenoviral-vectored vaccines that have primarily come from Denmark, US, UK, Israel, and now Qatar [11–24]. For instance, early surveillance of the Oxford AstraZeneca adenoviral-vectored vaccine and Pfizer-BioNTech vaccines in 383,812 adults in the UK have shown that new infections in the population dropped by 61% and 66% after the first dose and ~ 80% after the second dose, respectively [19]. Israel has reported the most extensive results from their mass vaccination drive in which 6.5 million people were vaccinated with two doses of the Pfizer-BNT162b2 vaccine [21]. Their analysis of 4.71 million such vaccinated individuals revealed a much higher vaccine efficacy of 91–97% in preventing new infections, asymptomatic and symptomatic infections, hospitalization and severe COVID, as well as death [21]. A single dose of Pfizer-BNT162b2 vaccine was also

observed to be effective in a smaller cohort of ~ 1.2 million people, but at a lower range of 57–72% for the same outcomes, as observed in the UK study [19].

Not much is known about vaccine effectiveness of inactivated viral vaccines like BBIBP-CorV in the real-world setting, a scenario in which many factors are less controlled than the clinical trials. These include less stringent adherence to vaccine schedules, different age spectrum of the population compared to the ideal age group of the trial participants, variable health status of the general population compared to trial volunteers that are primarily healthy, appearance of different spectrum of viral variants with time during the course of vaccination drives compared to the trials, etc. Only recently has the first study been published revealing the effectiveness of the inactivated vaccine platform developed by Sinovac in the Chilean population [26]. This study revealed a vaccine efficacy of 65.9% for preventing infection, 87.5% for preventing hospitalizations, 90.3% for preventing critical care hospital admissions, and 86.3% in preventing death.

Based on the initial promising results of phase 3 clinical trials of this vaccine, the Abu Dhabi Department of Health (DOH) issued recommendations to vaccinate Abu Dhabi residents 15 year or older to receive the Sinopharm's BBIBP-CorV COVID-19 vaccine on September 1, 2020. As of October 2021, over 20 million doses had been administered in the UAE and >86% of the population had been vaccinated, mostly with the Sinopharm vaccine [27,28]. Thus, the aim of the present study was to determine the effectiveness of the Sinopharm BBIBP-CorV vaccine under the real-world scenario in preventing hospital & critical care admissions as well as death in the general Abu Dhabi population that had already been infected with the virus.

2. Material and methods

2.1. Study population

We performed a retrospective cohort study to estimate Sinopharm BBIBP-CorV vaccine effectiveness against severe COVID-19 among Abu Dhabi residents between September 01, 2020 and May 1, 2021. The participants were aged 15 years and older who had prior exposure to COVID-19, as confirmed by the clinically-validated COVID-19 PCR test. Those that had received the Sinopharm BBIBP-CorV vaccine had been clinically cleared from the infection before receiving the vaccine, as per Department of Health (DOH) COVID-19 disease management policy. We followed a four-step approach to data collection: a) identify data source, b) screen data completeness, c) study eligibility, and d) include anonymous data for analysis (Fig. 1).

We identified $n = 214,940$ records that were PCR (+) for the virus, in which 176,640 (82.2%) cases could be linked to their vaccination status. These cases were classified into three groups: fully or partially vaccinated and non-vaccinated. Cases with missing or incomplete data were excluded from the analysis ($n = 38,300$) (Figs. 1 & 2). The outcome of interest was to determine 14 days post-vaccination admission to hospital general ward, critical units, and discharge outcome (death) in the completely vaccinated and

