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Research article

A real-world study of BBIBP-CorV vaccine effectiveness in a Sri Lanka rural province

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ABSTRACT

Objective: Real-world studies assessing the effectiveness of the BBIBP-CorV vaccine in low and middle-income countries are limited. We evaluated the BBIBP-CorV vaccine's effectiveness in reducing COVID-19 symptomatic disease, hospitalisation, severe disease, and mortality during the third wave of the pandemic in Sri Lanka.

Methods: We conducted a test-negative case-control study in North Central Province from May 2021 to February 2022. Evidence of vaccination was obtained from the national registry. The PCR-positive patients were cases, while negative individuals were controls. Adjusted vaccine effectiveness (aVE) was computed for fully, partially, and non-vaccinated groups in reducing symptomatic disease, hospitalisation, severe disease, and mortality.

Results: Our study involved 3305 cases and 3418 controls. The overall aVE for preventing PCR-positive infection in fully vaccinated was 30·8 % (95 % CI:17·9–41·6). In fully vaccinated over 60 years, the overall aVE was 72·3 % (95 % CI: 49·7–84·8). Full vaccination with BBIBP-CorV is effective in reducing hospitalisation, severe COVID-19 disease, and death, with aVE rates of 70·3 % (95 % CI: 57·9–79·0), 88·9 % (95 % CI: 81·8–93·2), and 92·3 % (95 % CI: 84·8–96·1) respectively.

Conclusion: Individuals who have received two doses of the BBIBP-CorV vaccine are protected against hospitalisation, severe COVID-19 disease, and death. Duration of protection against hospitalisation, severe COVID-19, and fatal COVID-19 sustained at least 121 days, with no sign of waning during that time.

1. Introduction

The first patient with severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2) was reported in Sri Lanka on 27 January 2020. By 5 December 2023, there had been 672,644 confirmed Coronavirus disease 2019 (COVID-19) cases, with 16,886 total deaths [1].

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The pandemic in Sri Lanka is divided into three waves: January 2020 to October 2020 (3396 cases, 13 deaths, case fatality rate (CFR) 0·38), October 2020 to April 2021 (92341 cases, 591 deaths, CFR 0·64) and 15 April 2021 to 31 December 2022 (576434 cases, 16,238 deaths, CFR 2·81) [2]. Virologically, three different periods are also being described: October 2020 to January 2021 (B.1.411), April 2021 to June 2021 (B.1.1.7 alpha), and July 2021 to October 2021 (B.1.617.2 delta and its sub-lineages AY.28, AY.104) [3]. The delta variant dominated the third wave, resulting in 96·4 % of all COVID-19 deaths in Sri Lanka. During the pandemic peak, from July to November 2021, seropositivity reached 30 %, and the case fatality rate reached 6·35 % [3].

The nation began vaccination against COVID-19 with the ChAdOx1-S (AstraZeneca or *Covishield*) vaccine in late January 2021 and BBIBP-CorV-Beijing (Sinopharm or *Covilo*) immunisation in May 2021. As a result, by February 2023, 14·75 million people, comprising 67·2 % of the population, were vaccinated with two doses [1]. Although seven vaccines were approved in Sri Lanka, only five vaccines were utilised; others were BNT162b2 or tozinomeran (Pfizer or *Comirnaty*), mRNA-1273 or elasomeran (Moderna or *Spikevax*), Gam-COVID-Vac (*Sputnik-V*), and the booster doses almost exclusively from *Comirnaty*. The BBIBP-CorV vaccine holds the most significant share of the island's vaccine coverage, contributing 72 % [4]. BBIBP-CorV vaccine has been demonstrated to have a seroconversion rate of 95 % two weeks after the second dose [5]. The antibodies targeting SARS-CoV-2 decrease over time, particularly among older people, after two doses of BBIBP-CorV. Nevertheless, T and B cells' response for up to 12 weeks after the second dose is critical to preventing severe disease [6].

Although a resource-poor country, Sri Lanka has excellent health indices with commendable public health responses during the COVID-19 pandemic [7–9]. Despite issues in vaccine availability in the context of global vaccine equity, the country managed to roll out a vaccination program with good coverage (187·3 vaccine doses per 100 population, 68·9 fully vaccinated per 100 population, and 38·4 boosted per 100 population, while the global data are 174·4, 66·3, and 31·9 respectively as of 05 April 2023) [10]. Initially, due to supply chain issues, BBIBP-CorV was the only vaccine available and was affordable in the country. However, the evidence on vaccine effectiveness (VE) in low and middle-income countries (LMIC) is scarce, highlighting the 10/90 gap [11]. In this evidence gap, real-world effectiveness studies conducted in LMIC are necessary to promote further use of vaccines.

Vaccine performance is measured by efficacy, effectiveness, and impact. Phase 2/3 randomised control trials measure the efficacy of vaccines [12]. Real-world observational studies measure effectiveness [12]. The World Health Organisation (WHO) recommended the test-negative case-control study design to guide VE studies in LIMC, owing to its cost-effectiveness and quickness in a pandemic [13]. Reduction in the incidence of infection and indirect effects of vaccination, such as herd protection, reflects the impact [12].

In this background, the objective of the present study was to evaluate the effectiveness of 2-dose β-propiolactone inactivated, aluminium hydroxide adjuvanted BBIBP-CorV in preventing death, severe disease, hospitalisation, and symptomatic infection in fully, partially, and not vaccinated people in North Central Province (NCP), Sri Lanka. We assessed the impact of the vaccine during the third wave by evaluating the cases, deaths, and vaccine coverage in Sri Lanka using available data at the Epidemiology Unit. This study estimated the VE during the third COVID-19 wave, where the delta variant predominated.

2. Methods

2.1. Study design

We adopted a test-negative case-control design to assess the BBIBP-CorV's vaccine effectiveness (VE) against COVID-19 infection by comparing vaccinated individuals to that among non-vaccinated individuals. Furthermore, we estimated the VE against symptomatic infection, hospitalisation, severe illness, and death due to COVID-19.

Individuals who tested positive for SARS-CoV-2 reverse transcriptase polymerase chain reaction (RT-qPCR) test were selected as cases, while negative individuals were chosen as unmatched controls. We also analysed the BBIBP-CorV vaccine programme in the country and its relationship with the COVID-19 case fatality rate to investigate the vaccine's impact.

2.2. Setting

The study participants were primarily from the North Central Province (NCP) in Sri Lanka. NCP comprises two districts: Anuradhapura, with an estimated mid-year population of 954,000 (4.3 % of Sri Lanka's population) in 2021, and Polonnaruwa, with an estimated mid-year population of 448,000 (2.0 % of Sri Lanka's population) [14]. A central COVID-19 tertiary care centre with 12 intensive care beds and 36 high-dependency beds was established in the Teaching Hospital Anuradhapura (THA). The only virology laboratory, *Methsirisewana*, conducting COVID-19 RT-qPCR in the NCP is at the THA (Annexure 1).

2.3. Ethics and consent statement

The study was reviewed and approved by the Ethics Review Committee, Faculty of Medicine and Allied Sciences, Rajarata University of Sri Lanka (ERC/2022/04). Ethics approval was received on 08 February 2022. The participants were recruited, and data was gathered by telephone interview; hence, consent was obtained verbally.

