

Bell's Palsy, an Adverse Event Following COVID Vaccines

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Abstract

Introduction:

Bell's palsy is one of the most concerning complications of the COVID vaccine that has impacted vaccine acceptance among the general population. These vaccines were introduced to provide immunity against the SARS-CoV-2 coronavirus and have been found to be quite effective. Little did we know that Bell's palsy could be one of its serious complications.

Materials and Methods:

We used various search engines to gather data in the form of a case series and case reports related to patients who were affected by the vaccine and had developed Bell's palsy.

Results:

A total of eleven case reports and 4 case series were included in the analysis. The vaccines mentioned in the case reports were Pfizer, Moderna, Sinovac, AstraZeneca, and Janssen, while the case series included Pfizer and Sinovac. The majority of patients were female and aged between 31-40 years. Right-sided laterality was observed in 45.45% of patients, left-sided laterality in 45.45% of patients, and bilateral laterality in 9.1% of patients. Three patients had a history of Bell's palsy or stroke. After treatment, three patients showed partial improvement, six patients fully recovered, and the status of two patients was unknown.

Conclusions:

Bell's palsy is a rare complication that can occur after receiving the COVID-19 vaccine. This review aims to increase awareness about this rare adverse event of the vaccine so that it can be properly addressed and managed. Additionally, it will serve as a foundation for future research on the administration of the COVID-19 vaccine.

Keywords: Adverse event, Bell's palsy, COVID vaccine, Facial nerve weakness, SARS-CoV-2

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Introduction

Since the start of the year 2020, when the first sequencing of SARS-CoV-2 became public, the scientific community has worked rapidly to develop a vaccine against the virus. These vaccines have been introduced to provide immunity against the SARS-CoV-2 Coronavirus and to protect high-risk patients who are more prone to complications. A safe and effective COVID-19 vaccine is recognized as a first-line tool for curtailing the ongoing pandemic (1). The first vaccine to receive authorization was a lipid nanoparticle–encapsulated mRNA-based vaccine that includes BNT162b2 from Pfizer and BioNTech, and mRNA-1273 (Moderna vaccine) with an efficacy of 95% (2).

In addition to the mRNA vaccines, other mechanisms employed included weakened viral vector-based vaccines that inject a weakened virus into a vector (AstraZeneca, Sputnik V), weakened virus injected directly (Sinopharm, Covaxin), killed virus vaccine (Sinovac), double-stranded DNA vaccine inserted into an adenovirus vector (Janssen), and some of the newer protein subunit-based vaccines (Novavax) (3).

There are many adverse effects that have been recognized in relation to the vaccine. It is important to recognize these adverse effects promptly to decrease the potential harm that can be caused. Inactivated vaccines are known to be safer than live ones but have lower immunogenicity and often require many doses to achieve adequate immunological memory (4). Live vaccines, on the other hand, generate a strong immune response that can last for many years; however, their safety is questionable as they can cause a mild infection that may be like the real infection (5).

Side effects from the vaccine have been documented in the literature. Some general systemic side effects include headache, fatigue, chills, shivering, diarrhea, fever, arthralgia, myalgia, nausea, and vomiting. Local side effects include local or regional pain, swelling, tenderness, redness, itch, and warmth (6). Some serious adverse effects of the vaccine included thrombotic adverse drug reactions following the administration of the AstraZeneca vaccine (7). Another adverse effect of facial swelling has been reported only in mRNA-1273 vaccine recipients with a history of injection of

dermatological filler. Besides facial swelling, other rare orofacial side effects have included Bell's palsy, swelling of the lips, face, or tongue associated with flare-up or anaphylaxis (8).

Among the orofacial side effects, Bell's palsy, an idiopathic seventh Cranial Nerve Palsy with an incidence rate of 12–25 per 100,000 people in the general population, has garnered attention (9). The potential link between COVID-19 vaccines and Bell's palsy is being investigated, with theories suggesting that the immune response triggered by the vaccine could lead to inflammation of the facial nerve, resulting in Bell's palsy. Inactivated vaccine technology, commonly used in vaccines against other viral infections, like influenza, contains various viral antigens that may impact the immune response in a broader population. Conversely, the BNT162b2 vaccine may induce innate immune activation and interferon production through a combination of mRNA and lipids potentially leading to facial nerve inflammation. Interferon therapy has been associated with facial nerve palsy (10).