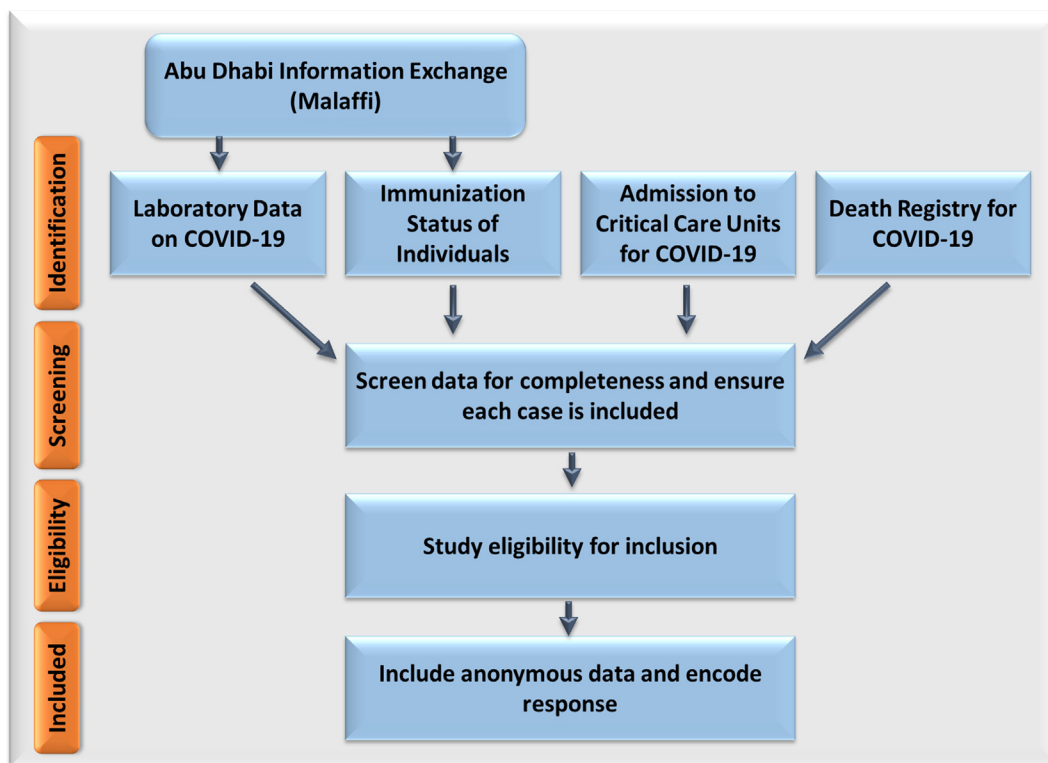


Fig. 1. Data collection plan. Flow chart of the data collection plan for the study.

partially vaccinated groups in comparison with the non-vaccinated group using survival analysis.

2.2. Definitions

Participants were considered fully vaccinated after receiving two doses of Sinopharm BBIBP-CorV vaccine, partially after getting one dose, and non-vaccinated if there was no documentation of vaccination. An individual was considered “immunized” if 14 days had elapsed after the second dose of the vaccination. Admission to hospital was defined if a case developed complications that required hospitalization to the general ward or intensive care units, as per DOH COVID-19 disease management guidelines. A case was considered deceased due to COVID-19 if the underlying cause of death was reported as COVID-19 disease. We excluded those cases from the analysis who had a documented positive PCR result, admitted to hospital, or deceased before the evaluation period ended, regardless of their vaccination status.

2.3. Randomization

Randomization of the study participants was not performed due to the “observational” nature of the present study. This retrospective study used the Abu Dhabi Health Information Exchange “Malaffi” to identify all unique patients above 15 years of age that had tested positive for the COVID-19 PCR test. Furthermore, their vaccination status was ascertained using specific criteria of the methodology described above and detailed in Fig. 2. The approach did not aim to randomize, but rather capture the full cohort of “PCR-positive” individuals for the specified period using a single digital platform known for its robustness and comprehensiveness (<https://www.doh.gov.ae/en/featured/malaffi>). This approach makes this study one of the most comprehensive real-world evidence study covering over 176,000 patients > 15 years old, over a period of 8 months.

2.4. Statistical analysis

Characteristics of the study subjects were described in percentages for the classified variables. We estimated vaccine effectiveness against severe COVID-19 by using Cox proportional hazard regression models. Adjusting for confounders, effectiveness was calculated as $(1 - \text{odds ratio}) \times 100\%$. We used survival analysis to estimate the case incidence density and quantify the strength of association between vaccine effectiveness and the outcomes of interest. Incidence rate ratios were calculated with 95% confidence interval (CI). CDC Epi Info version 7.1 and Stata 10 software were used in the data cleaning and analyzing process.

