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Adverse event of Sinovac Coronavirus vaccine: Deafness

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ABSTRACT

COVID-19 has spread worldwide and is one of the most threatening infectious diseases in the world. Vaccination is known as an effective method to protect susceptible populations against such diseases. The Coronavirus vaccine developed by Sinovac has been shown to have a high protective effect, but it also has potential adverse events. For example, our department saw two patients with reported cases of deafness that occurred after inoculation with the Sinovac Coronavirus vaccine. While deafness is only a rare adverse event from the Coronavirus vaccine, whether other vaccination centers, hospitals, and centers for disease control (CDCs) have encountered similar cases still needs to be investigated, reported, and analyzed.

The WHO named the New Coronavirus as 2019-nCoV officially and stated the virus as the cause of the pneumonia epidemic in Wuhan, Hubei, China. In addition, the International Committee on Taxonomy of Viruses announced that 2019-nCoV was officially classified as severe acute respiratory syndrome Coronavirus2 (SARS-CoV-2) [1]. COVID-19 has spread to nearly every country and has become one of the most threatening infectious diseases globally. According to the Johns Hopkins Center for Systems Science and Engineering University, the total number of known Coronavirus infections worldwide exceeds 200 million, while the deaths have reached 4.2 million worldwide. At present, there is no effective antiviral treatment for COVID-19, and the focus remains on the development of Coronavirus vaccines.

Vaccines are one of the most effective methods of protection against disease in susceptible populations. The use of vaccines should undergo clinical trial and be proven to be safe and effective before it is applied to large-scale populations. Randomized, controlled, double-blind phase III clinical trials evaluated vaccine safety and efficacy by comparing the incidence of adverse events between the vaccinated and the placebo groups. Consequently, safety and effectiveness usually take a long time to demonstrate, creating an unfortunate time strain on introducing possible life-saving vaccines. The rapid development of global COVID-19 has placed considerable pressure on the requirements for the development and safety of vaccines.

At present, progress has been made in the manufacturing and production of Coronavirus vaccines. Eighty-three vaccines worldwide have entered clinical trials using five technical approaches to vaccine production, including inactivated, adenovirus vector, recombinant subunit, nucleic acid, and attenuated influenza virus vector [2]. This article focuses on COVID-19 inactivated vaccine, which uses African green monkey kidney (vero) cells for viral culture amplification and via β propylene ester inactivated virus to retain the antigen component and induce an immune response in humans.

The phase I / II clinical trial of the Coronavirus inactivated vaccine developed by Beijing Kexing Zhongwei Biotechnology Co., Ltd. (sinovac), a subsidiary of Kexing Biology, started on April 16, 2020, and was released on June 13, 2020. The results showed that the positive rate of neutralizing antibody was more than 90% [3]. Furthermore, the detailed results of phase III clinical trials conducted by Brazilian medical workers showed that two doses of the Sinovac Coronavirus vaccine protected 50.7% of symptomatic patients with COVID-19 and 100% for moderate and severe cases [4].

At present, all provinces and cities in China are actively popularizing the new vaccine, advocating that citizens receive inoculation as soon as possible. The Coronavirus vaccine in China has been approved and administered to individuals from 18 years to over 100 years of age with a total of 2.2 billion doses of the Coronavirus vaccine administered nationwide, and 1.04 billion people have received a complete cycle of the vaccination. Among multiple vaccines, the Sinovac Coronavirus vaccine has been seen to have a wide coverage rate, and attention has also been given to the analysis of possible adverse events. Based on the existing clinical research results, the main adverse events caused by Coronavirus

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inactivated vaccine are pain and swelling at the injection site, and less severe reactions such as fever or allergic reaction [5]. The most common adverse event in the phase I and II clinical trials of Coronavirus vaccine was pain at the injection site, with a severity rating of one recovered within 48 h post vaccine [6,7]. At present, there is no report on other adverse events from receiving the Sinovac Coronavirus vaccine.

Deafness is the condition of lack of hearing or impaired hearing [8]. In our hospital, we found that two instances where patients experienced extreme sensorineural deafness after receiving the Sinovac vaccination. Following is a description of their medical history and the reported incidence of deafness post-vaccination.

