

How safe is COVID-19 vaccination among pregnant women and its outcome – A hospital-based retrospective study in Indian population

Niraj B. Pandit¹, Purvi R. Fulmali², Piyusha Chandrayan³, Kishor Chauhan³,
Dipika L. Bhil⁴, Manish N. Rasania⁴

¹Department of Community Medicine, SBKS MI and RC, Sumandeep Vidyapeeth, Vadodara, Gujarat, India, ²Department of Community Medicine Healthy Mother Healthy Child Project, Sumandeep Vidyapeeth, Vadodara, Gujarat, India, ³Department of Obstetrics and Gynaecology, Dhiraj Hospital, SBKS MIRC, Sumandeep Vidyapeeth, Vadodara, Gujarat, India, ⁴Department of Paediatrics, Dhiraj Hospital, SBKS MIRC, Sumandeep Vidyapeeth, Vadodara, Gujarat, India

ABSTRACT

Background: Although getting the Covid infection is equal for every person, during pregnancy, the women's immunity is a little lower than usual, so they are more prone to infection. That is why they should be taken care of with more precautions. A vaccine is the best weapon to fight such infection. Covishield and Covaxin are the two vaccines first introduced in country India including for pregnant women. The safety of the vaccine was a big concern as one of them is a newer type of vaccine. The current study was planned with objectives to understand the safety aspect of Covid19 vaccine on pregnancy outcome and Adverse events following immunization (AEFI) following vaccination. **Materials and Methods:** This was a hospital-based retrospective cohort study. The sample size was all the pregnant women who delivered a baby from July 2021 to April 2022 at the tertiary care hospital in Vadodara. These women were retrospectively assessed for the status of vaccination based on the record and other information related to ANC from the record. Total of 1974 women were eligible for study after inclusion-exclusion criteria. The collected data was analysed. **Result:** Of the 1974 pregnant women, 531 (27%) took any of one covid19 vaccine and 1443 (73%) did not take vaccine. There were 511 (96%) women opted for Covishield vaccine and 20 (4%) women who opted for Covaxin. Of 531 women who took vaccination, 46% women had AEFI. The risk of low birth weight (LBW) baby was 40% among vaccinated v/s 39% among non-vaccinated and congenital malformation was 0.6% among vaccinated v/s 1% among non-vaccinated women. On the contrary, the risk of premature birth was 8% among the vaccinated group v/s 13% among the non-vaccinated group and NICU admission following delivery was 8% among the vaccinated group v/s 12% among the non-vaccinated group. **Conclusion:** AEFI among pregnant women were found less compared to the general population. The study also revealed that both Covishield and Covaxin are found safe for pregnancy outcomes and can be given to pregnant women during any trimester of pregnancy message for a family physician.

Keywords: Congenital malformation, Covaxin, Covishield, LBW, NICU admission, pregnancy outcome

Address for correspondence: Dr. Niraj B. Pandit,
Department of Community Medicine, SBKS MIRC, Sumandeep
Vidyapeeth Deemed to be University, Piparia, Vadodara - 391 760,
Gujarat, India.
E-mail: drniraj74@gmail.com

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Introduction

With the diagnosis of the first unusual acute respiratory syndrome in China near the end of Dec 2019, the Covid19 pandemic started. It was a major world threat and now the disease entered an endemic phase in various countries including India.

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Government of India has given emergency approval for the use of two covid19 vaccines Covishield and Covaxin in the year 2021 and large-scale vaccination gradually started from 16th Jan 2021.^[1]

Covishield is a recombinant, replication-deficient chimpanzee adenovirus vector encoding the SARS- CoV-2 spikes (S) glycoprotein.^[2] The same variant type of vaccine was made for Ebola viral infection.^[3] In vector vaccine, genetic material from the COVID-19 virus is placed in a modified version of a different viral vector.

