BNT162b2 and mRNA-1273 Vaccine Effectiveness against SARS-CoV-2 and Variants in the Urban Underserved Population

CHIEN-HSIANG WENG, MD, MPH; SHENG ZHOU, MD, ScM; ANDREW SAAL, MD, MPH; MALLORY HAFFERTY; DANIEL C. McGUIRE; PHILIP A. CHAN, MD, MS

ABSTRACT

The real world COVID-19 vaccine effectiveness among the urban underserved Hispanic/Latino populations is unknown.

We evaluated the mRNA vaccine effectiveness in preventing SARS-CoV-2 infections at a major federally qualified health center in Providence, Rhode Island, and a total of 38,602 patients were included. Time period was used as the SARS-CoV-2 variant proxy.

Compared to the unvaccinated group, the adjusted vaccine effectiveness for 2 doses of BNT162b2 and mRNA-1273 were 94.6% and 97.5% respectively against the alpha variant/wild type, which dropped to 64.8% and 65.0% respectively against the delta variant and 31.6% and 25.6% respectively against the omicron variant. However, once received the booster dose (3rd dose) of BNT162b2 and mRNA-1273, the vaccine effectiveness against the omicron variant improved to 79.9% and 71.2% respectively.

Improving the COVID-19 vaccine education and encouraging to receive a booster dose may help further reduce the burden of SARS-CoV-2 infection in this population.

KEYWORDS: COVID-19; variants; vaccine effectiveness; underserved; Hispanic/Latino

The worldwide pandemic of coronavirus disease 2019 (COVID-19), caused by severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), has resulted in significant morbidity and mortality including in the United States (US). Two mRNA-based vaccines, BNT162b2 (Pfizer) and mRNA-1273 (Moderna), were developed and received emergency use authorization by the US Food and Drug Administration in December 2020. As of September 2022, over 591 million doses of the mRNA-based vaccines have been administered in the US.[1] Several SARS-CoV-2 variants have been identified since the pandemic. Two Variants of Concern (VOC) have been circulating globally since December 2020 and November 2021 respectively. The B.1.617.2 (Delta) variant was first identified in the US in March 2021 and soon became the predominant variant which resulted in the surge of COVID-19 cases in July 2021.[2] The B.1.1.529 (Omicron) variant was first reported in November 2021 and spread around the world. Both mRNA vaccines showed high efficacy in preventing symptomatic SARS-CoV-2 infection in randomized controlled trials.[3,4] This study is to evaluate mRNA vaccine effectiveness in real-world conditions in an urban underserved population in preventing SARS-CoV-2 infections between those fully vaccinated with two doses of mRNA vaccines, boosted with a 3rd dose of mRNA vaccines, and unvaccinated.

We reviewed data from a major federally qualified health center (FQHC) in Providence, Rhode Island, which consisted of 10 community clinics. Patients aged 12 years and older tested for SARS-CoV-2 by reverse-transcription polymerase chain reaction (RT-PCR) were included in this study from January 1, 2021 to December 31, 2021. The estimated vaccine effectiveness was assessed 14 days after receipt of the latest dose, using only the latest SARS-CoV-2 PCR test from each vaccinated patient and the first COVID-19 PCR test from those unvaccinated. Hybrid doses (different vaccine combinations) were omitted from analysis due to small number, as well as the J&J/Janssen COVID-19 vaccine. We used the period of time as the variant proxy-1/1/2021–6/30/2021 as the alpha variant (B.1.1.7)/wild type proxy, 7/1/2021–11/30/2021 as the delta variant (B.1.617.2) proxy, and 12/1/2021–12/31/2021 as the omicron variant (B.1.1.529) proxy. The patient population at this FQHC is predominantly Hispanic/Latino and 90% of households are under the 200% federal poverty level. χ^2 tests and Wilcoxon rank-sum tests were applied to determine statistically significant differences among groups. Logistic regression model was applied to yield the odds ratios (OR) then transformed to the incidence rate ratio (IRR). (IRR = OR / ((1-$P_{\text{infected unvaccinated group}}$)+($P_{\text{infected unvaccinated group}}$*OR)). Adjusted vaccine effectiveness was calculated by 100% x (1-IRR), adjusted for race/ethnicity, age groups (12–17, 18–39, 40–64, 65+ years old), and reinfection status (defined as a new infection >90 days from the previous positive SARS-CoV-2 PCR test). A two-sided significance threshold was set at P<0.05. The Providence Community Health Centers Review Committee approved the project. All analyses were run using STATA 13.1 (StataCorp, LLC) and SAS 9.4 (SAS Institute, Inc).

