



Side Effects of the Sinopharm/BBIBP COVID-19 Vaccine among Iranian Healthcare Workers: A Gender Assessment

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Abstract

Background: Since the outbreak of COVID-19, vaccination has been considered as an important measure against it. Side effects have always been an inseparable component of vaccination, which in this study, Sinopharm vaccine, its side effects and the differences of their manifestation amongst men and women have been investigated.

Objectives: This study aimed to compare the side effects of the Sinopharm vaccine among men and women working in some medical centers in Tehran, Iran.

Methods: This cross-sectional descriptive-analytical study on 890 healthcare workers of 7 medical centers in Tehran within 2 months, from late June to late August 2021. The samples were selected by the complete enumeration method, and the required data were collected using a questionnaire. Only those who received the Sinopharm vaccine at least 10 days before the study were included.

Results: Of 890 participants, 22.96% and 77.30% were women and men, respectively, and 65.8% of women and 78.1% of men were in the age range of 20-29 years. It was revealed that 74.75% of women and 26.16% of men had at least one side effect. The incidence of at least one side effect was significantly higher in women than in men ($P < 0.001$). It was also found that 12 side effects were significantly higher in women than in men. Most men and women had side effects within the first 24 h after vaccination. There was no significant difference in taking therapeutic measures to reduce or minimize the post-vaccination complications between men and women; however, 9.4% of men and 27.2% of women reported a decline in their ability to perform daily activities as they were unable to do their everyday tasks the day after vaccination which was significantly different between the two groups ($P < 0.001$).

Conclusion: The results showed that the occurrence rate of side effects after receiving the Sinopharm vaccine was significantly higher in women than in men. Moreover, women were significantly less able to perform daily routines than men.

Keywords: Adverse effects, COVID-19 vaccines, Gender

1. Background

In December 2019, a contagious infectious disease spread from Wuhan in China worldwide (1). On February 11, 2020, the World Health Organization (WHO) officially named the disease Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-COV-2) (2, 3). Dry cough, shortness of breath, fever, and bruising are the most critical symptoms of coronavirus disease 2019 (COVID-19) (4). According to the WHO, by July 9, 2022, over 550 million cases and over 6 million deaths were reported (5).

Although since the start of the pandemic, practical measures, such as quarantine and social distancing, have had crucial roles in lowering the risk of disease and reducing exposure to the virus, general vaccination has been the most effective preventive measure against this disease (6, 7) due to the lack of effective treatment and considering the groups at higher risks because of occupational, genetic, or age reasons (8).

In Iran, with a population of nearly 85 million people, 7,246,707 cases and 141,427 deaths were reported by July 9, 2022 (9). Sinopharm was one of the vaccines used in Iran. Sinopharm COVID-19 or BBIBP-CorV vaccine (7) is an inactivated SARS-COV-2 virus vaccine made against COVID-19 in China (7, 10).

The most common side effects of the Sinopharm vaccine have been reported as headache, diarrhea, nausea, dizziness, bruising, and fever (11). It should be noted that in most cases, these complications are generally harmless and mild; however, concerns about the side effects can be a deterrent to vaccination even for a small percentage of the population (7).

Despite the fact that men and women have shown almost the same incidence rate of the disease, the findings of previous studies have revealed that the virus, in addition to having different effects on men and women, has different consequences, such as higher mortality rates among men (12). These differences can be explained either due to the direct

effects of gender and the different roles of sex hormones in the regulation of the immune system (13) or because of its indirect relationship with occupational, social, and determining factors of chronic diseases (12).

These differences can lead to the question "Does the body show different responses to vaccination in men and women?"

Answering such questions can deepen our knowledge of what we are dealing with now.

Studies conducted in different countries have yielded important but different results (14-16). In the present study, in addition to such matters as the types of post-vaccination side effects, the difference in the rate of referral to the medical centers after the occurrence of complications and the severity and duration of maximum ineffectiveness of the vaccine in men and women were also examined and compared. This study aimed to find whether there was a significant relationship between the incidence of side effects of the Sinopharm vaccine and gender. If so, which complications specifically showed a significant difference between men and women. What is now known as vaccine hesitancy will fade with further research and informing everyone about vaccination (17). Awareness can be one of the most important factors helping us overcome this global crisis.

