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Association Between the BNT162b2 Messenger RNA COVID-19 Vaccine and the Risk of Sudden Sensorineural Hearing Loss

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Key Points

Question Is there an association between the BNT162b2 messenger RNA (mRNA) COVID-19 vaccine and sudden sensorineural hearing loss (SSNHL)?

Findings In this cohort study of 2 602 557 patients in Israel, an association was found between the BNT162b2 mRNA COVID-19 vaccine and SSNHL as reflected by the high ratio of observed to expected SSNHL cases; however, the effect size was very small.

Meaning Considering the small effect size of this association and the good prognosis for patients with SSNHL, the potential influence of this condition on public health appears to be relatively minor.

Abstract

Importance Identification of adverse events after vaccination increases awareness of vaccine-associated complications, leading to early diagnosis and treatment. Evidence remains scarce on the association between the BNT162b2 messenger RNA (mRNA) COVID-19 vaccine (Pfizer-BioNTech) and sudden sensorineural hearing loss (SSNHL).

Objective To assess the association between the BNT162b2 mRNA COVID-19 vaccine and SSNHL.

Design, Setting, and Participants This retrospective, population-based cohort study was performed from December 20, 2020, to May 31, 2021, using data from the largest health care organization in Israel. Patients 16 years or older who received the first vaccine dose between December 20, 2020, and April 30, 2021, and the second vaccine dose between January 10, 2021, and April 30, 2021, were included.

Exposures Receipt of first and second BNT162b2 mRNA COVID-19 vaccine doses.

Main Outcomes and Measures The main outcome was SSNHL based on *International Classification of Diseases, Ninth Revision (ICD-9)* codes in conjunction with concurrent prednisone dispensing. Observed cases of SSNHL, occurring within 21 days after each of the first and second

vaccine doses, were compared with the expected cases based on the experience of the population in 2018 and 2019. Standardized incidence ratios (SIRs) and attributable risks were computed.

Results Overall, 2 602 557 patients (mean [SD] age, 46.8 [19.6] years; 51.5% female) received the first dose of BNT162b2 mRNA COVID-19 vaccine, with 91 cases of SSNHL reported. Of these patients, 2 441 719 (93.8%) received the second vaccine dose, with 79 cases of SSNHL reported. The age- and sex-weighted SIRs were 1.35 (95% CI, 1.09-1.65) after the first vaccine dose and 1.23 (95% CI, 0.98-1.53) after the second vaccine dose. After the first vaccine dose, the estimated SIRs were more pronounced in female patients aged 16 to 44 years (SIR, 1.92; 95% CI, 0.98-3.43) and female patients 65 years or older (SIR, 1.68; 95% CI, 1.15-2.37). After the second vaccine dose, the highest estimated SIR was observed in male patients 16 to 44 years (SIR, 2.45; 95% CI, 1.36-4.07). The attributable risks were generally small, and the results were similar when 2019 was used as a reference to estimate the expected number of SSNHL cases.

Conclusions and Relevance This study suggests that the BNT162b2 mRNA COVID-19 vaccine might be associated with increased risk of SSNHL; however, the effect size is very small. Further studies are warranted to establish this possible association.

Introduction

Sudden sensorineural hearing loss (SSNHL) is an acute symptom, with patients experiencing unilateral abrupt impairment of hearing. This condition affects 5 to 27 per 100 000 people annually, and approximately 66 000 new cases occur per year in the US.[1] Sudden sensorineural hearing loss is defined as hearing loss of more than 30 dB over 3 consecutive frequencies in an interval of 72 hours.[2] The exact pathophysiologic mechanism of the disease is still unknown, with the most likely causative factor being viral infection.[3,4] Patients with SSNHL might experience permanent hearing loss and tinnitus; thus, prompt assessment, diagnosis, and treatment are essential.[2] Treatment consists of corticosteroids, which are usually given orally. Corticosteroids should be offered as soon as the loss of hearing is identified by audiography and preferably within 2 weeks of onset of hearing loss.[2] Intratympanic corticosteroid injection is given as salvage treatment; however, it may be used as primary treatment.

