



Original article

COVID-19 vaccination uptake and adverse events following COVID-19 immunization in pregnant women in Northern India: a prospective, comparative, cohort study

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Abstract

Objectives: The most commonly used vaccine in India, Covishield, is a recombinant adenovirus vector vaccine for which safety data in pregnant women are not available. The present study was conducted to assess the uptake of COVID-19 vaccines and monitor adverse events following COVID-19 immunization among pregnant women in northern India.

Patients and Methods: A prospective cohort study was conducted among pregnant women registered with the antenatal clinics in Chandigarh Union Territory (U.T.) in northern India. The study included 247 pregnant women and a comparative group of age-matched, non-pregnant women (247) who received the first dose of the COVID-19 vaccine and were followed up by telephone interviews for adverse events following immunization at three time points until 28 days after vaccination. Multivariate regression (logistic and linear) was used for the adjusted analysis, with adverse events following immunization and the duration of adverse events following immunization as the outcomes.

Results: The COVID-19 vaccination uptake rate was 66.8% among the pregnant women. The 28-day incidence rate of adverse events following immunization among the pregnant women was 76.5%. The overall 28-day incidence of adverse events following immunization in pregnant women did not differ significantly from that of non-pregnant women ($P=0.153$).

Conclusion: The Covishield vaccine is safe for pregnant women in India. Further follow-up of the cohort for fetomaternal outcomes needs to be conducted with an adequate sample size to confirm the overall safety profile of the vaccine.

Key words: adverse events following immunization, coronavirus disease 2019 (COVID-19) vaccine, Covishield, India, pregnancy

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Introduction

Vaccination is recommended as an effective method to manage the coronavirus disease 2019 (COVID-19) pandemic. Multiple COVID-19 vaccines have been introduced

worldwide that showed varying efficacies and effectiveness against the novel virus¹). However, very few safety studies have been conducted²). Recommendations are being modified according to safety data. A special group of adults, pregnant women, is being offered selected COVID-19 vaccines. A report on mRNA vaccines from the USA has revealed that these vaccines are safe during pregnancy^{3, 4}). Active surveillance and registries to gauge the fetomaternal outcomes and safety profiles of COVID-19 vaccines among pregnant women should be helpful in refining the recommendations²). Considering the adverse outcomes reported among pregnant women with COVID-19⁵) and safety data from other countries, India started vaccinating pregnant women on a voluntary basis under emergency use license from the first week of July 2021^{6, 7}). However, the most commonly used vaccine in India, Covishield, is a recombinant adenovirus vector

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vaccine for which safety data among pregnant women are not available. The guidelines of the Government of India emphasize the importance of collecting data on the safety profile of COVID-19 vaccines in pregnant women⁷. Close vigil on the adverse events following immunization (AEFIs) with COVID-19 vaccines among pregnant women needs to be maintained to establish safety and identify adverse effects to boost confidence in vaccination⁸. This also assists in identifying the appropriate time for vaccination during pregnancy and the best time gap between doses⁹. Evidence regarding COVID-19 vaccination shows that vaccine safety has been a major barrier among pregnant women while accepting vaccines in general¹⁰, and the same has been reported as a main concern by the majority of pregnant women^{11, 12}. Therefore, we conducted an observational study to assess the uptake of COVID-19 vaccinations and adverse events following COVID-19 immunization among pregnant women in northern India.

Patients and Methods

Study design

Prospective cohort study has been implemented.

Study area

This study was conducted in Chandigarh Union Territory (U.T.), North India. One of the study areas comprised slums and resettlement colonies^{13, 14}, with a population of 23,435; literacy rate, 68%; crude birth rate, 17.7 per 1,000 mid-year population; and, sex ratio (number of females per 1,000 males), 926. The other area consisted of established housing boards and society dwellings with a population of 16,172; literacy rate, 93.1%; crude birth rate, 6.1 per 1,000 mid-year population; and, sex ratio, 958. The study facilities were the primary health centers in these two areas. The antenatal clinics (ANC) in the primary health centers of these two areas registered 38–52 new ANC cases per month (newly registered pregnant women at the clinics).