2.4. Participants and data collection

Adults 18 years or older tested for COVID-19 in NCP were eligible to be recruited (Fig. 1). We excluded participants who could not be reached by phone to verify vaccination status or comorbidities, those who received vaccines other than BBIBP-CorV, those who

received a booster dose before COVID-19 RT-qPCR testing, and those who reported a prior RT-qPCR confirmed COVID-19 infection.

During the study period from May 2021 to February 2022, the "*Methsirisewana*" virology laboratory conducted all COVID-19 RT-qPCR tests in the NCP of Sri Lanka. The community-referred test results were forwarded to the regional epidemiology department for national statistical monitoring. We obtained patients' names, contact details, and COVID-19 PCR test results from these tests through the regional epidemiology department. Trained research assistants then contacted the participants to gather the basic demographic data, clinical data, and vaccination status. We calculated the Charlson comorbidity index for each study participant [15]. We also reviewed admission records at Teaching Hospital Anuradhapura to identify COVID-19-positive patients during the study period, contacting them by phone to collect the same data set. For deceased patients, data were extracted from their hospital records. We also collected data on community COVID-19 deaths from the regional epidemiology department, and the details of those deaths were obtained by telephoning the close relatives of the deceased. We checked for duplicate entries and eliminated them from the final

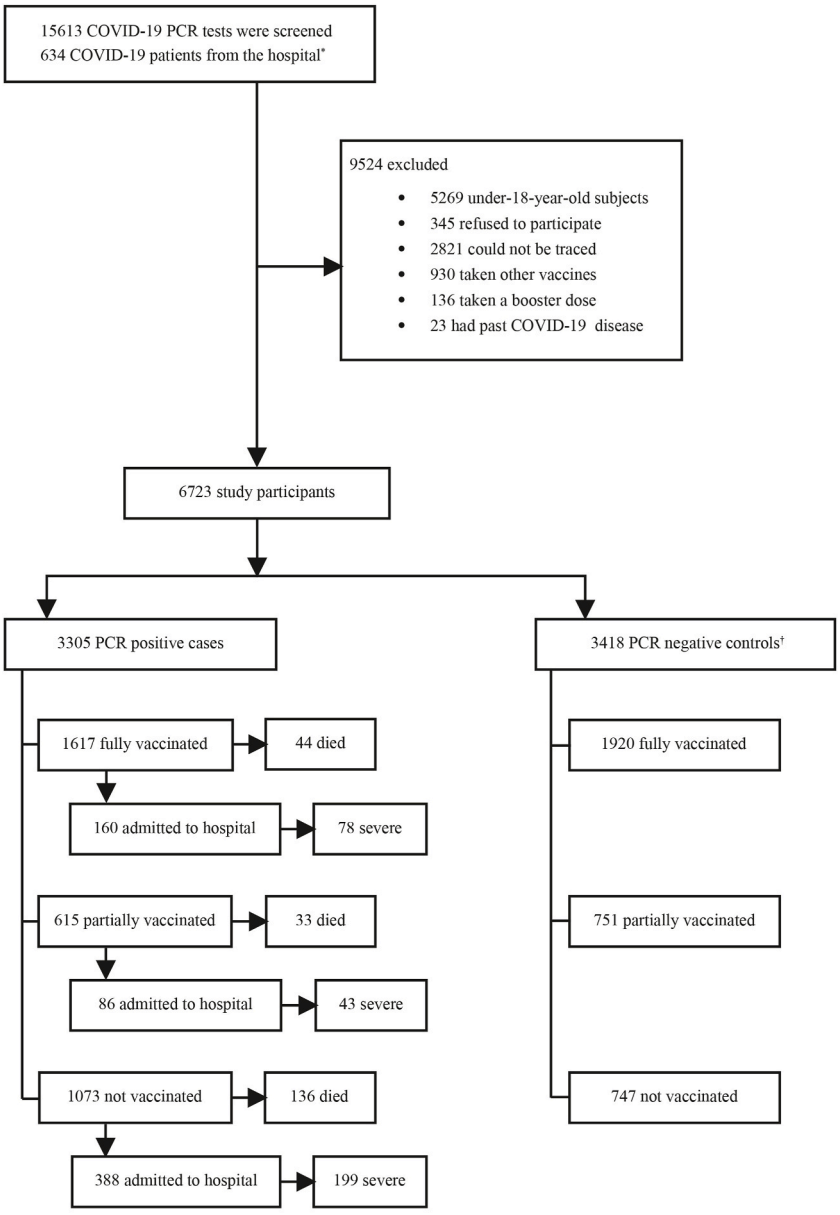

Fig. 1. Patient recruitment chart * Hospitalised COVID-19 patients are taken from Methsirisewana and Teaching Hospital Anuradhapura. † There were no hospitalisations, severe cases, or deaths in the PCR-negative control group.

database. However, we could not collect data on patients who had died or experienced severe illness in hospitals other than THA in NCP. Furthermore, we collected data on daily COVID-19 cases, deaths, and the BBIBP-CorV vaccination campaign in Sri Lanka from the epidemiology department to assess the vaccine's impact on the COVID-19 case fatality rate (CFR).

2.5. Vaccination status

We verified the vaccination status of the patients with the national COVID-19 vaccine registry [16]. We grouped the study participants into three groups considering their vaccination status at the time of COVID-19 PCR testing: fully vaccinated, not vaccinated, and partially vaccinated. The fully vaccinated group contained participants who underwent the testing 14 days after receiving two doses of BBIBP-CorV vaccines. The not-vaccinated group consisted of participants who had not received any vaccine or within two weeks of receiving the first dose of BBIBP-CorV vaccines at the time of testing. The partially vaccinated group consisted of participants who underwent testing 14 days after the first BBIBP-CorV vaccine dose and within 14 days of receiving the second dose (Fig. 2).

2.6. Outcomes

The primary outcome was VE with inactivated SARS-CoV-2 BBIBP-CorV vaccine against the laboratory-confirmed COVID-19 infection. The secondary outcomes were VE with inactivated BBIBP-CorV vaccine against symptomatic infection, hospitalisation, severe infection, and death. Symptomatic COVID-19 patients were defined as patients with positive RT-qPCR with any symptom (fever, chills, arthralgia and myalgia, headache, cough, breathlessness, fatigue, runny or congested nose, sore throat, ageusia, anosmia, diarrhoea, nausea, or vomiting). Hospitalisation is admission to a government hospital or COVID-19 treatment centre. Severe COVID-19 infection was defined as individuals with confirmed positive SARS-CoV-2 virus RT-qPCR requiring either supplemental oxygen, HDU, or ICU care during the hospital stay or dying due to COVID-19 disease. Death was defined as a death resulting from a clinically compatible illness in a confirmed case of COVID-19 unless there is a clear alternative cause of death [17].

2.7. Sample size

We calculated the sample size to a precision of estimates of $\pm$ 5 %, assuming the VE and vaccine coverage were 50 % in the NCP and the cases-to-control ratio was 1:1. The calculated minimum sample size was 3277 cases and 3277 controls [13].

