

Study of the Effect of Covid 19 Vaccination in Antenatal Women on Maternal and Fetal Outcome in Tertiary Care Teaching Hospital in Andhra Pradesh, India

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Abstract

Background: SARS-Cov-2 infection during pregnancy causes adverse effects on the maternal and foetal outcome. In order to minimize the adverse outcomes of COVID-19 infection, Government of India recommends COVID-19 vaccination during antenatal period with Covaxin and Covishield. Despite the recommendation of vaccination by the Government of India, there are few clinical trials and still there exists a gap in the knowledge and awareness of outcome of pregnant women after COVID-19 vaccination during pregnancy.

Materials and Methods: This is a prospective observational study conducted in 50 antenatal women who were already vaccinated at a tertiary care hospital in Southern India from August 2021 to October 2021. All antenatal women who were already vaccinated and attending the OPD were considered for further follow-up.

Results: This study was conducted among 50 antenatal women who received COVID-19 vaccination during pregnancy. Among these antenatal women, 27 (54%) were multigravida, 23(46%) were primigravida, 32(64 %) completed 2 doses of covid vaccination, and 18(36%) took a single dose in antenatal period. Among the vaccinated 27(54%) pregnant women had no symptoms after vaccination. Though 23(46%) women had symptoms after vaccination, symptoms are mild and resolved within 48 hours. All vaccinated antenatal women were observed till delivery, among them 46 (92%) had term deliveries, 4(8%) had preterm deliveries and 8[16%] new-born babies required NICU admission.

Conclusion: COVID-19 vaccination was not associated with adverse immediate pregnancy outcomes or new born complications. Hence COVID-19 vaccination is strongly recommended in antenatal period.

Keywords: SARS CoV-2, pregnancy, immunisation, safety and efficacy, birth outcome.

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Introduction

SARS COV-2 infection was a catastrophic pandemic which caused 3.8 million deaths worldwide [1]. Pregnant women and their babies in under-resourced settings bear the greatest burden of mortality and morbidity related to pregnancy complications, so it is not surprising that this is also true of COVID-19[2]. The COVID-19 pandemic has caused loss of life and poorer health outcomes in pregnancy, despite worldwide aggressive public health measures to control the spread [3]. The COVID-19 pandemic has demonstrated the urgent need to develop vaccine strategies optimised for pregnant women and their newborns. The Royal College of Obstetricians and Gynaecologists strongly recommends COVID-19 vaccination in pregnancy to reduce the rates of admission to the intensive care unit and premature delivery. Although not included in COVID-19 vaccine development trials, pregnant women had access to these vaccines since their initial release in the US and abroad. Antibody titres were higher in COVID-19 vaccinated women compared to actual SARS-COV2 infection [4]. These antibodies were present in umbilical cord blood and breast milk, suggesting that vaccination can confer maternal and perinatal immunity. Pregnant women have been reluctant to receive COVID-19 vaccination.

Studies on vaccination in pregnant women have shown no increased risk of pregnancy complications, and these studies were limited to mRNA vaccines. Vaccines are highly effective at reducing severe COVID-19 infection and death, with the number needed to vaccinate to avoid one maternal death being substantially lower in low-income and middle-income countries (LMICs) than in high-income countries. Hence there is a need for urgent action to ensure equitable access to immunization for pregnant women in LMICs who are particularly willing to be vaccinated, are at an increased risk of death from COVID-

19, where fewer vaccines are needed to save each life compared with high-income countries. The COVID-19 vaccine is a unique opportunity for the global health community to provide healthcare equity. The COVID-19 maternal immunization tracker, a joint initiative by Johns Hopkins University and Berman Institute of Bioethics Centre for Immunization Research, investigated and catalogued policy positions worldwide. As of April 2022, 162 countries recommended or permitted COVID-19 immunization for some, or all pregnant people compared with only 21 countries a year ago.

