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Original Research Article

Impact of pregnancy on antibody response to COVID-19 vaccine

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ABSTRACT

Background: Vaccination during pregnancy is a common and recommended practice to prevent maternal and infant morbidity from many infectious diseases. Likewise, pregnant women should be vaccinated against COVID-19 to protect themselves and their expectant children. The immune system is known to undergo alterations during pregnancy. Therefore, the present study was undertaken to determine the impact of pregnancy on antibody response in Bangladeshi pregnant women following two doses of the COVID-19 vaccine.
Methods: This cross-sectional study was conducted in the department of obstetrics and gynecology, Bangabandhu Sheikh Mujib medical university (BSMMU), Dhaka, Bangladesh from April 2022 to March 2023. This study included COVID-19-vaccinated 25 pregnant and 25 nonpregnant women attending the outpatient department (OPD) of obstetrics and gynecology, of BSMMU.
Results: The pregnant women were younger than the non-pregnant women. A few of the study subjects were hypertensive and/or diabetics and there was no difference between the study groups concerning hypertension and diabetes (p=0.500 and p=0.174 respectively). Over 20% of the study subjects were ever tested for COVID-19, but none were positive for COVID-19 infection. More than half of the subjects received Pfizer-BioNTech COVID-19 vaccination. In the majority of the pregnant and non-pregnant women, blood was collected after 6 weeks of the second dose of the vaccine. The IgG antibodies to SARS-CoV-2 were almost similar in both the study groups (15401.4 vs. 16575.6 AU/ml respectively) (p=0.742).
Conclusions: This study found that pregnancy did not significantly impact the antibody response to COVID-19 vaccination. The study also concluded that pregnant women respond well to the COVID-19 vaccines, mounting strong immune responses with final titers being fairly comparable to those in non-pregnant women of reproductive age.

Keywords: Pregnancy, Antibody response, COVID-19, Vaccine

INTRODUCTION

The current COVID-19 has created a global pandemic that is devastating to human lives and global economies. The outbreak started in Wuhan China in December 2019 and was declared a pandemic by the world health organization (WHO) on March 11, 2020.[1] More than 173 million cases and 3.7 million deaths have been attributed to COVID-19 globally.[2] Most cases of COVID-19 globally have evidence of human-to-human transmission. The transmission of the virus is known to occur more often through close contact with an infected person (within 2

meters) where respiratory secretions can enter the eye, mouth, nose, or airways. The other route is touching contaminating surfaces and subsequently touching one's mouth, nose, or eyes.[3] COVID-19 spreads primarily through contact routes and respiratory droplets but there is controversy about the airborne transmission of COVID-19.[4] Mechanical and physiological alterations in pregnancy increase susceptibility to infections. The immunologic alterations that occur during pregnancy not only may be protective of the fetal allograft but also may create vulnerability to viral infections. More than 73600 infections and 80 maternal deaths have occurred in pregnant women due to COVID-19 in the United States alone as of March 1, 2021.[5]

Pregnant women and their fetuses represent a high-risk population during infectious disease outbreaks.[1] SARS-CoV-2 infection is more severe in pregnant women compared to their non-pregnant counterparts, with an increased risk of hospital admission, ICU stay, and death.[5] More severe symptoms which suggest pneumonia and marked hypoxia are widely described with COVID-19 in immunosuppressed conditions. Most pregnant women experience only mild or moderate cold/flu-like symptoms e.g., cough, fever, shortness of breath, headache, and other relevant symptoms.[3] Whilst pregnant women are not necessarily more susceptible to viral illness, changes to their immune system in pregnancy can be associated with more severe symptoms. Pregnancy is known to be a hypercoagulable state and evidence suggests that individuals with COVID-19 are also hypercoagulable. COVID-19 infections are likely to be associated with an increased risk of maternal venous thromboembolism.[3]

There is no conclusive evidence currently that the virus is teratogenic, although there are case reports of preterm birth in women with COVID-19. There was evidence of fetal compromise and prelabour preterm rupture of the membrane.[3] Neonates are at greater risk of infections due to their immature immune systems.[6]

