

# Are You Suffering From Bell's Palsy?

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## STORY AT-A-GLANCE

- › Bell's palsy is a neurological disorder of the seventh cranial nerve that causes unilateral facial paralysis; thus far 13,137 cases of Bell's palsy have been recorded in VAERS following the COVID shot
- › Factors that increase the risk for the condition are high blood pressure, diabetes, pregnancy, obesity and upper respiratory health conditions. The general incidence has been measured between 30 and 39.9 per 100,000 depending on the population and geography
- › The incidence of Bell's palsy in people who have been vaccinated varies. For example, one study showed the incidence with CoronaVac used in Hong Kong was 66.9 per 100,000 and a shot equivalent to the Pfizer vaccine yielded 42.8 per 100,000 person years
- › There are several factors suggesting the incidence may not be fully noted in VAERS for several years. These include underreporting, the delay in posting reports, and the potential that Bell's palsy can develop more than one year after an incident
- › Research suggests there may be seasonal variations in the diagnosis. Consider adding complementary treatments to speed recovery, including acupuncture and herbal medications

**Bell's palsy is a neurological disorder of the seventh cranial nerve.<sup>1</sup> It's characterized by the sudden onset of symptoms that may begin with pain behind the ear, a stiff neck, slight fever or unilateral weakness and/or stiffness of the face. Ultimately, Bell's palsy**

causes unilateral facial paralysis. This is one of the adverse events reported after a COVID-19 injection.

As of January 14, 2022, the vaccine adverse event reporting system (VAERS) had recorded 13,137 cases of Bell's Palsy.<sup>2</sup> Each year the condition affects roughly 40,000 people in the U.S. and although it can affect any age group and either gender, the incidence appears to be higher in 15- to 45-year-olds.<sup>3</sup>

According to the National Institute of Neurological Disorders and Stroke (NINDS),<sup>4</sup> there are several factors that place you at higher risk for the condition, including obesity, high blood pressure, diabetes, pregnancy and upper respiratory conditions.

To measure if the incidence of Bell's palsy increases after a COVID shot, researchers calculate the rate per 100,000 people. This allows for direct comparison of two or more rates based on 100,000 people.<sup>5</sup> The incidence of Bell's palsy can vary depending on the population and when the measurement was taken.

It is crucial to use an accurate rate of incidence for a health condition in the population when comparing the incidence after receiving a medication or vaccine to determine if the drug increases the rate. For example, the National Organization for Rare Disorders (NORD) estimates the general incidence of Bell's palsy in the population is from 25 to 35 per 100,000.<sup>6</sup>

The annual incidence measure in three consecutive years in Japan during the mid-1980s yielded 30 in 100,000<sup>7</sup> but that incidence was significantly higher in 2017.<sup>8</sup> In this instance, the researchers postulated that the incidence of 39.9 per 100,000 they found was the result of an increase in herpes zoster infections, which "plays a causal role in Bell's palsy."<sup>9</sup>

Unfortunately, despite the severe effects it can have, the exact underlying cause of Bell's palsy is unclear.<sup>10</sup> Bell's palsy can resolve within weeks or months but roughly 25% may have persistence symptoms. Research data are being collected globally to determine if the COVID shot increases the rate of Bell's palsy.

## Is There an Increased Risk of Bell's Palsy After COVID Shot?

The short answer to this question is that there haven't been enough data collected as yet to determine causality. However, the indications are that Bell's palsy is potentially a "safety signal," which is an adverse event that may need further investigation as there is information to suggest it is caused by the administration of a medication or vaccine.<sup>11</sup>

One such signal involves a case report of a 61-year-old man who developed unilateral Bell's palsy shortly after receiving both his first and second dose of the Pfizer BioNTech COVID-19 vaccine.<sup>12</sup> The gentleman developed Bell's palsy the first time five hours after the first dose of the vaccine was administered. Six weeks later he took the second dose and developed Bell's palsy two days later.

In both cases, the unilateral facial paralysis occurred on the left side of his face. Although this was a case report, the researchers concluded, "The occurrence of the episodes immediately after each vaccine dose strongly suggests that Bell's palsy was attributed to the Pfizer-BioNTech vaccine, although a causal relationship cannot be established."<sup>13</sup>

In a press release accompanying publication of this case report,<sup>14</sup> it was noted that unilateral facial nerve palsy had been reported in clinical trials from Pfizer, Moderna and AstraZeneca, the three vaccines approved for use in the U.K.

