ORIGINAL ARTICLE

Clinico-epidemiological Profile, COVID-19 Vaccination, and Peripartum Outcomes among Pregnant Women in the Third Wave of COVID-19

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Abstract

Introduction: Coronavirus disease 2019 (COVID-19) infection leads to significant morbidity and mortality in women during pregnancy. As seen with other viral diseases in the past, vaccination, currently, is the most-effective eradication method and all pregnant women should be offered COVID-19 vaccination, if no contraindication exists. Despite approval by national and international authorities, many pregnant women are still hesitant to accept the vaccine.

Materials and methods: The current study is a retrospective cohort study involving 100 COVID-19 positive pregnant women and 300 negative women who delivered over 3 months. Their demographic, clinical data, vaccination details, and perinatal outcomes were recorded.

Results: A low vaccination rate against COVID-19 among pregnant women (26.25%) was reported. A total of 79 (79%) women in COVID-19 and 216 (72%) in non-COVID-19 group were unvaccinated. Most of the women in both groups received Covishield vaccine rather than Covaxin. The most common reasons for not getting the vaccine were unawareness about the vaccination approval in pregnancy (49%) followed by its unknown safety status (10%).

Conclusion: The prime barrier to maternal vaccination remains the safety concern associated with the COVID-19 vaccine. Vaccination strategies, when created keeping in mind the attitudes of these priority groups will help increase its uptake during the current pandemic.

Keywords: Coronavirus disease-2019 in pregnancy, Coronavirus disease-2019 infection, Pregnancy complications.

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Introduction

Since its onset, the coronavirus disease-2019 (COVID-19) pandemic has been a challenge for all epidemiologists, clinicians, and global organizations. A standardized treatment protocol is yet to be devised even after 3 years of the pandemic. This situation is worrisome when pregnant women are affected. The effects of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) on pregnant women and their fetuses are still unclear. It is considered that the infection leads to significant morbidity and mortality in women during pregnancy and in the postpartum period. Pregnancy, due to its inherent immunosuppressed state, increases the risk of severe infection, the need for intensive care and invasive ventilation.[1–3] Pregnant women, hence are categorized as high-risk population to acquire COVID-19 infection and there becomes an utmost need to avoid infection in them.[4]

Currently, non-pharmaceutical measures are highly effective methods to control the disease's spread. These include wearing face masks, maintaining social distancing, and personal hygiene, but following them for a long term will not be feasible. Vaccination, by providing herd immunity has become the most-effective eradication method, as seen in other viral epidemic diseases in the past.[5,6]

In the current situation, as suggested by experts, COVID-19 vaccination should be offered to pregnant women if no contraindication exists. The intent is to assess the risk–benefit on an individualized basis, so that pregnant women can make informed decisions, understanding the risk and morbidity associated with infection and that, it outweighs the undescribed risk of vaccination in pregnancy.

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As per the National Technical Advisory Group on Immunization (NTAGI), Ministry of Health and Family Welfare (MoHFW) recommendations in July 2021, pregnant women may be informed about the risks of exposure to COVID-19 infection along with the risks and benefits associated with the COVID-19 vaccines and they will have the choice to take the vaccination after assessing the risks and benefits associated.

In spite of the approval by national and international authorities for use in pregnant women, many still are hesitant to accept the vaccine. The foremost reason is the concern about vaccine safety, lack of abundant data, or possible long-term side effects. Additionally, despite repeated efforts by the experts, pregnant

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women initially were not included in the COVID-19 vaccine trials, although vaccination was later approved for use in pregnancy. However, global acceptance of vaccines among pregnant women is yet unknown and an understanding of the challenges associated with universal acceptance of vaccines, will aid the acceleration of its administration within this high-risk group. Studying the perinatal outcomes in women who were partly or fully vaccinated during pregnancy is also important.

Theiler et al. reported that vaccinated antenatal women had less likelihood of experiencing COVID-19 infection, and vaccination against COVID-19 during pregnancy was not associated with any increase in pregnancy or delivery complications such as preterm birth of small for gestational age babies.[7] Those unvaccinated, who had symptomatic infection, were at 70% risk of death compared with symptomatic non-pregnant women.

Materials and Methods

The current study is a retrospective cohort study, conducted in a tertiary care institute in India, over a period of 3 months. The Institute's annual delivery rate is in the range 20–22,000 per year. There is a separate facility with a level-II intensive care unit (ICU) for delivering women inflicted with COVID-19. The study population consisted of all pregnant women who delivered in the COVID-10 facility and 3 times that number in the non-COVID-19 facility between 15 December 2021 and 15 March 2022. The records of these women delivered during the study duration were obtained from the electronic database after due permission from the institutional ethical committee and were recorded in a predesigned proforma.