Previous evidence has shown an association between inactivated Influenza vaccine administration and Bell's palsy symptoms (9).

Bell's palsy, mentioned as a possible complication in COVID-19 vaccination information sheets, has raised concerns about vaccine acceptance (11). Bell's palsy is one of the dreaded complications of COVID-19 vaccines that has influenced vaccine acceptance rates. Our systematic review includes case series and reports of Bell's palsy following various SARS-CoV-2 COVID-19 vaccines post-FDA approval. The aim of our study is to compile reported cases and assess if Bell's palsy symptoms have partially improved in many cases, potentially increasing vaccine acceptance rates in the general population.

Materials and Methods

Data was gathered from various search engines using MeSH terms such as COVID, vaccine, and SARS. The inclusion criteria encompassed all case reports, case series, or reviews that discussed Bell's palsy following COVID vaccination from the inception to October 2022 post-FDA approval of the vaccine. Exclusion criteria comprised duplicate studies, those discussing additional neurological side effects in conjunction with Bell's palsy, studies linking

Bell's palsy to COVID infection, and studies conducted during the phase 3 clinical trial period to assess vaccine efficacy.

Results

A total of eleven case reports were gathered, summarized in Table 1. The cases involved individuals who received different vaccines, including Pfizer (n=4, 36.36%), Moderna (n=4,

36.36%), Sinovac (n=1, 9.1%), AstraZeneca (n=1, 9.1%), and Janssen (n=1, 9.1%). The majority of patients were female (n=6, 54.55%), followed by male (n=5, 45.45%). Most patients were in the 31-40 age group (n=5, 45.45%). Eight patients (72.7%) had no known co-morbidities, while 1 patient (9.1%) had a single co-morbidity, and 2 patients (18.2%) had multiple co-morbidities (Table 1).

Table 1: Overview of Case Reports

References	Age	Comorbid	Gender	Laterality	Days after dose 1	Days after dose 2	Prior stroke or Bells	Country	Ethnicity	Vaccine	House-Brackmann Facial Nerve Grading at the time of presentation	Recovery (House-Brackmann Facial Nerve Grading System)
Repajic et al ⁰⁹	57	HTN	F	Left	-	36h	Bells x 3	USA	Caucasian	Pfizer	Grade 4	Fully recovered (Grade 1)
Iftikhar et al ¹²	36	None	M	Left	-	1	None	Qatar	-	Moderna	Grade 6	Partially improved. (Grade 3)
Martin et al ¹³	34	None	F	Right	2	-	Bells during pregnancy	Spain	-	Moderna	Grade 3	Fully recovered (Grade 1)
Obermann et al ¹⁴	21	None	F	Right	2	-	-	Germany	-	Pfizer	Grade 4	Partially improved. (Grade 2)
Nishizawa et al ¹⁵	62	DM,HTN, Dyslipidaemia	F	Right	20	-	None	Japan	Filipino	Jansen	Grade 4	Not known
Burrows et al ¹⁶	61	DM,HTN, Dyslipidaemia	M	Right then Left palsy	5 h	2	None	UK	Caucasian	Pfizer	Right (Grade 5) Left (Grade 4)	Fully recovered (Grade 1)
Colella G, et al ¹⁷	37	None	M	Left	5	-	none	USA	Caucasian	Pfizer	Grade 6	Partially improved. (Grade 2)
Yu BY et al ¹⁸	36	None	F	Right	2	-	Bells	China	-	Sinovac	Grade 3	Fully recovered (Grade 1)
Pothiawala S. ¹⁹	46	None	M	Right	-	13	none	Singapore	-	Moderna	Grade 4	Not known
Corrêa DG et al ²⁰	42	None	M	Left	7	-	none	Brazil	-	Asterazanica	Grade 4	Fully recovered (Grade 1)
Cellina M et al. ²¹	35	None	F	Left	12h	-	none	Italy	Caucasian	Moderna	Grade 3	Fully recovered (Grade 1)

