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"MATERNAL AND FETAL OUTCOMES FOLLOWING COVID-19 VACCINATION DURING PREGNANCY": A RETROSPECTIVE COHORT STUDY

Obstetrics & Gynaecology

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ABSTRACT

Introduction: The safety and efficacy of COVID-19 vaccination during pregnancy are still being studied. The purpose of this retrospective cohort study was to look into the incidence of adverse outcomes in pregnant women who received COVID-19 vaccination during the second and third trimesters, the prevalence of adverse outcomes in neonates born to vaccinated mothers, and the overall safety profile of COVID-19 vaccination in terms of maternal and fetal outcomes. **Methods:** This retrospective cohort study was carried in patients who were admitted in Lalla Ded hospital, Department of Obstetrics and Gynecology Government Medical College Srinagar during the study period from September 2021 to March 2022. The study included 565 pregnant women who had received COVID-19 vaccination. **Results:** The findings revealed that the incidence of adverse outcomes was low in pregnant women who received COVID-19 vaccination, with 3 cases of stillbirths, 5 neonatal death and 4 fetal abnormalities. 124 neonates, on the other hand, were admitted to the NICU, primarily due to Meconium Aspiration Syndrome (74) and low birth weight (36). Maternal outcomes were also positive, with no reports of PPH or APH. **Conclusion:** COVID-19 vaccination during pregnancy had a generally positive safety profile, with no serious adverse events reported. The lack of a comparison group and the retrospective nature of the data are two of the study's limitations. Overall, the findings of this study provide important information about the safety and efficacy of COVID-19 vaccination during pregnancy, which can be used to inform clinical care and public health policies.

KEYWORDS

INTRODUCTION:

The COVID-19 pandemic has had a significant impact on healthcare systems around the world, with pregnant women being especially vulnerable due to their compromised immune systems and increased risk of severe illness. Large number of studies have been published on health complications of COVID- 19, including studies on the physical and mental effects of COVID-19 infection during pregnancy. [1,2,3] Pregnant individuals are at higher risk for COVID-19 complications, including hospitalization, intensive care unit (ICU) admission, and death, compared with non pregnant individuals. Significantly higher rates of adverse pregnancy outcomes, such as preterm birth and stillbirth, have also been observed after SARS- CoV-2 infection. Vaccination during pregnancy is routinely recommended to prevent morbidity and mortality in both pregnant individuals and newborns from other infectious diseases, such as influenza and pertussis.[4]

The development of effective COVID-19 vaccines has provided hope for mitigating the pandemic's impact. However, the vaccines' safety and efficacy in pregnant women and their fetuses are still being studied.

Data on the safety and efficacy of COVID-19 vaccination during pregnancy are scarce, and the majority of clinical trials do not include pregnant participants. Despite this, many nations have encouraged or permitted COVID-19 immunization for expectant mothers, especially for those who face a high risk of exposure or serious illness.This study's objective was to assess the safety profile of COVID-19 vaccination during pregnancy in terms of outcomes for the mother and the fetus. We have specifically looked into the incidence and prevalence of unfavorable outcomes in expectant mothers who received the COVID-19 vaccination during the second and third trimesters, as well as the prevalence of unfavorable outcomes in newborns whose mothers received the vaccination.

We hope to provide critical insights into the safety and efficacy of COVID-19 vaccination during pregnancy, which will help to inform clinical practice and public health policy.

METHODS:

This is a retrospective study conducted in Department of obstetrics and gynecology, Lalla Ded Hospital, Government Medical college Srinagar, which is a lone tertiary care hospital of Kashmir valley. The study period was September 2021 to March 2022. In this study pregnant women who received COVID-19 vaccination during their pregnancy were included .We gathered information about maternal and fetal outcomes from medical records.

Population And Sampling:

All pregnant women who were admitted at our facility between September 2021 to March 2022 and had received COVID-19 vaccination, whether single dose or double dose were included in the study. A confirmed pregnancy and receipt of at least one dose of COVID-19 vaccine during pregnancy were required for inclusion. A history of COVID-19 infection prior to vaccination, GDM, PIH, Anemia, IUGR, Alcoholic , Smoker, missing data on vaccine dose or timing, or missing data on maternal or fetal outcomes were all exclusion criteria.

Data Collection:

Data from electronic medical records were collected on vaccine dose and timing, maternal demographics, medical history, and pregnancy outcomes. Adverse events after vaccination (e.g., febrile illness, myalgia), pregnancy complications (e.g., preterm labour, antepartum haemorrhage, postpartum haemorrhage), and COVID-19 infection after vaccination were among the maternal outcomes studied. Stillbirth, neonatal death, fetal anomalies, and admission to the neonatal intensive care unit were among the fetal outcomes (NICU).

