

Sudden Hearing Loss Following Vaccination Against COVID-19

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IMPORTANCE Spontaneous adverse reaction reports of sudden hearing loss have been observed, and a population-based cohort study conducted in Israel showed an increase in the incidence of sudden sensorineural hearing loss (SSNHL) following vaccination with messenger RNA COVID-19 vaccine BNT162b2 (Pfizer-BioNTech). However, in this setting, the possibility of confounding remained.

OBJECTIVE To assess a potential association between COVID-19 vaccinations and SSNHL.

DESIGN, SETTING, AND PARTICIPANTS This register-based country-wide retrospective cohort study of 5.5 million Finnish residents was conducted from January 1, 2019, to April 20, 2022, and included all individuals who were identified from the population information system who were alive or born during the study period except individuals who had SSNHL during 2015 to 2018 according to specialized care derived diagnosis codes for SSNHL (*International Statistical Classification of Diseases and Related Health Problems, Tenth Revision [ICD-10]* code H91.2) as a primary or secondary diagnosis.

EXPOSURES The a priori primary risk period was 0 to 54 days following each COVID-19 vaccination. The risk periods for different vaccine doses did not overlap so that a later vaccine exposure ended the previous risk period. The secondary risk period was from 55 days following each COVID-19 vaccination until a subsequent COVID-19 vaccination. A secondary analysis included a risk time from 0 to 54 days following a positive polymerase chain reaction test result for SARS-CoV-2.

MAIN OUTCOMES AND MEASURES The incidences of SSNHL following COVID-19 vaccination were compared with the incidences before the COVID-19 epidemic in Finland. The Poisson regression model included calendar time, age, sex, diabetes, cardiovascular disease, other chronic diseases, and the number of visits in primary health care.

RESULTS For the 5.5 million Finnish residents included in the study, the comparison time comprised 6.5 million person-years, the primary risk time of 1.7 million person-years, and the secondary risk time of 2.1 million person-years. Before the COVID-19 epidemic in Finland, 18.7/100 000 people received a diagnosis of SSNHL annually. The study data suggested no increased risk for SSNHL following any COVID-19 vaccination. In particular, adjusted incidence rate ratios with 95% confidence intervals for the BNT162b2 vaccine's 3 doses were 0.8 (95% CI, 0.6-1.0), 0.9 (95% CI, 0.6-1.2), and 1.0 (95% CI, 0.7-1.4), respectively. There was no association between SARS-CoV-2 infection and an increased incidence of SSNHL.

CONCLUSIONS AND RELEVANCE The results of this cohort study show no evidence of an increased risk of SSNHL following COVID-19 vaccination. The study accounted for previous disease and other potential confounding factors. These results are based on diagnosis codes in specialized care but still need to be verified in settings that are capable of evaluating the degree of hearing loss.

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During the COVID-19 pandemic, there have been several case reports in which sudden sensorineural hearing loss (SSNHL) has been associated with COVID-19 vaccination.^{1,2} The European database of suspected adverse drug reaction reports, as retrieved on March 15, 2022, includes more than 1000 reports on COVID-19 vaccination-related SSNHL.³ These reports have been rare, as the cumulative number of administered COVID-19 doses in Europe exceeded 1.5 billion in March 2022.^{4,5} A 2021 US report that was based on data from the Vaccine Adverse Events Reporting System concluded that the incidence of SSNHL was lower after COVID-19 vaccination than in the nonvaccinated population. The only population-based cohort study on this subject, from Israel, reported an increased risk for SSNHL after administration of the BNT162b2 messenger RNA COVID-19 vaccine (Pfizer-BioNTech).⁶ In that study, the standardized incidence ratio was 1.4 (95% CI, 1.1-1.7) when compared with 2018 incidence in an age-standardized and sex-standardized population.

The association between SARS-CoV-2 infection and SSNHL is controversial. In a study by van Rijssen et al,⁷ there was no apparent association between SSNHL and COVID-19, as none of the 25 patients with SSNHL had a positive SARS-CoV-2 laboratory test result. However, in several case reports, SSNHL has followed SARS-CoV-2 infection.^{8,9}

Studies that can account for the characteristics of those vaccinated are warranted. This study aimed to examine a possible association between COVID-19 vaccination and SSNHL. Secondarily, we investigated the association between SARS-CoV-2 infection and SSNHL.

Methods

In the population of 5.5 million residents in Finland, a COVID-19 vaccination campaign was initiated on December 26, 2020. Priority was given to health care workers and to those with highest risk for COVID-19-related hospitalization and death. This included elderly individuals, those with preexisting diseases, and those residing in nursing homes.¹⁰ The vaccination campaign was launched with the adenoviral vector vaccine ChAdOx1, but most of the population was vaccinated with messenger RNA (mRNA) vaccines. Of these, availability was associated with more immunizations with the BNT162b2 than the mRNA.1273 vaccine, with minimal use of other vaccine products. Moreover, on October 7, 2021, the Finnish Institute for Health and Welfare (THL) recommended the BNT162b2 vaccine for male individuals younger than 30 years due to data showing an increased risk of myocarditis in young men, especially following a second dose of mRNA.1273.¹¹

We investigated a potential harmful effect of the COVID-19 vaccines by conducting an observational cohort study based on nationwide register data and studied the incidence of SSNHL in Finland. Follow-up is close to complete, and emigration from Finland is rare, as only 0.27% in 2020 and 0.24% in 2021 emigrated.¹² The study period was from January 1, 2019, until April 20, 2022, and the data were extracted from registers

Key Points

Question Are COVID-19 vaccinations associated with sudden sensorineural hearing loss (SSNHL) when assessed in a register-based country-wide observational study with data on potential confounding factors?

