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

Assessing beneficial or side effects of COVID-vaccinations requires personal rather than electronic investigations

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We read with interest the article by Alharbi et al. about a prospective study of vaccinee outcome, demographics, and comorbidities after single dose anti-SARS-CoV-2 vaccinations with either the Biontech Pfizer vaccine (BPV) or the Astra Zeneca vaccine (AZV) [1]. A protection rate of 92 % was calculated and SARS-CoV-2 infection after vaccination was associated with diabetes, obesity, and organ transplantation [1]. Nationality, male gender, and obesity were associated with the occurrence of breakthrough infections in the multivariable analysis [1]. Side effects reported included pain at the injection site, fever, fatigue, myalgia, and headache, reported by 5.8 % of the 17091 vaccinees [1]. The study is attractive but raises concerns that should be discussed.

Although it is claimed that real-world data were presented, we contest this claim due to the design of the study, delivery of individual data, analysis of the survey, and reporting of the results. Online surveys with a self-report system are not suitable for collecting comprehensive information about the side effects of a drug. First, there is no guarantee that the patient responded themselves and not a family member, a friend, or a caregiver. It is conceivable that some vaccinees have asked other people to fill in the questionnaire. Second, there is no guarantee that the answers given are correct. There could have been vaccines that invented side effects or didn't communicate real side effects for whatever reason. Third, people who are unable to respond for whatever reason automatically became non-responders and were excluded from the study. Fourth, not all included vaccinees were systematically tested by PCR for SARS-CoV-2 or other infections prior to vaccination, which is why it cannot be ruled out that some of the reported symptoms are more likely to result from acute infections or other acute diseases than from the vaccination. We should know how many patients did not respond and what was the reason for their non-response. It should be reported how many were hospitalized at the time of the investigation because of post vaccination side effects, how many did not want to participate, how many were unable to respond due to cognitive impairment. How many correctly filled in questionnaires got lost because of electronic transmission problems? It is also important to know whether the vaccinees had to fill out a systematic questionnaire or whether free text was used to communicate with the investigators. It is not reported how missing or incomplete data were handled. How many subjects were vaccinated despite an acute illness?

Another weakness of the design is that the latency between vaccination and reporting was different for each patient. It varied between three and eight months [1]. Due to the longer observation period, it is to be expected that those with long latencies were more likely to experience side effects than those with short latencies. Therefore, protection rates can be high for those with short latencies but low for those with long latencies.

The fact that only 5.8 % reported side effects does not reflect the true rate of side effects. Since not all vaccinees were systematically invited for a face to face follow-up, the actual side effect rate may exceed 5.8 %. Underreporting of side effects may occur in case of a low responder rate or in the case of incorrect information. Overreporting could be based on incorrect information or on symptoms caused by acute illnesses that were not taken into account.

Overall, the interesting study has some limitations and inconsistencies that call the results and their interpretation into question. Addressing these limitations could further strengthen and amplify the conclusions of the study. In order to assess the rate of breakthrough infections and the rate of side effects after SARS-CoV-2 vaccinations, personal follow-ups with a fixed post-vaccination period are warranted.

Abbreviations: AZV, AstraZeneca vaccine; BPV, Biontech Pfizer vaccine

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Ethics approval and consent to participate

Was in accordance with ethical guidelines. The study was approved by the institutional review board.

Consent to participate

Was obtained from the patient.

Consent for publication

Was obtained from the patient.

Code availability

Not applicable.

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Data Availability

All data are available from the corresponding author.

Author contribution

JF: design, literature search, discussion, first draft, critical comments, final approval,

Conflicts of interest

The author declares that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest

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Reference

[1] Alharbi NK, Al-Tawfiq JA, Alghnam S, Alwehaibe A, Alasmari A, Alsagaby SA, et al. Outcomes of single dose COVID-19 vaccines: eight month follow-up of a large cohort in Saudi Arabia. J Infect Public Health 2022;15(5):573–7. https://doi.org/10.1016/j.jiph.2022.04.001

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