2.8. Statistical analysis

The mean and standard deviation (SD) was utilised to describe continuous variables, and categorical variables were expressed as frequencies and percentages. The characteristics of the cases (RT-qPCR test positives) and controls (RT-qPCR test negatives) were compared using the independent-sample *t*-test (continuous variables) and Chi-square test of independence (categorical variables).

The VE was computed as VE = (1-odds ratio) x 100 %. The unadjusted and adjusted VE for the four outcome variables above were calculated with 95 % confidence intervals (95 % CI). Vaccination status (fully vaccinated vs. not vaccinated and partially vaccinated vs. not vaccinated) was included as an independent variable. The four outcome variables mentioned above were included separately as dependent variables.

Odds ratios calculated using the bivariate analyses were utilised to compute the unadjusted VE. Logistic regression was used to calculate the adjusted VE. VE was adjusted in logistic regression models for age, sex, calendar week, comorbidities (diabetes mellitus, hypertension, ischaemic heart disease, stroke, chronic kidney disease, chronic lung disease, chronic liver disease, cancer, immunodeficiency state, patients with organ transplant) and smoking habits (ever smoked vs. never smoked). All other variables except age were considered categorical covariates in the analysis.

Subgroup analyses were carried out with age groups (18–39, 40–59, and 60 years and above) and sex (female and male). P values were calculated to test the significance of the difference within each group. A P value less than 0.05 was considered significant.

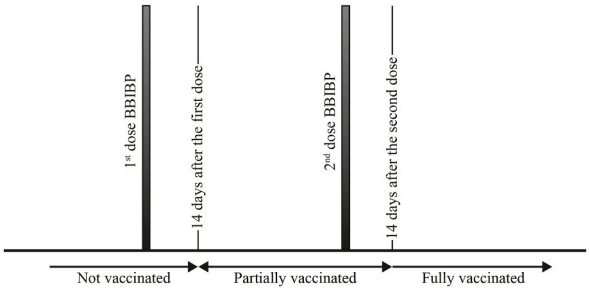

Fig. 2. Vaccination status.

2.9. Post hoc analysis

The fully vaccinated group was categorised into three subgroups depending on the duration between the second dose of the BBIBP-CorV and RT-qPCR. The three subgroups were '15–60 days', '61–120 days', and '121 days or more following the second dose of the BBIBP-CorV. Like the above analyses, the unadjusted and adjusted VE for the four outcome variables above were calculated with 95 % CI.

3. Results

The study was conducted from March to July 2022, inquiring into the peak period of the third wave of the COVID-19 pandemic in Sri Lanka from 1 May 2021 to 28 February 2022: 43 weeks and three days. There were 576,434 patients in the country and 19033 in the NCP (14249 in Anuradhapura and 4784 in Polonnaruwa district) during that time (Annexure 2, district-wise data in the third wave spanning 89 weeks and three days. The numbers are higher in the annexure because of the extended period) [1]. We screened community-referred 15613 COVID-19 PCR tests performed at the *"Methsirisewana"* virology laboratory and medical records of 634 COVID-19 patients admitted at the THA during the study period. We excluded 9524 and recruited 6723 as study participants. 3305 patients were selected as cases: 2677 were residing in the Anuradhapura district, 434 were in Polonnaruwa, and others (194) outside the NCP, but at the time of RT-qPCR testing were living in the NCP (table-1). Of 3305 patients, 3301 had symptoms during the RT-qPCR testing. Out of the hospital admitted 634 patients, 320 had developed severe disease and 213 died. Four patients from the community died before hospital admission, and seven hospitalised patients died unexpectedly and were not classified as having severe COVID-19 disease. 3418 individuals who tested negative for RT-qPCR were recruited as controls: 19 from Polonnaruwa, 3181 from Anuradhapura district, and 218 people from outside the NCP who were residing there at the time of the RT-qPCR test. The occupations of the participants are in Annexure 3.

As observed in Table 1, the age group over 60 represented 16·6 % of the cases. While in controls, it was 11·1 % ($p < 0{\cdot}001$). A higher Charlson comorbidity index (2–9) was observed among cases, 22·5 %, while in controls, it was 16·1 % ($p < 0{\cdot}001$).

Among 3305 cases, 1617 (48.9 %) were fully vaccinated, 615 (18.6 %) were partially vaccinated, and 1073 (32.5 %) were not vaccinated with the BBIBP-CorV vaccine. Among 3418 controls, 1920 (56.2 %) were fully vaccinated, 751 (22 %) were partially vaccinated, and 747 (21.8 %) were not vaccinated with the BBIBP-CorV vaccine. None of them had any other vaccines. However, per the government decision, a booster vaccination with BNT162b2 (Pfizer or *Comirnaty*) was administered. Among cases, 1523 (46·1 %) had booster (three had BBIBP-CorV, all others Pfizer), and among the control population, 1799 (52·6 %) had booster (four had BBIBP-CorV five had AstraZeneca or *Covishield* and all others Pfizer). However, none had taken the booster before the RT-qPCR test.

As observed in Table 2, the overall adjusted VE for PCR-positive infection among fully vaccinated individuals was 30·8 %. The adjusted VE with partial vaccination was 32·5 %. Partial vaccination with BBIBP-CorV led to reductions in hospitalisation, severe COVID-19 disease, and death, with overall adjusted VE rates of 49.7 % (29.0–64.7), 69.3 % (50.1–81.2), and 62.3 % (29.8–79.8), respectively. Full vaccination with BBIBP-CorV had resulted in a reduction in hospitalisation, severe COVID-19 disease, and death with overall adjusted VEs of 70·3 % (57·9–79·0), 88·9 % (81·8–93·2), and 92·3 % (84·8–96·1).

As observed in Fig. 3 (Week starting from 10 April 2021 to the week starting from 26 February 2022, 47 weeks), new cases peaked from the beginning of July to the end of September 2021, with the highest weekly new cases, CFR, and deaths in Sri Lanka. The rapid extinction of the peak was closely related temporally to the quick inoculation drive with the BBIBP-CorV vaccine, highlighting its impact.

Table 3 reports (Fig. 4) the adjusted VE since the second dose of BBIBP-CorV vaccination. Adjusted VEs against hospitalisation, severe disease, and death had been consistently high even after 120 days of the second dose.

4. Discussion

We report the real-world effectiveness of full or partial vaccination with the BBIBP-CorV vaccine in terms of its ability to reduce new cases, symptomatic illness, hospitalisation, severe disease, and deaths due to COVID-19 during the third wave of the pandemic in Sri Lanka, where delta variant was prominent. The third wave contributed to over 96 % of COVID-19 deaths. Two doses of BBIBP-CorV were 31 % effective in preventing COVID-19 disease but remarkably effective in preventing hospitalisation (70 %), severe disease (89 %), and deaths due to COVID-19 (92 %). Full vaccination was more effective than partial in preventing hospitalisation (70 % vs. 50 %), severe disease (89 % vs. 69 %), and death due to COVID-19 (92 % vs. 62 %). The impact of immunisation with the BBIBP-CorV vaccine demonstrates the reduction of COVID-19 incidence and CFR in Sri Lanka.

