

Original Research

COVID-19 vaccination, do women suffer from more side effects than men? A retrospective cross-sectional study

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Abstract

The vaccine was the only way to fight against Coronavirus-19 (COVID-19) from its statement as a pandemic till day. COVID-19 vaccines were approved by the world health organization (WHO) in December 2020. Despite a large number of studies regarding the efficacy and safety of COVID-19 vaccines, to our knowledge, there were limited studies that outlined the gender disparity towards COVID-19 vaccine adverse effects. This study aims to outline the variety of side effects among men and women after getting COVID-19 vaccines (either single or two doses). It is a cross-sectional study accomplished electronically from September to November 2021. The participants involved were 843 Health Care Workers (HCWs) from different cities in Iraq. The majority of respondents were females (664). Around 65% of males experienced adverse effects compared to 77% of females. A high frequency of severe pain was reported among females. Regarding dermatological reactions like swelling, redness and skin rash were also higher reported among female subjects. In addition to that, higher frequencies of moderate and severe systemic adverse effects and mild to moderate nausea was also reported more frequently among females. In terms of cardiopulmonary adverse effects, all the reported adverse effects were found more frequently among females. In conclusion, COVID-19 vaccines produced limited adverse effects and the majority of them were reported among women. This may be associated with hormonal and psychological factors related to them.

Keywords: COVID-19; Vaccination; Side effects

INTRODUCTION

COVID-19 caused by Severe Acute Respiratory Syndrome Coronavirus 2 (SARS-CoV-2). It has been spread at an exponential rate all over the world and was declared a global pandemic in March 2020 by the WHO.¹ From the announcement of COVID-19 as a pandemic today, the only option to eliminate it is to synthesize and develop an effective and safe vaccine.² Furthermore, the preferred option is an efficiently safe vaccine that does not cause serious side effects.¹ WHO approved the release of COVID-19 vaccines in December 2020.³ In March 2021, Iraqis began to receive the COVID-19 vaccines following online registration. The provided vaccines in Iraq were Pfizer-BioNTech, Oxford-AstraZeneca and Sinopharm.

Health care workers are already at high risk of acquiring the infection, so the WHO considered them the first group to receive the vaccination.⁴ However, with the rapid rate of production of vaccines, many concerns about their safety have emerged.⁵ Some adverse effects were reported after the release of COVID-19 vaccines to general populations in different countries around the world.¹⁻³ The biological differences between men

and women are believed to contribute to gender-specific vaccination responses.⁶ During the COVID-19 pandemic, the important influence of gender and sex has been highlighted.⁷

Males have nearly three times the risk of being admitted to the intensive care as well as a 40% higher mortality risk from COVID-19 than females, although both of them have relatively the same incidence of infection. Some of the reported disparities are explained by the variation of the biological factors in innate and adaptive immune responses between men and women.⁷ This may attributable to existing gender variation in the immune responses or special SARS-CoV-2 infectious mechanisms features which depend on the binding of the virus to the angiotensin-converting enzyme 2 (ACE2) receptor encoded on the X chromosome.⁸ According to a report done in 2001, eight of the ten medications were withdrawn from United State markets between 1997 and 2000. These medications caused greater health concerns to females than males.⁹ Many studies were done to determine side effects according to the type of vaccine following vaccination with COVID-19 vaccines in Arabian countries like Iraq, Saudi Arabia and Jordan.¹⁰⁻¹² Despite a large number of studies regarding the efficacy and safety of COVID-19 vaccines, only two randomized clinical trials (RCTs) and limited observational studies outlined the gender disparity toward COVID-19 vaccine adverse effects.

There was no explanation of gender variation in terms of vaccine efficacy.⁸ Women, on the other hand, had a considerably higher risk of adverse effects than men.⁷ According to the reported data of study done by Riad et al, females were more likely than males to experience post-vaccination adverse effects.⁵ In a study achieved by Hoffman et al., in Germany, also the occurrence and severity of post-vaccination side effects were

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higher in women. This study aimed to compare males and females in aspects regarding the incidence and severity of adverse effects after receiving COVID-19 vaccines.

