

Original Article

Side Effects of the COVID-19 Vaccination among the Personnel of Negah Eye Hospital, Tehran, Iran

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Abstract

Purpose: To investigate the complications of coronavirus vaccination among the personnel of Negah Eye Hospital, Tehran, Iran.

Patients and Methods: In this questionnaire-based survey we collected demographic characteristics as well as local and general vaccine complications among the personnel of Negah Eye Hospital, Tehran, Iran, including gastrointestinal, cardiac, pulmonary and ocular complications between June and August 2021.

Results: In this study, all personnel (n = 259) were evaluated. The mean age of participants was 42.58 ± 11.98 years. It was observed that 70.3 %, 24.7 %, and 5.0 % were vaccinated with AstraZeneca, Sputnik, and Bharat vaccines, respectively. Cases who were vaccinated with the first dose of AstraZeneca showed higher rate of fever ($P < 0.001$), chills ($P < 0.001$), muscle pain ($P = 0.001$), joint pain ($P = 0.004$), confusion ($P = 0.002$), drowsiness ($P < 0.001$), nausea ($P = 0.014$), and injection site pain ($P = 0.005$) compared to other types of vaccination. Post-injection complications mostly declined after the second dose. The most frequent complications secondary to vaccination were observed among younger and female participants ($P < 0.05$).

Conclusion: Complications were significantly higher after the first dose of AstraZeneca compared to Sputnik, and Bharat vaccines. Vaccine complications were higher after the first dose and remarkably decreased after the second dose of vaccination. Younger and female cases were in more risk of complication compared to older and male patients.

Keywords: Complications; COVID-19; Vaccination; Iran.

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Introduction

The initial cases of coronavirus were recorded in Wuhan, China in December 2019 ¹. Studies have shown that 56 % of affected individuals were male, with an average age of 59 years ¹. It is reported that severe signs and symptoms of the disease are more pronounced in people with concurrent systemic disorders, including cardiovascular and cerebrovascular diseases, as well as dysfunction of the endocrine, gastrointestinal, and respiratory systems ². Symptoms range from mild, such as cough, fever, headache, muscular pain, and gastrointestinal disorders, to severe complications of the respiratory system leading to death ^{3,4}. COVID-19 contamination appeared in 67 countries, including Iran, by March 2020 ⁴. This widespread involvement necessitated the establishment of urgent proceedings and strategies to control the pandemic. Public vaccination could be considered one of the prominent prophylactic strategies; however, there are concerns about the effectiveness and potential side effects of vaccination.

Numerous pharmaceutical companies investigated different types of vaccines in order to obtain final approval from the Food and Drug Administration (FDA) ⁶. Laboratory studies were performed on 184 vaccines, while trial injections were under investigation for only 85 vaccines ⁶. These vaccines were based on two general mechanisms. The first mechanism involved the development of vaccines based on genetic factors using messenger RNA (mRNA), which stimulated the immune system to secrete antibodies, such as Pfizer-BioNTech and Moderna vaccines. The second mechanism involved injecting modified coronavirus using a viral vector adenovirus, which also stimulated antibody secretion and was applied in the development

of other vaccines such as AstraZeneca, Sputnik, Johnson & Johnson, Sinopharm, and Covaxin ^{8,9}.

There have been several investigations about the complications of coronavirus vaccination. Local pain at the injection site (89.8 %), general tiredness (62.2 %), headache (45.6 %), muscular pain (37.1 %), and chills (33.9 %) were the most common complications reported by healthcare personnel injected with Pfizer-BioNTech in Czech Republic ¹⁰. Additionally, vascular thrombosis was recorded in 30 out of 5 million individuals who were injected with AstraZeneca in the European Economic Area ¹¹. Myocardial infarction was another complication of vaccination recorded in a 96-year-old woman injected with Moderna ¹². The European Medicines Agency's Pharmacovigilance Risk Assessment Committee reported vaccination complications in eight individuals who received a single dose of the Johnson & Johnson vaccine, with one case suffering a serious complication leading to death ¹³.

Vaccination is considered the most effective prophylactic measure for Covid-19 particularly among high-risk individuals. The majority of the worldwide population has been vaccinated with various vaccines, making the study of complications a priority for health policymakers.

In the current study, we aimed to evaluate the complications of coronavirus vaccination among the personnel of Negah Eye Hospital, Tehran, Iran, who received either single or two doses between June and August 2021.