2. Objectives

To the best of our knowledge, few studies have been conducted to compare the adverse side effects after receiving the vaccine with a gender focus. Independent studies on vaccine safety are needed to strengthen public confidence in vaccines and provide a better understanding of potential risk factors for vaccine side effects; therefore, the results may help reduce public skepticism about vaccines.

3. Methods

This cross-sectional descriptive-analytical study was conducted on 890 people (688 men and 202 women) studying and working at AJA University of Medical Sciences, Tehran, Iran, and the medical care teams in 7 selected AJA hospitals in Tehran. They all were enrolled in the study for 2 months between June and August 2021 and vaccinated (one or two doses) with the Sinopharm vaccine. The samples were selected using the enumeration sampling method, and researcher-made questionnaires were used to gather the required data. Data collection was done as self-reporting using a paper questionnaire. The participants were independent in responding. Seven selected AJA hospitals in Tehran that received the Sinopharm vaccine at least 10 days before the study were included. The questionnaires were filled out in the participants' workplaces and in the research team members'

presence.

The questionnaire included demographic information, such as gender, age, height, weight, marital status, underlying diseases (e.g., hypertension, hyperthyroidism, or hypothyroidism), kidney disease, heart disease, lung disease, skin disease, diabetes, history of allergy to influenza vaccine, history of COVID-19 disease, and the number of received doses of vaccine. The side effects included in the questionnaire were topical reactions (e.g., pain, swelling, and itching at the injection site); fever; itchy skin; shortness of breath; numbness in the face, body, arms, and legs; swelling in the beginning, mouth, or whole-body; anaphylactic shock; fatigue; cold-like symptoms; muscle aches; chills; swelling in the legs; nausea; vomiting; abdominal pain; diarrhea; sore throat; joint pain; excessive sweating; dizziness; nasal congestion; pain when swallowing; poor sleep quality; purple spots on the arms and legs; palpitations; flushing; severe drowsiness; excessive hunger and thirst; hives; hair loss; restlessness; eye socket pain; chest tightness; cough; hematuria (blood in urine); anorexia; and olfactory, visual, and sexual disorders.

Furthermore, the average time of the onset of complications, the need to refer to the emergency or medical centers due to the vaccine's side effects, the duration of maximum inefficiency, and difficulty in performing daily routines after vaccination were measured.

The questions of this questionnaire were prepared based on conducted studies, valid documents from the World Health Organization, Centers for Disease Control and Prevention, and valid articles. Subsequently, the questionnaire was carefully studied by ten faculty members and infectious disease specialists, and the necessary corrections were made. The validity of the questionnaire was confirmed using the content validity index (CVI), and the questions with a CVI of less than 0.7 were removed, and the questions with a CVI between 0.7 and 0.79 were reviewed. The reliability of the questionnaire was confirmed using Cronbach's alpha coefficient to assess the questions' internal consistency, which showed good reliability ($\alpha=0.86$).

Data were analyzed in SPSS software (version 22) using mean, standard deviation, tables, graphs, Chi-squared test, and Fisher's exact test. Since the number of missing data was small, missing data were replaced by mean and median for continuous variables and mode for categorical variables. The normality of data was tested by histogram and the Kolmogorov Smirnov test. The significance level was considered less than 0.05.

4. Results

4.1. Participants characteristics

A total of 890 individuals participated in this

study, of which 202 (22.96%) and 688 (77.30%) were female and male, respectively. Regarding the age range, 65.8% of women and 78.1% of men were 20-29 years old. It was found that 61.4% of women and 78.3% of men had a normal body mass index, and 26.6% of women and 5.4% of men were married.

It was also reported that 82% of women and 93.75% of men had no underlying diseases. Thyroid disorders (hypothyroidism or hyperthyroidism) were the most common underlying disease in both men and women, followed by addiction and hypertension among men (1.16% and 1%, respectively) and hypertension, allergies (seasonal, food, and

medicine), and skin diseases among women (3%, 2%, and 2%, respectively). Moreover, 42.1% of women and 32.8% of men had a previous history of COVID-19 disease (Table 1).

By August 25, when the participants completed the questionnaire, 98.5% of women and 98.3% of men had received both doses of the Sinopharm vaccine.