Of the 38,602 patients included, the median age was 34 years (IQR 23–51), and over 60% self-identified as Hispanic/Latino. A total of 43.0% of patients completed the primary vaccine series, 4.0% received a booster dose, and 53.0% were partially or unvaccinated. Of the 38,602 patients, 22,247 had

at least one SARS-CoV-2 PCR test and were included in the analysis. (**Table 1**)

Compared to the unvaccinated group, the adjusted vaccine effectiveness for 2 doses of BNT162b2 and mRNA-1273 were 94.6% and 97.5% respectively against the alpha variant/wild type, which dropped to 64.8% and 65.0% respectively against the delta variant. The effectiveness for 2 doses of BNT162b2 among different age groups (18-39, 40-64, ≥65 years old) against the alpha variant/wild type was similar; however, decreased effectiveness was observed with the increase of age against the delta variant (89.7% for 12–17 years old and 53.2% for 65 years and older). Even though 2 doses of BNT162b2 and mRNA-1273 showed similar all-age effectiveness against the delta variant, when stratified by age groups, mRNA-1273 showed higher effectiveness among those 65 years and older (65.4% vs 53.2%).

The effectiveness for 2 doses of BNT162b2 and mRNA-1273 further dropped to 31.6% and 25.6% respectively against the omicron variant. However, once received the booster dose (3rd dose) of BNT162b2 and mRNA-1273, the vaccine effectiveness against the omicron variant improved to 79.9% and 71.2% respectively. (**Table 2**)

In this study, we combined PCR testing data from the Rhode Island Department of Health and collaborating testing laboratories to capture as many tests as possible from our patients. Antigen testing may be less of an issue in this time period, when tests were scarce, than it would be in the recent months. The limitation of this study includes that it was a single study site and may not represent other settings in the United States. We were not able to compare the effectiveness of those who received a booster dose between age groups due to smaller sample size. The study was also limited by its observational, retrospective nature and use of administrative data. Thus, we may not know definitively whether the patients were PCR tested because of symptoms or due to known exposure or other reasons, and whether or to what extent we may be missing infections among patients who were not tested.

Table 1. Demographic characteristics of the study population

	SARS-CoV-2 variant proxy		
	01/01/2021–06/30/2021	07/01/2021–11/30/2021	12/1/2021–12/31/2021
	Alpha variant (B.1.1.7)/wild type	Delta variant (B.1.617.2)	Omicron variant (B.1.1.529)
Median age (IQR) years	33 (25–46)	33 (24–46)	32 (23–45)
Race/ethnicity			
Non-Hispanic White	881	602	186
Non-Hispanic Black	970	629	182
Hispanic/Latino	5,143	3,370	1,283
Asian	260	189	70
Other	4829	2763	890
Total unvaccinated (persons)/positive for SARS-CoV-2 PCR (persons)	11,575/1981	5,310/784	1,762/753
Total fully vaccinated (persons)/positive for SARS-CoV-2 PCR (persons)	508/4	2,196/114	784/232
Total boosted (persons)/positive for SARS-CoV-2 PCR (persons)	—	47/0	65/6

