

Determinants of Non-Acceptance of the COVID-19 Vaccine During Pregnancy in Pregnant and Postpartum Women: A Descriptive Cross-Sectional Study

Maryam Dehshiri; M.Sc.¹, Mehrdad Mansouri; M.D.², Mohammad Hossein Jarahzadeh; M.D.³, Nooshin Hatamizadeh; M.D.⁴

1 Department of Midwifery, Islamic Azad University, Meybod, Iran

2 Shahid Sadoughi University of Medical Sciences, Yazd, Iran

3 Department of Anesthesiology and Critical Care, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

4 Department of Obstetrics and Gynecology, School of Medicine, Shahid Sadoughi University of Medical Sciences, Yazd, Iran

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Abstract

Objective: The rate of COVID-19 vaccination hesitation among Iranian pregnant women is around 50%. The objective of the present study was to determine the reasons for the refusal of COVID-19 vaccination among pregnant and postpartum women.

Materials and methods: This descriptive cross-sectional study was performed on 304 pregnant and postpartum women in the comprehensive health centers of Yazd, Iran, between October 2022 and April 2023. Researchers collected the data of unvaccinated women through phone calls using a validated questionnaire. Data was collected using a questionnaire consisting of baseline characteristics and reasons for refusing vaccination. Descriptive statistics were used to analyze the data using SPSS version 22.

Results: The mean age of the pregnant and postpartum women participating in this study was 28.31 ± 6.47 years. The most common reasons for refusing the COVID-19 vaccine included fear of harming the fetus (32.2%), fear of side effects in the mother (25.7%), disbelief in COVID-19 disease and vaccine (13.8%), lack of information about the vaccine (12.8%), and negative opinions of the media and society (12.8%). Less common reasons included husband's disagreement (8.2%), history of COVID-19 infection (6.9%), gynecologists' disagreement (6.3%), history of infertility (5.9%), and underlying disease (3.3%). Astonishingly, among participants who did not inject a booster dose of the vaccine, 76% reported they didn't receive any training and recommendation on booster dose injection from health providers.

Conclusion: Findings highlight that the most common reasons for refusing the COVID-19 vaccine were fear of harming the fetus and fear of side effects in the mother.

Keywords: SARS-CoV-2; COVID-19 Vaccines; Vaccination Hesitancy; Pregnancy

Introduction

On 31st December 2019, the first outbreak of

SARSCoV-2 (coronavirus disease 2019 [COVID-19]) spread rapidly throughout Wuhan, China, and involved more than 213 countries in the world. The World Health Organization (WHO) declared COVID-19 as an International Emergency Concern

Correspondence:

Dr. Nooshin Hatamizadeh

Email: n_hatamaizadeh@yahoo.com



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on January 30, 2020 (1). pregnant and postpartum women Compared with nonpregnant women affected by COVID-19 may be more prone to severe disease course and complications including requiring hospitalization, intensive care unit (ICU) admission, ventilator usage, requiring intubation, and/or death (2, 3). Centers for Disease Control reported that pregnant women are three times more susceptible to requiring admission to the ICU or intubation and 1.5 times more susceptible to dying of COVID-19 infection than nonpregnant women (4). Previous studies found a link between COVID-19 and adverse pregnancy outcomes such as myocardial infarction, thromboembolic events, pre-eclampsia, premature ruptures of membranes, low birth weight, intrauterine growth restriction, intrauterine fetal distress, in-utero fetal death, premature birth, premature neonatal death, and cesarean deliveries (5-8). Vertical transmission of COVID-19 has also been observed in mothers infected with COVID-19, although it is uncommon and rare and can result in fetal hydrops and fetal death (9). Some key nonpharmaceutical ways to slow or prevent the spread of COVID-19 are wearing a face mask, social distancing, and hand hygiene (10). Several studies suggest that the COVID-19 vaccination is safe and effective for pregnant and breastfeeding women and fetuses and infants during pregnancy and breastfeeding through passive transplacental and breastmilk transmission of antibodies (11-14). The Society for Maternal-Fetal Medicine (SMFM), College of Obstetricians and Gynecologists (RCOG), American College of Obstetricians and Gynecologists (ACOG), CDC, and WHO recommend that pregnant and breastfeeding women become vaccinated against COVID-19 (2, 15, 16). In a meta-analysis, vaccination hesitancy in pregnant and breastfeeding women was estimated at 48.4% (17). A prospective study conducted in Iran showed that the rate of COVID-19 vaccination hesitation among pregnant women was around 50% (18). Several variables such as insufficient data on the safety of the COVID-19 vaccine for pregnant women, possible harm to the fetus or neonate, role of husband and healthcare providers, and interpersonal norms can affect vaccine hesitancy in pregnant and breastfeeding women (19-21). Although there is recommended evidence for COVID-19 vaccination in pregnant and breastfeeding women, and evidence also supports the safety and efficacy of the vaccine, vaccine hesitancy remains high in the target population. The objective of the present study was to

