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Incidence of Tinnitus After COVID-19 Vaccination Compared to Other Vaccines: A Propensity-Score Matched Analysis of a Large Real-World Claims Database

Ramzi Argoubi [1], Martina Furegato [1], Elise Berliner [2], Patricia Medina [1]

[1] Oracle Life Sciences, Paris, France, [2] Oracle Life Sciences, Kansas City, MO, USA

Background

Data from the Vaccine Adverse Event Reporting System (VAERS) and other surveillance platforms have documented cases of tinnitus after receiving mRNA vaccines.(1) The overall incidence remains rare, and causality between the vaccine and tinnitus is not yet established. A study using electronic medical records from 2.5 million patients found that new-onset tinnitus following COVID-19 vaccination was low compared to other vaccines.(2)

A retrospective chart review of 1254 patients, identified 27 cases of self-reported tinnitus shortly after vaccination, but no definitive correlation was established.(3)

This study aims to further investigate the incidence of tinnitus after COVID-19 vaccination compared to other vaccines using a large secondary Claims Database.

Objective

Investigate the incidence of newly diagnosed tinnitus after COVID-19 vaccination in comparison to other common vaccines.

Methods

Patients receiving COVID-19 mRNA vaccines (Moderna's Spikevax®, Pfizer-BioNTech's Comirnaty®, Novavax' Covovax®) between 2020–2023 or comparator vaccines (Influenza, zoster, DTaP, pneumococcal, hepatitis, meningococcal, HPV, etc.) between 2018–2023 were identified from Oracle Life Sciences' US Claims database. Patients with previous tinnitus or auditory problems (ICD10: H60-H95) were excluded. Cases of newly diagnosed tinnitus (ICD10: H93.1) weekly after vaccination were identified.

Propensity score matching (1:1) was performed among COVID-19 vaccine and each comparator, based on demographic variables and other baseline characteristics. The incidence of tinnitus was analyzed weekly after vaccination, comparatively between cases and controls using Chi-2 tests.

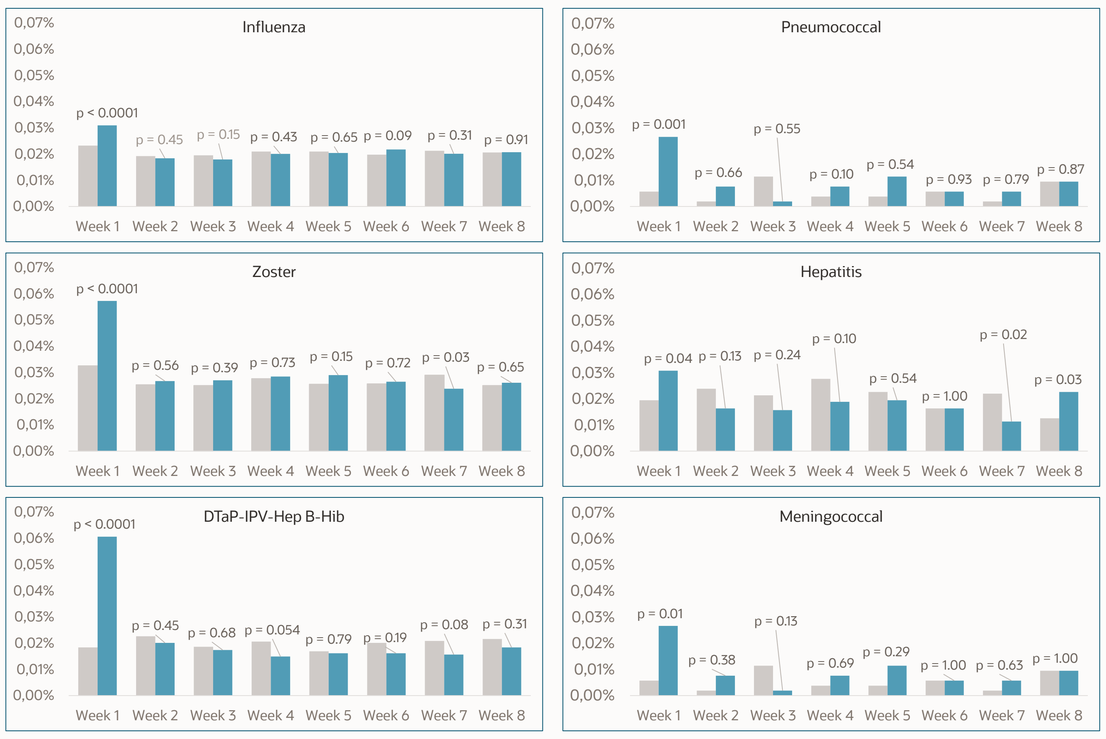
Multivariate logistic regression was performed to assess the effect of COVID-19 vaccine, versus each comparator vaccine, on the incidence of tinnitus at 3, 6 and 8 weeks post-vaccination.

