

Evaluation of Side Effects Associated with COVID-19 Vaccines in Pregnant Women

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Abstract

Background: A variety of vaccinations have been developed to fight the coronavirus disease 2019 (Covid-19) 2 years after the coronavirus epidemic spread globally. During clinical studies, these vaccinations were linked to mild to severe side effects. This study aimed to evaluate the short-term side effects of Covid-19 vaccination in pregnant women in Zabol (Iran).

Methods: This cross-sectional study was conducted between August and October 2021 to collect data on the adverse side effects of Covid-19 vaccinations among 117 pregnant women in Zabol (Iran). A questionnaire was used to collect demographic data, vaccination information, and vaccine complications. SPSS software Version 22 was used to analyze the data at 2 levels descriptive and inferential statistics.

Results: A total of 117 pregnant women aged 27.67 ± 5.14 years were included. After the first and second doses of Covid-19 vaccinations, 91 (86.7%) and 84 (71.8%) pregnant women, respectively, suffered adverse effects. Moreover, after the first dose, 55 (51.4%) and 60 (56.1%) of pregnant women reported fatigue and headache, and after the second dose, 39 (33.3%) and 37 (31.6%) reported fatigue and headache, respectively.

Conclusion: The side effects reported in our study after receiving Covid-19 vaccinations in pregnant women were similar to those described in clinical studies of vaccines and were mild to moderate, showing that injectable vaccines had safe profiles. More research is needed, however, to assess the long-term side effects of existing vaccines.

Keywords: Coronavirus Disease 2019, Oxford-Astrazenka, Pregnant Women, Side Effects, Sinopharm, Vaccine

Conflicts of Interest: None declared

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Introduction

Severe acute respiratory syndrome coronavirus was discovered during a highly infectious respiratory sickness epidemic in Wuhan, China, toward the end of December 2019. SARS-CoV-2 was the cause of the global coronavirus disease 2019 (Covid-19) outbreak (1). When the illness was first detected in Iran, health officials implemented preventative measures to decrease the disease burden (2). Because there is currently no licensed antiviral therapy for Covid-19, various vaccination trials have begun in the hopes of limiting the outbreak (3). Since November 11, 2020, around 259 Covid-19 vaccination projects have been undertaken (4). The Pfizer-BioNTech

mRNA and Oxford-AstraZeneca vaccines were among the first vaccines to be authorized and made available to the public (1). Several additional vaccines have been produced, including the Chinese-made BBIBP-CorV vaccine (also known as the Sinopharm COVID-19 vaccine) (5). The Oxford-AstraZeneca was first approved for use in select high-risk and vulnerable populations, including health care professionals and the elderly with chronic diseases before being made available to the entire public, except children and pregnant women (1). The Sinopharm vaccine (a type of inactivated vaccine) was one of the first vaccinations to get approval for use in Iran's general popu-

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↑What is “already known” in this topic:

There is little data about the safety of coronavirus disease 2019 (Covid-19) vaccination during pregnancy.

→What this article adds:

The purpose of this study was to evaluate the short-term adverse effects of Covid-19 immunization in pregnant women.