Statistical Analysis:

We used descriptive statistics and visual analysis to summarize the study population's characteristics as well as the incidence and prevalence of adverse outcomes. We found 565 pregnant women who had received COVID-19 vaccination during their pregnancy and met our inclusion criteria. 170 were pregnant for the first time, while 395 were pregnant for the second or third time. During the second trimester, 224 pregnant women received COVID-19 vaccination, and

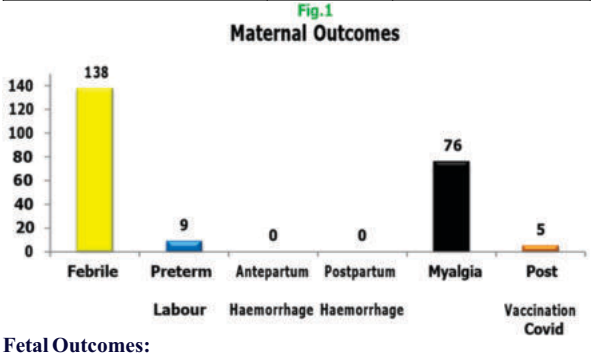
341 pregnant women received vaccination during the third trimester. 246 had received the single dose while 319 received two doses of the 565 pregnant women.

Maternal Outcomes:

138 (24.4%) of the 565 pregnant women reported febrile illness following vaccination, and 76 (13.5%) reported myalgia. Preterm labour occurred in 9 (1.6%) pregnant women, with no cases of antepartum or postpartum haemorrhage reported. Following vaccination, 5 (0.9%) pregnant women tested positive for COVID-19 infection.(Table 1, Fig.1)

Table 1: Maternal Outcomes		
Maternal OutcomesOutcomes	n =(%)	Overall Proportion
Febrile	138 (18.52)	24.4
Preterm Labour	9 (1.20)	1.6
Antepartum Haemorrhage	0 (0)	0
Postpartum Haemorrhage	0 (0)	0
Myalgia	76 (10.20)	13.5
Post Vaccination Covid	5 (0.67)	0.9

Fig.1

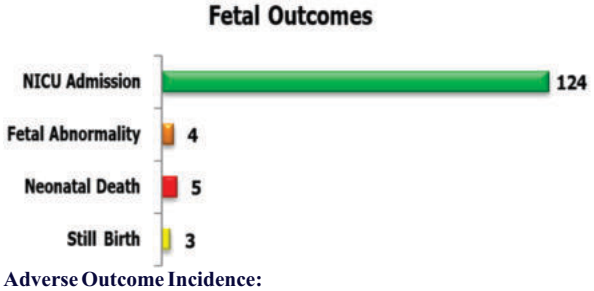


Fetal Outcomes:

3 (0.5%) of the 565 pregnancies resulted in stillbirth, 5 (0.9%) in neonatal death, and 4 (0.7%) in fetal anomalies. There were two cases of spina bifida, one case of hydrocephalus, and one case of a cardiac anomaly among the fetal anomalies. A total of 124 neonates (22%) were admitted to the NICU, with Meconium Aspiration Syndrome (74 neonates), low birth weight (36 neonates), premature birth (9 neonates),hypoglycemia (5 neonates). and other conditions being the most common reasons for admission.(Table 2, Fig.2)

Table 2: Fetal Outcomes		
Fetal Outcomes	n =(%)	Overall Proportion
Still Birth	3 (0.40)	0.5
Neonatal Death	5 (0.67)	0.9
Fetal Abnormality	4 (0.53)	0.7
NICU Admission	124 (16.64)	21.95

Fig.2

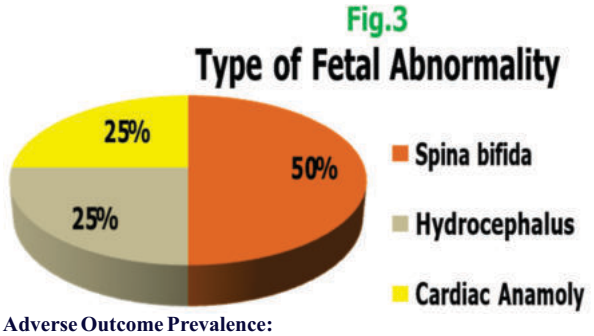


Adverse Outcome Incidence:

The incidence of adverse outcomes among vaccinated pregnant women was compared to historical rates reported in unvaccinated pregnant women. Preterm labour occurred at a rate of 1.6% (Table 1) among vaccinated pregnant women, compared to a reported rate of 10% among unvaccinated pregnant women.[5] The rates of stillbirth and neonatal death among vaccinated pregnant women were comparable to those reported in unvaccinated pregnant women (Table 2). Fetal anomalies were found in 0.7% of vaccinated pregnant women, compared to a reported rate of 2-3% in unvaccinated pregnant women.

