

DOI: <https://dx.doi.org/10.18203/2320-1770.ijrcog20233296>

Original Research Article

Clinical status of COVID-19 vaccinated pregnant women: an observational study in a tertiary care hospital in Bangladesh

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Received: 24 September 2023

Accepted: 13 October 2023

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ABSTRACT

Background: Pregnancy is a special but often stressful time. The COVID-19 pandemic exacerbated this stress. Clinical trials have demonstrated the safety of COVID-19 vaccines for pregnant and lactating women, leading to WHO approval. Consequently, the Bangladesh Government has initiated a vaccination campaign for all expectant mothers to protect them from COVID-19. This study aimed to assess the clinical status of COVID-19-vaccinated pregnant women.

Methods: A cross-sectional study was carried out at Department of Obstetrics & Gynaecology in Combined Military Hospital, Dhaka Cantonment, Bangladesh, spanning August to November 2021. The study included 50 pregnant women who had received COVID-19 vaccinations, selected through purposive sampling. Data analysis and dissemination were performed using MS Office tools.

Results: The study found that the average age was 19.2 ± 10.8 years, with 66% falling into the 25-35 age group. About 50% had a normal BMI, while 22% were overweight (BMI: 25.0-29.9 Kg/m²). Hypertension and diabetes were present in 16% and 12% of cases, respectively. Among the 50 pregnant women, 40% were nulliparous, and 60% were multiparous; in most of the cases (54%), multigravidity (1-5) was found. Vaccination distribution was 28% in the 1st trimester, 54% in the 2nd, and 18% in the 3rd trimester.

Conclusions: COVID-19 vaccination rates are notably higher among pregnant women aged 25-35. The frequency of normal BMI among COVID-19-vaccinated pregnant women is satisfactory. Most pregnant women opt for COVID-19 vaccination during their second trimester.

Keywords: Clinical status, COVID-19, Vaccinated, Pregnant women, SARS-CoV-2

INTRODUCTION

COVID-19, caused by a novel coronavirus identified as severe acute respiratory syndrome-coronavirus-2 (SARS-CoV-2), has led to substantial morbidity and mortality since the declaration of a global pandemic in March 2020.¹ Although it is considered probable that physiological, mechanical, and immunologic alterations in pregnancy affect susceptibility to COVID-19, limited data address this issue.^{2,3} COVID-19 vaccination for pregnant and lactating women is the subject of ongoing global debate

because of the lack of concrete data on the safety and efficacy of vaccination in these populations.^{4,5} The reproductive period of a woman, without accounting for biological variations, typically begins at menarche and concludes at menopause, spanning from 13 to 51 years, representing a relatively brief phase in a woman's life.⁶ During the COVID-19 pandemic, there has been an escalation in morbidities, necessitating intensive care, ventilatory support, and tragically, fatalities among symptomatic pregnant women. Additionally, there has been a notable increase in the incidence of preterm birth

(less than 37 weeks) and the need for caesarean deliveries.^{7,8} This heightened demand for intensive care among pregnant women becomes especially concerning in low-income and middle-income countries.⁵ When managing pregnant women with COVID-19, the use of pharmaceutical interventions should be approached cautiously due to the limited data available on the safety and efficacy of most drugs during pregnancy.⁹ These factors emphasize the importance of considering pregnant women as candidates for preventive measures, with vaccination being the gold standard for reducing morbidity and mortality.⁹ The challenges in developing COVID-19 vaccines revolve around ensuring safety for all, including pregnant and lactating individuals. Pregnant women and lactating mothers warrant special attention because vaccination's potential benefits and risks impact both their health and that of their offspring.⁶ Several nonclinical studies, such as those involving developmental and perinatal/postnatal reproductive toxicities (DART) in pregnant mammals vaccinated during early and late gestational stages, revealed no vaccine-related adverse effects on female fertility, embryo-fetal development, or postnatal development. Consequently, clinical trials involving pregnant women have been integrated into COVID-19 vaccination programs.¹⁰ It's important to note that COVID-19 vaccination in pregnant women has not been associated with negative impacts on their unborn babies, and there is no increased risk of miscarriage among vaccinated individuals.¹¹ The objective of the current study was to evaluate the clinical status of pregnant women who have received COVID-19 vaccinations.