In India, 2 types of vaccines are available Covisheild and Covaxin. Covisheild is a recombinant replication-deficient chimpanzees adenovirus vector encoding SARS-CoV-2 S-glycoprotein vaccine currently being developed by the Serum Institute of India, Pune based on the Astrazenica-Oxford model [5]. With the collaboration of the Indian Council of Medical Research [Indian Government funded Biomedical Research Agency], Bharath Biotech developed Covaxin, India's first indigenous COVID-19 vaccine. It comprised mostly of an entire inactivated SARS-CoV2 antigen. Phase 1 clinical trials were conducted across 12 institutes in India, including All India Institute of Medical Sciences [AIIMS] in New Delhi, AIIMS in Patna, Post Graduate Institute of Medical Sciences in Rohtak [6]. To date, in India the effectiveness of Covisheild is much higher than Covaxin. The safety of COVID-19 vaccination during pregnancy has not been adequately documented since no clinical trial included pregnant women. However, the benefits of receiving COVID-19 vaccine outweigh any known or potential risks of vaccination during pregnancy. Vaccination lowers the risk of infection and builds antibodies that help to protect the baby [7]. Nearly 4 out of 5 pregnant women in India had COVID-19 vaccine

hesitancy due to lack of awareness and disagreement of vaccine being unsafe during pregnancy. Pregnant women should be informed about the benefits and encouraged to take COVID-19 vaccine. In order to create awareness and prove the safety of vaccination during pregnancy, there emerges the need for further studies in this field.

The aim of this study is to observe the effect of COVID-19 vaccination in the antenatal period on maternal and fetal outcome and add information to the existing knowledge.

Materials and Methods

This is a prospective observational study which was conducted from August 2021 to October 2021 in a tertiary care hospital in Southern India among antenatal women attending outpatient department who were already vaccinated either with Covisheild or Covaxin.

All singleton pregnant women who received vaccination (including single dose, 2 doses) for COVID-19 in any period of gestation with regular follow-up checkups at the Department of Obstetrics and Gynaecology in a tertiary care hospital in Southern India were included in this study.

Women with multiple pregnancy, pregnant women who were already affected by COVID-19 before vaccination, those women who were vaccinated before pregnancy, pregnancies with pre-existing medical disorders like diabetes, hypertension, autoimmune disease and pregnancies with previous obstetric complications like preterm, PPRM, recurrent pregnancy loss were excluded from this study.

All antenatal women who were already vaccinated and attending the OPD were

considered for further follow-up. Only 72 women received vaccination in this period. Among 72 vaccinated antenatal women[ANW], 10 ANW lost follow up, 3 had gestational hypertension, 2 had gestational diabetes, 2 had previous history of preterm delivery, 2 did not give consent for the study, 1 had multiple gestation, 1 had history of recurrent pregnancy loss and 1 had history of preterm premature rupture of membranes. So among 72 ANW, 22 were excluded from this study, 50 ANW who received COVID-19 vaccination and who met the inclusion and exclusion criteria were included in this study.

All 50 ANW were observed till delivery and after delivery mother and baby were observed for a period of one week. The variables that were assessed for maternal outcomes are abortion, development of symptoms suggestive of preeclampsia, thrombosis, thromboembolic complications, development of oligohydramnios and preterm labour. The variables that were assessed in fetal outcome were teratogenic effects, preterm birth, IUGR, IUD or stillbirth, NICU admission and respiratory distress after birth.

After obtaining proper consent the data was collected on prefixed proformas and results were analysed and data was presented in the form of pie charts and bar diagrams

Results

This study was conducted among 50 antenatal women who received covid 19 vaccination during pregnancy. Among these ANW, 3 were less than 20 years age, 28 women fall under the age of 21 to 25 years, 13 women were aged between 26 to 30 years, 5 were aged between 31-35 years and one women was more than 35 years old.

Table 1: Distribution of study in gravida

Variable	Number of patients	Percentages
Multigravida	27	54
Primigravida	23	46

Among these 50 antenatal women 27 (54%) were multigravida, 23 (46%) were primigravida.

