

Understanding of COVID-19 vaccination in pregnant female – Hesitancy and acceptance: A prospective observational study



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Submission: 15-07-2022

Revision: 30-09-2022

Publication: 01-11-2022

ABSTRACT

Background: India is one of the most severely affected countries due to the COVID-19 pandemic. A higher risk of severe illness and complications from COVID-19 had been observed in pregnant women as compared to nonpregnant women. The government of India on July 2, 2021, provided approval for the vaccination of pregnant women against COVID-19. A little data regarding the safety or harm during pregnancy of vaccination were available that time. Lack of safety data, fear, mistrust, underestimation of efficacy of vaccine, and chaos due to pandemic makes indecisive surrounding for pregnant women and this causes hesitancy with decision making about the COVID-19 vaccination. **Aims and Objectives:** This study aims to analyze the willingness and hesitancy of pregnant women to get vaccinated against COVID-19. **Materials and Methods:** This prospective study was conducted in a tertiary care institute in Northern India. Five hundred antenatal women who were eligible for COVID-19 vaccination were included in this study. Informed consent has been taken and data were analyzed after filling face to face questionnaire regarding vaccine acceptance or hesitancy. **Results:** The present study revealed low acceptance of COVID-19 vaccination in pregnancy. Prime reasons for the same are no allowance by the family and the possibility of vaccine harming the baby. **Conclusion:** Specific efforts should be directed toward high-risk populations including pregnant women and those who are planning for pregnancy. This will promote vaccination rates by increasing people's trust in immunization and the health-care system.

Keywords: COVID-19; Pregnancy; India; Vaccination

Access this article online

Website:

<http://nepjol.info/index.php/AJMS>

DOI: 10.3126/ajms.v13i11.46597

E-ISSN: 2091-0576

P-ISSN: 2467-9100

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INTRODUCTION

India is one of the most severely affected countries due to the COVID-19 pandemic. A higher risk of severe illness and complications from COVID 19 had been observed in pregnant women as compared to non-pregnant women. Antenatal women were found to be 3 times more prone to admission in Intensive Care Unit or need intubation and more likely to die from COVID 19 than non-pregnant women in a report from Centers of Disease Control and Prevention.¹ Although around 2 years have passed since the onset of pandemic, no specific treatment against the disease is available. Therefore, it is important to avoid

infection either by social distancing, usage of face masks, and personal hygiene or through the most effective eradication method by herd immunity through vaccination. The COVID-19 vaccine drive in India was launched on January 16, 2021. All people older than 18 years are eligible in phase 4 of the vaccination drive from May 1, 2021. By July 20, 2021, 326.4 million people in India (23.4% of the population) had received the first dose of the vaccine, and 85.4 million people (6.1% of the population) had received the second dose.² The government of India on July 2, 2021 provided approval for the vaccination of pregnant women against COVID-19.³ The decision on vaccination of pregnant women was long welcomed by

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the obstetricians since the women are at high risk during pregnancy. A little data regarding the safety or harm during pregnancy of vaccination were available that time.⁴ Although ensuring effective and equitable distribution of COVID-19 vaccinations are a top governmental objective, acceptability is also crucial. The effectiveness of any vaccination campaign depends on the public's trust in vaccines and the organizations that deliver them along with its efficacy. Lack of safety data, fear, mistrust, underestimation of efficacy of vaccine, and chaos due to pandemic makes indecisive surrounding for pregnant women and this causes hesitancy with decision making about the COVID-19 vaccination. Vaccine apprehension is a common problem in India, exacerbated by ignorance and distrust, especially in rural regions. Vaccine adoption in low-income nations, where large-scale vaccination has yet to commence, is less well understood. Even before the existing COVID-19 pandemic, the World Health Organization (WHO) identified vaccine hesitancy, defined as the delay in accepting or refusing vaccines, as one of the ten leading health threats worldwide.⁵ Understanding the factors that influence COVID-19 vaccine acceptability is important since a lag in immunization in any country might lead to the emergence and dissemination of novel variations that can overcome vaccine and disease-induced immunity.