Results

We identified 6,204,224 patients who received a COVID-19 vaccine. Of them, 1,256 (0.020%) and 3,341 (0.054%) were newly diagnosed with tinnitus within the first and third week post-vaccination, respectively.

In the first week post-vaccination, proportions of patients developing tinnitus after COVID19 vaccine were significantly lower compared to vaccinations for Influenza (0.023% vs. 0.031%, p<0.0001), zoster (0.033% vs. 0.057%, p<0.0001), DTaP (0.018% vs. 0.061%, p<0.0001), pneumococcal (0.033% vs. 0.051%, p=0.001), hepatitis (0.019% vs. 0.031%, p=0.04), meningococcal (0.006% vs. 0.027%, p=0.01), HPV (0.004% vs. 0.018%, p=0.03) and salmonella vaccination (0.013% vs. 0.069%, p=0.01). Figure 1 shows the weekly incidence of tinnitus up to 8 weeks after vaccination in each PS-matched population.

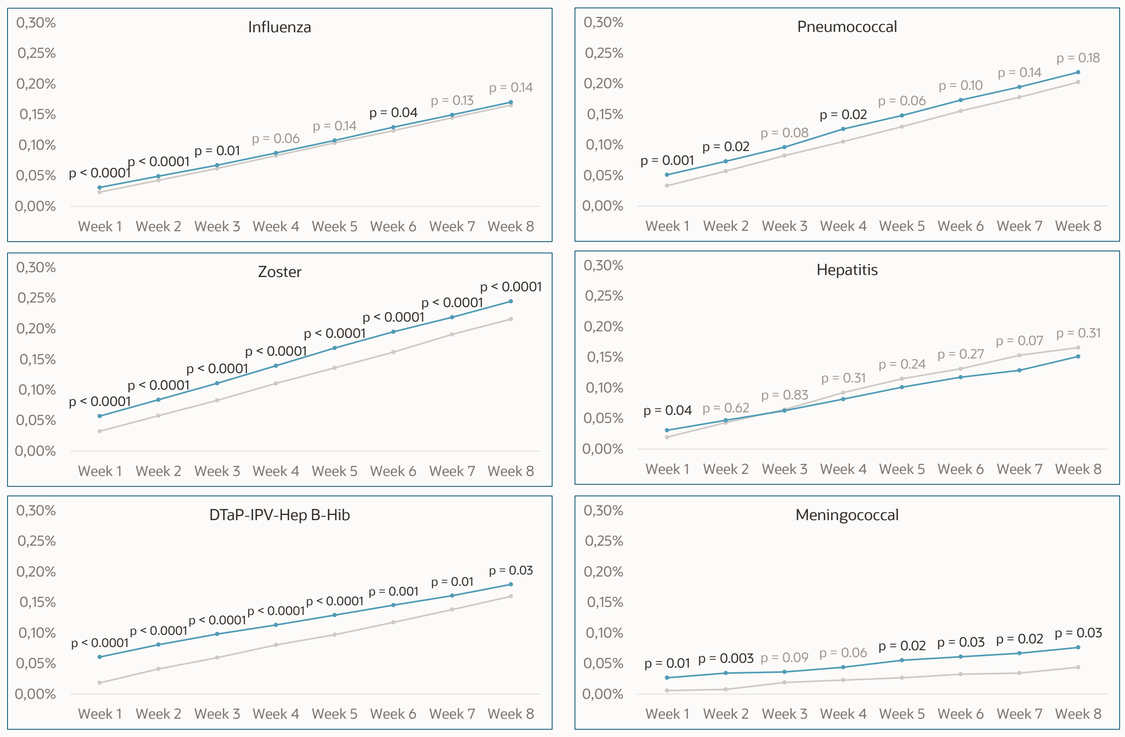
Figure 1. Weekly incidence of tinnitus after vaccination



