ORIGINAL ARTICLE

COVID Immunization Status of Pregnant Patients Delivering in a Tertiary Level Government Hospital in India

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Abstract

Introduction: Immunization is the most effective form of prevention against coronavirus disease-2019 (COVID-19) related complications during pregnancy. This study was done to see the prevalence of the COVID-19 immunization status in pregnant women delivering in a tertiary level Government Hospital in New Delhi, India, and associated side effects of COVID vaccine in pregnancy.

Materials and methods: A prospective cross-sectional study was conducted from 1st July 2022 to 31st December 2022 in a tertiary level, Government Hospital in New Delhi, India. The Institutional Ethical Committee provided approval for the study. A written questionnaire was given to all consecutive pregnant women delivering in the hospital, after taking written consent and details of COVID vaccine, number of doses, time of immunization (antenatal/postpartum), COVID infection status (antenatal/postnatal period) and adverse reactions encountered.

Observation and results: Women (842) were included in the study, out of which 87% (605/842) were vaccinated and 12.6% (218/842) were unvaccinated. The majority (70.4%) received Covishield while 29.6% received Covaxin. Adverse effect following vaccination was experienced by 9.2% (68/842) women and was mild.

Conclusion: The total vaccine coverage among the women enrolled in the study was 87%. There was no statistically significant difference (p-value = 0.095) in the side effects profile of the Covaxin and Covishield vaccines. Among the hesitancy factors observed in the unvaccinated group, safety concern regarding vaccines was the most dominant factor.

Keywords: Covaxin in pregnancy, Coronavirus disease-2019 in pregnancy, Coronavirus disease-2019 vaccine, Covishield in pregnancy, Immunization in pregnancy.

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Introduction

Pregnant women having coronavirus disease-2019 (COVID-19) infection are at increased risk of severe morbidity and mortality compared with non-pregnant women. Coronavirus disease-2019 during pregnancy is associated with an increased risk for adverse pregnancy outcomes like preterm birth, stillbirth, and maternal mortality. Immunization reduces the risk of severe/critical disease due to COVID-19 and also reduces COVID-19-associated hospitalizations and deaths.[1,2] There are two major benefits of vaccinating women in pregnancy: it protects the woman and also protects the developing fetus. Additionally, it triggers antibody production, which is transferred through the placenta and in breast milk) to protect the infant within the first months of life.[1–3]

To the best of our knowledge, using search engines like PubMed and Google, till date, there has not been any large study regarding the immunization status of COVID-19 vaccine amongst Indian pregnant and lactating women. Our study tries to focus on the prevalence of immunization amongst this group delivering in our health facility and also the level of acceptance of vaccines.

Materials and Methods

A prospective cross-sectional study was conducted at Dr. RML Hospital from 1st July 2022 to 31st December 2022. All consecutive women delivering in the labor room and willing to participate in the study were included. Performa recording the demographic details, details of immunization [type of COVID-19 vaccine, number of doses, time of immunization (antenatal/postpartum), COVID-19 infection status (antenatal/postnatal period), and adverse reactions encountered] was recorded.

Statistical Analysis

After the collection of the data, the qualitative variables were represented in the form of number and percentage (percentage of pregnant patients vaccinated against COVID-19, percentage of patients who received only one dose, percentage of patients who received both doses, type of COVID-19 vaccine received, percentage of patients who reported adverse effects to COVID-19 vaccine) and the quantitative (categorical) variables were presented in the form of mean.

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Table 1: Demographic profile of pregnant women at the time of first dose of vaccination

Demographic parameter	*Number of pregnant women (n = 842)*	*Percentage*
Age (in years) of pregnant women at the time of first dose of COVID vaccination		
20–25	210	24.94%
25–30	342	40.61%
30–35	258	30.64%
35–40	32	3.81%
Parity of pregnant women at the time of first dose of COVID vaccination		
Nullipara	280	33.25%
Parity 1	358	42.50%
Parity 2	187	22.23%
Parity 3	12	1.42%
Parity ≥ 4	5	0.59%
Timing of COVID vaccination		
Before pregnancy	702	83.40%
Less than 12 weeks of pregnancy	8	0.95%
12–24 weeks of pregnancy	96	11.40%
24–36 weeks of pregnancy	31	3.68%
More than 36 weeks of pregnancy	5	0.59%