determine the reasons for the refusal of COVID-19 vaccination during pregnancy among pregnant and postpartum women.

Materials and methods

This descriptive cross-sectional study was performed on pregnant and postpartum women in the comprehensive health centers of Yazd, Iran, between October 2022 and April 2023. Study inclusion criteria included all pregnant women in the second and third trimester of pregnancy and postpartum women, as well as over 18 years old who had not completed their COVID-19 vaccine injection during pregnancy. An incomplete COVID-19 vaccination is defined as a person who has not been vaccinated at all, a person who has received the first dose of the COVID-19 vaccine but has not returned for the second dose, or a person whose booster dose has arrived but has not yet returned for the COVID-19 vaccination. Exclusion criteria included pregnant women who were in their first trimester of pregnancy and who were unwilling to participate. In Iran, according to the national guidelines, injection of the COVID-19 vaccine is not recommended in the first trimester of pregnancy due to organogenesis. After approval of the study protocol, the telephone numbers of unvaccinated pregnant and postpartum women were obtained through the integrated health system (sib system). Researchers collected the data through phone calls using a validated questionnaire. Participants were informed of the aim and implications of the study, and verbal consent was also obtained from them after answering all questions during the phone call. The ideal sample size was estimated with PASS2021 software using a convenience sampling technique. Based on the Ayhan et al study, the minimum sample size was calculated to be 302 (3). Finally, 304 individuals participated in this study. A questionnaire consisting of 29 questions in two separate sections was used to collect data. This two-section questionnaire was as follows: baseline characteristics (Sociodemographic variables, and health status), and reasons for refusing vaccination. Sociodemographic variables were assessed using a question about age, education level, and employment status. Health status was assessed through questions about gestational trimester, gravidity, parity, number of children, history of abortion, history of infertility, history of underlying diseases, history of COVID-19 infection, history of flu shots, and history of COVID-19 vaccination with number of injections. The

researchers of the present study developed the second section of the questionnaire on reasons for refusing vaccination. To assess the validity of the questionnaire's content on the vaccination refusals, content experts (including 12 obstetricians, midwives, psychologists, and statisticians) were asked to determine the agreement degree of the questionnaire content with the research purpose.

$$n = \frac{z_{1-\alpha/2}^2(p(1-p))}{d^2}$$

Data analysis: All collected data were analyzed using SPSS version 22.0. The continuous variable (age) was presented by mean ± SD. Categorical variables like education level, occupation, underlying diseases, reproductive status, and current vaccination status were presented as numbers and percentages (%). Each rejection reason was presented in frequency and percentage.

Results

We received responses from a total of 304 women, consisting of 135 pregnant women and 169 breastfeeding women. The mean age of the pregnant and postpartum women participating in this study was 28.31 ± 6.47 years. 55.6% of the participants were pregnant and 44.4% were postpartum women. The majority of the participants in the study were housewives, while only 11.8% of them were employed. Approximately less than a quarter of the participants received either one or two doses of the COVID-19 vaccines or annual doses of flu, while the majority did not receive any type of vaccination. Also, according to the study, 18.8% of the individuals had a history of COVID-19 infection (Table 1).

