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Impact of Antenatal Covid-19 Vaccination on Mother and Foetus-A Prospective Study in Rural Medical College in Himachal Pradesh

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ABSTRACT

Background: Covid -19 pandemic has proved to be great havoc for the people worldwide. The advent of vaccination against Covid -19 has been a ray of hope and the results have been promising in the general population. Pregnant females had not been included in the trial phase initially due to ethical and safety issues. Hence this study was conducted to assess the safety of Covid 19 vaccination in the antenatal period, when its approval was given in pregnant & lactating mothers in India by health authorities.

Methods: Pregnant females were divided into 2 groups for study purpose. First group included 100 expectant mothers who got vaccinated against Covid -19 in the antenatal period and the second group included 100 pregnant females who never got vaccinated in spite of encouragement and motivation for the same. Both the groups were compared and analysed for maternal and perinatal outcome.

Results: In the current study, we found that the antenatal Covid -19 vaccination did not have any adverse effect on the pregnancy course and did not pose any threat to the foetus in utero, rather it reduced the risk of respiratory distress and neonatal intensive care unit (NICU) admissions of the new-born. As seen in our study, total 36% of the neonates requiring NICU admission for respiratory support, were all born to unvaccinated mothers.

Conclusion: Covid 19 vaccination is safe during pregnancy and hence more and more women of reproductive age group should be encouraged for the vaccination.

Keywords: Covid -19, SARS CoV-2, Maternal, NICU, Perinatal, Vaccination.

INTRODUCTION

Severe acute respiratory syndrome corona virus 2 (SARS-CoV-2) is the cause of serious life-threatening disease known as Corona virus disease-2019 (Covid-19) [1]. This pandemic has

put a great burden on the human lives, health care delivery systems and economy of all the countries of the world. Different preventive remedies like wearing masks, covering the mouth & nose, social distancing & personal hygiene had long been the only effective ways to prevent the disease until the advent of various vaccinations to prevent the corona virus [2]. Although there is no proof that the risk to contact Covid-19 infection is enhanced in pregnancy & the current data also suggests the same, but altered immune system of the pregnant females, in an effort to prevent rejection of the fetal allograft, poses an increased risk of infection & its associated severity, at least theoretically. Along with other physiological changes of pregnancy, there is more sensitivity for viral infections in pregnancy [3]. In some cases, the course & severity of SARS-CoV-2 infection is worsened by pregnancy specially in combination with additional risk factors such as advanced maternal age, hyperglycemia of pregnancy, hypertensive disorders of pregnancy, & morbidly excessive weight [4]. Multiple Covid -19 vaccines have been developed & manufactured globally. Different technologies have been used to develop the vaccinations. The vaccine development is based on the concept of antigen introduction into the body & hence generation of immune response [5]. Earlier, pregnant women have long been excluded from the vaccination trial group due to safety issues and liability concerns, both for the mother and fetus [6]. Then guidance issued by CDC and MoHFW India supported the introduction of Covid-19 vaccine to pregnant females [7]. As Covid 19 vaccine has recently been approved for pregnant women by ICMR with effect from 2nd July 2021, so its effects on mother and fetus are not yet documented in India therefore the aim of study to evaluate the effects of antenatal Covid -19 vaccination on pregnant mother, her fetus and newborn.

METHODS

A prospective and single centre study was done in Obstetrics and Gynaecology department at Maharishi Markandeshwar Medical College & Hospital after approval from Institutional Ethical Committee (MMMCH/IEC/22/513) from October 1st 2021 to 30th September 2022 and all subjects provided informed consent. Total of 100 antenatal patients who had been vaccinated with Covishield against Covid-19 (either single dose or both doses) in their antenatal period, were followed until delivery or termination of pregnancy and subsequently both maternal and fetal outcomes were studied and analysed until the discharge from hospital and till 6 weeks postpartum whoever reported to hospital for further follow-up or contacted telephonically if patient was not able to visit hospital due to any unforeseen reason. Following were the inclusion and exclusion criteria followed for both groups:

Inclusion Criteria:

1. All antenatal females of age 18-45 yrs.
2. Antenatal females vaccinated against Covid-19 during pregnancy (either single or both doses).

Exclusion Criteria:

1. Females vaccinated before conception.
2. Females infected with Covid-19 in the past.

Statistical Analysis: Data collected was entered in a Microsoft excel sheet. All categorical and numerical variables were expressed as frequency, percentage, and mean \pm SD (Standard deviation). Standard error of difference (SED) was calculated and observed SED of >1.96 was taken as significant and > 3 as highly significant, while error of <1.96 and in minus was taken as non-significant.

RESULTS

Total deliveries conducted at our institute were 886 from the month of October 2021 to March 2022. Out of these, 100 vaccinated patients were compared with 100 unvaccinated antenatal females matched for similar characteristics delivered during study period. In the present study, maximum people enrolled for the study belonged to age group of 21-35yrs with mean age of 29.89 ± 11.11 yrs. Youngest patient was of 18 yrs of age and eldest was of 44 yrs. Total 84/200 participants were primigravida, while 116 were multigravida. Maximum no (105) of vaccine doses were received in either second or third trimester, only few 27 vaccine doses were given in first trimester. Total no of doses of vaccination received were 132 in current study. Only 35% patients (70 doses) were fully vaccinated during pregnancy. 51 patients received their first dose antenatally and 11 received their second dose in antenatal period. These patients had received their first dose before conception.

