

COVID-19 Vaccine Adverse Effects among Breastfeeding Mothers, Child and Impact on Breastmilk Secretion

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ABSTRACT

Introduction: The WHO declared COVID-19 pandemic on 11 March 2020. In 2020, a huge organizational, scientific, and economic effort has led to vaccine availability directed against Corona Virus. Lactating mothers could also potentially infect the infant postnatally via droplet infection. Despite approval from government there still seems to be bit of suspicion and hesitancy among lactating mothers for vaccination due to lack of clinical trial. Therefore, we are trying to analyse the adverse effects of COVID-19 Vaccination among lactating mothers, their child, and its impact on breastmilk secretion. **Materials and Methods:** A cross-sectional study was conducted from September 2021 to December 31, 2021. Data were collected through questionnaire method. The survey was conducted among Lactating mothers attending Immunisation OP in a Tertiary Care Hospital, Chengalpet. Response to this survey was considered as consent from Participant. The questionnaire analysed Impact of Vaccine on Lactating Mothers and baby, and also the sociodemographic factors, COVID-19 Vaccine adverse effects, and knowledge about it. **Result:** A total of 300 lactating women participated in the survey. Majority of them belong to the age group 18-25 yrs (70%). Among the participants 42.9% are Healthcare Professional, 64.3% of lactating women participated in the survey are from urban community. Majority of them (83.3%) had Covishield vaccine and experienced fever (72.7%) followed by headache (27.3%) after vaccination. 70 % of them showed willingness to take vaccine and recommending to others also. None of them reported adverse effects on baby and milk secretion following vaccination. **Conclusion:** Based on our findings Vaccine did not producing major adverse effects on breastfeeding mother, child, and breastmilk secretion. Therefore, we recommend COVID-19 vaccine to breastfeeding mother without fear of affecting child and breastmilk Secretion. Our findings may help in guiding the clinician and breastfeeding mother about COVID-19 vaccine administration during lactation. **Novelty/Innovation:** None of the clinical trials have involved lactating mothers. Lactating mothers are worried about the safety of COVID-19 vaccination. Hesitancy is prevailing among lactating mother due to lack of clinical trial. We tried to gather information from lactating mothers who had vaccinated about the adverse effects among breastfeeding mother, child, and its impact on breastmilk secretion. Our main aim is to create awareness and promote Covid-19 vaccine among lactating mothers.

KEY WORDS: COVID-19, Vaccine, Breastfeeding, Mother, Child, Breastmilk.

Introduction

The WHO declared COVID-19 a pandemic on March 11, 2020. In response, a massive organizational, scientific, and economic effort has led to the availability of vaccines against the coronavirus. In India, three vaccines- Covishield, Covaxin, and Sputnik V received Emergency Use Authorization from the Drug Controller General of India. However, none of the clinical trials involved pregnant and lactating mothers. Breastfeeding and pregnant women were excluded from recent trials evaluating novel COVID-19 vaccines.^[1] In this current coronavirus disease

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2019 (COVID-19) pandemic, vaccination remains a critical strategy to curbing infections and reducing disease severity.^[2]

During the initial phase of vaccination, priority was given to healthcare workers and older people above 60 years. The vaccines were not recommended for individuals under 18 years, pregnant women, and lactating mothers due to a lack of safety data. However, the WHO and leading doctors recently recommended the use of vaccines in lactating mothers since the vaccines do not contain live replicating viruses and help develop antibodies against the disease, benefiting both the mother and the baby.

The American College of Obstetricians and Gynecologists (ACOG) recommended that the vaccine should be given to pregnant and lactating women based on their benefit and risk. ACOG also stated that mRNA-based vaccines pose a low risk to the fetus, as the mRNA is expected to degrade in circulation.^[3,4] The WHO and the Academy of Breastfeeding Medicine recommended that lactating women could continue to breastfeed even after vaccination, as it is unlikely for mRNA-based vaccines to be transmitted through breast milk.^[5,6] Lactating mothers could potentially infect the infant postnatally via droplet infection.^[7,8]

Despite approval from the government, there still seems to be some suspicion and hesitancy among lactating mothers regarding vaccination due to the lack of clinical trial data. Therefore, we are trying to analyze the willingness of COVID-19 vaccination among lactating mothers and collect details about adverse events that occurred after vaccination in lactating mothers.

Materials and Methods

A cross-sectional study was conducted from September 2021 to December 2021. Data were collected through a questionnaire method. The survey targeted lactating mothers attending the Paediatric Immunisation Outpatient Department (OP) in a Tertiary Care Hospital in Chengalpet, Tamil Nadu.

Eligibility Criteria

Participants were required to meet the following criteria:

1. Currently breastfeeding mothers.
2. Age 18 years and above.

3. Received the COVID-19 vaccine during the lactation period at least one month before the survey.

Consent

Informed and written consent was obtained from the patient explaining that patient details will not be disclosed anywhere in the research.