Side effect occurrence and common complications

A total of 151 (74.75%) women reported at least one side effect, whereas at least one complication was observed among 180 (26.16%) men. The incidence of at least one side effect was significantly higher in women than in men ($P < 0.001$) (Figure 1).

Table 1. Demographic characteristics of the studied subjects

Characteristic	Female		Male	
	n	%	n	%
	202	100	688	100
Age group (years)	<20	12	114	16.7
	20-29	134	539	78.1
	30-39	23	17	2.5
	40-49	15	13	2
	50-59	5	5	0.8
	>60	1	0	0
Body mass index	Underweight	12.5	11	1.7
	Normal	61.4	511	78.3
	Overweight	20.1	117	17.9
	Obese	6	14	2.1
Marital status	Single	73.4	650	94.6
	Married	26.6	33	5.4
Number of received doses	Single dose	1.5	12	1.7
	Two doses	98.5	676	98.3
Case history	Without underlying disease	82	645	93.75
	Hypertension	3	7	1
	Hypothyroidism/ hyperthyroidism	5	9	1.30
	History of allergies	2	5	0.72
	Nervous disease	1.5	1	0.14
	Renal disease	1	1	0.14
	Lung disease	0.5	1	0.14
	Dermatosis	2	2	0.29
	Heart disease/cardiovascular disease	0.5	1	0.14
	Liver disease	0.5	1	0.14
	Diabetes mellitus	1	4	0.58
	Addiction	0.5	8	1.16
	Others	1.5	3	0.43
	History of flu vaccine allergy	2	3	0.4
	History of COVID-19	42.1	226	32.8

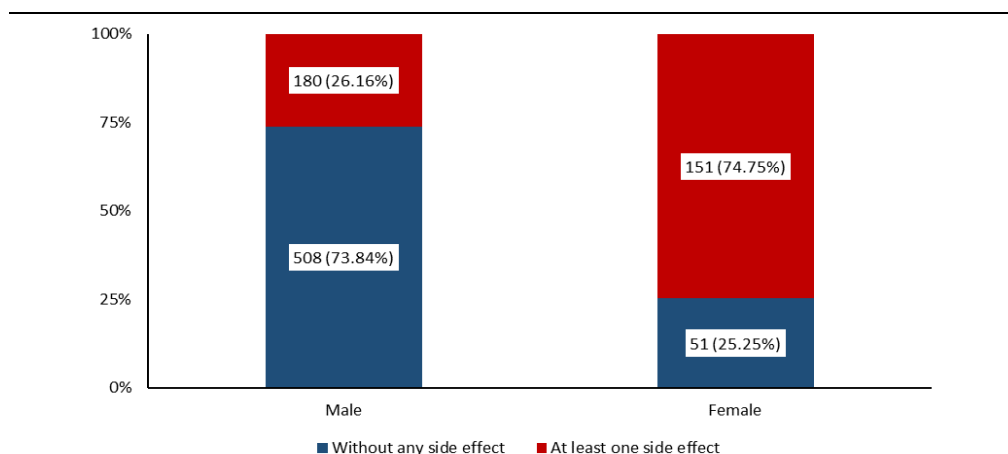


Figure 1. Frequency of side effects among men and women

Topical reactions at the injection site (e.g., pain, swelling, and burning), fever, and fatigue were the most common complications reported in both men and women. However, the occurrence rate varied between the two groups. Regarding this, 41.6% of women showed topical reactions, 35.1% fatigue, and 16.3% fever, and 19.3% of men showed fever, 11.2% fatigue, and 10.9% topical reactions. Among the 39 complications listed in Table 2, 12 complications showed a significant difference in the frequency of occurrence in men and women, including topical reactions, fatigue, muscle pain, dizziness and headache, cold-like symptoms, poor sleep quality, itchy skin, nasal congestion, palpitations, joint pain, hunger, thirst, and numbness in the face, body, arms, and legs (Figure 2).

4.2. Onset, duration, and severity of side effects

Based on the results, 73.3% of men and 69.5% of women reported the onset of complications within the first 24 h after receiving the vaccine (Figure 3).

About 4.1% of men and 1.5% of women experiencing the side effects of the vaccine referred to the hospital to control their health status/complications. There was no significant difference in the referral rate between the two groups ($P=0.078$) (Table 3).