The 61-year-old man also had several comorbidities associated with increased risk for COVID, including a high BMI, high cholesterol, high blood pressure and Type 2 diabetes. After both incidents he was prescribed a course of steroids. The second occurrence required an evaluation by an ear, nose and throat physician and a referral to an ophthalmologist.

During a follow-up phone call by the scientists, the patient shared that he "... has been advised to discuss future mRNA vaccines with the GP on a case-by-case basis, taking into account risk versus benefit of having each vaccine."<sup>15</sup> While this case is impressive on its own, further studies have also demonstrated a potential link between Bell's palsy and the COVID shots.

## **Data Show COVID Shot May Increase Risk of Bell's Palsy**

A June 2021 paper in the Journal of the American Medical Association<sup>16</sup> reported that during two Phase 3 vaccine trials, there were seven cases of Bell's palsy in the vaccine group and one in the placebo group. The analysis in this study suggested that the rate of Bell's palsy was higher in patients who contracted the illness than in those who received the vaccine.

However, it is odd to note that the rate of Bell's palsy in the vaccine groups in these studies were much lower than in the general population. For example, there were eight reported cases of Bell's palsy, seven of which were in the vaccine group that translated into an incidence of 19 per 100,000 according to the researchers.<sup>17</sup>

Neither the placebo group nor the vaccine group came close to the recorded rate in the general population which could range between 30 and 39.9 per 100,000. Yet, in January 2022, a case series and nested case-control study<sup>18</sup> evaluated the risk of Bell's Palsy occurring within the first 42 days after receiving BNT162b2, equivalent to the Pfizer vaccine, or CoronaVac made by Sinovac Biotech in Hong Kong, and found much higher numbers.

In this case, data were gathered from vaccine recipients between February 23, 2021, and May 4, 2021. There were 28 clinically confirmed cases after the CoronaVac vaccine and 16 after the Pfizer vaccine. The data showed the rate was 66.9 cases per 100,000 person-years for CoronaVac and 42.8 per 100,000 person-years for the Pfizer vaccinations.

Another study<sup>19</sup> published in 2021 used the World Health Organization pharmacovigilance database and identified 0.6% (600 per 100,000) of Bell's palsy. While the researchers did not find this rate varied significantly from the rate following other viral vaccines, it is 20 times higher than the rate in the general population, which should indicate a safety signal.

## **Other Factors Suggest the Incidence May Be Higher**

As has been reported, Bell's palsy may occur after the first or second injection. According to the Bloomberg tracker, 536 million doses have been given in the U.S.<sup>20</sup> According to VAERS there were 13,137 cases of confirmed Bell's palsy as of January 14, 2022.<sup>21</sup> This is a rate of 24.5 per 100,000 if you consider each injection is a potential incident to develop Bell's palsy.

While it appears to be within the range normally found in the general population, there are several factors to consider. First, these are the doses given and not the number of people who received them, as many people have received two, and sometimes three, injections.

Additionally, VAERS data are notoriously underreported. One recent analysis found the underreporting factor was 41.<sup>22,23</sup> This means there may have been 538,617 cases of Bell's palsy, which would make the rate 100 per 100,000.

Even if the underreporting factor is not as high as 41, the video story of jab-injured patient Brittany Galvin demonstrates that the VAERS reports that are received are not efficiently investigated or posted to the database in a timely fashion.<sup>24</sup> She audio recorded a conversation with a VAERS investigator who told her that despite her case being considered "high" it would be 13 to 19 months from the time she reported her side effects until the case was posted in the database.

Added to these challenges is the potential that Bell's palsy can develop more than one year after an incident that triggers the condition. One study<sup>25</sup> published in 2017 evaluated the sample of 1,025,340 Korean individuals and found an annual incidence of 0.057% (57 per 100,000). The researchers then identified patients who had had mastoidectomy and matched them against control participants.