A total of 100 pregnant women infected with SARS-CoV-2 delivered in the study duration and 300 women who delivered in the non-COVID-19 facility was included in the study. Demographic and clinical data regarding gravida, parity, booking status, socioeconomic class, existing comorbidities, vaccination details, and perinatal outcomes were recorded. The women were telephonically contacted regarding knowledge, acceptance, and hindrances to the vaccine acceptance.

Categorical variables were presented as numbers and percentages (%). Quantitative data with non-normal distribution was reported as median with 25th and 75th percentiles (interquartile range). The data normality was checked by using the Kolmogorov–Smirnov test. The association of quantitative variables that were not normally distributed was analyzed using the Mann–Whitney test and qualitative variables were analyzed using Chi-square test. If any cell had an expected value of less than 5, then Fisher's exact test was used. The data entry was done in the Microsoft Excel spreadsheet and the final analysis was done with the use of Statistical Package for Social Sciences (SPSS) software, version 25.0 (IBM, Chicago, USA). For statistical significance, *p*-value of less than 0.05 was considered statistically significant.

Definitions

Vaccination Policy of India

Currently, in India, three vaccines have been approved for use in pregnancy. One is an inactivated vaccine (Covaxin) and the other two are based on non-replicating viral vector platforms (Covishield and Sputnik V). A pregnant woman can be vaccinated at any time of the pregnancy. To help them make an informed decision to be vaccinated, they should be provided with information about the risks of COVID-19 infection in pregnancy, the benefits of vaccination, along the likely side effects.

Types of Vaccines

- "Covishield" vaccine, which is produced in genetically modified human embryonic kidney (HEK) 293 cells, is a ChAdOx1nCoV-19 corona virus recombinant vaccine, manufactured by Serum Institute of India Pvt. Ltd. Complete vaccination course consists of 2 doses, 0.5 mL each, 4–12 weeks apart, to be taken intramuscularly.
- "Covaxin" is a whole virion, inactivated coronavirus vaccine, produced by inactivated SARS-CoV-2 strain (NIV-2020-770) and is the India's first indigenous COVID-19 vaccine, manufactured by Bharat Biotech, that provides effectiveness with above 110 geometric mean titer (GMT). It is administered as 2 doses of 0.5 mL intramuscularly on day 0 and day 28. The efficacy is found to be 63.6% against asymptomatic COVID-19 cases.

Booked Pregnancy

Those pregnant women, who had at least three antenatal visits at our center were labeled as booked, while unbooked women were those who had no prenatal care throughout the pregnancy, those who registered at our unit but had less than two antenatal clinic visits, and women referred as an obstetric emergency from other facilities.

Results

The women who had COVID-19 disease during delivery (n = 100) were grouped as I and the non-infected women as group II (n = 300). The mean age of the study group was 25 years and ranged 22–28 years, comparable in both groups (Table 1). In group I, 42 (42%) and 58 (58%), and in group II, 107 (35.6%) and 193 (64.3%) were primigravida and multigravida respectively (p = 0.257). A total of 40 (40%) women in group I and 109 (36.3%) women in group II had comorbidities (p = 0.511). The majority of the women, both groups I (74%) and II (75%) were unbooked and underwent an uncomplicated vaginal delivery (58% among group I and 64% among group II). The most common indication of cesarean in both groups was fetal distress. The majority of the women, 79 (79%) in group I and 216 (72%) in group II had not received even a single dose of vaccine. Among those who were vaccinated, 10 (47%) and 11 (52%) in group I; and 52 (61.9%) and 32 (38.1%) in group II received one dose and a full course of vaccine, respectively. On comparing the type of vaccination in both the study groups, it was observed that, in group A among those who received the vaccine, 14 (66.6 %) had been administered the Covishield vaccine. In group II, among those who were vaccinated, 52 (61.9%) and 32 (38.1%) received Covaxin and Covishield vaccines, respectively. This difference was statistically significant (p = 0.0.018). All the vaccinated women in group I received their vaccine before the onset of pregnancy, while in group B, 85.72% of women got vaccinated during pregnancy itself ($p \leq 0.001$). None of the women in any group reported any adverse effects following vaccination.

There was no statistically significant difference in the peripartum period in women of both groups, and none of them needed ICU admission or prolonged hospital stay. While assessing the reason for not getting vaccinated, it was inferred that the majority of women in both groups were not offered vaccination during pregnancy, but showed their interest in getting the jab after delivery.