The COVID-19 pandemic has influenced the entire world, with a wide effect on medical, social, and economic issues. Several studies[5-7] have assessed the association between sudden hearing loss and COVID-19, reporting an increased risk of hearing loss during or after COVID-19. After the introduction of the BNT162b2 messenger RNA (mRNA) COVID-19 vaccine (Pfizer-BioNTech), we believed that more SSNHL cases were being diagnosed with proximity to COVID-19 vaccination, suggesting an association between the COVID-19 vaccine and SSNHL. However, Formeister et al[8] recently reported that the incidence of SSNHL occurring after COVID-19 vaccination does not exceed that of the general population and may be lower. In the current study, we take advantage of the electronic databases of the largest health organization in Israel to examine the association between vaccination with the BNT162b2 mRNA COVID-19 vaccine and SSNHL.

Methods

The study was approved by the institutional review board of the Lady Davis Medical Center and conducted in accordance with the Declaration of Helsinki.[9] Owing to the retrospective nature of the study, a waiver of informed consent was granted by the institutional review board. This study followed

the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) reporting guideline.

Source of Data

This study is based on data from the computerized database of Clalit Health Services (CHS), which provides inclusive health care for more than half of the Israeli population (approximately 4.7 million people). Health care coverage in Israel is mandatory according to the National Health Insurance Law (1995) and is provided by 4 groups akin to not-for-profit health maintenance organizations (HMOs), which are charged with providing a broad package of benefits stipulated by the government. The 4 HMOs are both health care insurers and health care organizations, thus financing and supplying health services. Membership in a specific HMO is voluntary, and members can freely switch to another HMO. All members of the different HMOs have a similar health insurance plan and similar access to health services, including low medication copayments. The CHS maintains a database that receives data from multiple sources, including records of primary care physicians, community specialty clinics, hospitalizations, laboratories, and pharmacies. Designed for administrative and clinical management, the database is available for clinical studies. Several high-quality population-based studies[10,11] have been conducted based on data retrieved from this database.

Study Design and Population

We performed a retrospective cohort study with a nonconcurrent historic comparative group. In this approach, the observed cases of SSNHL appearing after COVID-19 vaccination were compared with the expected cases of SSNHL as estimated based on the experience of the CHS population in 2018 and 2019 before the COVID-19 pandemic and vaccine introduction in Israel.

To estimate the observed cases of SSNHL after the first vaccine dose, we identified all CHS members aged 16 years or older who received the first dose of the vaccine from December 20, 2020, the start date of the mass COVID-19 vaccination campaign in Israel, until April 30, 2021. Identified individuals constitute the population for the estimation of the standardized incidence ratio (SIR) of SSNHL after the first vaccine dose. Among these individuals, those who were not diagnosed with SSNHL after the first vaccine dose and received the second vaccine dose by April 30, 2021, constituted the population for the estimation of SIR after the second vaccine dose.

Study Variables

Identification of patients with SSNHL was based on *International Classification of Diseases, Ninth Revision (ICD-9)* codes (388.2, 389.1, 389.10-389.13, 389.15-389.18, 389.8, and 389.9) from discharge diagnosis, emergency department visits, primary care physician visits, and community specialty clinic visits. However, the *ICD-9* codes include diagnosis of sensorineural hearing loss and do not contain an explicit diagnosis for SSNHL. Hence, a diagnosis of SSNHL was considered only in patients who were concurrently treated with prednisone, which is the standard of care for this condition, defined as purchasing a prescription starting from the date of diagnosis up to 30 days after diagnosis.

Data on the receipt of the BNT162b2 mRNA COVID-19 vaccine were retrieved from the CHS database. These data are considered complete because since the start of the COVID-19 pandemic, the Israeli Ministry of Health has been collecting all COVID-19–related data and activities, including vaccination status, in a national database. The collected data are transferred daily to the HMOs.