Our findings revealed strikingly high VE in mitigating severe outcomes of COVID-19. This remarkable success can be attributed to the unique properties of the BBIBP-CorV vaccine, as it is an inactivated vaccine triggering a robust T-cell response. The vaccine stimulates a more comprehensive and enduring form of immunity. The prolonged presence of T-cell immunity is believed to play a crucial role in providing lasting protection against the severe complications of COVID-19 [18]. The insights gained from our study highlight the significance of the BBIBP-CorV vaccine in effectively combating the ongoing pandemic, particularly in preventing severe illnesses and reducing the strain on healthcare systems worldwide.

Our study has several strengths relative to the previous studies. We coupled the data obtained from study participants with the national COVID-19 vaccine registry to improve the accuracy of the data about BBIBP-CorV vaccination. We collected data on possible covariates using the Charlson comorbidity index that could affect the outcome and adjusted the VE for those covariates. Our study participants were all from the single PCR testing laboratory, *"Methsirisewana."* To increase the generalisability, we included all adults

Table 1
Baseline characteristics of study participants (n = 6723).

Characteristics	Cases n = 3305	Controls n = 3418	Statistical significance	Distribution of cases				Vaccination status		
				Non-hospitalised n = 2671	Hospitalised and survived cases*		Deaths# n = 213			
					Non-severe* n = 307	Severe* n = 118		No n = 1820	Partial n = 1366	Full n = 3537
Age Mean (SD) years	42·9 (15·5)	41·5 (13·8)	t(6721) = 3·89 p < 0·001	40·7 (14·3)	44·5 (15·4)	52·8 (16·3)	63·3 (13·3)	39·7 (16·0)	42·7 (13·2)	43·3 (14·3)
Age group			$\chi^2(3) = 43·04$							
Missing	0	0	p < 0·001	0	0	0	0	0	0	0
18–39 years (%)	1496 (45·3)	1660 (48·6)		1334 (49·9)	127 (41·4)	26 (22·0)	9 (4·2)	991 (54·5)	578 (42·3)	1587 (44·9)
40–49 years (%)	744 (22·5)	783 (22·9)		633 (23·7)	60 (19·5)	24 (20·3)	27 (12·7)	333 (18·3)	360 (26·4)	834 (23·6)
50–59 years (%)	518 (15·7)	595 (17·4)		390 (14·6)	63 (20·5)	25 (21·2)	41 (19·2)	261 (14·3)	288 (21·1)	564 (15·9)
≥60 years (%)	547 (16·6)	380 (11·1)		314 (11·8)	57 (18·6)	43 (36·4)	136 (63·8)	235 (12·9)	140 (10·2)	552 (15·6)
Sex			χ^2 (1) = 5·74							
Missing	0	0	p = 0·017	0	0	0	0	0	0	0
Male (%)	1706 (51·6)	1864 (54·5)		1362 (51·0)	160 (52·1)	69 (58·5)	118 (55·4)	971 (53·4)	721 (52·8)	1878 (53·1)
Female (%)	1599 (48·4)	1554 (45·5)		1309 (49·0)	147 (47·9)	49 (41·5)	95 (44·6)	849 (46·6)	645 (47·2)	1659 (46·9)
Ethnicity			χ^2 (3) = 10·11							
Missing	0	0	p = 0·018	0	0	0	0	0	0	0
Sinhala (%)	3137 (94·9)	3272 (95·7)		2576 (96·4)	297 (96·7)	99 (83·9)	169 (79·3)	1663 (91·4)	1293 (94·7)	3453 (97·6)
Tamil (%)	22 (0·7)	29 (0·8)		21 (0·8)	1 (0·4)	0 (0)	0 (0)	12 (0·7)	17 (1·2)	22 (0·6)
Muslim (%)	146 (4·4)	113 (3·3)		74 (2·8)	9 (2·9)	19 (16·1)	44 (20·7)	145 (8·0)	54 (4·0)	60 (1·7)
Other (%)	0 (0)	4 (0·1)		0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	2 (0·1)	2 (0)
Education			χ^2 (2) = 71·57							
Missing	119	1	p < 0·001	1	0	0	118	75	16	29
Grade 4 or lower (%)	185 (5·6)	108 (3·2)		115 (4·3)	22 (7·2)	14 (11·9)	37 (38·9)	73 (4·2)	39 (2·9)	181 (5·2)
Grade 5 to GCE O/L (%)	1655 (50·1)	1547 (45·3)		1404 (52·6)	129 (42·0)	72 (61·0)	51 (53·7)	894 (51·2)	754 (55·9)	1554 (44·3)
Beyond GCE O/L (%)	1346 (40·7)	1762 (51·6)		1151 (43·1)	156 (50·8)	32 (27·1)	7 (7·4)	778 (44·6)	557 (41·3)	1773 (50·5)
Marital status			χ^2 (2) = 0·93							
Missing	0	0	p = 0·630	0	0	0	0	0	0	0
Single (%)	523 (15·8)	523 (15·3)		467 (17·5)	44 (14·3)	6 (5·1)	6 (2·8)	404 (22·2)	144 (10·5)	498 (14·1)
Married (%)	2768 (83·8)	2876 (84·1)		2194 (82·1)	262 (85·4)	111 (94·1)	205 (96·2)	1410 (77·5)	1216 (89·0)	3018 (85·3)
Other (%)	14 (0·4)	19 (0·6)		10 (0·4)	1 (0·3)	1 (0·8)	2 (0·9)	6 (0·3)	6 (0·4)	21 (0·6)
Comorbidities			χ^2 (1) = 28·82							
Missing	0	0	p < 0·001	0	0	0	0	0	0	0
One or more (%)	792 (24·0)	636 (18·6)		472 (17·7)	105 (34·2)	66 (55·9)	150 (70·4)	374 (20·5)	272 (19·9)	782 (22·1)
None (%)	2513 (76·0)	2782 (81·4)		2199 (82·3)	202 (65·8)	52 (44·1)	63 (29·6)	1446 (79·5)	1094 (80·1)	2755 (77·9)
CCI			χ^2 (9) = 82·49							
Missing	0	0	p < 0·001	0	0	0	0	0	0	0
0 (%)	2052 (62·1)	2287 (66·9)		1837 (68·8)	165 (53·7)	34 (28·8)	16 (7·5)	1231 (67·6)	880 (64·4)	2228 (63·0)
1 (%)	510 (15·4)	581 (17·0)		411 (15·4)	53 (17·3)	20 (16·9)	27 (12·7)	246 (13·5)	268 (19·6)	577 (16·3)
2 (%)	317 (9·6)	315 (9·2)		214 (8·0)	43 (14·0)	26 (22·0)	34 (16·0)	144 (7·9)	119 (8·7)	369 (10·4)
3 (%)	201 (6·1)	140 (4·1)		110 (4·1)	25 (8·1)	18 (15·3)	50 (23·5)	90 (4·9)	59 (4·3)	192 (5·4)
4 (%)	123 (3·7)	48 (1·4)		59 (2·2)	14 (4·6)	7 (5·9)	43 (20·2)	54 (3·0)	19 (1·4)	98 (2·8)

(*continued on next page*)

Table 1 (*continued*)

