The Effectiveness of the Two-Dose BNT162b2 Vaccine: Analysis of Real-World Data

Gabriel Chodick,1,2,a Lilac Tene,1,4 Ran S Rotem,1 Tal Patalon,1 Sivan Gazit,1 Amir Ben-Tov,1 Clara Weit,1 Inbal Goldshtein,1 Gilad Twig,2,4,5,6
Dani Cohen,1,2 and Khitam Muhsen1,2

1Maccabi Institute for Research and Innovation, Maccabi Healthcare Services, Tel Aviv, Israel; 2Sackler Faculty of Medicine, Tel Aviv University, Tel Aviv, Israel; 3Department of Environmental Health, Harvard T.H. Chan School of Public Health, Boston, Massachusetts, USA; 4Israel Defense Forces Medical Corps, Ramat-Gan, Israel; 5Department of Military Medicine, Faculty of Medicine, Hebrew University of Jerusalem, Jerusalem, Israel; and 6Institute of Endocrinology, Sheba Medical Center, Ramat-Gan, Israel

Background. Coronavirus disease 2019 (COVID-19) messenger RNA (mRNA) vaccines were shown to be highly efficacious in preventing the disease in randomized controlled trials; nonetheless, evidence on the real-world effectiveness of this vaccine is limited. Study objective was to evaluate the effectiveness of BNT162b2 vaccine in preventing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection and COVID-19-related hospitalization and mortality.

Methods. This historical cohort study included members of a large health provider in Israel that were vaccinated with at least 1 dose of BNT162b2. The primary outcome was incidence rate of a SARS-CoV-2 infection confirmed with real-time polymerase chain reaction (rt-PCR), between 7 and 27 days after second dose (protection-period), as compared to days 1–7 after the first dose, where no protection by the vaccine is assumed (reference-period).

Results. Data of 1 178 597 individuals vaccinated with BNT162b2 were analyzed (mean age 47.7 years [SD = 18.1], 48.4% males) of whom 872 454 (74.0%) reached the protection period. Overall, 4514 infections occurred during the reference period compared to 728 during the protection period, yielding a weighted mean daily incidence of 54.8 per 100 000 (95% confidence interval [CI]: 26.1–115.0 per 100 000) and 5.4 per 100 000 (95% CI: 3.5–8.4 per 100 000), respectively. The vaccine effectiveness in preventing infection was 90% (95% CI: 79%–95%) and 94% (95% CI: 88%–97%) against COVID-19. Among immunosuppressed patients, vaccine effectiveness against infection was 71% (95% CI: 37%–87%). The adjusted hazard ratios for hospitalization in those infected were 0.82 (95% CI: .36–1.88), 0.45 (95% CI: .23–.90), and 0.56 (95% CI: .36–.89) in the age groups 16–44, 45–64, and ≥75 years, respectively.

Conclusions. The effectiveness of the BNT162b2 vaccine is comparable to the one reported in the phase III clinical trial.

Keywords. COVID-19; BNT162b2; vaccine; effectiveness; real-world data.

In Israel, COVID-19 vaccination using BNT162b2 mRNA vaccine started on 19 December 2020, with priority given initially to individuals aged ≥60 years, healthcare workers and high-risk groups with chronic conditions. By comparing vaccinated with unvaccinated Israelis, a recent real-world data analysis [3, 4] estimated the vaccine effectiveness (VE) of 2 doses of BNT162b2 in reducing COVID-19 risk at 91%. Comparisons of vaccinated and unvaccinated individuals might be challenging given inherited unmeasured characteristics that may differ between the groups such as perceived infection risk, poorer compliance with COVID-19 preventive measure which might result in biases [5]. This challenge is amplified when vaccine uptake is rapid. We propose an alternative design that overcomes this pitfall with a cohort study of vaccinated individuals only comparing the incidence of the infection during the first few days after immunization with first vaccine dose to at least 1-week post second dose. This design allows a valid estimation of the VE given that COVID-19 incidence was similar in the vaccine and placebo arms during the first week after immunization in the RCT [6].