Table 2: Vaccination variables in the study

Vaccination	Number of patients	Percentages
Covaxin	6	12
Covishield	44	88
Dosage of vaccination		
Single dose	18	36%
2 doses	32	64
vaccinated in first trimester		
Yes	7	14
No	43	86

Among 50 antenatal women 6 [12%] took Covaxin, 44 (88%) took Covishield vaccination. 32 (64 %) took 2 doses in antenatal period, 18 (36%) took single dose in antenatal period. 7 (14%) women vaccinated in first trimester, 43 (86%) ANW vaccinated after first trimester.

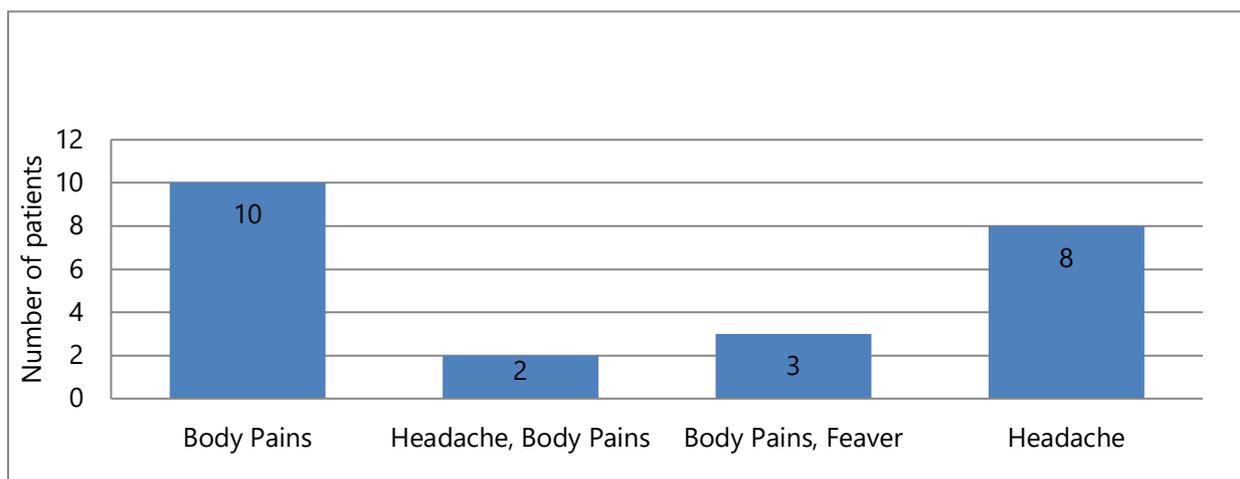


Figure 1: Post vaccination symptoms

27 (54%) had no symptoms post-vaccination, 10 (20%) experienced body pains, 2 (4 %) women experienced headaches and body pains, 3 (6%) women had body pains and fever, and 8 (16%) women experienced headache. Though 23 (46%) members had symptoms after vaccination, symptoms are mild and resolved within 48 hours.

Table 3: Maternal outcome details in study

Term/preterm delivery	Number of patients	Percentages
Term delivery	46	92
Preterm delivery	4	8
Mode of delivery		
Forceps delivery	2	4
caesarean delivery	16	32
vaginal delivery	32	64

46 (92%) enrolled for vaccination underwent term delivery, 4 (8%) underwent preterm delivery. In these 50 deliveries 2 underwent forceps delivery, 16 underwent caesarean delivery, and 32 underwent normal vaginal delivery.

Table 4: Fetal outcome details in study

Fetal outcome	Number of patients	Percentages
Live births	50	100
APGAR score at 5 minutes		
9-10	29	58
8-9	16	32
7-8	5	10
Birth weight		
above 2.5 kg	42	84
between 2-2.5 kgs,	7	14
1.5 to 2 kg	1	2

All the women in study ended their pregnancy by delivering 50 live newborns. All the neonates were assessed based on Appearance, Pulse, Grimace, Activity, Respiration score (APGAR score). 29 (58%) newborns had APGAR score of 9 to 10, 16 (32%) neonates had APGAR score of 8 to 9, 5 (10%) neonates had APGAR score of 7 to 8. Of the 50 newborns, 42 (84%) neonates weighed above 2.5 kg, 7 (14%) weighed between 2-2.5 kgs, 1 (2%) baby weighed between 1.5 to 2 kg. Among the new-borns, 42(84%) were returned to the mother side immediately after delivery and 8(16%) of new-borns were admitted into NICU for mild respiratory distress, preterm, meconium-stained liquor, 7 neonates returned to mother within 48 hours, one baby who was between 1.5-2 kgs was kept in NICU till baby reached adequate weight gain.

