Bell Palsy and COVID-19
Overcoming the Fear of “Known Unknowns”

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The emergency use authorization of the first 2 messenger RNA COVID-19 vaccines in the US has given rise to a fascinating study of otolaryngological medical and social influence issues. As of May 1, 2020, the COVID-19 pandemic has resulted in more than 151 million cases and 3.2 million deaths worldwide. In the US, these statistics include 32.4 million cases (9757 per 100 000 population) and 576 000 deaths (173 per 100 000 population).\(^1\) The cold sterility of numbers is difficult to put into context. Likewise, when Pfizer-BioNTech and Moderna revealed cases of Bell palsy in their vaccine trials, concerns grew regarding the potential of the vaccines to cause Bell palsy. Numbers thrown out to either demonstrate or refute safety are likewise difficult for the public to contextualize. Epidemiologically, linking the vaccine with an adverse event requires accurate estimation of event incidence in association with the vaccine, comparison with a nonvaccinated group, and understanding of the background incidence.

Historical background rates for safety surveillance provide some context, but their use is not without caveats. Rates vary not only by patient factors such as age (older age associated with higher incidence) and sex (mixed results), but also by geography, time, and collection method (traditional vs electronic medical record [EMR] review, hospital-based vs general practice–based vs “door-to-door” assessment).

Although many publications cite an incidence of 11.0 to 51.9 per 100 000 person-years,\(^2\) these rates can vary widely. For example, a large study in the UK using Clinical Practice Research Datalink (one of the world’s largest longitudinal databases containing EMRs from more than 640 UK general practices) identified 14 460 patients with Bell palsy, an overall incidence of 37.7 per 100 000 person-years from 2001 to 2012. Only new cases of Bell palsy were included.\(^3\) In contrast, an Israeli study using EMR data from a health maintenance organization from 2003 to 2012 identified 4463 patients with an overall incidence of 87.0 per 100 000 person-years.\(^4\) Further confounding background rates, the COVID-19 pandemic itself has been theorized to affect the incidence of Bell palsy, with mixed findings.

In this issue of JAMA Otolaryngology, Tamaki et al\(^4\) queried a large-scale EMR database contributed to by 41 health care organizations during a 1-year span to look more specifically at rates of Bell palsy in patients with a COVID-19 diagnosis. Of 348 088 identified patients with COVID-19, 284 had a diagnosis of Bell palsy within 8 weeks of COVID-19 diagnosis: 153 patients had new-onset Bell palsy, whereas 131 had recurrent Bell palsy. The authors translate this to an 8-week incidence of 82 per 100 000 patients with COVID-19. However, if using a crude analysis and assuming a prepandemic rate of 40 per 100 000 person-years and no seasonality, Bell palsy would be expected to naturally occur in only 21 of 348 088 patients during an 8-week period. This suggests that COVID-19 could...
be a risk factor for Bell palsy. It would be interesting to determine historical rates of Bell palsy using this database and compare them with the rate during the pandemic. Furthermore, Tamaki et al\textsuperscript{4} compared matched COVID-19-vaccinated patients (without a known history of COVID-19) with COVID-19-positive patients and found that vaccinated patients had a lower incidence of Bell palsy. Although these data do not directly determine the risk associated with vaccination, the inference is that the risk of acquiring Bell palsy with COVID-19 is greater than the risk of Bell palsy associated with the vaccine.

Also in this issue of \textit{JAMA Otolaryngology}, Shemer et al\textsuperscript{5} report their evaluation of the Pfizer-BioNTech BNT162b2 vaccine and Bell palsy. An analysis of emergency department admission data at a major medical center from January 1 to February 28, 2021, revealed 37 patients who were admitted for Bell palsy, 21 of whom had received the vaccine. Compared with matched controls who were admitted for other reasons, there was no difference in vaccination rates. In other words, the Bell palsy cohort was not overrepresented by vaccinated individuals. The authors also reviewed the crude incidence rate of Bell palsy during the same calendar period in the preceding 5 years and did not find significant differences.

In both studies, the adverse effects of COVID and Bell palsy may be slightly underreported owing to a short data collection interval. Data on the vaccinated group was collected for 3 months by Tamaki et al\textsuperscript{4} and for 2 months by Shemer et al.\textsuperscript{5} Not all patients likely would have 8 weeks of postvaccination observation before data were analyzed for the studies. Future analysis during a longer period of observation will be valuable.

What other real-world data can provide further input? The Vaccine Safety Datalink, which is maintained by the Centers for Disease Control and Prevention, monitors prespecified potential safety signals at 9 participating health care organizations using data from all health care encounters. As of February 13, 2021, data are available from 629,523 vaccinated individuals. The Vaccine Safety Datalink reported 21 cases of Bell palsy in vaccinated individuals. This finding is comparable to the 20.3 adjusted expected events among the unvaccinated comparators, thus indicating no increased risk.\textsuperscript{6}

Additional sources of real-world data come from voluntary patient safety reporting databases. The disadvantage of such data is also the potential for underreporting. Although they cannot be used to calculate incidence, the data nonetheless provide perspective. From an Israeli adverse event reporting database, 59 and 14 patients reported Bell palsy after the first and second vaccine dose, respectively, among 4.76 million recipients of the first dose and 3.41 million recipients of the second dose.\textsuperscript{7} As of May 15, 2021, a similar reporting tool\textsuperscript{8} maintained by the Centers for Disease Control and Prevention returned 1743 events of Bell palsy and/or facial paralysis after approximately 270 million COVID-19 vaccine doses administered among 156 million individuals who have received at least 1 dose.\textsuperscript{9}

Although it will take time to collect additional data to reduce confounding variables, no analysis is perfect. However, whichever rate one looks at regarding Bell palsy incidence, such numbers pale in comparison with the aforementioned case rate and death rate due to SARS-CoV-2. While ascertaining the adverse event rate is important in seeking medical knowledge, socially our minds become confused by methodologic quibbling and statistical calculation regarding Bell palsy, sometimes distracting us from the real consequences of an uncontrolled pandemic. The already present danger of the “known knowns” of COVID-19 is overcome by the perseveration and anxiety of “known unknowns” of the vaccines. Socially, our ability to appreciate and act on risk is in small part influenced by intellect and rationality, but in large part enacted by instinct and emotion. I hope that patients will continue to see their physicians as trusted sources. Our role as physicians is to distill these academic exercises into actionable guidance for patients.