

Side effects after COVID-19 vaccination: a comparison between the most common available vaccines in Iran

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ABSTRACT

Background and Objectives: Since the coronavirus disease 2019 (COVID-19) pandemic began, several vaccines have been manufactured to subside it. This study aimed to determine the prevalence of side effects after injecting common COVID-19 vaccines available in Iran.

Materials and Methods: This cross-sectional study was accomplished on Shahid Beheshti University of Medical Sciences (Tehran, Iran) employees during January and September 2022. Eligible participants were selected based on the simple random method and interviewed about side effects after injecting COVID-19 vaccine.

Results: The mean age of 656 participants was 38.03 ± 9.53 years, and 453 (69.1%) were female. The prevalence of post-vaccination side effects was higher after receiving the first dose (53.2%) than the second (35.9%) and third (49.4%) doses. Across all three vaccine doses, the overall proportion of side effects was higher following AstraZeneca than the others. The most common side effect after the first dose of the vaccine was myalgia (41.9%), followed by fever (36.6%), chills (31.6%), local reactions (27.0%), headache (25.5%), and sweating (21.6%). People experienced mainly myalgia (23.3%) and fever (20.3%) after injecting the second dose of the vaccine. Additionally, the participants had myalgia (37.2%), fever (30.8%), chills (29.2%), local reactions (26.0%), and headache (24.4%) after the third dose of the vaccine.

Conclusion: AstraZeneca had a higher proportion of post-vaccination adverse effects than Sputnik V, Pastocovac, and Sinopharm. The most common side effects were flu-like syndrome and local reactions at the injection site. Furthermore, people rarely experienced life-threatening side effects. Thus, the available COVID-19 vaccines in Iran are safe.

Keywords: Adverse effects; COVID-19 vaccines; Iran; Safety; SARS-CoV-2

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INTRODUCTION

In late 2019, severe acute respiratory syndrome coronavirus-2 (SARS-CoV-2), the etiologic agent of COVID-19, emerged in Wuhan, China. It spread rapidly worldwide and claimed the lives of many infected persons. Subsequently, on March 11, 2020, the World Health Organization (WHO) declared that the world is facing a novel pandemic (1, 2). As a result, preventive and therapeutic measures were adopted simultaneously to deal with this health threat. Despite conducting numerous clinical trials, no drug has been approved to treat COVID-19 patients. Thus, authorities recommended several preventive strategies, for instance, social distancing, quarantine, mask-wearing, avoiding dispensable travels, frequent hand washing, and vaccination (3, 4).

During the last three years, several vaccines have been developed to protect against SARS-CoV-2 (5). They are manufactured using different platforms, for instance, mRNA (Pfizer-BioNTech), viral vector (AstraZeneca, Sputnik V, and Pastocovac), inactivated virus (Sinopharm), and protein subunit (Novavax) (6). People experience a broad spectrum of side effects after COVID-19 vaccination, from transient mild local and systemic reactions to rare, life-threatening conditions (e.g., anaphylaxis and thromboembolic events) (7, 8). Vaccine-induced side effects are the basis for the hesitation of the subsequent doses of vaccines (9). Vaccine hesitancy is challenging in controlling the COVID-19 pandemic by reducing vaccine coverage (10).

In Iran, the most available vaccines against SARS-CoV-2 are AstraZeneca, Sinopharm, and Sputnik V (11). So, this study aimed to determine the prevalence of side effects after injecting the above vaccines.

MATERIALS AND METHODS

Study design and participants. This cross-sectional study was conducted on the employees of Shahid Beheshti University of Medical Sciences (Tehran, Iran) during January and September 2022. The inclusion criteria were: employees of Shahid Beheshti University of Medical Sciences; willingness to participate in the study; age above 18 years; and has received at least one dose of COVID-19 vaccine (either Sputnik V, AstraZeneca, or Sinopharm for the first dose). Also, to facilitate data analysis, we excluded

participants vaccinated with uncommon vaccines (Barekat and SpikoGen) for the third dose. Using Cochran's formula and considering the prevalence (P) of fever=40.6% (12), $\alpha=5\%$, $d=P/10$, and 15% drop in the participants, the sample size was estimated to be 647. First, we obtained information on the study population from the university. Then, samples were selected from eligible individuals based on the simple random sampling method.