Statistical Analysis

The observed numbers of cases of SSNHL that occurred within 21 days after each of the first and second vaccine doses were compared with the expected number of cases based on estimation from historic data. The time window of 21 days is deemed to be sufficient for short-term complications, without being so long as to dilute the effect, and is in line with the time window used in a recently published similar study.[8] Observed cases after the first vaccine dose were assessed in those who received the first dose between December 20, 2020, and April 30, 2021, and the observed cases after the second vaccine dose were assessed in those who received the second dose between January 10, 2021, and April 30, 2021. Both cohorts were retrospectively followed up through May 31, 2021, for SSNHL ascertainment. Kaplan-Meier curves were used to depict the distribution of time to SSNHL since the receipt of the first and the second vaccine doses. The expected cases of SSNHL after vaccination were estimated based on the experience of the CHS population, used as the reference standard population, in 2018 and 2019 during the same period (January to May). The number of SSNHL cases expected to occur within 21 days after each vaccine dose was calculated by multiplying sex- and age group (16-44, 45-64, and ≥65 years)–specific rates in the reference population by the person-time at risk of the corresponding stratum among those who received the vaccine. Standardized incidence ratios were calculated by dividing the observed by the expected number of SSNHL cases for each vaccine dose, sex, and age group (16-44, 45-64, and ≥65 years). We used an indirect standardization technique to control for age and sex. The sex- and age-weighted (adjusted) SIRs were estimated by dividing the sum of the sex- and age-specific observed cases by the expected cases of SSNHL. We calculated the attributable risk fraction (ARF) among vaccinated individuals as (SIR − 1)/SIR and computed attributable risks (ARs) for 100 000 vaccine doses by multiplying the risk after each vaccine dose by the ARF. The 95% CIs for SIR, ARF, and AR estimates were computed using the mid-*P* exact test. $P < .05$ for the 2-tailed tests was considered to be statistically significant.

We performed 2 sensitivity analyses in which we calculated SIRs for follow-up of 60 days after the first and second vaccine doses instead of the 21 days used in the main analysis. For the first vaccine dose, this analysis was confined to data from 113 579 individuals who received the first vaccine dose by March 31, 2021, and have no documentation of second dose receipt during the following 60 days. For the second vaccine dose, this analysis relied on data from 2 317 305 individuals who received the second vaccine dose by March 31, 2021. As in the main analysis, both cohorts were retrospectively followed up through May 31, 2021, for SSNHL ascertainment. Because of the small number (n = 13) of individuals with SSNHL after the first vaccine dose, only the age- and sex-weighted SIR is reported, whereas for individuals with SSNHL after the second vaccine dose, the age- and sex-specific as well as the weighted SIRs are presented.

Results

Overall, 2 602 557 CHS members (mean [SD] age, 46.8 [19.6] years; 51.5% female) received the first dose of the BNT162b2 mRNA COVID-19 vaccine between December 20, 2020, and April 30, 2021. Of these individuals, 2 441 719 received the second vaccine dose between January 10, 2021, and April 30, 2021. The sex and age distributions of the vaccinated individuals and of the reference control groups are given in the eTable in the Supplement. Sudden sensorineural hearing loss was detected within 21 days in 91 patients after the first vaccine dose, reflecting a 21-day cumulative incidence of 3.50 per 100 000 individuals, and in 79 patients after the second vaccine dose, reflecting a 21-day cumulative incidence of 3.24 per 100 000 individuals (Table 1 and Table 2). The distribution of time to SSNHL since the receipt of each vaccine dose is depicted in the Figure.

Person-times at risk and incidence rates for the vaccinated populations and the reference populations in previous years are given in Table 3. The incidence rate of SSNHL was 60.77 (95% CI, 48.29-73.26) per 100 000 person-years after the first vaccine dose and 56.24 (95% CI, 43.83-68.64) per 100 000 person-years after the second vaccine dose. The corresponding incidence rates of SSNHL in the previous reference years were 41.50 (95% CI, 37.98-45.01) per 100 000 person-years in 2018 and 44.46 (95% CI, 40.85-48.07) per 100 000 person-years in 2019 (Table 3).