METHODS

This single-centered cross-sectional study was conducted at Department of Obstetrics & Gynaecology in Combined Military Hospital (CMH) Dhaka Cantonment, a tertiary-level Hospital in Dhaka, Bangladesh, spanning from August 2021 to November 2021. The study included 50 pregnant women, covering all trimesters, aged between 19 to 37 years. These women had received the mRNA vaccine (AstraZeneca) and had comorbidities such as hypertension, diabetes, obesity, and hypothyroidism. The study encompassed both primiparous and multiparous participants. Ethical approval for the study was obtained from the hospital's ethical committee, and written consent was obtained from all participants before data collection. Patients who had tested positive for COVID-19 and were hospitalized for the infection were excluded from the study. All demographic and clinical information was meticulously recorded, and data analysis and dissemination were carried out using MS Office tools.

RESULTS

In this study, a diverse group of participants aged between 19 and 37 years were included, with a mean age of 19.2±10.8 years. The majority of participants (66%) fell within the 25-35 years age group, indicating a significant representation of women in their prime reproductive years.

A smaller percentage (28%) belonged to the 25-35 years age group, while only 6% were in the 36-37 years age group.

Table 1: Distribution of participants as per age (n=50).

Age (years)	N	%
19-24	14	28
25-35	33	66
36-37	3	6

Table 2: BMI category (Kg/m²) of study participants (n=50).

Parameters	N	%
BMI category (Kg/m²)		
Underweight (<18.5)	7	14
Normal weight (18.5-24.9)	26	52
Overweight (25.0-29.9)	13	26
Obesity		
Obesity class I (30.0-34.9)	3	6
Obesity class II (35.0-39.9)	1	2
Obesity class III (≥40)	0	0

Table 3: Distribution of participants as per gravidity (n=50).

Gravidity	N	%
Nulligravidity (0)	15	30
Low multigravidity (1-5)	27	54
Grand multigravidity (≥6)	8	16

When assessing the participants' Body Mass Index (BMI) categories, the study found that slightly over half of the women (52%) had a normal BMI falling within the range of 18.5 to 24.9 Kg/m², which is generally considered a healthy weight.

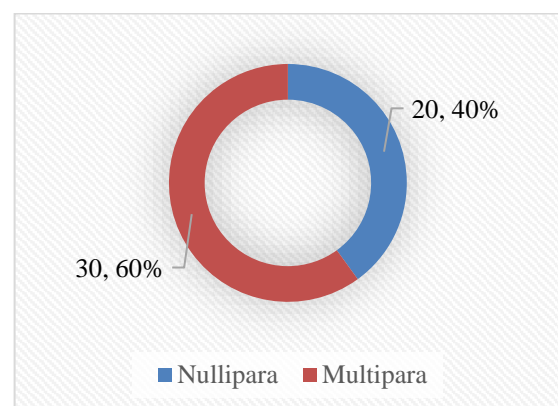


Figure 1: Distribution of participants as per parity (n=50).

However, a notable portion of participants presented with different BMI categories: 14% were underweight (BMI <18.5), 26% were overweight (BMI: 25.0-29.9), and 8% were classified as obese (BMI >29.9). Regarding their

obstetric history, 40% of the 50 pregnant women were nulliparous, indicating that they had not previously given birth, while the majority (60%) were multiparous, suggesting they had previous childbirth experiences.

Table 4: Distribution of comorbidities among study subjects (n=50).

Comorbidities	N	%
HTN	8	16
DM	6	12
Obesity	6	8
Hypothyroidism	2	4

Table 5: Distribution of timing at first vaccine dose among study subjects (n=50).

Weeks	N	%
1 st trimester (<14)	14	28
2 nd trimester (>14 and <28)	27	54
3 rd trimester (>28)	9	18

In terms of gravidity, the study found that 54% of cases had low multigravidity (1-5 pregnancies), indicating a moderate history of pregnancies, while 30% showed nulligravidity (0), suggesting they were experiencing their first pregnancy.

The study also explored comorbidities among the study subjects. It was observed that 16% of the cases had hypertension, highlighting the presence of a common medical condition among the pregnant women in this study. Additionally, 12% of the participants had diabetes mellitus, another 12% were classified as obese, and 4% had hypothyroidism, indicating a range of health conditions that may influence their pregnancy outcomes. Regarding COVID-19 vaccination, the study found that vaccination coverage varied across trimesters. Among the 50 pregnant women, 28% had been vaccinated in the 1st trimester, 54% in the 2nd trimester, and 18% in the 3rd trimester. This distribution suggests that a significant proportion of pregnant women opted for vaccination in the second trimester, followed by the first trimester and, to a lesser extent, the third trimester.