Patient 1

A 30-year-old male patient was admitted to the hospital on May 2, 2021, due to ‘‘hearing loss in the right ear accompanied with dizziness lasting four days”. His condition was characterized by hearing loss in the right ear with tinnitus and dizziness four days after receiving a single dose of the Sinovac Coronavirus vaccine. The initial symptom was dizziness, which lasted for several hours and did not alleviate when changing his physical position. Currently, the patient has expressed a significant reduction in dizziness than before, with only occasional dizziness attacks; however, hearing loss has had no noticeable improvement. The patient was admitted to our hospital department for pure tone audiometry. The results showed that the right ear experienced severe sensorineural hearing loss. Dix Hallpike test (-), roll test (-). Conferring to the results, he was diagnosed with ‘‘sudden hearing loss with vertigo” per diagnostic criteria and guidelines for diagnosis and treatment of sudden hearing loss (2015) [9]. Described as in good health previous to diagnosis, physical examination after admission discovered the external auditory canal was smooth and that the tympanic membrane was intact. Supplementary examination, including hematological examination, was normal, and all other abnormalities of the brain, temporal bone, and internal auditory canal were ruled out using CT and MRI of the brain, brain function imaging, temporal bone CT, internal auditory canal MRI and cervical vascular ultrasound. Organic lesions in brain and inner ear were excluded, and other systemic diseases and genetic factors were as well. Psychological factors such as stress from work or life and emotional instability were also excluded.

A treatment plan was given to address hearing loss that included intravenous glucocorticoid (methylprednisone), Ginkgo biloba extract, Mecobalamin neurotrophic drugs including batroxobin at an initial dose of 10 IU for the first treatment, followed by 5 IU the following next day, fibrinogen determination before use [10]. To test for the effectiveness of treatment, the patient received pure tone audiometry on May 7 and May 10, respectively, and it was discovered that the average hearing threshold of the damaged frequency of the right ear was improved by less than 10 dB, which was judged as an ineffective treatment.

Patient 2

A 64-year-old female patient was admitted to our hospital on May 25, 2021 because of ‘‘hearing loss in her left ear lasting four days”. The characteristics of her medical history are described as developing hearing loss in her left ear, accompanied by tinnitus, persistent chirping sound, ear tightness, slight dizziness, and no sense of rotation four days after receiving the Sinovac Coronavirus vaccine. She received pure tone audiometry in our hospital and the results showed that her left ear had severe sensorineural deafness. Due to her condition, she was admitted to the hospital as having ‘‘sudden hearing loss”.

It was reported that the patient was previously of good health. Physical examination after admission showed that the external auditory canal was smooth, and the tympanic membrane was intact. The auxiliary examination also showed the hematological examination to be normal. There were no abnormalities found in CT, and MRI evaluation of the brain or brain functional imaging, temporal bone CT, internal auditory canal MRI and cervical vascular ultrasound, and organic lesions in brain and inner ear were excluded. Similarly, other systemic diseases were excluded along with genetic and psychological factors such as stress from work, life, or emotional instability. Treatment plan for the patient included intravenous glucocorticoid (methylprednisone), Ginkgo biloba extract, Mecobalamin neurotrophic drugs, including batroxobin, with an initial dose of 10 IU, after which a dose of 5 IU was administered the next day for treatment. To assess for treatment effect, the patient received pure tone audiometry on May 30, June 2 and June 6, respectively, and the average hearing threshold improvement of the damaged frequency of the left ear was less than 10 dB, which was judged as ineffective treatment.

Through these two cases, we believe that the Coronavirus inactivated vaccine developed by Beijing Kexing Zhongwei Biological Technology Co., Ltd. may have potential adverse events that include deafness, which is total frequency profound hearing loss, accompanied by tinnitus, with or without vertigo. Treatment for these cases also proved to be ineffective. Moreover, deafness was unrelated primary disease and psychological condition and occurred without inducement. Therefore, we suggest that patients that have experienced unilateral sensorineural hearing loss in the past should see a doctor immediately following vaccination with the Coronavirus vaccine if they experience sensorineural hearing loss in the contralateral ear as to receive treatment and avoid irreversible damage.

For deafness that onsets post-inoculation with the Coronavirus vaccine, it also warns us to consider the possible adverse events of the inactivated vaccine. Currently deafness is only a rare adverse event following the Coronavirus inactivated vaccine. However, whether other vaccination centers, hospitals and Centers for Disease Control (CDCs) have encountered similar instances still needs to be reported and analyzed. Although there are few adverse events in clinical trials and no reports on deafness, long-term and extensive safety monitoring of vaccine safety and efficiency is still needed. This also warms us that those who experience discomfort following vaccination should seek healthcare as soon as possible. For the healthcare professionals, better data collection and monitoring after receiving the vaccination should be implemented.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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