This study aims to analyze the willingness of pregnant women to get vaccinated against COVID-19. We have advanced beyond merely analyzing vaccine uptake rates to collect and analyze data on the factors that influence vaccine uptake and hesitation, which is crucial for designing effective vaccine provision and messaging.

Aims and objectives

To investigate the acceptance of COVID 19 vaccination and study the reasons behind the refusal or hesitation for vaccination among pregnant women.

MATERIALS AND METHODS

This prospective study was conducted in a tertiary care institute in Northern India. Our institute had been designated as COVID referral center during COVID waves also and was having a load of around 500 patients in second wave and 250 patients in third wave. The study was pre-approved by the Institutional Ethics Committee for the final permission. Five hundred antenatal women who were eligible for COVID vaccination were included in this study.

Eligibility criteria: All pregnant women who come in for antenatal care in all trimesters explaining about

the risks and benefits of the COVID-19 vaccines (Covishield and Covaxin) that are available in the country. Informed consent has been taken and data were analyzed after filling face to face questionnaire regarding vaccine acceptance or hesitancy. The project has been approved by the ethical committee of this institute. The questionnaire included the detailed socio demographic profile, associated comorbidities, previous COVID infection, vaccination history, and questions regarding acceptance or reluctance of COVID vaccination. The primary outcome that was measured was reluctance or acceptance of COVID vaccination in pregnancy. Descriptive statistics has been used to analyze the continuous and categorical data and are presented in the form of mean, standard deviation, and percentage, while proportions are analyzed using Chi-square test. $P \leq 0.05$ has been considered statistically significant.

RESULTS

The sociodemographic characteristics are highlighted in Table 1. Out of 500 pregnant women who completed the questionnaire, 90 women (18%) stated their intent to receive the vaccine during pregnancy. There is no statistical difference in acceptance rates of vaccination in pregnancy on the basis of education in our study, as shown in Figure 1. Associated comorbidity in pregnancy such as diabetes, hypertension, and heart disease was present in 2.8% and 85% which were reluctant to take vaccine during pregnancy. About 47% of patients who intended to be vaccinated were in the third trimester and 58% of females who were reluctant for vaccination were in second trimester of their pregnancy ($P=0.01$) (Figure 2). Out of 500, 320 women had undergone COVID testing previously and 80% were reluctant to vaccinate. Only ten females had suffered COVID previously and all had mild symptoms of COVID.

Vaccine acceptance to tetanus toxoid was observed in 90% of patients and 90% had observed no symptoms to tetanus

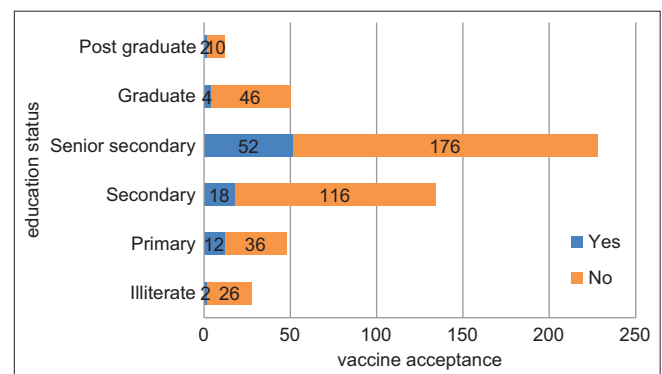
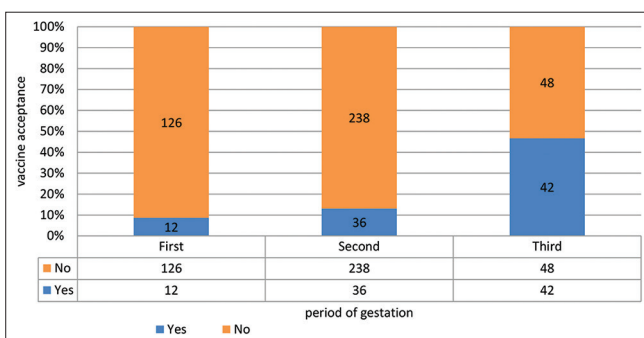