Table 2. Vaccine effectiveness against different SARS-CoV-2 variants

	Vaccine effectiveness in % (95% CI)		
	SARS-CoV-2 variant proxy		
	Alpha variant (B.1.1.7)/wild type	Delta variant (B.1.617.2)	Omicron variant (B.1.1.529)
Fully vaccinated			
BNT162b2 (2 doses)			
All ages	94.6 (83.4–98.3)	64.8 (54.2–73.0)	31.6 (19.6–42.5)
Age 12–17 years old	—	89.7 (67.9–96.8)	63.6 (38.8–79.6)
Age 18–39 years old	93.7 (57.3–99.1)	65.5 (49.2–76.8)	33.4 (16.3–48.3)
Age 40–64 years old	96.0 (72.4–99.4)	51.0 (24.4–68.8)	4.4 (–22.8–29.5)
Age ≥ 65 years old	92.5 (49.4–99.0)	53.2 (3.0–78.4)	–17.3 (–69.7–35.3)
mRNA-1273 (2 doses)			
All ages	97.5 (82.5–99.7)	65.0 (52.9–74.1)	25.6 (10.7–39.0)
Age 12–17 years old	—	—	—
Age 18–39 years old	—	71.2 (53.1–82.5)	17.4 (–5.3–37.5)
Age 40–64 years old	—	55.4 (31.6–71.4)	24.4 (1.0–44.6)
Age ≥ 65 years old	94.1 (59.4–99.2)	65.4 (27.4–84.1)	49.2 (–1.8–78.8)
Fully vaccinated and boosted†			
BNT162b2 (3 doses)	—	—	79.9 (44.3–93.5)
mRNA-1273 (3 doses)	—	—	71.2 (24.0–90.8)

* The vaccine effectiveness was adjusted for race/ethnicity, age groups (12-17, 18-39, 40-64, 65+), and reinfection status (defined as a new infection >90 days from the previous positive SARS-CoV-2 PCR test).
† Stratification by age group was not done for the fully vaccinated and boosted group due to the smaller sample size.

As one of the first studies from the real-world condition and the medically underserved Hispanic/Latino dominant population, our findings in the New England region evidenced the high effectiveness against the omicron (B.1.1.529) variant infection from 2 doses of the BNT162b2 and mRNA-1273 with the booster dose (3rd), consistent with other recent studies.[5] Improving the COVID-19 vaccine education and encouraging to receive a booster dose may help further reduce the burden of SARS-CoV-2 infection in this population.

References

1. Centers for Disease Control and Prevention. COVID Data Tracker. https://covid.cdc.gov/covid-data-tracker. Accessed September 9, 2022.
2. Centers for Disease Control and Prevention. What You Need to Know About Variants. https://www.cdc.gov/coronavirus/2019-ncov/variants/delta-variant.html. Accessed September 9, 2022.
3. Polack FP, et al. Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine. *N Engl J Med* 2020; 383(27): 2603-2615.
4. Baden LR, et al. Efficacy and Safety of the mRNA-1273 SARS-CoV-2 Vaccine. *N Engl J Med* 2021; 384(5): 403-416.
5. Andrews N, et al. Covid-19 Vaccine Effectiveness against the Omicron (B.1.1.529) Variant. *N Engl J Med* 2022; 386:1532-1546.

Authors

Chien-Hsiang Weng, MD, MPH, Brown University Warren Alpert Medical School, Providence, RI.

Sheng Zhou, MD, ScM, Yale University School of Medicine, New Haven, CT.

Andrew Saal, MD, MPH, Providence Community Health Centers, Providence, RI.

Mallory Hafferty, Providence Community Health Centers, Providence, RI.

Daniel C. McGuire, MBA, Providence Community Health Centers, Providence, RI.

Philip A. Chan, MD, MS, Warren Alpert Medical School of Brown University and Rhode Island Department of Health, Providence, RI.

Funding

None

Conflict of Interest Disclosures (includes financial disclosures)

The authors have no conflicts of interest relevant to this article to disclose.

Ethics approval

The study was approved by the Providence Community Health Centers Review Committee. The authors assert that all procedures contributing to this work comply with the ethical standards of the relevant national and institutional committees on human experimentation and with the Helsinki Declaration of 1975, as revised in 2008.

Prior presentations

None.

Data Availability Statement

The data that support the findings of this study are available on request from the corresponding author, C-H W. The data are not publicly available due to their containing information that could compromise the privacy of research participants.

Correspondence

Chien-Hsiang Weng, MD, MPH

Box G-MHRI, Brown University, Providence, RI 02912

chien-hsiang_weng@brown.edu