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Letter to the Editor

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Assessing Possible Side Effects of Sputnik-V Requires an Appropriate Study Design with Extensive Follow-Up

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LETTER TO THE EDITOR

We read with interest the article by Ameer *et al*. [Ameer, B. R. *et al*., 2023] on a cross-sectional study of Sputnik-V side effects in 2532 vaccinees collected between September and October 2021 at a single tertiary centre in Karnataka [Ameer, B. R. *et al*., 2023]. Minor adverse events were reported in 29% of patients [Ameer, B. R. *et al*., 2023]. The most common adverse events after the first dose were fever, local tenderness, myalgia, and headache [Ameer, B. R. *et al*., 2023]. The most common adverse events after the second dose were fever, myalgia, headache, and local tenderness [Ameer, B. R. *et al*., 2023]. It was concluded that the nature of the adverse events was similar to that reported by the vaccine manufacturer [Ameer, B. R. *et al*., 2023]. The study is excellent but has limitations that are cause of concerns and should be discussed.

The main limitation of the study is that it focuses on vaccinees who had a phone, were able to pick up and make calls. Vaccinees with serious side effects that resulted in confinement to bed, hospitalisation or even admission to an intensive care unit may have been overlooked. So we should know what happened to the 20'% of vaccinees who did not respond after the first dose and the 16% who did not respond after the second dose.

What is misleading is that the design favours reporting only mild side effects and the reported results give the impression that Sputnik-V is almost completely save, but real data tells a different story. In a study of 602 vaccinees receiving the first Sputnik-V dose, severe digestive problems were reported in 7 patients, and severe weakness and lethargy in 55 patients [Nabizadeh, E. *et al*., 2023]. After the second Sputnik-V dose, 602 patients experienced severe allergic reactions, 7 severe respiratory problems, 7 facial oedema, and 27 severe weakness and lethargy [Nabizadeh, E. *et al*., 2023]. Taking all side effects into account, 66% of those vaccinated reported side effects after the first or second dose of Sputnik-V [Nabizadeh, E. *et al*., 2023]. In a study of 126 vaccinees who received Sputnik-V, 6 vaccinees developed asthma-like symptoms after the first dose and 7 after the second dose [Akrami, M. *et al*., 2023]. In addition, a significant decrease in hematocrit, mean corpuscular volume of erythrocytes and neutrophil count was observed after vaccination [Akrami, M. *et al*., 2023]. There are also reports about vaccinees who developed a vaccine-induced thrombotic thrombocytopenia (VITT) syndrome with subsequent venous sinus thrombosis after vaccination with Sputnik-V [Safina, D. R. *et al*., 2022]. In a study of 80 female vaccinees who received Sputnik-V, 5% developed menstrual disorders [Abdollahi, A. *et al*., 2022]. A 40 year-old female healthcare worker developed severe, persistent eczematous lesions two days after the first Sputnik-V dose, that were unresponsive to antihistamines and were still present at the one-month follow-up [Ameri, M. *et al*., 2022]. A 26 year-old female developed acute disseminated encephalomyelitis (ADEM) four weeks after receiving the first dose of Sputnik-V [Lazaro, L. G. *et al*., 2022].

A second limitation of the study is that the follow-up phone call was conducted on day 7 post-injection [Ameer, B. R. *et al*., 2023]. Since side effects can occur up to a month after vaccination [Hosseini, R. *et al*., 2023], it is conceivable that many of the side effects were simply overlooked because due to the short follow-up period. In this context, we should know whether during the telephone call after the second dose, the vaccinees were also asked about side effects that only occurred after the first telephone call, or only about side effects that occurred after the second dose.

A third limitation is that defining major events (requiring hospitalisation) still requires defining

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which reasons for hospitalisation were vaccine-related and which were not. Therefore, we should know how many of the vaccinees required hospitalisation for some reason within four weeks of the first or second Sputnik-V dose. A re-evaluation of these recordings must decide whether or not they could be related to vaccination.

In summary, the interesting study has limitations that put the results and their interpretation into perspective. Addressing these issues would strengthen the conclusions and could improve the status of the study. Before concluding that Sputnik-V causes only mild side effects, a study design has to be chosen that only includes all vaccinees and follows them over a long period of time.

REFERENCES

1. Ameer, B. R., Akshaya, K. M., Bhargava, M. & Jamal, J. "Adverse events among beneficiaries who received a dose of Sputnik V vaccine at a tertiary care hospital in coastal Karnataka, India." *Indian Journal of Community Medicine*, 48.3 (2023): 418-421.
2. Nabizadeh, E., Honarmandpour, F., Mashhadizade, R. & Honarmandpour, A. "Side effects comparison of coronavirus vaccines among healthcare workers in Shoushtar, Iran." *Clinical Pathology*, 16.0 (2023): 2632010X231166798.
3. Akrami, M., Hosamirudsari, H., Faraji, N., Behnush, B., Goudarzi, F., Hesari, E., Akbarpour, S., Najafi, A. & Nateghi, S. "Sputnik V vaccine-related complications and its impression on inflammatory biomarkers in healthcare providers." *Indian Journal of Medical Microbiology*, 43.0 (2023): 79-84.
4. Safina, D. R., Gismatullina, E. I. & Esin, R. G. "Tserebral'nye venoznye trombozy, assotsiirovannye s COVID-19 [Cerebral venous thrombosis associated with COVID-19]." *Zhurnal Nevrologii i Psikhiatrii imeni S. S. Korsakova*, 122.9 (2022): 128-131.
5. Abdollahi, A., Naseh, I., Kalroozi, F., Kazemi-Galougahi, M. H., Nezamzadeh, M., Sabeti Billandi, S. & Yousefi Zoshk, M. "Comparison of side effects of COVID-19 vaccines: Sinopharm, AstraZeneca, Sputnik V, and Covaxin in women in terms of menstruation disturbances, hirsutism, and metrorrhagia: A descriptive-analytical cross-sectional study." *International Journal of Fertility and Sterility*, 16.3 (2022): 237-243.
6. Ameri, M., Abolmaali, M., Alwedaie, S. M. J., Nabavi, M., Rahimian, N. & Hamidabad, N. M. "Severe persistent eczema in a recipient of the Gam-COVID-Vac vaccine." *European Journal of Case Reports in Internal Medicine*, 9.1 (2022): 003042.
7. Lazaro, L. G., Perea Cossio, J. E., Luis, M. B., Tamagnini, F., Paguay Mejia, D. A., Solarz, H., Fernandez Liguori, N. A. & Alonso, R. N. "Acute disseminated encephalomyelitis following vaccination against SARS-CoV-2: A case report." *Brain, Behavior, and Immunity - Health*, 20.0 (2022): 100439.
8. Hosseini, R. & Askari, N. "A review of neurological side effects of COVID-19 vaccination." *European Journal of Medical Research*, 28.1 (2023): 102.

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