Discussion

Pregnancy is a unique immunological state. The maternal immune system faces great challenges. Establishing and maintaining tolerance to the allogenic fetus while preserving the ability for protection against microbial infections is challenging. A successful pregnancy relies on finely tuned immune adaptations both systemically and locally. This study was conducted among 50 antenatal women who received covid vaccination during pregnancy. The present study included the ANW who were vaccinated during all trimesters, whereas a study done by Tamar Wainstock in Israel included the women who were vaccinated in third trimester

only and another study done by Helena Blakeway include ANW who took vaccination after first trimester[7,8].

All antenatal women who had vaccination were followed till delivery, no vaccinated antenatal women in our study have encountered complications like bleeding per vagina, threatened abortion, oligohydramnios, IUGR. There were 4 preterm vaginal deliveries in this study group with an incidence of 8%. other early studies, though estimates vary widely [9-12] The prevalence of preterm deliveries in general population is 7-11% [13]. Hence there was no increase in the preterm vaginal deliveries due to vaccination.

Our findings support recently published research by the CDC which was the first study published on this issue. The CDC study too reported no increased risk for adverse outcomes among vaccinated women similar studies found that unvaccinated pregnant women have more adverse outcome (13). All of the above mentioned studies support COVID-19 vaccination during pregnancy, since not only does it not have a negative impact on perinatal outcomes, but it also may be beneficial and protective for pregnant women. Currently, the Royal College of Obstetricians and Gynaecologists (RCOG) does not specify any stage of gestation at which to avoid COVID-19 vaccination but mentions that pregnant women can choose to delay vaccination until 12 weeks of gestation in low-risk situations: COVID-19 vaccines can be given at any time in pregnancy (14).

Another significant factor that should be considered is the gestational period in which pregnant women should get vaccinated so as to have the greatest protection. Recently, Mithal *et al* found that the antibody transfer ratio seemed to increase with latency from vaccination, suggesting that earlier vaccination may produce greater infant immunity (15). Studies on other vaccinations supported that placental transfer ratios increased when there was a longer time between maternal infection and delivery (16). However, some other studies have found that the Tdap vaccine may be more effective when administered during the second trimester of pregnancy [17].

Providers who care for pregnant women should be familiar with guidelines for medical management of COVID-19, including considerations for management of COVID-19 in pregnancy. As the COVID-19 vaccine is relatively new, advice on vaccination changes very often. When vaccination first started in the United Kingdom, many pregnant women turned to their midwives and obstetricians for advice, but given the lack of clear guidance at that point, it was difficult for healthcare professionals to counsel these women (18).

Conclusion

COVID-19 infection during the antenatal period increases both maternal and fetal morbidity and mortality and also adds to the health expenditure. As it is well known that prevention is better than cure COVID 19 vaccination during the antenatal period either prevents COVID-19 infection or decreases the morbidity. In this observational study, COVID 19 vaccination was not associated with adverse immediate pregnancy outcomes or new born complications. Hence, COVID 19 vaccination can be recommended in the antenatal period to limit the maternal and fetal morbidity.

Limitations

The major limitation of study was small sample size, hence the results cannot be generalised. Future focus should be on larger studies and comparative studies in order to arrive at a conclusion of effect of COVID-19 vaccination on pregnancy and foetal outcome. Long-term effects of COVID-19 vaccination were not studied.

Ethical approval: The study was approved by the Institutional Ethics Committee.

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