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# Association of COVID-19 infection and COVID-19 vaccination with idiopathic sudden sensorineural hearing loss in Malaysia: a case-control study

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## Abstract

**Background** Previous studies indicated that the SARS-CoV-2 virus and COVID-19 vaccines may contribute to idiopathic sudden sensorineural hearing loss (ISSNHL). This nationwide study sought to evaluate the correlation between COVID-19 infection and vaccination with ISSNHL.

**Methods** This case–control study analysed samples from adults aged 18 years and older who visited the otorhinolaryngology department in 32 government hospitals in Malaysia for pure tone audiometry(PTA) between January 25, 2020 and June 30, 2022. Cases comprised patients diagnosed with ISSNHL, while controls consisted of individuals with normal PTA assessments presenting for other otorhinolaryngology-related symptoms during the same period. Patients with known causes of hearing loss were excluded. Cases and controls were matched in a 1:5 ratio based on age (± 5 years) and index date (± 10 days). The study investigated the association between ISSNHL and both COVID-19 vaccination and COVID-19 infection using conditional logistic regression, with statistical significance set at $P < 0.05$ for two-sided tests.

**Results** A total of 187 ISSNHL cases and 935 matched controls were included. The mean (SD) age of participants was 42.4 (12.3) years, and 704 (62.7%) were female. Cases had a higher proportion of COVID-19 infections compared to controls [16 (8.6%) vs 44 (4.7%), $P = 0.034$], while both groups had similar proportions of COVID-19 vaccination [90 (48.1%) vs 415 (44.5%), $P = 0.377$]. Individuals who tested positive for COVID-19 had a significantly higher likelihood of developing ISSNHL compared to those without COVID-19 infection at the time of diagnosis (aOR:2.49; 95% CI:1.176 – 5.260; $P = 0.017$). However, there was no statistically significant association between COVID-19 vaccination and ISSNHL.

**Conclusions** This study provides significant insights into the intricate correlation between ISSNHL, COVID-19 infection, and vaccination. The recognized hazard linked to infection emphasizes the significance of monitoring auditory health in COVID-19 patients.

**Keywords** Case–control, Hearing loss, Idiopathic sudden sensorineural hearing loss, COVID-19, COVID-19 vaccine

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## Background

Infection with viruses like the cytomegalovirus (CMV), mumps, and Epstein-Barr virus has been linked to sensorineural hearing loss [1–3], especially in the pediatric population. It is believed that CMV triggers an immune-mediated response that leads to sudden onset sensorineural hearing loss (SSNHL) [2]. Furthermore, researchers have shown that varicella zoster virus impairs the vestibulocochlear nerve [4], and rubella directly damages the cochlear epithelium and stria vascularis [5]. Meanwhile, available evidence suggests that SARS-CoV-2 virus may result in a range of audiovestibular symptoms, such as tinnitus, balance disorders, and varying degrees of sensorineural hearing loss [6, 7]. Systematic review and meta-analysis have described that about one-third of SSNHL patients were found to be positive for COVID-19 at the time of presentation in 2020–2021 [8]. Despite studies from various parts of the world investigating the link between SSNHL and SARS-CoV-2 virus, good-quality evidence from the Southeast Asia region is scarce. Accordingly, more clinical data from one of the world's fastest-growing regions is needed since we understood that COVID-19 presentations were different across geographical variations [9]. COVID-19 vaccines, like any other vaccine, have been reported to have both local and systemic side effects. Pain, itchiness, paresthesia, and joint or muscle discomfort at the injection site were the prevalent local side effects, whereas fever, chills, tiredness, headache, nausea, myalgia, pyrexia, and dyspnea were the common systemic side effects [10]. Aside from that, studies had also reported SSNHL among patients who received COVID-19 vaccination [11–15]. Databases of post-vaccination adverse events from several western nations revealed that there were recorded cases of hearing loss after COVID-19 vaccination [16, 17]. This study aims to address these gaps by exploring the association between COVID-19 infection, COVID-19 vaccination, and idiopathic SSNHL (ISSNHL), specifically within the context of Malaysia. By doing so, we contribute to understanding the broader spectrum of COVID-19's impact on auditory health and enable timely interventions for improved prognosis [18].