Despite their higher risk, pregnant women were not included in initial COVID-19 vaccine trials. The first vaccine trial began in pregnant women in February 2021 with the vaccine of Pfizer/BioNTech.[5] Based on limited data, advisory committees from the centers for disease control and prevention (CDC) and advisory committee on immunization practices (ACIP), the American college of obstetricians and gynaecologists (ACOG), and the American academy of pediatrics (AAP) have issued guidance indicating that COVID-19 vaccines should not be withheld from pregnant women.[2] The WHO statement revised on June 2, 2021, recommends vaccination in pregnant women when the benefits of vaccination outweigh the potential risks.[7] The health ministry of Bangladesh gave permission and directions for COVID-19 vaccination in pregnant women on August 09, 2021.[8]

The COVID-19 vaccination is the most promising means of controlling the spread of the COVID-19 global pandemic. Vaccination during pregnancy will reduce maternal and newborn morbidity and mortality; it will add an impetus to the ongoing control COVID-19 pandemic. The current vaccines have a safety profile and higher efficacy. As pregnant women were not included in initial vaccine trials and data on vaccine efficacy in this population is limited, therefore exploratory analysis is necessary to evaluate vaccine response in pregnant women to see whether it is similar or different from that in nonpregnant individuals. The proposed study will provide data on antibody generation in response to COVID-19 vaccination in pregnant and nonpregnant women.

Therefore, this study was undertaken to evaluate the impact of pregnancy on antibody response to covid-19 vaccine.

METHODS

This cross-sectional study was conducted in the department of obstetrics and gynecology with the help of department of haematology, BSMMU, Dhaka, Bangladesh from April 2022 to March 2023. This study included COVID-19-vaccinated 25 pregnant and 25 nonpregnant women attending the OPD of obstetrics and gynecology, of BSMMU within the study period.

These are the following criteria to be eligible for enrollment as our study participants:

Inclusion criteria

Pregnant women with gestational age between 13 to 34 weeks, non-pregnant women with age between 18-45 years, received two doses of the COVID-19 vaccine and 4 to 8 weeks passed after the second dose of vaccination were included.

Exclusion criteria

Previous history of vaccine allergy, diagnosed as the case of AEFI after COVID-19 vaccination, uncontrolled chronic diseases, diagnosed case of an immunosuppressed and cancer patient and history of previous COVID-19 symptomatic infection and COVID-19-positive women were excluded.

Data collection procedure

Informed written consent was taken from the patients who voluntarily agreed to participate in the study. A total of 50 subjects attending the OPD of obstetrics and gynecology (BSMMU) were enrolled in the study. Relevant history was taken from the subjects followed by necessary clinical examination. Blood samples were drawn from the antecubital vein of the study subjects 4-8 weeks after the second dose of vaccination. Data were collected from the patients on variables of interest using a semi-structured questionnaire designed for the interview, observation, clinical examination, and hematological investigation of

the patients. Gestational age was determined based on the last menstrual period and confirmed by ultrasound examination. About 3 ml of blood was drawn from the antecubital vein of the study subjects with proper aseptic precautions. The collected blood samples were sent to the haematology department of BSMMU, Dhaka for centrifugation to obtain serum, which was then analyzed for the qualitative and quantitative determination of IgG antibodies to SARS-CoV-2 on the ARCHITECT system. The competent laboratory personnel in the department of haematology, BSMMU, Dhaka, performed this procedure.

Statistical analysis

All data were recorded systematically in preformed data collection form. Quantitative data was expressed as mean and standard deviation; qualitative data was expressed as frequency distribution and percentage. Data were analyzed using the unpaired t test, chi-square (X^2) test, and Fisher's exact test. A $p<0.05$ considered as significant. Statistical analysis was performed by using SPSS 25.0 (Statistical package for social sciences) for Windows version 10. Ethical clearance for the study was taken from institutional review board of BSMMU, Dhaka, Bangladesh.

