



# Adverse Event Reporting after mRNA COVID-19 Vaccination: A Bell's Palsy Case the Day after

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## Abstract

Vaccination against Coronavirus disease-2019 is still occurring, and in the post-marketing surveillance phase of the circulation of COVID-19 vaccines, some rare and important adverse reactions are increasingly reported around the world. The use of large-scale vaccination programs is known to have generated concerns about adverse events after immunization. Bell's palsy has been described as a potential side effect of SARS-CoV-2 mRNA vaccines. We present the case of a previously healthy 54-year-old female patient who developed Bell's palsy the morning after receiving the first dose of the BNT162b2 (Pfizer-BioNTech) vaccine. She was discharged home with a diagnosis of Bell's palsy and improved on follow-up. The correlation between Bell's palsy and the Pfizer BNT162b2 mRNA vaccine is cause or coincidence? However, the causal relationship between the mRNA vaccine and Bell's palsy development should receive attention and needs to be further researched.

**Keywords:** Coronavirus disease; Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2); Bell's palsy; Vigi base; COVID-19 mRNA vaccines; BNT162b2 vaccine

## Introduction

Since the first reports of novel Coronavirus (COVID-19) in Wuhan, Hubei province, China [1], Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2), the infection continues to cause a deleterious effect on society, placing an enormous burden on public health and worldwide economic. In this regard, by the end of 2020, several vaccines against SARS-CoV-2 had become available for use in different parts of the world via emergency use authorization, preconditioned evaluation even if incomplete, for emergency. The vaccines that have given much hope against this fatal pandemic and save precious human lives. Major vaccines include (none) replicating viral vectors, virus-like particles, DNA platform, live-attenuated vaccines, inactivated vaccines, recombinant protein-based vaccines, plant-based vaccines, and RNA platform [2]. The mRNA-based vaccines consist of SARS-CoV-2 RNA, and once it has been injected, genetic material helps in making SARS-CoV-2-specific protein. This protein is recognized by human body to start defensive immune reaction. Among the COVID-19 vaccines that have completed phase III studies, is the new generation vaccine Pfizer-BioNTech, produced by Pfizer in the United States. As of February 2021, the Pfizer-BioNTech BNT162b2 mRNA vaccine was the first COVID-19 vaccine to receive emergency use authorization by the United States Food and Drug Administration (FDA) [3], which uses mRNA technology. Afterwards, several vaccines have been authorized for use around the world and countries and territories have joined the race to vaccinate their inhabitants, therefore the worldwide vaccination campaign against COVID-19 disease is still ongoing. Yet, several temporally related adverse effects have already been reported with these vaccines, even if through isolated case reports. For instance, since marketing authorization, acute inflammatory neuropathies with COVID-19 vaccines were reported, including facial nerve palsy [4]. Facial paralysis, also known as acute peripheral facial nerve palsy of unknown cause, commonly manifests with sudden onset of unilateral facial paralysis, and its etiology is uncertain, and it may be triggered by numerous causes [5]. Incidence rate of Bell's palsy in the general population which is estimated at 15 to 30 cases per 100,000 person-years [6]. Bell's palsy has been reported as an adverse event in COVID-19 mRNA vaccine trials. Safety data from Pfizer-BioNTech mRNA COVID-19 vaccine pre-licensure trials documented four cases of facial nerve palsy in vaccine recipient, while none happened in the placebo group [7]. Indeed, a total of 43,548 participants underwent randomization, of whom 43,448 received injections: 21,720 with BNT162b2 and 21,728 with placebo. The cases facial paralysis was labeled as medically attended

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adverse event. After the global release of vaccines, facial paralysis has attracted intense attention around the world. Until recently, there have been reports cases Bell's palsy after administration of mRNA vaccines in the general population, consisting mainly of case reports. Indeed, facial nerve palsy has been observed as a rare neurological adverse event in preventing SARS-CoV-2 infection. Our literature search was updated till November 20<sup>th</sup>, 2021. There have been previous reports of Bell's palsy after administration of mRNA vaccines in the general population [6-12]. A large population-based study examining the association between BNT162b2 mRNA COVID-19 vaccine and Bell's palsy and providing estimates by age, sex, and history of Bell's palsy. Data from this study suggests that the BNT162b2 mRNA COVID-19 vaccine might be associated with increased risk of Bell's palsy [13]. Moreover, male sex and advanced age ( $\geq 65$  years) were risk factors for increased reporting of facial paralysis with COVID-19 vaccines. For the monitoring of vaccine adverse events of the Pfizer-BioNTech vaccine in Saudi Arabia, a cross-sectional (online survey) study was conducted in a retrospective manner with 455 participants, found three cases of Bell's palsy [14]. As for Bell's palsy alone, a recent study conducted on VigiBase, the World Health Organization's (WHO) global database the highlighted that, facial paralysis was disproportionately more frequently reported with COVID-19 vaccines than with other viral vaccines, and the reported mean time-to-onset was days [4]. We report a case of otherwise healthy 54-year-old white Caucasian women who developed facial palsy within day after as an early side effect associated with vaccination with Pfizer-BioNTech COVID-19 vaccines.