Figure 1 illustrates the distribution of reasons given by participants who refused to receive the COVID-19 vaccination. In this study, the most common reasons for refusing the COVID-19 vaccine included fear of harming the fetus (32.2%), fear of side effects in the mother (25.7%), disbelief in COVID-19 disease and vaccine (13.8%), lack of information about the vaccine (12.8%), and negative opinions of the media and society (12.8%). Less common reasons included husband's disagreement (8.2%), history of COVID-19 infection (6.9%), gynecologists' disagreement (6.3%), history of infertility (5.9%), and underlying disease (3.3%). Astonishingly, among participants who did not refer to receiving a booster dose of the vaccine, 76% of them reported they didn't receive any training and

recommendation on booster dose injection from health providers (Table 2 & Figure 1).

Table 1: Sociodemographic, Pregnancy, and Health status of participants Sample, n =304

Variables	Categories	Value
Age	Age, Mean ± SD	28.31 ±6.47
	≤ 25	123 (40.5)
	26-30	70 (23)
	31-35	63 (20.7)
	36-40	38 (12.5)
Education	≥41	10 (3.3)
	Under diploma	104 (34.2)
	Diploma	125 (41.1)
	Bachelor	70 (23.0)
Occupation	Master & PhD	5 (1.6)
	Housewife	268 (88.2)
Gravity	Employed	36 (11.8)
	G1	100 (32.9)
	G2	91 (29.9)
	G3	69 (22.7)
Parity	G4 & more	44 (14.5)
	Nulliparity	74 (24.3)
	P1	111 (36.5)
Abortion	P2 & More	119 (39.1)
	Yes	82 (27.0)
Alive child	No	222 (73.0)
	0	75 (24.7)
	1	110 (36.2)
	2	73 (24.0)
Gestational age	3 & More	46 (15.1)
	Second trimester	96 (31.6)
	Third trimester	73 (24.0)
History of infertility	Fourth trimester (postpartum)	135 (44.4)
	Yes	31 (10.2)
Have a high-risk pregnancy	No	273 (89.8)
	Yes	96 (31.6)
History of COVID-19 infection	No	208 (68.4)
	Yes	57 (18.8)
History of flu vaccination	No	247 (81.3)
	Yes	66 (21.7)
History of COVID-19 vaccination	No	238 (78.3)
	No	235 (77.3)
	Yes	69 (22.7)
	1 dose	42 (13.8)
	2 doses	27 (8.9)

Discussion

Recent studies have reported a low acceptance rate of COVID-19 vaccination among pregnant women (3, 22).

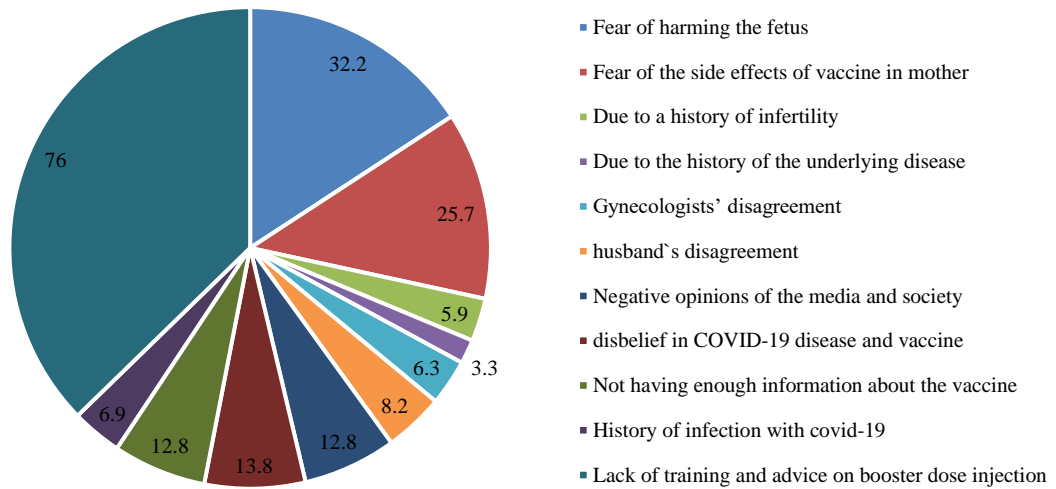


Figure 1: Frequency of reasons for refusing the COVID-19 vaccination

Table 2: Distribution of participants according to reasons for refusing COVID-19 vaccination