Figure 1: Vaccine acceptance in relation to education status

Table 1: Sociodemographic characteristics of patients in both groups

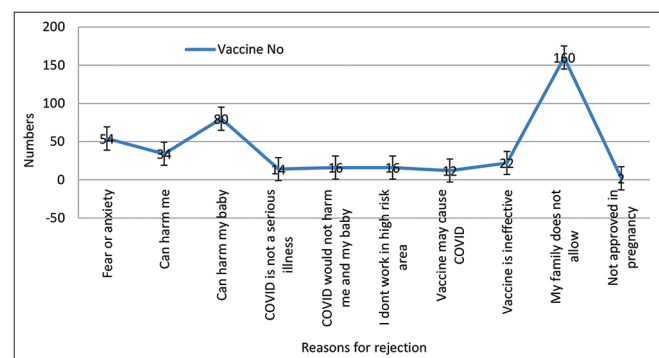
S. No.	Parameters analyzed	COVID vaccine acceptance (Yes) n=90	COVID vaccine acceptance (No) n=410	Total	P value
1.	Age (years)				
	<20	4 (4.4%)	26 (6.3%)	30	0.518
	20–25	50 (55.5%)	206 (50.2%)	256	
	26–30	30 (33.3%)	114 (27.8%)	144	
	31–35	4 (4.4%)	54 (13.2%)	58	
	36–40	2 (2.2%)	10 (2.4%)	12	
2.	Gravida				
	1	30 (33.3%)	180 (44%)	210	0.110
	2	28 (31.1%)	122 (29.7%)	150	
	3	22 (24.4%)	78 (19%)	100	
	4	8 (8.8%)	14 (3.4%)	22	
	5	0	10 (2.4%)	10	
	6	0	6 (1.5%)	6	
	8	2 (2.2%)	0	2	
3.	Parity				
	0	34 (37.7%)	196 (47.8%)	230	0.653
	1	38 (42.2%)	136 (33.2%)	174	
	2	16 (17.7%)	64 (15.6%)	80	
	3	2 (2.2%)	8 (2%)	10	
	4	0	6 (1.5%)	6	
4.	Education status				
	Illiterate	2 (2.2%)	26 (6.3%)	28	0.274
	Primary	12 (13.3%)	36 (8.8%)	48	
	Secondary	18 (20%)	116 (28.3%)	134	
	Senior secondary	52 (57.7%)	176 (43%)	228	
	Graduate	4 (4.4%)	46 (11.2%)	50	
	Post graduate	2 (2.2%)	10 (2.4%)	12	
5.	Trimester				
	First	12 (13.3%)	126 (30.7%)	138	0.01
	Second	36 (40%)	238 (58%)	272	
	Third	42 (46.7%)	48 (11.7%)	90	

**Figure 2:** Relation of vaccine acceptance with period of gestation

vaccine. About 21% of patients received COVID vaccine in pregnancy. Ninety patients have received first dose of vaccine in pregnancy at the time of enrollment in study, 42% of patients were in third trimester.

The various reasons for refusal for vaccine uptake are represented in Figure 3. The most common reasons given by the enrolled patients for vaccination was non-allowance by the family and the possibility of vaccine harming baby.

No post-vaccination symptoms were seen in 68% patients. Fever was the most common symptom post-vaccination (Figure 4).