## Methods

### Study design and participants

This nationwide case–control study was conducted at 32 government hospitals in Malaysia, involving adults aged 18 years or older who visited the otorhinolaryngology department and underwent pure tone audiometry (PTA) assessment. Patients were recruited once throughout the study period, either as cases or controls. Cases included patients diagnosed with ISSNHL who exhibited an abnormal PTA assessment result. The index date for the cases was defined as the date of their first abnormal PTA assessment result. Controls were individuals who presented to the otorhinolaryngology department for other otorhinolaryngology-related symptoms and consistently exhibited normal PTA assessments throughout the study period. Consistent with the cases, the index date of the controls was defined as the date of their first normal PTA assessment result. The case was classified as idiopathic if no underlying cause was identified after completing a comprehensive investigation protocol for sensorineural hearing loss [19]. This protocol included a wide range of diagnostic evaluations such as radiographic imaging, laboratory testing, vestibular assessments, and other relevant tests. Patients with known causes of hearing loss, such as noise-induced hearing loss, presbycusis, trauma, tumors, autoimmune diseases, and infections, were excluded as cases.

### Case–control design

Controls were matched to cases in a 5:1 ratio based on age (± 5 years) and index date (± 10 days). Age was matched because age is a known risk factor for sensorineural hearing loss [20]. This matching process allowed us to eliminate any potential bias between age groups. Simultaneously, the index date was included for matching, as it was crucial due to the variation over different time periods on the trends of COVID-19 vaccination and SARS-CoV-2 virus variants.

Matching was conducted using the *ccoptimalmatch* R package to ensure optimal pairing, allowing each case to be paired with the most suitable control among all possible matches [21]. We matched controls without replacing them, ensuring each control can only be allocated to a single case.

### Exposures

The exposures of interest were COVID-19 infection and COVID-19 vaccination. Data on the number of doses of COVID-19 vaccination administered to each patient at the time of their recruitment as either cases or controls were collected. Vaccination status was categorized into two categories: primary risk, referring to the most recent dose administered within 28 days before the index date, and secondary risk, referring to the dose administered more than 28 days before the index date. A 28-day cut-off was chosen because adverse events within this timeframe were deemed most likely related to the vaccine [22].

The COVID-19 infection was ascertained by reverse transcription polymerase chain reaction (RT-PCR) or antigen rapid test kit (RTK-Ag) for SARS-CoV-2 on respiratory specimens, comprising samples from the

nasopharynx and/or saliva. We determined the date of the COVID-19 infection by referring to the most recent positive SARS-CoV-2 test sample date before the index date. The COVID-19 infection status was further characterized into primary and secondary risk periods based on a cut-off value of 30 days [23].

The severity of COVID-19 infection was stratified into two clinical categories: Category 2a and below, encompassing patients with mild symptoms like sore throat, running nose, cough, loss of taste, and loss of smell; and Category 2b and above, comprising patients requiring medical intervention or hospitalization due to symptoms such as prolonged fever lasting two or more days, shortness of breath, chest pain, and worsening lethargy [24].

### Outcomes

All patients with the primary outcome of ISSNHL were recruited as cases in this study. In this study, ISSNHL was defined as the rapid onset of hearing impairment in either ear, characterized by a pure-tone average of hearing thresholds at 0.5, 1.0, 2.0, and 4.0 kHz equal to or greater than 30-dB, affecting at least three consecutive frequencies, occurring within a 3-day window and of unknown etiology [25]. Controls were defined as individuals with a pure-tone average of hearing thresholds at 0.5, 1.0, 2.0, and 4.0 kHz less than 25-dB hearing level in both ears during the study period. Secondary outcomes included the severity of ISSNHL classified according to Centers for Disease Control and Prevention (CDC) classifications [26], treatment for ISSNHL, and level of recovery assessed using modified Siegel's criteria [27] at the 1-month follow-up.

### Data sources

Data spanning from January 25, 2020, to June 30, 2022, was collected retrospectively from 32 government hospitals, including records of inpatient and outpatient encounters. The data was accessed either from electronic or paper medical records. Patient data included demographic information, date of diagnosis, comorbidities, clinical presentation, PTA assessment, and treatment. The information on exposure was extracted from the national COVID-19 surveillance system (MySejahtera) and Malaysia Vaccine Administration System (MyVAS) databases. Personal identification enabled linkage to these databases, which provided information on COVID-19 infections, clinical classifications of COVID-19, types of COVID-19 vaccines administered, vaccination dates, and doses administered. De-identified data was used for analysis.