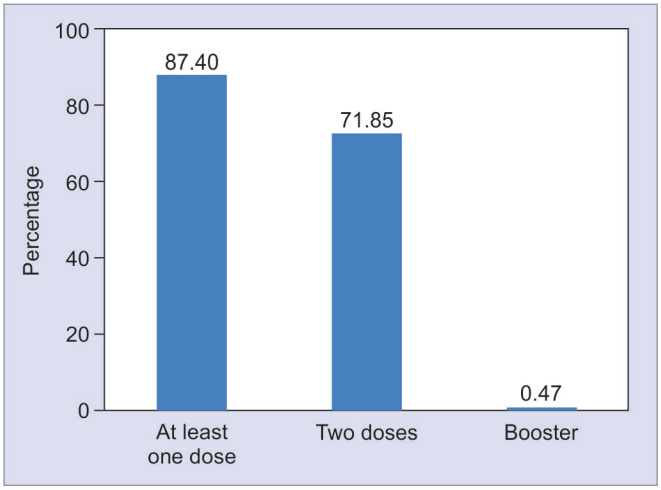

Fig. 1: Vaccination status in terms of number of doses received

Results

A total of 842 pregnant women were enrolled in the study. The majority of women were in the age-group of 25–30 years (40.61%). The majority of women were primipara (42.5%), followed by nullipara (33.25%). The majority of women (83.4%) had undertaken the first dose before pregnancy (Table 1). It was observed that 87% (736/842) received at least one dose of the COVID-19 vaccine, 0.4% (4/842) had received a booster dose, and 12.6% (214/842) women were unvaccinated (Fig. 1). Among the immunized women, 510 (70.4%) received Covishield and 218 (29.6%) received Covaxin

Table 2: Type of COVID vaccination in pregnant women

Vaccination type	*No. of pregnant women*
Covaxin	218 (29.6%)
Covishield	510 (70.4%)
Total	736

Table 3: Proportion of pregnant women with side effects to COVID vaccination (*N* = 736)

Vaccine	*No. of pregnant women with adverse effects*	*No. of pregnant women with no adverse effects*
Covaxin	14 (20.6%)	204
Covishield	45 (79.4%)	464
Total	59	668

(Table 2). It was seen that 68 (9.2%) women experienced adverse effects due to vaccination. There was no statistically significant difference (p-value = 0.095) in the side effects associated with Covaxin and Covishield vaccines (Table 3). Generalized body ache for 2–3 days was observed in 38 women (55.8%) which was the most common side effect.

Among the hesitancy factors observed in the unvaccinated group, safety concern regarding vaccines was the most dominant factor in 92 out of 214 patients (42.9%), followed by fear of adverse effects in 75 (35.04%), lack of awareness in 42 (19.62%) and logistic factors in 5 (2.33%, Table 4).

Discussion

Coronavirus disease-2019 was declared a pandemic on March 11, 2020. India has suffered three waves of pandemic till now. First wave (16th July 2020 to 31st Jan 2021), second wave (16th March 2021 to 6th May 2021), and third wave (01-January-2022 to 20-February-2022) of the outbreak.[4,5] The second wave of COVID-19 was more severe than the first wave. The third wave occurred when this study was begun. COVID-19 vaccine immunization was approved at the end of the second wave. On 2nd July 2021, COVID-19 immunization was approved for use in pregnant women in India. The vaccines currently approved in India are Covishield (Astra Zeneca vaccine), Sputnik V (Imported from Russia) and Covaxin (Indigenous from Bharat Biotech). The reported side effects of these vaccines are pain at the injection site, ipsilateral axillary lymph node enlargement, fever, fatigue, and headache.[6]

The present study was done on 842 pregnant woman delivery in a public teaching hospital in New Delhi, India, from 1st July 2022 to 31st December 2022. Of the total 842 pregnant females, 736 (87%) received at least one dose of the COVID vaccine, 605 (87%) of these women received both doses of the vaccine, 4 (0.5%) women received a booster dose, and 106 (12.6%) women were unvaccinated. Effective counseling done at antenatal visits played an important role in overcoming vaccine hesitancy and increasing the rate of primary vaccination. However, throughout 6–8 months, as the COVID-19 testing, the positivity rate as well as severity of illness caused by omicron in the general population decreased (the ICMR reported a positivity rate of 1–3% in Delhi and a recovery rate of more than 98.7% from July to September 2022, in the given study period), the vaccination coverage, particularly that of booster dose decreased.

Table 4: Factors for vaccine hesitancy in non-vaccinated pregnant women

Factors	*Number of pregnant women (n = 214)*	*Percentage*	*Chi-square*	*p-value (significance level of 0.05)*
Safety concern	92	42.99%		
Fear of adverse effects	75	35.04%		
Lack of awareness	42	19.62%	3.505	<0.050
Logistic factors	5	2.33%		
Total	214	100.00%		

In the present study, among the vaccinated women, the majority, (510 females: 70.4%) received Covishield and 218 (29.6%) received Covaxin. Total of 68 (9.2%) women experienced adverse effects due to vaccination. Of these 68, 14 (6.4%) had received Covaxin and 54 (10.4%) had received Covishield. Bodyache was observed as the most common side effect followed by headache. Side effect profiles of Covaxin vs Covishield vaccine are statistically nonsignificant.

The National Technical Advisory Group on Immunization (NTAGI) and The National Expert Group on Vaccine Administration for COVID-19 (NEGVAC) have recommended vaccination in pregnant women. Based on these recommendations from NTAGI, the Union Ministry of Health and Family Welfare (MoHFW) approved the vaccination of pregnant women against COVID-19, on 2 July 2021.

A study published by Global Network for Women and Children's Health Research, from February to November 2021 found that only 12.9% of pregnant women in India were COVID-19 vaccinated.[7]

A multinational observational, prospective study published in Lancet in 2023 l reported that vaccine effectiveness for women receiving two doses was 74% and that with booster was 91% in the inter-COVID period 2022.[8] This study included 18 countries, excluding India.