METHOD

Study design and participants: This is an online retrospective cross-sectional study using a electronic form to collect information from the participants. The participants of the study were recruited using a convenience sampling approach. The study was conducted between September and November 2021 to evaluate COVID-19 vaccine adverse reactions among HCWs in Iraq. The participants involved were 843, aged between 23 and 61 years old from different cities in Iraq. The inclusion criteria were any Iraqi HCWs received one of COVID-19 vaccines (single or double doses). While the exclusion criteria included: non-vaccinated Iraqi HCWs and general population.

Measurement tools

The participants' information was collected electronically using a self-administered survey developed by Google form which was available online. Only one response was allowed to be submitted by each participant. Answers were checked carefully to prevent the duplication of the responses. Web-sites and online techniques (social media such as Telegram, Facebook and Messenger) were used to distribute the questionnaire to a variety of medical groups.

The questionnaire

Demographic information: section one of the survey asked about the respondents' demographic (gender, age, occupation, vaccine type and dose, previous infection of COVID-19, and the occurrence of any adverse effects after the vaccine. Section two included closed-ended questions (multiple-choice questions) describing the vaccine's main systemic and local adverse effects. Single open question had been added to describe unpredicted adverse events and additional questions were included to describe whether any medical advice, analgesic, or drug was used to manage these adverse effects.

Ethical approval

The protocol of the study was approved by the University of Mosul's Medical Research Ethics Collegiate Committee, CCMRE-phA-22-6. The participants were notified that their participation in the survey was optional so their consent should be obtained before answering the questions.

Statistical analysis

The research data was collected using Google Forms. For entering data, Excel 10 (Microsoft, Albuquerque, NM, USA) was used, while for coding and analysis of data, SPSS version 25 (IBM SPSS Statistics for Windows, USA) was used. By employing means, standard deviation and other descriptive statistics, different demographic parameters (sex, age, specialty, duration of working experience, type of vaccine, doses number, symptoms incidence) were compared. The frequency of adverse effects, analgesic type and consultation of the doctor

were evaluated separately among males and females using both the Chi-square test and Fisher exact test. A statistical significant of p-value is considered of less than 0.05%.

RESULTS

A total of 843 individuals were survived with the average age (SD) of the study population was 32.39 (6.88). The average years of experience was 7.96 (6.79). There were 664 (78.8%) females and 179 (21.2%) males among the total participants. The higher percentage of younger respondents were male (51.4%) compared with female (37.9%). 84.9% of male respondents have completed their second vaccine's dosage. The Pfizer vaccine was used mostly among the study participants. The fundamental demographic features of the study participants was shown in Table 1. A significant association between age, experience years, vaccination status, vaccine type, and the appearance of adverse effects.

Table 1. The participants' basic demographic characteristics			
Variable	Sex		P-value
	Men 179 (21.2)	Women 664 (78.8)	
Age n (%)			0.003
20 – 29 years	92 (51.4)	249 (37.5)	
30 – 39 years	65 (36.3)	318 (47.9)	
40 years and older	22 (12.3)	97 (14.6)	
Specialty			0.599
Doctors	94 (52.5)	321 (48.3)	
Dentists	39 (21.8)	153 (23.0)	
Pharmacists	46 (25.7)	190 (28.6)	
Graduation level			0.322
Graduated	146 (81.6)	519 (78.2)	
Postgraduates	33 (18.4)	145 (21.8)	
Years of Experience			0.004
< 5 years	86 (48.0)	229 (34.5)	
5 – 9 years	45 (25.1)	184 (27.7)	
10 – 14 years	24 (13.4)	146 (22.0)	
15 – 19 years	7 (3.9)	50 (7.5)	
20 years and more	17 (9.5)	55 (8.3)	
Vaccination status			0.006
One dose only	27 (15.1)	165 (24.8)	
Two doses	152 (84.9)	499 (75.2)	
Type of vaccine			0.021
Sinopharm	37 (20.7)	117 (17.6)	
AstraZeneca	51 (28.5)	136 (20.5)	
Pfizer	91 (50.8)	411 (61.9)	
Symptoms			0.000
Yes	116 (65)	512(77)	
No	63 (35)	152(23)	
Onset of symptoms (n=628)			0.049
After the first vaccine dose	53 (45.7)	218 (42.6)	
After the second dose	30 (25.9)	93 (18.2)	
After the first and second dose	33 (28.4)	201 (39.3)	
The previous infection's history			0.285
Infected	90 (50.3)	304 (45.8)	
Not infected	89 (49.7)	360 (54.2)	
Corticosteroid use (n=635)			0.081
Yes	20 (14.4)	46 (9.3)	
No	119 (85.6)	450 (90.7)	