Within 3 weeks post-vaccination, the incidence of tinnitus was significantly lower in patients receiving COVID-19 vaccine compared to vaccines for influenza (0.062% vs. 0.067%, p=0.01), zoster (0.083% vs. 0.111%, p<0.0001) and DTaP (0.060% vs. 0.098%, p<0.0001) vaccines. No significant difference was found compared to other vaccines.

Figure 2 shows a bivariate analysis of the cumulative incidence of tinnitus at each timepoint (up to 8 weeks post-vaccination) using Chi-2 tests. Figure 3 shows Odds ratios of the incidence of tinnitus within 3, 6, and 8 weeks post-vaccination estimated from multivariate logistic models. Each model was adjusted on the comparative treatment groups and baseline covariates.

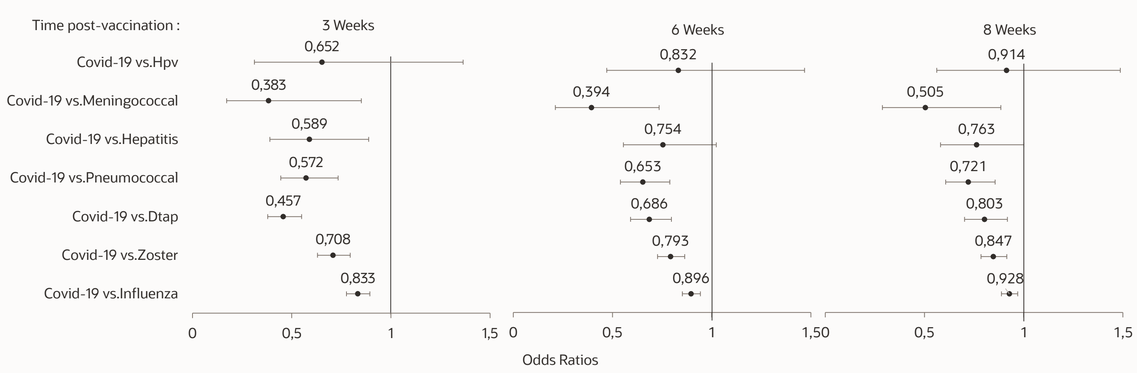
Figure 2. Cumulative incidence of tinnitus after vaccination



COVID-19 vaccination was associated with a significantly lower incidence of tinnitus 3 weeks post-vaccination compared to influenza (OR=0.833 [0.776 ; 0.894]), zoster (OR=0.708 [0.630 ; 0.795]), DTaP (OR=0.457 [0.379 ; 0.550]), pneumococcal (OR=0.572 [0.445 ; 0.734]), hepatitis (OR=0.589 [0.390 ; 0.888]) and meningococcal (OR=0.383 [0.172 ; 0.851]) vaccines. The same analysis using 6 and 8 weeks post-vaccination showed similar results (Figure 3).

Covariates significantly associated with a higher probability of tinnitus incidence include: Male gender, older age, baseline medical conditions like depression, hypercholesteremia, cerebrovascular disease, chronic pulmonary disease and the use of oral corticosteroids at baseline.

Figure 3. Incidence of tinnitus post-vaccination – Multivariate logistic regression



Conclusion

In this large retrospective study using claims data, we examined the incidence of newly diagnosed tinnitus following COVID-19 vaccination in comparison to other common vaccines. Findings suggest that while tinnitus may occur following COVID-19 vaccination, it appears to be a rare event and is less common than after many other common vaccinations. This study provides further reassurance regarding the safety profile of mRNA COVID-19 vaccines in terms of tinnitus risk. Further research may help elucidate the underlying mechanisms and long-term outcomes in individuals who develop tinnitus following vaccination.

Reference

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