In the present study, various hesitancy factors among unvaccinated pregnant women were observed, which were safety concerns, fear of contracting COVID-19 infection observed in 42.9% of women, risk of adverse effects on the fetus, lack of knowledge regarding the importance of vaccination, and various logistic reasons. In another study done by a global network of Women and Children Health Research that only 48% of pregnant females in given sites in India had knowledge about vaccine effectiveness and were receptive towards vaccination and only 22.8% of pregnant women believed that COVID-19 the vaccine is safe in pregnancy.[8]

Vaccine hesitancy presents a major obstacle to achieving vaccination coverage that is broad enough to result in herd immunity and slow community transmission. Efforts to optimize COVID-19 vaccine uptake should identify reasons for and characteristics associated with vaccine refusal and use that information to tailor approaches to individuals. Vaccines also did not alter menstrual cycles.[9]

Our study was done after the third wave. Fortunately, the third wave subsided. It was also noted that during our study we had no COVID-19 positive COVID-19 RTPCR report. It was the widespread coverage done of COVID-19 vaccination that the third wave was mild compared to the first wave.[10–12]

Conclusion

The total vaccine coverage among the women enrolled in the study was 87%. There was no statistically significant difference (p-value = 0.095) in the side effects profile of the Covaxin and Covishield vaccines. Among the hesitancy factors observed in the unvaccinated group, safety concern regarding vaccines was the most dominant factor.

Clinical Significance of the Study

The vaccine coverage of single dose COVID-19 vaccine was 87.40% and that of two doses was 71.85% in the above study. Such high vaccine coverage, in accordance with the Government of India COVID-19 immunization policy significantly decreased the severity of the third wave.

Authors' Contribution

BU: Collected the data; RM: Wrote the title and manuscript; RM, NC and NP: Wrote the manuscript. Manuscript was read and approved by all four authors.

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References

1. Thompson MG, Stenehjem E, Grannis S, et al. Effectiveness of COVID-19 vaccines in ambulatory and inpatient care settings. N Engl J Med 2021;385(15):1355–1371. DOI: 10.1056/NEJMoa2110362.
2. Haas EJ, Angulo FJ, McLaughlin JM, et al. Impact and effectiveness of mRNA BNT162b2 vaccine against SARS-CoV-2 infections and COVID-19 cases, hospitalisations, and deaths following a nationwide vaccination campaign in Israel: An observational study using national surveillance data. Lancet 2021;397(10287):1819–1829. DOI: 10.1016/S0140-6736(21)00947-8.
3. Ioannou GN, Locke ER, O'Hare AM, et al. COVID-19 vaccination effectiveness against infection or death in a national U.S. health care system: A target trial emulation study. Ann Intern Med 2022;175(3):352–361. DOI: 10.7326/M21-3256.
4. Singh S, Sharma A, Gupta A, et al. Demographic comparison of the first, second and third waves of COVID-19 in a tertiary care hospital at Jaipur, India. Lung India 2022;39(6):525–531. DOI: 10.4103/lungindia.lungindia_265_22.
5. Thakkarwad S, Asalkar M, Sharma N. Maternal COVID-19 infection and perinatal outcome in three waves of COVID pandemic: A cross-sectional study. J South Asian Feder Obs Gynae 2023;15(3):297–303. DOI: 10.5005/jp-journals-10006-2225.
6. Ministry of Health and Family Welfare Government of India. COVID-19 vaccines-operational guidelines. Available at: www.mohfw.gov.in.
7. Naqvi S, Saleem S, Naqvi F, et al. Knowledge, attitudes, and practices of pregnant women regarding COVID-19 vaccination in pregnancy in 7 low- and middle-income countries: An observational trial from the Global Network for Women and Children's Health Research. BJOG 2022;129(12):2002–2009. DOI: 10.1111/1471-0528.17226.

8. Pregnancy outcomes and vaccine effectiveness during the period of omicron as the variant of concern, INTERCOVID-2022: A multinational, observational study 2023;401. Available at: www.thelancet.com.
9. Garg R, Lal P, Agrawal P, et al. Menstrual cycle changes after COVID-19 infection: Does coronavirus-induced stress lead to hormonal change? J South Asian Feder Obst Gynae 2022;14(3):248–252. DOI: 10.5005/jp-journals-10006-2027.
10. Garg R, Agarwal R, Yadav D, et al. Histopathological changes in placenta of severe acute respiratory syndrome coronavirus 2 (SARS-Cov-2) infection and maternal and perinatal outcome in COVID-19. J Obstet Gynecol India 2023;73:44–50. DOI: 10.1007/s13224-022-01666-3.
11. Malhotra J, Agrawal P, Garg R, et al. Corona virus disease (COVID-19) and pregnancy: What obstetricians should know. J South Asian Feder Obst Gynae 2019;11(6):337–339. DOI: 10.5005/jp-journals-10006-1744.
12. Agarwal N, Garg R, Singh S, et al. Coronavirus disease 2019 in pregnancy: Maternal and perinatal outcome. J Educ Health Promot 2021;10(1):194. DOI: 10.4103/jehp.jehp_954_20.