Study population

Pregnant women registered with the ANC clinics of the above facilities and non-pregnant women (confirmed by enquiring the last menstrual period date) who came for COVID-19 vaccination at the above sites were included after they were informed about the study and provided written consent. Women less than 18 years of age and those who did not consent to participate in the follow-up (five women who said they were visiting the area and were not residents) were excluded.

Study cohort

Pregnant women who took the 1st dose of the COVID-19 vaccine.

Control cohort

Age-matched non-pregnant women who received the 1st dose of the COVID-19 vaccine from the respective areas where the pregnant women were enrolled.

Sample size and sampling

All eligible and consenting pregnant women (complete enumeration) who were vaccinated in the period between July 10, 2021 and October 15, 2021.

Study cohort: 247.

For comparison between the pregnant and non-pregnant reproductive age groups, a ratio of 1:1 was used.

Control group: 247.

Participant enrollment, follow-up and data collection

A registry (ChaPCoV-Chandigarh-based cohort of COVID-19-vaccinated pregnant women) was established in the above study areas to study AEFIs among pregnant women. The present study is a part of this registry. All pregnant women registered with the ANC clinic of the study centers were counselled by auxiliary nurse midwives (ANMs) of the respective areas for COVID-19 vaccination. The pregnant women who received the COVID-19 vaccination were asked for their willingness to be followed up for the AEFIs until 28 days after vaccination. A comparative group of age-matched, non-pregnant women who received the first dose of the COVID-19 vaccine on the same day as the pregnant women was also followed up for AEFIs until 28 days. If a non-pregnant woman of the same age was not available on a particular day, a non-pregnant woman of age ± 1 years of that of the pregnant women was included as a control. Sociodemographic data were collected for both the groups. The variables collected included education, occupation, socioeconomic status, parity, abortions, pre-existing diseases, current tobacco use, and history of COVID-19. The socioeconomic status was assessed using the B.G. Prasad classification, which was based on the per-capita income of the family¹⁵. The participants were followed up by phone call by a healthcare worker at three time points following the vaccination: after 24 h (2nd day), after 1 week (8th day), and after 4 weeks (29th day), and the occurrence and duration of AEFIs were recorded. If the participant could not be reached through phone, a home visit was conducted to collect data on AEFIs. A training session for ANMs on COVID-19 vaccination among pregnant and lactating women was conducted by the investigators. A written operational definition of all the variables and outcomes of the study was shared with the health staff involved in the study.

Data analysis

The analysis was conducted using SPSS 20.0. Categorical variables were expressed as frequencies and percentages.

The normality of continuous variables was tested using the Kolmogorov–Smirnov test, and the variables were not normally distributed. A univariate analysis between categorical variables was performed using the chi-square and Fisher exact tests, whereas the Mann–Whitney test was used between the continuous variable and the two groups of participants (pregnant cohort and controls). Multivariate regression (logistic and linear) was used for the adjusted analysis with AEFIs with the duration of the AEFI as the outcome. Statistical significance was set at P value <0.05 .

Ethical considerations

Ethical approval to conduct the study was obtained from the Institute Ethics Committee of the Postgraduate Institute of Medical Education and Research, Chandigarh (ref. NK/7566/Study/258). Written informed consent was obtained from all the participants after they were provided with all relevant information. Any severe and serious AEFIs found during the follow-up were intimated to the district immunization officer, and they were appropriately managed. Mild AEFIs were managed according to the operational guidelines issued to the medical officers of Chandigarh healthcare institutes. All data were kept secure and confidential by the investigators.

Results

During the study period from July 10 to October 15, 2021, 384 pregnant women were registered and were undertaking ANC follow-ups. Among them, 14 were vaccinated against COVID-19 before the last menstrual period (LMP) of their pregnancy; hence, 370 were eligible for the COVID-19 vaccination. Among the eligible women, 247 were willing to be vaccinated during the study period, resulting in a vaccination uptake rate of 66.8%. Of these, 112 (45.3%) were in their second trimester, whereas 82 (33.2%) and 53 (21.5%) were in their third and first trimesters, respectively. The median period of gestation of the enrolled pregnant women was 22 weeks, which was also the period of gestation (POG) at the time of COVID-19 vaccination.

These 247 COVID-19-vaccinated women were followed up prospectively, and 247 age matched COVID-19-vaccinated controls (non-pregnant, women of reproductive age group) during the study period were also followed up as the comparator group.