Table 1: Socio-Demographic Data

Parameter		Vaccinated	Non-vaccinated
Age in years	<21	3	6
	21-35	84	88
	>35	13	6
	Mean age	29.89 (\pm 11.11)	28 (\pm 10)
Area	Urban	45	44
	Rural	55	56
Parity	Primi Gravida	42	42
	Multi Gravida	58	58
Trimester of Covid vaccination	1 st	27	-
	2 nd	53	-
	3 rd	52	-

28 Patients in vaccinated group had associated obstetric complications such as Gestational Diabetes Mellitus (GDM), Hypertensive disorder of pregnancy, previously scarred uterus, obstetric cholestasis of pregnancy and non vaccinated group (23 patients) too had these complications. Non vaccinated group developed abruption in 3 cases.

Non obstetric complications in vaccinated group were epilepsy in one patient and sub-clinical hypothyroidism in 8 subjects and in non vaccinated group mitral valve replacement in one and sub-clinical hypothyroidism in 9 patients was observed .

136 participants underwent a vaginal delivery, 72 from vaccinated and 64 from unvaccinated group. SED calculated was 4, highly significant. Caesarean delivery rate was almost equal in both the groups –vaccinated (28) & non-vaccinated (36) with non-significant z -score of 0.78. Among those vaccinated 13 patients developed Covid infection positivity, while 10 in non-vaccinated group. There was no postpartum complication that could be linked to vaccination as described in table 2.

Table 2: Maternal Outcome

Parameter		Vaccinated	Not-Vaccinated	Z - Score
Associated Complications in antepartum	Total	28	23	0.82 NS
		Out of 28 patients, 19 had obstetric complications	Out of 23, 13 patients had associated obstetric complications	1.8 NS
Mode of Delivery	Vaginal	72	64	4 S
	LSCS	28	36	-0.78 NS
Maternal Post - Partum Complications	Covid infection	13	10	0.6NS
	Post Partum haemorrhage	1 previous case of LSCS having extensive adhesions	Nil	
	Fits	1 case of epilepsy received labour analgesia	1 case of Postpartum psychosis	
	Wound Sepsis	Nil	1	

NS: Not significant, S: Significant & LSCS: Lower Segment Cesarian Section

Most patients delivered at term i.e., at a gestation of 37-42 weeks, 93 in vaccinated & 90 among non-vaccinated respectively. Only seven out of 100 patients delivered premature at gestational age of < 37 weeks in vaccinated group and 10 patients in non-vaccinated category. Fetal complications including pre-labour rupture of membranes, intrauterine fetal deaths, meconium-stained liquor or fetal distress were analyzed in both the groups and were not significant statistically. Among the vaccinated group, only 7 neonates required NICU admission (3 for phototherapy, 1 for congenital malformation and 3 for only observation in view of transient tachypnoea of newborn) and in non-vaccinated group 18 neonates were admitted in NICU for various complications like 9 for respiratory support ,6 for phototherapy, 2 for congenital malformations & only 1 for observation. None of the neonates born to antenatally vaccinated mothers had low APGAR score while 10 neonates born to non-vaccinated mothers had low APGAR. 7 neonates among vaccinated & 17 among non-vaccinated were having low birth weight of <2.5 kg and none had large birth weight as described in table 3.

Table 3: Fetal Outcome

Parameters	Vaccinated	Not Vaccinated	Z - Score
<37 weeks Gestational age at delivery	7	10	-0.75 NS
37-42 weeks Gestational age at delivery	93	90	0.7 NS
Premature rupture of membranes	11	23	-2.0NS
Intrauterine demise /	2	7	-1.7NS

Abortion			
Meconium-stained liquor	7	10	-0.7 NS
NICU admission	7	18	-2.4 NS
O2/Ventilator support	Nil	9	-3.2 NS
Phototherapy	3	6	
Observation	3	1	
Congenital malformation	1	2	
Low APGAR score	Nil	10	-3 NS
Low birth weight	7	17	-2.2 NS

NS: Not significant, S: Significant & APGAR: appearance, pulse, grimace, activity, and respiration

DISCUSSION

COVID-19 infection during pregnancy may result in rapid deterioration of health of pregnant women and could also affect the fetus. The benefits of vaccination to the pregnant women outweigh its potential risks. We received our index case of Covid-19 positive pregnancy in July 2020, while our fully vaccinated index case in antenatal period delivered a healthy baby in October 2021 without any undue antenatal, intranatal and postnatal complication on mother, fetus and newborn. She conceived accidentally after receiving first dose of vaccination as she got her periods, though scanty after the first dose of vaccination, so she received her second dose as well. Till date the baby is doing well. In our study, mean age of subjects was 29.89 ± 11.11 yrs. There was not much of variation in rural and urban population, which shows that by the time this study was conducted, both the populations were equally aware about the vaccination drive for prevention of Covid. Even after the issuance of the guidelines for vaccination in pregnant and lactating women, we could get controls who have not received any dose of vaccination. We tried to motivate women for vaccination still women were reluctant to get vaccination due to their own myths and fears.