Covaxin is an indigenous, inactivated vaccine, and the method is time tested. It is developed using whole – virion-inactivated vero cell-derived platform technology. They contain dead viruses incapable of infecting people but still able to instruct the immune system to mount a defensive reaction against an infection. Vaccine-induced neutralizing antibody titres were observed with two divergent SARS-CoV-2 strains.^[4]

Initially in India Covid19 vaccination program in which priority was given to frontline workers and the geriatric population. But the massive caseload and deaths were noticed during the second wave of covid19 from the months Feb 21 to July 21.^[5] The number of cases and deaths are reported on various sites. However, the most important group was the pregnant women during the second wave.

During the second wave of covid19 pandemic, there are many pregnant women get infected and even reported deaths also.^[2] These reports had created havoc among authorities and expert working in Covid19. Based on available information and evidence that is six months experience of general population and other international reports National Technical Advisory Group on Immunization recommended the use of Covid19 vaccine among pregnant women on 2nd July 2021.^[6]

Although more than 90% of infected pregnant women recovered without any need for hospitalisation, rapid deterioration in health occurred in a few and that might affect the foetus also. Such a report also supported to initiate Covid-19 vaccination among pregnant women.^[7]

Covid-19 infections during pregnancy may result in a rapid drop in the health of pregnant women and could also affect foetus, although ministry of health and family welfare (MOHFW) has approved vaccination of pregnant women for COVID-19 vaccines with balancing the risks, advantages and the disadvantages of getting vaccinated.^[8] The fact sheet says that a frontline worker or a vaccinator needs to counsel pregnant women about the availability, value and precautions of the vaccine,^[8] although low coverage of the Covid vaccination among pregnant women is expected and will increase as vaccine availability and access improve, and the same time, it is expected to collect more safety data for such new type of vaccine.^[9]

India crossed 200 Cr vaccine doses in July 2022^[10] which is the world's fastest vaccine coverage drive after China. Because of

such high vaccine coverage, the forth and further waves are found to be under control as per the Ministry of Health and Family Welfare report and there is a decrease in the daily positivity rate of Covid patients.^[11]

Like any vaccine, COVID vaccination has also adverse event following immunization (AEFI) on the individuals and they are usually like fever, body ache, pain, redness, swelling, site pain, vomiting, headache, etc. These are known AEFI, but during pregnancy, it can cause negative effects on the baby's growth and development in utero. So, one needs to be careful about those side effects.^[12]

Pregnant women represent the cohort which was not included in the COVID vaccination's clinical trials in the initial days. So that it was safety concerns about the new types of vaccine impact on the outcome of pregnancy.^[13] As family physician and primary care physicians are coming across questions about the safety of Covid19 vaccine during the ANC period. As there is limited research available and particularly from India on the impact of covid19 vaccination on pregnancy outcome. So the current study was planned to understand the safety aspect of Covid19 vaccine on pregnancy outcomes.

Materials and Methods

This was a hospital-based retrospective cohort study. The study was a part of a larger project of Sumandeep Vidyapeeth flagship project named Healthy Mother Healthy Child (HMHC).

The sample size was all the pregnant women who delivered babies from July 2021 to April 2022 at Dhiraj hospital, a Sumandeep Vidyapeeth-affiliated hospital. These women were retrospectively assessed for the status of vaccination based on the record which the project is collecting for all women since Covid19 vaccination started. In the current project, the data were collected from ANC mothers who are coming to Dhiraj Hospital from their first visit till the delivery at Dhiraj Hospital. All records related to ANC care and various important events were recorded in HMHC software and fetched for study. For the study purpose, the retrospective project data was fetched.

Sample population – Dhiraj Hospital – is located in Vadodara of Central Gujarat. The ANC mothers of Vadodara and surrounding villages are coming for the utilizing services of Dhiraj Hospital. Thus, participants were from Vadodara and surrounding villages.

Total 2064 women delivered during the period of 10 months. These were the study population enrolled in the study. The sample size of the study was 1974 excluding the exclusion criteria like not fully ANC care taken, not delivered at Dhiraj Hospital, lost to follow up and not ready to give consent on initial recruitment. The inclusion criteria were the women who are ready to give consent, and delivered babies in the Dhiraj Hospital.

