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Letter to the Editor

Assessing the nature and rate of side effects to SARS-CoV-2 vaccines requires well-powered, prospective studies

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We read with interest the article by Wang et al. about a cross-sectional study about adverse reactions in vaccinees having received three doses of a vector-or RNA-based SARS-CoV-2 vaccine carried out by means of an online questionnaire [1]. It was found that pain was the most common local side effect, that fatigue and drowsiness were the most common systemic adverse reactions, and that vaccines >60 years of age were not at increased risk to experience side effects [1]. There was no difference regarding the profile of adverse reactions between vector- and RNA vaccine brands [1]. The study is appealing but carries limitations that raise concerns and should be discussed.

The main limitation of the study is that vaccines were investigated by means of an electronic questionnaire [1]. With this type of investigation there is no guarantee that the information provided by the patient regarding vaccine brand, side effects, tolerability, and effect are true. It is not guaranteed that the affected vaccine himself answered the questions and not any of his relatives or caregivers who had access to the electronic questionnaire. In addition, it is conceivable that a vaccine is on vacation or in the hospital and does not have access to the questionnaire during this time. These patients will miss the request to fill in the forms and will be excluded from the investigation. An online questionnaire is also biased regarding those who are familiar with electronic media and have access to them. Therefore, the study is biased towards the inclusion of younger compared to older vaccines. We should know whether relatives or caregivers were allowed to fill in the form in case the vaccine was physically or mentally incapable to understand the questions and to fill in the form. We should know how the authors got access to the IP addresses of the vaccines.

A further limitation is the low number of vaccines having received an RNA-based vaccine (n=89) [1]. The low number of patients in this cohort makes comparison between the vector-based and the RNA-based vaccine group unreliable.

Another limitation is that no explanation was provided why the included patients did not report severe side effects, which are increasingly recognised after SARS-CoV-2 vaccinations [2]. Severe side effects affect the central nervous system (CNS), in form of cerebrovascular disease, immunological CNS disease, epilepsy, and others, the peripheral nervous system (PNS), in form of Guillain-Barre syndrome, Parsonage-Turner syndrome, myasthenia, or myositis, the cardiovascular system, in form endocarditis, myocarditis, or myocardial infarction [3], and the kidneys, manifesting as renal failure [4]. Despite the inclusion of >3000 vaccines, none of these severe adverse reactions was reported [1].

We should know the difference between “anaphylaxis” and “mild allergy” [1].

Overall, the interesting study has limitations that call the results and their interpretation into question. Clarifying these weaknesses would strengthen the conclusions and could improve the study. Assessing the type and rate of side effects to SARS-CoV-2 vaccines, well-powered and prospective studies are required.

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