Materials and Methods

This questionnaire-based survey was conducted in two phases: questionnaire designing and data collection. This study was approved by the Ethics Committee of the Ophthalmic

Research Center, Shahid Beheshti University of Medical Sciences, with the approval number IR.SBMU.ORC.REC.1400.010.

Questionnaire Design

In this phase, a researcher - designed questionnaire was created based on possible complications of coronavirus vaccination reported in literature. Complications were classified into distinct categories of general (fever, chills, weakness, muscle pain, joint pain, confusion, drowsiness, fainting, edema, herpes, allergy), gastrointestinal (anorexia, nausea, vomiting, abdominal pain, diarrhea), local (injection site pain, redness, hardness, inflammation, itching, axillary lymphoid nodes), cardiac and pulmonary (shortness of breath, cough, asthma, chest pain), and ocular complications. Then, clear and appropriate questions were designed to collect accurate information for each complication.

The questionnaire was presented to an expert panel consisting of physicians ($n = 4$), biostatisticians ($n = 1$), and research methodologists ($n = 1$) to assess its face and content validity. Lastly, we asked ten health workers from Negah Eye Hospital to review the questionnaire and identify any unclear items.

The questionnaire also covered demographic characteristics such as age, sex, field of work, and level of education. Comorbidities of systemic diseases and history of previous coronavirus disease were also recorded. Additionally, information regarding coronavirus vaccination, including type, dosage, and date of injection, was gathered.

Data Collection

In this phase, the final questionnaire was

distributed to all personnel of Negah Eye Hospital who were vaccinated with various types of coronavirus vaccines. The study population included ophthalmologists, optometrists, nurses, and other healthcare workers, who were asked to fill out the questionnaire. To increase the response rate, questionnaires were distributed in both paper and online formats. For cases with unanswered questions, other interviewing methods such as telephone or face-to-face interviews were conducted.

Statistical Analysis

To describe the data, we used frequency (percent), mean $\pm$ SD, median, and range. All statistical analyses were performed using SPSS software version 25 (Armonk, NY: IBM Corp.).

Results

In the current study, all personnel of Negah Eye Hospital ($n = 259$) were invited to report complications following coronavirus vaccination. The percentage of males was 54.1 %, and the mean age of the study population was 42.58 ± 11.98 years (table 1). In total, 70.3 %, 24.7 %, and 5.0 % of our cases were vaccinated with AstraZeneca, Sputnik, and Baharat vaccines, respectively. It was found that 18 % of our cases had suffered from Covid-19 infection before vaccination. The mean interval between previous coronavirus infection and vaccination was 7.29 ± 3.79 months.

Cardiopulmonary diseases were the most frequently reported previous systemic diseases of our cases, affecting 9.6 % of them, with 36.8 % being controlled by hypertension medications. A total of 6 cases (3.3 %) who

Table 1: Epidemiologic characteristic of our cases

Variable		Total	Vaccine type		
			AstraZeneca (n = 182)	Sputnik (n = 64)	Baharat (n = 13)
Age (Yr.)	Mean $\pm$ SD	42.58 $\pm$ 11.98	38.98 $\pm$ 9.9	53.4 $\pm$ 11.59	39.92 $\pm$ 9.53
	Median (Range)	40 (21,80)	37 (21,78)	53 (27,80)	41 (24,57)
History of covid-19 before vaccine (Month)	Mean $\pm$ SD	7.74 $\pm$ 3.34	7.96 $\pm$ 3.07	7.29 $\pm$ 3.79	8.33 $\pm$ 4.04
	Median (Range)	7 (1,14)	7 (1,14)	6 (2,12)	6 (6,13)
Sex, n (%)	Female	119 (45.9 %)	93 (51.1 %)	18 (28.1 %)	8 (61.5 %)
	Male	140 (54.1 %)	89 (48.9 %)	46 (71.9 %)	5 (38.5 %)
Medications					
	Diabetes	6 (7.9 %)	6 (14.3 %)	0 (0.0 %)	0 (0.0 %)
	Hypertension	28 (36.8 %)	9 (21.4 %)	18 (64.3 %)	1 (16.7 %)
	Multiple	14 (18.4 %)	7 (16.7 %)	5 (17.9 %)	2 (33.3 %)
	Thyroid	10 (13.2 %)	8 (19.0 %)	2 (7.1 %)	0 (0.0 %)
	Immunologic	5 (6.6 %)	2 (4.8 %)	0 (0.0 %)	3 (50.0 %)
	Gastrointestinal	5 (6.6 %)	3 (7.1 %)	2 (7.1 %)	0 (0.0 %)
	Neurologic	3 (3.9 %)	2 (4.8 %)	1 (3.6 %)	0 (0.0 %)
	Hormone	3 (3.9 %)	3 (7.1 %)	0 (0.0 %)	0 (0.0 %)
	Anti-Allergic	2 (2.6 %)	2 (4.8 %)	0 (0.0 %)	0 (0.0 %)
Diseases					
	Cardiopulmonary	25 (9.6 %)	9 (4.9 %)	14 (21.9 %)	2 (15.4 %)
	Thyroid	21 (8 %)	17 (9.3 %)	2 (3.1 %)	2 (15.4 %)
	Allergic	17 (6.5 %)	12 (6.6 %)	4 (6.3 %)	1 (7.7 %)
	Diabetes	13 (5 %)	8 (4.4 %)	5 (7.8 %)	0 (0.0 %)
	Neurologic	7 (2.7 %)	5 (2.7 %)	0 (0.0 %)	1 (7.7 %)
	Gastrointestinal	6 (2.3 %)	4 (2.2 %)	2 (3.1 %)	0 (0.0 %)
	Tumor	4 (100 %)	3 (100.0 %)	1 (100.0 %)	0 (0.0 %)
	Rheumatism	4 (1.5 %)	1 (0.5 %)	0 (0.0 %)	3 (23.1 %)
	Renal	3 (1.1 %)	1 (0.5 %)	2 (3.1 %)	0 (0.0 %)