Findings In this cohort study of 5.5 million Finnish residents, the data suggested no increased risk for SSNHL following any COVID-19 vaccination.

Meaning Although a large previous cohort study found an increased risk for SSNHL following vaccination with BNT162b2, the present study, which considered additional potential confounders, such as preexisting disease, found no such association.

on May 5, 2022. Surveillance, including the safety of vaccines used in the national vaccination program, was part of the THL's duties.¹³ The THL has the statutory right, notwithstanding confidentiality provisions, to access and link necessary data from the national registers.

Cohort

From the population information system, we identified all individuals who were alive or born during the study period. This register included the birth date, sex, and unique personal identification code for all permanent residents of Finland. The personal identification code enabled linkage to other registers, and we used it to retrieve exposure, outcome, and comorbidity information for the cohort. Individuals with a specialized care diagnosis of sudden hearing loss, identified with the *International Statistical Classification of Diseases and Related Health Problems, Tenth Revision (ICD-10)* diagnosis code H91.2 from the Care Register for Health Care¹⁴ during 2015 to 2018, were removed from the cohort.

Comorbidity Data

We combined data from multiple sources to define prestudy comorbidity information for the cohort. Comorbidity conditions were identified until the start of the study period, which was December 31, 2018. The availability of information preceding 2018 depended on the data source: starting from January 1, 2015, we included information from the care register for health care¹⁴ and the register for social assistance,¹⁵ and starting from January 1, 2018, from the register for reimbursement of medical expenses (Social Insurance Institute of Finland).¹⁶ Based on these 3 data sources, dichotomic risk factors included in the analysis were diabetes, cardiovascular disease, nursing home residency, assisted living, and other institutional living. Other chronic diseases associated with increased risk for COVID-19 hospitalizations and mortality¹⁷ were included in the analyses as a count (0, 1, 2, 3 or more). Starting from January 1, 2015, the register for primary health care visits¹⁸ provided a count (0, 1, 2, 3 or more) of any primary care contacts as a proxy for care-seeking behavior. The included primary care contacts were individual visits, physical visits or remote visits, outpatient care, dental care, vaccinations, and occupational health.

Exposure Data: Vaccination and Infection

The national vaccination register¹⁹ provided the vaccination dates and product names. Of vaccinations recorded within 14 days, only the first date represented a new vaccination dose, and the latter one was discarded as a duplicate record. To assess the secondary aim regarding SARS-CoV-2 infections, we used data from the Finnish National Infectious Diseases Register.²⁰ After January 1, 2020, we used the first positive SARS-CoV-2 laboratory test sample date per individual as the SARS-CoV-2 infection date. We ignored reoccurring infections. Most SARS-CoV-2 infections were detected based on a positive polymerase chain reaction (PCR) laboratory test result.

Outcome Data and Follow-up

Diagnoses in specialized care visits and hospital ward periods are sent to the care register for health care.¹⁴ For any individual, the first occurrence of the *ICD-10* diagnosis code starting with H91.2 (sudden idiopathic hearing loss) in the care register for health care after January 1, 2019, was considered as an incident case of SSNHL. The follow-up of an individual ended at the time of the outcome or death or the end of the study, whichever happened first.

Time-Varying COVID-19 Vaccination Status

The vaccination status was defined as (1) pre-epidemic unvaccinated, (2) epidemic unvaccinated, and (3) vaccinated. The vaccination status for the entire cohort until February 29, 2020, was pre-epidemic unvaccinated, then epidemic unvaccinated from March 1, 2020, until December 26, 2020, when the COVID-19 vaccinations in Finland started. For each vaccinated individual, the status first changed to prevaccination (30 days before the first vaccination) and then to vaccinated from the date of the first vaccination. The vaccinated state was further split into primary risk (0 to 54 days following any vaccination) and secondary risk (55 days and more following any vaccination until a subsequent vaccination) states, labeled by the dose and product of the latest vaccination. If individuals received multiple vaccine doses, a new primary risk period always overruled the previous risk period.

Time Varying SARS-CoV-2 Infection Status

The SARS-CoV-2 infection status was defined as uninfected or infected. The initial infection status for the whole cohort was uninfected. Following the start of the COVID-19 epidemic, the status of some changed to infected. The infected status was further split into primary and secondary risk periods, which were identical to those corresponding vaccination, except that a vaccination did not end the infection risk period. Reinfections were not considered.