As of 25 February 2021, Israel ranks first in vaccine coverage with 75% of the individuals aged ≥16 years vaccinated with at
least 1 dose of BNT162b2 vaccine. The aim of the current study was to expand our previous research on first dose [7] and assess the effectiveness of 2-dose BNT162b2 vaccine in reducing the risk of SARS-CoV-2 infection in a large cohort of immunized individuals, employing a vaccine-only study design.

METHODS

Study Design and Data Sources
The data used for this retrospective cohort study were obtained from Maccabi Healthcare Services (MHS), a state-mandated sick fund, covering 2.6 million members or 25% of residents in Israel. According to the National Health Insurance Law, membership in sick funds is free and open to all Israeli citizens. MHS database includes extensive demographic data, anthropometric measurements, diagnoses from community clinics and hospitals, medication dispensing information, and comprehensive laboratory data from a single central laboratory.

Study Population and Design
The study population consisted of all MHS members aged ≥16 years who were vaccinated with at least 1 dose of the BNT162b2 vaccine during a mass immunization program from 19 December 2020 to 20 February 2021. Excluded from analysis were patients who had a documented positive SARS-CoV-2 prior to vaccination date (n = 13,656) and individuals who joined MHS after February 2020 and therefore had an incomplete medical history (n = 33,666).

The results of the phase III trial [6] provide experimental evidence that the BNT162b2 vaccine confers no or little protection against SARS-CoV-2 infection during the first 7 days post vaccination with the first dose. This is also supported by a recent analysis of the infection cycle threshold (Ct) over time among infected vaccinees in MHS, where viral load substantially decreased only after 12 days after first dose [8]. Therefore, we used the incidence of infection in days 7–27 after the second dose, which was defined as the protection period based on the phase III trial data [1]. We limit to 27 days to allow sufficient time for post infection follow-up.

Study Endpoints
COVID-19 infection was defined as having at least 1 record of primary positive SARS-CoV-2 real-time polymerase chain reaction (rt-PCR) test obtained from nasopharyngeal swabs [9]. The tests are offered to all Israeli citizens free of charge and without a need for referral, regardless of having symptoms.

We also collected information regarding hospitalizations due to COVID-19 among infected patients and subsequent mortality. Follow-up for COVID-19-related hospitalizations and deaths started from day after first date of positive rt-PCR tests and lasted until date of hospitalization/death, leaving MHS, 3 March 2021, or 21 days of follow-up, whichever occurred first. Data of symptoms among infected individuals were documented by primary care physicians at the time of referral to rt-PCR test.

Additional Variables
Demographic and clinical data were collected from MHS’s central databases. This included age at immunization with the first dose of BNT162b2, sex, body mass index (BMI), and coexisting comorbidities including cancer, immunocompromised conditions (eg, recipients of hematopoietic cell or solid organs transplant, patients under immunosuppressive therapy, asplenia, and chronic renal failure: advanced kidney disease, dialysis, or nephrotic syndrome), hypertension, diabetes [10], and cardiovascular diseases [11]. Data on member’s enumeration area of residence as reported by the Israeli Central Bureau of Statistic and Points Business Mapping Ltd© [12] were used to assess socioeconomic status (SES), and data on membership in ultraorthodox Jewish and Israeli Arab communities were collected due to epidemiological data supporting different health-related COVID-19 behavior patterns [13].