Reasons for refusing COVID-19 vaccination	n	%
Fear of harming the fetus	Yes	98 32.2
	No	206
Fear of side effects in the mother	Yes	78 25.7
	No	226
Disbelief in COVID-19 disease and vaccine	Yes	42 13.8
	No	262
Not having enough information about the vaccine	Yes	39 12.8
	No	265
Negative opinions of the media and society	Yes	39 12.8
	No	265
Husband's disagreement	Yes	25 8.2
	No	279
History of infection with covid-19	Yes	21 6.9
	No	283
Gynecologists' disagreement	Yes	19 6.3
	No	285
Due to a history of infertility	Yes	18 5.9
	No	286
Due to the history of the underlying disease	Yes	10 3.3
	No	294
Lack of training and advice on booster dose injection	Yes	19 76
	No	6

Vaccine hesitancy during pregnancy can be a challenge, and the decision-making process for medication use during pregnancy can be complex (23). The objective of this study was to examine the reasons behind the refusal of COVID-19 vaccines by pregnant and postpartum women in Yazd, Iran. The majority of reasons for refusing the COVID-19

vaccine in this study were fear of harming the fetus, fear of side effects in the mother, disbelief in COVID-19 disease and vaccine, lack of information about the vaccine, and negative opinions of the media and society respectively. Along with our findings, in other studies concerns about harming their unborn children or birth defects, worry and doubts about safety and side effects of the COVID-19 vaccine were the predominant reported reasons for refusing the vaccination (3, 18, 19, 24, 25). A qualitative interview study conducted on pregnant women in the UK revealed that some women desired more information about the safety and side effects and they perceived the potential risk of COVID-19 vaccines to be greater than the risk from COVID-19 virus itself (26). Consistent with our findings lack of information about the COVID-19 vaccines and disbelief in COVID-19 disease and vaccine were other major reasons for refusing of COVID-19 vaccine. Many people believed they were immune from COVID-19 due to their youth, health, or previous mild COVID-19 (25). Although the CDC deemed Pregnant and breastfeeding women as a high-risk population, they were excluded from the initial clinical research on COVID-19 vaccines (3). Also, Kiefer et al. reported that one of the main reasons for vaccine hesitancy is the lack of available data on the vaccines. However, a majority of participants who are hesitant towards the vaccines have stated that more vaccine data could potentially change their minds towards accepting the vaccines. This suggests that increasing the amount of data available about COVID-19 vaccines, particularly about their safety

during pregnancy, could help to alleviate vaccine hesitancy (27). This may indicate a lack of knowledge about the vaccine's protective effect on pregnant individuals and fetuses, as well as a lack of safety data for pregnant individuals. A study by Geoghegan et al. in Ireland showed significant emphasis on scientific data, which could be due to the current media landscape (28).

Recent studies have reported a low acceptance rate of COVID-19 vaccination among pregnant women (3, 22). Vaccine hesitancy during pregnancy can be a challenge, and the decision-making process for medication use during pregnancy can be complex (23). The objective of this study was to examine the reasons behind the refusal of COVID-19 vaccines by pregnant and postpartum women in Yazd, Iran. The majority of reasons for refusing the COVID-19 vaccine in this study were fear of harming the fetus, fear of side effects in the mother, lack of information about the vaccine, disbelief in COVID-19 disease and vaccine, and negative opinions of the media and society respectively. Along with our findings, in other studies concerns about harming their unborn children or birth defects, worry and doubts about safety and side effects of the COVID-19 vaccine were the predominant reported reasons for refusing the vaccination (3, 18, 19, 24, 25). Safety concerns were mainly associated with the perceived rapid development of the vaccine and inadequate pregnancy data (25). A qualitative interview study conducted on pregnant women in the UK revealed that some women desired more information about the safety and side effects and they perceived the potential risk of COVID-19 vaccines to be greater than the risk from COVID-19 virus itself (26). Consistent with our findings lack of information about the COVID-19 vaccines was another major reason for refusing of COVID-19 vaccine. Also, Kiefer et al. reported that one of the main reasons for vaccine hesitancy is the lack of available data on the vaccines. However, a majority of participants who are hesitant towards the vaccines have stated that more vaccine data could potentially change their minds towards accepting the vaccines. This suggests that increasing the amount of data available about COVID-19 vaccines, particularly about their safety during pregnancy, could help to alleviate vaccine hesitancy (27). In the present study, another main reason for refusing the COVID-19 vaccine was disbelief in COVID-19 disease and vaccine. Golder et al. reported many people believed they were

