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Healthcare Providers Vaccination against COVID-19: Safety Concerns

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ABSTRACT:

This study examined parameters that may affect the severity and type of side effects associated with COVID-19 vaccine administration at Imam Khomeini Hospital in Ardabil, Iran. Based on a reliable and valid questionnaire, data were collected from 149 hospital employees at random. 77.2% of the study participants were women, and 52% were between the ages of 30-39. Approximately 50% of the participants had a healthy body mass index. Of the participants, 76.5% had no underlying disease. The prevalence of complications after injection of the first dose (regardless of vaccine type) included fever (45%), chills (28.3%), injection site complications (34.9%), myalgia (46.3%), weakness and fatigue (43%), headache (24.2%), thrombocytopenia (1.3%), cough (4%), nausea (6.7%), diarrhea (6.7%), and other complications (5.4%). After receiving a second dose, the most frequently reported adverse reactions were fatigue and weakness. This pattern was repeated for third dose. Injection of the first dose of vaccine induced the most severe side effects. The results demonstrated a significant relationship between severity and duration of side effects and participants' age, sex, body mass index, diet quality, physical activity, and complementary medicines. Participants with underlying health conditions and those using corticosteroids had higher adverse effects incidences. A significant positive correlation (0.878%) was observed between fever severity and chills. SputnikV and AstraZeneca vaccines were associated with more side effects. In general, the rate and severity of side effects after vaccination are directly related to female gender, low body mass index, previous infection, and young age.

Keywords: COVID-19; Vaccines; Side effects; Health Personnel.

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1. Introduction

Infectious diseases such as COVID-19 are most effectively prevented by vaccination. As the COVID-19 virus spreads rapidly and has a high mortality rate, the production of a vaccine for this disease is necessary for implementing the solution. Today, mass COVID-19 vaccination can limit disease outbreaks and death rates [1-4].

Sinopharm®, AstraZeneca®, Sputnik V®, and Covaxin® are foreign vaccines that are allowed to be injected in Iran. Iranian vaccines, including COVIran Barekat®, SpicoGen®, and PastoCovac® vaccines, have obtained permission for injection. Sinopharm, Covaxin, and COVIran Barekat are inactivated vaccines used for immunization. Both Sputnik and AstraZeneca were developed using viral vector technology. SARS-CoV-2 spike proteins can be found in SpicoGen and PastoCovac, which are recombinant proteins [5-8]. Therefore, the unwanted consequences of these vaccines must be investigated. Vaccine effectiveness and side effects need to be studied because populations worldwide have genetic differences [2, 7, 9].

According to the available data, the most commonly reported local side effect of vaccination is pain following injection. Fatigue, headaches, myalgia and arthralgia, as

systemic side effects, are frequently reported. Various factors, including female gender, young age, pre-existing medical conditions, and compromised immune system, have been identified as contributing to the occurrence and severity of these effects. Several studies have explored negative reactions to COVID-19 vaccines in various regions [7, 9-11].
But one of the major limitations of these studies is that it does not consider the role of nutrition, weight, physical activity, and exercise. It also does not consider the effect of supplements use on the undesirable effects onset or severity. Therefore, the main goals of this project were to report the frequency of side effects following COVID-19 vaccination among the medical staff of Imam Khomeini Hospital in Ardabil. In addition, it was examined the possible contributions of demographic factors, nutrition, medication, vaccine type, and previous contagion with COVID-19.

2. Materials and Methods

Phosphoric acid and ammonium hydroxide were purchased in analytical grade. Also, special filters are used in the experiments, which are purified viruses.

2.1 Study population

Among healthcare workers employed at the Imam Khomeini hospitals of the Ardabil University of Medical Sciences, Iran, participants were chosen and data collected between May 7 and June 7, 2022. The estimated number of health personnel was approximately 500 staff, as obtained from hospital management. The calculated sample size in this statistical population was calculated by considering a 50% incidence of side effects, an error of 5%, and a confidence interval of 95%, resulting in a minimum of 200 participants. The questionnaires were distributed in two ways: in printed form and by sharing an online link. Each participant provided consent to complete one of the questionnaires. The survey was divided into four primary sections: general information about the participants (age, gender, height, weight, level of education, area of expertise, sports activities, nutritional quality, underlying diseases, and smoking status), history of COVID-19 infection, symptoms (intensity, duration), and information related to the type of systemic and local side effects experienced from all three vaccine doses.