Study instrument and data collection. Five infectious disease specialists designed a research-made checklist to assess vaccine-related side effects. It comprised of the following sections: 1) baseline characteristics of participants (age, gender, history of underlying diseases, vaccine type per each dose); 2) side effects after each dose of vaccination (hypersensitivity, flu-like symptoms, systemic side effects, and local reactions such as pain, redness, and swelling). After completing the informed consent form, all individuals were interviewed based on the checklist. A research team member recorded data in an online platform made by the Vista software group.

Statistical analysis. Data were processed using SPSS version 18.0 with a significant level below 0.05. Variables were described as frequency, percentage, mean, and standard deviation. Also, values were compared between groups using the Chi-square or Fisher's exact tests as indicated.

Ethical considerations. This study was approved by the research ethics committee of Shahid Beheshti University of Medical Sciences (IR.SBMU.RE-TECH.REC.1400.507). All steps of the study were performed following the Helsinki declaration.

RESULTS

Baseline characteristics of participants. The mean age of 656 participants was 38.03 ± 9.53 years (range: 19-70), 453 were female (69.1%) and 203 were male (30.9%). Regarding occupation type, 60.2% were healthcare workers, and the others were non-healthcare workers (39.8%). The most common underlying disease was diabetes mellitus (2.1%), followed by malignancy (0.9%) and asthma (0.5%). Furthermore, 16 individuals (2.4%) were immunocompromised. Nobody had history of renal diseases, hepatic diseases,

or organ transplantation. Fig. 1 depicts the COVID-19 vaccines that were administered at each dose. Among the studied population, 656, 615, and 438 people received the vaccine's first, second, and third doses, respectively.

Side effects after the first dose of the vaccine. After the first dose of the vaccine, 53.2% of the participants experienced at least one side effect. The overall proportion of side effects was significantly higher among people vaccinated with AstraZeneca (85.6%), compared with Sputnik V (51.1%) and Sinopharm (26.4%) ($P < 0.001$). The most common side effect after the first dose of the vaccine was myalgia (41.9%), followed by fever (36.6%), chills (31.6%), local reactions (27.0%), headache (25.5%), sweating (21.6%). Table 1 shows the prevalence of vaccine-related side effects after the first dose in detail and one-by-one comparisons between vaccine types.

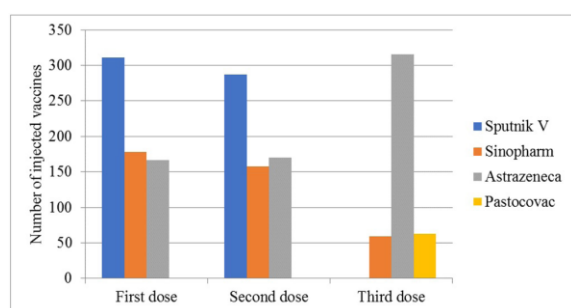


Fig. 1. Administered COVID-19 vaccines at each dose

Side effects after the second dose of the vaccine. After the second dose of the vaccine, 35.9% of the participants experienced at least one side effect. Overall proportion of side effects was significantly higher among people vaccinated with AstraZeneca (48.2%), compared with Sputnik V (37.6%) and Sinopharm (19.6%) ($P < 0.001$). The most common side effect after the second dose of the vaccine was myalgia (23.3%), followed by fever (20.3%), chills (17.9%), local reactions (17.4%), headache (15.0%), and sweating (11.1%). Table 2 presents the prevalence of vaccine-related side effects after the second dose in detail and one-by-one comparisons between vaccine types.