**Figure 3:** Reasons for vaccine rejection

DISCUSSION

Maternal immunization is a public health approach that protects women and their fetuses against infection. COVID-19 vaccinations are successful in preventing serious disease in all populations, including pregnant women.⁶ Despite the fact that more than 100 nations recommend COVID-19 immunization during pregnancy, COVID-19 vaccination in pregnant women has trailed behind that in non-pregnant persons of the same age.⁷⁻⁹ Sixty-eight percentages of pregnant women had completed the primary COVID-19 vaccine series as

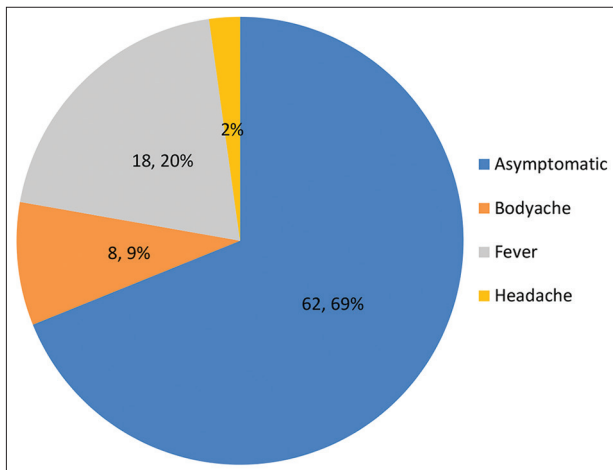


Figure 4: Post vaccination symptoms

of February 2022, according to the US Vaccine Safety Datalink.⁹ Long-standing inequities in maternal morbidity and death are anticipated to be exacerbated by persistent broad discrepancies in COVID-19 immunization during pregnancy by race or ethnicity. The present study revealed that 82% of women enrolled in study are reluctant to take COVID vaccine. Given the threat of new emerging variants around the world and an Indian health-care system that might be quickly overwhelmed by future outbreaks, this incidence of COVID-19 vaccination reluctance is quite worrying. In a research done in Turkey in 2021, just 37% of respondents said they would get the COVID-19 vaccine if it was recommended for pregnant women.¹⁰ Top most reasons for declining COVID vaccination in pregnancy were vaccination that is not allowed by the family members in pregnancy (39%), which can harm the baby (19%) and fear and anxiety of pregnant women (13%). It is necessary to evaluate the impact of subjective norms imposed by contemporaries.¹¹ Alfetlawi *et al.*, discovered that two-thirds of the participants in their study were willing to vaccinate provided their peers did so beforehand.¹² The chance of getting a pregnant mother to vaccinate will increase if friends and family members advise so. Similar findings were also highlighted regarding COVID vaccine acceptance and reluctance in an online survey conducted over 16 countries.¹³ Lower acceptance of vaccination in pregnancy suggests that women are understandably more suspicious about receiving a new vaccine whilst pregnant and they want safety information and data that is directly related to pregnancy. Thus, the earlier availability of vaccine safety data relating to pregnancy, and its communication, is significant. Out of 90 patients who had received first dose of vaccine in our study, 62 patients developed no post vaccination effects. Fever was most commonly observed in rest patients. Clinical evidence on the safety of the COVID-19 vaccine in pregnant women found no difference in adverse effects in post-vaccination status

between pregnant and non-pregnant women.¹⁴ However, this was not extensively investigated. Furthermore, pregnant women were shown to have a higher frequency of fever than non-pregnant women raising concerns about the vaccine's safety among pregnant women.^{15,16}

There is no statistical difference in acceptance rates of vaccination in pregnancy on the basis of education in our study as shown in Figure 1. This finding is of concern as it demonstrates that even educated are skeptical of the safety of the COVID-19 vaccine highlighting the challenge that health-care authorities will potentially face in engendering public trust in this pandemic control strategy within vulnerable groups. Incidentally, in an increasingly digital age, misinformation around the pandemic and the vaccine is rife, especially on social media platforms.¹⁷ It is essential for social media agencies to identify and flag potentially harmful misinformation and considers active promotion of content from public health agencies.