3. Results

The demographic characterization of study cases is shown in Table 1. A majority of participants were males (64.8%) with 76.4% of the infected individuals from nationalities other than Emirati (UAE citizens). Most cases were between the age of 20–49, with only 5.6% of the cases below the age of 19, while 14.8% were above the age of 50 years (Table 1). Within this cohort of 176,640 individuals, 35.6% (n = 62,931) were fully vaccinated, while 12.3% (n = 21,768) were partially vaccinated, leaving 52% of the cohort (n = 91,941) unvaccinated (Fig. 2). The age distribution of the fully-, partially-, and non-vaccinated groups essentially mirrored each other, revealing appropriate age-matching between the control and test groups (Supplementary Fig. 1).

The completely- and partially-vaccinated groups were compared to the non-vaccinated group using survival analysis to determine three specific outcomes 14 days post-vaccination that included: admission to 1) hospital general ward, 2) critical units, and 3) death. As can be seen, when it came to hospital admissions in the general ward, the incidence rate (per 1000 person-years) was 30.5 (95% CI, 28.2–33), while admission to the critical care

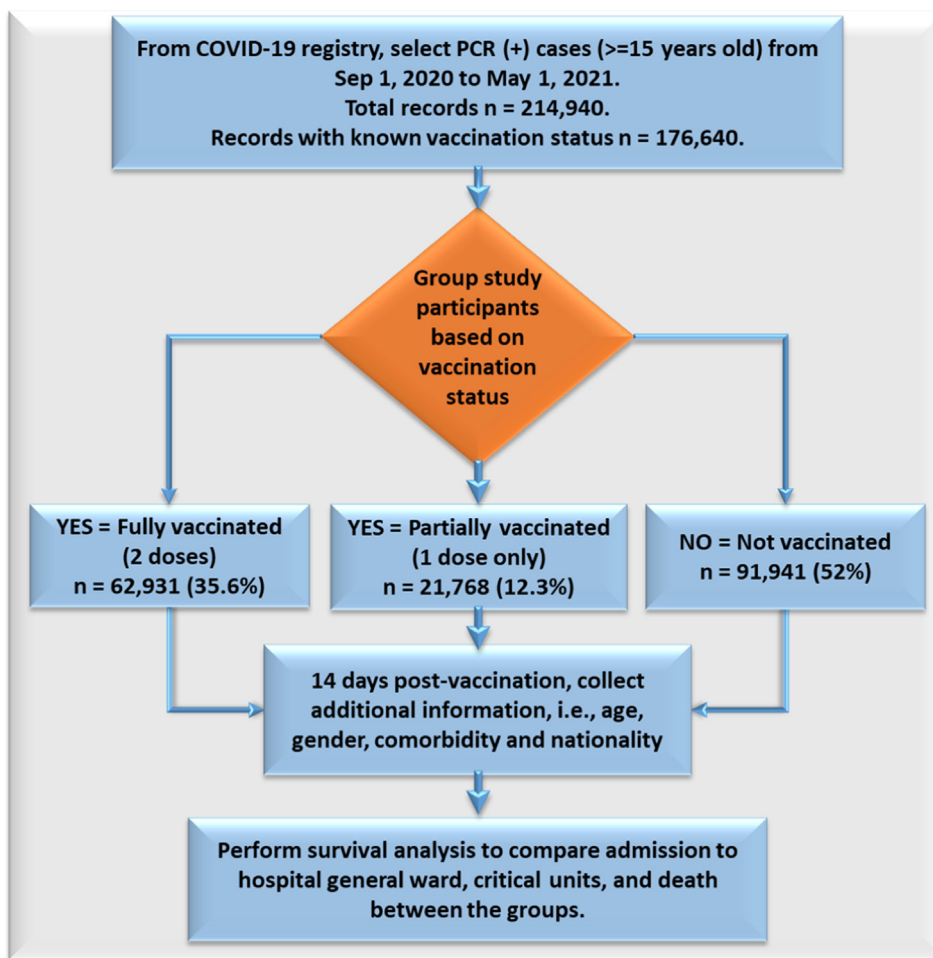


Fig. 2. Study design and participant numbers. The study participants were divided into three groups (fully vaccinated with two doses of vaccine, partially vaccinated with one does of the vaccine, and unvaccinated) and followed for admission to the general hospital ward, critical care units, or death. See text for details.