It was also found that 65 men (9.4%) and 55 women (27.2%) had a decrease in the ability to perform daily routines the day after vaccination showing a significant difference between the two

Table 2. Comparison of side effects of COVID-19 vaccines

Side effects	Female		Male		P-value
	n	%	n	%	
1. Fever	33	16.3	133	19.3	0.337
2. Injection site pain, swelling, redness, or rash *c	84	41.6	75	10.9	0.000
3. Fatigue *c	71	35.1	77	11.2	0.000
4. Muscle pain *c	42	20.8	49	7.1	0.012
5. Dizziness and headache *c	41	20.3	44	6.4	0.000
6. Flu-like syndrome *c	15	7.4	24	3.5	0.016
7. Chills	10	5	27	3.9	0.521
8. Decreased sleep quality *c	14	6.9	10	1.5	0.000
9. Rashes *f	13	6.4	6	0.9	0.000
10. Nasal congestion *f	10	5	8	1.2	0.002
11. Paresthesia (in face, body, and limbs) *f	8	4	7	1	0.009
12. Dyspnea	6	3	8	1.2	0.100
13. Hyperhidrosis	8	4	7	1	0.086
14. Palpitations *f	9	4.5	3	0.4	<0.000
15. Joint pain *f	6	3	4	0.6	<0.012
16. Diarrhea	3	1.5	6	0.9	0.423
17. Sore throat	0	0	8	1.2	0.210
18. Nausea	4	2	4	0.6	0.083
19. Dysosmia and dysgeusia	3	1.5	5	0.75	0.391
20. Abdominal pain	2	1	5	0.7	0.660
21. Severe drowsiness	3	1.5	4	0.6	0.197
22. Anaphylactic shock (anesthesia or severe asthma)	3	1.5	3	0.4	0.134
23. Flushing	3	1.5	3	0.4	0.080
24. Akathisia	2	1	2	0.3	0.223
25. Starvation and polydipsia *f	3	1.5	1	0.13	<0.038
26. Hives	1	0.5	2	0.3	0.539
27. Purple spots	2	1	1	0.15	0.131
28. Visual impairment	1	0.5	2	0.3	0.539
29. Cough	1	0.5	1	0.15	0.403
30. Alopecia	2	1	0	0	0.051
31. Vomiting	1	0.5	1	0.15	0.403
32. Odynophagia	1	0.5	1	0.15	0.403
33. Hematuria	0	0	1	0.15	1
34. Swelling of the face or mouth	1	0.5	0	0	0.227
35. Swelling of legs	1	0.5	0	0	0.227
36. Eye sore pain	0	0	1	0.15	1.000
37. Sexual disorders	0	0	1	0.15	1.000
38. Chest discomfort	0	0	1	0.15	1.000
39. Delusional disorder	0	0	0	0	-
40. Lip twitching or swelling	0	0	0	0	-
41. Thrombocytopenia and coagulopathy	0	0	0	0	-
42. Ataxia	0	0	0	0	-
43. Getting energized	0	0	0	0	-
44. Anorexia	0	0	0	0	-
45. Hearing disorders	0	0	0	0	-
46. Runny nose	0	0	0	0	-
47. Other disorders	3	1.5	5	0.75	0.391

*c and *f represent Chi-squared test and Fisher's exact test ($p<0.05$)