The median age of the pregnant and non-pregnant study participants was 25 years. The majority of pregnant and non-pregnant women had education up to or below the higher secondary school level. There were significant differences in occupation ($P<0.001$), socioeconomic status ($P=0.001$), parity ($P<0.001$), and abortions ($P=0.014$) between the study groups. Education, tobacco usage/non-usage, pre-existing disease, and history of COVID-19 were comparable

between the pregnant and non-pregnant study participants ($P>0.05$) (Tables 1 and 2).

The 28-day AEFI incidence rate in pregnant women was 76.5%. Fever (56.3%), followed by body pain (55.1%), local pain (39.7%) and swelling (12.6%) were the major AEFIs reported. Among those with AEFIs, the majority had multiple AEFIs (70.4%). The most common combination of AEFIs was fever and body pain (44.1%). The overall 28-day incidence of AEFIs in pregnant women did not differ significantly from that in non-pregnant women ($P=0.153$). Although the incidence of fever, body pain, and other side effects were significantly higher among pregnant women than those among non-pregnant women in the univariate analysis, the adjusted analysis showed no such difference. However, weakness was reported to be significantly lower among the pregnant women than the non-pregnant women in the present study. One serious AEFI that was reported among pregnant women was in one woman who was hospitalized for one day due to complaints of vomiting and giddiness on the day following vaccination (Table 3).

The duration of AEFIs among pregnant women was similar to that among non-pregnant women (Table 3).

The incidence of AEFIs within 24 h, from 1–7 days, and from 8–28 days are listed in Tables 4 and 5. The overall AEFI incidence rate within 24 h of vaccination among the pregnant women was 72.1%. The overall AEFI incidence rates from 1–7 days and from 8–28 days of vaccination among pregnant women were 16.6% and 1.2%, respectively. Weakness within 24 h was significantly lower among pregnant women than that among non-pregnant women in the present study. Fever between days 1–7 was reported to be significantly higher among pregnant women than that among non-pregnant women (Tables 4 and 5, respectively).

Discussion

The COVID-19 vaccination uptake rate among pregnant women was 66.8% in the present study from north India. Lipkind *et al.* and Theiler *et al.*, from their larger cohort of pregnant women in the USA, reported lower COVID-19 vaccine uptakes of 21.8% and 7%, respectively^{16, 17}. The difference in the uptake may be due to the differences in the time periods of COVID-19 vaccination of the cohorts in the present and previous studies. Previous studies from the USA included pregnant women vaccinated between December 2020 and July 2021, during which data on AEFI following COVID-19 vaccination among pregnant women were not available in India, as COVID-19 vaccination for pregnant women was allowed much later in India, i.e., from July 2021. This might have resulted in a lower uptake rate in these studies as compared to the current study. Other potential reasons might be variations in the acceptance rates, confidence in vaccine safety, and attitude towards the vi-

Table 1 Comparison of socio-demographic characteristics between the pregnant women and non-pregnant women

Socio-demographic characteristics	Pregnant women	Non-pregnant women	P value
	N=247 n (%)	N=247 n (%)	
Age median (IQR)	25 (23,28)	25 (22,28)	0.457
Education			
Illiterate	25 (10.1)	25 (10.1)	0.768
Higher secondary or below	177 (71.7)	183 (74.1)	
Graduate & above	45 (18)	39 (15.8)	
Occupation			
Home maker	241 (97.6)	183 (74.1)	<0.001^a
Employed	6 (2.4)	29 (11.7)	
Unemployed	0 (0)	35 (14.2)	
Below poverty line ^b	42 (17)	56 (22.7)	0.114
SES (BG Prasad) ^c			
I	12 (4.9)	13 (5.3)	0.001
II	76 (30.8)	38 (15.4)	
III	79 (32)	83 (33.6)	
IV	67 (27.1)	90 (36.4)	
V	13 (5.3)	23 (9.3)	

IQR: Inter Quartile range; SES: Socio Economic Status; COVID-19: Coronavirus disease 2019.