Right-sided facial palsy was observed in 5 patients (45.45%), left-sided in 5 patients (45.45%), and bilateral in 1 patient (9.1%). Three patients (27.3%) had a history of Bell's palsy or stroke. The ethnicity of the patients varied, with 4 (36.4%) being Caucasians, 1 (9.1%) Filipino, and 6 (54.5%) unknowns. Most patients showed improvement post-treatment, with 6 patients (54.5%) fully recovered and 3 patients (27.3%) partially recovered, while the follow-up status of 2 (18.2%) patients was unknown. The onset of palsy varied, with 5 patients (45.45%) experiencing it in < 5 days, 2 patients (18.2%) in 5-10 days, and 1 patient (9.1%) in 16-20 days after the first dose. 3

patients (27.27%) noticed palsy in <5 days and 1 patient (9.1%) at the 13th day after the administration of the second dose of the vaccine. One patient (9.1%) experienced palsy after both doses. Table 2 includes four case series, three related to Pfizer and one to Sinovac. The cases comprised 23 females and 42 males. Left-sided facial palsy was reported in 35 patients, while right-sided palsy was observed in 30 patients.

The onset of palsy varied, with 32 patients experiencing it after the first dose, 18 after the second dose, and 3 after both doses. Nine patients showed partial recovery after treatment (Table 2 and 3 and 4).

Table 2: Overview of Case Series

References	Female	Male	Left palsy	Right palsy	Palsy after dose 1	Palsy after dose 2	Palsy after both doses	Vaccine	Partially recovered
Shemer ²²	4	5	6	3	5	1	3	Pfizer	3
Shemer ²³	4	8	1	11	NA	NA	NA	Pfizer	6
Wan ¹⁰	9	19	20	8	19	9	0	Sinovac	NA
Wan ¹⁰	6	10	8	8	8	8	0	Pfizer	NA

Table 3: Summary all the case reports mentioned in the case series by Shemer et al (22).

References	Age	Comorbid	Gender	Laterality	Days after dose 1	Days after dose 2	Prior stroke or Bells	Country	Vaccine	House-Brackmann Facial Nerve Grading at the time of presentation	Recovery (House-Brackmann Facial Nerve Grading System)
Shemer et al ²²	86	HTN	F	Left	14	-	-	Israel	Pfizer	Grade 4	Not Available
	78	Cardiac pacemaker	F	Left	26	5	-	Israel	Pfizer	Grade 6	Partially recovered
	79	HTN, Asthma	M	Right	4	2	-	Israel	Pfizer	Grade 4	Partially recovered.
	69	None	F	Right	3	-	-	Israel	Pfizer	Not Available	Not Available
	73	Dyslipidaemia	F	Left	12	-	-	Israel	Pfizer	Grade 4	Not Available
	77	HTN, stroke, prostate cancer	M	Left	22	1	stroke	Israel	Pfizer	Not Available	Not Available
	64	None	M	Left	7	-	-	Israel	Pfizer	Grade 3	Not Available
	51	HTN, OSA, Meniere's Disease	M	Right	30	9	-	Israel	Pfizer	Grade 3	Partially recovered.
	35	None	M	Left	4	-	-	Israel	Pfizer	Not Available	Not Available

Table 4: Summary all the case reports mentioned in the case series by Shemer et al (23)

