

REPLY

Neurological side effects of COVID-19 vaccines are rare

We read with interest the letter by Finsterer & Scorza on our review of potential neurological effects of COVID-19 vaccines.¹ Their content is not dissimilar to our conclusion that post-vaccine neurological events are, at this time, relatively rare and that possible long-time effects will need further prospective monitoring. It is, of course, essential to remind Finsterer & Scorza that this is an evolving field, and evidence will change as time goes. Therefore, pontification with the help of the retroscope is always welcomed.

Some new evidence needs to be updated and clarified.

The main safety concerns in the viral vector platform are blood clots reported with Vaxzevria (previously COVID-19 Vaccine AstraZeneca).² By March 22, 2021, the EU drug safety database reported 62 cases of cerebral venous sinus thrombosis (CVST) in people who received the vaccine. This is a slight increase in the risk of this in the general population.³ Conversely, another study compared the incidence rate of venous thromboembolic events between the Oxford-AstraZeneca vaccine population and the entire Danish population before vaccination. It suggested that the reported thromboembolic events do not increase.⁴ The European Medicines Agency concluded that the combination of blood clots and low blood platelets is extremely rare. The causality of CVST with the vaccine requires further investigation. According to the Joint CDC and FDA Statement, the same blood clot incidence was also associated with the Johnson & Johnson viral vector vaccine, but still appears to be an extremely rare event.⁵

There is also new evidence in the mRNA platform. Aside from the published phase 3 trials, real-world data⁶ showed a similar number of neurological events between vaccinated and unvaccinated populations. Other safety results are also consistent with the extensive safety and tolerability assessments conducted in Phase 1/2 and Phase 3 trials. The Advisory Committee on Immunization Practices (ACIP) of the CDC also presented similar data compared to the unvaccinated group. No statistical signals were detected for Bell's palsy, convulsions/seizures, hemorrhagic or ischemic stroke, and venous thromboembolism.⁷ Despite the limitation of neurological adverse events reporting, public media showed a few cases of people with continuous trunk movements and limbs or walking difficulties.⁸ These reports were considered mainly as functional neurological disorders. The causality between these symptoms and vaccination was uncertain.

Based on the current evidence, though more neurological adverse effects were reported with the massive worldwide vaccination, the causality is yet to be confirmed. As the vaccinated population increases, inevitable more neurological incidents will be seen. The link

between them and the vaccine association will need to be tested by comparing their incidence rate with epidemiological data preceding the pandemic. We agree that it is essential to establish a transparent and efficient reporting system of vaccination safety. This will require full collaboration between regulators, healthcare workers, the industry, and the general public.

KEYWORDS

adverse effect, blood clot, safety, SARS-CoV-2

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CONFLICT OF INTEREST

The authors report no conflicts of interest in relation to this work.

DATA AVAILABILITY STATEMENT

Not applicable.

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