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Sudden sensorineural hearing loss after receiving an inactivated viral vaccine, Sinopharm: Two-case report

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Abstract

The prevalence of Coronavirus Disease 2019 is a global threat. Due to the high mortality rate caused by this disease, the vaccination is mandatory to protect patients against it and reduce the mortality. Rapid development and widespread use of vaccines have raised the possibility of adverse side effects over the course of administration and follow-up. In this study, we investigated an adverse event of sudden sensorineural hearing loss in two patients receiving first dose of Sinopharm, an inactivated viral vaccine. Both patients experienced sudden hearing loss in their left ear some days after receiving the first dose of the Sinopharm and had normal otoscopic examinations in both ears and mild to severe sensorineural hearing loss was reported in the left ear. After imaging evaluation with magnetic resonance imaging which showed no pathologic points. Two patients were treated with prednisolone and valacyclovir. Both patients experienced response and had good prognosis in their follow-up. Our study showed that there is no direct evidence of an association between Coronavirus Disease 2019 vaccination. A viral infection can cause sudden sensorineural hearing loss and should be considered as a possible side effect after vaccination. Although the number of side effects reported in clinical trials has been very low, long-term follow-up of patients is needed to assess the vaccine's safety, given the incidence of these cases.

Keywords

Sinopharm, COVID-19 vaccine, sensory neural hearing loss, adverse effect, COVID vaccine, case report

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Introduction

Clinical status due to severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) is designated by the World Health Organization as Coronavirus Disease 2019 (COVID-19).[1] A pandemic was declared in 2019 for the emerging disease, which was rapidly spreading from China to the rest of the world.[2,3] The high mortality rate of this disease has made vaccination to prevent transmission of the infection and reduce mortality one of the most important issues since the beginning of the pandemic.

To stop the spread of the disease and the associated mortality, the pandemic necessitated the rapid development and distribution of vaccination. There is no reason to be reluctant to vaccinate, even though a large number of adverse events have been reported after vaccination. Audiovestibular disorders are a rare adverse event, and their risk rates have not increased in association with COVID-19 vaccination.[4] In December 2020, two vaccines, the BNT162b2 mRNA Pfizer-BioNTech and the mRNA-1273 SARS-CoV-2Moderna, were licensed for emergency application by the US Food and Drug Administration (FDA).[5,6]

After introducing these two vaccines, other vaccines were produced, approved, and injected worldwide.

Given the widespread and early vaccination of individuals due to the emergency conditions of the disease and the

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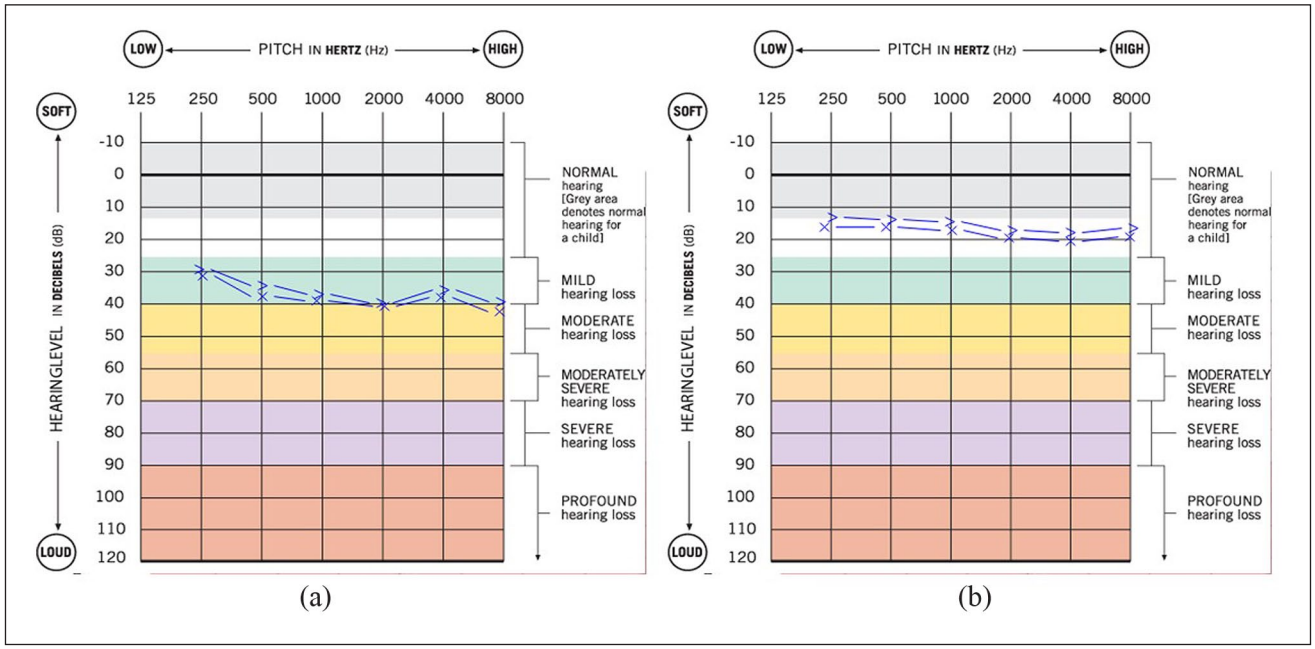