Statistical Analyses

We conducted a survival analysis that considered exact person times at risk until the first occurrence of SSNHL or end of follow-up. We used a single Poisson regression model to estimate adjusted incidence rate ratios (aIRRs) between each vaccine exposure state and the pre-epidemic unvaccinated state and similarly between each infection exposure state and the

uninfected state. Time-invariant covariates included in the regression were sex, chronic disease count, diabetes, cardiovascular disease, nursing home care, assisted living, other institutional living, and the number of visits at primary care as a proxy of care-seeking behavior. The time-dependent covariates were vaccination status, SARS-CoV-2 infection status, calendar month, and age group, with lower group limits at ages 0, 12, 20, 30, 40, 50, 60, 70, and 80 years. To account for non-linear changes in the incidence of SSNHL by calendar month, we used a natural spline function.²¹ The number of knots used (7) was chosen based on Akaike information criteria among choices 6 to 12.

We assumed that the incidence of SSNHL was a piecewise constant depending on the time-dependent and time-invariant covariates. As all covariates were categorical, individuals contributed events and person time to follow-up groups based on the covariates. Each individual's person time and number of SSNHL occurrences (0 or 1) were then aggregated for all follow-up states.

Via Poisson regression, we modeled the log incidence of SSNHL and estimated the regression parameters and their standard errors. We used a normal approximation to derive 95% CIs for the parameter estimates on the log scale. Exponentiating the parameter estimates provided the aIRRs. We conducted the analyses with R, version 4.2 (R Foundation).²²

Sensitivity Analyses

We specified 2 additional regression models to assess the association of (1) calendar time adjustment and (2) risk factor and care-seeking adjustment with the vaccination exposure aIRRs. The analyses were otherwise identical to the main analysis, but the first model excluded the calendar adjustment, and the second model further excluded the comorbidity and infection exposure covariates, leaving only the following covariates: sex, age group, and vaccination status.

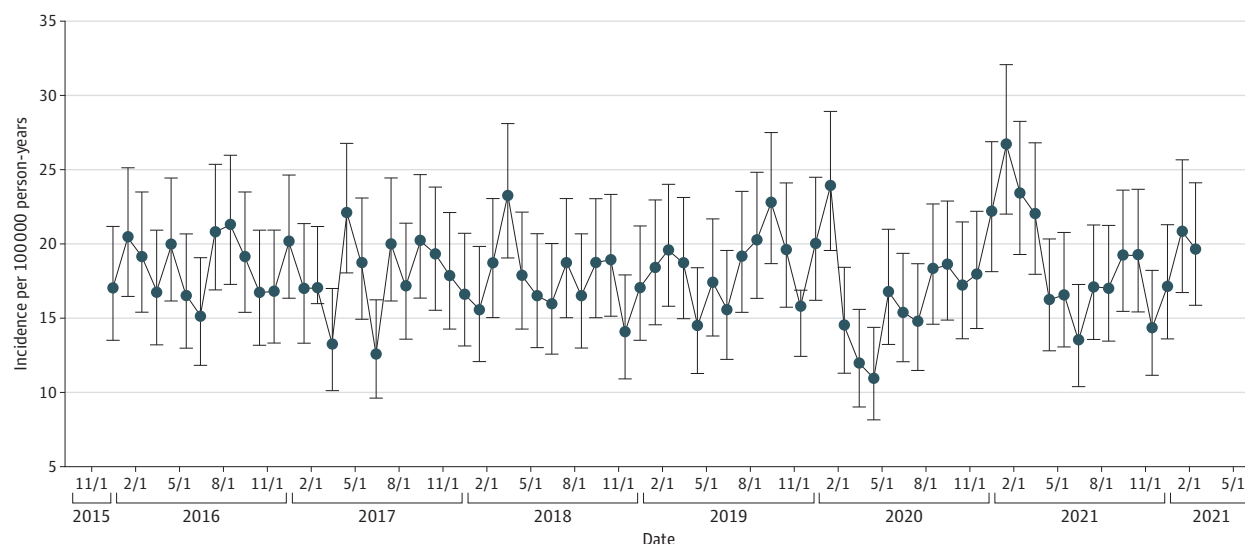
Results

In the whole population of Finland between 2016 and 2019, the crude monthly incidence of SSNHL varied from 13 to 23/100 000 person-years (pyrs) (Figure 1). In 2020, April and May showed the lowest incidences after 2016 (11 and 12/100 000 pyrs, respectively) and February 2021, the highest incidence regarding this outcome (27/100 000 pyrs). Since then, the monthly incidences varied at the same level as before 2020, between 14 and 21/100 000 pyrs.

Incidence During Unvaccinated Time

During follow-up time preceding the COVID-19 epidemic in Finland between January 1, 2019, and March 1, 2020, 1216 participants in the cohort developed SSNHL within 6.5 million pyrs of follow-up time, and the crude incidence per 100 000 pyrs was 18.7 (95% CI, 17.7-19.8) (Table). There was a sudden decrease in the incidence of SSNHL at the start of the epidemic in March 2020, which was followed by a slow increase back to the pre-epidemic level by the end of 2020 (eFigure in the Supplement). During March to December 2020, the incidence of SSNHL was

Figure 1. Incidence of Sudden Sensorineural Hearing Loss Before and During the Study Period in Finland



Incidence per 100 000 person-years of sudden sensorineural hearing loss in specialized care by calendar month. Vertical whiskers indicate 95% CIs, assuming a Poisson distribution of the monthly counts. The follow-up for the

current study started January 1, 2019, and the epidemic in Finland started in March 2020.

lower than before the epidemic (15.7; 95% CI, 14.5-16.8). Soon after the COVID-19 vaccinations began during early 2021, the observed crude incidence during unvaccinated time decreased, likely in association with the age-dependent and health-dependent vaccination campaign in Finland (eFigure in the Supplement).