2.2 Analysis of the statistical data

To describe the quantitative variables in terms of the conditions, the mean (mean ± standard deviation) or median (first quartile and third quartile) was utilized, while frequency reports (%), agreement tables, chi-square, and t-test were employed for qualitative demographic variables (such as age, gender, body mass index, vaccine side effects, underlying diseases, and their relationships), when necessary. A t-test (parametric data) or a Mann-Whitney test (nonparametric data) is used to compare two groups. For analyses of more than two groups, one-way analysis of variance (ANOVA) and Tukey's mean comparisons were performed at a significance level of $P \leq 0.05$. To reduce data and group vaccine complications, cluster analysis was applied. To determine correlations between variables, Pearson's correlation analysis was utilized. All analyses were done with SPSS version 26 and a P-value of less than 0.050 was considered statistically significant.

3. Results and Discussion

3.1 Demographic Data

The demographic characteristics of the participants are summarized in Table 1. According to the results, 77.2% of the participants were female. The participants' age varied from 27 to 55 years, and the most (52%) fell within 30-39 years. Approximately 50% of the participants had a healthy body mass index (BMI), and about 43.6% had a BMI higher than 25, classifying them as overweight. 76.5% of participants reported no chronic diseases and the rest had at least one. The most prevalent diseases were allergies (6.7%), hypertension (HTN) (4%), asthma, chronic obstructive pulmonary disease (COPD) (1.3%), and diabetes (1.3%).
In terms of consumption of food supplements, especially vitamin D, only 30-40% of the studied population was at the optimal level.
The study participants were distributed across various wards, with 30.9% in the ICU, 16.1% on the infectious disease ward, and 11% on the general ward. Additionally, 18.1% were simultaneously active on various wards. At the peak of the pandemic, the high burden on patients caused most wards to change to COVID-19 wards. Consequently, over 87% of participants were working on COVID-19 wards, and 60.8% had been active for more than six months.
Moreover, 69.1% (103 individuals) of the participants tested positive for COVID-19 or exhibited symptoms of the disease before receiving the first vaccine dose. 31.2%, 20.4%, and 52.4% of patients reported mild, moderate, and severe symptoms of COVID-19, respectively. Among the patients with severe infection, 41.7% were hospitalized and 2% required intensive care.

Table 1: The demographic data.

Gender	Male	34 (32.8)
	Female	115 (77.2)
Age	<29 yrs.	41 (27.5)
	30-39 yrs.	78 (52.3)
	>40 yrs.	30 (20.1)
Smoking	Yes	7 (4.7)
	No	142 (95.3)
Timely use of medical supplement	Yes	56 (37.6)
	No	93 (62.4)
Timely sport activities	Low	91 (61.1)
	Medium	43 (28.9)
	High	15 (10.1)
BMI	Healthy	67 (44.9)
	Overweight	65 (43.6)
	Obese	11 (7.38)
	Thin	6 (4.0)
Occupation	Nurses	105 (70.5)
	Medical Residents	20 (13.4)
	Nursing assistants	14 (9.4)
	General physicians and specialists	6 (4)
	Subspecialists	4 (2.6)

3.2 Adverse reactions to COVID-19 vaccine

AstraZeneca, Sinopharm, Sputnik V, Bharat, COV Iran, Barekat, SpicoGen, and PastoCovac are the vaccines that are injected. Table 2 summarizes the vaccine types injected in the first, second, and third doses.

Table 2: The frequency of vaccines injected in 3 vaccination periods.