## Case Presentation

The patient was 54-year-old white Caucasian women developed left facial palsy the day after receiving her first dose of SARS-CoV-2 mRNA vaccine, BNT162b2 BioNTech COVID-19 a mRNA named Comirnaty. In past medical history, hypertension, allergy to nickel and moderate COVID-19 infection in December 2020, including cough, fever, myalgias, gastrointestinal symptoms, anosmia, without evidence of pneumonia, identified through screening by Reverse Transcription-Polymerase Chain Reaction (RT-PCR). Currently takes antihypertensive therapy with eprosartan 600 mg/hydrochlorothiazide 12.5 mg 1 tablet in the morning. The patient received the first injection mRNA vaccine at 10 a.m. on June 8<sup>th</sup>, 2021. She presented to our Emergency Department (ED) 4 days after symptoms onset and reported waking up the morning after the vaccination with inability to move the muscles that control smiling, blinking, and other facial movements along with numbness and pain around the left ear, tingling and pain of the left chest, malaise but not hyperpyrexia. In fact, in ED she complained incomplete left eye closure, loss of facial symmetry, left loss of taste sensation, hypersensitivity to sounds; in addition, salivation and lacrimation was impaired (Figure 1). Main vital signs were a heart rate of 72 beats per minute, a temperature of 36.9°C, maintaining oxygen saturation of 98% on room air, and blood pressure of 130/90 mmHg. Axial non-contrast Computed Tomography (CT) head of the patient showing no abnormalities (Figure 2). The patient was referred to the Neurology Department where a physical and neurological examination concluded with left peripheral facial palsy, remaining neurological examination was normal. His ear examination was normal bilaterally. The patient was discharged the same day with a clinician diagnosed of left Bell's palsy and recommendation for the following therapy: prednisone, 75 mg/day for 2 days, which was subsequently tapered to 50 mg/day for 3 days, 25 mg/day for 2 days and 15 mg/day for the



Figure 1: Our 54-year-old patient with left-sided facial nerve paralysis.

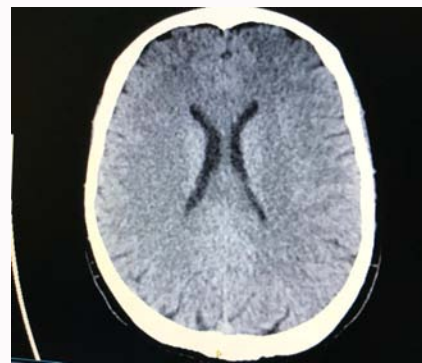


Figure 2: Axial noncontrast CT head of the patient showing no abnormalities.

next 3 days, with a total of 10 days of treatment, protection for the cornea with artificial tears and left eye dressing at night, water-soluble B-complex vitamins were subsequently added for 10 days, famciclovir 500 mg orally 3 times a daily for 8 days, pantoprazole 40 mg orally once a day, and was shown face muscle training. Indeed, a facial therapy program is tailored to the patient, was offered. After 4 weeks, the patient's physical examination and neurological examination are entirely normal.

## Discussion and Conclusion

Serious adverse events of the novel COVID-19 vaccinations are ever-evolving and receiving constant attention. After widespread implementation of vaccination campaigns, association between vaccination with the mRNA COVID-19 vaccine and Bell's palsy in the general population are beginning to emerge in the literature. Consequently, the FDA recommended strict surveillance of its occurrence in the vaccinated general population. We describe this new case of facial paralysis significant for temporal relationship with the Anti-COVID-19 vaccination. In fact, the symptoms appeared hours and not days after the first vaccine administration compared to other cases mentioned and those within clinical studies. Given health authorities' recommendation of surveillance for cases of Bell's palsy, we believe that this case should be shared with the scientific community in a timely fashion. Our case highlights the importance of continuing to monitor for side effects and complications on an individual basis following mRNA vaccine technology. Clinicians should be alert to people who develop Bell's palsy following SARS-

CoV-2 mRNA vaccination for treatment should be swift and decisive, because vaccine-associated Bell's palsy generally responds very well to the oral corticosteroids. Bell's palsy is usually a benign condition with high spontaneous recovery rates of 71% [15]. The exact causal relationship between the mRNA vaccines and the onset of Bell's palsy needs to be investigated further. We cannot prove that Bell's palsy was an adverse reaction to the mRNA vaccine in our patient. Therefore, an increasing body of evidence obliges us to reflect on the close relationship between Bell's palsy and COVID-19 vaccination. Vaccines are considered the best approach for countering the Covid-19 pandemic, therefore should be noted that the available coronavirus mRNA vaccines offer substantial public health benefit and that Bell's palsy usually resolves in most cases. In Israel, although a fourth wave of COVID came in summer 2021, it is estimated that, completely, two thirds of hospitalizations and deaths have been prevented by the mRNA vaccine campaign [16].

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