Incidence Before and After Vaccination

Within the COVID-19 vaccinated population, the incidence of SSNHL did not show a temporal pattern associated with vaccination, and the incidences during the main risk periods were similar to the incidences before vaccination and those after the main risk periods (Figure 2). The crude incidences of SSNHL during the main risk period 0 to 54 days following the first COVID-19 vaccine dose with ChAdOx1, BNT162b2, and mRNA.1273 were 22.1 (95% CI, 11.4-38.7), 21.2 (95% CI, 17.5-25.6), and 18.5 (95% CI, 10.3-30.5), respectively, per 100 000 pyrs, and the aIRR estimates were less than 1, indicating no increased risk of SSNHL after the first vaccination dose (Table). For the 30 days preceding the first vaccination doses, the aIRRs were similarly less than 1 for the BNT162b2 and mRNA-1273 vaccines, indicating no increase in the incidence from before to after vaccination. For ChAdOx1, the aIRR estimate was lower during the main risk period than the 30 days prevaccination (0.4; 95% CI, 0.2-0.8 vs 0.9; 95% CI, 0.5-1.5).

The main and secondary risk periods following the second and third vaccinations showed no significant differences to the pre-epidemic unvaccinated time in the adjusted analysis. The point estimates for the aIRRs varied between 0.7 and 1.2, and all confidence intervals included 1 (Table).

Incidence After Infection

As the secondary aim, we explored how SARS-CoV-2 infection was associated with risk for SSNHL. There was no strong evidence of an increased risk of SSNHL following SARS-CoV-2 infection. The aIRR for the main risk period 0 to 54 days following infection was 1.1 (95% CI, 0.7-1.8), and the aIRR for the secondary risk period 55 days onwards from infection was 1.1 (95% CI, 0.7-1.6), both suggesting no significant change in the incidence of SSNHL compared with the uninfected time.

Sensitivity Analyses

Removing the calendar adjustment produced similar or up to 25% higher vaccination-related aIRRs compared with the main analysis (eTable in the Supplement). However, the aIRRs vs the pre-epidemic unvaccinated time were still mostly less than 1 or close to 1. The aIRR comparing the epidemic unvaccinated time with the pre-epidemic unvaccinated time was higher without calendar adjustment (0.9; 95% CI, 0.8-1.0). Removing the risk factor and care-seeking covariates from the model had almost no association with the vaccination exposure results.

Discussion

This cohort study investigated the proposed association between COVID-19 vaccinations and SSNHL by conducting a nationwide study with high-quality data sources. We compared the incidence of SSNHL following vaccinations with the incidence before the COVID-19 epidemic in Finland. To remove possible confounding by age and sex, we accounted for them in the analysis. Additionally, as opposed to previous studies, we also adjusted our analy-

Table. Incidence and Adjusted Incidence Rate Ratios of Sudden Sensorineural Hearing Loss

| Exposure | Risk time, d | Event count | Person-years (100 000) | Incidence (95% CI) | aIRR (95% CI) |
|----------------------|--------------|-------------|------------------------|--------------------|---------------|
| Unvaccinated | | | | | |
| Before March 2020 | NA | 1216 | 65.0 | 18.7 (17.7-19.8) | 1 [Reference] |
| After March 2020 | NA | 1079 | 75.5 | 14.3 (13.5-15.2) | 0.6 (0.5-0.7) |
| ChAdOx1 | | | | | |
| First dose | -30 to 1 | 16 | 0.3 | 54.0 (30.9-87.7) | 0.9 (0.5-1.5) |
| | 0 to 54 | 12 | 0.5 | 22.1 (11.4-38.7) | 0.4 (0.2-0.8) |
| | ≥55 | 14 | 0.3 | 46.4 (25.4-77.9) | 1.2 (0.7-2.2) |
| Second dose | 0 to 54 | 6 | 0.3 | 20.8 (7.7-45.4) | 0.6 (0.3-1.4) |
| | ≥55 | 23 | 0.7 | 33.5 (21.2-50.2) | 0.9 (0.6-1.6) |
| Third dose | 0 to 54 | 0 | 0.0 | NA | NA |
| | ≥55 | 0 | 0.0 | | |
| BNT162b2 | | | | | |
| First dose | -30 to -1 | 76 | 3.0 | 25.8 (20.3-32.3) | 0.8 (0.6-1.1) |
| | 0 to 54 | 111 | 5.2 | 21.2 (17.5-25.6) | 0.8 (0.6-1.0) |
| | ≥55 | 55 | 2.7 | 20.4 (15.3-26.5) | 0.8 (0.6-1.2) |
| Second dose | 0 to 54 | 104 | 5.4 | 19.4 (15.8-23.5) | 0.8 (0.6-1.2) |
| | ≥55 | 275 | 12.1 | 22.7 (20.1-25.6) | 1.0 (0.7-1.4) |
| Third dose | 0 to 54 | 78 | 3.1 | 25.2 (19.9-31.4) | 1.0 (0.7-1.4) |
| | ≥55 | 100 | 3.3 | 30.5 (24.9-37.2) | 1.2 (0.8-1.8) |
| mRNA-1273 | | | | | |
| First dose | -30 to -1 | 9 | 0.5 | 19.7 (9.0-37.5) | 0.7 (0.4-1.4) |
| | 0 to 54 | 15 | 0.8 | 18.5 (10.3-30.5) | 0.8 (0.5-1.4) |
| | ≥55 | 6 | 0.4 | 15.1 (5.6-32.9) | 0.7 (0.3-1.5) |
| Second dose | 0 to 54 | 20 | 0.8 | 25.0 (15.3-38.6) | 1.2 (0.7-1.9) |
| | ≥55 | 32 | 1.8 | 18.1 (12.4-25.5) | 0.9 (0.6-1.4) |
| Third dose | 0 to 54 | 35 | 1.2 | 29.2 (20.3-40.6) | 1.1 (0.7-1.8) |
| | ≥55 | 30 | 1.0 | 28.8 (19.4-41.1) | 1.2 (0.7-2.1) |
| SARS-CoV-2 infection | 0 to 54 | 18 | 1.25 | 14.4 (8.6-22.8) | 1.1 (0.7-1.8) |
| | ≥55 | 23 | 1.81 | 12.7 (8.0-19.0) | 1.1 (0.7-1.6) |

