No evidence of an increased risk for cardiac complications following mRNA COVID-19 vaccines

No hay evidencia de un mayor riesgo de complicaciones cardíacas después de las vacunas de ARNm COVID-19

Dear Editor,

We appreciate the ideas shared by Mungmunpuntipantip and Wiwanitkit.[1] Although we are aware of the existence of case reports describing adverse cardiac events associated with mRNA COVID-19 vaccines,[2] the best available evidence from blinded, placebo-controlled, randomized clinical trials (RCTs) showed no increased risk of tachycardia and other cardiac complications following the Pfizer-BioNTech COVID-19 vaccine.[3] Although serious adverse events may be missed because negatively adjudicated events do not undergo further scrutiny,[4] clinical trial evidence is essential to ensure the safety and efficacy of the vaccine and further increase public acceptance.

Moreover, real-world surveillance studies to monitor the safety and effectiveness of COVID-19 vaccines have been published.[5] A recent study[6] based on the pharmacovigilance post-marketing database of the World Health Organization reported the occurrence of 103,954 adverse events among 30,523 patients between December 15, 2020, and January 24, 2021. A total of 4201 (4%) cardiovascular adverse events from the Pfizer-BioNTech vaccine were reported, and the most common complications were tachycardia, flushing, and hypertension. It was shown that acute myocardial infarction, cardiac arrest, and circulatory collapse were associated with the vaccine used in the age group >75 years.

However, confounding factors are common sources of bias in observational clinical studies, and the occurrence of cardiovascular events is typically more prevalent in older individuals. In addition, there is evidence of changes in heart rate in response to vaccination.[7] We also emphasize that tachycardia is a common finding in post-acute COVID-19 syndrome, and it may be clinically present as sinus tachycardia, postural orthostatic tachycardia syndrome, or inappropriate sinus tachycardia.[8] Longitudinal investigations suggest that 9% of post-acute COVID-19 patients report palpitations at 6 months.[9] Therefore, as many patients are vaccinated in the post-acute phase of the disease, we can expect that, in many cases, the tachycardia results from infection and not from the immunizing agent.

It has been recommended that the most crucial factor to be evaluated is the actual existence of spontaneous post-vaccination adverse events that do not result from the presence or exacerbation of existing comorbidities.[10] Therefore, case reports do not have sufficient evidence to support causality and draw conclusions about the increased risk of cardiac complications after vaccination. Cardiovascular adverse events are also often associated with the general population, even without intervention.[6] In any case, we agree with the need for a medical evaluation of individuals with pre-existing medical conditions prior to the use of any vaccine.

In clinical and epidemiological research, temporality and the strength with which an observed event is associated with an intervention are critical elements to support causality. To date, there is no evidence of an increased risk of tachycardia and other cardiac complications following the Pfizer-BioNTech COVID-19 vaccine.

Funding

None declared.

Conflict of interest

None declared.

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https://doi.org/10.1016/j.eimc.2022.09.001