CLINICAL AND EXPERIMENTAL VACCINE RESEARCH

Clin Exp Vaccine Res 2023;12:25-31
https://doi.org/10.7774/cevr.2023.12.1.25
pISSN 2287-3651 • eISSN 2287-366X

Adverse events following immunisation with the first dose of sputnik V among Iranian health care providers

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Received: November 7, 2021
Revised: January 19, 2022
Accepted: December 22, 2022

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No potential conflict of interest relevant to this article was reported.

Purpose: Since late 2019, the novel coronavirus disease has been a global concern, and alongside preventive strategies, including social distancing and personal hygiene, vaccination is now the primary hope for controlling the pandemic. Sputnik V is an adenovirus vector vaccine used against coronavirus disease 2019 (COVID-19) among Iranian health care providers, and there is a lack of information regarding the Adverse Events Following Immunisation (AEFI) by Sputnik V among the Iranian population. The present study aimed to evaluate AEFI by Sputnik V vaccine among Iranian population.

Materials and Methods: Every member of the Islamic Republic of Iran Medical Council received their first dose of the Sputnik V vaccine in Mashhad (Iran) and was referred to receive their second dose enrolled in the present study and asked to fill an English language checklist asking about development of any AEFI following immunization with the first dose of Sputnik V vaccine.

Results: A total number of 1,347 with a mean±standard deviation age of 56.2±9.6 years filled the checklist. Most of the participants were male (838 [62.2%]). The present study demonstrated that immunization with the first dose of Sputnik V results in at least one AEFI in 32.8% of the Iranian medical council members. Most of the AEFI was related to musculoskeletal symptoms, including myalgia. By considering the age of 55 years as a cut-off point, individuals younger than 55 had a higher rate of AEFI (41.3% vs. 22.5%, $p=0.0001$). Male gender, use of analgesics, beta-blockers, and previous COVID-19 infection have a lower chance of developing AEFI ($p<0.05$).

Conclusion: The present study demonstrated that most of the AEFI was related to musculoskeletal symptoms, including myalgia, and older individuals, male gender and those receiving analgesics and beta-blockers were less likely to develop AEFI following immunization with the first dose of Sputnik V.

Keywords: Immunization, Vaccination, COVID-19

Introduction

Severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection causes the novel coronavirus disease 2019 (COVID-19) is considered a global health issue that leads to considerable mortality worldwide [1]. While there is no definite cure available for the treatment of COVID-19, prevention strategies are the most promising management strategy in every country [2]. Alongside considering preventive strategies including social distancing and personal hygiene, vaccination is now the hope for controlling the pandemic. There are different types of COVID-19 vaccines, including mRNA-based

vaccines, subunit vaccines, viral vector vaccines, and whole pathogen vaccines [2]. Regarding the immediate need for controlling the pandemic, health care organizations in different regions of the world approved different COVID-19 vaccines for clinical use among their populations [1]. Each of the COVID-19 vaccines has its unique efficacy and side effects. Adenovirus vector-based vaccines are among the COVID-19 vaccines with high efficacy after their first dose with lesser side effects than mRNA-based vaccines [2]. Sputnik V is a COVID-19 vaccine applied in two separate doses at least 3 weeks apart, announced in August 2020. Sputnik V carries two recombinant adenovirus vectors coding SARS-CoV-2 spike protein. The first dose contains a recombinant adenovirus type 26 vector, and the second contains a recombinant adenovirus type 5 vector [1]. A recent network meta-analysis demonstrated that Sputnik V is a clinically effective vaccine for protecting against COVID-19 and inducing synthesis of SARS-CoV-2 neutralizing antibodies (standardized mean difference >1.3) [3]. The most recent report of the Sputnik V vaccine demonstrated that the vaccine's efficacy is 91.6% [4]. However, in some European countries, Sputnik V is the least trusted vaccine according to the study by Rzymski et al. [5], but in some other countries, including Iran, the vaccine is considered among the first approved types of COVID-19 vaccine for use among health care providers. Among different available vaccines worldwide, Iran approved the administration of Sinopharm, AstraZeneca, and COVIran Barekat vaccines in the early phases of the pandemic and is recently developing ten COVID-19 jabs [6,7]. While severe side effects of COVID-19 vaccines are considered to be limited to very small population groups, the side effects are not been widely studied after the widespread use of Sputnik V. Early results of the Sputnik V vaccine demonstrated that the vaccine could successfully induce the development of SARS-CoV-2 antibody in 76 individuals without any serious adverse event. The phase I/II trial on the Sputnik V vaccine demonstrated that more than half of patients experienced mild adverse effects of vaccination which was "pain at the injection site" [8]. The subsequent trial on 22,000 individuals in Moscow demonstrated no moderate to severe adverse events during three weeks of receiving the first dose of vaccine, and 94% of participants reported mild symptoms [9]. The present study aimed to evaluate Adverse Events Following Immunisation (AEFI) by Sputnik V in health care workers registered in the Iranian medical council of Mashhad, Iran.