^aFishers exact test; ^bFamilies earning less Rs. 1,479 per capita are defined as below poverty line in Chandigarh, India; ^cBG Prasad scale is used to measure the socio-economic status of the family of the study participants in India. It classifies the families into 5 classes based on the monthly per capita income (Class I- \geq Rs 7,863, Class II- Rs 3,931–7,862, Class III- Rs 2,359–3,930, Class IV- Rs 1,179–2,358, Class V- Rs $<$ 1,179). Bold represents statistically significant values.

Table 2 Comparison of clinical characteristics between the pregnant women and non-pregnant women

Clinical characteristics	Pregnant women	Non-pregnant women	P value
	N=247 n (%)	N=247 n (%)	
Gravida			
Primi	96 (38.9)	–	–
Multi	151 (61.1)	–	–
History of abortions	N=151	N=113	
Yes	53 (35.1)	24 (21.2)	0.014
No	98 (64.9)	89 (78.8)	
Parity	N=130	N=143	
Primipara	81 (62.3)	43 (30.1)	<0.001
Multipara	49 (37.7)	100 (69.9)	
Current tobacco usage ^a	N=247	N=247	
Yes	0 (0)	1 (0.4)	1.000 ^b
No	247 (100)	246 (99.6)	
Preexisting diseases			
Hypothyroid	20 (8.1)	10 (4)	0.06
Diabetes	0 (0)	1 (0.4)	1.000
Allergies	0 (0)	5 (2)	0.061
Hypertension	1 (0.4)	3 (1.2)	0.623
COVID-19 disease history			
Yes	1 (0.4)	1 (0.4)	1.000
No	246 (99.6)	246 (99.6)	

COVID-19: Coronavirus disease 2019. ^ain past 30 days; ^bFishers exact test. Bold represents statistically significant values.

Table 3 Comparison of overall AEFI incidence till 28 days after taking the COVID-19 vaccine between the pregnant and non-pregnant women

	Pregnant women	Non-pregnant women	<i>P</i> value	Adjusted <i>P</i> value ^a
	N=247	N=247		
	n (%)	n (%)		
Any AEFIs till 28 days	189 (76.5)	175 (70.9)	0.153	–
Fever	139 (56.3)	116 (47)	0.038	0.734
Body pain	136 (55.1)	103 (41.7)	0.003	0.532
Weakness	7 (2.8)	22 (8.9)	0.004	0.014
Local pain at injection site	98 (39.7)	113 (45.7)	0.172	–
Swelling	31 (12.6)	22 (8.9)	0.191	–
Cold	2 (0.8)	2 (0.8)	1.000 ^b	–
Cough	2 (0.8)	1 (0.4)	1.000 ^b	–
Sore throat	2 (0.8)	1 (0.4)	1.000 ^b	–
Others	23 ^c (9.3)	8 ^d (3.2)	0.005	0.269
Any hospitalization	1 (0.4)	0 (0)	1.000 ^b	–
Number of AEFIs Median (IQR)	2 (1,3)	1 (0,3)	0.104	–
Multiple AEFIs (>1)	133 (70.4)	116 (65.4)	0.37	–
Duration of AEFIs (Days) Median (IQR)	2 (1.3,3.8)	2.5 (2,3.3)	0.357	–

AEFI: Adverse Events Following Immunization; COVID-19: Coronavirus disease 2019; IQR: Inter Quartile range.

^aAdjusted for occupation, socio-economic status, parity and abortion history. ^bFishers exact test. ^cVomiting (7), Headache (6), Abdominal pain (4), Anxiety (4), Itching in palms (1), Dizziness (1). ^dDiarrhoea (3), Vomiting (1), Headache (2), Dizziness (2). Bold represents statistically significant values.

Table 4 Comparison of AEFI incidence within 24 h after taking the COVID-19 vaccine between the pregnant and non-pregnant women

	Pregnant women	Non-pregnant women	<i>P</i> value	Adjusted <i>P</i> value
	N=247	N=247		
	n (%)	n (%)		
Any AEFI within 24 hours	178 (72.1)	174 (70.4)	0.691	–
Fever	131 (53)	116 (47)	0.208	–
Body pain	127 (51.4)	102 (41.3)	0.024	0.989
Weakness	6 (2.4)	21 (8.5)	0.003	0.013
Local pain at injection site	95 (38.5)	113 (45.7)	0.101	–
Swelling	30 (12.1)	20 (8.1)	0.136	–
Cold	2 (0.8)	1 (0.4)	1.000 ^b	–
Cough	1 (0.4)	1 (0.4)	1.000 ^b	–
Sore throat	1 (0.4)	1 (0.4)	1.000 ^b	–
Others	18 (7.3)	6 (2.4)	0.012	0.266
Any hospitalization	1 (0.4)	0 (0)	1.000 ^b	–