immune from COVID-19 due to their youth, health, or previous mild COVID-19 (25). However the CDC deemed Pregnant and breastfeeding women as a high-risk population, they were excluded from the initial clinical research on COVID-19 vaccines (3). In this study, many women reported due to negative opinions of the media and society refused the COVID-19 vaccine. Issues with mistrust are more common in the general population and low- and middle-income countries toward government, health services, or pharmaceutical companies (29-33). A study by Geoghegan et al. in Ireland showed significant emphasis on scientific data, which could be due to the current media landscape (28). Misinformation can lead to false allegations of safety and efficacy and even conspiracy theories. This can create barriers to confidence and compliance (25). It is important to monitor social media platforms for fake news and misleading information regarding COVID-19 vaccines (34, 35).

In the present study, fewer common reasons for refusing the COVID-19 vaccines included husband's disagreement, history of COVID-19 infection, gynecologists' disagreement, history of infertility, and underlying disease, respectively. Also, the majority of participants who did not receive the booster dose reported not receiving any training or recommendations on booster dose injection from healthcare providers. In Iran, a study by Moini et al. (2023) showed that 9.7% of participants reported husband disapproval as the reason for refusing the COVID-19 vaccines which is consistent with the results of our study (18). History of COVID-19 infection studied as another reason for refusing the COVID-19 vaccine. In this study, 57 out of 304 participants with a previous history of COVID-19, 21 reported a history of COVID-19 infection as a reason for refusal. In line with our findings, another study conducted by Masa'deh et.al in Jordan showed that women who had previously been infected with COVID-19 reported higher hesitancy levels than those who hadn't (20). Also, some healthcare providers and obstetricians-gynecologists are not setting a good example by getting vaccinated. The reasons behind this could be due to the lack of COVID-19 vaccine safety data for pregnant women, unawareness of current guidelines, and concerns about adverse effects on the fetus and maternal physiology, which is consistent with this study (36). Moreover, in this study, 10.2% of participants had a history of infertility, and 5.9% of them reported a

history of infertility as a refusal reason for receiving the COVID-19 vaccine. According to Wang et al., vaccine hesitancy was high among infertile couples, resulting in a low vaccination rate compared to the general population (37). In this study, the least common reason for not accepting the COVID-19 vaccine was an underlying medical condition among the participants. Borga et al.'s study showed that having an underlying disease is associated with less doubt about the vaccine, which is aligned with the results of the present study (38).

In this study, it is understood that mothers' attitudes are influenced by many social, and personal factors. This study shows that vaccination decisions were largely based on a lack of knowledge about the impacts of the vaccine and concern for their unborn, rather than being 'anti-vax'. Improving health literacy and verifying the authenticity of data sources could enhance public trust. Information should extend beyond the vaccine alone.

Strengths and weaknesses of the research: This study has a limitation due to its focus on a single center in Yazd, Iran. As such, the findings of this study may not be generalizable to the wider Iranian society, particularly rural areas and cities that have distinct social, cultural, and religious beliefs. On the other hand, the present study is powerful in revealing the main reasons underlying the refusal of pregnant and breastfeeding women who disagree with vaccination and will guide the academic and political studies to be carried out.

Conclusion

The most common reasons for refusing the COVID-19 vaccine were fear of harming the fetus and fear of side effects in the mother. In addition, the majority of participants who did not receive the booster dose reported not receiving any training or recommendations on booster dose injection from healthcare providers. Our research highlights the necessity of clear and accurate scientific knowledge to reassure expecting mothers about the safety of the COVID-19 vaccine. It is essential to improve education on vaccines and health literacy for pregnant and breastfeeding women as it has the potential to increase vaccination coverage. Social media plays a crucial role in providing information on vaccines. Therefore, it is important to manage the information and news on vaccines effectively to enhance public confidence in vaccines.

Conflict of Interests

Authors declare no conflict of interests.

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