### Statistical analysis

Sample size calculations were performed using G* Power Software 3.1.9.7 for Windows, employing the difference between two independent proportions model [28]. For the first exposure of interest, focusing on SARS-CoV-2 infection, the COVIDNOW Malaysia Database reported 3,777,394 confirmed COVID-19 cases from February 2020 to June 2022, within a population of 25,340,200 [29]. Therefore, assuming 14.9% SARS-CoV-2 infection among the controls, a minimum sample size of 91 cases and 455 controls was required to have a power of 80% (using a 2-sided $\alpha = 0.05$) to demonstrate an OR of 0.3 for SARS-CoV-2 infection. In the second exposure of interest, the focus was on the SARS-CoV-2 vaccination. At the time of sample size calculation, approximately 24,700,000 individuals within the population had received at least one dose of the vaccine, resulting in a vaccination coverage of 97.5%. To ensure adequate statistical power, a minimum sample size of 21 cases and 105 controls was determined to be necessary to achieve 80% power for detecting an odds ratio of 0.1 for vaccination.

Data analysis was conducted using R Statistical Software (v4.2.2; R Core Team 2022) and the R Survival Package. Categorical variables were expressed as frequencies and percentages, and between-group differences were assessed using Fisher's exact test or $\chi 2$ test. Continuous variables were presented as mean (SD), and differences between cases and controls were evaluated using independent t-tests. The association between independent variables and ISSNHL was assessed using conditional logistic regression. Crude odds ratio (OR) and adjusted OR (aOR) were calculated. Covariates demonstrating between-group differences ($P \leq 0.25$) were included in the regression model for calculating aORs. Gender, COVID-19 infection, and the status of COVID-19 doses received were included in the adjusted model. Statistical significance was set at $P < 0.05$ for two-sided tests.

## Results

### Demographic and clinical characteristics of the study population

In this study cohort, 1122 patients were included, comprising 187 cases and 935 controls. The cohort had a mean (SD) age of 42.4 (12.3) years, with 704 female patients (62.7%). Among them, 759 patients (67.6%) were Malay, and 563 (54.6%) had no medical comorbidities. Demographic and clinical characteristics stratified by group are detailed in Table 1. Of note, the ISSNHL group predominantly consisted of males and patients with comorbidities such as diseases of circulatory system, genitourinary and endocrine, nutritional or metabolic diseases, in comparison to controls (Table 1).

**Table 1** Demographic and clinical characteristics of the study population

| Variables | Overall (n = 1122) | ISSNHL (n = 187) | Control (n = 935) | *p*- value |
|---|---|---|---|---|
| Age, y | | | | 0.71[a] |
| Mean (SD) | 42.4(12.3) | 42.7(12.5) | 42.3(12.3) | |
| Gender, n (%) | | | | < 0.001[b] |
| Male | 418(37.3) | 96(51.3) | 322(34.4) | |
| Female | 704(62.7) | 91(48.7) | 613(65.6) | |
| Ethnicity, n (%) | | | | 0.020[b] |
| Malay | 759(67.6) | 134(71.7) | 625(66.8) | |
| Chinese | 167(14.9) | 33(17.6) | 134(14.3) | |
| Indian | 119(10.6) | 16(8.6) | 103(11) | |
| Others[c] | 77(6.9) | 4(2.1) | 73(7.8) | |
| Comorbid, n (%) | | | | |
| No medical comorbid | 563(54.6) | 108(57.8) | 455(53.8) | 0.37[d] |
| Diseases of circulatory system, n (%) | | | | |
| Yes | 229(22.2) | 58(31.0) | 171(20.2) | 0.002[d] |
| No | 803(77.8) | 129(69.0) | 674(79.8) | |
| Diseases of genitourinary system, n (%) | | | | < 0.001[b] |
| Yes | 23(2.2) | 11(5.9) | 12(1.4) | |
| No | 1009(97.8) | 176(94.1) | 833(98.6) | |
| Endocrine, nutritional or metabolic diseases, n (%) | | | | < 0.001[d] |
| Yes | 193(18.7) | 58(31.0) | 135(16.0) | |
| No | 839(81.3) | 129(69.0) | 710(84.0) | |
| Neoplasm, n (%) | | | | 0.38[b] |
| Yes | 26(2.5) | 3(1.6) | 23(2.7) | |
| No | 1006(97.5) | 184(98.4) | 822(97.3) | |
| Diseases of nervous system, n (%) | | | | 0.30[b] |
| Yes | 21(2.0) | 2(1.1) | 19(2.2) | |
| No | 1011(98.0) | 185(98.9) | 86(97.8) | |
| Diseases of respiratory system, n (%) | | | | 0.40[b] |
| Yes | 51(4.9) | 7(3.7) | 44(5.2) | |
| No | 981(95.1) | 180(96.3) | 801(94.8) | |
| Diseases of digestive system, n (%) | | | | 0.49[b] |
| Yes | 17(1.6) | 2(1.1) | 15(1.8) | |
| No | 1015(98.4) | 185(98.9) | 830(98.2) | |
| Diseases of musculoskeletal system, n (%) | | | | 0.90[b] |
| Yes | 12(1.2) | 2(1.1) | 10(1.2) | |
| No | 1020(98.8) | 185(98.9) | 835(98.8) | |
| Others, n (%) | | | | |
| Yes | 53(5.1) | 3(1.6)[e] | 50(5.9)[f] | 0.016 |
| No | 979(94.9) | 184(98.4) | 795(94.1) | |

