Review of: "Side effects of COVID-19 vaccination in Pakistani population: A cross sectional study"

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Potential competing interests: No potential competing interests to declare.

The authors present an important study in the ongoing discussion about COVID-19 vaccination side effects. Their study rigorously categorizes side effects across several vaccines. The study also assesses post-vaccination COVID-19 illness, a crucial measurement for determining vaccine effectiveness. However, the authors need to expand and clarify their methods section. They also need to be careful when discussing results that do not have statistical significance, as mentioning absolute changes without the statistical results is incomplete.

Abstract

- “development of extreme complications (1.4%) was lower in those who contracted the disease after vaccination compared to those who contracted COVID-19 before being fully vaccinated (7.1%).”- Yet this is not statistically significant, as demonstrated by the article (“Only 3 (4·2%) out of 71 participants were hospitalized due to COVID-19 infection after being fully vaccinated, while 10 (7·1%) out of 141 participants were hospitalized before being fully vaccinated (p=0·809).”). The statistical significance must be mentioned here, as without it this statement is potentially misleading.

Introduction

- “Approximately 71.1% of the global population has received at least one dose…”- Please include the date for this reference, as this number will change over time.
- “In Pakistan, a heterogeneity regarding vaccine acceptance…”- Please clarify exactly what is meant by a “heterogeneity” here. Perhaps a heterogeneity among certain demographic groups? Across vaccine formulations?

Methodology

- How were participants selected or recruited to participate in the survey? How was the survey made available or advertised to potential participants?
- “interview-based questionnaire technique”- Does this mean that the participants were interviewed? If so, who performed the interviews and in what setting did they take place?
- “fully vaccinated individuals”- Was there any additional inclusion criteria other than being fully vaccinated for COVID-19? I suspect that living in Pakistan is another criterion. Was this study only available to Pakistani citizens or were immigrants also able to participate? Was there an age criterion, or did this study include adult and pediatric

participants?

Results

- I suggest providing both the number of participants as well as percentages for this data.
- “moderate pain”, “severe pain”- How were moderate and severe pain defined?
- “more prominent symptom after administration of CanoSino vaccine”- I suggest providing both the number of participants as well as percentages for this data.
- “The administration of the Pfizer vaccine resulted in muscle fatigue among 26% of the study participants”- Was muscle fatigue noted for any of the other vaccines? It seems odd that only the Pfizer vaccine is mentioned for this symptom.
- “Pfizer BioNTech being the most common booster COVID-19 vaccine and with a high rate of post-vaccination side-effects”- Please reword
- “Blood group”- There have been some studies that have looked at the incidence of COVID-19 and blood type. I suspect that the authors were curious if there was a relationship between blood type and COVID-19 side effects. However, I do not see this variable discussed anywhere in the manuscript.
- “BMI and age were also significantly associated with fatigue, muscle pain, severe pain at injection site…”- Please provide the statistical results in the main body of the test
- “extreme difficulties in their daily routines”- How were extreme difficulties in one’s daily routines defined?

Discussion

- “Studies conducted in India and Bangladseh also reported mild post vaccination side-effects”- This is very different from the previous sentence, which emphasizes *severe* side effects
- “hospitalization rate (reduced from 7·1% to 4·2%) and development of extreme complications (reduced from 7·1% to 1·4%)”- Does this refer to complications and hospitalizations of any cause of specifically from COVID-19?
- “prior to vaccination was 12% as compared to 6% in the vaccinated participants.”- Some of this depends on when the participants were surveyed relative to their vaccination. If a person completed the vaccination series one day prior to completing this survey, then the window for a potential post-vaccination bout of COVID-19 is too small to be considered viable. The authors need to include descriptive statistics for time from vaccination to survey completion for the participants (if available), although I recognize that asking participants to recall the exact date of vaccination is an arguably unreasonable question. At the very least, this should be mentioned as a limitation of the study.
- “while those 6% vaccinated, who contracted infection, had low incidence of infection”- This should be clarified. I suspect that the authors may have meant a low incidence of hospitalization or disease severity.
- “Our study results show that COVID-19 symptoms, hospitalization rate (reduced from 7·1% to 4·2%) and development of extreme complications (reduced from 7·1% to 1·4%) were less in those who had the infection post vaccination compared to those who had COVID-19 prior to the vaccination.”- Again, these results are not statistically significant. Therefore, while the authors are correct that these rates were indeed reduced with vaccination, they must note that this difference is not significant.
- “So, it can be inferred that being vaccinated is safe and there are no extreme side effects and complications involved.”-

I do not believe we can conclude that these vaccines cannot result in severe side effects or complications, even though the rate of these complications may be low. The authors note side effects such as confusion and difficulty breathing among vaccine recipients, which could be interpreted as severe. Furthermore, they mention that some participants experienced “extreme” difficulties with their daily routine, which could also be considered a severe side effect. Finally, this study cannot definitively conclude that these vaccines produce not severe side effects given reports published elsewhere of said severe side effects, although again it can suggest that these effects are likely to be very rare.