The HMHC project staff is collecting all information on new ANC and follow-up ANC mothers on each visit. The socio-demographic, ANC care, lab investigation, expert advice, USG information, etc., data were fetched from the HMHC software and used for the current study. The study was approved by the institutional ethics committee of Sumandeep Vidyapeeth. The informed consent was obtained from all the participants.

The sociodemographic information, vaccine status, hospital admission and delivery related, and baby's outcome information were collected from the data of the HMHC software.

Statistical analysis was done by using the Epi Info software and other analysis were done in Microsoft excel. There were two independent variables, one who were vaccinated and one who were not vaccinated for them we applied incidence rate and relative risk test to see the significance of the variables.

Result

In the current study, 1974 women delivered under the HMHC project and their data were analysed for the study. Of them, 531 (27%) took any of two covid19 vaccines and 1443 (73%) did not take vaccine. There were 511 (96%) women who received Covishield vaccine and 20 (4%) women who received Covaxin. These were the women, who were vaccinated with at least one dose of COVID-19 vaccine during the ANC period. The socio-demographic profile of these women is given in Table 1, as it was observed that significantly high number of vaccinated

women were in 21–25 year age group and were rural women. Majority (51%) ANC women received vaccine during the second trimester, following 29% who received it in the first trimester and 20% who received it in the third trimester of pregnancy.

In Table 2, out of 531 women who had taken vaccination, 46% of women had AEFI. Thus, the prevalence of AEFI was found 46% among ANC women. The majority of women had fever (28%) as AEFI, following injection site pain 11%, body ache 3%, and headache and weakness 2%. There were 54% of women who had no adverse effect after taking the vaccination. There was no reporting of any serious AEFI like hospital admission or death.

Table 3 shows that out of 1974 there were 518 (26%) vaccinated mothers and 1440 (73%) non-vaccinated women had no history of Covid infection before or during pregnancy. There were 13 vaccinated mothers and 3 non-vaccinated mothers having a history of Covid infection.

Table 4 shows the pregnancy outcome and vaccination status. Covaxin numbers were few so for calculation and various analyses, combine numbers were used. It was observed that there are 8% incidence of having pre-mature baby among vaccinated mothers, 88% of full-term delivery and 4% incidence of having post-term delivery.

There were 776 babies born with low birth weight babies. The incidence of low birth weight babies was 40% among mothers who have taken vaccination during pregnancy and 39% babies

Table 1: Socio-demographic profile of pregnant women (n=1974)

	Covishield (%)	Covaxin (%)	Total vaccinated(%)	Total non-vaccinated(%)
Age-wise distribution				
≤20	88 (17)	3 (15)	91 (17)	292 (20)
21–25	281 (54)	7 (35)	288 (54)	780 (54)
25–30	116 (23)	7 (35)	123 (23)	312 (22)
31–35	23 (5)	3 (15)	26 (5)	55 (4)
>35	3 (1)	0	3 (1)	4 (0)
Total	511 (100)	20 (100)	531 (100)	1443 (100)
Pregnancy status at time of vaccine				
First Trimester	151 (30)	4 (20)	155 (29)	N/A
Second Trimester	258 (50)	13 (65)	271 (51)	N/A
Third Trimester	102 (20)	3 (15)	104 (20)	N/A
Total	511 (100)	20 (100)	531 (100)	N/A
Religion				
Hindu	501 (98)	18 (90)	519 (98)	1375 (95)
Other	10 (2)	2 (10)	12 (2)	68 (5)
Locality				
Rural	340 (67)	9 (45)	349 (66)	771 (53)
Urban	171 (33)	11 (55)	182 (34)	672 (47)
Education				
Illiterate	67 (13)	1 (5)	68 (13)	229 (16)
Primary	260 (50)	8 (40)	268 (50)	741 (51)
Secondary	127 (25)	7 (35)	134 (25)	300 (21)
Higher secondary education	40 (8)	2 (10)	42 (8)	109 (7)
Under graduate	14 (3)	2 (10)	16 (3)	38 (3)
Postgraduate	3 (1)	0	3 (1)	26 (2)

with low birth weight whose mothers have not taken Covid vaccination.