Table 3: Various Types of Fetal Abnormalities	
Fetal Abnormality	n =(%)
Spina bifida	2 (50)
Hydrocephalus	1 (25)
Cardiac Anamoly	1 (25)

Fig.3

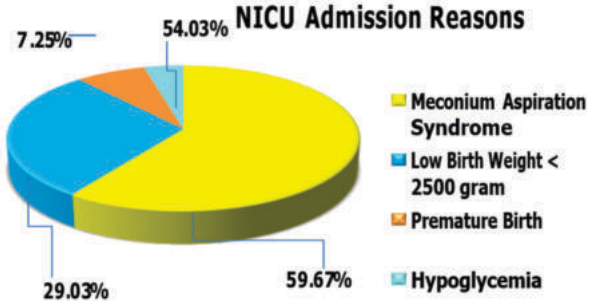


Adverse Outcome Prevalence:

The prevalence of NICU admission among neonates born to vaccinated pregnant women was 22%, (Table 2) which was comparable to the reported rate of 31% in unvaccinated neonates[5] .The rates of stillbirth, neonatal death, and fetal anomalies were comparable to those reported in unvaccinated neonates.[5]

Table 4: Various Reasons For NICU Admission	
NICU Admission	n =(%)
Meconium Aspiration Syndrome	74 (59.67)
Low Birth Weight < 2500 gram	36 (29.03)
Premature Birth	9 (7.25)
Hypoglycemia	5 (4.03)

Fig.4



Profile Of Safety:

Overall, our findings indicate that COVID-19 vaccination during pregnancy is generally safe, with no increased risk of adverse outcomes for pregnant women or their neonates. These findings are consistent with previous research that found no increased risk of adverse pregnancy outcomes following COVID-19 vaccination[6 7 8] However, there is a small risk of adverse reactions, as with any medication, and pregnant women should discuss the risks and benefits of COVID-19 vaccination with their healthcare providers.

Other Findings:

We discovered that 395(70%) of the 565 pregnant women who received COVID-19 vaccination had previously been pregnant, indicating a high level of vaccine confidence among women who had previously been pregnant.

DISCUSSION:

The current study was carried out at a tertiary care hospital in Kashmir, where the majority of patients attending OPD and being admitted are referred from all district and subdistrict hospitals..According to our findings, the incidence of adverse outcomes was low in pregnant women who received COVID-19 vaccination during the second and third trimesters, with only a few cases of preterm labour and febrile illness reported. Furthermore, the prevalence of adverse outcomes was low in neonates born to mothers who received COVID-19 vaccination during pregnancy, with only a few cases of stillbirth, neonatal death, and fetal abnormalities reported. Our findings are consistent with previous research indicating that COVID-19 vaccination is safe during pregnancy [9-12 ,13, 14, 15, 16, 17, 18-20] . Symptoms of covid-19 vaccination are typically mild to moderate and appear within three days of vaccination. The majority of cases occur the day after vaccination and resolve within one to two days. The second dose is linked to more frequent and severe side effects. The vaccine side effect profile in pregnancy appears to be similar to that in non- pregnant people, with the most common symptoms being pain at the injection site, fatigue, headache, and myalgia. We discovered no evidence of an increased risk of adverse pregnancy outcomes following vaccination. [9 10 13 15 17] A large prospective cohort study involving 7809 pregnant women discovered

that covid-19 vaccines were well tolerated among pregnant women,lactating or thinking about getting pregnant. Pregnant women had a lower risk of several reactions, including fever after Pfizer dose 2 (odds ratio 0.44, 0.38 to 0.52; P< .001) and fever after Moderna dose 2 (0.48, 0.40 to 0.57; P <0.001) compared with those who were neither pregnant nor lactating.The frequency of complaints following vaccination was comparable to that seen in non pregnant patients, and reports of adverse outcomes were uncommon. Furthermore, a prospective study of 83 vaccinated pregnant women who were age matched with 166 vaccinated female non-pregnant controls discovered that the frequency of complaints following vaccine administration did not differ between pregnant and non-pregnant patients (18.1% v 16.9%; P=0.20). [18] COVID-19 vaccine effectiveness has been shown to be high in pregnant people, similar to the general population.[19 20] Because COVID-19 vaccine–derived maternal antibodies cross the placenta,[21] vaccination during pregnancy could potentially protect newborns in the early months of life, similar to well-established benefits of influenza and pertussis vaccination during pregnancy [22 23 24]

Our findings have important implications for clinical practise and public health policy. Our findings add to the growing body of evidence supporting the safety of COVID-19 vaccination during pregnancy, and emphasize the importance of vaccination for pregnant women in order to protect both themselves and their infants from COVID-19.

Limitations:

Our study has limitations that should be acknowledged. For starters, our study was retrospective in nature and relied on data gathered from medical records, which could be biased or contain incomplete information. Furthermore, our study lacked a control group of pregnant women who did not receive the COVID-19 vaccine, limiting our ability to make direct comparisons between vaccinated and unvaccinated women.Larger prospective studies with a control group, as well as studies examining the long-term safety and efficacy of COVID-19 vaccination during pregnancy, could be future research directions. Overall, our findings shed light on the safety of COVID-19 vaccination during pregnancy, which can help to inform clinical practice and public health policies.

CONCLUSION:

Preliminary findings did not show obvious safety signals among pregnant persons who received Covishield Covid-19 vaccines. However, more longitudinal follow-up, including follow-up of large numbers of women vaccinated earlier in pregnancy, is necessary to inform maternal, pregnancy, and infant outcomes. COVID-19 vaccination during pregnancy can generally be considered safe and does not increase the risk of adverse outcomes in pregnant women or neonates.

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