Table 1: Association of baseline characteristics with COVID-19 and non-COVID-19

Baseline characteristics	*COVID-19 (n = 100)*	*Non-COVID-19 (n = 300)*	*Total*	*p-value*
Age (years)	25 (22–28)	26 (22–30)	26 (22–29)	0.143
Preeclampsia				
Booked	26 (26%)	75 (25%)	101 (25.25%)	0.842
Unbooked	74 (74%)	225 (75%)	299 (74.75%)	
Gravida				
Primigravida	42 (42%)	107 (35.67%)	149 (37.25%)	0.257
Multigravida	58 (58%)	193 (64.33%)	251 (62.75%)	
Comorbidity	40 (40%)	109 (36.33%)	149 (37.25%)	0.511
Preeclampsia	15 (15%)	8 (8%)	23 (4.75%)	0.413
Mode of delivery				
NVD	65 (65%)	204 (68%)	269 (67.25%)	0.58
Cesarean	35 (35%)	96 (32%)	131 (32.75%)	
Baby outcome				
Healthy	97 (93%)	300 (100%)	397 (99.25%)	<0.09
GCA baby	0 (0%)	0 (0%)	0 (0%)	
IUD	0 (0%)	0 (0%)	0 (0%)	
Preterm	3 (3%)	0 (0%)	3 (0.75%)	
Intrapartum complications				
None	97 (97%)	300 (100%)	397 (99.25%)	0.015
Cesarean hysterectomy	1 (1%)	0 (0%)	1 (0.25%)	
PPH	2 (2%)	0 (0%)	2 (0.50%)	
Vaccination status				
No	79 (79%)	216 (72%)	295 (73.75%)	0.168
Yes	21 (21%)	84 (28%)	105 (26.25%)	
Type of vaccine				
Covaxin	7 (33.33%)	52 (61.90%)	59 (56.19%)	0.018
Covishield	14 (66.67%)	32 (38.10%)	46 (43.81%)	
Number of doses				
1	10 (47.62%)	52 (61.90%)	62 (59.05%)	0.234
2	11 (52.38%)	32 (38.10%)	43 (40.95%)	
Vaccination during pregnancy				
No	21 (100%)	12 (14.29%)	33 (31.43%)	<0.0001
Yes	0 (0%)	72 (85.71%)	72 (68.57%)	
Reason for not getting vaccinated				
Not enough studies	8 (10.13%)	10 (4.63%)	18 (6.10%)	0.45
Vaccination not offered	41 (51.90%)	105 (48.61%)	146 (49.49%)	
Reluctant to vaccination	4 (5.06%)	13 (6.02%)	17 (5.76%)	
Not readily available	1 (1.27%)	12 (5.56%)	13 (4.41%)	
Expensive	4 (5.06%)	12 (5.56%)	16 (5.42%)	
Scared of getting the vaccine	1 (1.27%)	12 (5.56%)	13 (4.41%)	
Vaccine can cause infection	4 (5.06%)	13 (6.02%)	17 (5.76%)	
Cannot acquire COVID-19 infection	3 (3.80%)	11 (5.09%)	14 (4.75%)	
Questionable efficacy	2 (2.53%)	7 (3.24%)	9 (3.05%)	
Unknown safety status	11 (13.92%)	21 (9.72%)	32 (10.85%)	
Would like to get vaccinated				
No	29 (36.71%)	0 (0%)	29 (9.83%)	<0.0001
Yes	50 (63.29%)	216 (100%)	266 (90.17%)	

GCA, gross congenital anomaly; IUD, intrauterine demise; NVD, normal vaginal delivery; PPH, postpartum hemorrhage

Most of the women in both groups underwent vaginal delivery without any intrapartum or postpartum complications. The neonatal outcomes were also comparable in both groups (Table 2). The duration of hospital stay was 24 hours in women who delivered vaginally and 48 hours after cesarean delivery.

Discussion

Women with pregnancy are considered to be a high risk. Pregnancy *per se* has not been found to increase the risk of COVID-19 infection and most of these women (>90%) are asymptomatic or have mild disease without the need for hospitalization, but rapid deterioration of health may occur in few.[1,8–10] According to the Centers of Disease Control (CDC), although the overall risk is low, pregnant women in all trimesters, are more likely to deteriorate from COVID-19 as compared to non-pregnant women and also, are at increased risk of pregnancy-associated complications and poor fetal outcomes such as prematurity and low birth weight. Those with preexisting medical conditions such as high blood pressure, diabetes, obesity, and age above 35 years are at increased risk of severe illness due to COVID-19.