Table 1
Baseline characteristics of study participants.

Characteristic	No. (%)			
	Fully Vaccinated	Partially Vaccinated	Not Vaccinated	Overall Sample
	n = 62,931 (35.6)	n = 21,768 (12.3)	n = 91,941 (52)	n = 176,640
Age groups				
15–19	1,550 (2.5)	778 (3.6)	7,624 (8.3)	9,952 (5.6)
20–24	4,671 (7.4)	1,694 (7.8)	7,842 (8.5)	14,207 (8)
25–29	8,522 (13.5)	3,309 (15.2)	13,435 (14.6)	25,266 (14.3)
30–34	11,743 (18.7)	4,199 (19.3)	16,984 (18.5)	32,926 (18.6)
35–39	12,015 (19.1)	4,142 (19)	14,966 (16.3)	31,123 (17.6)
40–44	9,051 (14.4)	2,941 (13.5)	10,467 (11.4)	22,459 (12.7)
45–49	6,106 (9.7)	1,876 (8.6)	6,642 (7.2)	14,624 (8.3)
50–54	4,344 (6.9)	1,296 (6)	4,940 (5.4)	10,580 (6)
55–59	2,562 (4.1)	690 (3.2)	3,627 (3.9)	6,879 (3.9)
60–64	1,340 (2.1)	396 (1.8)	2,349 (2.6)	4,085 (2.3)
65–69	605 (1)	238 (1.1)	1,417 (1.5)	2,260 (1.3)
70–74	246 (0.4)	113 (0.5)	792 (0.9)	1,151 (0.7)
75–79	103 (0.2)	59 (0.3)	421 (0.5)	583 (0.3)
80+	73 (0.1)	37 (0.2)	435 (0.5)	545 (0.3)
Sex				
Female	41,731 (45.4)	6,437 (29.6)	13,913 (22.1)	62,081 (35.1)
Male	50,192 (54.6)	15,328 (70.4)	49,005 (77.9)	114,525 (64.8)
Null	18 (0)	3 (0)	13 (0)	34 (0)
Nationality				
Nationals	14,099 (22.4)	4,132 (19)	23,527 (25.6)	41,758 (23.6)
Expatriates	48,832 (77.6)	17,636 (81)	68,414 (74.4)	134,882 (76.4)

units was 2.7 (95% CI, 2.1–3.5) for the fully vaccinated group. This resulted in a vaccine effectiveness of 80% (95% CI, 78–81.4) for the general hospital admission and 92.2% (95% CI, 89.7–94.1) for the critical care admission, respectively, compared to the non-vaccinated group (Table 2). No protection was observed for the partially vaccinated group for either of these outcomes. When it came to protection from death, the incidence rate (per 1000 person-years) was 0 (95% CI, 0–0.3 for the fully vaccinated group, resulting in a vaccine effectiveness of 97% (95% CI, 83–99.9) which was highly desirable (Table 2). The partially vaccinated group showed an incidence rate of 1.2 (95% CI, 0.6–2.5), resulting in a vaccine effectiveness of 27.9% (95% CI, –61–72.6) (Table 2), which shows some reduction in the death rate; however, it was not statistically significant, and well below the 50% threshold set by WHO and the US Food and Drug Administration (FDA) for effectiveness of COVID-19 vaccines [29].

