



TO STUDY VACCINE SAFETY OUTCOME OF FETUS AND INFANT UPTO TWO MONTHS OF AGE OF COVID-19 VACCINATED PREGNANT WOMEN AS COMPARED TO THOSE OF UNVACCINATED PREGNANT WOMEN
(A study of 150 cases and 150 controls)

Paediatrics

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ABSTRACT

This study is designed as an observational case control study involving covid-19 vaccinated pregnant women and covid-19 unvaccinated pregnant women. Sample size 150 antenatal vaccinated women(cases) and 150 unvaccinated pregnant women(controls) as per inclusion criteria. Ethical clearance and consent taken before inclusion in study as per format with duration of 12 months. Post-natal mother and infant follow up was done till 2 months of age. Out of 150 cases 75 (50%) had taken 1 dose and 75 (50%) had taken 2 doses of covid-19 vaccination. Out of 150 deliveries(cases), 24(16%) were preterm, 126 term (84%); 29 (19.33%) have NICU stay (for prematurity, RDS, NJ, VLBW); 2 death and 1 still birth and 4 were admitted under 2 month of age. As compared to controls of 150, 17 (11.3%) were preterm and 133(88%) were full term; 27(18%) have NICU stay (for prematurity, RDS, NJ, VLBW) and 2 death and 2 still birth and 1 congenital malformation (hydrocephalus) and 4 were admitted under 2 month of age. p value =0.239.

KEYWORDS

Covid-19 Vaccination, Pregnant Woman

INTRODUCTION

The COVID-19 pandemic has caused loss of life and poorer health outcomes, outside and in pregnancy, despite worldwide aggressive public health measures to control the spread. Mass vaccination is a key method by which countries are aiming to control the pandemic. Theoretically, COVID-19 vaccines are safe for use in pregnancy, as they do not contain a live attenuated virus. For COVID-19 vaccination in pregnancy, there has been no major safety signal from animal reproductive toxicology studies, the very small number of inadvertent pregnancies in vaccine trials, the Centres for Disease Control and Prevention (CDC) V-safe postvaccination health checker (with limited data on >30,000 pregnant women, but only 827 women have given birth), or a formal pregnancy registry (>1800 enrolled to date). Immunization during pregnancy is a simple and effective way to protect the mother and child from certain infections. The immunological changes occur during pregnancy which may be responsible for the susceptibility of certain infectious diseases that increases the risk of more serious outcomes¹. Vaccination of pregnant women can protect to mother against vaccine-preventable infections, and in so doing potentially protect the fetus. Immunization during pregnancy can also directly protect the fetus and infant via transferred of antibodies from the mother to the fetus. This is why vaccinations during pregnancy are so important. Vaccination Introduction during pregnancy is a cost-effective strategy to improve pregnancy outcomes in India. Based on vast previous experience with other vaccines in pregnancy and no hypothesized mechanism for harm, similar efficacy and side effects are anticipated with COVID-19 vaccination in pregnancy². However, pregnant women were excluded from the initial randomized controlled trials (RCTs) testing the safety and efficacy of COVID-19 vaccines. Although randomized trials of COVID-19 vaccination in pregnancy have now begun, the results will not be available until 2022 at the earliest. Pregnant women have been reluctant to receive COVID-19 vaccination and guidance for healthcare professionals has not been consistent. Some guidelines initially recommended against routine COVID-19 vaccination in pregnancy but pivoted as safety data accumulated, whereas others recommended routine vaccination from the start. Current recommendations in several countries including india allow for vaccination during pregnancy for those who fall into other priority groups, such as health care workers and many pregnant individuals have already opted to receive a covid-19 vaccine. Inadvertent vaccination in early pregnancy will also occur, since several priority groups contain a high proportion of reproductive -age individuals. Given current limited evidence on covid-19 vaccination during pregnancy, safety monitoring is essential from the outset of large-scale deployment. In addition to traditional pharmacovigilance approaches, comprehensive safety assessment in fetal and infants upto two months, Introduction after covid-19 vaccination in antenatal mothers will need to be generated through observational epidemiologic studies in large populations, such as those using routinely- collected data sources like health administrative databases and registries. So this study is an

attempt to understand the covid-19 vaccination in antenatal mothers and its safety outcomes and effects in fetus and infants up to two months².



Figure1: Sources: https://images.hindustantimes.com/img/2021/07/09/550x309/20210707_Pune-PVG-MN_Pregnant_Woman_Vaccination_002_1625839152013_1625839151597.JPG

AIMS AND OBJECTIVES

- To assess the vaccine safety profile of fetus and infants (up to 2 months of age) of mothers who are immunized for covid 19 vaccination in ante-natal period in comparison with fetus and infants of unvaccinated mothers with similar safety profile.
- To study the outcomes in fetus and infants up to two months following covid-19 vaccination in antenatal mothers.
- To document and characterize the clinically important adverse events in fetus and infants up to two months following covid-19 vaccination in pregnant woman and compare with unvaccinated women of similar safety profile.