Maximum subjects got vaccinated in either second or third trimester, only few got vaccinated in first trimester. First trimester is considered to be most unsafe, as maximum fetus development takes place in first trimester, all drugs are not considered safe in first trimester and so are the concerns with Covid vaccination. Till date not much of the data is available about Covid vaccination use in pregnancy especially first trimester.

Z-score was not significant concerning presence of antepartum medical, surgical or obstetrical complications in pregnant women that may affect pregnancy outcome independent of vaccination.

As far as mode of delivery is concerned, SED calculated was 4, highly significant. This suggests that vaccinated individuals had a higher chance of vaginal delivery, which could be attributed to lesser obstetrical complications and reduced chances of respiratory compromise in mother due to Covid infection in the vaccinated group as these complications reduce the threshold for trial of labour and indirectly reduces chances of vaginal delivery. Caesarean delivery rate was almost equal in both the groups –vaccinated (25) & non-vaccinated (30) with non-significant z -score of 0.78.

Covid infection positivity was found even in vaccinated pregnant females, but Z-score (0.6) for the same was non-significant. This points towards the fact that the vaccination doesn't guarantee complete protection against Covid infection, but definitely reduces the chances of infection in vaccinated patients. Contrary to current study, Theiler RN *et al.* in the year 2021 said in their study that vaccinated women are less likely to contract Covid after vaccination as compared to their non-vaccinated counterparts [8].

There was no postpartum complication that could be linked to vaccination.

Fetal outcome was also analyzed in both the groups as shown in Table 3. Z-score for premature delivery was -0.75, meaning it was non-significant. This is indicative of the fact that Covid vaccination does not increase chances of preterm labour. Stock *et al.* and Wainstock *et al.* also said the same that vaccination does not pose increased risk for premature labour [9,10].

Fetal complications including pre-labour rupture of membranes, intrauterine fetal deaths, meconium-stained liquor or fetal distress were found to be non-significant statistically. Z-score varied from +- 0.7 to -3.2. This further suggested that vaccination does not have increased risk for fetal morbidity as well as mortality.

Neonatal intensive care unit (NICU) admission data was not statistically significant as z-score was in minus, but it was observed that more neonates of non-vaccinated mothers required respiratory support & hence NICU admissions, thereby suggesting some protective role of vaccination in neonates against respiratory distress among newborn of mothers born to antenatally vaccinated mothers. This protection may be due to placental transfer of antibodies formed in mother after vaccination during pregnancy. Same observation was made by Blakeway *et al.* in 2021 in a study done at England. They concluded that there was no significant increase in NICU admissions among infants born to antenatally vaccinated mothers against Covid-19 [11].

Halasa NB *et al.* in 2022 found that maternal Covid -19 vaccination was effective by 61% to reduce the hospitalization among infants less than 6 months old, further supporting that antibodies to neonates may be transferred passively thro' placenta and breast milk [12].

Low APGAR score was seen in neonates born to non-vaccinated mothers. Though data was not significant statistically (Z-score = -3), but considering the small sample size, there is probability of vaccination being protective to newborn by way of some kind of passive immunity.

With a statistically non-significant Z-score of -2.2, no detrimental effect of vaccination was found on fetal weight. Similarly, Bookstein-Peretz *et al.* (2021) in Israel in their study concluded that antenatal Covid vaccination did not significantly increase the risk for small for gestation babies [13].

A retrospective study conducted at our institute in 2021 on patients admitted in Covid ward/ICU in pre-vaccination era showed a mortality rate of 13.2 %, out of which, maternal mortality was there in 2 patients, however no maternal mortality was observed after the beginning of vaccination drive [14, 15].

Thus, on comparing the maternal and fetal outcomes in terms of antepartum, intrapartum and postpartum outcomes in both the groups, it has been found that vaccination did not has any negative effect on mother & fetus, with a possibility of some protective role against respiratory complications after birth, though a definitive role cannot be proven by our study due to small sample size. Larger studies are needed to validate the results and to form a definitive conclusion for far and against of Covid vaccination.

CONCLUSION

Administration of Covid-19 vaccination during pregnancy does not affect the pregnancy adversely, rather it is advantageous as there are less chances of contracting severe disease to mother as well as fetus after the reception of vaccination during pregnancy. Thus, it can be concluded safely that Covid-19 vaccination is a boon rather than ban in pregnancy and more women in reproductive age group should come forward for the same. Special emphasis should be made in communicating the women regarding safety of vaccine to pregnant women and their fetus in utero as well as their newborn via various means of mass communication like media and personal counselling by obstetricians, paediatricians, and other health care

workers. As still there are lots of myths regarding Covid vaccination even in health care workers in spite of the guidelines issued by Govt and various health care societies.

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