Multivariate analysis based on Cox proportional hazard regression models corroborated the unadjusted findings and reached the same qualitative conclusions with respect to vaccine effectiveness for the three outcomes under consideration (Table 3). Additionally, subjects aged 30–59 years old experienced significantly higher risk for all outcomes compared with those below 30 years old; while the same finding would generally apply to individuals above 60 years old, the small percentage of this population limits conclusions with

regard to the ability of the vaccine to prevent hospital admissions and death in this age group. Female subjects had a higher risk for hospital admissions, but lower risk for either critical admissions or death. Finally, expatriates (non-UAE citizens) reported lower risk for all three outcomes compared with UAE citizens.

Analysis of the cumulative risk of these outcomes with time confirmed the results obtained. As can be seen, the fully-vaccinated group (green color in Fig. 3) could be distinctly separated from the non-vaccinated group (blue color in Fig. 3) and partially-vaccinated group (pink color in Fig. 3) throughout the time course since entry of the subjects into the study for hospitalizations into either the general ward (Fig. 3A) or critical care units (Fig. 3B), respectively. The non-vaccinated group overlapped with the partially-vaccinated group for entry into the general ward of the hospital as well as the critical care units (Fig. 3A & B), confirming that essentially no protection could be observed from one dose of the vaccine 14 days post vaccination. The same was observed for protection from death where the fully-vaccinated group could be easily separated from the non-vaccinated or partially-vaccinated group (Fig. 3C). The unusual presentation of the last graph (Fig. 3C) is most likely due to the small number of deaths observed in the fully-vaccinated group; however, it does not affect the overall results and conclusions which show no difference between the non-vaccinated and partially-vaccinated groups.

Table 2
Incident cases of primary outcomes and estimated vaccine effectiveness.

Outcome	Fully vaccinated	Partially vaccinated	Not vaccinated
Hospital admissions			
No. of participants	62,931	21,768	91,941
No. of incident cases	622	1,004	3,909
Person-years	20,414.3	5,556.2	25,948.6
Incidence density per 1000 person-years (95% CI)	30.5(28.2–33)	180.7 (169.9–192.2)	150.6 (146–155.5)
Vaccine effectiveness (95% CI), %	79.8 (78–81.4)	–20 (–28.6–11.8)	[Reference]
Critical care admissions			
No. of participants	62,931	21,768	91,941
No. of incident cases	55	189	909
Person-years	20,488.4	5,734.3	26,558.8
Incidence density per 1000 person-years (95% CI)	2.7(2.1–3.5)	33(28.6–38)	34.2 (32.1–36.5)
Vaccine effectiveness (95% CI), %	92.2 (89.7–94.1)	3.7 (–12.8–18.1)	[Reference]
Deaths			
No. of participants	62,931	21,768	91,941
No. of incident cases	1	7	45
Person-years	20,494.7	5,776.6	26,772.5
Incidence density per 1000 person-years (95% CI)	0(0–0.3)	1.2(0.6–2.5)	1.7 (1.3–2.3)
Vaccine effectiveness (95% CI), %	97.1 (83–99.9)	27.9 (–61–72.6)	[Reference]

Table 3
Multivariate analysis based on Cox proportional hazard regression model to confirm unadjusted findings.

Variable	Hospital admissions		Critical admissions		Deaths	
	Hazard ratio (95% CI)	P	Hazard ratio (95% CI)	P	Hazard ratio (95% CI)	P
Fully vaccinated	0.26 (0.24–0.28)	<0.001	0.09 (0.07–0.12)	<0.001	0.04 (0.01–0.31)	0.002
Partially vaccinated	1.35 (1.26–1.45)	<0.001	1 (0.85–1.17)	0.959	0.88 (0.39–1.95)	0.749
Age 30–59 years old	2.21 (2.05–2.38)	<0.001	5.93 (4.47–7.87)	<0.001	5.14 (0.64–41.24)	0.124
Age 60 + years old	9.52 (8.73–10.38)	<0.001	54.88 (41.35–72.85)	<0.001	254.06 (35–1844.32)	<0.001
Female	1.55 (1.46–1.64)	<0.001	0.78 (0.69–0.88)	<0.001	0.59 (0.34–1.04)	0.069
Expatriate	0.4 (0.37–0.42)	<0.001	0.54 (0.47–0.61)	<0.001	0.22 (0.12–0.39)	<0.001
No. of subjects	176,640		176,626		176,640	
No. of failures	5,535		1,153		53	

Omitted or reference categories: non-vaccinated, age 15–29 years old, male or unknown gender, and UAE nationals.