Figure 1. (a) Case 1 baseline audiogram showed mild sensorineural hearing loss in the left ear. (b) Posttreatment audiogram showed recovery to normal hearing in the left ear.

lack of long-term studies to evaluate all side effects of vaccines, it is not surprising that reports of apparent complications after vaccination (Adverse events [AE]) also increased.[7]

The article mentioned serious and rare side effects, including Guillain–Barré syndrome and thrombosis with thrombocytopenia syndrome after vaccination with Johnson vaccine and myocarditis after vaccinations with Pfizer-BioNTech and Moderna COVID-19.[8]

During the pre-vaccination clinical trials, auditory complications were not reported as a side effect.[9] Shortly after vaccination, auditory side effects, including sudden sensorineural hearing loss (SSNHL), tinnitus, earache and/or exacerbation of Menière's, and autoimmune inner ear disease, were reported in the vaccine adverse events reporting system established by the Centers for Disease Control and Prevention and FDA in the United States.[7,10,11]

SSNHL is a hearing loss of $\geqslant$30 dB at three consecutive frequencies developing within 72 h, usually due to idiopathic causes.[12–14] Other causes of this complication include viral infections, vasculitis, autoimmune diseases, and tumors.[14–16]

Considering the fact that SSNHL in some cases may be associated with infections, vasculitis, tumors, certain genetic conditions and cardiovascular risk factors, and anecdotal case reports of SSHL following vaccination have suggested that vaccines may be the cause of hearing loss in some cases, in this case series study, we presented two patients suffering from this complication after receiving the COVID-19 vaccine, Sinopharm, in Iran to investigate the connection between sudden sensorineural hearing loss and receiving viral vaccine.

Case series

Case 1

A 36-year-old man with no previous medical history was referred to the ear, nose, and throat (ENT) department of Taleghani Hospital 2 days after receiving the first dose of Sinopharm vaccine for sudden hearing loss in the left ear. Otoscopic examinations were normal in both ears. In the requested audiogram, mild sensorineural hearing loss was reported in the left ear and normal hearing in the right ear (Figure 1(a)). The patient did not report any other side effects after vaccination. Magnetic resonance imaging (MRI) with and without gadolinium requested from the patient's brain showed no pathological evidence. The patient was treated with prednisolone 60 mg daily and 1000 mg valaciclovir three times daily for 10 days, then his condition improved. The control audiogram was normal after the treatment. (Figure 1(b)) No hearing loss was observed in the 4 months' follow-up after recovery. Finally, the patient was advised to receive another available vaccine as a second dose.

Case 2

The second patient was a 60-year-old man with a history of hypertension since 15 years ago who developed a sudden hearing loss in his left ear 3 days after receiving the first dose of the Sinopharm. The patient was referred to the otolaryngology clinic of Taleghani Hospital. The otoscopic examination was normal. An audiogram was requested in which severe sensorineural hearing loss of the left ear was reported.