[a] Independent t-test was performed

[b] Chi-square test was performed

[c] Others, inclusive Bumiputera Sabah, Bumiputera Sarawak, foreigner, Sikh, Orang Asli

[d] Fisher's exact test was performed

[e] Others, inclusive disease of the blood or blood-forming organs, diseases of the visual system and sleep–wake disorders

[f] Others, inclusive disease of the blood or blood-forming organs, diseases of the immune system, mental. behavioural or neurodevelopmental disorder, diseases of the visual system, diseases of the skin, pregnancy, childbirth or the puerperium, developmental anomalies, symptoms, signs or clinical findings, not elsewhere classified, certain infectious or parasitic diseases, sleep–wake disorders

**Table 2** Presenting symptoms, hearing loss characteristics, and outcome of patients with ISSNHL (n = 187)

| Variables | Statistics, n (%) | |
|---|---|---|
| Associated audiological symptoms[a] | | |
| Tinnitus | 150(80.2) | |
| Ear fullness | 35(18.7) | |
| Vertigo | 54(28.9) | |
| Ear pain | 6(3.2) | |
| Blocked ears | 8(4.3) | |
| Nausea | 7(3.7) | |
| Vomiting | 9(4.8) | |
| Treatment used[a] | | |
| Systemic steroid | 125(66.8) | |
| Intratympanic steroid | 72(38.5) | |
| Antiviral | 11(5.9) | |
| Vitamin (Vitamin B, Vitamin C, Vitamin E etc.) | 93(49.7) | |
| Betahistine | 37(19.8) | |
| Vasoactive and hemodilution (Pentoxifylline/ Aspirin/ Dextran/ Voluven / Gingko Biloba etc.) | 25(1.4) | |
| No treatment | 4(2.1) | |
| Others[b] | 3(1.6) | |
| Pure Tone Assessment (dB), M (SD) | Right side | Left side |
| Upon diagnosis | 48.36(34.7) | 57.32(36.1) |
| 1-month post diagnosis | 39.42(30.3) | 48.22(33.1) |
| Laterality (n = 187) | | |
| Unilateral | 131(70.1) | |
| Bilateral | 56(29.9) | |
| Severity of affected ear/s(n = 243) | Unilateral | Bilateral |
| Mild | 29(22.1) | 37(33.0) |
| Moderate | 14(10.7) | 11(9.8) |
| Moderately severe | 16(12.2) | 14(12.5) |
| Severe | 36(27.5) | 21(18.8) |
| Profound | 36(27.5) | 29(25.9) |
| Recovery status of affected ear/s during follow-up at 1 month | Unilateral[c] | Bilateral[d] |
| Complete recovery | 24(18.3) | 20(17.9) |
| Partial recovery | 12(9.2) | 13(11.6) |
| Slight improvement | 22(16.8) | 5(4.5) |
| No improvement | 39(29.8) | 45(40.2) |
| Non-serviceable ear | 13(9.9) | 11(9.8) |

[a] Multiple response

[b] Others, inclusive Augmentin, Budesonide, Pantoprazole

[c] 21 missing data

[d] 18 missing data

The presenting symptoms, hearing loss characteristics, and outcomes of patients with ISSNHL are detailed in Table 2.