Characteristics	Cases n = 3305	Controls n = 3418	Statistical significance	Distribution of cases				Vaccination status		
				Non-hospitalised n = 2671	Hospitalised and survived cases*		Deaths# n = 213			
					Non-severe* n = 307	Severe* n = 118		No n = 1820	Partial n = 1366	Full n = 3537
5 (%)	48 (1·5)	23 (0·7)		22 (0·8)	4 (1·3)	4 (3·4)	18 (8·5)	25 (1·4)	12 (0·9)	34 (1·0)
6 (%)	26 (0·8)	15 (0·4)		8 (0·3)	3 (1·0)	6 (5·1)	9 (4·2)	18 (1·0)	2 (0·1)	21 (0·6)
7 (%)	22 (0·7)	9 (0·3)		9 (0·3)	0 (0)	3 (2·5)	11 (5·2)	9 (0·5)	5 (0·4)	17 (0·5)
8 (%)	4 (0·1)	0 (0)		0 (0)	0 (0)	0 (0)	4 (1·9)	3 (0·2)	1 (0·1)	0 (0)
9 (%)	2 (0·1)	0 (0)		1 (0)	0 (0)	0 (0)	1 (0·5)	0 (0)	1 (0·1)	1 (0)
CCI categorised			χ^2 (1) = 44·17							
Missing	0	0	p < 0·001	0	0	0	0	0	0	0
0 to 1 (%)	2562 (77·5)	2868 (83·9)		2248 (84·2)	218 (71·0)	54 (45·8)	43 (20·2)	343 (18·8)	218 (16·0)	732 (20·7)
2 to 9 (%)	743 (22·5)	550 (16·1)		423 (15·8)	89 (29·0)	64 (54·2)	170 (79·8)	1477 (81·2)	1148 (84·0)	2805 (79·3)
Smoking habits			χ^2 (2) = 23·96							
Missing	62	1	p < 0·001	2	0	0	60	43	6	14
Current smoker (%)	294 (9·1)	426 (12·5)		257 (9·6)	19 (6·2)	9 (7·6)	10 (6·5)	173 (9·7)	160 (11·8)	387 (11·0)
Ex-smoker (%)	110 (3·4)	84 (2·5)		43 (1·6)	0 (0)	7 (5·9)	60 (39·2)	58 (3·3)	41 (3·0)	95 (2·7)
Never smoked (%)	2839 (87·5)	2907 (85·0)		2369 (88·8)	288 (93·8)	102 (86·4)	83 (54·2)	1546 (87·0)	1159 (85·2)	3041 (86·3)
Alcohol consumption			χ^2 (1) = 30·61							
Missing	87	2	p < 0·001	2	0	0	85	53	14	22
Yes (%)	710 (22·1)	955 (28·0)		615 (23·0)	54 (17·6)	26 (22·0)	17 (13·3)	391 (22·1)	340 (25·1)	934 (26·6)
No (%)	2508 (77·9)	2461 (72·0)		2054 (77·0)	253 (82·4)	92 (78·0)	111 (86·7)	1376 (77·9)	1012 (74·9)	2581 (73·4)
Social distancing			χ^2 (1) = 1·43							
Missing	126	2	p = 0·231	3	0	0	123	82	16	30
Always/Mostly (%)	3148 (99·0)	3372 (98·7)		2641 (99·0)	306 (99·7)	117 (99·2)	88 (97·8)	1722 (99·0)	1332 (98·7)	3466 (98·8)
Never/ Sometimes (%)	31 (1·0)	44 (1·3)		27 (1·0)	1 (0·3)	1 (0·8)	2 (2·2)	17 (1·0)	17 (1·3)	41 (1·2)
Close COVID contact			χ^2 (1) = 4·81							
Missing	118	1	p = 0·028	1	0	0	117	75	16	28
Yes (%)	2741 (86·0)	3001 (87·8)		2293 (85·9)	281 (91·5)	95 (80·5)	76 (79·2)	1523 (87·2)	1182 (87·6)	3037 (86·5)
No (%)	446 (14·0)	416 (12·2)		377 (14·1)	26 (8·5)	23 (19·5)	20 (20·8)	223 (12·8)	167 (12·4)	472 (13·5)
Vaccination status			χ^2 (2) = 96·02							
Missing	0	0	p < 0·001	0	0	0	0	NA	NA	NA
Not vaccinated (%)	1073 (32.5)	747 (21·8)		685 (25·6)	185 (60·3)	69 (58·5)	136 (63·8)	NA	NA	NA
Partially vaccinated (%)	615 (18·6)	751 (22·0)		529 (19·8)	40 (13·0)	14 (11·9)	(15·5)	NA	NA	NA
Fully vaccinated (%)	1617 (48·9)	1920 (56·2)		1457 (54·5)	82 (26·7)	35 (29·7)	44 (20·7)	NA	NA	NA

*Seven hospitalised patients died but were not classified as severe COVID-19 cases as they did not require supplemental O_2 therapy, ventilation, or HDU-ICU care.

#Four patients brought from the community died and were not hospitalised.

CCI - Charlson's comorbidity index, NA: not applicable.

over 18 years, irrespective of age, gender, ethnicity, or educational background. We did not exclude any participants with multiple comorbidities to reflect the real-world scenario.

Our study has several limitations, but we took every possible measure to mitigate them. We did not include severe COVID-19 patients and COVID-19 deaths diagnosed only with positive lateral flow tests. However, this exclusion criterion was utilised to identify the cases correctly as per the eligibility criteria. Furthermore, some study participants did not initially come from the two districts. However, they were residing within the NCP at the time of the PCR testing, which had little effect on the study outcomes.

Additionally, there is a recall bias as we contacted the participants over the telephone and inquired about an illness they had

Table 2
Vaccine effectiveness in preventing RT-PCR positivity, symptoms, hospital admission, severe disease, and death among partially and fully vaccinated participants. VE: unadjusted vaccine effectiveness, aVE: adjusted vaccine effectiveness, 95 % CI: 95 % confidence interval, NA: not applicable.