Materials and Methods

The present cross-sectional study was approved by the Academic Center for Education, Culture, and Research (ACECR) Khorasan-Razavi ethic committee (IR.ACECR.JDM.REC.1399.011) and took place at Mashhad Medical Council in May 2021. Every member of the Islamic Republic of Iran Medical Council received their first dose of the Sputnik V vaccine in Mashhad (Iran) and was referred to receive their second dose enrolled in the present study and asked to fill an English language checklist after giving written informed consent. The checklist consists of four main parts. The first part contained questions about the demographic data, including age, gender, and nationality. Moreover, the participants were asked about their previous COVID-19 infection before the first dose or after Sputnik V. The second part contained questions about any underlying medical illness grouped based on the International Classification of Diseases, 11th Revision disease categories. The third part contained questions about the drug categories based on the generic drug category provided by the united states food and drug administration. The last part contained questions about the AEFI based on the previous reports on COVID-19 vaccines and grouped according to the time of occurrence.

The study data were analyzed by IBM SPSS software ver. 20.0 (IBM Corp., Armonk, NY, USA), and p-value >0.05 considered a significant result. The relationship between AEFI and underlying diseases or medication history was evaluated by the chi-square test. Forward stepwise binary logistic regression was used to evaluate the effect of underlying diseases, history of previous COVID-19, and medication on the development of AEFI.

Results

A total number of 1,347 individuals filled out the study checklist. All the participants were Iranian with a mean±standard deviation age of 56.2±9.6 years. Most of the participants were male (838 [62.2%]). While most of the participants were not previously infected by SARS-CoV-2 (897 [66.6%]), 143 individuals (10.6%) refused to report their previous infection status. Most of the patients were before vaccination. Only nine participants (0.7%) had confirmed COVID-19 infection after receiving the first dose of the vaccine, and 213 participants (15.8%) refused to answer this question as they were not tested for the infection but have clinical manifestations of COV-

 https://doi.org/10.7774/cevr.2023.12.1.25

Table 1. Frequency of drugs used by the study population

Drug category	Using drugs	Not using drugs
Analgesics	33 (2.4)	1,314 (97.6)
Antianxiety drugs	14 (1.0)	1,332 (98.9)
Anticoagulants and thrombolytics	47 (3.5)	1,299 (96.4)
Antidiarrheas	1 (0.1)	1,345 (99.9)
Antihistamines	15 (1.1)	1,331 (98.8)
Antipsychotics	1 (0.1)	1,346 (99.9)
Barbiturates	0	100 (100.0)
Cold cures	0	100 (100.0)
Cytotoxics	0	100 (100.0)
Expectorants	1 (0.1)	1,346 (99.9)
Immunosuppressives	4 (0.3)	1,343 (99.7)
Sedetives	6 (0.4)	1,341 (99.6)
Hormones	17 (1.3)	1,330 (98.7)
Anticids	52 (3.9)	1,295 (96.1)
Antibacterials	7 (0.5)	1,340 (99.5)
Anticonvalsants	7 (0.5)	1,340 (99.5)
Antiemetics	2 (0.1)	1,345 (99.9)
Antihypertensives	119 (8.8)	1,228 (91.2)
Antipyretics	0	1,347 (100.0)
Beta-blockers	72 (5.3)	1,275 (94.7)
Corticosteroids	8 (0.6)	1,339 (99.4)
Decongestants	1 (0.1)	1,346 (99.9)
Laxatives	7 (0.5)	1,340 (99.5)
Vitamins	143 (10.6)	1,204 (89.4)
Antiarrhythmics	12 (0.9)	1,335 (99.1)
Antibiotics	7 (0.5)	1,340 (99.5)
Antidepressants	23 (1.7)	1,324 (98.3)
Antifungals	1 (0.1)	1,346 (99.9)
Anti-inflamations	16 (1.2)	1,331 (98.8)
Antivirals	1 (0.1)	1,346 (99.9)
Bronchodilators	6 (0.4)	1,341 (99.6)
Cough suppressants	0	1,347 (100.0)
Diuretics	29 (2.2)	1,318 (97.8)
Hypoglicemics (oral)	38 (2.8)	1,309 (97.2)
Muscle relaxants	2 (0.1)	1,345 (99.9)
Sleep drugs	18 (1.3)	1,329 (98.7)