AEFI: Adverse Events Following Immunization; COVID-19: Coronavirus disease 2019. ^aAdjusted for occupation, socio-economic status, parity and abortion history; ^bFishers exact test. Bold represents statistically significant values.

tality of the COVID-19 vaccination reported by pregnant women from the USA and India¹²). Studies from the Czech Republic, France, and Ethiopia reported acceptance rates of 66.7%, 29.5%, and 62.04%, respectively, for COVID-19 vaccination among pregnant and postpartum women^{11, 18, 19}). A six-country survey of the European region reported 61% willingness among pregnant women to be vaccinated with

the COVID-19 vaccine²⁰). Compared to the non-pregnant state, pregnancy itself significantly lowered the COVID-19 vaccine acceptance rate among women in the United Kingdom²¹). In the Czech Republic, only 3.6% of participants intended to receive the vaccine immediately¹⁸), whereas a much higher percentage of participants from India in the present study underwent vaccination. A multi-country sur-

Table 5 Comparison of AEFIs incidence during 1–7 days and 8–28 days after taking the COVID-19 vaccine between the pregnant and non-pregnant women

	Pregnant women	Non-pregnant women	<i>P</i> value	Adjusted <i>P</i> value
	N=247	N=247		
	n (%)	n (%)		
Any AEFI between 1 and 7 days	41 (16.6)	22 (8.9)	0.010	0.064
Fever	26 (10.5)	10 (4)	0.006	0.007
Body pain	23 (9.3)	12 (4.9)	0.054	–
Weakness	1 (0.4)	2 (0.8)	1.000 ^b	–
Local pain at injection site	18 (7.3)	10 (4)	0.120	–
Swelling	6 (2.4)	2 (0.8)	0.285 ^b	–
Cold	0 (0)	1 (0.4)	1.000 ^b	–
Sore throat	1 (0.4)	0 (0)	1.000 ^b	–
Others	6 (2.4)	1 (0.4)	0.122 ^b	–
Any AEFI between 8 & 28 days	3 (1.2)	4 (1.6)	1.000 ^b	–
Fever	2 (0.8)	2 (0.8)	1.000 ^b	–
Body pain	1 (0.4)	3 (1.2)	0.623 ^b	–
Weakness	0 (0)	1 (0.4)	1.000 ^b	–
Cold	0 (0)	1 (0.4)	1.000 ^b	–
Cough	1 (0.4)	0 (0)	1.000 ^b	–
Others	1 (0.4)	1 (0.4)	1.000 ^b	–

AEFI: Adverse Events Following Immunization; COVID-19: Coronavirus disease 2019. ^aAdjusted for occupation, socio-economic status, parity and abortion history; ^bFishers exact test. Bold represents statistically significant values.

vey also reported that vaccine acceptance for the COVID-19 vaccine was generally the highest in India (up to 80%)¹², which was also found in the current study. The full vaccination rate for children in the present study area, that reached 82.8%²², might have also been a factor promoting the COVID-19 vaccine uptake of pregnant women in the present study¹². However, the existing barriers for the non-uptake of vaccines by 33.2% of pregnant women in the current settings need to be explored by qualitative studies to improve the coverage of COVID-19 vaccination.

The majority of the vaccinated women were in the second trimester (45.3%), which is in line with the findings of Gray *et al.* (46%)²³. In contrast, Lipkind *et al.* reported that the majority of vaccinated women were in the third trimester (61.8%)¹⁷.