Table 2: Covid-19 infection before and after vaccination

Variable	Total	Vaccine type		
		AstraZeneca (n=182)	Sputnik (n=64)	Bharat (n=13)
History of Covid19	47 (18.1 %)	27 (14.9 %)	17 (26.6 %)	3 (23.1 %)
COVID after vaccine				
One day after injection of the second dose	1 (16.7 %)	1 (16.7 %)	0 (0.0 %)	0 (0.0 %)
Two weeks after the first dose of vaccination	1 (16.7 %)	1 (16.7 %)	0 (0.0 %)	0 (0.0 %)
One month after the first dose of vaccination	2 (33.3 %)	2 (33.3 %)	0 (0.0 %)	0 (0.0 %)
Two months after the first dose of vaccination	2 (33.3 %)	2 (33.3 %)	0 (0.0 %)	0 (0.0 %)
Total	6	6(3.3 %)	0 (0.0 %)	0 (0.0 %)

Table 3: Epidemiologic characteristic of cases with Covid-19 infection after vaccine

Variable	Level	N (%)
Mean Age $\pm$ SD		40.66 $\pm$ 8.04
Sex	Male	1 (0.4 %)
	Female	5 (1.9 %)
Underlying disease	Diabetes	1 (0.4 %)
	Thyroid	2 (0.7 %)
	Gastrointestinal	1 (0.4 %)
	Neurologic	1 (0.4 %)
	Medicine	
	Anti-Allergic	3 (1.2 %)
	Diabetes	1 (0.4 %)
	Gastrointestinal	1 (0.4 %)
	Multiple medicine	1 (0.4 %)

received AstraZeneca vaccine suffered from coronavirus disease after vaccination within different intervals. Among them, 5 (83.3 %) cases were female, as shown in tables 2 and 3. Significantly higher rate of fever ($P < 0.001$), chills ($P < 0.001$), muscle pain ($P = 0.001$), joint pain ($P = 0.004$), confusion ($P = 0.002$), drowsiness ($P < 0.001$), nausea ($P = 0.014$), and injection site pain ($P = 0.005$) were reported after AstraZeneca vaccine compared to other types of vaccination (Table 4). Participants who were injected with Bharat vaccine experienced diarrhea more frequently than those with Sputnik and AstraZeneca vaccines ($P = 0.021$).

Post-injection complications mostly declined after the second dose of vaccines. The majority of complications were seen within the first week of vaccine injection.

The most frequent complications secondary to vaccination were also observed among younger and female participants ($P < 0.05$) (Table 5).