Side effects after the third dose of the vaccine. After the third dose of the vaccine, 49.4% of the participants experienced at least one side effect. The overall proportion of side effects was significantly higher

among people vaccinated with AstraZeneca (57.8%), compared with Pastocovac (34.9%) and Sinopharm (20.3%) ($P < 0.001$). The most common side effect after the third dose of the vaccine was myalgia (37.2%), followed by fever (30.8%), chills (29.2%), local reactions (26.0%), headache (24.4%), and sweating (18.9%). Table 3 demonstrates the prevalence of vaccine-related side effects after the third dose in detail and one-by-one comparisons between vaccine types.

DISCUSSION

This study investigated the prevalence of side effects after the injection of common COVID-19 vaccines available in Iran. Our findings revealed that many participants experienced at least one side effect after vaccination, with the highest and lowest proportions after AstraZeneca and Sinopharm vaccines. Furthermore, the most common side effects after all doses of vaccines were myalgia, fever, chills, local reactions, headache, and sweating.

Zare et al. reported that the overall proportion of side effects was higher among people vaccinated with AstraZeneca (88.8%) compared with Sputnik V (81.9%) (12). Another study revealed that post-vaccination side effects were more frequent after injecting AstraZeneca (81.6%) than Sinopharm (60.0%) (13). The study by Babaee et al. found that Sputnik V (82.7%) had more side effects compared with AstraZeneca (70.5%) and Sinopharm (37.4%) (11). Therefore, there was a consensus among studies that people experienced more side effects after vaccination with vector-based vaccines than Sinopharm, which is consistent with our findings. These differences probably result from the various platforms used to produce vaccines. However, there was disagreement in the literature about which vector-based vaccines (AstraZeneca or Sputnik V) had more side effects.

In agreement with our findings, Omeish et al. illustrated that people experienced more local reactions (78.4% vs. 66.8%) and flu-like symptoms (27.6% vs. 19.1%) after injecting the first dose of the vaccine compared with the second dose (14). In contrast, according to the study by Riad et al. the total number of post-vaccination side effects was higher following the second dose than the first dose (15). This discrepancy in post-vaccination side effects by dose may be attributed to the differences in study design and vaccines injected at various doses.

Table 1. Side effects after the first dose of the vaccine

Side effects	Sputnik V (n=311)	Sinopharm (n=178)	AstraZeneca (n=167)	Total (n=656)	P-value ^a	P-value ^b	P-value ^c
Overall proportion of side effects	159 (51.1)	47 (26.4)	143 (85.6)	349 (53.2)	<0.001	<0.001	<0.001
Hypersensitivity	4 (1.3)	2 (1.2)	2 (2.4)	10 (1.5)	>0.999	0.459	0.436
Local reactions	69 (22.2)	30 (16.9)	78 (46.7)	177 (27.0)	0.163	<0.001	<0.001
Flu-like symptom							
Fever	114 (36.7)	15 (8.4)	111 (66.5)	240 (36.6)	<0.001	<0.001	<0.001
Sweating	59 (19.0)	7 (3.9)	76 (45.5)	142 (21.6)	<0.001	<0.001	<0.001
Chills	99 (31.8)	8 (4.5)	100 (59.9)	207 (31.6)	<0.001	<0.001	<0.001
Myalgia	131 (42.1)	24 (13.5)	120 (71.9)	275 (41.9)	<0.001	<0.001	<0.001
Sore throat	9 (2.9)	2 (1.1)	14 (8.4)	25 (3.8)	0.342	0.008	0.001
Rhinorrhea	13 (4.2)	4 (2.2)	14 (8.4)	31 (4.7)	0.262	0.058	0.010
Gastrointestinal side effects							
Nausea	7 (2.3)	2 (1.1)	19 (11.4)	28 (4.3)	0.498	<0.001	<0.001
Diarrhea	6 (1.9)	2 (1.1)	10 (6.0)	18 (2.7)	0.717	0.019	0.014
Abdominal pain	5 (1.6)	3 (1.7)	6 (3.6)	14 (2.1)	>0.999	0.204	0.324
Neurological side effects							
Headache	71 (22.8)	19 (10.7)	77 (46.1)	167 (25.5)	0.001	<0.001	<0.001
Seizure	1 (0.3)	0 (0)	1 (0.6)	2 (0.3)	>0.999	>0.999	0.484
Limb paralysis	1 (0.3)	1 (0.6)	0 (0)	2 (0.3)	>0.999	>0.999	>0.999
Visual disturbances	0 (0)	1 (0.6)	2 (1.2)	3 (0.5)	0.364	0.122	0.612
Impaired level of consciousness	2 (0.6)	2 (1.1)	4 (2.4)	8 (1.2)	0.642	0.122	0.612
Speech impairment	0 (0)	1 (0.6)	2 (1.2)	3 (0.5)	0.364	0.122	0.612
Cardiovascular side effects							
Palpitations	10 (3.2)	3 (1.7)	22 (13.2)	35 (5.3)	0.392	<0.001	<0.001
Chest pain	7 (2.3)	2 (1.1)	16 (9.6)	25 (3.8)	0.498	<0.001	<0.001
Dyspnea	8 (2.6)	5 (2.8)	15 (9.0)	28 (4.3)	>0.999	0.002	0.014
Limb thrombosis	0 (0)	1 (0.6)	1 (0.6)	2 (0.3)	0.364	0.349	>0.999
Skin side effects							
Rash	3 (1.0)	3 (1.7)	3 (1.8)	9 (1.4)	0.673	0.426	>0.999
Urticaria	1 (0.3)	1 (0.6)	1 (0.6)	3 (0.5)	>0.999	>0.999	>0.999