They found the incidence of Bell's palsy was three times higher in the group who had had a mastoidectomy than the control group. The prevalence was much higher during the first postoperative year, but the results showed the prevalence was 3 times higher in the mastectomy group than the control group after the final analysis 10 years postoperatively.<sup>26</sup>

## **Seasonal Variations May Exist**

Interestingly, there is evidence that Bell's palsy may have seasonal variations. One paper<sup>27</sup> published in 2018 evaluated patients in Germany who presented to the emergency department between January 1, 2010, to June 30, 2017.

The scientists found the number of patients presenting with Bell's palsy differed significantly by month across the year. There was a higher likelihood the condition would be diagnosed in December and a lower likelihood in July. There didn't appear to be any significant difference in the variation when the group was stratified by age and sex.

The researchers acknowledged that because the patient population was hospital-based, patients with mild unilateral facial paralysis may choose to see their primary care physician and not go to an emergency department. However, they concluded, "The results indicate that environmental factors occurring more frequently in the cold season may play a role in the pathogenesis of Bell's palsy."<sup>28</sup>

## **What Indicators May Predict Recovery?**

Researchers have also been interested in the physiological and clinical indicators that may predict favorable outcomes. Two studies published in 2020 analyzed potential indicators. The first<sup>29</sup> evaluated a small group of 63 patients and followed them for three months. The patients were evaluated with the House-Brackmann facial function scoring system and electroneurography to compare the difference between potentials of facial muscles on both sides of the face.

They did not find statistically significant differences in patients with Bell's palsy who had good and poor prognosis when they looked at factors such as age, sex, diabetes, high blood pressure, dyslipidemia or the House-Brackmann grade. They found the best predictive value in this group was the electroneurography measurement.

The second study<sup>30</sup> used a cohort of 1,364 patients diagnosed between 2005 and 2017. These researchers found there were multiple clinical factors that appeared to be associated with favorable outcomes, including patients who had good electromyography results, no diabetes, controlled high blood pressure and a lower degree of paralysis measured using the House-Brackmann grade.

## **Consider Complementary Treatments**

Individuals who have a new diagnosis of Bell's palsy are likely to be prescribed steroids to regain nerve function. The NINDS<sup>31</sup> recommends steroids are started within the first 72 hours of symptoms. Although the benefits have not been established, individuals may have an increased probability of recovery with the addition of antiviral agents to treatment.

However, there are also alternative treatments that may increase the potential for a favorable outcome. For example, according to the Idiopathic Facial Paralysis Korean Medicine Clinical Practice Guideline, acupuncture is a “strongly recommended” treatment modality.<sup>32</sup>

One study<sup>33</sup> published in 2019 compared the effectiveness of acupuncture against drugs in the treatment of Bell's Palsy through a systematic review of randomized control trials. The review included 11 studies with an overall sample size of 1,258 participants.

Evaluation of the results of these 11 studies revealed that acupuncture improved the cure rate and showed a significant difference between individuals who use only drug treatments and those who use medications and acupuncture. The review didn't evaluate the safety of acupuncture with Bell's palsy but did find it appeared to be an effective therapy. However, the researchers cautioned:<sup>34</sup>

*“Results of the present meta-analysis showed that acupuncture was associated with increased cure rate and total effective rate of the treatment of Bell's palsy in comparison with drugs. However, the results should be interpreted cautiously, because of the poor quality and heterogeneity of the included studies.”*

Another study<sup>35</sup> sought to investigate whether the addition of herbal medicine with acupuncture could encourage faster recovery and if the combination increased the degree of recovery rather than with acupuncture alone. Researchers used a retrospective chart review in patients hospitalized between 2004 and 2019.

The cohort of 856 patients were split into one group that received herbal medicine with acupuncture therapy and another that received only acupuncture therapy. Each of the patients received the same advice on diet, exercise and a healthy lifestyle from one doctor. The primary outcome measure was the speed of recovery, and the secondary outcome measure was the degree of recovery using the House-Brackmann facial grading scale.

The researchers found that a combined treatment had greater efficacy in terms of speed of recovery and that the addition of herbal medications shorten the time for initial recovery. However, the researchers found no significant difference between the groups in the degree of recovery.

The follow up period in most studies evaluating facial palsy is approximately six months or more.<sup>36</sup> However, the researchers were only able to observe patients in this study for approximately one month, which may have been insufficient to reflect differences in the degree of recovery.

## Sources and References

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