lation, followed by pregnant women. The dead viral antigens are employed to generate antibodies that prepare the immune system for further virus assaults (4, 6). Inactivated viruses maintain their potential to replicate in vivo with mild or asymptomatic symptoms (7). Clinical trials of manufactured vaccines showed short-term side effects—such as pain, redness or swelling at the injection site, fatigue, headache, chills, fever, and muscle and joint pain—in the vaccine group compared with the placebo group. In addition, the incidence of serious side effects was similar in both the vaccine and placebo groups. Also, in the first and second phase clinical trials of the Sinopharm vaccine in 640 participants in China, the most common side effects reported by vaccine recipients were injection site pain and fever, which were mild and self-limiting and did not require treatment (4, 8). In addition to clinical trials, several additional studies have looked into the adverse effects of produced vaccines. In this context, Saeed et al investigated the side effects of the Covid-19 Sinopharm vaccination among UAE citizens. After the first dose of the vaccine, the researchers discovered that injection site pain, fatigue, and headache were more common in those younger than 49 years than in people over 49 years old. In all groups, the most prevalent adverse effects after the second dosage were injection site pain, fatigue, lethargy, headache, and tenderness (4). Alhazmi et al investigated the negative effects of Oxford-AstraZeneca and Pfizer-BioNTech vaccines in Saudi Arabia's general population. According to the researchers, 60% of those receiving the vaccine had adverse effects after the vaccination, with fatigue (90%) and pain at the injection site being the most common (85%) (1). The exclusion of pregnant women from clinical trials of produced vaccinations was one of the most crucial aspects of the studies. Even though these women had a greater risk of severe Covid-19-related illness, hospitalization, premature birth, and other complications than nonpregnant women (9). Covid-19 vaccinations should not be withheld from pregnant women, according to limited evidence from the Center for Disease Control and Prevention, the Advisory Committee on Immunization Practices, the American College of Obstetricians and Gynecologists, and the American Academy of Pediatrics (10). As a result, according to the Ministry of Health directives, the Sinopharm vaccine was chosen for injection among pregnant women in Iran. As previously mentioned, a number of studies have been done to assess the side effects of Covid-19 vaccines, but they are scarce, and some populations, such as pregnant women, have been ignored. The danger of Covid-19 vaccines must also be understood, and pregnant women must be informed, in order to improve immunization perception. Therefore, this study aimed to assess the short-term side effects of Covid-19 vaccination in a group of pregnant women in Zabol (Iran).

Methods

Design

This cross-sectional study was conducted over 3 months, from August 20 to October 20, 2021, in Zabol, Iran.

Participants

The samples of 117 pregnant women referred to vaccination clinics in Zabol were sampled using a convenience sampling method. Inclusion criteria were participants aged 18 years or over and gestational age preferably over 12 weeks. Respondents younger than 18 years and incomplete submissions were excluded.

Data Collection

The information was collected using a questionnaire based on previous studies (4, 11-13). The research questionnaire was divided into 2 sections. The first section contained demographic information such as age, education level, occupation, income, presence of underlying disorders, type of underlying disease, and Covid-19 history. The second segment focused on information about the Covid-19 vaccination, such as the type of vaccine given, the number of doses given, and the first and second dose adverse effects. The most common side effects reported in other researchers' studies were evaluated in the side effects section (1, 4, 11, 12). Pain, swelling, redness, and a burning sensation (heat or heat), or severe itching, as well as side effects after the injection such as fatigue, headache, chills, diarrhea, and vomiting, were all graded on a scale of 1 to 4 (mild, moderate, and severe). Also, the participants were categorized based on income into low (under 5 million Rials/Month), intermediate (between 5 and 10 million Rials/Month), high (between 10 and 20 million Rials/Month), and very high (more than 20 million Rials/Month). Mild fever (between 38°C and 40°C); severe fever (above 40°C); paresthesia; swelling of the eyes, face, and nose; and anaphylactic shock were also evaluated. In addition to the above, participants were questioned about any other negative effects they may have had. Also, pregnant women were asked to report any drugs they took after receiving Covid-19 vaccinations, as well as whether or not they saw a physician thereafter to account for the influence of confounding agents in the study. The report of reactions on the first week of the vaccination was recorded and reviewed.

Statistical Analysis

In SPSS software Version 22, the research data were examined at 2 levels—descriptive and inferential statistics. The demographic characteristics of pregnant women, as well as the side effects of the Covid-19 vaccination, were assessed using frequency, frequency percentage, mean, and standard deviation. Pregnant women were divided into 2 groups based on the existence or lack of adverse effects from Covid-19 vaccination injections, as well as the kind of vaccine received, and were investigated for various demographic variables and side effects using the independent *t*, chi-square, or Fisher exact tests.

Ethical Considerations

The Ethics Committee of Zabol University of Medical Sciences approved the current study (IR. ZBMU. REC. 1400.076). Pregnant women were given the assurance that the study would be conducted with their informed permission and that their personal information and data would be

considered confidential.