Type of vaccine	Dose 1 and 2 %	Dose 3 %
AstraZeneca	18.1	52.3
Sinopharm	28.2	26.2
Sputnik V	45.6	8.7
Bharat	5.4	1.3
COVIran Barekat	2.7	3.4
SpicoGen	-	2
PastoCovac	-	6

The prevalence of complications after every dose injection (regardless of the vaccine type) is summarized in Table 3. Systemic side effects include fever, chills, musculoskeletal pain, weakness, malaise, and headaches. The presence of pain is a frequent local complication.

As shown in Table 3, the risk of all complications following vaccination was higher after the first injection. Side effects lasted less than 24 hours for 50% of individuals. 56.2% of individuals experienced side effects for less than 24 h following the second and third doses, respectively. In 12-14% of individuals, side effects were reported for a period of over 48 hours.

Table 3: Side effects after the first, second, and third dose of vaccination regardless of type.

Side effects	Injection dose		
	First	Second	Third
Fever	45.0	34.9	35.6
Chill	38.3	24.2	27.5
Injection site pain	34.9	26.8	21.5
Muscular pain	46.3	33.6	30.2
Fatigue	43.0	37.6	31.5
Headache	24.2	18.1	18.8
Cough	4.0	2.0	3.4
Diarrhea	6.7	4.0	2.7
Nausea	6.7	3.4	3.4
Others	5.4	7.2	6.0

3.3 Side effects categorization by gender

We summarize the rate of systemic and local side effects for each gender and vaccine dose (Table 4). This table shows a consistent pattern of side effects across all three vaccination periods. Specifically, the severity of certain side effects, including fever, was increased after the 3rd dose in men than the first and 2nd doses. Overall, fever incidence after each three-dose vaccine regimen was higher in men than in women, while women experienced more complications such as chills, headaches, and muscle pain.

Table 4: First, second, and third dose side effects by gender regardless of vaccine type (F: Female, M: Male).

Side effects	Injection dose					
	First		Second		Third	
	F	M	F	M	F	M
Fever	42.6	52.9	33.0	41.1	22.6	77.4
Chill	40.8	29.4	25.2	20.5	82.9	17.1
Injection site pain	35.6	32.5	26.0	29.4	75.0	25.0
Muscular pain	49.5	35.2	36.5	23.5	84.4	15.6
Fatigue	40.0	52.9	37.0	38.2	76.6	23.4
Headache	26.0	17.6	20.4	11.7	89.3	10.7

3.4 Side effects in different vaccines

There was a range of 30% to 80% of individuals experiencing no significant adverse reactions after receiving their first dose of vaccines. Sinopharm and Bharat were associated with the least severe side effects, compared to AstraZeneca, Sputnik V, and Barekat injections.
It should be noted that both systemic and local side effects, such as myalgia, fever, chills, fatigue, weakness, headaches, and injection site pain, were more common after the first dose than after the second and third doses.

3.5 Side Effects at Different Ages

Vaccine side effects were compared between two age groups: under 40 and over 40. Different age groups experience different adverse reactions independent of the vaccine type. In the age group below 40 years, fever, chills, injection site pain, and headache were common; however, in the age group 40 years and older, myalgia and fatigue were commonly reported (Table 5).

Table 5: Side effects after the first, second and third dose of any vaccine according to age.

Side effects	Injection dose					
	First		Second		Third	
Fever	<39	≥40	<39	≥40	<39	≥40
Chill	48.7	30.0	36.1	30.0	36.1	33.0
Injection site pain	43.7	16.7	26.9	13.3	28.6	23.3
Muscular pain	44.5	53.3	25.2	33.3	19.3	30.0
Fatigue	33.6	40.0	31.9	40.0	26.9	43.3
Headache	41.2	50.0	36.1	43.3	29.4	40.0

3.6 Relationship between BMI and side effects

People who are thin usually experience fevers, chills, and headaches, while obese people typically experience myalgia (Table 6).
The complication rate for fever was 49.3% in the BMI group below 25 and 40.8% in the 25 and above groups, respectively. The shivering complication rate was the same in both groups (38.4%). Injection site pain was the same in both groups, but myalgia, weakness, fatigue, and headache were more common in the less than 25 group than in the other groups (Table 6).
Side effects severity differed slightly between groups with BMI below 25 and above 25. BMI at the first dose significantly affected the severity of side effects. Patients with BMI<25 was more likely to suffer from fatigue, weakness, and chills.