Table 4: Types of complication after first dose of vaccine

		Vaccine type		
Complication		AstraZeneca (n=182)	Sputnik (n=64)	Bharat (n=13)
Local	Injection Site Pain	118 (64.8 %)	27 (42.2 %)	8 (61.5 %)
	Redness	6 (3.3 %)	3 (4.7 %)	0 (0.0 %)
	Hardness	21 (11.5 %)	2 (3.1 %)	0 (0.0 %)
	Inflation	6 (3.3 %)	2 (3.1 %)	1 (7.7 %)
	Itching	4 (2.2 %)	0 (0.0 %)	0 (0.0 %)
General	Axillary Lymphoid nodes	1 (0.5 %)	1 (1.6 %)	1 (7.7 %)
	Fever	97 (53.3 %)	16 (25.0 %)	4 (30.8 %)
	Chills	93 (51.1 %)	13 (20.3 %)	3 (23.1 %)
	Weakness	94 (51.6 %)	23 (35.9 %)	6 (46.2 %)
	Muscle pain	108 (59.3 %)	20 (31.3 %)	3 (23.1 %)
	Joints pain	63 (34.6 %)	8 (12.5 %)	2 (15.4 %)
	Confusion	35 (19.2 %)	1 (1.6 %)	0 (0.0 %)
	Drowsiness	54 (29.7 %)	4 (6.3 %)	0 (0.0 %)
	Faint	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
	Edema	7 (3.8 %)	0 (0.0 %)	0 (0.0 %)
	Herpes	7 (3.8 %)	0 (0.0 %)	1 (7.7 %)
	Allergy	22 (12.2 %)	4 (6.3 %)	2 (15.4 %)
	Anorexia	28 (15.4 %)	2 (3.1 %)	2 (15.4 %)
	Nausea	26 (14.3 %)	2 (3.1 %)	0 (0.0 %)
	Vomit	7 (3.8 %)	0 (0.0 %)	0 (0.0 %)
Gastrointestinal	Abdominal pain	21 (11.5 %)	1 (1.6 %)	0 (0.0 %)
	Diarrhea	18 (9.9 %)	1 (1.6 %)	2 (15.4 %)
	Shortness of Breathe	13 (7.1 %)	0 (0.0 %)	0 (0.0 %)
Cardiac and pulmonary	Caught	5 (2.7 %)	0 (0.0 %)	0 (0.0 %)
	Asthma	11 (6.0 %)	1 (1.6 %)	2 (15.4 %)
	Chest pain	14 (7.7 %)	2 (3.1 %)	0 (0.0 %)
Ocular	Blurred vision	3 (1.5 %)	0 (0.0 %)	0 (0.0 %)
	Need to see a doctor	6 (3.3 %)	1 (1.6 %)	0 (0.0 %)
	Duration of complications			
	First week	157 (86.3 %)	46 (71.9 %)	11 (84.6 %)
	After first week	4 (2.2 %)	2 (3.1 %)	0 (0.0 %)

Table 5: Types of complication after second dose of vaccine

		Vaccine type		
		AstraZeneca(n=182)	Sputnik(n=64)	Baharat(n=13)
General	Fever	48 (31.2 %)	10 (26.3 %)	0 (0.0 %)
	Chills	38 (24.5 %)	8 (21.1 %)	0 (0.0 %)
	Weakness	46 (29.7 %)	15 (39.5 %)	1 (16.7 %)
	Muscle pain	55 (35.5 %)	9 (23.7 %)	0 (0.0 %)
	Joints pain	24 (15.5 %)	4 (10.5 %)	0 (0.0 %)
	Confusion	12 (7.7 %)	0 (0.0 %)	0 (0.0 %)
	Drowsiness	33 (21.3 %)	0 (0.0 %)	0 (0.0 %)
	Faint	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
	Edema	2 (1.3 %)	0 (0.0 %)	0 (0.0 %)
	Herpes	1 (0.6 %)	0 (0.0 %)	0 (0.0 %)
Local	Allergy	14 (9.1 %)	3 (7.9 %)	0 (0.0 %)
	Injection Site Pain	70 (44.9 %)	13 (34.2 %)	1 (16.7 %)
	Redness	3 (1.9 %)	1 (2.6 %)	0 (0.0 %)
	Hardness	6 (3.9 %)	0 (0.0 %)	0 (0.0 %)
	Inflation	3 (1.9 %)	1 (2.6 %)	0 (0.0 %)
	Itching	1 (0.6 %)	0 (0.0 %)	0 (0.0 %)
Gastrointestinal	Axillary Lymphoid nodes	0 (0.0 %)	0 (0.0 %)	0 (0.0 %)
	Anorexia	12 (7.7 %)	0 (0.0 %)	0 (0.0 %)
	Nausea	7 (4.5 %)	3 (7.9 %)	0 (0.0 %)
	Vomit	2 (1.3 %)	0 (0.0 %)	0 (0.0 %)
	Abdominal pain	6 (3.9 %)	0 (0.0 %)	0 (0.0 %)
	Diarrhea	6 (3.9 %)	0 (0.0 %)	0 (0.0 %)
Cardiac and pulmonary	Shortness of Breathe	5 (3.2 %)	0 (0.0 %)	0 (0.0 %)
	Caught	2 (1.3 %)	0 (0.0 %)	0 (0.0 %)
	Asthma	1 (0.6 %)	0 (0.0 %)	0 (0.0 %)
	Chest pain	8 (5.2 %)	0 (0.0 %)	0 (0.0 %)
Ocular	Blurred vision	0 (0 %)	0 (0 %)	0 (0 %)
	Need to see a doctor	2 (1.3 %)	1 (2.7 %)	0 (0.0 %)
	Duration of complications			
	First week	118 (80.8 %)	24 (64.9 %)	3 (50.0 %)
	After first week	3 (2.1 %)	1 (2.7 %)	0 (0.0 %)