MATERIALS AND METHODS

This study is designed as an observational case control study involving covid-19 vaccinated pregnant women and covid-19 unvaccinated pregnant women. Sample size 150 antenatal vaccinated women(cases) and 150 unvaccinated pregnant women(controls) as per inclusion criteria. Ethical clearance and consent taken before inclusion in study as per format within duration of 12 months. Post-natal mother and infant follow up was done till 2 months of age. Results were analysed with help of standard statistical tests.

RATIONALE OF STUDY

Pregnancy remained an exclusion criterion for all the COVID-19 vaccine trial; therefore, the efficacy of the COVID-19 vaccines in pregnant women is unavailable. However, given the effectiveness of

the influenza vaccines elucidated in a meta-analysis conducted by Quach et al., it can be hypothesized that the effects of vaccine on pregnancy would be minimal, but more data would be needed for confirmation. Present study is an attempt to understand the covid-19 vaccination in antenatal mothers and its safety outcomes and effects in fetus and infants up to two months. So this study is for comparison of vaccine safety outcome of fetus and infant upto two months of age of covid-19 vaccinated pregnant women as compared to those of unvaccinated pregnant women.

RESULTS

(1) In the present study, total 150 cases were included, out of which 16% were preterm and 84% were term. Out of 150 controls, 12% were preterm and 88% were term. There was no significant difference in the incidence of prematurity between the two groups.

Deshayne B Fell, et al³ 2022 conducted a retrospective cohort study in which incidence of preterm birth was 6.5% among those vaccinated during pregnancy and 6.9% among those who were unvaccinated during pregnancy and which was not significant.

Table No.1

	PRETERM	TERM	TOTAL
CASE	24(16%)	126(84%)	150
CONTROL	17(12%)	133(88%)	150

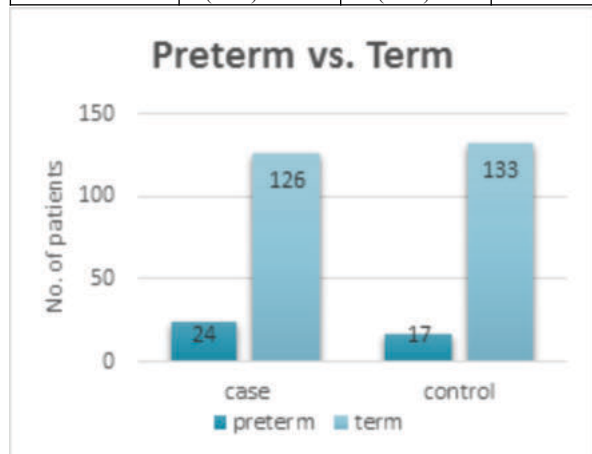


Chart no 1

(2) In the present study, total 150 cases were included, out of which 19.3% having nicu stay and 80.6% having no nicu stay and 42(28%) were LBW and 108(72%) were normal weight. Out of 150 controls, 18% having nicu stay and 82% having no nicu stay and 45(30%) were LBW and 105(70%) were normal weight. There was no significant difference in the incidence of nicu stay and incidence of LBW between the two groups.

Table No.2

	NICU stay	No NICU Stay	LBW	NORMAL WEIGHT
CASE	29 (19.3%)	121 (80.6%)	42 (28%)	108 (72%)
CONTROL	27 (18%)	123 (82%)	45 (30%)	105 (70%)

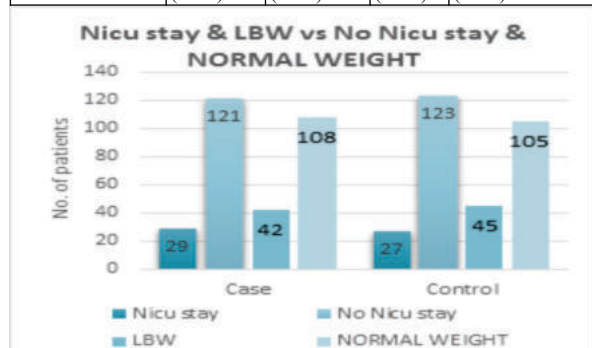


Chart no 2

(3) In the present study, total 150 cases were included, out of which 0.66% were still birth and 1.3% expired and 98% survived. Out of 150 controls, 1.3% were still birth and 1.3% expired and 97.3% survived. There was no significant difference in the incidence of still birth and death between the two groups.

Table No 3

	Stillbirth	Death	Survived	Total
CASE	1 (0.66%)	2 (1.3%)	147 (98%)	150
CONTROL	2 (1.3%)	2 (1.3%)	146 (97.3%)	150
Total				300

(4) In the present study, total 150 cases were included, out of which 0% congenital malformation and 100% were normal. Out of 150 controls, 0.7% congenital malformation and 99.3% were normal. There was no significant difference in the incidence of congenital malformation between the two groups.