Data were reported as No. (%).

^aSide effects were compared between Sputnik V and Sinopharm.

^bSide effects were compared between Sputnik V and AstraZeneca.

^cSide effects were compared between Sinopharm and AstraZeneca.

According to Camacho Moll et al. the most common systemic side effect after the first dose of the vaccine was headache (38.2%), followed by myalgia (32.1%), fatigue (27.5%), fever (23.0%), desire to sleep (22.7%), and chills (20.3%). Additionally, people experienced headache (26.4%), fatigue (23.3%), myalgia (18.0%), desire to sleep (14.6%), malaise (12.6%), and fever (11.5%) after the second dose of vaccine. Also, many individuals experienced local reactions after the first (66.6%) and second (52.2%) doses of the vaccine (16). Another study illustrated

that the most common systemic side effect after the first dose of the vaccine was sore throat (51.8%), followed by myalgia (37.6%), fever (33.1%), and headache (32.3%). Furthermore, people experienced sore throat (40.4%), myalgia (28.4%), headache (23.1%), and fever (19.7%) after the second dose of the vaccine. Also, many individuals experienced local reactions after the first (78.4%) and second (66.8%) doses of the vaccine (14). Generally, more people had flu-like symptoms and local reactions after vaccination, which aligns with our findings.

Table 2. Side effects after the second dose of the vaccine

Side effects	Sputnik V (n=287)	Sinopharm (n=158)	AstraZeneca (n=170)	Total (n=615)	P-value ^a	P-value ^b	P-value ^c
Overall proportion of side effects	108 (37.6)	31 (19.6)	82 (48.2)	221 (35.9)	<0.001	0.026	<0.001
Hypersensitivity	4 (1.4)	2 (1.3)	2 (1.2)	8 (1.3)	>0.999	>0.999	>0.999
Local reactions	40 (13.9)	24 (15.2)	43 (25.3)	107 (17.4)	0.719	0.002	0.022
Flu-like symptom							
Fever	69 (24.0)	11 (7.0)	45 (26.5)	125 (20.3)	<0.001	0.562	<0.001
Sweating	39 (13.6)	4 (2.5)	25 (14.7)	68 (11.1)	<0.001	0.739	<0.001
Chills	64 (22.3)	10 (6.3)	36 (21.2)	110 (17.9)	<0.001	0.779	<0.001
Myalgia	77 (26.8)	16 (10.1)	50 (29.4)	143 (23.3)	<0.001	0.551	<0.001
Sore throat	9 (3.1)	4 (2.5)	4 (2.4)	17 (2.8)	>0.999	0.775	>0.999
Rhinorrhea	9 (3.1)	3 (1.9)	6 (3.5)	18 (2.9)	0.552	0.819	0.504
Gastrointestinal side effects							