RESULTS

The present study aimed to evaluate the COVID-19 vaccine response in pregnant women and then compare the findings with non-pregnant women. Table 1 shows that the pregnant women were relatively younger than their non-pregnant counterparts (26.7±3.9 vs. 30.4±5.9 years, p=0.013). In terms of occupation, pregnant women were predominantly housewives (76%), whereas non-pregnant women were mostly service-holders (56%) (p=0.025). Sixty percent of the pregnant women were multigravida and 40% were primigravida. The mean gestational age of the pregnant mothers was 32.8±5.3 weeks. There was a significant difference between the pregnant and nonpregnant groups regarding age and occupation (p<0.05).

Table 2 shows that only a few study subjects were hypertensive and/or diabetics. There was no difference between hypertension and diabetes in both study groups (p=0.500 and p=0.174 respectively). The groups were almost identical in terms of BMI as well (p=0.556). One subject in each study group had asthma (p=0.955). Two (8%) cases of pregnant women had hypothyroidism compared to 1 (4%) case in the non-pregnant group (p=0.500). There was no statistically significant difference between the pregnant and nonpregnant groups for their comorbidities (p>0.05).

Table 3 found that about one-quarter (24%) of the pregnant women and 20% of the non-pregnant women had ever tested for COVID-19 (p=0.733), but none was positive for COVID-19 infection. None of the pregnant and non-pregnant women/their family members ever experienced any symptoms of disease. There was also no statistically significant difference between the pregnant and non-pregnant groups by their COVID-19 information (p>0.05).

Table 4 shows that 60% of the pregnant women and 52% of the non-pregnant women received the Pfizer-BioNTech COVID-19 vaccination. Five (20%) subjects from each group received moderna, 4 (16%) subjects from the pregnant group and 7 (28%) from the non-pregnant group had the Sinopharm vaccine. The mean gestational age at which the pregnant women received the first dose vaccine was 20.6 weeks. There was no statistically significant difference between the pregnant and non-pregnant groups in terms of the brand of vaccine they received (p>0.05).

Table 5 shows that in nearly two-thirds (64%) of the pregnant women and 80% of the non-pregnant women, blood was collected after 6 weeks of the second dose of the vaccine to determine the level of IgG antibodies to SARS-CoV-2. The antibody level was almost similar in both the study groups (15401.4 vs. 16575.6 AU/ml respectively) (p=0.742). There was no statistically significant difference between the pregnant and non-pregnant groups for blood collection time and antibody level (p>0.05).

Table 1: Distribution of sociodemographic characteristics between the study groups.

Socio-demographic characteristics	Group		P value
	Pregnant, (n=25)	Non-pregnant, (n=25)	
Age (in years)	26.7±3.9	30.4±5.9	0.013
Residence			
Inside Dhaka	25 (100.0)	23 (92.0)	0.245
Outside Dhaka	0 (0.0)	2 (8.0)	
Education			
Primary	0 (0.0)	2 (8.0)	0.225
SSC	0 (0.0)	2 (8.0)	
HSC	8 (32.0)	7 (28.0)	
Graduate	17 (68.0)	14 (56.0)	
Mothers' occupation			
Housewife	19 (76.0)	11 (44.0)	0.025
Service holder	5 (20.0)	14 (56.0)	
Student	1 (4.0)	0 (0.0)	

Continued.

Socio-demographic characteristics	Group		P value
	Pregnant, (n=25)	Non-pregnant, (n=25)	
Gravida			
Multigravida	15 (60)	-	-
Primigravida	10 (40)	-	-
Mean gestational age	32.8±5.3	-	-

Table 2: Distribution of patients by their comorbidities.