Side effects of vaccines

After receiving their vaccines, all respondents were asked whether they experienced any side effects. Only 116 (65%) males out of 843 participants said that they had experienced side effects compared to 512 (77%) females. Table 2 shows the distribution of the reported side effects in both genders. Females were shown to have a higher frequency (25.3%) of severe pain than males (14.0%) according to Table 2 and the Chi-square test. Regarding the dermatological reactions such as redness, skin rash and swelling were also highly distributed in females ($p < 0.05$). Concerning systemic symptoms such as headache, tiredness, fever, myalgia and chills; females had significantly greater rates of severe and moderate adverse effects ($p < 0.05$). In respect to GIT symptoms, females experienced mild to moderate nausea at a higher frequency than males ($p < 0.05$). All the reported cardiopulmonary adverse

Table 2. The distribution of side effects among the study groups

Variable	Sex		P-value
	Men	Women	
The adverse effect of vaccination			0.000
Yes	116 (65)	512 (77)	
No	63 (35)	152 (23)	
Pain at site of injection			0.002
None	16 (8.9)	27 (4.1)	
Mild	50 (27.9)	169 (25.5)	
Moderate	88 (49.2)	300 (45.2)	
Sever	25 (14.0)	168 (25.3)	
Dermatological			
Redness			0.004
None	151 (84.4)	473 (71.2)	
Mild	24 (13.4)	148 (22.3)	
Moderate	3 (1.7)	33 (5.0)	
Sever	1 (0.6)	10 (1.5)	
Swelling			0.000
None	133 (74.3)	380 (57.2)	
Mild	40 (22.3)	190 (28.6)	
Moderate	6 (3.4)	79 (11.9)	
Sever	0 (0.0)	15 (2.3)	
Skin rash			0.048
None	174 (97.2)	641 (96.5)	
Mild	1 (0.6)	19 (2.9)	
Moderate	2 (1.1)	1 (0.2)	
Sever	2 (1.1)	3 (0.5)	
Systemic reactions			
Tiredness			0.000
None	73 (40.8)	137 (20.6)	
Mild	54 (30.2)	154 (23.2)	
Moderate	37 (20.7)	220 (33.1)	
Sever	15 (8.4)	153 (23.0)	
Headache			0.000
None	88 (49.2)	248 (37.3)	
Mild	52 (29.1)	158 (23.8)	
Moderate	24 (13.4)	166 (25.0)	
Sever	15 (8.4)	92 (13.9)	
Myalgia			0.003
None	73 (40.8)	194 (29.2)	
Mild	51 (28.5)	167 (25.2)	
Moderate	36 (20.1)	184 (27.7)	
Sever	19 (10.6)	119 (17.9)	