Statistical Analysis
Continuous variables were expressed as means (standard deviations [SD]) and medians (interquartile range [IQR]). Categorical variables were summarized as counts and percentages. Cumulative incidence plots of SARS-CoV-2 infection were created using Kaplan-Meier survival analysis and compared with the log-rank test. The comparison of the incidence rate of rt-PCR-confirmed SARS-CoV-2 infection between the 2 study periods was performed using generalized linear models, applying a negative-binomial distribution with a log-link and log-daily number of individuals-at-risk as an offset. The offset was used to scale the counts of SARS-CoV-2 infections to daily incidence, expressed as cases per 100 000. The dependent variable was the number of positive PCR per day during each study period. VE was defined as infection relative risk reduction and calculated as: (1 – relative risk) × 100. Analyses were stratified by age group, sex, patients residing in ultraorthodox Jewish or Israeli Arab sector, and chronic illness. We also stratified the analysis by calendar period to assess the potential effect of new SARS-CoV-2 variants that were spread during the study period (Supplementary Figure 1) [14]. Binary logistic regression models were used to estimate odds ratios (ORs), adjusted odds ratios (aORs), and 95% confidence intervals (CIs) for COVID-19 symptoms among infected patients. All binary logistic regression models estimating the aORs simultaneously controlled for age, sex, sector, SES, and chronic conditions. Adjusted hazard ratios (aHRs) for COVID-19-related hospitalization or death among infected patients were calculated using Cox proportional hazards model adjusting for age, sex, calendar period of immunization, sector, and clinical characteristics. The corresponding adjusted survival curves were drawn. Proportional
hazards assumption was confirmed according to Schoenfeld residuals tests and graphical evaluations. To assess potential “healthy vaccinee” bias where incidence in the first days after first dose are lower than general population due to selection of COVID-19-free patients, we performed a sensitivity analysis limiting the reference-period to days 5–7 after first dose (N = 1 175 741). Analyses were done using IBM-SPSS version 27 (Armonk, NY: IBM Corp) and R packages magrittr, readtext, dplyr, ggplot2, tidyverse, survival, forestplot, and survminer.

**Ethics Approval**
The study protocol was approved by the MHS Ethics Committee.

**RESULTS**
Overall data of 1 178 597 individuals vaccinated with BNT162b2 were analyzed (mean age 47.7 years [SD = 18.1], 48.4% males) of whom 872 454 (74.0%) had more than 1 week of follow-up after the second dose (Table 1). Study population accounts for approximately 80% of the total number of members eligible for vaccination in MHS.

SARS-CoV-2 PCR test was performed by 60 931 individuals (5.2%) during the reference period compared to 27 456 (3.1%) individuals during protection period. The proportion of patients tested with rt-PCR SARS-CoV-2 during the reference and protection periods was 5.2% (n = 60 931) and 3.1% (n = 27 456), respectively. The respective number of individuals who tested positive was 4514 (7.4% test positive rate) and 728 (2.7%), representing a weighted mean incidence rate of 54.8 per 100 000 persons (95% CI: 26.1–115.0) and 5.4 per 100 000 (95% CI: 3.5–8.4). Lower incidence of SARS-CoV-2 PCR-confirmed infection rate between reference period and protection period was found across all age groups (Figure 1). The overall VE was estimated at 90% (95% CI: 79%–95%), which was materially unchanged when limiting reference-period to days 5 to 7 after first dose, VE against infection was 92% (95% CI: 75%–97%) (Supplementary Table 1).

VE estimates were 92% (95% CI: 83%–96%) and 90% (95% CI: 80%–95%) in the age groups 16–44 and 45–64 years, respectively, 82% (95% CI: 63%–92%) in the age group 65–74 years and 82% in those aged ≥75 years (95% CI: 61%–91%). In patients with diabetes and patients with cardiovascular diseases, the estimated VE was 82% (95% CI: 62%–92%). Somewhat lower VE (71%; 95% CI: 37%–87%) was calculated among immunosuppressed patients, approaching 52% (95% CI: −26% to 82%) in those who were ≥65 years (Figure 2). In stratified analysis among immunosuppressed patients during the first month of the vaccination campaign, VE was 70% (95% CI: 35%–86%) compared to 84% (95% CI: 60%–94%) in the second month (Supplementary Table 2). The overall estimated VE in preventing COVID-19 was 94% (95% CI: 87%–97%), and 75% (95% CI: 44%–88%) among immunosuppressed patients (Figure 2).