When compared there were fewer congenital anomalies incidence, 3 (0.6%) among the babies whose mothers took a

vaccine during pregnancy, and 15 (1%) mothers who delivered babies with congenital malformation who did not take a vaccine.

Out of 1974, there were 210 babies got admitted to the NICU and out of that 8% were vaccinated women's babies and 12% of babies are from non-vaccinated mothers.

Out of 776 low births weight babies, there were 212 (27%) babies from vaccinated mothers and the other 564 (73%) babies were from non-vaccinated mothers. The relative risk and P value for this association of Covid19 vaccination and low birth weight baby was found not significant.

In the cohort of mothers and their babies, total 18 major congenital anomalies were found. Of them, 3 (0.6%) among vaccinated mother's babies and 15 (1%) among non-vaccinated mother's babies. This difference is also statistically not significant.

The relative risk for prematurity and NICU admission was protected with Covid19 vaccination. It means that babies who were born to mothers with Covid19 vaccine had less chance to get prematurity (RR = -0.624, CI = 0.453-0.859, P = -0.0039) and less change to get NICU admission (RR -0.699, CI = 0.508-0.964, P = 0.028) [Table 5].

Table 2: Reported AEFI by women as self-reported (n=531)

Side effects type	Covishield (%)	Covaxin (%)	Total
Body ache	16 (3)	0	16 (3)
Headache	13 (2)	0	13 (2)
Fever	140 (27)	7 (35)	147 (28)
Injection site pain	51 (10)	4 (20)	55 (11)
Weakness	13 (3)	0	13 (2)
No any side effects	278 (54)	9 (45)	287 (54)
Total	511 (96)	20 (4)	531

Table 3: Covid disease status of registered participants with Covid19 vaccine status

Covid19 infection H/o	Covishield (%)	Covaxin (%)	Total vaccinated	Total non-vaccinated
No covid19 infection	498 (97)	20 (100)	518 (97)	1440 (98)
Covid infection	13 (3)	0	13 (3)	3 (2)
Total	511 (100)	20 (100)	531 (100)	1443 (100)

Table 4: Pregnancy outcome of the Covid19 vaccinated women

Pregnancy outcome	Covishield	Covaxin	Total vaccinated	Total non-vaccinated
Pre-term <37 weeks	42 (8)	0	42 (8)	183 (13)
Term delivery 37-42 weeks	466 (91)	2 (10)	468 (88)	1258 (87)
Post-term >42 weeks	3 (1)	18 (90)	21 (4)	2 (0)
Total	511 (100)	20 (100)	531 (100)	1443 (100)
Outcome related to weight				
LBW	202	10	212 (40)	564 (39)
Congenital anomalies	3	0	3 (0)	15 (1)
NICU admission	37	6	43 (8)	167 (12)
IUD	7	0	7 (2)	24 (2)

Table 5: Association of various pregnancy outcome variables and covid19 vaccination status

	Vaccinated	Not vaccinated	Total	RR (95% CI)	P	Significance status
LBW						
Yes	212 (40)	564 (39)	776	1.0215 (0.903-1.154)	0.73	Not significant
No	319 (60)	879 (61)	1198			
Total	531 (100)	1443 (100)	1974			
Pre-mature						
Yes	42 (8)	183 (13)	225	0.6237 (0.453-0.859)	0.0039	Significant
No	489 (92)	1260 (87)	1749			
Total	531 (100)	1443 (100)	1974			
Congenital Anomalies						
Yes	3 (0.6)	15 (1)	18	0.543 (0.158-1.869)	0.3335	Not significant
No	528 (99.4)	1428 (99)	1956			
Total	531 (100)	1443 (100)	1974			
NICU admission with serious illness						
Yes	43 (8)	167 (12)	210	0.6997 (0.508-0.964)	0.028	Significant
No	488 (92)	1276 (88)	1764			
Total	531 (100)	1443 (100)	1974			