Values are presented as number (%).

ID-19. The rest of the population (1,125 [83.5%]) either did not have COVID-19 symptoms or tested negative for the infection. Vitamins (19.6%) and antihypertensive drugs (8.8%) were the most commonly used drugs (3.5%) (Table 1). Receiving analgesics (p=0.013), anticonvulsants (p=0.042), beta-blockers (p=0.020), vitamins (p=0.001), and antidepressants (p=0.023) were related to the development of AEFI. Binary logistic regression revealed that among the medications used by the study population, using analgesics (p=0.008, Exp(B)=0.356), vitamins (p=0.010, Exp(B)=0.600), antidepressants (p=0.030, Exp(B)=0.355), and diuretics (p=0.009, Exp(B)=3.94) were correlated with development of AEFI. Endocrine, nutritional or metabolic diseases (7.1%), and diseases of the circulatory system (3.1%) were the most common underlying diseases among the study population (Table 2). Among the underlying diseases, only having a nervous system disorder was correlated with the development of AEFI (p=0.035).

Table 2. Frequency of the underlying diseases among the study population

Underlying diseases	Positive	Negative
Infectious or parasitic disease	2 (0.1)	1,345 (99.9)
A disease of the blood or blood-forming organs	11 (0.8)	1,336 (99.2)
Endocrine, nutritional or metabolic diseases	96 (7.1)	1,251 (92.9)
A disease of the nervous system	9 (0.7)	138 (99.3)
A disease of the ear or mastoid process	8 (0.6)	1,339 (99.4)
A disease of the respiratory system	13 (1.0)	1,334 (99.0)
A disease of the skin	10 (0.7)	1,337 (99.3)
Conditions related to sexual health	0	1,347 (100.0)
Mental, behavioral, or neurodevelopmental disorders	1 (0.1)	1,346 (99.9)
The disease of the musculoskeletal system or connective tissue	10 (0.7)	1,337 (99.3)
Neoplasms	15 (1.1)	1,332 (98.9)
A disease of the immune system	15 (1.1)	1,332 (98.9)
Sleep-wake disorders	9 (0.7)	1,338 (99.3)
A disease of the visual system	12 (0.9)	1,335 (99.1)
A disease of the circulatory system	42 (3.1)	1,305 (96.9)
A disease of the digestive system	32 (2.4)	1,315 (97.6)
A disease of the genitourinary system	8 (0.6)	1,339 (99.4)

Values are presented as number (%).

Among the study population, 906 individuals (67.26%) did not report any AEFI. By considering the age of 55 years as a cut-off point, individuals younger than 55 had a higher rate of AEFI (41.3% versus 22.5%, p=0.0001). Males had significantly lower AEFI than females (27% versus 41%, p=0.0001). In contrast to males, females experienced more chills (8.2% versus 4.6%, p=0.009), fever (11.8% versus 7.4%, p=0.007), fatigue (13.9% versus 8.2%, p=0.001), injection site adverse effects (4.5% versus 1.9%, p=0.008), skin and connective tissue adverse events (1.7% versus 0.4%, p=0.041), musculoskeletal system adverse effects (20.2% versus 16%, p=0.048), nervous system adverse effects (17.9% versus 8.3%, p=0.0001), and blood and lymphatic system adverse effects (1.9% versus 0.6%, p=0.033). As presented in Fig. 1, the most common side effects in each main AEFI category include blood and lymphatic system, nutrition and metabolism, nervous system, musculoskeletal system, skin, and connective tissue, injection