Among patients infected with SARS-CoV-2 in the reference period, 70.1% (n = 3179) were symptomatic vs 38.6% (n = 281) among those infected during the protection period (aOR = 0.32; 95% CI: .27–.39, P < .001) (Table 2). The largest difference in proportion of symptomatic cases was evident among patients aged 16–44 years (69.9% vs 30.7% respectively, P < .001).

Overall, 513 (43.6 per 100 000 persons) and 144 (16.5 per 100 000 persons) deaths occurred among vaccinated individuals during the reference vs protection periods, respectively. Of these, 39 and 11 occurred among patients with COVID-19, respectively. Fatality cases and rates (% of infected) during protection period vs reference period in patients aged 45–64, 65–74, and 75y and above were: none vs 3 (0.2%), 1 (0.7%) vs

**Table 1. Characteristics of Study Population by Period of Follow-Up**

|                     | Days 1–7 After 1st dose (Reference Period) | Days 7–27 After 2nd dose (Protection Period) |
|---------------------|-------------------------------------------|---------------------------------------------|
| N                   | 1 178 597 (100)                           | 872 454 (100)                               |
| Sex                 |                                            |                                             |
| Male                | 569 392 (48.4)                            | 420 010 (48.1)                              |
| Female              | 608 277 (51.6)                            | 452 444 (51.9)                              |
| Age, years, mean ± SD | 47.7 ±18.1                                | 52.3 ±17.1                                  |
| BMI kg/m², mean SD  | 26.4 ±5.3                                 | 26.8 ±5.2                                   |
| SES level, median (IQR) | 7 (5, 8)                                 | 7 (6,8)                                     |
| Ultraorthodox       | 41 947 (3.6)                              | 27 668 (3.2)                                |
| Arabs               | 44 474 (3.8)                              | 26 672 (3.1)                                |
| Immunosuppression   | 27 822 (2.4)                              | 25 459 (2.9)                                |
| Diabetes mellitus   | 113 769 (9.7)                             | 104 152 (11.9)                              |
| Cardiovascular diseases | 70 716 (6.0)                             | 66 252 (7.6)                                |
| Hypertension        | 251 323 (21.3)                            | 229 892 (26.4)                              |
| Cancer              | 95 935 (8.1)                              | 90 512 (10.4)                               |

Abbreviations: BMI, body mass index; IQR, interquartile range; SD, standard deviation; SES, residential socioeconomic status rank.
Risk for hospitalization among patients infected in protection period and reference period are shown in Figure 3, with aHRs of 0.82 (95% CI: .36–1.88), 0.45 (95% CI: .23–.90), and 0.56 (95% CI: .36–.89) in persons aged 45–64, 65–74, and ≥75 years, respectively. Reduced risk of hospitalization was calculated among patients with obesity (aHR = 0.40; 95% CI: .22–.73), hypertension (aHR = 0.56; 95% CI: .36–.86), and diabetes (aHR = 0.46; 95% CI: .25–.86). We found little difference in hospitalization rates in patients with immunosuppression (aHR = 1.38; 95% CI: .51–3.72) or cancer (aHR = 1.04; 95% CI: .49–2.23) that were infected with SARS-CoV-2.

DISCUSSION

Our analysis of vaccinated individuals indicates 90% effectiveness of the BNT162b2 mRNA vaccine in preventing rt-PCR-confirmed SARS-CoV-2 infection and 94% against COVID-19, with lower effectiveness among those with immunosuppression. Our findings are in line with the estimated 95% vaccine efficacy for COVID-19 reported in the phase III RCT [6], as well as 86%–94% effectiveness against SARS-CoV-2 infection in recent observational studies [3, 15, 16].