With the experience of the population in 2018 used as reference, the age- and sex-weighted SIRs were 1.35 (95% CI, 1.09-1.65) for the first vaccine dose and 1.23 (95% CI, 0.98-1.53) for the second dose (Table 1). Stratified analysis by sex and age groups showed that the magnitude of the SIRs after the first vaccine dose tended to be higher in females aged 16 to 44 years (SIR, 1.92; 95% CI, 0.98-3.43) and 65 years or older (SIR, 1.68; 95% CI, 1.15-2.37). After the second vaccine dose, the highest estimated SIR was observed in males aged 16 to 44 years (SIR, 2.45; 95% CI, 1.36-4.07) (Table 1). The ARs were generally small, with the highest AR of 3.74 per 100 000 vaccinees detected in women 65 years or older (Table 1). The pattern of the association was similar when we repeated the analysis by using the experience of the population in 2019 as reference (Table 2).

In the sensitivity analysis, extending follow-up to 60 days after the first vaccine dose was available for 113 579 vaccinated individuals who had not received the second dose. Of these patients, only 13 had SSNHL, yielding an age- and sex-weighted SIR of 1.86 (95% CI, 1.04-3.10), using 2018 as reference population. Extending follow-up to 60 days after the second vaccine dose was assessed in 2 317 305 individuals, of whom 205 had SSNHL. The results were similar to the results for 21-day follow-up, with an age- and sex-weighted SIR of 1.15 (95% CI, 1.00-1.23) and the highest SIR observed in males aged 16 to 44 years (SIR, 2.07; 95% CI, 1.41-2.93) (Table 4).

Discussion

This population-based cohort study reveals a potential association between BNT162b2 mRNA COVID-19 vaccine uptake and increased risk of SSNHL, although the effect size is very small. This association appears to differ between age groups and to be more pronounced in females after the first vaccine dose and in males after the second dose. The introduction of the BNT162b2 mRNA COVID-19 vaccine by Pfizer-BioNTech in late 2020 was accompanied with safety concerns. Reported adverse effects include local reactions, such as pain at the injected site, and systemic adverse events, such as fatigue and fever.[12] Severe adverse events were reported in 1.2% of the vaccine group compared with 0.7% of the placebo group.[13] To date, several studies,[11-14] including randomized clinical trials and observational studies, have investigated the safety of COVID-19 vaccines, with more emphasis on severe adverse events. Some of these studies[8,15] have assessed the association of the COVID-19 vaccine with specific adverse events, including otoneurologic manifestations, such as SSNHL and Bell palsy. In general, these studies[11,14] investigated adverse events that were included in prior safety studies, revealed an imbalance between the vaccine and placebo groups in clinical trials, addressed hypothetical concerns, or focused on emerging concerns that have arisen during surveillance. However, except for 1 preliminary study,[8] none of these studies have included SSNHL as an adverse event.

In the current study, the rationale for examining the association between BNT162b2 mRNA COVID-19 vaccine uptake and SSNHL relied primarily on the observation of some cases of SSNHL diagnosed a few days after vaccine uptake in our institute. Of interest, similar anecdotal reports were rapidly emerging from the otolaryngology community that led researchers from Johns Hopkins

University to conduct a preliminary analysis to examine the association between COVID-19 vaccination and SSNHL.[8] These researchers assessed self-reported data from the Centers for Disease Control and Prevention (Vaccine Adverse Event Reporting System) that include reports after the SARS-CoV-2 vaccine (BNT162b2 mRNA COVID-19 vaccine by Pfizer-BioNTech and mRNA-1273 COVID-19 vaccine by Moderna) and found that the incidence of SSNHL after COVID-19 vaccination did not exceed that of the general population and may be even lower, suggesting no association between inoculation with COVID-19 mRNA vaccination and SSNHL.[8] However, because of the nature of self-reporting, this approach has some limitations and therefore could not find such an association. Compared with the previous study,[8] our study has the advantage of looking at the association after each vaccine dose and assessing whether specific patient characteristics, such as sex and age, might be associated with a higher risk of SSNHL. Indeed, our study found that the magnitude of association differs by vaccine dose, age, and sex.

