Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

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Letter to the editor

Real-world safety data for the Pfizer BNT162b2 SARS-CoV-2 vaccine, historical cohort study' by Shasha et al

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To the Editor

We read with interest the article by Shasha et al. about real-world safety data for the Pfizer vaccine BNT162b2 in a large cohort of 394 609 participants [1]. Four diagnoses were used as outcome parameters: Bell's palsy, herpes zoster, Guillain–Barré syndrome (GBS), and numbness and tingling [1]. It was found that numbness and tingling occurred more frequently among vaccinees than in controls but not the other three outcome variables [1]. A merit of this study is that possible adverse reactions were addressed, but concerns remain.

One limitation of the study is that the end points were identified by visit diagnoses. The authors themselves admit that this method of data acquisition might lead to 'partial or inaccurate' diagnoses [1]. Diagnosing GBS, for example, requires application of the Brighton criteria. Application of the Brighton criteria implies that patients with suspected GBS undergo cerebrospinal fluid investigations and nerve conduction studies in addition to history and clinical examinations. It would be interesting to know if the patient with GBS in the investigated cohort fulfilled the Brighton criteria or not.

Another limitation is that the cause of sensory symptoms was not sufficiently explored, which admittedly is inherent to the retrospective design. Attributing sensory symptoms of the face to anxiety is unsupported by the presented data because various differentials were not excluded. Sensory symptoms (numbness and tingling) were 'mainly on one side of the face', so small-fibre neuropathy is rather unlikely to be the cause of these symptoms given the fact that small-fibre neuropathy usually manifests in the feet and the hands [2]. Attributing sensory symptoms of the face to processing of reports in mass media about a suspected association between severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) vaccinations and facial palsy is misleading as sensory abnormalities of the face suggest that the trigeminal nerve, rather than the facial nerve is affected. As mononeuritis or polyneuritis cranialis is a confirmed complication of SARS-CoV-2 infections [3] and as SARS-CoV-2 vaccinations imitate the infection, it is warranted that mononeuritis of a clinically affected cranial nerve is appropriately excluded. Sensory disturbances in the face can be, for example, the initial manifestation of a herpes zoster infection.

A further limitation is that 41% of the eligible vaccinees were excluded for reasons of matching. Though inclusion of these 41% might bias the evaluation, valuable information could be achieved as well. In particular, it would be interesting to know if comparison of the entire cohort of eligible vaccinees with the control cohort results in conclusions at variance from those reported. Matching for the number of co-morbidities but not the type of co-morbidity is also a bias.

Selection of only four outcome parameters "of concern" was established by identifying outcomes by clinical visits. However, more than four outcome parameters can be assessed upon clinical visits. Considering only the neurological adverse effects of SARS-CoV-2 vaccinations, the spectrum of adverse reactions is much broader, including headache, myalgia, venous sinus thrombosis, transverse myelitis, small-fibre neuropathy, immune encephalitis, and others in addition to GBS and facial palsy. Headache is by far the most prevalent of the neurological adverse effects and can be easily assessed by clinical visits as well as myalgia. We should know why only four outcome measures were selected although the medical health maintenance organisation (MHMO) database offered more options.

The term Bell's palsy is inaccurate. Bell's palsy is a facial nerve palsy of undetermined cause. If a facial palsy is attributed to a

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reaction against the vaccination then the term Bell's palsy should be avoided.

Overall, this interesting study has limitations that challenge the results and their interpretation. Real-world data rather indicate that the spectrum of adverse effects of any of the commercially available SARS-CoV-2 vaccinations is broader than anticipated, under-reported and played down. Adverse effects need to be thoroughly elaborated to draw clearer pictures than those frequently sold. The real world is more unsafe than its propagated image.

Transparency declaration

The authors have no conflicting interests. None received.

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Not applicable.

Consent for publication

Not applicable.

Availability of data and material

All data reported are available from the corresponding author.

Author contributions

JF contributed to design, literature search, discussion, first draft and critical comments; FS contributed to literature search, discussion, critical comments and final approval.

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