To our knowledge, this is the largest cohort of vaccinated persons that assessed VE. With this sizable sample and 728 incident PCR-confirmed SARS-CoV-2 infections starting at 7 days after second dose, we were able to estimate VE among different subpopulations. VE in patients with underlying chronic conditions including diabetes, hypertension, cardiovascular diseases, or cancer was somewhat lower (approximately 82%) compared to the population average of 90%. In a previous observational study from a large health provider in Israel [3], VE in persons with diabetes or hypertension was similar to the general population, although patients with over 3 major chronic morbidities had diminished effectiveness. A more substantial difference was found among immunosuppressed patients who had an average VE of 70%, which was further reduced among the elderly. Current data on the risk of COVID-19 morbidity patients with immunosuppression are limited [17] as these patients more strongly adhere to exposure-limiting precautions compared to the general population. Thus, more research is required to characterize the immunologic profile of these groups to ensure optimal protection [18].

In addition to estimating VE, our analysis evaluated the potential benefit of the vaccine in reducing the risk of COVID-19 hospitalizations and death among patients with vaccine failure in preventing infection. Individuals who were infected starting at day 7 after the second dose were substantially less likely to present symptoms and to be hospitalized compared to those who were infected in the reference period. A comparable reduction of 60% in hospital admissions after vaccination was observed in a previous observational study [16]. Similarly, our
Figure 2. Estimated BNT162b2 mRNA vaccine effectiveness and 95% CIs against PCR-confirmed SARS-CoV-2 infection by age, sector, and comorbidity. Abbreviations: CI, confidence interval; mRNA, messenger RNA; PCR, polymerase chain reaction; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2.

Table 2. Proportion of Symptomatic COVID-19 Infection Among Patients With Positive SARS-CoV-2 PCR

| Reference Period (N) | Protection Period (N) |
|----------------------|-----------------------|
| n | % | n | % | OR* | 95% CI |
|----------------------|-----------------------|
| Total | 4514 | 728 | 3163 | 70.1% | 281 | 38.6% | 0.32 | 0.27 | 0.39 |
| Sex | Male | 2289 | 356 | 1552 | 67.8% | 124 | 34.8% | 0.28 | 0.22 | 0.37 |
| | Female | 2225 | 372 | 1611 | 72.4% | 157 | 42.2% | 0.35 | 0.27 | 0.45 |
| Age, years | 16–44 | 2323 | 163 | 1624 | 69.9% | 50 | 30.7% | 0.16 | 0.11 | 0.24 |
| | 45–64 | 1617 | 308 | 1250 | 77.3% | 133 | 43.2% | 0.25 | 0.19 | 0.33 |
| | 65–74 | 337 | 146 | 204 | 60.5% | 59 | 40.4% | 0.50 | 0.33 | 0.76 |
| | ≥75 | 237 | 111 | 85 | 35.9% | 39 | 35.1% | 1.0 | 0.68 | 1.93 |
| Jewish Ultra-orthodox | 701 | 49 | 540 | 77.0% | 25 | 51.0% | 0.34 | 0.17 | 0.65 |
| Arabs | 242 | 25 | 157 | 64.9% | 12 | 48.0% | 0.54 | 0.22 | 1.33 |
| Obesity | 1107 | 245 | 833 | 75.2% | 108 | 44.1% | 0.33 | 0.24 | 0.45 |
| Immunosuppression | 79 | 56 | 54 | 68.4% | 32 | 57.1% | 0.81 | 0.35 | 1.89 |
| Diabetes | 411 | 170 | 265 | 64.5% | 73 | 42.9% | 0.48 | 0.32 | 0.73 |
| Cardiovascular disease | 212 | 92 | 125 | 59.0% | 38 | 41.3% | 0.56 | 0.32 | 0.98 |
| Hypertension | 798 | 297 | 530 | 66.4% | 135 | 45.5% | 0.56 | 0.41 | 0.75 |
| Cancer | 230 | 90 | 143 | 62.2% | 39 | 38.9% | 0.56 | 0.32 | 0.98 |