Abbreviations: aIRR, incidence rate ratio adjusted for sex, age group, chronic disease count, diabetes, cardiovascular disease, nursing home care, assisted living, other institutional living, and number of visits at primary care as a proxy of care seeking behavior, and calendar time; ChAdOx1, ChAdOx1-S (recombinant), Vaxzevria, adenoviral vector vaccine, AstraZeneca; BNT162b2, Comirnaty, mRNA vaccine, BioNTech/Pfizer; mRNA, messenger RNA; mRNA.1273, Spikevax, mRNA vaccine, Moderna; NA, not applicable.

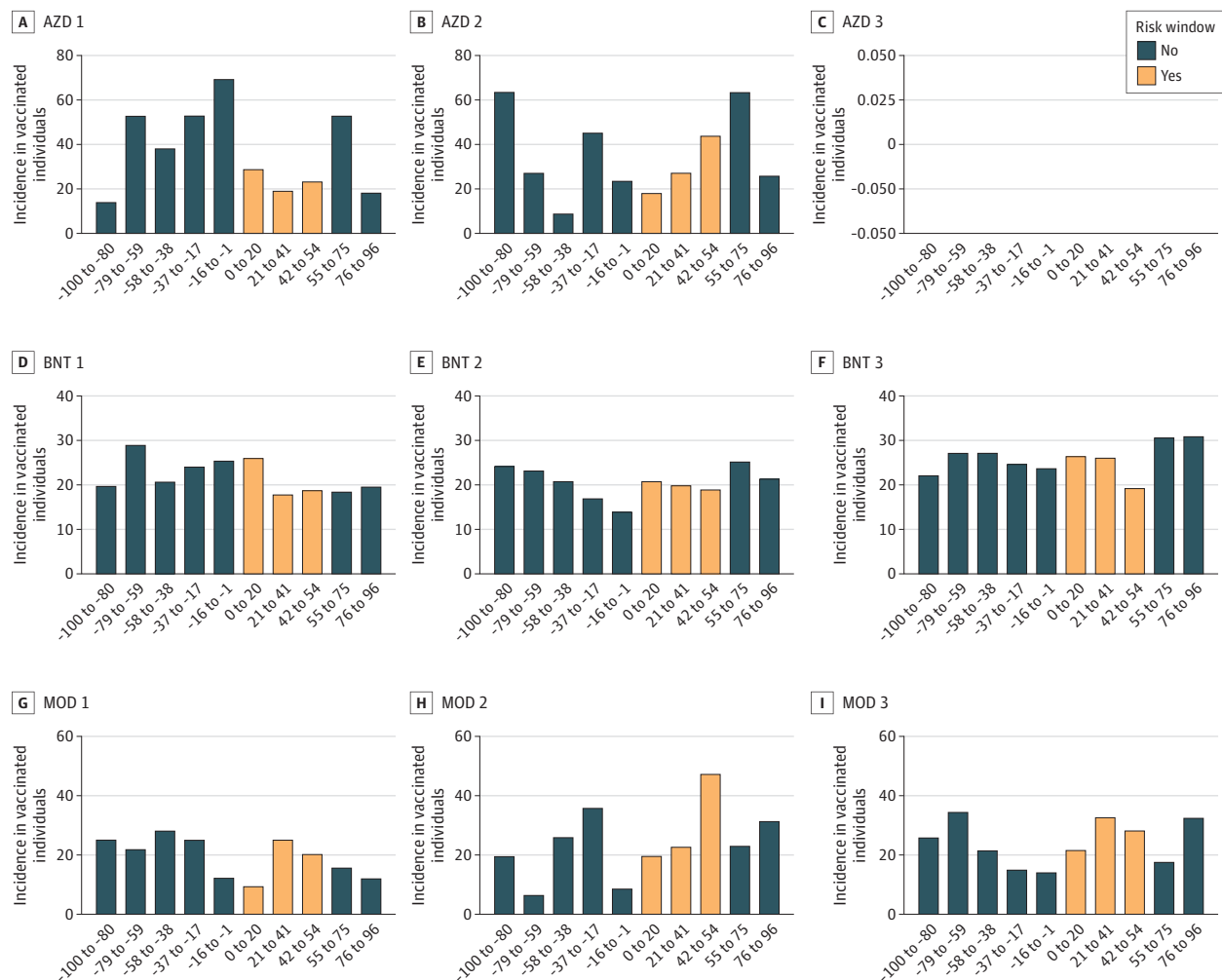
sis for individual differences in underlying diseases and care-seeking behavior, as well as temporal changes in the incidence of SSNHL unrelated to vaccination. In summary, we found no evidence of an association of COVID-19 vaccination with the incidence of SSNHL. The aIRR estimates associated with the main risk periods, from 0 to 54 days after vaccination, were mostly close to 1 or lower.