### History of COVID-19 infection and COVID-19 vaccination among patients with ISSNHL and control

In the overall study population, 60 patients (5.4%) were diagnosed with COVID-19 infection. The proportion of patients diagnosed with COVID-19 was higher in the ISSNHL group compared to the control group ([16 (8.6%) vs 44 (4.7%), $P = 0.034$]. There were no statistical significant differences in the severity of COVID-19 infection and risk periods between patients in the ISSNHL group and the control group (Table 3).

Of the total cohort, 505 patients (45.1%) received COVID-19 vaccination, with 90 (48.1%) in the ISSNHL

**Table 3** History of COVID-19 infection and COVID-19 vaccination among patients with ISSNHL and control

| Variables | Overall | | ISSNHL | | Control | | *p*-value |
|---|---|---|---|---|---|---|---|
| | N | n (%) | N | n (%) | N | n (%) | |
| **COVID 19 Infection** | | | | | | | |
| COVID-19 infection at time of PTA screening | 1122 | | 187 | | 932 | | 0.034 |
| Yes | | 60(5.4) | | 16(8.6) | | 44(4.7) | |
| No | | 1059(94.6) | | 171(91.4) | | 888(95.3) | |
| COVID-19 severity throughout COVID-19 infection | 39 | | 11 | | 28 | | 0.31 |
| Category 2a and below | | 35(89.7) | | 9(81.8) | | 26(92.9) | |
| Category 2b and above | | 4(10.3) | | 2(18.2) | | 2(7.1) | |
| COVID-19 risk periods | 60 | | 16 | | 44 | | 0.62 |
| Primary risk | | 9(15.0) | | 3(18.8) | | 6(13.6) | |
| Secondary risk | | 51(85.0) | | 13(18.3) | | 38(86.4) | |
| **COVID-19 Vaccination** | | | | | | | |
| Received COVID-19 vaccination | 1119 | | 187 | | 932 | | 0.38 |
| Yes | | 505(45.1) | | 90(48.1) | | 415(44.5) | |
| No | | 614(54.9) | | 97(51.9) | | 517(55.5) | |
| Number of doses received | 505 | | 90 | | 415 | | 0.17 |
| Complete Primary Series | | 292(57.8) | | 59(65.6) | | 233(56.1) | |
| Incomplete Primary Series | | 41(8.1) | | 8(8.9) | | 33(8.0) | |
| Complete Booster | | 172(34.1) | | 23(25.6) | | 149(35.9) | |
| Type of vaccines received | 505 | | 90 | | 415 | | 0.097 |
| COMIRNATY | | 320(63.4) | | 61(67.8) | | 259(62.4) | |
| CoronoVac | | 85(16.8) | | 19(21.1) | | 66(15.9) | |
| Ad26.COV2.S | | 45(8.9) | | 3(3.3) | | 42(10.1) | |
| Combination of vaccines | | 55(10.9) | | 7(7.8) | | 48(11.6) | |
| Vaccination risk periods | 505 | | 90 | | 415 | | 0.15 |
| Primary risk | | 96(19.0) | | 22(24.4) | | 74(17.8) | |
| Secondary risk | | 409(81.0) | | 68(75.6) | | 341(82.2) | |

group and 415 (44.5%) in the control group. There were no statistical significant differences identified in COVID-19 vaccine recipients, the number of doses received, the types of vaccines received, or the vaccination risk periods between patients in the ISSNHL group and the control group. (Table 3).

### Association between ISSNHL with COVID-19 infection and COVID-19 vaccination

Individuals who tested positive for COVID-19 displayed a heightened likelihood of experiencing ISSNHL compared to those without COVID-19 infection (aOR:2.49; 95% CI:1.176 – 5.260; $P=0.017$). The study's findings revealed that males exhibited 2.03 times higher odds of developing ISSNHL in comparison to females (aOR: 2.03; 95% CI: 1.479–2.795; $P<0.001$). There was no observed association between COVID-19 vaccination status and ISSNHL as delineated in Table 4.