Chills			0.008
None	124 (69.3)	382 (57.5)	
Mild	33 (18.4)	126 (19.0)	
Moderate	14 (7.8)	89 (13.4)	
Sever	8 (4.5)	67 (10.1)	
Fever			0.011
None	90 (50.3)	249 (37.5)	
Mild	34 (19.0)	164 (24.7)	
Moderate	32 (17.9)	169 (25.5)	
Sever	23 (12.8)	82 (12.3)	
Transient visual disturbances			0.348
None	162 (90.5)	586 (88.3)	
Mild	12 (6.7)	60 (9.0)	
Moderate	3 (1.7)	16 (2.4)	
Sever	2 (1.1)	2 (0.3)	
Burning sensation of eye			0.038
None	166 (92.7)	588 (88.6)	
Mild	9 (5.0)	48 (7.2)	
Moderate	0 (0.0)	21 (3.2)	
Sever	4 (2.2)	7 (1.1)	
Gastrointestinal reaction			
Nausea (n=502)			0.000
None	147 (82.1)	454 (68.4)	
Mild	26 (14.5)	114 (17.2)	
Moderate	3 (1.7)	69 (10.4)	
Sever	3 (1.7)	27 (4.1)	
Vomiting			0.053
None	175 (97.8)	627 (94.4)	
Mild	2 (1.1)	20 (3.0)	
Moderate	0 (0.0)	15 (2.3)	
Sever	2 (1.1)	2 (0.3)	
Diarrhea			0.593
None	156 (87.2)	589 (88.7)	
Mild	17 (9.5)	49 (7.4)	
Moderate	4 (2.2)	22 (3.3)	
Sever	2 (1.1)	4 (0.6)	
Cardiopulmonary reactions			
Difficulty in breathing			0.052
None	164 (91.6)	570 (85.8)	
Mild	9 (5.0)	77 (11.6)	
Moderate	6 (3.4)	15 (2.3)	
Sever	0 (0.0)	2 (0.3)	
Palpitation			0.025
None	153 (85.5)	505 (76.1)	
Mild	14 (7.8)	110 (16.6)	
Moderate	10 (5.6)	37 (5.6)	
Sever	2 (1.1)	12 (1.8)	
Sore throat			0.028
None	148 (82.7)	497 (74.8)	
Mild	26 (14.5)	121 (18.2)	
Moderate	1 (0.6)	33 (5.0)	
Sever	4 (2.2)	13 (2.0)	
Others (minors)			
Joint pain			0.406
Back pain	2 (50.0)	5 (16.1)	
Somnolence	0 (0.0)	4 (12.9)	
Metallic taste	0 (0.0)	6 (19.4)	
Insomnia	0 (0.0)	4 (12.9)	
Lymphadenopathy	2 (50.0)	8 (25.8)	
	0 (0.0)	4 (12.9)	
Use of analgesia (n=692)			0.02
Yes	104 (58.8)	448 (68.1)	
No	73 (41.2)	210 (31.9)	



effects were found to be more common in women than in men ($p < 0.05$). In the study population, However, males used analgesia more frequently than females ($p < 0.05$).

Medical seeking

All participants were asked; What type of analgesic they used to manage their symptoms and whether or not they had requested medical advice about their side effects following vaccination. Table 3 illustrated the frequency of use of all analgesics recorded, with paracetamol being the most commonly taken by both genders. Only a small percentage of respondents said they requested medical help to relieve their symptoms, and no significant association was found in terms of gender.

Variables	Sex		P value
	Men	Women	
Type of antalgics used (n=533)			0.688
paracetamol	91 (92.9)	391 (89.9)	
diclofenac	2 (2.0)	13 (3.0)	
ibuprofen	3 (3.1)	24 (5.5)	
mefenamic acid	1 (1.0)	4 (0.9)	
aspirin	1 (1.0)	1 (0.2)	
meloxicam	0 (0.0)	2 (0.5)	
Physician consultation			0.295
Yes	12 (6.7)	61 (9.2)	
No	167 (93.3)	603 (90.8)	

DISCUSSION

This study aimed to compare males and females in aspects regarding adverse effects after receiving one or two doses of COVID-19 vaccines. This study is one of the limited studies that compared genders after receiving COVID-19 vaccines.

The largest proportion of the participants was females, as females constituted the majority of HCWs. From 2003, females represented the majority of students in medical colleges because of their higher marks on school bachelor tests, by findings published in the previous studies.¹³

In general side effects were minimal and tolerated and they were self-limiting in both sexes, however, females reported more adverse effects compared to males.