Results

Participants' Demographic and General Characteristics

In general, 117 pregnant women with a mean (\pm SD) age of 27.67 ± 5.14 years, ranging from 20 to 40 years were included in the study. The majority of the pregnant women in the study had at least a middle school education ($n = 41$), and 76.9% ($n = 90$) had an income that was considered to be middle class. Moreover, 29.9% ($n = 35$) have previously been diagnosed with Covid-19. Furthermore, 13% of them have recently been diagnosed with Covid-19. Only 22.2% ($n = 26$) had a history of any chronic diseases, most of whom had diabetes 13.7% ($n = 16$). Regarding the type of vaccine received, most pregnant women received the Sinopharm (89.7% [$n = 105$]), followed by AstraZenka (12.3% [$n = 12$]) (Table 1).

Side effects of Covid-19 Vaccine in Pregnant Women

The results related to the side effects of Covid-19 vaccines among the participants are presented in Tables 2 and 3. As demonstrated in Table 2, a total of 91 (86.7%) and 84 (71.8%) pregnant women, respectively, experienced the side effects of Covid-19 vaccines after the first and

second doses. A total of 110 (94%) pregnant women reported side effects from Covid-19 vaccines. Mild to moderate pain at the injection site within 3 days after injection was one of the most common local reactions reported by vaccine recipients—54.2% ($n = 58$) reported pain after the first dose and 36.8% ($n = 43$) after the second dose. Also, 9.3% ($n = 10$) reported redness after the first dose and 7.7% ($n = 9$) after the second dose. Swelling was reported by 17.8% ($n = 19$) after the first dose and by 12% ($n = 14$) after the second dose at the injection site by a lower percentage of pregnant women. In general, local reactions were reported to be mostly mild to moderate in severity. Headache and fatigue were the most common systemic events reported among participants. More than half of pregnant women reported fatigue (51.4% [$n = 55$]) and headache (56.1 [$n = 60$]) after the first dose, and 33.3% ($n = 39$) and 31.6% ($n = 37$) reported fatigue and headache after the second dose, respectively. Mild fever (38°C to 40°C) was reported by 21.5% ($n = 23$) and 6.8% ($n = 8$) of pregnant women after the first and second doses, respectively. Also, 7.5% ($n = 6$) of participants reported high fever (temperature, $\geq 40^{\circ}\text{C}$) after the first dose, while only 0.9% ($n = 1$) reported high fever after the second dose. Chills from the Covid-19 vaccine were reported by 36.4% ($n = 39$) and 11.1% ($n = 13$) of participants after the first and second doses, respectively. After receiving the first dose of the vaccination, the majority of participants had muscle pain (49.5% [$n = 53$]) and joint pain (25.2% [$n = 27$]). Approximately 18.7% ($n = 20$) of participants experienced nausea or vomiting after receiving the first dose of the vaccine. In addition, a minor percentage of participants suffered diarrhea after receiving the first (7.5% [$n = 8$]) and second (2.6% [$n = 3$]) doses. About one-third of participants reported paresthesia after the first dose and 17.9% ($n = 27$) after the second dose. Vomiting and swelling of the eyes, face, and nose (1.7% [$n = 2$]) were the least common systemic reactions among pregnant women after receiving 2 doses of the vaccine. None of the participants had anaphylactic shock after receiving the second dose (Table 2). Most participants had mild to moderate systemic symptoms, similar to allergy reactions, except 3 participants (2.8%) who reported severe fatigue and 1 (0.9%) participant who reported severe chills after receiving the first dose of the vaccination (Table 3). Medication was taken by 26.2% ($n = 28$) and 17.1% ($n = 20$) of participants, respectively, to alleviate the adverse effects of the first and second injections, and just 1 participant had seen a physician after the second dose.