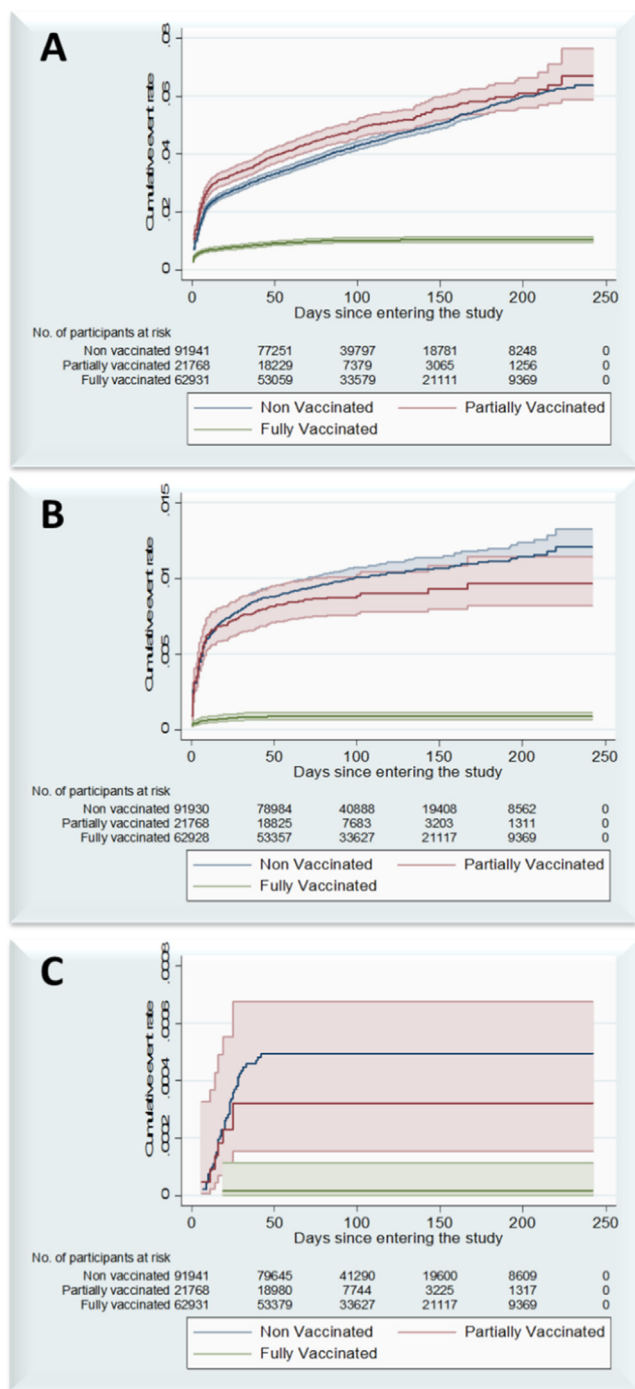


Fig. 3. Effectiveness of the Sinopharm BBIBP-CorV vaccine. Graphs revealing the cumulative risk of: **A)** admission into a hospital general ward, **B)** admission into critical care units, and **C)** death. The number of patients in each category are listed below the graphs.