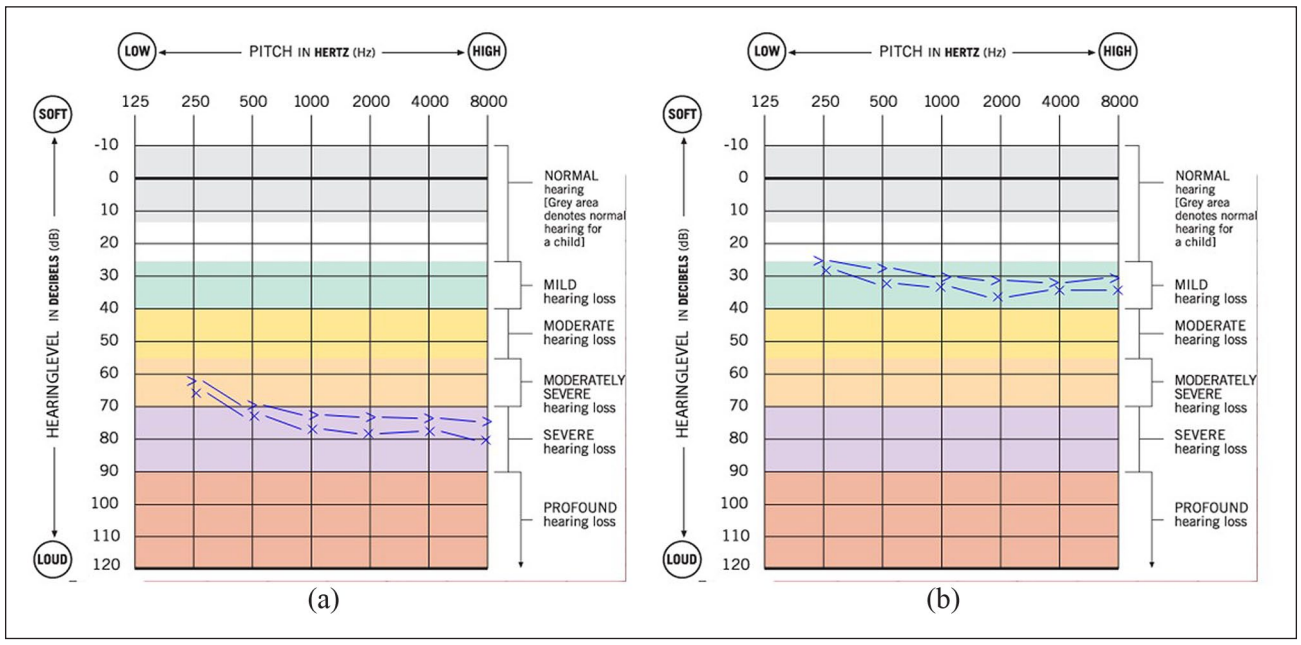

Figure 2. (a) Case 2 baseline audiogram showed severe sensorineural hearing loss in the left ear. (b) Posttreatment audiogram showed significant improvement in the left ear.

(Figure 2(a)) No pathological findings were reported on brain MRI. The patient was treated with 75 mg prednisolone and 1000 mg valacyclovir three times per day. After a 10-day treatment period, the patient's hearing improved to mild sensorineural hearing loss (Figure 2(b)). No recurrence was observed in the 3-month follow-up. The patient did not receive a second dose of the vaccine.

Discussion

Sinopharm is an inactivated viral vaccine against novel coronavirus infection (COVID-19) developed by Sinopharm's Beijing Institute of Biological Products.[17] Due to the low global distribution of the Sinopharm vaccine, there are few studies on the side effects of this vaccine. This study examined two patients who developed SSNHL after injection of this vaccine.

Several cases of SSNHL have been reported after other vaccinations against influenza, tetanus, diphtheria, meningococcus, and rabies.[12,13,15,16,18,19] Despite many reports, the cause of this complication is still unknown.[16]

Studies have reported an incidence of SSNHL between 5 and 20 per 100,000 people. Recent studies have reported the incidence of this complication in 1.5–1.7% of patients.[20,21] Wichova et al.[7] reported that the incidence of SSNHL has increased by more than two-fold to 2.44 and 3.85% in 2020 and 2021, respectively. This finding suggests a possible link between COVID-19 disease or related vaccines and SSNHL.