Sudden sensorineural hearing loss is a rare, severe condition that affects approximately 5 to 20 of 100 000 people yearly in high-income countries.^{23,24} In 40% to 60% of cases, hearing will recover to normal levels in a few weeks of follow-up.^{25,26} It is possible that a delay in or even absence of seeking help will be associated with a decrease in the incidence of diagnosed SSNHL cases. We found a reduction in the incidence of SSNHL during unvaccinated time during the COVID-19 epidemic and at the start of the epidemic the decrease was sudden (eFigure 1 in the Supplement). Reasons may include a decrease in the demand and supply of health care services and patient-physician encounters. During the COVID-pandemic, such was shown by a reduced testing for autoimmune disease-related antibodies.²⁷ Regarding other possible reasons for lower

incidence during the epidemic, we are unaware of any changes in the diagnosis processes or guidelines during the study from 2019 to 2022.

One weakness of this study was that we defined SSNHL according to the diagnostic decision of each clinician and not to a standardized predefined definition. In a previous study by Härkönen et al,²⁶ 68% of SSNHL cases that were based only on diagnosis did not fulfill the criteria of SSNHL when audiograms were reevaluated based on the American Academy of Otolaryngology-Head and Neck Surgery guidelines (sensorineural hearing loss of 30 dB or greater over at least 3 contiguous audiometric frequencies occurring within a 72-hour period).²⁸ However, audiograms, proper clinical history, and investigation were likely used since we only used data from specialized care through which, according to our experience and internal data in THL, most cases are diagnosed by otorhinolaryngologists. Moreover, we have no reason to believe that any of the possible misclassification would be selectively occurring by vaccination status. Clearly, future research should be based on objective findings that fulfill international criteria for SSNHL, and all included audiograms should be reevaluated.²⁸

Figure 2. Incidence of Sudden Sensorineural Hearing Loss and Time from Dose of COVID-19 Vaccines



Incidence per 100 000 person-years of sudden sensorineural hearing loss in specialized care by days from the vaccinations. An individual case may be represented in adjacent panels if interdose interval was fewer than 100 days. The primary risk time, 0 to 54 days from a vaccine dose, is in orange, with other

periods in blue. The numbers 1 to 3 indicate vaccine dose number. AZD indicates ChAdOx1, ChAdOx1-S (recombinant), Vaxzevria, adenoviral vector vaccine, AstraZeneca; BNT, BNT162b2, Comirnaty, messenger RNA (mRNA) vaccine, BioNTech/Pfizer; MOD, mRNA.1273, Spikevax, mRNA vaccine, Moderna.

One previous large-scale retrospective follow-up study was recently conducted by Yanir et al⁶ in Israel. During 21-day risk times following the first and second doses of the BNT162b2 mRNA COVID-19 vaccine, small standardized incidence ratios were 1.4 and 1.2, respectively, and small attributable risks were 9 and 6 per 1 million vaccinated individuals, respectively. Their comparison was based on incidence in the population during 2018 and 2019, and the analysis corrected for age and sex. However, for example, chronic disease, especially diabetes and cardiovascular disease, remained as very likely confounders, and the authors correctly concluded that their results would need confirmation from elsewhere. We found no signs of confounding in our less adjusted model, as adjusting for diabetes and cardiovascular disease was not associated with the results (eTable in the Supplement). Sudden hearing loss definitions differed, but this study's definition relied on clinicians choosing the specific ICD-10 coding for sudden hearing loss, while Yanir et al⁶ started

with a broader spectrum of individual ICD-9 codes that also included codes without a sudden start (the ICD-9 codes starting with 389) and required prednisolone treatment as a marker of an idiopathic sudden hearing loss diagnosis. It seems plausible that those vaccinated had more underlying diseases and were more likely to be receiving treatment with prednisolone. This would potentially lead to an overestimation of the incidence of SSNHL following vaccination, although Yanir et al⁶ state that chronic diseases per se are an unlikely source of bias. Lastly, in both studies, the vaccination exposure may have been associated with health care seeking and the objectivity of the diagnostic procedures during routine clinical work. Our results provided no confirmation for the study by Yanir et al.⁶ This also aligns with a previous US study that showed no association between SARS-CoV-2 vaccination and SSNHL.⁵