Discussion

The current retrospective hospital-based cohort study included 1974 mothers who delivered babies during a specified period of 10 months. Of them, 531 women received at least 1 dose of COVID-19 vaccine during pregnancy. The age distribution of women was almost similar for the vaccination group and non-vaccination group. More than 50% of women were from the age group of 21–25 years age in both the groups. Socio-demographic distribution shows that 95% of women were Hindu and 5% other religions in the non-vaccine group, whereas 98% of women were Hindu and only 2% were from other religions in the vaccine group. Almost 66% of women were from rural background in the vaccination group whereas 53% in the non-vaccination group. Rural women are leading in Covid19 vaccination coverage. Illiterate (13%) and primary-level educated (50%) women took Covid19 vaccine. Thus rural background and literacy were not major hurdles for Covid19 vaccination in the rural area of Gujarat. The government health system was found to be strong in providing health education and convincing for Covid19 vaccine on ground.

AEFI is an important event with any vaccination including Covid19 vaccine. In the present study, it was asked to all pregnant ladies who took either Covishield or Covaxin. The main AEFI were fever (28%) and injection site pain (11%), others like body ache, headache and weakness were almost negligible. Almost 54% of pregnant ladies did not report any AEFI. This prevalence of AEFI was found quite low among pregnant women compared to the general population. Study done by N Pandit *et al.* reported nearly 70% of AEFI following both types of Covid19 vaccines among the Indian population.^[14] A study from Indonesia by Supangat *et al.* so reported nearly 62% of AEFI prevalence among medical students following CoronaVac vaccine.^[15] In the previous study done in Mumbai on 243 pregnant women, there was only one case of AEFI has been reported so far, according to the civic body.^[16] Thus, current retrospective study reported quite low AEFI among pregnant women in comparison to the general population.

The study revealed that Covid19 vaccination is not significantly associated with an increased risk of low birth weight or congenital malformation, but it was observed that Covid19 vaccination is protective for babies to reduce pre-maturity and NICU admission.

Ruderman RS *et al.* conducted a study in Chicago and found that an anomaly was found among 4.2% of women who took vaccine compared to 5.1% of women who did not take Covid19 vaccine during pregnancy.^[17] A similar observation was recorded by Wang PH *et al.* from Taiwan and reported that Covid19 mRNA vaccine is safe during pregnancy for foetus^[18] and also Theiler RN *et al.* also observed similar result in his study from Mayo Clinic.^[19] Blakeway H *et al.* from London also reported similar safety for mRNA vaccine.^[20] S Prasad *et al.*,^[21] Carbone L *et al.*^[22] and Shafiee, A^[23] reported

in their systematic review that no risk of adverse outcome of pregnancy like stillbirth, miscarriage premature delivery or any other post-partum complication to a mother or baby following Covid19 vaccine.

There were no studies found from India and similar developing countries. The study by Ruderman RS *et al.* from Chicago reported the safety of Covid19 vaccine on pregnancy outcomes for mRNA vaccine.^[17]

According to the Dagan N *et al.* study, they also found out that there is 96% effectiveness in the Covid19 vaccination and its outcome of pregnancy.^[24] Vaccination of pregnant women may also provide protection for their newborns. A study by Collier AY *et al.* found binding and neutralizing antibodies in the cord blood of infants born to mothers who were vaccinated with mRNA vaccines and in the mother's breast milk.^[1]

Thus, this is the kind of first study from India for the Covishield and Covaxin with a clear indication that these two Indian Covid19 vaccines are safe for pregnant women and their outcome babies. This is a key message for primary care and family physician to convince their client about the safety of vaccines to the baby and mother. There are a few limitations like single hospital-based study, and not community based. However, the strength is the cohort study with proper data monitoring. The study team has no relation with vaccine manufacturer or government agencies. It is an institutional funding project.

Conclusion

This is the first study from India which has assessed the use of newer type vaccines Covishield and Covaxin among pregnant women. Covaxin is a known and time-tested method of vaccine. Covid19 pandemic has made everything on a fast track, thus vaccine use also. But finally the current study has proved that Covishield and Covaxin both are safe to give pregnant women for the health of mother and baby as outcome. This is a big news for the newer method of vaccine for future scope. Also the primary care and family physician assured their group of clients with confidence in vaccination programme.

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Conflicts of interest

There are no conflicts of interest.

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