In the current study, the majority of women, 65 (65%) in group I and 204 (68%) in group II underwent vaginal delivery. The pregnancy-associated comorbidities in both groups were found to be similar. Although 3 (3%) women affected with COVID-19 had preterm vaginal delivery ($p < 0.09$), all had satisfactory fetal outcomes. Two women in group I, had postpartum hemorrhage (PPH) during delivery which was successfully managed; however, one woman underwent a cesarean hysterectomy, due to PPH refractory to medical management, and this difference was statistically significant ($p = 0.015$). There was no difference in the pregnancy comorbidities, peripartum, and fetal outcomes among the vaccinated and unvaccinated group.

Evidence regarding maternal and fetal benefits and associated harm, along with effects on pregnancy outcomes should be weighed carefully when considering vaccination in pregnant women. The absolute risk of severe COVID-19 has been found to be low in pregnant women, but pregnancy is definitely a risk factor for severe disease.[11,12] Maternal, neonatal, and obstetrical complications have been well documented in women with COVID-19 infection during pregnancy.[13–17]

Several COVID-19 vaccines, such as Covishield and Covaxin, have been developed and approved recently. These vaccines, however, without widespread acceptance, cannot curb the epidemic. The immunity level in the community needs to reach at least 75% to stop the COVID-19 pandemic. Hence vaccine delivery strategies must be boosted to determine the vaccine acceptance needed for society to return to prepandemic conditions.[18] According to the World Health Organization (WHO), vaccine hesitancy, defined as the delay in acceptance or refusal of vaccines is one of the top-10 threats to global health, even prior to the current COVID-19 pandemic.[19,20]

In spite of the persistent efforts by national and international organizations to promote and encourage COVID-19 vaccination among pregnant women, there lies hesitancy and unawareness about the same. The current study reported a low vaccination rate against COVID-19 among pregnant women, that is, 26.25% (Table 3). Most of the women in both the groups received Covishield vaccine rather than Covaxin. The most common reasons for not getting the vaccine in both groups were unawareness about the vaccination approval in pregnancy (49%) followed by its unknown safety status (10%).

The results are similar to a study by Ayhan et al. who reported low acceptance of COVID-19 vaccination (37%) in a sample of 300 pregnant women. The main refusal reasons were the lack of data about the safety of the vaccine in the pregnant population and possible harm to the fetus.[21]

The top-three reasons reported by Skjefte et al., to decline COVID-19 vaccination during pregnancy even if the vaccine were safe and free, were that they did not want to expose their developing baby to any possible harmful side effects (65.9%), they wanted to see more safety and effectiveness data among pregnant women (48.8%) and were concerned that the vaccines have not been tested adequately due to political reasons (44.9%).[22]

The strongest predictors of COVID-19 vaccine acceptance were confidence in vaccine safety and efficacy, trust in public health agencies/health science, belief in mass vaccination of their own country, the importance of vaccines, as well as compliance with mask guidelines. Hence, it becomes especially important for countries to establish vaccine confidence through effective community engagement and transparent communication.

The COVID-19 vaccine's current acceptance levels are insufficient to meet the requirements for community immunity of at least 75% as per Skjefte et al.[22] Vaccine acceptance and its predictors among pregnant women vary globally and, therefore, campaigns targeting this population should be specified for each country, so as to attain the largest impact. Important considerations while offering vaccines include the level of activity of the virus in the local community, lack of safety data specific to its use in pregnancy, the potential efficacy of the vaccine risk, and potential severity of maternal disease including the possible effects of the disease on the fetus (preterm birth) and newborn, timing of vaccination during pregnancy. Counseling should also address the expected side effects which are more prevalent among younger people due to overreaction of the immune system. Pyrexia is one of the most common side effects reported with COVID-19 vaccines, can be managed by acetaminophen, which is considered safe during pregnancy and should not theoretically impact the antibody response to COVID-19 vaccines.[23]

Furthermore, COVID-19 did not affect the obstetric condition, mode of delivery, and perinatal outcomes in the third wave. Most of the women suffering from COVID-19 infection at the time of delivery were unvaccinated. Thus, vaccination against COVID-19 infection did not decrease the risk of acquiring infection in pregnancy but may have reduced the risk of severe infection in pregnancy.

Conclusion

Vaccination against COVID-19 infection has been recommended for pregnant women. Though it may not prevent the infection but reduces the severity of the disease. However, its acceptance has been lowering in pregnant women as compared to the general population. The concern of many women regarding safety remains a barrier to maternal vaccination. This study reported low acceptance of COVID-19 vaccination in a sample of pregnant women. Lack of awareness and concerns about vaccine safety were the major reasons for hesitancy. Identifying attitudes among priority groups will be useful for creating vaccination strategies that increase uptake during the current pandemic.