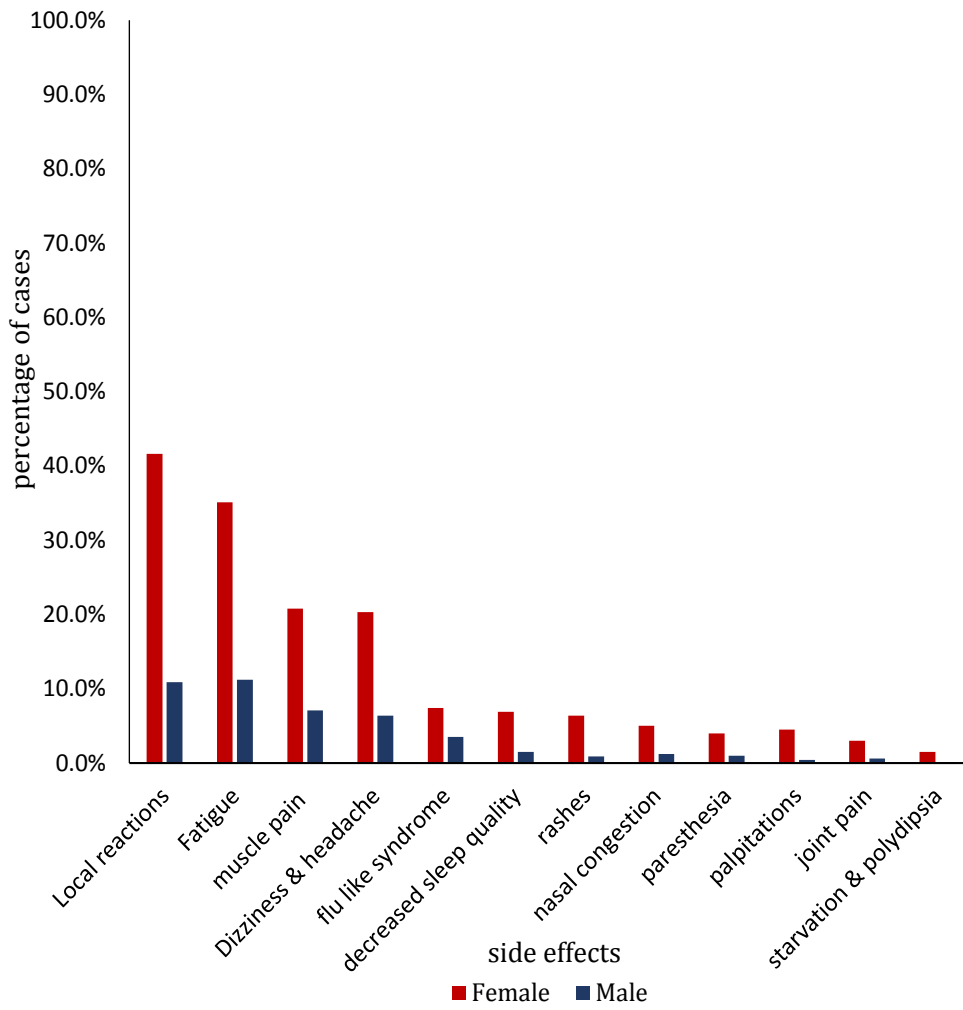


Figure 2. Significantly different side effects among men and women

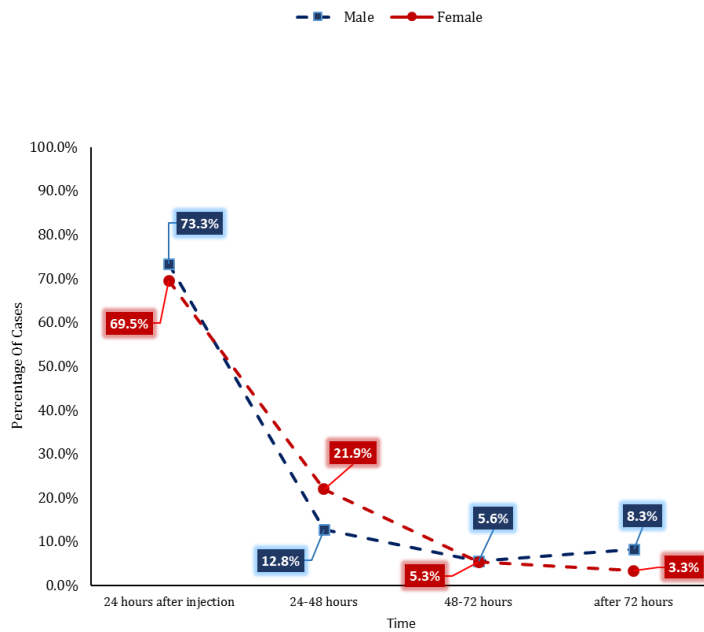


Figure 3. Time of side effects occurrence

groups ($P < 0.001$) (Table 4). A total of 26 (3.8%) men reported a decreased ability to do daily activities for 1 day, 11 (1.6%) for up to 2 days, and 14 (2.0%) for up to 3 days after vaccination.