Comorbidities	Group		P value
	Pregnant, (n=25)	Non-pregnant, (n=25)	
HTN	1 (4.0)	2 (8.0)	0.500
DM	4 (16.0)	1 (4.0)	0.174
BMI (kg/m^2)			
18.5-24.9 (Normal weight)	17 (68.0)	15 (60.0)	0.556
25-29.9 (Overweight)	8 (32.0)	10 (40.0)	
Asthma	1 (4.0)	1 (4.0)	0.955
Hypothyroidism	2 (8.0)	1 (4.0)	0.500
β-thalassemia trait	1 (4.0)	0 (0.0)	0.500

Table 3: Distribution of patients by their COVID-19 information, (n=50).

COVID-19 information	Group		P value
	Pregnant, (n=25)	Non-pregnant, (n=25)	
Ever tested for COVID-19	6 (24.0)	5 (20.0)	0.733
Ever positive for COVID-19	0 (0.0)	0 (0.0)	-
Ever had COVID-19 symptoms	0 (0.0)	0 (0.0)	-
Any member of your family acquired a COVID-19 infection	0 (0.0)	0 (0.0)	-
Have you ever contacted with COVID-19 infected people	0 (0.0)	1 (4.0)	0.500

Table 4: Distribution of patients by type of COVID-19 vaccination received.

COVID-19 vaccine received	Group		P value
	Pregnant, (n=25)	Non-pregnant, (n=25)	
Vaccine brand			
Pfizer-BioNTech	15 (60.0)	13 (52.0)	0.581
Moderna	5 (20.0)	5 (20.0)	
AstraZeneca	1 (4.0)	0 (0.0)	
Sinopharm	4 (16.0)	7 (28.0)	
1st dose vaccination during pregnancy week	20.6±6.2	-	-

Table 5: Distribution of patients by their level of IgG antibodies to SARS-CoV-2.

COVID-19 vaccination and IgG antibody level	Group		P value
	Pregnant, (n=25)	Non-pregnant, (n=25)	
Blood collected after COVID-19 vaccination			
4-6 weeks	9 (36.0)	5 (20.0)	0.208
6-8 weeks	16 (64.0)	20 (80.0)	
Blood antibody (AU/ml)	15401.4±13805.2	16575.6±11180.5	0.742

DISCUSSION

A total of 25 pregnant women and 25 non-pregnant women with two doses of COVID-19 vaccination, attending the department of obstetrics and gynecology of BSMMU were included in this study.

In this present study, the mean age of nonpregnant women was 30.4 (±5.9) years and pregnant women was 26.7 (±3.9) years. The mean gestational age of the pregnant women was 32.8 (±5.3) weeks. The mean gestational age at which pregnant women received 1st dose of COVID-19 vaccine was 20.6 weeks. Gray et al study found that the mean age

of nonpregnant women was 38.4 years and pregnant women was 34.1 years. The mean gestational age at the first vaccine dose was 23.2 weeks.[5]

In the present study, antibody levels were measured 4-8 weeks after 2nd dose of COVID-19 vaccination. Both pregnant and nonpregnant women developed positive antibody responses to the COVID-19 vaccine. The Antibody (IgG antibody to SARS-CoV2) level was 15401.4 AU/ml and 16575.6 AU/ml in pregnant and nonpregnant women respectively. This study showed Antibody response in pregnant women is fairly comparable to that of their nonpregnant counterparts. Studies, conducted to date, have shown that pregnant women respond well to the COVID-19 mRNA vaccines (BNT162b2 and mRNA-1273), mounting strong immune responses with final titers that are comparable to those in non-pregnant women of reproductive age, and with similar safety and reactogenicity profiles.[5,9-11] Population-level statistics have shown that COVID-19 vaccinations are beneficial in preventing severe/critical COVID-19 and maternal death in expectant women.[12-16] Recent data from the CDC show that maternal mRNA vaccination is 61% effective in preventing newborn hospitalization for COVID-19 in the first 6 months of life. These studies involved pregnant women who received COVID-19 mRNA vaccines primarily in the third trimester.[5,9,17-20] Additionally, these studies showed the presence of anti-SARS-CoV-2-specific antibodies capable of neutralization and immune effector functions in umbilical cord blood at delivery.[21] Therefore, immunization of pregnant women against COVID-19 has the potential to benefit both the mother and the fetus and newborn by reducing the risk of adverse pregnancy outcomes related to severe maternal COVID-19 illness and by giving newborns immunity through the transfer of maternal antibodies through the placenta and breastmilk.[22]