Nausea	4 (1.4)	2 (1.3)	8 (4.7)	14 (2.3)	>0.999	0.064	0.106
Diarrhea	3 (1.0)	3 (1.9)	4 (2.4)	10 (1.6)	0.671	0.432	>0.999
Abdominal pain	2 (0.7)	2(1.3)	4 (2.4)	8 (1.3)	0.618	0.201	0.686
Neurological side effects							
Headache	41 (14.3)	11 (7.0)	40 (23.5)	92 (15.0)	0.021	0.012	<0.001
Seizure	3 (1.0)	0 (0)	0 (0)	3 (0.5)	0.555	0.298	N/A
Limb paralysis	0 (0)	0 (0)	0 (0)	0 (0)	N/A	N/A	N/A
Visual disturbances	1(0.3)	1 (0.6)	3 (1.8)	5 (0.8)	>0.999	0.147	0.624
Impaired level of consciousness	1 (0.3)	1 (0.6)	3 (1.8)	5 (0.8)	>0.999	0.147	0.624
Speech impairment	0 (0)	0 (0)	0 (0)	0 (0)	N/A	N/A	N/A
Cardiovascular side effects							
Palpitations	9 (3.1)	3 (1.9)	10 (5.9)	22 (3.6)	0.552	0.155	0.063
Chest pain	6 (2.1)	5 (3.2)	6 (3.5)	17 (2.8)	0.531	0.376	0.846
Dyspnea	9 (3.1)	5 (3.2)	6 (3.5)	20 (3.3)	>0.999	0.819	0.846
Limb thrombosis	1 (0.3)	0 (0)	1 (0.6)	2 (0.3)	>0.999	>0.999	>0.999
Skin side effects							
Rash	2 (0.7)	2 (1.3)	0 (0)	4 (0.7)	0.618	0.532	0.233
Urticaria	1 (0.3)	1 (0.6)	0 (0)	2 (0.3)	>0.999	>0.999	0.483

Data were reported as No. (%). N/A: not applicable.

^aSide effects were compared between Sputnik V and Sinopharm.

^bSide effects were compared between Sputnik V and AstraZeneca.

^cSide effects were compared between Sinopharm and AstraZeneca.

Data about the side effects of Pastocovac (Soberana) is scarce. Pastocovac and Sinopharm were compared in terms of post-vaccination side effects in a study by Tavakoli et al. Fatigue (18.4% vs. 13.2%, $P<0.001$), dizziness (6.6% vs. 9.4%, $P=0.015$), and pain at the injection site (10.1% vs. 7.4%, $P=0.002$) were more prevalent after injection of Sinopharm than Pastocovac. However, in terms of allergy to vaccines, general weakness, fever, and chills, the groups did not differ (17).

In line with the literature (18), in our study, some

people experienced thromboembolic events mainly after vaccination with AstraZeneca and Sputnik V, with the incidence below 1%. Immune thrombotic thrombosis has been reported mainly after administering vector-based vaccines by producing platelet-activating antibodies against platelet factor-4 (PF4). Vascular thrombosis can have severe life-threatening consequences, such as cerebral venous sinus thrombosis and pulmonary emboli (18).