Abbreviations: CI, confidence interval; COVID-19, coronavirus disease 2019; OR, odds ratio; PCR, polymerase chain reaction; SARS-CoV-2, severe acute respiratory syndrome coronavirus 2. *Mutually adjusted for all listed variables and calendar epidemiologic week.
results indicate a lower case-fatality of COVID-19 cases infected during protection period compared to the reference period as was previously observed [3]. However, it can be argued that a hospitalization rate of 6.9% and case-fatality rate of 1.5% in those after the second dose are not negligible, especially not in patients with immunosuppression. It therefore might be important to retain awareness among vaccinated patients and their caregivers to possible severe COVID-19 when breakthrough infection occurs.

Previous observational studies compared vaccinated and matched unvaccinated patients, which could introduce selection bias due to unmeasured confounders such as health literacy, perceived feelings of vulnerability to COVID-19, and differences in health seeking behavior [5, 19]. Moreover, these comparative studies are also susceptible to a healthy vaccine bias, as immunized individuals are more likely to feel well on the vaccination date while patients with symptoms or suspected contacts are discouraged from immunization [20]. Rigorous matching in these studies was employed to make the vaccinated and unvaccinated populations comparable but is done at the cost of excluding many vaccinated individuals for whom a match cannot be found. For example, in the study by Dagan et al [3], more than half of the vaccinated persons were excluded and only 16 180 (24%) out of 67 492 patients with immunosuppression who were vaccinated could be matched. This potentially might limit the generalizability of findings, especially among persons with more complex medical conditions. The current study design was based upon internal comparisons among vaccinated individuals to avoid such bias.

This study has some limitations. Although 74% of the study participants were included in both periods, follow-up distributed differently over calendar time. However, when analyses were stratified by calendar week, results remained materially unchanged. In addition, we assessed COVID-19 symptoms from physician reports at patient’s visits. Thus, symptoms that developed after that visit were not captured in our data.

Additional limitation is change in health-seeking behavior between the periods where patients after 2 doses may have a lower test rate, leaving more asymptomatic infections undocumented. Nevertheless, this potential information bias is likely insignificant, as VE calculated for all infections was similar or lower to the one calculated for symptomatic cases. Finally, the "healthy vaccinee" effect should also be considered when using the incidence in the first days after first dose as a reference period, although sensitivity analysis suggested that the attenuation in the estimated VE is relatively small.

With more than 86% of adults in MHS are currently covered with at least 1 dose of BNT162B2, COVID-19 morbidity is still significant. Although the relative importance of children and young adolescents in SARS-CoV-2 transmission is still unclear, their vaccination seems to be essential to support herd immunity. This underlines the importance of several COVID-19 pediatric vaccines trials that are underway [21].

We report a high effectiveness of the BNT162b2 vaccine for preventing documented SARS-CoV-2 infection in real-world setting, corroborating estimates reported in previous randomized trial and observational analyses. Our study also suggests that second dose of the vaccine reduced, but not nullified, the risk of hospitalization among infected patients. The relationship between immunosuppression and BNT162b2 VE should be further explored. Although this early evidence is highly encouraging, new challenges are imposed with the emergence of the
new SARS-CoV-2 variants. Therefore, it is necessary to reassess the effectiveness of the vaccine periodically in the general population and in various subpopulations.

**Supplementary Data**

Supplementary materials are available at *Clinical Infectious Diseases* online. Consisting of data provided by the authors to benefit the reader, the posted materials are not copyedited and are the sole responsibility of the authors, so questions or comments should be addressed to the corresponding author.

**Notes**

*Potential conflicts of interest.* All authors: No reported conflicts of interest. All authors have submitted the ICMJE Form for Disclosure of Potential Conflicts of Interest. Conflicts that the editors consider relevant to the content of the manuscript have been disclosed.

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