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LETTER TO THE EDITORS

Bell's palsy following COVID-19 vaccination

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Dear Sirs,

Currently two Coronavirus Disease 2019 (COVID-19) vaccines have been granted emergency use and marketing authorization by the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) [1, 2]. Initial efficacy and safety data for both BNT162b2 (Pfizer-BioNTech) and mRNA-1273 (Moderna) vaccines have been published [3, 4]. To the best of our knowledge, there is no mention of facial paralysis in the article describing safety and efficacy of the BNT162b2 vaccine [3], however, four such adverse events were eventually highlighted in product monographs published by the relevant regulatory bodies [1, 5]. Although FDA vaccine review memoranda do mention the occurrence of facial paralysis in the test group for both vaccines [1, 2], consumer/patient information sheets of neither of the vaccines distributed in North America warn about Bell's palsy as a possible adverse effect [6].

Here, we report a case of an otherwise healthy 37-year-old white Caucasian male who developed facial palsy within days after COVID-19 vaccination. We were given written, explicit informed consent to disclose the information reported in this letter. The patient received the first injection of the mRNA Vaccine BNT162b2 on 8th January, 2021, and the following day he developed symptoms including malaise, fatigue, and headache, but not hyperpyrexia. From the 11th, he complained of ingravescent left-sided latero-cervical pain irradiating ipsilaterally to the mastoid, ear, and retro-maxillary region. On 13th January upon awakening, he noticed a marked monolateral muscle weakness and attended the Maxillofacial Unit at our University Hospital. He presented with a left-sided facial droop accompanied by reduced mobility (paresis), with flattening of forehead's skin and marionette line (labial-buccal sulcus) ipsilaterally as well as mild flattening of the nasolabial fold (Fig. 1). Lagophthalmos and mild labial hypomobility was also recorded. This clinical presentation was accompanied by a moderate Bell's sign (failure to close the eye on the affected side with exposure of the sclera). No history of trauma, cold or other identifiable triggers was reported and no other signs or symptoms were present. Specifically, no history of a preceding infection, including recent SARS-CoV-2 infection, was reported and there was no evidence of a cutaneous rash suggestive of Herpes Zoster infection. The patient was referred to the Neurology Department with a provisional diagnosis of hemifacial paresis and discharged the same day with a clinical diagnosis of Bell's palsy—an acute unilateral facial nerve paresis or paralysis with onset in less than 72 h and without identifiable cause [7]. No data are available concerning neurophysiological and cerebrospinal fluid investigations, as these were not deemed essential given that Bell's palsy is fundamentally a clinical diagnosis and that there is no specific laboratory test to confirm the disorder. Laboratory or other diagnostic tests can surely be useful in excluding other conditions such as Lyme disease (not common in our geographical area) or neuropathies such as Guillain–Barre' syndrome, or also brain tumours. These are especially useful when clinical presentation is not typical, and hence were not undertaken in our patient.

Our patient started treatment with corticosteroids (Prednisone, 50 mg/day), eye drops (artificial tears) and eye dressing at night. The clinical signs worsened and progressed to complete paralysis within 2 weeks and were accompanied by severe pain (VAS 8/10) to the same hemiface. To date (5th February), systemic symptoms have resolved, facial mobility has only partially improved and pain sensation still persists (VAS 4/10). This is consistent with the natural history of the disease [7].

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Fig. 1 Clinical photograph of our 37-year-old patient with left-sided facial droop

Of the 73,868 volunteers (36,901 effectively receiving vaccine) taking part in the two large phase three vaccine trials [1–4], eight cases of suspect Bell's palsy were reported, with a total of seven in the groups receiving a vaccine (1:5272) and one in placebo groups (1:36,938). For the BNT162b2 vaccine, there were four cases of Bell's palsy in the vaccine group compared with no cases in the placebo group, and occurred at day 37 after Dose 1 (participant did not receive Dose 2) and days 3, 9, and 48 after Dose 2 [1]. For the mRNA-1273 vaccine, there were three reports of facial paralysis in the vaccine group (22, 28, and 32 days after Dose 2) and one in the placebo group [2, 4]. In other words, all but one cases occurred after the second dose of vaccine. The FDA pointed out that the cases in the vaccine groups did not represent a frequency above that expected in the general population [1] and concluded that currently available information was insufficient to determine a causal relationship with the vaccine. Nevertheless, the FDA recommended surveillance for cases of Bell's palsy with deployment of the vaccine into larger populations [2]. In compliance with these recommendations, we reported what we believe was the first case described in the peer-reviewed scientific literature of Bell's palsy following Pfizer-BioNTech vaccination.

Facial paresis/paralysis associated with the mRNA-1273 vaccine developed in participants with concurrent medical conditions or disease history [2]. Conversely, to the best of our knowledge, clinical/health data of the four participants who reported facial paralysis are not available for the BNT162b2 vaccine. Reporting has important clinical and pharmacovigilance implications and we believe that providing detailed information can help recognise and manage this condition. Because no information has been shared to date regarding clinical conditions and medical or disease history of the participants developing facial paralysis post-BNT162b2 vaccination, this does not allow us to gauge the likelihood of a cause–effect relationship and the possible role of comorbidities. To this regard, it is surprising that whilst the onset of Bell's palsy was reported 37 days after the first dose [1], this participant did not receive a second dose that should have been administered 21 days after the first injection [3]. Hence, our case is currently the only peer-reviewed report that describes in some detail the signs and symptoms that led to a diagnosis of Bell's palsy in a COVID-19 BNT162b2 vaccine recipient, and the first to be reported in the scientific literature for any COVID-19 vaccine post-marketing. Although a causal relationship cannot be established for most rare adverse events, the timing and mode of onset of the palsy strongly suggests that it was related to BNT162b2 vaccine injection. 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.

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Compliance with ethical standards

Conflicts of interest None of the authors declare any conflict of interests.

Ethical approval Our patient gave his informed written consent to participate in the study.

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