Table 6: Vaccine side effects according to BMI following the first, second, and third dose.

Side effects	Injection dose					
	First		Second		Third	
Fever	<25	≥25	<25	≥25	<25	≥25
Chill	49.3	40.8	35.6	34.2	31.5	39.5
Injection site pain	38.4	40.8	23.3	25.0	27.4	27.6
Muscular pain	35.6	34.2	31.5	22.4	19.20	30.0
Fatigue	50.7	42.1	32.9	34.2	30.1	30.3
Headache	45.2	40.8	37.4	36.8	32.9	30.3

3.7 History of COVID-19 infection

Among the participants, 103 (69.1%) were infected with Covid-19 or had a positive PCR test from the time of the covid-19 infection until the injection of the first dose of the vaccine. Among those with a previous infection, 53 (35.6 %) reported their symptoms as severe, 32 (44.3 %) reported their symptoms as mild, and the rest described their symptoms as moderate (Table 7). COVID-19 vaccine complications have mostly occurred in groups with a history of Covid-19 (Table 7) ($P \leq 0.05$).

Table 7: Frequency of side effects based on COVID-19 history (P: Positive, N: Negative).

Side effects	Injection dose					
	First		Second		Third	
	P	N	P	N	P	N
Fever	49.5	34.8	44.2	29.9	44.9	25.4
Chill	42.7	28.3	30.8	20.6	32.1	22.5
Injection site pain	38.8	26.1	28.8	25.8	28.2	14.1
Muscular pain	49.5	39.1	48.1	25.8	28.2	32.4
Fatigue	48.5	30.4	46.2	33.0	35.9	26.8
Headache	26.2	19.6	26.9	18.1	25.6	11.3

After the injection of the vaccine, some side effects usually appear in the person's body, which indicate that the person's immune system is activated to defend itself, and these side effects are often short-term and harmless. AstraZeneca, Sinopharm, Sputnik V, Bharat, COVIran Barekat, SpicoGen, and PasteCovac were the vaccines injected in this study.
This study found that the incidence and severity of adverse reactions tended to be higher in individuals aged < 40 years. As Yan et al. concluded, the AstraZeneca and

Sputnik V vaccines were better tolerated by older individuals [12].

It is imperative to emphasize that several surveys have concluded that younger individuals typically experience more side effects following vaccination [12-14].

This study reported several cases of rare and potentially dangerous adverse reactions, including significant memory loss associated with the Sputnik V vaccine, excessive coughing and shortness of breath associated with the vaccine, as well as a positive test result following a Sputnik V vaccination followed by five days of remdesivir treatment. The study also reported severe weakness and lethargy by AstraZeneca vaccine. This was followed by a hospital stay in the intensive care unit. It is worth noting that these reports differ from those of Zare et al., who did not report severe side effects [15].

The most prevalent side effects in this study were fever, chills, injection site pain, myalgia, fatigue, and headache after the first dose of vaccine injection, regardless of type. Other studies and clinical trial data on vaccines support this conclusion. However, side effects in this study were lower. This may be attributed to differences in race, geographical location, and environmental factors among the study populations [15, 16].

The duration of side effects varied among individuals and depended on the type of vaccine; however, in more than 40% of the studied population, side effects lasted less than 24 h. A similar trend was observed following the second vaccine injection. Study of Zare et al. also showed that side effects after vaccination lasted seven days [15].

The AstraZeneca vaccine was studied on 1592 Saudi Arabian citizens and approximately 35% experienced one side effect following their first vaccination. It was found that 30.5% of patients suffered injection site pain, 30.2% suffered fevers, 27.5% suffered muscle pain, 23.8% suffered gastrointestinal symptoms, and 19.2% suffered skin rashes. This is consistent with this study's findings. In this study, females reported more pain at the injection site than males, and males were more likely to experience fever complications. According to the AstraZeneca vaccine study, younger individuals experience more adverse effects [17].