Table 3. The frequency of the adverse events based on the time of occurrence

Adverse events	No complication	4 Hours post-vaccination	1–3 Days post-vaccination	4–28 Days post-vaccination
Injection site adverse events				
Injection site				
Prurits	1,307 (97.0)	13 (1.0)	23 (1.7)	3 (0.2)
Bruising	1,320 (98.0)	6 (0.4)	19 (1.4)	1 (0.1)
Swelling	1,295 (96.1)	9 (0.7)	40 (3.0)	2 (0.1)
Erythema	1,295 (96.1)	11 (0.8)	38 (2.8)	2 (0.1)
Tenderness	1,104 (82.0)	61 (4.5)	151 (11.2)	10 (0.7)
Pain	1,003 (74.5)	93 (6.9)	209 (15.5)	10 (0.7)
Warmth	1,284 (95.3)	19 (1.4)	36 (2.0)	4 (0.3)
Induration	1,301 (96.6)	8 (0.6)	33 (2.4)	3 (0.2)
COVID-19 arm	1,342 (99.6)	0	4 (0.3)	1 (0.1)
Other adverse events				
Blood and lymphatic system				
Lymphadenopathy	1,332 (98.9)	3 (0.2)	7 (0.5)	5 (0.4)
Lymphopenia	1,346 (99.9)	0	1 (0.1)	0
Nutrition and metabolism				
Decreased apetite	1,321 (98.1)	3 (0.2)	20 (1.5)	3 (0.2)
Nausea	1,314 (97.6)	9 (0.6)	19 (1.4)	5 (0.4)
Vomiting	1,336 (99.2)	2 (0.1)	8 (0.6)	1 (0.1)
Diarrhea	1,325 (98.4)	5 (0.4)	12 (0.9)	5 (0.4)
Abdomina pain	1,325 (98.4)	1 (0.1)	16 (1.2)	5 (0.4)
Nervious system				
Headache	1,184 (87.9)	47 (3.5)	96 (7.1)	14 (1.0)
Dizziness	1,307 (97.0)	10 (0.7)	24 (1.8)	3 (0.2)
Bell's palsy	1,344 (99.8)	1 (0.1)	1 (0.1)	1 (0.1)
Musculuskeletal system				
Myalgia	1,109 (82.3)	65 (4.8)	156 (11.6)	13 (1.0)
Arthralgia	1,275 (94.7)	14 (1.0)	47 (3.5)	11 (0.8)
Skin and connective tissue				
Hyperhydrosis	1,334 (99.0)	4 (0.3)	8 (0.6)	1 (0.1)
Prurits	1,338 (99.3)	5 (0.4)	4 (0.3)	0
Rash	1,334 (99.0)	3 (0.2)	3 (0.2)	4 (0.3)
Thromboembolic events				
Cerebral venous sinus thrombosis	1,343 (99.7)	0	0	4 (0.3)
Splanchnic vein thrombosis	1,344 (99.8)	1 (0.1)	1 (0.1)	1 (0.1)
Arterial thrombosis	1,344 (99.8)	1 (0.1)	1 (0.1)	1 (0.1)
New-onset, worsening, severe or persistent headache plus blurred vision	1,342 (99.6)	0	4 (0.3)	1 (0.1)
Shortness of breath	1,339 (99.4)	0	4 (0.3)	4 (0.3)
Chest pain	1,339 (99.4)	1 (0.1)	5 (0.4)	2 (0.1)
Leg swelling	1,343 (99.7)	1 (0.1)	2 (0.1)	1 (0.1)
Persistent abdominal pain	1,343 (99.7)	0	3 (0.2)	1 (0.1)
Confusion	1,337 (99.3)	1 (0.1)	4 (0.3)	2 (0.1)
Seizure	1,341 (99.6)	2 (0.1)	3 (0.2)	1 (0.1)
Unusual skin bruising or petechiae	1,342 (99.6)	1 (0.1)	2 (0.1)	2 (0.1)
Fatigue	1,206 (89.5)	24 (1.8)	108 (8.0)	6 (0.4)
Malaise	1,232 (91.5)	26 (1.9)	84 (6.2)	4 (0.3)
Fever	1,224 (90.9)	31 (2.3)	88 (6.5)	4 (0.3)
Chills	1,266 (94.0)	22 (1.6)	57 (4.2)	2 (0.1)
Influenza like symptoms	1,274 (94.6)	14 (1.1)	55 (4.1)	4 (0.3)

Values are presented as number (%).