Side effects and Related Factors of the Second Dose related factors

We categorized the participants into 2 main groups: pregnant women who experienced side effects and pregnant women who did not experience side effects. The 2 groups were compared using several parameters, including age, gestational age, previous SARS-CoV-2 infection, history of chronic diseases, and number of doses received (Table 4). According to the findings, there was no statistically significant difference in age, presence or absence of underlying disease, type of underlying disease, history of

Table 1. General characteristics of participants in this study

Characteristic	Participants (n = 117)
Age, years	27.67 \pm 5.14
Education level	
middle school or less	41 (35)
high school	34 (29)
Diploma	23 (19.7)
College or above	19 (16.2)
Work status ^a	
Government	13 (11.1)
Free	45 (38.5)
Housewife	59 (50.4)
Income level ^b *	
Low	19 (16.2)
Medium	90 (76.9)
High	7 (6)
Very High	1 (0.9)
Previously infected with COVID-19 ^b	
Yes	35 (29.9)
No	82 (70.1)
Currently Infected with COVID-19 ^b	
Yes	12 (10.3)
No	105 (89.7)
chronic diseases	
Yes	26 (22.2)
No	91 (77.8)
kinds of chronic diseases	
Diabetes	16 (13.7)
Hypertension	2 (1.7)
Respiratory Disorders	6 (5.1)
heart disease	1 (0.9)
None	92 (78.6)
Type of vaccine received	
Sinopharm	105 (89.7)
Oxford/AstraZeneca	12 (12.3)
Received doses	
First dose	52 (44.4)
Second dose	65 (55.6)

Values in parentheses are percentages; ^aMean \pm standard deviation and ^bfrequencies.

* low: <5 million Rials; intermediate: between 5 and 10 million Rials; high: between 10 and 20 million Rials; very high > 20 million Rials.

Table 2. Local and systemic reactions reported after injection of COVID-19 vaccine among participants

Characteristic	Participants With Side Effects	
	One dose N=91 (86.7%)	Two dose N=84 (71.8 %)
Local Events		
Redness at injection site	10 (9.3)	9 (7.7)
Swelling at injection site	19 (17.8)	14 (12)
Pain at injection site	61 (57)	40 (34.2)
Systemic Events and Use of Medication		
Fatigue	55 (51.4)	39 (33.3)
Headache	60 (56.1)	37 (31.6)
Chills	39 (36.4)	13 (11.1)
Muscle Pain	58 (54.2)	43 (36.8)
Joint Pain	28 (26.2)	18 (15.4)
Burning and Pruritus at injection site	12 (11.2)	8 (6.8)
Vomiting	20 (18.7)	2 (1.7)
Diarrhea	8 (7.5)	3 (2.6)
Mild fever	23 (21.5)	8 (6.8)
high fever	8 (7.5)	1 (0.9)
Paresthesia	31 (29)	21 (17.9)
Swelling of the eyes, face and nose	3 (2.8)	2 (1.7)
Use drug or see a doctor		
Taking medication to mitigate side effects	28 (26.2)	20 (17.1)
Go to doctor	0	1 (0.9)

Table 3. Some local and systemic reactions based on severity after injection of COVID-19 vaccine among participants

Characteristic	Severity			Severity		
	Mild	Moderate	Severe	Mild	Moderate	Severe
	First dose N(%)			Second dose N (%)		
Local Events						
Redness at injection site	10 (9.3)			9 (7.7)		
Swelling at injection site	19 (17.7)			14 (12)		
Pain at injection site	35 (32.7)	26 (24.3)		29 (24.8)	11 (9.4)	
Systemic Events and Use of Medication						
Fatigue	42 (39.3)	10 (9.3)	3 (2.8)	34 (29)	5 (4.3)	
Headache	49 (45.8)	11 (10.3)		32 (27.3)	5 (4.3)	
Chills	35 (32.7)	3 (2.8)	1 (0.9)	9 (7.7)	4 (3.4)	
Muscle Pain	53 (49.5)	1 (0.9)		40 (34.2)	3 (2.6)	
Joint Pain	27 (25.2)	1 (0.9)		18 (15.4)		
Burning and Pruritus at injection site	12 (11.2)			8 (6.8)		
Vomiting	20 (18.7)			2 (1.7)		
Diarrhea	8 (7.5)			3 (2.6)		