References	Comorbid	Laterality	Prior stroke or Bells	Country	Vaccine	House-Brackmann Facial Nerve Grading at the time of presentation	Recovery (House-Brackmann Facial Nerve Grading System)
Shemer et al ²³	None	Right	-	Israel	Pfizer	Grade 4	Partially recovered.
	None	Right	-	Israel	Pfizer	Not Available	Partially recovered.
	HTN, BPH, Diabetes	Right	-	Israel	Pfizer	Not Available	Not Available
	None	Right	-	Israel	Pfizer	Not Available	Partially recovered.
	Dyslipidaemia	Right	-	Israel	Pfizer	Grade 4	Not Available
	Hepatitis C	Right	-	Israel	Pfizer	Not Available	Not Available
	None	Right	-	Israel	Pfizer	Grade 3	Partially recovered.
	Small fiber neuropathy	Right	-	Israel	Pfizer	Grade 4	Partially recovered.
	None	Right	-	Israel	Pfizer	Grade 2	Not Available
	Diabetes	Right	-	Israel	Pfizer	Grade 3	Not Available
	None	Left	-	Israel	Pfizer	Grade 3	Partially recovered.
	Dyslipidaemia, hypothyroidism, thalassemia	Right	-	Israel	Pfizer	Grade 3	Not Available

El-Shitany et al. (24) conducted a cross-sectional study using an online survey to document side effects of the Pfizer vaccine among Saudi citizens. Bell's palsy was identified as a rare side effect, with 3 individuals out of 237 (1.3%) reporting it after the first dose, which was not statistically significant. Additionally, 5.3% of the study population had previous exposure to Coronavirus, and 0.7% had not been previously infected, indicating Bell's palsy as a potential side effect.

Discussion

Myths and superstitions have surrounded the public, which has been a major deterrent towards achieving mass vaccination against the SARS-CoV-2 virus. In addition to the myths, there are also religious, social, economic, and political barriers against vaccinations (25).

Being aware of the side effects of the COVID-19 vaccine and creating general awareness will help lower fears and increase the vaccine acceptance rate among individuals (26).

One of the potential side effects associated with the COVID-19 vaccine is Bell's palsy. The estimated incidence rate of Bell's palsy in the general population ranges from 15 to 30 cases per 100,000 person-years (15). Bell's palsy is characterized by unilateral paralysis of the facial nerve, typically of unknown cause and with a rapid onset (27). The exact mechanism of Bell's palsy following vaccination is not fully understood, but theories suggest potential autoimmune reactions, such as mimicry of host molecules by the vaccine antigen or activation of dormant autoreactive T cells. Other possible mechanisms include reactivation of latent herpes simplex type 1 infections in the geniculate ganglia of facial nerves or immune-mediated demyelination similar to Guillain-Barré syndrome (10).

While the precise cause remains unclear, various potential mechanisms have been proposed, including immune, infective, ischemic mechanisms, and reactivation of the herpes simplex virus in the geniculate ganglion (28). Additionally, factors such as trauma, diabetes, obesity, hypertension, pre-eclampsia, autoimmune conditions, pregnancy, and viral infections have been suggested as other potential causes (29,17). The pathophysiology

involves inflammation or oedema of the facial nerve, possibly triggered by the reactivation of a dormant virus in the central nervous system post-vaccination or following a viral infection (27). Previous studies have investigated cases of facial paralysis following vaccination against various diseases, including influenza, hepatitis B, polio, diphtheria-tetanus-pertussis, acellular pertussis, meningococcal, and measles-mumps-rubella vaccines (13,29). Our study involves a systematic review of case series and reports of Bell's palsy cases following different SARS-CoV-2 vaccines.

A) Clinical trial:

During the clinical trial phase of the mRNA-1273 (Moderna) vaccine, among the 30,351 volunteers who participated in the trial, three cases of Bell's palsy were reported in the vaccinated group, while one case was reported in the placebo group (1). In patients who were administered the BNT162b2 (Pfizer) vaccine, 161.3 out of 455 patients were found to have Bell's palsy (30). Both studies concluded that the higher number of patients in the vaccine group warranted close monitoring and suggested that it was more than a chance event.

However, during a clinical trial involving the AstraZeneca vaccine, three individuals reported Bell's palsy from the vaccinated group and two reported it in the placebo group. This study concluded that this was merely a chance event and was comparable to the rate of Bell's palsy occurrence in the general population (17).

Although the Moderna trial report concluded that a temporal relationship between the vaccine administration and the development of Bell's palsy could not be established (31), a case report mentioned by Martin et al. stated that a temporal association was more likely as the appearance of Bell's palsy was 2 days after the Moderna vaccine was administered (13).