Based on our result, few vaccinated people had hy-

Table 3. Side effects after the third dose of the vaccine

Side effects	Pastocovac (n=63)	Sinopharm (n=59)	AstraZeneca (n=316)	Total (n=438)	P-value ^a	P-value ^b	P-value ^c
Overall proportion of side effects	22 (34.9)	12 (20.3)	182 (57.8)	216 (49.4)	0.073	0.001	<0.001
Hypersensitivity	0 (0)	0 (0)	7 (2.2)	7 (1.6)	N/A	0.606	0.602
Local reactions	11 (17.5)	4 (6.8)	99 (31.3)	114 (26.0)	0.073	<0.001	<0.001
Flu-like symptom							
Fever	4 (6.3)	5 (8.5)	126 (39.9)	135 (30.8)	0.738	<0.001	<0.001
Sweating	3 (4.8)	2 (3.4)	78 (24.7)	83 (18.9)	>0.999	<0.001	<0.001
Chills	6 (9.5)	4 (6.8)	118 (37.3)	128 (29.2)	0.745	<0.001	<0.001
Myalgia	11 (17.5)	8 (13.6)	144 (45.6)	163 (37.2)	0.553	<0.001	<0.001
Sore throat	3 (4.8)	2 (3.4)	29 (9.2)	34 (7.8)	>0.999	0.250	0.197
Rhinorrhea	1 (1.6)	3 (5.1)	31 (9.8)	35 (8.0)	0.353	0.032	0.246
Gastrointestinal side effects							
Nausea	2 (3.2)	1 (1.7)	14 (4.4)	17 (3.9)	>0.999	>0.999	0.483
Diarrhea	2 (3.2)	0 (0)	8 (2.5)	10 (2.3)	0.496	0.675	0.366
Abdominal pain	2 (3.2)	0 (0)	12 (3.8)	14 (3.2)	0.496	>0.999	0.277
Neurological side effects							
Headache	9 (14.3)	6 (10.2)	92 (29.1)	107 (24.4)	0.489	0.015	0.002
Seizure	0 (0)	0 (0)	0 (0)	0 (0)	N/A	N/A	N/A
Limb paralysis	0 (0)	0 (0)	0 (0)	0 (0)	N/A	N/A	N/A
Visual disturbances	1 (1.6)	0 (0)	1 (0.3)	2 (0.5)	>0.999	0.305	>0.999
Impaired level of consciousness	0 (0)	0 (0)	4 (1.3)	4 (0.9)	N/A	>0.999	>0.999
Speech impairment	0 (0)	0 (0)	0 (0)	0 (0)	N/A	N/A	N/A
Cardiovascular side effects							
Palpitations	2 (3.2)	0 (0)	6 (1.9)	8 (1.8)	0.496	0.625	0.595
Chest pain	2 (3.2)	1 (1.7)	8 (2.5)	11 (2.5)	>0.999	0.675	>0.999
Dyspnea	1 (1.6)	1 (1.7)	5 (1.6)	7 (1.6)	>0.999	>0.999	>0.999
Limb thrombosis	0 (0)	0 (0)	2 (0.6)	2 (0.5)	N/A	>0.999	>0.999
Skin side effects							
Rash	1 (1.6)	0 (0)	6 (1.9)	7 (1.6)	>0.999	>0.999	0.596
Urticaria	0 (0)	0 (0)	2 (0.6)	2 (0.5)	N/A	>0.999	>0.999

Data were reported as No. (%). N/A: not applicable.

^aSide effects were compared between Pastocovac and Sinopharm.

^bSide effects were compared between Pastocovac and AstraZeneca.

^cSide effects were compared between Sinopharm and AstraZeneca.

persensitivity after the first (1.5%), second (1.3%), and third (1.6%) doses of the vaccine. Although the prevalence of hypersensitivity to the vaccine was 1-2%, it remains unclear why it is higher than in previous studies (19, 20). In a survey in Korea, 5.8 per million people had anaphylaxis after the COVID-19 vaccine, of which 83.9% were within 30 minutes of vaccination. For this reason, experts recommend that vaccinated individuals always stay at vaccination centers for 15-30 minutes so that treatment measures can be taken in case of

anaphylaxis (19).

Our study had some limitations, including individual differences in reporting post-vaccination side effects and recall bias. Furthermore, due to the lack of Sputnik V vaccine import to Iran, none of the studied population injected it for the third dose. Thus, three more available vaccines in Iran for the third dose (AstraZeneca, Sinopharm, and Pastocovac) were entered into the analysis. It was challenging to discuss the side effects of Pastocovac because previous studies in this field are limited.

CONCLUSION

AstraZeneca had more post-vaccination adverse effects than Sputnik V, Pastocovac, and Sinopharm. The most common side effects were flu-like syndrome and local reactions at the injection site. Furthermore, people rarely experienced life-threatening side effects. Thus, it can be concluded that the available COVID-19 vaccines in Iran are safe.

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