We defined a 55-day risk time following vaccination. A portion of the cases in our study may have been initially evaluated

in primary care, with their first specialized care visit within a couple of weeks; therefore, we used a longer risk period compared with the previous study by Yanir et al⁶ in which the risk period was 21 days following vaccination.⁶ That study reported results from a secondary analysis that used a 60-day risk period with unchanged results. As we were unable to detect the exact symptom-onset dates from the registers and only were aware of the diagnosis dates, we may have misclassified some cases to a risk time when their true classification would have been the preceding period. However, only for misclassifications concerning dose 1 would this window have been unvaccinated time.

A peak was seen in the SSNHL incidence around February 2021 (Figure 1). We are unaware of what caused this peak, but it did not resemble the pattern seen in COVID-19 cases or COVID-19 deaths in the country.²⁹ Also, in our analysis, SARS-CoV-2 infection remained unassociated with an increased incidence of SSNHL; thus, this peak was likely not due to SARS-CoV-2 infections. The vaccination dates were also not clustered around the SSNHL peak.³⁰

Limitations

We may have misclassified individuals as uninfected in case they were infected but did not seek health care or virus testing. Although virus testing was inadequate after the emergence of a fast-spreading Omicron virus variant, by early 2021, at least half of the

SARS-CoV-2 infections in the country had been detected and registered according to results from serological surveys.³¹ That our large study revealed no association between SARS-CoV-2 infections and SSNHL aligns with a SSNHL patient series with negative SARS-CoV-2 PCR test results.⁷ Other studies have reported isolated case reports in which otherwise asymptomatic patients with SSNHL have had a positive SARS-CoV-2 PCR test result⁹ and also highly symptomatic patients with COVID-19 with concomitant SSNHL.⁸ The current analysis accounted for individual patients' characteristics, including disease history, and showed no evidence of the suspected association between COVID-19 vaccinations and SSNHL.

Conclusions

This cohort study set out to examine, and possibly confirm, a signal of SSNHL following administration of mRNA COVID-19 vaccine BNT162b2. We also investigated the possible signal following administration of COVID-19 vaccines ChAdOx1 and mRNA.1273. The study results suggest that there was no association between these vaccines and the incidence of SSNHL. Studies with more detailed clinical data would be needed to reproduce this study with a more objective diagnosis of sudden hearing loss.

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Acquisition, analysis, or interpretation of data: Nieminen, Kivekäs, Nohynek, Hovi.

Drafting of the manuscript: All authors.

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Supervision: Kivekäs, Artama, Nohynek, Hovi.

Other - literature search: Hovi.

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REFERENCES

- Zhao H, Li Y, Wang Z. Adverse event of Sinovac coronavirus vaccine: deafness. *Vaccine*. 2022;40(3):521-523. doi:10.1016/j.vaccine.2021.11.091
- Canales Medina M, Ramirez Gómez M. Tinnitus, sudden sensorineural hearing loss, and vestibular neuritis as complications of the AstraZeneca COVID-19 vaccine. *Cureus*. 2022;14(1):e20906. doi:10.7759/cureus.20906
- EudraVigilance. European database of suspected adverse drug reaction reports. Accessed March 15, 2022. <https://www.adrreports.eu/>
- European Centre for Disease Prevention and Control. COVID-19 vaccine tracker. Accessed May 8, 2022. <https://vaccinetracker.ecdc.europa.eu/public/extensions/covid-19/vaccine-tracker.html#distribution-tab>
- Formeister EJ, Wu MJ, Chari DA, et al. Assessment of sudden sensorineural hearing loss after COVID-19 vaccination. *JAMA Otolaryngol Head Neck Surg*. 2022;148(4):307-315. doi:10.1001/jamaoto.2021.4414
- Yanir Y, Doweck I, Shibli R, Najjar-Debbiny R, Saliba W. Association between the BNT162b2 messenger RNA COVID-19 vaccine and the risk of sudden sensorineural hearing loss. *JAMA Otolaryngol Head Neck Surg*. Published online February 24, 2022. doi:10.1001/jamaoto.2021.4278
- van Rijssen LB, Derks W, Hoffmans R, et al. No COVID-19 in patients with sudden sensorineural hearing loss (SSNHL). *Otol Neurotol*. 2022;43(2):170-173. doi:10.1097/MAO.0000000000003438
- Koumpa FS, Forde CT, Manjaly JG. Sudden irreversible hearing loss post COVID-19. *BMJ Case Rep*. 2020;13(11):e238419. doi:10.1136/bcr-2020-238419
- Kilic O, Kalciglu MT, Cag Y, et al. Could sudden sensorineural hearing loss be the sole manifestation of COVID-19? an investigation into SARS-CoV-2 in the etiology of sudden sensorineural hearing loss. *Int J Infect Dis*. 2020;97:208-211. doi:10.1016/j.ijid.2020.06.023
- Finnish Institute for Health and Welfare. Arranging COVID-19 vaccinations in Finland. Accessed May 13, 2022. <https://thl.fi/en/web/infectious-diseases-and-vaccinations/what-s-new/coronavirus-covid-19-latest-updates/vaccines-and-coronavirus/arranging-covid-19-vaccinations-in-finland>
- Karlstad Ø, Hovi P, Husby A, et al. SARS-CoV-2 vaccination and myocarditis in a Nordic cohort study of 23 million residents. *JAMA Cardiol*. 2022;7(6):600-612. Published online April 20, 2022. doi:10.1001/jamacardio.2022.0583
- Statistics Finland. Migration 2021, vital statistics and population. Accessed October 3, 2022. <https://www.stat.fi/en/publication/cl2t2gtjcq3e60fvz08ngpkplp>
- Finlex. Communicable Diseases Act. Accessed December 21, 2021. <https://www.finlex.fi/en/laki/kaannokset/2016/en20161227>
- Finnish Institute for Health and Welfare. Register description, care register for health care. Accessed December 31, 2021. <https://thl.fi/en/web/thlfi-en/statistics-and-data/data-and-services/register-descriptions/care-register-for-health-care>
- Finnish Institute for Health and Welfare. Register of social assistance. Accessed May 4, 2022. <https://thl.fi/en/web/thlfi-en/statistics-and-data/data-and-services/register-descriptions/social-assistance>
- Kela. Quality description—statistics on reimbursements for medical expenses. Accessed May 4, 2022. <https://www.kela.fi/web/en/statistics>