In another trial involving the Pfizer vaccine, out of the 21,500 volunteers who received the vaccine, four cases of Bell's palsy were reported, while none were reported in the placebo group (32). Recent studies have mentioned case reports pertaining to mRNA COVID-19 vaccines, even though during the phase 3 clinical trial, the FDA did not find the frequency of Bell's palsy above that of the general population (18).

B) Case reports and Case series:

Our study included eleven case reports and four case series. Two case series by Shemer were conducted in Israel and involved patients who developed Bell's palsy after receiving the Pfizer vaccine (n=21) (22,23). Another case series from Hong Kong included cases of Bell's palsy following Sinovac (n=28) and Pfizer vaccines (n=16) (10). Additionally, a case series from Saudi Arabia reported 3 patients with Bell's palsy after receiving the Pfizer vaccine (24). The case reports involved individuals with Bell's palsy who received various vaccines, including Pfizer (n=4, 36.36%), Moderna (n=4, 36.36%), Sinovac (n=1, 9.1%), AstraZeneca (n=1, 9.1%), and Janssen (n=1, 9.1%). The majority of reported cases of Bell's palsy were associated with mRNA-based Pfizer and Moderna vaccines. Cases reported due to the AstraZeneca vaccine were mostly linked to Guillain-Barre syndrome, which was not within our inclusion criteria, so we did not discuss these studies.

Regarding gender differences in our compiled case reports (Table 1), many patients were female (n=6, 54.5%). However, in the compiled data from the case series (Table 2), the majority were males (n=42, 64.6%). Although the WHO Pharmacovigilance Database reported that 67.8% of patients who developed Bell's palsy post mRNA vaccination were females (32), a case series by Wan et al. found that many patients who developed Bell's palsy after Sinovac vaccination were males (10). No gender differences were observed in recipients of the BNT162b2 vaccine, which could explain the discrepancies in the literature related to gender (32). In the case reports, the average age was 31-40 years. In the case series by Shemer et al. (22,23), the mean age was mentioned to be 51 years. This was similar to case series by Wan that mentioned the median age as 57.5 after Sinovac (CoronaVac) vaccination and 47.5 years after Pfizer (BNT162b2) vaccine (10). One possible explanation for the age of individuals primarily affected being <60 years is the mechanism of action of Bell's palsy occurring post-vaccination. Younger people have stronger and more potent immune systems, which may lead to inflammatory effects on blood vessels, muscles, and other tissues (10). A healthy immune system could also be the reason why most people (n=6,

54.5%) affected in the case reports had no co-morbidities.

When we looked at which side of the face was affected, in the case reports, the cumulative data showed that an equal number of patients (n=5, 45.45%) had right-sided laterality and an equal number had left-sided laterality (n=5, 45.45%). However, the combined data from the case series (Table 2) showed that many patients had left-sided laterality (n=35, 53.8%).

Regarding the time duration, 36.4% of patients had palsy in <5 days after the administration of the first dose of the vaccine. 27.27% of patients noticed palsy in <5 days after the administration of the second dose of the vaccine. The short time duration suggests a temporal relation between vaccine administration and the appearance of Bell's palsy (13). Consensus in both case reports and case series showed that many cases appeared after only the first dose of the vaccination.

Most cases of facial palsy have been known to resolve with time (15). This correlates with our study, where most patients' facial weakness improved after treatment. In the case reports, 9 out of 11 patients (81.8%) showed improvement, with 3 patients partially improved and 6 patients fully improved. The status of two patients was unknown. In the case series, 9 (13.8%) partially improved. Many patients in the case series were lost to follow-up (10). However, long-standing facial weakness causes significant morbidity, along with a higher percentage of psychological distress (17). Soeiro et al. proposed type I interferon as the potential mechanism linking mRNA COVID-19 vaccines to Bell's palsy. Therefore, the mRNA COVID-19 vaccine should be considered an additional risk factor for Bell's palsy (33). In our study, we also found that most case reports and case series were from mRNA vaccines Pfizer and Moderna, which could be a contributing factor.