In a study conducted by Langunov et al., 76 participants were examined for side effects following SputnikV vaccination. There were five common side effects identified: injection pain (58%), fever and chills (50%), headache (42%), fatigue (28%), and musculoskeletal pain (24%). Similar findings were found in this study [18].

According to Babamahmoudi et al. report, the similar side effects were observed following the SputnikV vaccine. As we found in our study, women and young individuals were significantly more likely to experience these side effects [7].

Our study revealed that the most severe side effects of the first and second doses of SputnikV, AstraZeneca, Sinopharm, Barekat, and Bharat vaccines were related to their respective vaccines. These findings were consistent with those reported by other researchers [19, 20].

After the first dose, systemic adverse events such as fever, chills, muscle pain, weakness, and fatigue were more prevalent than after the second and third doses [20].

In terms of gender and age, the majority of participants in our study were young and female; however, age and gender had a significant impact on complications depending on the type of vaccine. The highest complications rate was observed in women after the first dose. The number of side effects varied depending on gender and vaccine dose. Systemic and local side effects were similar across all three vaccination periods. Some side effects, such as fever, were more severe in men after the third dose compared to the first and second doses. There is consistency with other studies in this regard. Jahan et al. (2021) study on more than 474 Bangladeshi people showed that age and gender contributed to side effect severity. In this study, the highest prevalence of complications was observed in young and women [21].

According to the analysis, the impact of vaccine type on fever and chills was statistically significant. However, it was insignificant for myalgia and injection site pain. When comparing the average effect of vaccine type on various complications, it was observed that AstraZeneca and COVIran Barekat had the highest severity of fever complications. This was with percentages of 56.96% and 85.00%, respectively. The percentages of AstraZeneca and SputnikV were 56.96% and 46.76%, as well, with no significant difference. Bharat and Sinopharm had the lowest ratings with percentages of 22.66% and 11.30%, respectively different from the others.

Based on the effects of vaccine type on chill severity, COVIran Barekat, AstraZeneca, and SputnikV vaccines were found to have the most severe chills. Bharat and Sinopharm were second. There was the least amount of pain experienced at the injection site among Sinopharm, whereas it was the highest among AstraZeneca. Both were placed in the same group. SputnikV had the greatest myalgia severity, while Sinopharm had the lowest. Statistically, there was no significant difference between them, so they were placed together.

The relationship between vaccine side effects was investigated and Pearson's correlation revealed a highly significant positive correlation between fever and chills (0.878%). In over 87% of cases, the fever was accompanied by chills. Additionally, there was a significant positive association between fever and myalgia (0.614%), and between chills and myalgia (0.521%).

This study employed cluster analysis to compare vaccine side effects severity, resulting in the identification of two distinct clusters. AstraZeneca and COVIran Barekat vaccines were assigned to the first cluster. Bharat, Sinopharm, and SputnikV vaccines were assigned to the second cluster.
Our study results suggest that body mass index was not an effective factor in reducing vaccination side effects. Furthermore, there was no notable variance in side effects between vitamin D supplement recipients and those who did not [22].

4. Conclusion

The most frequent local side effect reported in this study was injection site pain and fever, chills, myalgia, fatigue and weakness, and headaches were most prevalent systemic ones. These undesirable reactions were more common after the AstraZeneca and SputnikV vaccines. Generally, the rate and severity of adverse reactions after vaccination are directly related to female gender, low body mass index, previous infection, and young age. After the first dose, side effects were more prevalent and severe than those following the second and third doses.

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Conflict of interest

There is no conflict of interest.

Ethics

Following approval from the university's ethics committee (IR.ARUMS.REC.1401.008), the survey was shared with the hospital’s medical staff, and the participants' medical history and information were collected anonymously through coding. The identities and particulars of the participants were kept confidential at all stages of the research.

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