 https://doi.org/10.7774/cevr.2023.12.1.25

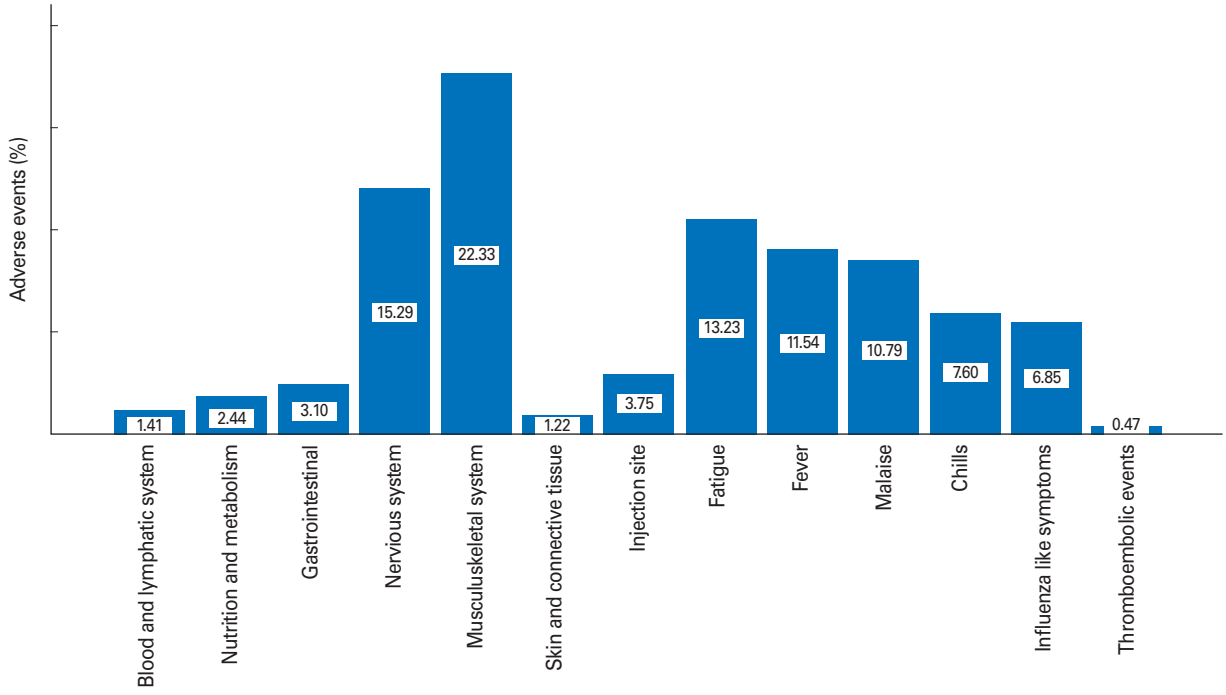

Fig. 1. Percent of the primary vaccination adverse events.

Table 4. frequency of the adverse events reported within the first 30 minutes of vaccination

Variable	15–30 Minutes post-vaccination
Injection site adverse events	
Injection site prurits	1 (0.1)
Injection site bruising	1 (0.1)
Injection site swelling	1 (0.1)
Injection site erythema	1 (0.1)
Injection site tenderness	21 (1.6)
Injection site pain	32 (2.4)
Injection site warmth	4 (0.3)
Injection site induration	2 (0.1)
Other adverse events	
Headache	6 (0.4)
Vasovagal reaction	25 (1.8)
Hypersensetivity reactions	12 (0.8)
Dizziness	3 (0.2)
Myalgia	4 (0.3)
Rash	3 (0.2)
Fatique	3 (0.2)
Malasie	1 (0.1)
Confusion	3 (0.2)

Values are presented as number (%).

site, thromboembolic events, as well as fatigue, malaise, fever, chills, and influenza-like symptoms were myalgias (21.56%). Pain (18%) and tenderness (25.5%) were the most common adverse event at the injection site, and a headache was the most common (12.1%) general adverse event (Table 3). The most common adverse event within 30 minutes of vaccination was the vasovagal reaction (1.8%) and injection site pain (2.4%) (Table 4). A binary logistic regression demonstrated that individuals older than 55 are less likely to develop AEFI ($p=0.0001$). Moreover, male gender, use of analgesics, beta-blockers, and previous COVID-19 infection have a lower chance of developing AEFI ($p<0.05$) (Table 5).