Questionnaire Content

The questionnaire was designed to gather comprehensive information on several key areas:

1. Adverse Effects: Analysis of any adverse effects experienced by the lactating mothers and their babies, post-vaccination.
2. Impact on Breast Milk Secretion: Assessment of any changes in breast milk production following vaccination.
3. Sociodemographic Factors: Collection of sociodemographic data, including age, education level, occupation, and socioeconomic status.
4. COVID-19 Vaccine History: Information on the type of COVID-19 vaccine received, the number of doses, and the timing of the vaccination.
5. Knowledge and Awareness: Evaluation of the participants' knowledge and awareness regarding COVID-19 vaccines.

All data were collected using the following question template.

1. Name
2. Age
3. Religion
4. Contact details
5. Occupation
 - (a) Professional, healthcare
 - (b) Professional, not healthcare
 - (c) Others
6. Geographic location
 - (a) Rural
 - (b) Urban
7. Previous Breast feeding experience
 - (a) Yes

- (b) No
- 8. Educational status
 - (a) 12th
 - (b) UG
 - (c) PG, Ph.D
- 9. No of children
- 10. Is there any associated risk factor (disease)?
- 11. Duration of Breast Feeding
 - (a) <6 week
 - (b) >6 week - 6 months
 - (c) 6 months - 1year
 - (d) >1 year
- 12. Are u aware about COVID-19 vaccine recommendation in breastfeeding mother?
 - (a) Yes
 - (b) No
- 13. Are u aware of side effects of COVID -19 Vaccine?
 - (a) Yes
 - (b) No
- 14. Are u aware of types of COVID Vaccine available?
 - (a) Yes
 - (b) No
- 15. Information source of COVID - 19 vaccine
 - (a) Social media
 - (b) Newspaper
 - (c) Friends
- 16. Are u willing to take COVID- 19 vaccine?
 - (a) Yes
 - (b) No
- 17. Reason for unwillingness to take vaccine
- 18. Which Vaccine you took?
 - (a) Covishield
 - (b) Covaxin
 - (c) Sputnik
- 19. How many doses you had?
 - (a) 1 dose
 - (b) 2 doses
- 20. What side effects you experienced following vaccination

- (a) Fever
- (b) Myalgia
- (c) Headache
- (d) Pain
- (e) Allergy
- 21. Is there any effect on baby following your vaccination?
 - (a) Yes
 - (b) No
- 22. Is there any effect on milk secretion following vaccination
 - (a) Normal
 - (b) Decreased

Statistical Analysis

Data were analyzed using the Statistical Package for the Social Sciences (SPSS) Version 22.0. Descriptive statistics were used to summarize the data. For inferential statistics, the student t-test was applied where necessary to determine the significance of differences between groups. A p-value of less than 0.05 was considered statistically significant.

Results

Age

A total of 300 lactating women participated in the survey. The age distribution of the participants shows that a significant majority of them fall within the younger age groups. Specifically, 70% (n=210) of the participants belong to the 18-25 years age group, making it the most represented category in the survey (Figure 1). P-value is less than 0.05 which implies younger lactating women are disproportionately participated in this study.

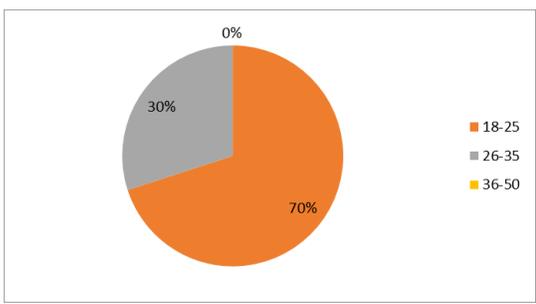


Figure 1: Age Distribution

Occupation

Among the participants 42.9% (n=129) are Healthcare Professional, 28.6% (n=86) are professional, not healthcare, 28.6% (n=86) belongs to other occupation (Figure 2). This distribution indicates that a significant portion of the sample is composed of healthcare professionals, making up nearly half of the participants. P value is (p=0.002) significant which implies that healthcare professionals are actively participated in the survey compared with other occupation.

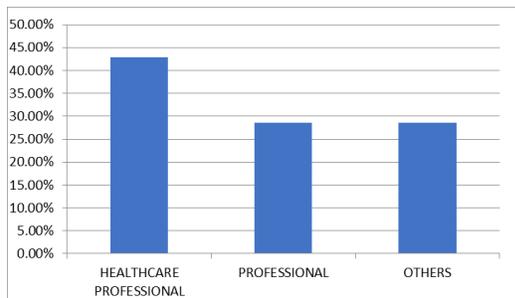


Figure 2: Occupation

Demographics

Among the lactating women who participated in the survey, 64.3% (n=193) were from urban communities, while 35.7% (n=107) were from rural populations (Figure 3). P value (p < 0.0001) which is statistically significant indicating that most of the participants are from urban population.