on-reimbursements-for-medical-expenses-quality-description?inheritRedirect=true

17. Salo H, Lehtonen T, Auranen K, Baum U, Leino T. Predictors of hospitalisation and death due to SARS-CoV-2 infection in Finland: a population-based register study with implications to vaccinations. *Vaccine*. 2022;40(24):3345-3355. doi:10.1016/j.vaccine.2022.04.055

18. Finnish Institute for Health and Welfare. Register of primary health care visits. Accessed May 4, 2022. <https://thl.fi/en/web/thlfi-en/statistics-and-data/data-and-services/register-descriptions/register-of-primary-health-care-visits>

19. Baum U, Sundman J, Jääskeläinen S, Nohynek H, Puumalainen T, Jokinen J. Establishing and maintaining the National Vaccination Register in Finland. *Euro Surveill*. 2017;22(17):30520. doi:10.2807/1560-7917.ES.2017.22.17.30520

20. THL. Finnish National Infectious Diseases Register. Accessed December 19, 2021. <https://thl.fi/en/web/infectious-diseases-and-vaccinations/surveillance-and-registers/finnish-national-infectious-diseases-register>

21. Hastie TJ, Tibshirani RJ. *Generalized Additive Models*. Routledge; 1990.

22. R Core Team. R: the R Project for Statistical Computing. Accessed May 6, 2022. <https://www.r-project.org/>

23. Alexander TH, Harris JP. Incidence of sudden sensorineural hearing loss. *Otol Neurotol*. 2013;34(9):1586-1589. doi:10.1097/MAO.0000000000000222

24. Kuo CY, Chung CH, Wang CH, Chien WC, Chen HC. Increased incidence in hospitalised patients with sudden sensorineural hearing loss: a 14-year nationwide population-based study. *Int J Audiol*. 2019;58(11):769-773. doi:10.1080/14992027.2019.1627009

25. Schreiber BE, Agrup C, Haskard DO, Luxon LM. Sudden sensorineural hearing loss. *Lancet*. 2010;375(9721):1203-1211. doi:10.1016/S0140-6736(09)62071-7

26. Härkönen K, Kivekäs I, Rautiainen M, Kotti V, Vasama JP. Quality of life and hearing eight years after sudden sensorineural hearing loss. *Laryngoscope*. 2017;127(4):927-931. doi:10.1002/lary.26133

27. Nagy E, Infantino M, Bizzaro N, et al; European Autoimmunity Standardisation Initiative. The impact of the COVID-19 pandemic on autoimmune

diagnostics in Europe: a lesson to be learned. *Autoimmun Rev*. 2021;20(12):102985. doi:10.1016/j.autrev.2021.102985

28. Chandrasekhar SS, Tsai Do BS, Schwartz SR, et al. Clinical practice guideline: sudden hearing loss (update). *Otolaryngol Head Neck Surg*. 2019;161(1 suppl)(suppl):S1-S45. doi:10.1177/0194599819859885

29. World Health Organization. Finland: WHO coronavirus disease (COVID-19) dashboard with vaccination data. Accessed May 3, 2022. <https://covid19.who.int>

30. THL. COVID-19 vaccinations in Finland—THL user interface for database cubes and reports. Accessed May 13, 2022. https://sampo.thl.fi/pivot/prod/en/vaccreg/cov19cov/fact_cov19cov?row=dateweek20201226-525425&column=cov_vac_age-630311.518413.&column=cov_vac_age-610735.610734.533184.533177.533181.533162.533171.533169.533182.533176.533173.533183.533179.533178.533166.518413

31. THL. Report of THL serological population study of the coronavirus epidemic. Accessed May 6, 2022. https://www.thl.fi/roko/cov-vaestoserologia/sero_report_weekly_en.html