Likewise, 17 (8.4%) women reported a decreased ability to perform daily routines for 1 day, 13 (6.4%) up to 2 days, and 13 (6.4%) up to 3 days after vaccination (Figure 4).

Table 3. Post-vaccination referral rate among men and women

		Female		Male		P-value
		n	%	n	%	
Hospitalization due to side effects	Yes	3	1.5	28	4.1	0.078
	No	199	98.9	660	95.9	

Table 4. Assessment of ability to perform daily routines among men and women

Perform daily tasks	Female		Male	
	Frequency	Percent	Frequency	Percent
Yes	147	72.8	623	90.6
No	55	27.2	65	9.4
Total	202	100.0	688	100.0
Day remain	Frequency	Percent	Frequency	Percent
1	17	30.9	26	40
2	13	23.7	11	17
3	13	23.7	14	21.6
4	6	10.9	2	3
5	1	1.8	5	7.8
7	4	7.2	3	4.6
10	0	0	1	1.5
14	0	0	2	3
21	1	1.8	1	1.5
Total	55	100.0	65	100.0

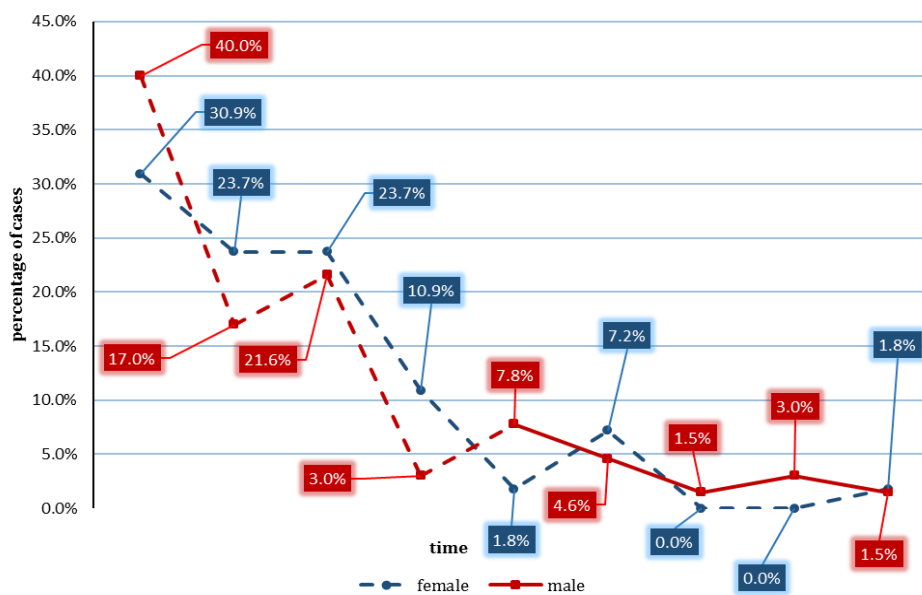


Figure 4. Percentage of people with decreased ability to perform daily tasks per day after vaccination

5. Discussion

Since the global outbreak of coronavirus in December 2019, general vaccination has been recognized as one of the essential effective measures to control the disease. The Sinopharm vaccine has been one of the vaccines used in Iran. In this study, various side effects of COVID-19 vaccines among healthcare workers were examined using questionnaires.

As shown in Table 2, fever, topical injection site reactions, and fatigue (18.6%, 17.8%, and 16.6%, respectively) were the three most common complications in the studied population. This finding was consistent with the results of many previous studies including the WHO study, a survey carried out by Almufty et al., and studies conducted in the Czech Republic (11, 17, 18).

The differences in the severity of complications between men and women were compared. As

mentioned earlier (Figure 2), in our study, 12 complications (e.g., topical reactions, fatigue, and muscle pain) showed a significantly higher occurrence rate in women than in men. The results of previous studies have reported this finding on the effects of different vaccines, including AstraZeneca and Sputnik (16, 18, 19). However, the results of some studies showed no significant difference between men and women (15, 20). Similar differences in response to vaccines, such as MMR and influenza, have been reported, and different hypotheses have been put forward to justify them (21, 22). It should be noted that race, age, vaccine type, and population size are other factors that may affect the results of this monitoring (7, 16, 18, 23, 25)

Consistent with the results of other studies, the complications were mild, and in most cases, they needed no referral to medical centers and hospitalization (18, 26). The results of the present study showed that in the case of complications, 4.1% of men and 1.5% of women went to the hospital to control their health status.