Similar to the findings of this study, a cross-sectional study conducted in Malaysia among general population, also females experienced more adverse events compared to males.¹⁴ In another research accomplished in Germany by Hoffman et al, to evaluate the incidence of local and systemic adverse effects following vaccination with COVID-19 vaccines, women were also more likely to experience both local and systemic side effects. However, allergic reactions and vaccination complications were not detected. These findings were similar to the reports of the Centers for Disease Control and Prevention (CDC).¹⁵

In contrast to our result, a study performed in Saudi Arabia to report post-vaccination side effects among the general population. They found that males experience more adverse

effects compared to females.²

Pain at the injection site was the most prevalent adverse effect and treatments were not required for most of these respondents; as the pain was minor in most of them. Severe pain was reported more frequently among females than males. Whereas the precise reason for these gender differences is uncertain. Numerous psychosocial and biological factors appear to be important contributors. In an observational study that was done in the United Kingdom to report side effects following vaccination with Pfizer and AstraZeneca vaccines among general population, Pain at the injection site was identified in less than half of the participants and it is more common among women.¹⁶ In a study conducted by Hoffman et al, reported that 72% of females have no pain while 78% of males indicated they have no pain.¹⁵ Some theories revealed that both endogenous opioids and genetics have a fundamental role in these variations, while lots of studies imply that sex hormones influence pain sensitivity. Nevertheless, more researches into the particular modulatory influence of sex hormones on pain in male and female are needed. Along with stereotypical sex roles that may lead to disparities in pain expression, psychosocial processes including stress exposure and the ability to cope with pain could also explain the gender difference in pain threshold.¹⁷ In the aspect of systemic symptoms such as headache, tiredness, myalgia, chills and fever; women had a significantly greater incidence of moderate and severe side effects. Headache was also more common among females according to a study done by Menni et al in United Kingdom.¹⁶ In a study done in Germany, to report the incidence of adverse effects following vaccination with one of COVID-19 vaccines among HCWs, headache, chills and fever were also more common in women.¹⁸

Regarding the dermatological reactions, like swelling, skin rash and redness were also more common among female participants. In the German study, also swelling and redness were more among females, although the difference between them and males was not significant.¹⁵ Although rare, 90% of allergic responses were reported in females according to CDC report.¹⁹

In 2019, a study conducted to report vaccination side effects from 1990 to 2016 to the CDC, women reported 80% of severe allergic responses (anaphylaxis) in adults.²⁰

Other vaccines such as the influenza H1N1 vaccine have shown that females experienced greater vaccine-related adverse effects and have higher immunological reactions than males.²¹ According to theories tried to explain the gender-based disparity in self-reported vaccine adverse effects of COVID-19 vaccination. Women's sex hormones estradiol (in addition to their other roles) increases the formation of antibodies. Females also have a stronger immunological response, On the other hand, testosterone act in the opposite manner by decreasing immune response but at the same time increasing male susceptibility to viral infection.^{15,21,22} Furthermore, the social structure of masculinity and femininity played an important role in this issue, since women are more likely to request medical aid than men who may face several obstacles to getting assistance.



Limitation of the study

Although the sample size was high and recruitment of the studied sample population was from different cities in Iraq. The study was associated with some limitations; there was a lack of information regarding the participant's medical history such as chronic health conditions and drugs. Since the study is a descriptive one using a cross-sectional design and an electronic questionnaire, only persons who are using the internet in regular bases are eligible to participate. The elderly and people in the rural area represented the minority of the respondents. The study was based on trust and employed subjective assessments, to obtain accurate findings direct personal interview is preferable. Researchers mainly evaluated the vaccinations' short term side effects; a long term follow up

research in the general public is needed. A more comprehensive study including all approved vaccines is also recommended.

CONCLUSION

The objective of this study was to see which gender experienced more severe adverse effects after receiving COVID-19 vaccines. The study concluded that the majority of side effects reported with COVID-19 vaccines were tolerated and not severe. However, the occurrence of these side effects was more common in women than in men which may be attributed to the hormonal and psychological variation between them. A longitudinal follow up study may give us more powerful results.

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