## Discussion

In this study, we aimed to assess the association between COVID-19 infection and COVID-19 vaccination with ISSNHL. Despite a plethora of research studies on the effects of SARS-CoV-2 on hearing loss, it is still unclear whether it represents an actual risk factor for the development of ISSNHL. The available evidence is discordant and inconclusive, with high heterogeneity among studies.

Despite some studies concluding that the evidence on incidence change in SSNHL between pre-pandemic and pandemic periods was inconsistent and contradictory due to the overall low quality of available studies [8, 30], our findings revealed a noteworthy twofold higher risk of ISSNHL among individuals with COVID-19 infection at the time of diagnosis. This aligns with emerging evidence suggesting a potential link between SARS-CoV-2 infection and auditory complications [31–33]. Moreover, the increasing incidence of ISSNHL during the COVID-19 pandemic compared to the pre-pandemic period, as reported by Kandakure et al. [34] and Wagatsuma et al. [35] further suggests a possible

**Table 4** Conditional Logistic Regression between variables with ISSNHL

| Variables | Crude OR (95% CI) | | | *p*-value | Adjusted OR (95% CI) | | | *p*-value[a] |
|---|---|---|---|---|---|---|---|---|
| Gender | | | | | | | | |
| Female | 1 | - | | - | 1 | - | | - |
| Male | 1.99 | (1.449, | 2.719) | < 0.001 | 2.03 | (1.479, | 2.795) | < 0.001 |
| Ethnicity | | | | | | | | |
| Malay | 1 | - | | - | | | | |
| Chinese | 1.16 | (0.749, | 1.784) | 0.51 | | | | |
| Indian | 0.76 | (0.432, | 1.327) | 0.33 | | | | |
| Others | 0.64 | (0.143, | 2.910) | 0.57 | | | | |
| Comorbidities | | | | | | | | |
| Yes | 0.81 | (0.572, | 1.160) | 0.26 | | | | |
| No | 1 | - | | - | | | | |
| COVID-19 Infection at time of diagnosis | | | | | | | | |
| Yes | 2.41 | (1.160, | 4.993) | 0.018 | 2.49 | (1.176, | 5.260) | 0.017 |
| No | 1 | - | | - | 1 | - | | - |
| Received COVID-19 vaccination at time of diagnosis | | | | | | | | |
| Yes | 1.89 | (0.961, | 3.718) | 0.065 | | | | |
| No | 1 | - | | - | | | | |
| Status of COVID-19 vaccination received | | | | | | | | |
| Complete primary | 2.12 | (1.016, | 4.432) | 0.045 | 2.10 | (0.992, | 4.455) | 0.53 |
| Incomplete primary | 1.75 | (0.681, | 4.509) | 0.24 | 1.93 | (0.751, | 4.969) | 0.17 |
| Complete booster | 1.09 | (0.431, | 2.777) | 0.85 | 1.10 | (0.410, | 2.813) | 0.89 |
| Unvaccinated | 1 | - | | - | 1 | - | | - |

[a] *OR* Odd ratio; *CI* Confidence interval

connection between COVID-19 and ISSNHL. In addition, Kilic et al. [36] described that SSNHL may be the first symptom of COVID-19, advocating for SARS-CoV-2 screening in SSNHL patients. Similarly, children have also shown observations of manifesting hearing loss following COVID-19 infection [37]. Building upon the existing evidence, our study demonstrated a male predilection for ISSNHL, in line with most studies and in accordance with what is already known about SSNHL [8, 25].

Previous research has postulated three main mechanisms leading to the occurrence of SSNHL associated with SARS-CoV-2 infection. The first mechanism involves the virus's affinity for the angiotensin-converting enzyme 2 (ACE2) receptor, which allows it to damage the blood-labyrinth barrier and invade inner ear structures [38, 39]. The second mechanism is the activation of the inflammatory process and excessive oxidative stress due to the production of reactive oxygen species and proinflammatory cytokines, especially associated with severe COVID-19 infection, which may lead to indirect damage to the inner ear [40]. The third proposed mechanism is that the SARS-CoV-2 can trigger neuroinflammatory mechanisms, leading to sensory impairments (including auditory and vestibular) in the brainstem [41].