Discussion

This questionnaire-based survey was conducted on 259 participants who received different types of Covid-19 vaccinations, including AstraZeneca, Sputnik, and Bharat, at varying percentages in our eye hospital. Surprisingly, 47 (18 %) of our cases had a history of Covid-19 infection, and 6 (3.3 %) cases suffered from subsequent coronavirus disease after the first injection of AstraZeneca. Similar to our results Mathioudakis et al.,¹⁴ reported a previous history of Covid-19 infection in 26 % of their cases.

Muscle pain (59.8 %) and edema (3.8 %) were the most and least reported complaints after AstraZeneca vaccine, respectively, while diarrhea was the most common complaint after the Bharat vaccine. Overall, general complications decreased after the second dose of all vaccines. Additionally, females and younger cases presented with more frequent complications compared to males and older individuals.

General complications were reported more frequently after AstraZeneca (50 %) compared to other vaccines (25 %). As our vaccines were viral vector types, they caused more general and systemic complications compared to mRNA vaccines such as Pfizer, similar to results reported by Mathioudakis et al.,¹⁴. General complications also were reported by Riad et al.,¹⁰ and Klugar et al.,¹⁵ from 30 % to 60 % and 25 % to 75 %, respectively that are in line of our results.

There were a declining percentage of complications after the second dose of the vaccine in our study, similar to findings reported by Mathioudakis et al.,¹⁴ who found less complications requiring hospital care after

the second dose of the vaccine. Similarly, in a study by Andrzejczak-Grządko et al.,¹⁶ the second dose complications of the AstraZeneca vaccine were less common than the complications of the first dose of this vaccine. A higher percentage of our cases had local site injection complications (at least 65 %). In Riad et al.,¹⁰ and Klugar et al.,¹⁵ studies, injection site complications were also high, ranging from 75 % to 90 %, respectively, while Mathioudakis et al.,¹⁴ reported fewer injection site complications with viral vector vaccines compared to mRNA vaccines.

Different systemic diseases were associated with our cases, ranging from 1 % to 10 %, with the most frequent incidence being cardiopulmonary disease. A higher incidence of vaccine complications was observed among German healthcare workers with a history of chronic illness and medication intake, although we did not find any association in this regard¹⁵. We found that the most frequent types of complication secondary to vaccination were observed among younger and female participants. Intensive general complications were detected in younger German cases (≤ 39 years) receiving viral vector vaccines in Mathioudakis et al.,¹⁴ study, but the difference was not statistically significant. Riad et al., and¹⁰ Klugar et al.,¹⁵ have also reported a higher incidence of complications in younger cases, which aligns with our study. Furthermore, a higher incidence of complications was reported among female healthcare workers by Klugar et al.,¹⁵ similar to our results.

Additionally, it was found that previous Covid-19 infection was not associated with a higher incidence of post-vaccine complications, similar to results in the study by Andrzejczak-Grządko et al.,¹⁶. Conversely, Mathioudakis et al.,¹⁴ and Klugar et al.,¹⁵

reported more self-reported complications in cases with prior Covid-19 infection.

Conclusion

Systemic complications were significantly higher after the first dose of AstraZeneca compared to Sputnik, and Bharat vaccines. Vaccine complications were higher after the first dose and remarkably decreased after the second dose of vaccination. Younger and female cases were in more risk of post vaccine complications compared to older and male ones.

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Footnotes and Financial Disclosures

Conflict of interest:

The authors have no conflict of interest with the subject matter of the present manuscript.