A systematic review investigated cases of audiovestibular symptoms after COVID-19. In this study, the prevalence of hearing loss, tinnitus, and vertigo were 7.6, 14.8, and 7.2%, respectively.[22] Another study analyzed hearing symptoms after the COVID-19 vaccination and found that the most common disorder was hearing loss, followed by tinnitus and dizziness.[7] Studies have hypothesized the cause of SSNHL after COVID-19 vaccination. These include viral reactivation, decreased clinical course of COVID-19, a known potential risk for ear symptoms, and exacerbation of migraine headaches.[22–27]

Since most people are vaccinated with Pfizer and Moderna, there are more studies on the two vaccines and their side effects. SSNHL was also reported after vaccinating with Pfizer. Both vaccines are manufactured using RNA adenoviral vectors that induce high seroprevalence and strong immune responses in the general population. These findings may eventually lead to the reactivation of previously latent viruses eliciting a response similar to Ramsay Hunt syndrome or Bell's palsy.[22,26,27] Several cases of Bell's palsy have also been reported after the COVID-19 vaccination and are relatively more common than SSNHL. However, the reason for this association is still unclear.[28,29] Hypotheses for this complication expressed in studies include an immunological response to viral antigens in vaccines and the production of antibodies and cytokines. This induced immune response can damage the cochlea through an autoimmune process, leading to vasculitis and vascular ischemia.[11,13]

Corticosteroids can be used as primary treatment within 2 weeks to treat SSNHL after vaccination of COVID-19, similar to the case of unvaccinated SSNHL.[14] Based on the hypotheses mentioned above, it can be acknowledged that the immediate administration of systemic steroids in these patients can reduce and inhibit the immune response to

vaccination and the formation of antibodies. Despite the benefits of the systemic application of steroids in treating patients with SSNHL, this effect has not been thoroughly investigated.[7,11] Patients included in the present study also experienced a complete improvement in symptoms after receiving corticosteroid and valacyclovir treatment. They also had no complaints of auditory problems after several months of follow-up.

A case report study by Zhao et al.,[30] found that the Sinovac, an inactivated vaccine, may cause deafness, which is a deep, total frequency hearing loss with tinnitus, with or without vertigo. The treatment provided to these patients did not improve their symptoms.

According to this report and Zhao et al.,[30] auditory impairments after receiving an inactivated coronavirus vaccine are one of the most important and very rare side effects. Given the very low number of adverse reactions reported in clinical trials, long-term follow-up of patients is required to assess vaccine safety.

The cause of the audiovestibular symptoms remains unknown, although it has been suggested that symptoms may have developed as a result of administration of Sinopharm's COVID-19 vaccine. Administration of the Sinofarm COVID-19 vaccine may result in vestibular hearing symptoms in some individuals with a history of middle ear-related hearing loss. Therefore, further research is needed to confirm whether this is the case.[31]

Conclusion

We concluded that there is no direct evidence of an association between COVID-19 vaccination and SSNHL, and case reports and studies have documented SSNHL as a post-vaccination adverse event. A viral infection can cause SSNHL and should be considered as a possible side effect after vaccination. Although the number of side effects reported in clinical trials has been very low, long-term follow-up of patients is needed to assess the vaccine's safety, given the incidence of these cases.

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Author contributions

F.J. contributed to the study's concept and design. F.J. and M.A., contributed to acquisition of data. D.N. and M.A. contributed to drafting of the article. F.J. contributed to critical revision of the article for important intellectual content. M.A. and F.J. contributed to study supervision. All authors read and approved the final article.

Availability of data and materials

Data in the current study are available from the corresponding author on reasonable request.

Declaration of conflicting interests

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Ethics approval

Institutional review board's approval for this case report is not required at our institution. To keep ethical principles, the names of the patients were not mentioned in the article, and their rights were protected.

Informed consent

Written informed consent was obtained from the patients for participating in the study and publication of this case report.

Human right

All authors adhered to the Helsinki Declaration; patient confidentiality and anonymity were preserved.

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