The impact of the COVID-19 immunization during pregnancy is still being monitored. To better understand any impacts of the vaccine on pregnancies and babies, the CDC will continue to follow patients who received the vaccination throughout all trimesters of pregnancy. According to data, taking an mRNA COVID-19 vaccine while pregnant lowers the risk of developing a serious illness and other COVID-19-related side effects. Recent research compared expecting mothers who received the mRNA COVID-19 vaccine to expecting mothers who did not. Researchers discovered that the COVID-19 vaccine significantly decreased the probability of developing severe COVID-19 illness.[12-15,23,14] One study that examined pregnant women admitted to hospitals discovered that the majority had never had a vaccination.[25] According to additional research, the COVID-19 vaccine may help reduce stillbirths by lowering the risk of serious illness in expectant mothers.[26]

The present study, although did not formally investigate the qualitative response of the pregnant women to the vaccine, no immediate adverse reactions like abortion or any other major maternal complication were reported by the participants except mild pain and temperature. The safety of mothers or their unborn children who got the mRNA COVID-19 vaccination (Moderna or Pfizer-BioNTech) late in pregnancy has not been questioned according to data from vaccine safety monitoring systems.[10,11,27-30] Pregnant women who got an mRNA COVID-19 vaccine just before or during early pregnancy (before 20 weeks of pregnancy) did not have an increased risk of miscarriage, according to researchers.[11,27,28,31] According to data from studies conducted in the United States, Europe, and Canada, receiving an mRNA COVID-19 vaccine while pregnant did not increase the risk of complications such as preterm birth, stillbirth, bacterial infections of the placenta, or excessive maternal blood loss after delivery.[11,23,31,32] Vaccinating pregnant women with the COVID-19 vaccine before and during the first trimester was not linked to an increased risk of birth abnormalities that may be seen on prenatal ultrasound, according to a Chicago study.[24] According to recent research, completing a two-dose main mRNA COVID-19 vaccine series while pregnant can reduce the risk of COVID-19-related hospitalization in infants under the age of six months. According to these reports, the majority of infants hospitalized with COVID-19 were born to expectant mothers who had not received a prenatal vaccination.[21,33] An additional investigation discovered that receiving a booster dose of the mRNA COVID-19 vaccination during pregnancy dramatically raised the levels of antibodies discovered in umbilical cord blood. Accordingly, receiving a COVID-19 booster while pregnant can help further protect babies from COVID-19.[21,34]

Therefore, in the current study, all the findings found pregnant women who receive COVID-19 vaccine have their bodies produce COVID-19 antibodies just like non-pregnant women do. Getting a COVID-19 vaccine can help protect mothers and babies from serious health problems from COVID-19. So pregnant women should stay up to date with their COVID-19 vaccines, including getting a COVID-19 booster shot when it is time to get one.

Limitations

The study was single-center-based. We took a small sample size due to the short study period, so it cannot be generalized to the entire population. After evaluating those patients, we did not follow up on them and did not know the durability of immune response in the long term with these patients.

CONCLUSION

We know that pregnancy influences the immune response. Understanding how it affects antibody production after COVID-19 vaccination is crucial for maternal and neonatal health. Importantly, vaccination during pregnancy not only protects the mother but also provides

passive immunity to the newborn, reducing the risk of severe illness in early life. The study concluded that pregnant women respond well to the COVID-19 vaccines, mounting strong immune responses with final titers after 2nd dose of the vaccine is almost comparable to those in non-pregnant women of similar reproductive age. COVID-19 vaccines are efficacious for preventing future SARS-CoV2 infections.

Recommendations

Further multicentered studies with a prospective study design including a larger sample size need to be done to validate the findings of our study and a follow-up study is needed to observe immune response durability.

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