Additional risk factors for the severity of the disease in pregnancy include maternal comorbidities such as age over 40, obesity, chronic hypertension, and diabetes mellitus. Pregnant women should be considered a high-risk population for serious COVID-19 infection for all of the reasons stated above, and there are clear benefits to both mother and fetus from avoiding this disease during pregnancy.¹⁸ COVID-19 vaccine should be offered only to pregnant women with underlying health conditions that place them at greater risk of severe COVID-19 or if exposure to COVID-19 could not be avoided, according to the expert committee in the United Kingdom.¹⁹ In our study, 2.8% of patients had comorbidities and 85% were reluctant to take vaccine during pregnancy. The public's trust in these vaccines is a critical factor in their uptake. Clear government communication and advice are required to help establish trust in the system and increase vaccine uptake.

Vaccination acceptability is usually lower during pregnancy. Understanding how health-care providers promote maternal immunizations, as well as pregnant women's knowledge, attitudes, and concerns, is critical to increasing vaccination uptake. The acceptability of prenatal immunization among patients and the level of confidence in vaccine recommendations were studied in a recent multicenter questionnaire survey from the United Kingdom. Concerns about probable adverse effects for the baby, as well as concerns about the efficiency and necessity of immunization, were the most often reported reasons for avoiding maternal immunization, according to this study.²⁰ The primary challenges to vaccination acceptance in the pregnant population, according to a review published in 2015, were vaccine safety, the idea that vaccines are not

needed or effective, not recommended by health-care personnel, and a lack of understanding about vaccines.²¹ In India, tetanus toxoid injection during pregnancy is under health policy and is extensively monitored by both obstetricians and primary care doctors. The present study revealed that tetanus vaccine acceptability was substantially greater among the study participants than COVID-19. Both the COVID-19 vaccine acceptance and denial groups had around 90% tetanus vaccination acceptance. As a result, pregnant women are aware of the benefits of tetanus vaccination for maternal and newborn health.

Several variables contribute to differences in vaccine reluctance and acceptance rates. According to a systematic review, many characteristics such as socioeconomic background, education, and occupation, as well as political will and faith in the government, influenced likelihood to receive COVID-19 vaccine.²² Lack of vaccine information, as well as risk perceptions, safety and effectiveness of new vaccines, availability, and cost, are all important factors in vaccine uptake.²³ The rapid development of vaccinations, as well as political intervention, were considered to be variables influencing vaccine acceptability.²⁴

COVID-19 pandemic has posed distinct challenges in women's health care globally. As a result, pregnancy must be treated as a priority group, and efforts must be made judiciously, promptly, and based on scientific data in developing policies and guidelines that will allow health care to ensure safe, prudent, and timely management to this extremely vulnerable population. Physicians, hospital administrators, and policymakers should target on those who exhibit vaccine hesitancy or rejection and execute extensive interventions since they may be able to change their attitudes with more information and trust in vaccines. Target-based approach to overcome vaccine hesitance would entail making available credible information, promoting pro vaccine campaigns, improving accessibility, promoting women leaders, and facilitating transformational change.

Limitations of the study

Present study has small sample size.

CONCLUSION

The present study revealed low acceptance of COVID vaccination in pregnancy. Prime reasons for the same are no allowance by the family and the possibility of vaccine harming the baby. No significant vaccine acceptance rates were observed on the basis of age, parity, associated comorbid conditions, and educational status of the patients. Educational and public awareness campaigns should

be stepped up, employing a variety of media platforms, and reaching out to the general public through health-care professionals. Specific efforts should be directed toward high-risk populations including pregnant women and those who are planning for pregnancy. This will promote vaccination rates by increasing people's trust in immunization and the health-care system.

ACKNOWLEDGMENT

The authors would like to thank all the subjects for their consent to participate in this study.

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Authors' Contributions:

PS- Concept and design of the study, **MC-** Concept and drafting of manuscript, **MV-** Design of study and preparation of manuscript, **VM-** Concept of study and revision of manuscript, **SC-** reviewed literature and preparation of manuscript, **RY-** Data collection and statistical analysis.

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Source of Support: Nil, **Conflicts of Interest:** None declared.