4. Discussion

This study evaluated effectiveness of the Sinopharm BBIBP-CorV vaccine administered to the population of the emirate of Abu Dhabi, UAE 14 days post vaccine administration in fully- or partially-vaccinated individuals. Vaccine effectiveness normally is defined as the ability to “prevent” new infections in real-world settings; while, in our case, we measured the ability of the vaccine to prevent severe COVID-19 or death and not newly acquired infections, as the population analyzed was already PCR (+) for

SARS-CoV-2. Thus, due to its design, it made our study a more unbiased account of vaccine efficacy by comparing “the severity of breakthrough infections in already vaccinated individuals *versus* infections in non-vaccinated” individuals. The vaccine effectiveness in fully vaccinated individuals was 80%, 92%, and 97% in preventing hospital admissions, critical care admissions, and death, respectively (Fig. 3). This was similar or better than the interim results of the phase 3 trial of the vaccine reported from UAE and Bahrain which showed that 2 doses of this vaccine, administered to individuals > 18 years of age at an interval of 21 days, had an efficacy of 78.1% against symptomatic SARS-CoV-2 infection and 100% protection against severe COVID-19 [9].

Interestingly, the single dose of the vaccine was found to be ineffective in preventing critical care admission with limited protection against death due to COVID-19. Several confounding factors could have led to the lack of effectiveness of the single dose of vaccine in the real-world setting, including the nature of the vaccine. Inactivated viral vaccines tend to initiate weaker immune responses needing multiple doses since the virus cannot replicate or infect cells. Being a retrospective study, data pertaining to the immunological responses of the vaccinees receiving a single vaccine dose in our cohort was not available. However, data from the phase 1 and 2 clinical trials of this vaccine has shown that a vast majority of the participants seroconverted by day 14 after the first dose of the vaccine, while only a minority could induce neutralizing antibodies during this time period; furthermore, the magnitude of these responses in both cases was low initially and improved with time and addition of extra doses [6,7]. Thus, this insufficient but developing immune response against the virus after the single dose may explain the slight and statistically insignificant protection against death that was observed in our cohort receiving only one dose of the vaccine. Additionally, other factors could also have been involved in the lack of effectiveness of the single vaccine dose, including individual behavior of the vaccinated individuals towards measures designed to prevent infection, such as social distancing, wearing masks, washing hands, variability in the use of general screening tests prevalent in Abu Dhabi, and/or biological factors such as the appearance of viral variants, possibilities of reinfection, differences in duration of vaccine immunity, etc.

UAE is among the countries with the highest coverage of COVID-19 vaccination in the world, with more than 70% of the population already vaccinated by the end of June 2021 [27,28]. Despite that, there was a peak in the numbers of COVID-19 cases during the period of data collection in January 2021[30], which could be due to reinfection since the country was open for travel and January was the peak of winter travelling when there was a heavy influx of travelers from around the world [31]. During this time, the number of individuals that were vaccinated with only one dose of the BBIBP-CorV vaccine were more; however, the cases started to gradually fall in numbers after the peak when more people had been vaccinated with two doses of the vaccine [31]. Since then, the cases started to go up again which could have resulted in the introduction and spread of newer variants of the SARS-CoV-2 that have been emerging in various parts of the world [32]. During the period of data collection for this study, a majority of cases belonged to the Alpha and Beta variants of the virus [33]. Therefore, the present study also gives a fair estimate of the effectiveness of the vaccine against these variants that could have a higher potential to escape from the host immunity. Although we cannot give accurate estimates of its effectiveness against these variants, the drop in the number of cases after the peak as the vaccination rates increased is highly suggestive that the vaccine was probably effective against these variants. It is important to highlight that during the period of study, the Delta variant was not present; therefore, the effectiveness of the vaccine might change after the emergence of new

variants such as Delta. According to the Genetic Testing Registry (GTR), by June 27, 2021 the circulating variants in the UAE included the Beta variant at 39.2%, followed by the Delta variant at 33.9%, while the Alpha variant was present at 11.3%, revealing the infectious nature of the newer variants and the potential of the vaccine to prevent their spread [34]. The Delta variant is the most contagious variant so far that is steadily replacing the other variants [35]. This may be due in part to its higher replication rate, revealing viral loads at ~ 1000 times higher in the upper respiratory tract than the original variants early in infection, possible escape from the vaccine-generated immune response, and duration of vaccine protection [32,35]. Thus, surveillance and analysis of post vaccine efficacy in vaccinated populations is critical in informing public health policy measures, especially in the midst of an ensuing pandemic where the rates of infection and vaccine availability may suddenly change, as is being observed in countries around the world.