The inability to perform daily activities was observed in 9.4% of men and 27.2% of women. However, Kadali et al. studied the side effects of the Moderna vaccine among the people vaccinated in some medical centers in the US. They found that 79.7% of the vaccinated people were able to perform their daily activities the day after getting the vaccine (27).

The sample size included in this study (n=890) provided an acceptable statistical population to confirm the questions statistically. Additionally, a complete list of side effects of COVID-19 vaccines was presented, allowing us to easily compare the severity of different complications and the occurrence of each in men and women.

As the results showed, the incidence of at least one side effect was significantly higher in women than in men ($P<0.001$). Moreover, topical reactions, fatigue, muscle aches, dizziness and headache, cold-like symptoms, poor sleep quality, itchy skin, nasal congestion, palpitations, joint pain, hunger, thirst, and numbness in the face, body, and extremities were significantly higher in women than in men after receiving the Sinopharm vaccine. Most men and women had complications within the first 24 h of vaccination. The need for treatment to reduce the side effects of the vaccine in both groups was less than 5% showing no significant difference. However, 9.4% of men and 27.2% of women reported an inability to perform daily activities the day after vaccination, and there was a significant ($P<0.001$) difference between the two groups in this regard.

5.1. Study limitations

To the best of our knowledge, this study was one of the studies in this field conducted on this particular issue among Iranian medical workers.

However, it had several weaknesses and limitations, including inequality of the statistical population of men and women, lack of monitoring of the subjects by serological and laboratory tests, and the lack of a classification of individuals based on their different responsibilities in the hospital, and therefore, different exposure rates to COVID-19 disease. Furthermore, since the information about each person was obtained by completing the questionnaire by him/herself, errors such as recall errors might have occurred. In addition, people's criteria for the severity of the complications and the likelihood of the need to go to the hospital could also vary.

5.2. Recommendations for future research

The results obtained in this study were statistically significant; however, we need to be aware of the molecular processes leading to these results to make definitive decisions. Our recommendation for future studies is to focus on cellular mechanisms to discover chemical and biological pathways.

5.3. Clinical implications for health managers and policymakers

Based on the results of the current study, 12 complications were significantly higher in women than in men, including topical reactions, fatigue, muscle aches, dizziness and headache, cold-like symptoms, poor sleep quality, itchy skin, nasal congestion, palpitations, joint pain, hunger, thirst, and numbness in the face, body, and extremities, after receiving the Sinopharm vaccine. Therefore, intervention policies considering these points can help to identify a more targeted strategy for the vaccination campaign. Moreover, they are essential to identify priority groups for vaccination against COVID-19 and develop efficient and effective vaccination strategies. They can also provide insights into some of the most influential decision-making factors concerning various case scenarios and objectives of public health in management, according to gender effects.

6. Conclusion

The results of this study, which was one of the studies conducted on vaccine safety among Iranian medical workers, showed that fever, topical injection site reactions, and fatigue were the three most common complications in the studied population. It was also found that 12 complications were significantly higher in women than in men after receiving the Sinopharm vaccine, including topical reactions, fatigue, muscle aches, dizziness and headache, cold-like symptoms, poor sleep quality, itchy skin, nasal congestion, palpitations, joint pain, hunger, thirst, and numbness in the face, body, and extremities. Furthermore, women were significantly

less able to perform daily routines than men.

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Footnotes

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

Authors' contributions: All authors meet the International Committee of Medical Journal Editors authorship criteria.

The authors thank IN AA, and MY designed the study. AA, FK, MN, and MF contributed to data collection and the creation of data resources. MK and AA checked and verified the dataset and prepared it for analysis. MK did the statistical analysis with support from AA, MM, and NK.

AA, NK, MM, and MN wrote the manuscript. FK, MN, and FKZ reviewed and edited the manuscript. IN, MY, and FK supervised the work. All authors had full access to all the data in the study and had final responsibility for the decision to submit it for publication.

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