	Overall n = 6723		Age groups						Sex			
			18–39 years n = 3156		40–59 years n = 2640		60 years or more n = 927		Male n = 3570		Female n = 3153	
Positive PCR test	Cases 3305	Controls 3418	Cases 1496	Controls 1660	Cases 1262	Controls 1378	Cases 547	Controls 380	Cases 1706	Controls 1864	Cases 1599	Controls 1554
Not vaccinated (%)	1073 (32·5)	747 (21·9)	531 (35·5)	460 (27·7)	349 (27·7)	245 (17·8)	193 (35·3)	42 (11·1)	563 (33·0)	408 (21·9)	510 (31·9)	339 (21·8)
Partially vaccinated (%)	615 (18·6)	1920 (56·1)	248 (16·6)	330 (19·9)	285 (22·6)	363 (26·3)	82 (15·0)	280 (73·7)	317 (18·6)	1052 (56·4)	298 (18·6)	347 (22·3)
Fully vaccinated (%)	1617 (48·9)	0	717 (47·9)	870 (52·4)	628 (49·8)	770 (55·9)	272(49·70)	0	826 (48·4)	0	791 (49·5)	868 (55·9)
Missing	0		0	0	0	0	0		0		0	0
Partial VE for positive PCR (95 % CI)	43·0 (34·3–50·5)		34·9 (20·0–47·1)		44·9 (31·0–56·0)		69·2 (50·6–80·8)		43·1 (30·9–53·2)		42·9 (29·8–53·6)	
Partial aVE for positive PCR (95 % CI)	32·5 (19·0–43·8)		33·4 (14·8–47·9)		9·9 (−24·9–35·0) P = 0·532		60·8 (16·4–81·6) P = 0·015		21·5 (−1·5–39·3) P = 0·065		44·0 (26·1–57·5)	
VE positive PCR (95 % CI)	41·4 (34·3–47·7)		28·6 (16·3–39·1)		42·7 (30·5–52·9)		78·9 (69·3–85·4)		43·1 (33·4–51·4)		39·4 (28·4–48·8)	
aVE positive PCR (95 % CI)	30·8 (17·9–41·6)		12·8 (−9·3–30·4) P = 0·23		40·0 (17·1–56·5) P = 0·002		72·3 (49·7–84·8)		36·0 (18·8–49·5)		21·6 (−1·0–39·2) P = 0·06	
Positive PCR test with Symptoms	Symptoms 3031	No 3692	Symptoms 1400	No 1756	Symptoms 1131	No 1509	Symptoms 500	No 427	Symptoms 1559	No 2011	Symptoms 1472	No 1681
Not vaccinated (%)	895 (29·5)	925 (25·1)	432 (30·9)	559 (31·8)	286 (25·3)	308 (20·4)	177 (35·4)	58 (13·6)	479 (30·7)	492 (24·5) 466 (23·2)	416 (28·3)	433 (25·8)
Partially vaccinated (%)	495 (16·3)	871 (23·6)	217 (15·5)	361 (20·6)	222 (19·6)	426 (28·2)	56 (11·2)	84 (19·7)	255 (16·4)	1053 (52·4)	240 (16·3)	405 (24·1)
Fully vaccinated (%)	1641 (54·1)	1896 (51·4)	751 (53·6)	836 (47·6)	623 (55·1)	775 (51·4)	267 (53·4)	285 (66·7)	825 (52·9)	0	816 (55·4)	843 (50·1)
Missing	0	0	0	0	0	0	0	0	0		0	0
Partial VE for symptomatic infection (95 % CI)	41·3 (32·2–49·1)		22·2 (4·0–37·0) P = 0·019		43·9 (29·5–55·3)		78·2 (65·7–86·1)		43·8 (31·5–53·9)		38·3 (24·0–49·9)	
Partial aVE for symptomatic infection (95 % CI)	33·4 (20·2–44·4)		28·0 (8·0–43·6) P = 0·008		20·2 (−10·8–42·5) P = 0·178		75·7 (50·1–88·1)		23·9 (1·4–41·2) P = 0·039		41·7 (23·8–55·4)	
VE for symptomatic infection (95 % CI)	10·5 (−0·2–20·1)		−16·2 (−36·4-0·9) P = 0·065		13·4 (−4·9–28·6) P = 0·142		69·3 (56·9–78·2)		19·5 (6·0–31·1) P = 0·06		−0·8 (−18·9–14·6) P = 0·929	
aVE for symptomatic infection (95 % CI)	17·1 (1·8–30·0)		−15·5 (−44·3–7·5) P = 0·204		37·5 (13·6–54·9) P = 0·005		71·3 (48·8–83·9)		22·7 (1·9–39·0) P = 0·034		8·4 (−17·7–28·7) P = 0·494	
Hospitalisation	Hospitalised 634	No 6089	Hospitalised 162	No 2994	Hospitalised 239	No 2401	Hospitalised 233	No 694	Hospitalised 344	No 3226	Hospitalised 290	No 2863
Not vaccinated (%)	388 (61·2)	1432 (23·5)	107 (66·0)	884 (29·5)	151 (63·2)	443 (18·5)	130 (55·8)	105 (15·1)	220 (64·0)	751 (23·3)	168 (57·9)	681 (23·8)
Partially vaccinated (%)	86 (13·6)	1280 (21·0)	16 (9·9)	562 (18·8)	39 (16·3)	609 (25·4)	31 (13·3)	109 (15·7)	38 (11·0)	683 (21·2)	48 (16·6)	597 (20·9)
Fully vaccinated (%)	160 (25·2)	3377 (55·5)	39 (24·1)	1548 (51·7)	49 (20·5)	1349 (56·2)	72 (30·9)	480 (69·2)	86 (25·0)	1792 (55·5)	74 (25·5)	1585 (55·4)
Missing	0	0	0	0	0	0	0	0	0	0	0	0
Partial VE for hospitalisation (95 % CI)	75·2 (68·3–80·6)		76·5 (59·8–86·2)		81·2 (72·7–87·1)		77·0 (63·1–85·7)		81·0 (72·8–86·7)		67·4 (54·3–76·8)	

(*continued on next page*)

Table 2 (*continued*)