In the study conducted by Charles Yap, et al¹, the neonatal outcomes within the live birth infant cohort showed preterm birth (<37 weeks) incidence at 9.4% (60 out of 636), small for gestational age incidence of 3.2% (23 out of 724), and congenital anomalies were seen in 2.2% (16 out of 724). No neonatal deaths were reported.

Table No 4

	CONG. MAL-FORMATION	NO CONG. MAL-FORMATION	TOTAL
CASE	0	150	150
CONTROL	1 (0.7%)	149 (99.3%)	150

(5) the overall comparison of the neonatal outcomes between the cases and controls. There was no significant difference in the incidence of prematurity, Low birth weight, neonatal death, congenital malformation and NICU admission between the two groups. This shows that covid-19 vaccine in antenatal mothers quite safe in antenatal period, it will not adversely affect the neonatal outcomes as it was observed in our study.

Table No 5

	CASES	CONTROLS
PRETERM	24 (16%)	17 (11.3%)
NICU STAY	29 (19.3%)	27 (18%)
LBW	42 (28%)	45 (30%)
STILL BIRTH	1 (0.66%)	2 (1.3%)
DEATH	2 (1.3%)	2 (1.3%)
CONG. MALFORMATION	0	1 (0.7%)
ADM. UNDER 2MONTH OF AGE	33 (22%)	31 (20.6%)
NEED O2 SUPPORT	10 (6.6%)	11 (7.3%)

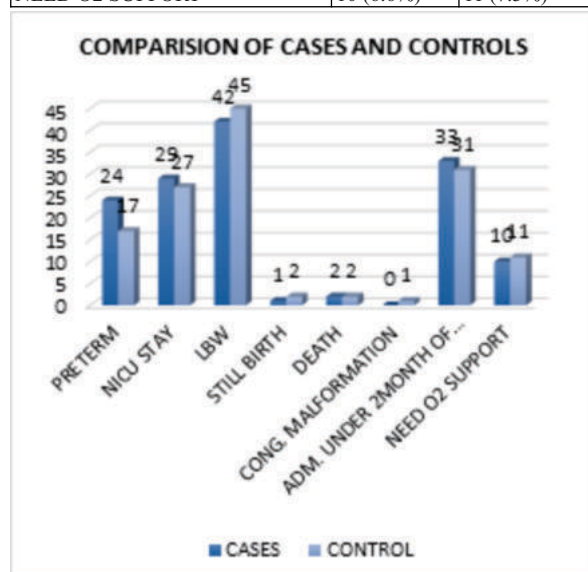


Chart no 3

CONCLUSIONS

- Covid 19 vaccine in antenatal mothers is found safe in the view of fetal and neonatal outcomes like prematurity, low birth weight, death, stillbirth and congenital malformation and hospital stay.
- Fetal outcome in vaccinated antenatal mother and unvaccinated antenatal mother is almost same in form of still birth, prematurity, low birth weight, death, congenital malformation and hospital stay, suggesting that immunization to antenatal mother is safe during pregnancy.

REFERENCES:

- [1] <https://www.cdc.gov/media/releases/2021/s0811-vaccine-safe-pregnant.html>
- [2] Fell DB, Dimitris MC, Hutcheon JA, Ortiz JR, Platt RW, Regan AK, Savitz DA. Guidance for design and analysis of observational studies of fetal and newborn outcomes following COVID-19 vaccination during pregnancy. *Vaccine*. 2021 Apr 1;39(14):1882-1886. doi: 10.1016/j.vaccine.2021.02.070. Epub 2021 Mar 2. PMID: 33715900; PMCID: PMC7923848.
- [3] Fell DB, Dhinsa T, Alton GD, Török E, Dimanlig-Cruz S, Regan AK, Sprague AE, Buchan SA, Kwong JC, Wilson SE, Häberg SE, Gravel CA, Wilson K, El-Chaâr D, Walker MC, Barrett J, MacDonald SE, Okun N, Shah PS, Dougan SD, Dunn S, Bisnaire L. Association of COVID-19 Vaccination in Pregnancy With Adverse Peripartum Outcomes. *JAMA*. 2022 Apr 19;327(15):1478-1487. doi: 10.1001/jama.2022.4255. PMID: 35323842; PMCID: PMC8949767.
- [4] Yap C, Ali A, Prabhakar A, Prabhakar A, Pal A, Lim YY, Kakodkar P. Comprehensive literature review on COVID-19 vaccines and role of SARS-CoV-2 variants in the pandemic. *Ther Adv Vaccines Immunother*. 2021 Nov 24;9:25151355211059791. doi: 10.1177/25151355211059791. PMID: 34870090; PMCID: PMC8637774.