The 28-day AEFI incidence rate in pregnant women was 76.5%. Fever (56.3%), followed by body pain (55.1%), was the most common AEFI reported by the pregnant women enrolled in the present study, whereas local injection site pain/soreness was the most common AEFI reported in the USA after the 1st dose (up to 88%), and only 1–4.2% reported fever following the first dose of the vaccine^{3, 23}. The overall 28-day incidence of AEFIs in the pregnant women did not differ significantly from that in non-pregnant women ($P=0.153$), corroborating the results of Shimabukuro *et al.* and Kadali *et al.*^{3, 24}. However, weakness was reported to be significantly lower among pregnant women than that among

nonpregnant women in the present study. This is in contrast to Shimabukuro *et al.*'s preliminary findings of AEFIs among pregnant women in the USA that indicated injection site pain to be higher among pregnant women than that among non-pregnant women, whereas other AEFIs such as body pain, chills, fever, and headache were lower among pregnant vaccinees³. The different findings may be due to the different vaccines assessed in the studies and the methodologies used to elicit the response. The lower frequency of weakness among pregnant women than that among non-pregnant women in the present study may be because weakness and fatigue are also considered natural effects of pregnancy.

One serious AEFI was reported in a pregnant woman who was hospitalized for one day for complaints of vomiting and giddiness on the day following vaccination. This finding was attributed to acute gastroenteritis. She was put on conservative management with intravenous fluids and antiemetics before discharge. A similar serious AEFI was recorded in a pregnant woman vaccinated with Covaxin among 234 pregnant women vaccinated in Mumbai, India²⁵. Shimabukuro *et al.* found no significant difference in the severe reactions between the pregnant and non-pregnant vaccinees³, whereas Kadali *et al.* and Goldshtein *et al.* reported no life-threatening adverse effects in the pregnant women^{24, 26}.

The importance of generating evidence on the safety of COVID-19 vaccines among pregnant women needs to

be viewed with the background of their exclusion from COVID-19 vaccine trials²⁷). In this study, we attempted to address this lacuna. These safety data will increase confidence in COVID-19 vaccination campaigns and the uptake of COVID-19 vaccines among pregnant women, as safety has been one of the major barriers⁸).

The median duration of AEFIs among pregnant women was two days, whereas Goldshtein *et al.* reported a shorter duration of one day²⁶). No abortions or stillbirths were reported among the vaccinated pregnant women in the present study, whereas abortions were reported among the vaccinees from the USA³; this might be due to the relatively small number of samples and the shorter follow-up period in our study. Kharbanda *et al.* reported no association between the receipt of COVID-19 vaccines and spontaneous abortions³). The current system of AEFI recording and reporting for COVID-19 vaccination in India comprises direct observation of the vaccinees for 30 minutes immediately after vaccination, followed by passive reporting of any AEFIs by the vaccinees thereafter. The reported AEFIs were collected through an online COWIN portal created for this purpose²⁸). However, the COVID-19 AEFI reporting system in India has not been up to the mark, in general²⁹). There is a registry of pregnant women infected with SARS CoV-2 available in one state of India³⁰); however, no surveillance system for COVID-19-vaccinated pregnant women could be found in India.

Strengths and limitations

The strengths of the current study include the prospective design and age-sex matched inclusion of pregnant and

non-pregnant women, with three points of data collection to limit recall bias. This is the first study to report AEFIs among COVID-19-vaccinated pregnant women in India. Limitations include a small sample size, leading to inadequate power. A post-hoc analysis with an alpha error of 5% based on the proportions of AEFI among the pregnant and non-pregnant women reported in the study indicated the power to be 29.5%. Other limitations include participants hailing only from a single region in India, and the non-availability of Covaxin (the second most popular vaccine in India after Covishield) for pregnant women (owing to the policy decision of the U.T. health administration) for follow-up in the study.

Conclusion

The COVID-19 vaccine uptake rate among pregnant women was 66.8% in northern India. The 28-day AEFI incidence rate among Covishield-vaccinated pregnant women was 76.5%, with one serious AEFI of hospitalization for one day. There was no significant difference in the AEFI incidence rates between pregnant and non-pregnant women. Thus, the Covishield vaccine may be safe for pregnant women in India. Further follow-up of the cohort for fetomaternal outcomes needs to be conducted on a larger sample of participants to confirm the overall safety profile of the vaccine. In the future, multi-centric studies need to be planned with an adequate sample size and using the Covaxin vaccine. It is also essential to capture real-world data on AEFIs among the COVID-19-vaccinated pregnant women by establishing a nationwide surveillance system.

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