Table 2: Association of outcome with vaccination status

Baseline characteristics	*Not vaccinated (n = 295)*	*Vaccinated (n = 105)*	*Total*	*p-value*
Booked/unbooked				
Booked	71 (24.07%)	30 (28.57%)	101 (25.25%)	0.362†
Unbooked	224 (75.93%)	75 (71.43%)	299 (74.75%)	
Gravida				
Primigravida	114 (38.64%)	35 (33.33%)	149 (37.25%)	0.334†
Multigravida	181 (61.36%)	70 (66.67%)	251 (62.75%)	
Comorbidity	96 (32.54%)	53 (50.48%)	149 (37.25%)	0.06
Preeclampsia	10 (3.39%)	5 (4.76%)	15 (3.75%)	0.525†
Age (years)	26 (22–29)	27 (22–30)	26 (22–29)	0.392‡
Mode of delivery				
NVD	209 (70.85%)	60 (57.14%)	269 (67.25%)	0.06†
Cesarean	86 (29.15%)	45 (42.86%)	131 (32.75%)	
Indication of cesarean				
Anhydramnios	1 (1.16%)	0 (0%)	1 (0.76%)	0.193*
Antepartum eclampsia	1 (1.16%)	1 (2.22%)	2 (1.53%)	
Breech	4 (4.65%)	2 (4.44%)	6 (4.58%)	
Cord prolapse	1 (1.16%)	0 (0%)	1 (0.76%)	
CPD	9 (10.47%)	0 (0%)	9 (6.87%)	
Eclampsia	0 (0%)	1 (2.22%)	1 (0.76%)	
Failed IOL	8 (9.30%)	6 (13.33%)	14 (10.69%)	
Fetal distress	26 (30.23%)	14 (31.11%)	40 (30.53%)	
Footling breech	1 (1.16%)	0 (0%)	1 (0.76%)	
Hand prolapse	0 (0%)	1 (2.22%)	1 (0.76%)	
MSL	5 (5.81%)	8 (17.78%)	13 (9.92%)	
MSL with fetal distress	2 (2.33%)	0 (0%)	2 (1.53%)	
Placenta increta	1 (1.16%)	0 (0%)	1 (0.76%)	
Placenta previa	0 (0%)	1 (2.22%)	1 (0.76%)	
Previous 2 LSCS	2 (2.33%)	0 (0%)	2 (1.53%)	
Previous LSCS	18 (20.93%)	11 (24.44%)	29 (22.14%)	
Previous LSCS with breech	1 (1.16%)	0 (0%)	1 (0.76%)	
Previous LSCS with scar tenderness	1 (1.16%)	0 (0%)	1 (0.76%)	
Rupture uterus	1 (1.16%)	0 (0%)	1 (0.76%)	
Scar tenderness	1 (1.16%)	0 (0%)	1 (0.76%)	
Second stage arrest	3 (3.49%)	0 (0%)	3 (2.29%)	
Baby outcome				
Healthy	290 (98.31%)	101 (96.19%)	391 (97.75%)	0.344*
GCA baby	1 (0.34%)	1 (0.95%)	2 (0.50%)	
IUD	2 (0.68%)	2 (1.90%)	4 (1%)	
Preterm	2 (0.68%)	1 (0.95%)	3 (0.75%)	
Intrapartum complications				
None	293 (99.32%)	104 (99.05%)	397 (99.25%)	0.6*
Cesarean hysterectomy	1 (0.34%)	0 (0%)	1 (0.25%)	
PPH	1 (0.34%)	1 (0.95%)	2 (0.50%)	

CPD, cephalopelvic disproportion; GCA, gross congenital anomaly; IOL, induction of labor; IUD, intrauterine demise; LSCS, lower segment cesarean section; MSL, meconium-stained liquor; NVD, normal vaginal delivery; PPH, postpartum hemorrhage

Table 3: Association of COVID-19/non-COVID-19 with vaccination status

COVID-19/non-COVID-19	*Not vaccinated (n = 295)*	*Vaccinated (n = 105)*	*Total*	*p-value*
COVID-19	79 (26.78%)	21 (20%)	100 (25%)	0.168†
Non-COVID-19	216 (73.22%)	84 (80%)	300 (75%)	
Total	295 (100%)	105 (100%)	400 (100%)	

Ethical Approval

The study is done keeping in mind the ethical standards of the responsible committee on human experimentation (Institutional and National) and with the Helsinki Declaration of 1975, as revised in 2008. Ethical clearance for the study was taken from the institutional ethics committee. Being a retrospective study, a consent waiver was granted by the institutional Ethics Committee.

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