DISCUSSION

This study aimed to assess the clinical status of COVID-19-vaccinated pregnant women. In this study, the participants exhibited a broad age range, spanning from 19 to 37 years, with an average age of 19.2±10.8 years. Notably, the highest proportion of participants (66%) fell within the 25-35 years age group, indicating a significant representation of individuals in the prime reproductive years. Additionally, 28% of the participants belonged to the 19-24 years age group, while a smaller proportion (6%) was in the 36-37 years age group. The findings from this study are in line with existing theories and research. It is observed that pregnant individuals, particularly those in younger age brackets, are less likely to receive COVID-19

vaccinations compared to non-pregnant women of reproductive age.¹² Furthermore, the study highlights that the perception of the risk associated with contracting COVID-19 plays a substantial role in determining the likelihood of vaccination among pregnant individuals.¹³ These insights emphasize the importance of addressing vaccination disparities in the pregnant population and the need for targeted interventions to enhance vaccine uptake, particularly among younger pregnant women.

Upon evaluating the Body Mass Index (BMI) categories of the participants, the study revealed that just over half of the women (52%) maintained a normal BMI, falling within the healthy range of 18.5 to 24.9 Kg/m². Nevertheless, a substantial proportion of the participants exhibited varying BMI categories: 14% were underweight (BMI <18.5), 26% were overweight (BMI: 25.0-29.9), and 8% were categorized as obese (BMI > 29.9). In a separate study, it was observed that the most prevalent BMI category among the cases was within the normal range (18.5-24.9), accounting for 22.1% of the participants.¹⁴ The investigation extended to assess the comorbidities within the study cohort. The results revealed that 16% of the cases had hypertension, underlining the prevalence of this common medical condition among the pregnant women in the study.

Moreover, 12% of the participants were diagnosed with diabetes mellitus, another 12% were categorized as obese, and 4% had hypothyroidism, signifying a spectrum of health conditions that could potentially impact their pregnancy outcomes. This diversity of comorbidities underscores the need for comprehensive healthcare management during pregnancy, considering these underlying health factors. In the earlier study, the prevalence of various pregnancy-related conditions was documented as follows: Chronic diabetes was present in 8.2% of the cases, chronic hypertension in 2.1%, gestational diabetes in 7.5%, gestational hypertension in 4.5%, pre-eclampsia in 3.0%, and severe pre-eclampsia in 0.1%.¹⁴ These findings provide insight into the occurrence of these specific pregnancy-related conditions within the study population. In this study, out of the 50 pregnant patients, a substantial portion (40%) were nulliparous, indicating that they were experiencing their first pregnancy.

In contrast, more than half of the women (60%) were multiparous, suggesting that they had previous childbirth experiences. Additionally, one study found that the presence of congenital defects detected through ultrasonography was not associated with vaccination during the teratogenic window.¹⁵ This lack of association was held even after adjusting for potential confounding factors such as age at delivery, nulliparity, chronic hypertension, and hemoglobin A1c levels during the first trimester. These findings imply that vaccination during pregnancy did not appear to increase the risk of congenital defects in the study population, accounting for various influencing factors.

Within this study's cohort of 50 pregnant women, 14 individuals (28%) received the vaccine during the 1st trimester, 27 (54%) during the 2nd trimester, and 9 (18%) during the 3rd trimester. This observation lends significant support to the recommendation that pregnant individuals should consider receiving a booster dose. Research indicates that vaccine efficacy tends to decrease as time passes following the administration of the second or third dose of mRNA vaccines.^{16,17} Therefore, administering a booster dose may be crucial in maintaining protection, particularly for pregnant individuals during different stages of pregnancy.

Limitations

It's important to note that this study had a single-centered design and a relatively small sample size. Additionally, the study took place over a brief period. Consequently, the findings of this study may have limitations in terms of their generalizability to the broader population of the entire country. The narrow focus and limited sample size should be considered when interpreting the results, and further research with larger and more diverse cohorts and an extended study duration would be valuable for a more comprehensive understanding of the situation.

CONCLUSION

There is a noticeable trend of higher COVID-19 vaccination rates among pregnant women falling within the age range of 25 to 35 years. This suggests that this particular age group is more inclined towards getting vaccinated during pregnancy. Additionally, the frequency of pregnant women with a normal BMI who have received COVID-19 vaccination is at a satisfactory level, indicating that a significant portion of those receiving the vaccine falls into this healthy weight range. Furthermore, it is observed that a majority of pregnant women prefer to receive their COVID-19 vaccinations during the third trimester of their pregnancy, indicating a preference for later stages of pregnancy for vaccination. This information highlights important patterns in COVID-19 vaccination behavior among pregnant women.

Funding: No funding sources

Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Akhter H, Yasmin S, Nahar K. Clinical status of COVID-19 vaccinated pregnant women: an observational study in a tertiary care hospital in Bangladesh. *Int J Reprod Contracept Obstet Gynecol* 2023;12:3289-93.