Discussion

The present study demonstrated that with immunization by the first dose of Sputnik V among the Iranian population, 32.8% developed at least one AEFI. Individuals older than 55 years of age, male gender, and those receiving beta-blockers, or analgesics are less likely to develop AEFI.

Emergency management of COVID-19 forced global health care systems to early use of even COVID-19 vaccines not completed their phase 3 clinical trials to control the pandemic. Among the available COVID-19 vaccines used in Iran, the Sputnik V vaccine has been used for the vaccination of health care workers among the Iranian population. The technology of the Sputnik V vaccine is reported to be similar to Both Johnson & Johnson and AstraZeneca vaccines. Therefore, it has been suggested that Sputnik V may have the same rare

Table 5. Binary regression model for the development of vaccination adverse events

Variable	B	SE	Wald	p-value	Exp (B)
Age	-0.897	0.133	45.773	0.0001	0.408
Gender	-0.569	0.125	20.716	0.0001	0.566
Analgesics	-1.308	0.387	11.456	0.001	0.270
Beta-blockers	-0.772	0.258	8.968	0.003	0.462
Previous COVID-19	-0.015	0.003	23.801	0.0001	0.985

SE, standard error; COVID-19, coronavirus disease 2019.

side effects as the AstraZeneca vaccine, including thrombosis [10]. However, in Russia, the Gamaleya National Center of Epidemiology and Microbiology denied such possible side effects [10]. Seven participants (0.51%) reported Vaccine-Induced Immune Thrombotic Thrombocytopenia in our population, including cerebral venous sinus thrombosis and splanchnic vein thrombosis. It has been reported that 14% of individuals receiving the Sputnik V vaccine may experience side effects [11]. Weakness and muscle pain are among the common side effects which may develop during the first day of vaccination [11]. Pagotto et al. [12] evaluated the side effects of Sputnik V in 707 health care workers in Argentina.

In contrast to our population, their participants were younger (35 years versus 56 years), and 4.9% of their patients had previous COVID-19. They reported that 71.3% of their population had events supposedly attributable to vaccination or immunization, much higher than our study (32.8%) [12]. They reported that 3 (0.4%) of their patients tested positive for COVID-19, which was lower than our population (nine individuals [0.6%]). Similar to their study, we demonstrated that individuals older than 55 had a lower rate of events [12]. Montalti et al. [13] reported that 16.4% of individuals in the Republic of San Marino receiving the first dose of Sputnik V had local and systemic reactions. Injection site pain (24.8%) was the most common injection site AEFI. The most common systemic symptoms were asthenia (23.8%) and headache (18.5%). Similar to a study, they demonstrated that most AEFI occurs in younger individuals [13].

In conclusion, adenovirus-based vaccines, including Sputnik V, are favorable to other COVID-19 vaccines as they do not need to be stored in cold rooms at -80°C [14]. Moreover, the vaccine has been considered among the inexpensive COVID-19 vaccines and is reported to have 100% efficacy in preventing COVID-19–related death [14]. Our study demonstrated that AEFI develops in less than one-third of individuals receiving the first dose of Sputnik V. However, regarding the novel variants of the SARS-CoV-2, the widespread use of Sputnik V should be reconsidered by health care organizations. Although Sputnik V had high efficacy in producing neutralizing antibodies against SARS-CoV-2, the vaccine's efficacy has been questioned by introducing novel variants, including the B.1.351 variant [14,15].

Study limitations

One of the main limitations of the present study is that we did not evaluate the neutralizing activity induced by Sputnik V in our population [14]. Moreover, our study relied on the self-reporting of symptoms, and some of the answers may not reflect the actual side effects of vaccination.

The present study's main strength is considering medical staff as the target population. This group of individuals is more alert of developing any side effects and could complete the checklist more specifically. Moreover, the present study grouped the clinical adverse effect following vaccination on the Iranian population, which has not been widely studied the clinical adverse effect following Sputnik V immunization.

Conclusion

The present study demonstrated that immunization with the first dose of Sputnik V results in AEFI in 32.8% of Iranian members of the Iranian medical council. Most of the AEFI was related to musculoskeletal symptoms, including myalgia. Moreover, older individuals, male gender, and those receiving analgesics and beta-blockers were less likely to develop AEFI following immunization with the first dose of Sputnik V.

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