Compared to these results, the inactivated Sinopharm BBIBP-CorV vaccine initially showed less effectiveness (72.8 and 78%, depending upon the viral strain used in the vaccine), as assessed by the interim phase 3 clinical trials [9]. In the real-world setting, the early results presented in this study reveal comparable vaccine effectiveness when it comes to two doses of the vaccine, effectiveness that has ranged from 80% to 97%, depending upon the outcome studied (Table 2, Fig. 3). Granted that our study design did not let us consider prevention of new infections, we were still able to assess how well the patients did once exposed to the virus post complete vaccination compared to non-vaccinated patients or those vaccinated with a single dose. This effectiveness is similar to the vaccine efficacy revealed by the mRNA-based vaccines in the real-world setting [19–25], vaccines that are much more expensive and inaccessible to the developing world due to challenges imposed by their requirement for subzero temperatures for their transportation unlike the BBIBP-CorV vaccine that only requires routine refrigerated temperature (4°C) for its shipment and storage. It is no surprise that the single dose provided little to no protection in preventing general and critical care admissions, or death since the first dose only primes the immune system, while the second dose is needed to elicit the dominant immune response. This suggests that a second dose is critical for developing an effective immune response and further boosters may be needed to increase and retain vaccine effectiveness in the population either with the same (homologous) or a different (heterologous) vaccine. As a result, UAE has already allowed a third dose of the vaccine after six months, and even allowed using Pfizer-BNT162b2 for boosting the current responses, a so-called mix and match approach [10,36]. Similarly, Saudi Arabia has published new guidelines making it mandatory for pilgrims to get a booster with BNT162B2 or other mRNA or viral vector vaccines, if initially inoculated with an inactivated vaccine [37].

5. Conclusions, strengths, and limitations

This study reports effectiveness of the Sinopharm BBIBP-CorV classical inactivated vaccine in the real-world setting based on a novel study design where only the infected population was studied to determine the ability of the vaccine to prevent hospitalizations or death. Based on a cohort of 176,640 individuals that were PCR positive for SARS-CoV-2 and whose vaccination status could be traced, the data reveals that two doses of the vaccine were highly effective in preventing COVID-19-related hospital and critical care admissions and death, similar to the mRNA and viral-vectored vaccines. This makes BBIBP-CorV a highly valuable tool against COVID-19, especially in the under developed world due to its less stringent requirements for storage and shipment, unlike the experimental

mRNA-based vaccines that require much more stringent requirements of subzero temperatures for their storage and transportation. However, a single dose of the vaccine revealed no protection against hospitalizations, but some statistically insignificant protection against death, observations that need to be explored further. The study design provided an unbiased approach to data acquisition, which is the strength of this study, but the design was not appropriate to determine the rate of infection in vaccinated individuals, which can be considered a limitation of this work. Similarly, risk assessment based on comorbidities could also not be assessed.

Ethical Approval

This study was approved by the Abu Dhabi Health Research and Technology Ethics Committee (approval numbers DOH/CVDC/2021/994, DOH/CVDC/2021/995, and DOH/CVDC/2021/996) of the UAE Ministry of Health and Prevention.

CRedit authorship contribution statement

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Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Acknowledgments

Funding: This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Additional contributions

We are grateful for support, data and information provided by the Department of Health, Abu Dhabi, the Abu Dhabi Health Services Company (SEHA) and the SEHA Hospitals, Abu Dhabi Health Information Exchange Malaffi. Particular thanks to Ms Faiza Medeni from the Department of Health, Abu Dhabi for facilitating the data collection, Ms Shahad Omar Alshamlan from the Abu Dhabi Public Health Center, Abu Dhabi for facilitating coordination among authors, and Dr. Waqar Ahmad, Department of Biochemistry & Molecular Biology, College of Medicine & Health Sciences for help with referencing.

Appendix A. Supplementary material

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.vaccine.2022.02.039>.

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