	Overall n = 6723		Age groups						Sex			
			18–39 years n = 3156		40–59 years n = 2640		60 years or more n = 927		Male n = 3570		Female n = 3153	
Partial aVE for hospitalisation (95 % CI)	49·7 (29·0–64·7)		41·1 (−14·3–69·7) P = 0·117		49·1 (9·4–71·4)		61·8 (16·3–82·6) P = 0·016		56·3 (24·2–74·7) P = 0·003		46·1 (10·1–67·7) P = 0·018	
VE for hospitalisation (95 % CI)	82·5 (78·8–85·6)		79·2 (69·7–85·7)		89·3 (85·0–92·4)		87·9 (82·7–91·5)		83·6 (78·7–87·4)		81·1 (74·8–85·8)	
aVE for hospitalisation (95 % CI)	70·3 (57·9–79·0)		43·3 (−9·3–70·6) P = 0·09		84·7 (70·5–92·1)		73·1 (49·4–85·7)		71·6 (52·6–83·0)		61·9 (35·6–77·5)	
Severe Disease	Severe 320	No 6403	Severe 35	No 3121	Severe 114	No 2526	Severe 171	No 756	Severe 179	No 3391	Severe 141	No 3012
Not vaccinated (%)	199 (62·2)	1621 (25·3)	24 (68·6)	967 (31·0)	74 (64·9)	520 (20·6)	101 (59·1)	134 (17·7)	114 (63·7)	857 (25·3)	85 (60·3)	764 (25·4)
Partially vaccinated (%)	43 (13·4)	1323 (20·7)	2 (5·7)	576 (18·5)	18 (15·8)	630 (24·9)	23 (13·5)	117 (15·5)	21 (11·7)	700 (20·6)	22 (15·6)	623 (20·7)
Fully vaccinated (%)	78 (24·4)	3459 (54·0)	9 (25·7)	1578 (50·6)	22 (19·3)	1376 (54·5)	47 (27·5)	505 (66·8)	44 (24·6)	1834 (54·1)	34 (24·1)	1625 (54·0)
Missing	0	0	0	0	0	0	0	0	0	0	0	0
Partial VE for severe disease (95 % CI)	73·5 (62·9–81·1)		86·0 (40·6–96·7) P = 0·002		79·9 (66·0–88·2)		73·9 (56·3–84·4)		77·4 (63·7–86·0)		68·3 (48·7–80·4)	
Partial aVE for severe disease (95 % CI)	69·3 (50·1–81·2)		72·4 (−39·1–94·5) P = 0·119		80·8 (56·2–91·6)		55·6 (−0·8–80·4) P = 0·052		61·7 (18·3–28·0) P = 0·013		76·2 (47·5–89·2)	
VE for severe disease (95 % CI)	81·6 (76·0–86·0)		77·0 (50·4–89·4)		88·8 (81·7–93·1)		87·7 (81·7–91·7)		82·0 (74·2–87·4)		81·2 (71·8–87·5)	
aVE for severe disease (95 % CI)	88·9 (81·8–93·2)		81·8 (30·1–95·3) P = 0·013		95·7 (88·4–98·4)		85·8 (70·6–93·1)		88·4 (75·7–94·5)		89·2 (75·8–95·2)	
Death	Died 213	Survived 6510	Died 9	Survived 3147	Died 68	Survived 2572	Died 136	Survived 791	Died 118	Survived 3452	Died 95	Survived 3058
Not vaccinated (%)	136 (63·8)	1684 (25·9)	7 (77·8)	984 (31·3)	43 (63·2)	551 (21·4)	86 (63·2)	149 (18·8)	80 (67·8)	891 (25·8)	56 (58·9)	793 (25·9)
Partially vaccinated (%)	33 (15·5)	1333 (20·5)	0 (0·0)	578 (18·4)	15 (22·1)	633 (24·6)	18 (13·2)	122 (15·4)	16 (13·6)	705 (20·4)	17 (17·9)	628 (20·5)
Fully vaccinated (%)	44 (20·7)	3493 (53·7)	2 (22·2)	1585 (50·4)	10 (14·7)	1388 (54·0)	32 (23·5)	520 (65·7)	22 (18·6)	1856 (53·8)	22 (23·2)	1637 (53·5)
Missing	0	0	0	0	0	0	0	0	0	0	0	0
Partial VE for death (95 % CI)	69·3 (54·9–79·2)		100 (NA-NA)		69·6 (44·7–83·3)		74·4 (55·2–85·4)		74·7 (56·4–85·4)		61·7 (33·4–77·9)	
Partial aVE for death (95 % CI)	62·3 (29·8–79·8) P = 0·002		60·9 (NA-100) P > 0·999		51·2 (−28·3–81·5) P = 0·146		70·6 (21·6–89·0) P = 0·014		59·2 (−18·4–86·0) P = 0·098		65·7 (−9·8–89·3) P = 0·071	
VE for death (95 % CI)	84·4 (78·0–89·0)		82·3 (14·4–96·3) P = 0·015		90·8 (81·5–95·4)		89·3 (83·4–93·2)		86·8 (78·7–91·8)		81·0 (68·6–88·5)	
aVE for death (95%CI)	92·3 (84·8–96·1)		100 (NA-NA) P = 0·996		97·7 (87·8–99·6)		92·2 (82·3–96·6)		94·6 (82·1–98·4)		93·5 (78·8–98·0)	

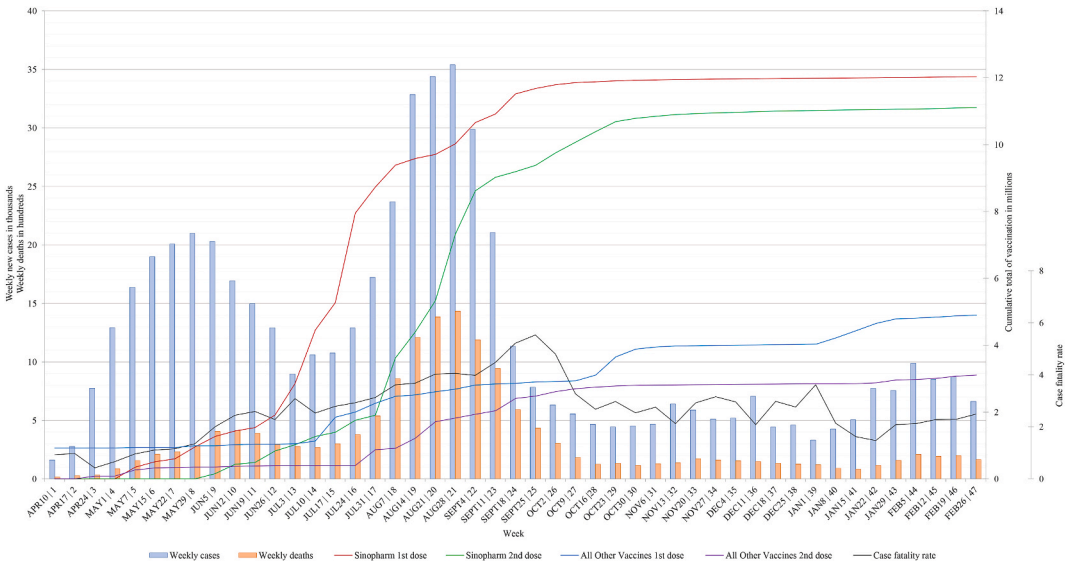

Fig. 3. Cases, deaths & vaccination in COVID-19 from April 2021 to February 2022 (third wave).

Table 3
Vaccine efficacy since the second dose of BBIBP-CorV.

	Overall n = 6723		VE (95 % CI)	aVE (95 % CI)
Positive PCR	Cases n = 3305	Controls n = 3418		
Not vaccinated	1073	747		
Partially vaccinated	615	751		
Fully vaccinated				
Tested between 15 and 60 days	676	826	43·0 (34·6–50·4)	28·0 (13·3–40·2)
Tested between 61 and 120 days	677	825	42·9 (34·4–50·2)	47·4 (31·2–59·8)
Tested after 121 days	264	269	31·7 (17·1–45·7)	55·7 (32·9–70·7)
Symptoms	**Symptoms n = 3031**	**No n = 3692**		
Not vaccinated	895	925		
Partially vaccinated	495	871		
Fully vaccinated				
Tested between 15 and 60 days	663	839	18·3 (6·3–28·8)	10·2 (−8·1–25·4)
Tested between 61 and 120 days	713	789	6·6 (−7·1–18·5)	38·9 (20·4–53·1)
Tested after 121 days	265	268	−2·2 (-24·15·7)	54·3 (31·6–69·5)
Hospitalised	**Hospitalised n = 634**	**No n = 6089**		
Not vaccinated	388	1432		
Partially vaccinated	86	1280		
Fully vaccinated				
Tested between 15 and 60 days	54	1448	86·2 (81·5–82·7)	71·7 (56·9–81·4)
Tested between 61 and 120 days	71	1431	81·7 (76·2–85·9)	76·2 (59·0–86·3)
Tested after 121 days	35	498	74·1 (62·8–81·9)	75·8 (54·2–87·2)
Severe disease	**Severe n = 320**	**No n = 6403**		
Not vaccinated	199	1621		
Partially vaccinated	43	1323		
Fully vaccinated				
Tested between 15 and 60 days	24	1478	86·8 (79·7–91·4)	90·6 (82·1–95·1)
Tested between 61 and 120 days	37	1465	79·4 (70·6–85·6)	90·9 (80·5–95·8)
Tested after 121 days	17	516	73·2 (55·5–13·8)	89·8 (75·8–95·7)
Death	**Died n = 213**	**Survived n = 6510**		
Not vaccinated	136	1684		
Partially vaccinated	33	1333		
Fully vaccinated				
Tested between 15 and 60 days	18	1484	85·0 (75·3–90·9)	89·4 (76·3–95·3)
Tested between 61 and 120 days	18	1484	85·0 (75·3–90·9)	96·0 (87·7–98·7)
Tested after 121 days	8	525	81·1 (60·2–90·8)	94·8 (80·9–98·6)

VE: unadjusted vaccine effectiveness, aVE: adjusted vaccine effectiveness, 95 % CI: 95 % confidence interval.

