

Side Effects of Sputnik V Vaccine in the Medical Staff of Dedicated COVID-19 Hospital

Dear Editor

The Coronavirus-2019 (COVID-19) pandemic, caused by Severe Acute Respiratory Syndrome-coronavirus-2 (SARS-CoV-2), has been the most important challenge to health systems during the last three years.¹ Vaccination against infectious diseases is the most cost-effective public health intervention, and the importance of vaccination against COVID-19 has been declared by World Health Organization (WHO).² Sputnik V is a heterologous COVID-19 vaccine consisting of two immunogenic components of a recombinant adenovirus type 26 (rAd26) vector and a recombinant adenovirus type 5 (rAd5) vector. Both carry the gene of the full-length SARS-CoV-2 spike glycoprotein (rAd26-S and rAd5-S). They should be injected in two doses separated by at least 21 days interval.^{3, 4} This study was designed to assess the side effects of Sputnik V on healthcare workers.

This prospective cohort study was performed at the biggest hospital in the West Azerbaijan province. We enrolled all hospital staff, who were going to be vaccinated with sputnik V. The protocol was approved by the ethics committee of the university (IR.UMSU.REC.1400.075). Written informed consent was obtained from the participants. Three self-reported forms were used. The first and second forms were filled out 72 hours after the first and second doses of Sputnik V. The last form was completed six months after the second dose. Questions were about the local and systemic side effects after vaccination. The SPSS package (version 24.0; Windows, Chicago, USA) was used for data analysis. Differences between groups were determined by the MacNemar test. $P < 0.05$ was considered statistically significant.

Of 731 hospital staff, 713 completed the study. Eighteen health workers completed less than three forms and were excluded. Participants' age was between 22 to 60 years old. Sex distribution was 358 males versus 355 females. A history of affliction with at least one non-communicable disease (NCD) was reported by 89 participants (12.5%), in which diabetes-mellitus had the highest prevalence with 22 cases (3.1%).

The most common local adverse effect was injection site pain, with 460 (64.5%) and 347 (48.7%) cases at the first and second doses, respectively. The pain was relieved without taking medicine in most cases (83.2% and 87.3% of the first and second doses, respectively).

The most-reported systemic adverse effects were fever (460 cases, 64.5%) and fatigue (312 cases, 45.2%) after the first dose and 332 (46.7%) and 202 (28.3%) cases after the second dose. Systemic symptoms were relieved without taking medication in most cases (71.9% and 77.7% of the fever also 83.3% and 76.2% of the fatigue at the first and second doses, respectively). The difference in the prevalence of systemic side effects after the first and second doses was significant for most items (table 1).

PCR-positive COVID-19 infection between the first dose and the second dose was recorded in 18 cases (2.5%). More than half of the infected participants (55.5%) needed to be hospitalized. However, the rate of PCR-positive COVID-19 infection during six months after the second dose was 66 (9.2% of all participants), and 6 (9% of PCR-positive cases) of them were hospitalized. The rate of hospitalization was significantly lower after receiving the second dose. No case of death due to COVID-19 was recorded during the study.

The prevalence of injection site pain after the first dose was significantly higher in females ($P < 0.001$), attending physicians ($P = 0.009$), and participants with chronic hypertension ($P < 0.001$). Except for the occupational group, the significant differences persisted at the second dose. Fever after the administration of both doses had a significantly higher rate in females ($P = 0.002$) and attending physicians ($P = 0.047$).

Injection site pain, fever, and fatigue were found the most common adverse effects, respectively; and in most cases, these side effects were relieved without taking medications. Besides, the incidence of all listed side effects was lower after the second dose than the first dose of the vaccine. The rate of hospitalization for COVID-19 infection was significantly lower after receiving the second dose.

Table 1: Side effects and immunity of vaccine after the first and second doses

Symptom		Severity	First Dose N (%)	Second Dose N (%)	P value
Local side effects	Pain	No	253 (35)	366 (51)	<0.001
		Mild	382 (53)	303 (42)	<0.001
		Severe	78 (11)	44 (6)	0.001
	Redness and swelling	No	615 (86)	639 (90)	0.05
		Mild	88 (12)	68 (9)	0.08
		Severe	10 (1)	6 (0.8)	0.31
Systemic side effects	Urticaria	No	693 (97)	697 (98)	0.50
		Yes	20 (2.8)	12 (1.7)	0.15
	Angioedema	Angioedema	0 (0)	4 (0.5)	<0.001
	Fever	No	253 (35)	380 (53)	<0.001
		Mild	331 (46)	258 (36)	<0.001
		Severe	129 (18)	75 (10.5)	<0.001
	Flu-like Symptoms	No	605 (85)	641 (90)	0.004
		Mild	96 (13)	68 (9.5)	0.02
		Severe	12 (1.6)	4 (0.5)	0.04
	Gastrointestinal symptoms	No	615 (86)	649 (91)	0.004
		Mild	84 (12)	62 (9)	0.05
		Severe	14 (2)	2 (0.3)	0.002
	Fatigue	No	391 (55)	511 (77)	<0.001
		Mild	260 (36)	154 (22)	<0.001
		Severe	62 (9)	48 (7)	0.16
Hospitalization	Yes	2 (0.3)	0 (0)	0.15	
Immunity	Symptoms of COVID-19 infection and COVID-19 PCR report	No symptom	564 (79)	463 (65)	<0.001
		Mild non-specific Symptoms without the performance of PCR test	115 (16)	141 (20)	0.07
		COVID-19 infection symptoms with the negative PCR test	14 (2)	41 (6)	<0.001
		PCR positive without hospitalization	8 (1.1)	60 (8.4)	<0.001
		PCR positive & Hospitalization	10 (1.4)	6 (0.8)	0.31
		Hospitalization among PCR-positive cases	10 (55.5)	6 (9)	<0.001

In accordance with Gonzalez and colleagues' study, the effectiveness of Sputnik V to prevent hospitalization and death due to COVID-19 was considerable even after the first dose.⁵ In our study, the efficacy of Sputnik V in the prevention of death due to COVID-19 was 100%, and no remarkable side effect was detected.

In conclusion, the side effects of Sputnik V are not persistent, most of them are relieved even without taking medicine. Its adverse effects have a higher prevalence among younger individuals and females.

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Keywords • COVID-19 • Coronavirus • Vaccine • Sputnik V • Efficacy • Side effect

Authors' Contribution

A.V, M.H, C.D, A.N, and A.M contributed to the conception and design, acquisition, analysis, or interpretation of data. All authors contributed to drafting and revising the manuscript critically for important intellectual content. All authors have read and approved the final manuscript and agree to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Aida Varghaei¹, MD;  Mohammad Heidari², MD; Chiman Daneshyar¹, MD; Armin Nouri¹, MD; Amir Mikaeilvand¹, MD 

¹Clinical Research Development Unit, Imam Khomeini Hospital, Urmia University of Medical Sciences, Urmia, Iran;

²Social Determinants of Health Research Center, Clinical Research Institute, Urmia University of Medical Science, Urmia, Iran

Correspondence:

Amir Mikaeilvand, MD;

Department of Cardiology, Taleghani Hospital, Kashani St., Postal code: 57158-43401, Urmia, Iran

Tel: +98 44 33465371

Fax: +98 44 33444591

Email: a.mkvnd.cardio@gmail.com

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