Table 4. Univariate analysis of the participants who presented with side effects compared to those without side effects due to COVID-19 vaccination

Characteristic	Pregnant women with side effects, n = 110 (94%)	Pregnant women without side effects, n = 7 (6%)	P Value*
Age, Mean (SD)	27.44±5.08	31.14±5.21	0.074
History of chronic diseases, n (%)			
Yes	24 (20.51)	2 (1.71)	0.686
No	86 (73.49)	5 (4.29)	
History of chronic diseases, n (%)			
Diabetes	16 (13.67)	0	0.061
Hypertension	2 (1.71)	0	
Respiratory disorders	4 (3.42)	2 (1.71)	
Heart disease	1 (0.85)	0	
None	87 (74.35)	5 (4.29)	
Recently of COVID-19, n (%)			
Yes	10 (8.55)	2 (1.71)	0.108
No	100 (85.45)	5 (4.29)	
History of COVID-19			
Yes	35 (29.91)	0	0.076
No	75 (64.09)	7 (6)	
Received two doses			
One doses	49 (41.87)	3 (2.57)	0.932
Two doses	61 (52.13)	4 (3.43)	
Type of vaccine received			
Sinopharm	98 (83.74)	7 (6)	0.368
Oxford-AstraZeneca	12 (10.26)	0	

SD: Standard deviation. *The alpha criterion for the P value was set to 0.05.

Covid-19, number of doses injected, and kind of vaccination received between pregnant women with and without problems ($P > 0.05$).

The most prevalent adverse effects related to injectable

vaccination were also evaluated using univariate analysis. The rate of adverse effects caused by the injection of 2 doses of vaccination among pregnant women was not statistically significant ($P > 0.05$) based on the kind of vac-

Table 5. Univariate analyses testing different side effects significantly associated with sinopharm and pfizer-biontech COVID-19 vaccines

Side effect	Univariate Analysis		
	Sinopharm n=105	AstraZeneca n=12	P Value
Redness at injection site	9	0	0.593
Swelling at injection site	11	3	0.166
Pain at injection site	36	4	1.000
Fatigue	34	5	0.538
Headache	31	6	0.198
Chills	11	2	0.624
Muscle Pain	38	5	0.761
Joint Pain	17	1	0.695
Burning and Pruritus at injection site	8	0	1.000
Vomiting	2	0	1.000
Diarrhea	3	0	1.000
Mild fever	7	1	0.593
high fever	1	0	1.000
Paresthesia	19	2	1.000
Swelling of the eyes, face and nose	2	0	1.000

cine received (Table 5).

Discussion

Pregnant women with Covid-19 are at an elevated risk for adverse outcomes, and Covid-19 immunization during pregnancy is advised. However, there is little evidence for the safety of Covid-19 immunization during pregnancy. Thus, this study aimed to assess the short-term side effects of Covid-19 vaccination in pregnant women. According to our findings, 91 and 84 of the 117 evaluated pregnant women reported adverse effects after receiving the first and second doses of the Sinopharm and AstraZenka vaccines, respectively. In previous investigations, women experienced more side effects with both doses of the Covid-19 vaccination (14, 15). In a study by Saeed et al (4), women reported 83% and 98.5% of side effects with the first and second doses of the Covid-19 Sinopharm vaccine, respectively compared with men, which was consistent with the findings of our study. In another study by Alhazmi et al in Saudi Arabia on 515 participants in the general community, 60% of participants experienced side effects with Covid-19 (Pfizer–BioNTech and Oxford–AstraZeneca) vaccinations (1), which is less than the current study's stated number. This might be due to the type of vaccination received, gender, and other factors. The majority of pregnant women who got the Sinopharm vaccination were assessed in this study, whereas Alhazmi et al evaluated the general Saudi population who were vaccinated with the Pfizer–BioNTech and Oxford–AstraZeneca vaccines (1). In general, the incidence of complications varies depending on factors such as age, vaccination type, vaccine dose, gender, and other factors (4, 11, 16), which might explain the disparity between the current research and that of Alhazmi et al and other's comparable studies. Mild to severe pain, fatigue, headache, and muscular pains were the most prevalent adverse effects of the Sinopharm and Oxford–AstraZeneca vaccinations in pregnant women. These findings were in line with those published in the first and second phases of the Sinopharm vaccine (8), as well as the third phase of the Pfizer–BioNTech and Oxford–AstraZeneca vaccines (11,