The COVID-19 vaccination has been highly effective in preventing SARS-CoV-2 infection and reducing the risk of virus transmission. Despite the emergence of new variants, the COVID-19 vaccines are still found to be beneficial in averting severe illness, including hospitalizations and deaths [42]. Addressing vaccine hesitancy arising from the fears of hearing loss is therefore crucial to ensure the continued success of vaccination campaigns. Unfavourably, Avci et al. [43] demonstrated that the incidence of hearing loss may be higher after inactivated COVID-19 vaccination in patients who had already contracted COVID-19, especially within the past 6 months, as compared to patients without COVID-19 infection. Our study aimed at supplementing available evidence regarding the risk of hearing loss after COVID-19 vaccinations. Furthermore, there were no particular clinical or demographic risk factors delineated for individuals suffering from SSNHL [16].

Showing favourable outcome, we found no significant link between COVID-19 vaccination and ISSNHL at the population level, which is reassuring given widespread concerns about the potential adverse effects of COVID-19 vaccines. We delved into potential nuanced associations by considering vaccine types, the number of doses, and the risk period following vaccination. Encouragingly,

there were no statistically significant associations in any of these aspects. However, this is in contrast to the retrospective cohort analysis with a no concurrent historic comparative group by Yanir et al. [44], which suggested an association between the BNT162b2 mRNA COVID-19 vaccine and an elevated risk of SSNHL. Nonetheless, our results align with a recent investigation by Nieminen et al. [45] Their extensive register-based nationwide retrospective cohort study, encompassing 5.5 million Finnish residents, found no association between various COVID-19 vaccines and SSNHL incidence. Similarly, United States showed a comparable rate of reported SSNHL following vaccinations between the three COVID-19 vaccine types (Ad26.Cov2.S [Janssen/Johnson & Johnson], mRNA-1273 [Moderna], and BNT162b2 [Pfizer-BioNTech]) [16].

A notable strength of our study lies in the adherence to a robust investigation protocol for ISSNHL [19], ensuring consistency and standardization in diagnosis. Besides that, by matching the case and control groups based on age and index date, bias is minimized and comparability between the groups are enhanced. Moreover, the nationwide scope and large sample size augment the statistical power and generalizability of our results.

### Limitations

Despite the above strengths, our study also has limitations including the inability to rule out past or current asymptomatic infections, which may have led to an underestimation of the reported strength of the association. Additionally, the retrospective design and reliance on medical records could introduce information bias. Given that COVID-19 is associated with long-term complications, a longitudinal cohort study would be useful to assess the incidence of ISSNHL over time in COVID-19 survivors.

## Conclusions

In conclusion, our study demonstrates a significant association between COVID-19 infection and ISSNHL, particularly among males, while showing no significant link between COVID-19 vaccination and ISSNHL. These findings underscore the importance of monitoring auditory health in COVID-19 patients and support the continued safety of COVID-19 vaccines. Future research should explore the long-term implications of COVID-19 on hearing function to better guide public health strategies and patient care.

### Abbreviations

| | |
|---|---|
| ISSNHL | Idiopathic sudden sensorineural hearing loss |
| PTA | Pure tone audiometry |
| SNHL | Sensorineural hearing loss |
| SSNHL | Sudden sensorineural hearing loss |
| RT-PCR | Reverse transcription polymerase chain reaction |
| RTK-Ag | Antigen rapid test kit |

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### Authors' contributions

NSAR and SYL analysed the data. NSAR, LXJ, and LEL drafted the manuscript. LXJ and LEL revised the data analysis. LCC and PRD edited the manuscript. NAA and PRD provided the study design advice and guidance. All authors read, reviewed and approved the manuscript.

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### Data availability

The datasets generated during the current study are not publicly available due to the need for confidentiality but are available from the corresponding author on reasonable request.

## Declarations

### Ethics approval and consent to participate

This matched case-control study was approved by the Medical Research and Ethics Committee, Ministry of Health Malaysia (NMRR ID-22-01122-JC4) with a waiver of informed consent granted due to the utilization of secondary data. This study was conducted in accordance with the Malaysian NIH Guidelines for Conducting Research in the MOH Institutions & Facilities 3rd Edition 2021.

### Consent for publication

Not applicable.

### Competing interests

The authors declare no competing interests.

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## Publisher's Note