In the literature, there were also rare cases mentioned related to bilateral laterality, where a patient had Bell's palsy after the first and second dose of the vaccine. 3 (4.6%) cases were mentioned in the case series, and one such case report was mentioned by Burrows et al (16). Interestingly, this patient had no previous history of Bell's palsy, but had multiple co-morbidities (DM, HTN, dyslipidaemia), which could have been a contributing factor.

C) Other neurological effects of the vaccine:

Desai in RRNMJ Neuromuscular Journal reported a case of a 69-year-old female with a history of Myasthenia Gravis (MG) who presented to the emergency room with an acute attack of respiratory distress and generalized weakness following the second dose of the mRNA-1273 COVID-19 vaccine (Moderna). Her pulmonary function test showed negative inspiratory pressure, but her CXR was normal. She was taking her medication properly, but her MG worsened with the vaccine. She then recovered with plasma exchange (34).

Another recently published case report involved a 72-year-old Japanese man with a known history of hypertension, hyperlipidaemia, hyperuricemia, and heart valve disease who was on warfarin. He complained of diplopia after his second dose of the Moderna vaccine. There were no symptoms between the first and second doses of the vaccine. His neurological examination showed restricted abduction in both eyes, ataxia of the limbs and trunk, and loss of tendon reflexes. A PCR test for COVID-19 was negative, and MRI of the head showed no abnormal findings. Miller Fisher Syndrome was diagnosed as a subtype of Guillain-Barre Syndrome based on his findings and the presence of anti-GQ1b antibodies in serum. He received intravenous immunoglobulin (IVIg) therapy, which gradually improved his symptoms. On the 7th day, he developed right-sided peripheral facial nerve palsy, for which steroids and antiviral agents were given, considering the possibility of Bell's palsy. These treatments gradually improved all symptoms. His muscle weakness and ataxia almost improved, and he was discharged after 3 weeks. Follow-up after 1 month showed that diplopia and facial nerve palsy had also disappeared (35). Miller Fisher Syndrome has been reported after influenza and pneumococcal vaccines, and there have been four cases reported after Pfizer COVID-19 vaccines in the literature (36). However, this is the only reported case of a neurological side effect following the Moderna COVID-19 vaccine (35).

D) Strengths and limitations of our study:

One of the strengths of our study is its comprehensive coverage of almost all Covid-19 vaccines approved by the FDA and associated

with reported cases of facial palsy in various countries. Additionally, the study includes patients from diverse ethnic backgrounds and provides information on recovery time and follow-up status. It offers a detailed examination of the side effects, particularly facial palsy, following Covid vaccine administration, which has not been extensively studied in phase 3 vaccine efficacy trials.

However, some limitations were observed in the compiled case series and reports. These include the unknown medium and long-term effects of the vaccines. One study also noted the limitation of self-reporting by healthcare professionals, which may lead to underreporting and was specific to a particular ethnicity (24).

Additionally, in cases reported in Israel, there was a lack of information on patient follow-up, grading, long-term recovery status, and previous history of COVID or viral illness (23). Some studies did not mention patient ethnicities (12-14,18-20).

Conclusion

While various potential pathways, such as viral, autoimmune, or innate immune activation, have been proposed as potential causes of Bell's palsy following COVID-19 vaccination, these mechanisms may be complex and not universally applicable. Further investigation is needed to elucidate the mechanism of Bell's palsy post-COVID-19 vaccination. Overall, the risk of developing Bell's palsy after receiving a COVID-19 vaccine is low, and many individuals who receive the vaccine do not experience this side effect (10). It seems, Bell's palsy is a rare adverse event following COVID-19 vaccination. This review article may be one of the first to systematically document cases of Bell's palsy following COVID-19 vaccination. Based on the existing literature, the total number of vaccination doses administered globally compared to the number of Bell's palsy cases reported is likely underestimated. The goal of this review is to increase awareness among the general population about this potential side effect for prompt management. Further research, particularly in obtaining vaccination history from individuals with Bell's palsy, is essential for effective management of the condition.

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