16). Consistent with the findings of the present study, the most common side effects of the Covid-19 Sinopharm vaccine among UAE residents include pain at the injection site, fatigue, lethargy, headache, and tenderness after the first dose, and pain at the injection site, fatigue, lethargy, headache, and tenderness after the second dose, all of which were mild to moderate in severity (4). In another study, Alhazmi et al found that the most common side effects of Pfizer–BioNTech and Oxford–AstraZeneca vaccines in the general population of Saudi Arabia were fatigue (90%), injection site pain (85%), fever (66%), and headache (62%), respectively (1), consistent with the findings of our study. Moreover, similar results were reported in a recent study by Menni et al in London (13). The first dose of the vaccination had more negative effects on pregnant women than the second dose. The negative effects of the Covid-19 vaccination are more severe after the first dosage, according to the Centers for Disease Control and Prevention (4). Some studies, however, found that the prevalence of adverse effects after the second vaccination dose was somewhat higher than the first (4, 14). Local pain at the vaccine injection site was the most prevalent adverse effect encountered by pregnant women, as verified by previous research (1, 14, 15). After injection site pain, the most prevalent adverse effects of the first dose of the Covid-19 Sinopharm vaccine were headache (56.1%) and fatigue (51.4%), respectively. Saeed et al reported fatigue and headache as the most prevalent adverse effects of the Covid-19 Sinopharm vaccine after pain at the injection site in those younger than under 49 years, which is similar to our findings (4). Women with underlying diseases, a history of Covid-19, and 2 vaccination doses experienced higher adverse effects, although the difference was not statistically significant. In this regard, Alhazmi observed no statistically significant difference between the 2 groups receiving the vaccination (with and without side effects) in terms of a history of Covid-19 and underlying diseases in research done on the general population in Saudi Arabia (1). Although the difference was not statistically significant, pregnant women who got the Sinopharm vaccination experienced a higher frequency of pain at the

injection site, fatigue, and postinjection headache than women who received the Oxford-Astrazenka vaccine, according to our findings. The Sinopharm vaccine was the only one licensed for Iranian pregnant women and other vaccines such as Astrazenka have been used by some pregnant women under certain circumstances, so only 12 pregnant women were vaccinated with the Oxford vaccine-Astrazenka (the first dose was injected before pregnancy) in our study, a decision reflected in our study sample, where only about 10% received the Oxford-Astrazenka vaccine. Thus, it would be enlightening if we included more pregnant women who have received other vaccines, especially Oxford- Astrazenka. However, receiving vaccines other than Sinopharm for pregnant women was limited at the time of our study. We found that just 1% of pregnant women are required to visit a physician because of the adverse effects of the Covid-19 vaccine, a fact that might reassure pregnant women about the vaccine's safety.

Despite being one of the few studies in Iran to look at the adverse effects of Covid-19 vaccines in a specific population, our study has several limitations. The long-term negative effects of the Covid-19 vaccination could not be assessed because of the lack of an online questionnaire for participants, and a larger sample size was not available due to quarantine circumstances and other factors. Moreover, polling was difficult during the Covid-19 pandemic, particularly for studies that targeted pregnant women from particular social groups.

Conclusion

The findings revealed that adverse effects after receiving the first and second doses of the Covid-19 Sinopharm and Oxford-Astrazenka vaccines in pregnant women were prevalent, predictable, mild to moderate, nonserious, and non-life threatening. The most prevalent side effects reported by women were injection site pain, fatigue, headache, muscular pains, fever, and chills. To our knowledge, this is the first study on the negative side effects of the Oxford-Astrazenka and Covid-19 Sinopharm vaccines on expectant mothers.

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Conflict of Interests

The authors declare that they have no competing interests.

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