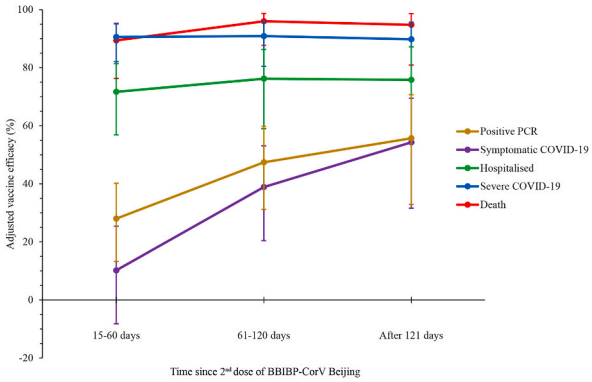

Fig. 4. Adjusted vaccine efficacy of BBIBP-CorV over time.

months back. However, recall bias may only be relevant to mild symptoms, as the possibility of forgetting is lower in the case of severe illness or hospitalisation. Also, we collected data from hospitals, intensive care units, and death registries and compared it with information provided by patients and their close relatives to reduce the recall bias. The immune status of the study participants was not assessed, which may impact the VE estimates. Unmeasured covariables may be associated with vaccination and outcomes, but we incorporated many covariates reported in the published literature. Significantly, we had access to a comprehensive national vaccine registration system.

There are few studies on the effectiveness of the BBIBP-CorV vaccine in the community after the vaccination. A test-negative case-control study conducted in Guangzhou city, China, where the delta variant predominated, demonstrated that two doses of the BBIBP-CorV vaccine had an effectiveness of 59·0 % in preventing COVID-19 infection, 70·2 % in preventing moderate disease and 100 % against severe disease [19]. A retrospective cohort study in Abu Dhabi, United Arab Emirates (UAE) demonstrated that full vaccination with BBIBP-CorV had a VE of 80 % preventing hospitalisation, 92 % preventing severe disease, and 97 % preventing death. This study also stated that full vaccination is much more effective in preventing severe illness than partial vaccination with BBIBP-CorV [20]. Another retrospective case-control study in UAE during the delta wave confirmed a VE of 95 % with full vaccination with BBIBP-CorV against hospitalisation, while only 62 % with partial vaccination [21]. These findings were consistent with the results of our study, where the two doses of BBIBP-CorV prevented hospitalisation (70 %), severe disease (89 %), and death (92 %). Moreover, in our study, full vaccination demonstrated a superiority to partial vaccination in preventing hospitalisation (70 % vs. 50 %), severe disease (89 % vs. 69 %), and death (92 % vs. 62 %), keeping with the published literature. A retrospective cohort study conducted in Morocco demonstrated that the VE to prevent severe illness in fully vaccinated with BBIBP-CorV was 96·4 % in less than 60 years compared to a low 53·3 % among older patients [22]. Our findings were consistent with the previously published findings, as participants aged 40–59 years reported an adjusted VE of 95·7 % against severe disease, while the participants in the age group 60 years or more displayed a slightly lower adjusted VE of 85.8 % against severe disease. A test-negative case-control study conducted in Morocco demonstrated consistently high VE (87 %) against severe or critical hospitalisation due to COVID-19 during the first three months after the second dose of BBIBP-CorV [23]. We have demonstrated the same consistently high VE against hospitalisation, severe disease, and death over four months since the second dose of the BBIBP-CorV vaccine.

Compared to the VE studies conducted in high-income countries using messenger RNA (mRNA) vaccines, our study with BBIBP-CorV indicated lower VE in preventing COVID-19 infection. A test-negative case-control study conducted among healthcare personnel demonstrated a VE of 88·8 % with full vaccination with BNT162b2 (Pfizer or *Comirnaty*) and 96·3 % with mRNA-1273 (Moderna or *Spikevax*) [24]. However, the vaccine's effectiveness in preventing hospitalisation, severe disease, and death with two doses of BBIBP-CorV is on par with the mRNA vaccine utilised in high-income nations. A review documented that two doses of Pfizer or Moderna have a VE of 80–95 % in preventing hospitalisation and death due to COVID-19, proving BBIBP-CorV's VE in preventing severe disease and death comparable with mRNA vaccines [25,26].

Our study concludes that two doses of the BBIBP-CorV vaccine are highly effective in preventing COVID-19-related hospitalisations, severe disease, and death due to the delta variant. Duration of protection against hospitalisation, severe COVID-19, and fatal COVID-19 sustained at least 121 days, with no sign of waning during that time.

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Role of the funding source

The study's funder had no role in study design, data collection, analysis, interpretation, or manuscript writing. All authors had full access to the data in the study and are fully responsible for deciding to submit it for publication.

Data sharing

All case record forms, de-identified datasets, and related codes for analysis will be made available upon request. Requests for data should be addressed to the corresponding author (sisira.siribaddana@gmail.com).

Data availability statement

Data will be available on request.

CRediT authorship contribution statement

Lanka Wijekoon: Writing – review & editing, Writing – original draft, Visualization, Validation, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. **Nuwan Wickramasinghe:** Writing – review & editing, Visualization, Validation, Methodology, Formal analysis, Data curation. **Thilina Rathnasekara:** Writing – review & editing, Visualization, Validation, Software, Data curation. **Thejana Somathilake:** Writing – review & editing, Validation, Resources. **Chamara Sarathchandra:** Writing – review & editing, Resources, Project administration. **Hemal Senanayake:** Writing – review & editing, Resources, Investigation. **Prasanna Weerawansa:** Writing – review & editing, Resources, Investigation. **Ranjan Ganegama:** Writing – review & editing, Resources. **Yuntao Zhang:** Writing – review & editing, Methodology, Conceptualization. **Yunkai Yang:** Writing – review & editing, Methodology, Conceptualization. **Rui Ma:** Writing – review & editing, Methodology, Conceptualization. **Yaowen Zhang:** Writing – review & editing, Validation, Formal analysis. **Deying Xie:** Writing – review & editing, Resources, Project administration, Funding acquisition. **Zhaofeng Li:** Writing – review & editing, Resources, Project administration, Funding acquisition. **Xiaodan Liu:** Writing – review & editing, Resources, Project administration, Funding acquisition. **Shouyi Qin:** Writing – review & editing, Resources, Project administration, Funding acquisition. **Sisira Siribaddana:** Writing – review & editing, Supervision, Project administration, Methodology, Investigation, Funding acquisition, Conceptualization.

Declaration of competing interest

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Appendix A. Supplementary data

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