Shiraz E-Med J. 2021 December; 22(12):e116278. doi: 10.5812/semj.116278.

Published online 2021 July 31. **Letter**

Adverse Effects of Gam-COVID-Vac (Sputnik V) Vaccine

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Received 2021 May 16; **Revised** 2021 June 07; **Accepted** 2021 June 10.

Keywords: Gam-COVID-Vaccine, COVID-19, Adverse Reactions

Dear Editor,

The COVID-19 pandemic caused by Coronavirus-2 Acute Respiratory Syndrome (SARS-CoV-2) has incurred detrimental effects on health systems (1, 2). Given the desperate need to develop vaccines as quickly as possible, much effort has been made to develop and manufacture vaccines to prevent the transmission of COVID-19 to healthy individuals (3-5). Numerous studies have focused on medication therapy and patient recovery; however, vaccination will significantly affect the mortality rate by reducing infection with COVID-19 (3-9). Nonetheless, like any other compound, vaccines can also cause local and systemic complications (4-12).

The present study enrolled 100 healthcare providers of Shahid Mohammadi Hospital in Bandar Abbas city who had received the first dose of Gam-COVID-Vac (Sputnik V). The study was approved by the Ethics Committee of Hormozgan University of Medical Sciences (IR.HUMS.REC.1399.541). An online questionnaire was developed to assess demographic details and local and systemic complications of vaccination. These individuals were assessed at three time points: the first, third, and seventh days after vaccination in terms of local complications, including pain at the injection site, warmth, redness, and swelling, and systemic complications, including weakness and fatigue, headache, myalgia, bone pain, arthralgia, palpitation, diarrhea, nausea and vomiting, anorexia, coughing, sneezing, sore throat, runny nose, fever, chills, and urticaria. The participants were also followed for serious complications or mortality during one month after the first dose of vaccination.

Among the 100 participants studied, 10 had a history of infection with COVID-19 in the past six months. Among these 10 individuals, weakness and lethargy were observed in six individuals on day one, three individuals on day three, and one individual on day seven. Headache was reported by five individuals on day one, and one individual on day three. Myalgia was observed in eight individuals on day one, five individuals on day three, and two individuals on day seven. This complication was more frequent in participants with a history of COVID-19 compared to those without a history of COVID-19 in the past six months (80 vs. 53%). Bone pain was reported by eight individuals on day one, three individuals on day three, and one individual on day seven. Generally, this complication had a higher frequency percentage in those with a history of COVID-19 compared to those without it (80 vs. 43%). Anorexia was reported by three individuals on day one and one individual one day three (30% in group with a history of COVID-19 vs. 12% in group with no history of COVID-19).

Our results showed that 42% of the participants suffered from headaches on day one, 18% on day three, and 5% on day seven. Headache and asthenia were among the most common complications of the vaccine in a study by Logunov et al., in which a similar vaccine to that in the present study was used (5). The present study exhibited more cases of severe myalgia (Table 1). In another study, Zhu et al. reported myalgia in 18% of patients after vaccination with a similar dose (12).

Regarding the relationship between the history of COVID-19 in the past six months and vaccination complications, only myalgia and rhinorrhea on day one had a significant relationship with a positive history of COVID-19 in those receiving vaccination, but no significant relation-

Table 1. Local and Systemic Complications of Gam-COVID-Vaccine on Days One, Three, and Seven

Symptoms	Day 1				Day 3				Day 7			
	Asymptomatic	Mild	Moderate	Sever	Asymptomatic	Mild	Moderate	Sever	Asymptomatic	Mild	Moderate	Sever
Weakness	53	13	17	17	70	19	9	2	93	5	1	1
Headache	58	11	3	4	82	11	3	4	95	2	2	1
Myalgia	47	11	23	19	67	16	14	3	92	6	1	1
Bone pain	57	10	16	17	78	10	11	1	94	5	1	0
Palpitation	84	4	6	6	91	3	6	0	96	3	1	0
Diarrhea	95	3	2	0	93	5	2	0	98	1	1	0
Nausea and Vomiting	88	6	2	4	93	2	3	2	96	2	0	2
Anorexia	77	9	11	3	88	7	5	0	98	2	0	0
Rhinorrhea	93	5	2	0	96	2	1	1	97	1	2	0
Sore throat	91	5	4	0	92	6	2	0	96	2	1	1
Fever	68	20	5	7	91	8	1	0	100	0	0	0
Chills	64	11	10	15	91	6	3	0	99	1	0	0
Urticaria	95	4	1	0	99	1	0	0	100	0	0	0
Warmth	83	6	11	0	91	6	3	0	100	0	0	0
Redness	93	7	0	0	97	3	0	0	100	0	0	0
Swelling	92	4	3	1	98	2	0	0	100	0	0	0

ship was noted between this variable on other days (days three and seven). The history of infection with COVID-19 had no significant association with other local complications.

With regard to adenovirus type-5 vaccine, a higher percentage of local and systemic complications were reported in the present study than in previous studies (5, 12). This difference can probably be attributed to the geographical, genetic, or sample size differences. Pain at the injection site was also the most common complication in inactivated SARS-COV-2 vaccines (11). Regarding mRNA-1273 vaccines, pain at the injection site was most frequently reported (10). Fatigue, headache, myalgia, and chills were the most common systemic complications of mRNA-1273-based COVID-19 vaccines (10). With regard to the relationship of history of COVID-19 and post-vaccination complications, rhinorrhea on day one, sneezing on day one, and sneezing on day three were observed in those with a history of COVID-19, respectively 9.5, 23, and 21 times higher than those without such a history. Although the history of COVID-19 was not investigated in their study, Baden et al. indicated that those who had COVID-19 at the time of vaccination experienced fewer complications than those who did not have COVID-19 (10).

In the present study, weakness, myalgia, headache, and pain at the injection site were the most frequently reported adverse reactions among people who received the first dose of Gam-COVID-vac. No serious complications or mortality was seen during the one-month follow-up.

Footnotes

Authors' Contribution: HR.S and M.KJ contributed in conception, design, and statistical analysis. Other authors contributed in data collection and manuscript drafting. M.KJ supervised the study. All the authors approved the final version of the manuscript.

Conflict of Interests: The authors have no conflicts of interest.

Ethical Approval: The present study was approved by the Ethics Committee of Hormozgan University of Medical Sciences (IR.HUMS.REC.1399.541).

Funding/Support: Financial support was received from the Clinical Research Development Center of Hormozgan University of Medical Sciences, Bandar-Abbas, Iran.

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