Although our results reveal a significant association between the BNT162b2 mRNA COVID-19 vaccine and SSNHL as reflected by the high ratio of observed to expected SSNHL cases, referring to this result alone may be misleading. Indeed, the small estimated ARs suggest that the influence on public health is relatively minor. Considering our findings along with those of other studies[5-7] that showed an increased risk of SSNHL during or after COVID-19, we are convinced that the benefits of vaccinations against COVID-19 explicitly outweigh the possible association with SSNHL, which is in any case uncommon and has a high recovery rate if diagnosed and treated in a timely manner.

Limitations

Limitations of this study include the use of *ICD-9* codes to identify patients with SSNHL. The *ICD-9* includes diagnosis of sensorineural hearing loss but does not contain an explicit diagnosis for SSNHL. To identify cases of SSNHL, our search involved matching a new diagnosis of loss of hearing with concurrent prednisone treatment, which is the standard of care for this condition. Patients who did not receive prednisone, either because they sought medical consultation too late for treatment or because of a contraindication for oral corticosteroid treatment, were not enrolled in the study. Furthermore, the current treatment protocol for SSNHL is oral prednisone followed by salvage intratympanic corticosteroid injection. However, patients who were treated only with intratympanic corticosteroid injection might not have been included in the study. We are aware that the improved specificity of SSNHL, related to the use of this algorithm in our study, is obtained at the expense of impairing the sensitivity of identifying patients with SSNHL. However, the same algorithm was used both after the vaccine was available and before the COVID-19 pandemic. If there is any bias, it should be similar; hence, any misclassification related to this algorithm is likely nondifferential.

Another potential limitation is that health care–seeking behavior is not uncommon shortly after receiving vaccines, and such behavior may lead to increased ascertainment of prevalent conditions (ie, ascertainment bias). However, SSNHL is characterized by abrupt onset; therefore, it is unlikely that a patient would not be seen by a physician, regardless of vaccination status. Hence, we assume that the influence of this bias is minimal. Another limitation in the current study is the lack of evaluation of the severity of hearing loss and posttreatment outcomes. In addition, this retrospective cohort study relies on data originally collected for purposes of administrative and clinical management and not specifically for the purpose of the current study; as such, a possible limitation may be related to the quality of the data. However, information about the receipt of the BNT162b2 mRNA COVID-19 vaccine is considered to be complete because these data are prospectively collected by the Israeli Ministry of Health. Although our large sample size has allowed us to conduct stratified analysis by age and sex, adjustment was limited only to age and sex. Hence, residual confounding remains a

major concern for the current study because we have not controlled for other potential confounders, such as cardiovascular risk factors and coagulation disorders, which are risk factors for SSNHL and might differ between vaccinated individuals and the general population. People who were vaccinated were older (and may be sicker) than the reference population. The lack of additional data detailing the health characteristics of the exposure groups is a serious limitation. However, almost 80% of individuals in this age group (≥16 years of age) had received the COVID-19 vaccine at the time of the study, suggesting that vaccinated individuals might be representative of the general population. In addition, this was a retrospective cohort study with a nonconcurrent historic comparative group; the lack of a concurrent control group might introduce bias owing to secular trends and changes of treatment and in diagnostic criteria over time. However, we relied on the most recent years immediately before the COVID-19 pandemic; therefore, no major temporal differences are expected. On the basis of the limitations inherent in the study design, this study should be considered as hypothesis generating, and future studies are needed to confirm the findings.

Conclusions

This cohort study suggests that the BNT162b2 mRNA COVID-19 vaccine might be associated with an increased risk of SSNHL; however, the effect size is very small. Considering these findings along with the good prognosis for patients with SSNHL, we suggest that the benefits of the BNT162b2 mRNA COVID-19 vaccine outweigh its potential association with SSNHL. However, sharing these findings with health care professionals who are involved in SSNHL assessment might lead to early recognition and treatment, which are crucial to improve outcome. Further studies are warranted to establish this possible association.

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