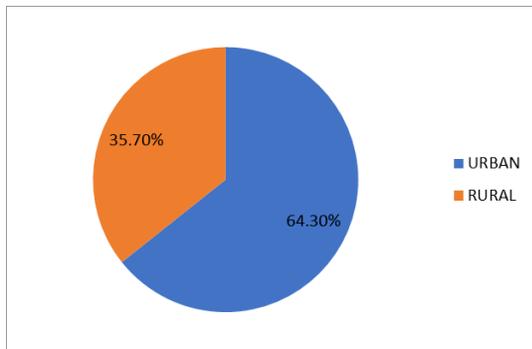


Figure 3: Demographic Data

Adverse effects and Impact of vaccine

Among the participants, 50% (n=150) had previous breastfeeding experience. A significant majority, 92.9% (n=279), reported having no associated risk factors, while only 7.1% (n=21) had risk factors such

as diabetes. In terms of breastfeeding duration, 35.7% (n=107) of the lactating women in this survey had been breastfeeding their children for more than one year, while 64.3% (n=193) had been breastfeeding for less than one year.

Regarding awareness of COVID-19 vaccine side effects, 64.3% (n=193) of participants were knowledgeable. Most participants, 83.3% (n=243) received the Covishield vaccine, and 75% (n=225) had completed the two-dose regimen. None of the participants chose the Sputnik vaccine (Table 1). Additionally, 92.9% (n=279) were aware of the recommendations for COVID-19 vaccination among lactating mothers.

Table 1: Vaccine information

Vaccine	Participants
Covishield	243(83.3%)
Covaxin	57(16.7%)
Sputnik	0(0%)

There was a statistically significant association between the level of education and vaccine acceptance, with a p-value of 0.034. Among the side effects reported, fever was the most common, affecting 72.7% (n=218) of participants, followed by headache at 27.3% (n=82). No adverse effects on the baby or impact on milk secretion were reported following vaccination (Figure 4).

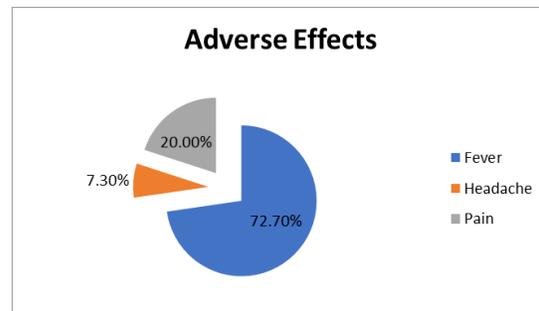


Figure 4: Adverse effects of Vaccine on Mothers

Discussion

In this study we analysed the adverse effects following COVID-19 vaccination among lactating mothers, their babies and its impact on breast milk secretion. Our study includes major lactating women in the age group 18-25 yrs. This indicates a higher

participation rate among younger lactating mothers. Interestingly, there were no participants in the 36-50 years age group. This absence suggests that lactating mothers in this age range were less prevalent in the population attending the Paediatric Immunisation Outpatient Department during the study period. Lactating mothers are more commonly seen in the reproductive age group of 18 -25 years. This age range typically corresponds to the period when women are most fertile and biologically prepared for childbirth and breastfeeding.

Overall, more than 60% of lactating women are willing to take vaccine in our study which is similar to the study done by Michael et al.^[9] However various other studies showed the range (30%-80%).^[10,11] Differences are explained by different timing of study and differences in the incidence rate of COVID-19 cases. Many of them hesitate to take vaccine due to lack of safety data and clinical trials. Some mothers feared the risk of adverse reactions to the baby due to the effect of vaccination.

Based on our findings, educated working women have taken vaccine due the fear of high-risk exposure. Low /uneducated lactating mothers were hesitant to take vaccine due to the fear of side effects which is similar to other studies.^[10-13] According to our data, healthcare professionals make up the majority of those opting for vaccination. As frontline workers, they are at a high risk of COVID-19 transmission, which poses a significant threat to their babies.

Majority of them took Covishield Vaccine. This is explained by easy availability of COVISHIELD Vaccine. Majority of them not opted for COVAXIN and Sputnik due to limited stock during the study period.

Breastfeeding mothers after receiving COVID-19 vaccine experienced similar side effects as normal individuals.^[6,14,15] Most common side effects were pain at Injection site, fever, headache and vomiting which are similar to side effects experienced by other common people.

In our study we did not find any impact on breastfeeding outcome or breast milk secretion. Previous studies reported impact on breast feeding and breast milk secretion.^[1,16] Impact was more among those who reported adverse effects such as pain, fever, headache, fatigue, chills.

Previous literature found that maternal illness and earlier breastfeeding cessation are associated.^[16] This is explained by the fact that metabolic demand and insensible water loss are increased by maternal fever which reduces total body water available for milk production.^[17] Vaccine adverse effects are much less in severity and duration compared to actual COVID-19 infection. COVID-19 infection is more severe and longer in duration which results in hospitalisation and produce negative impact on breastfeeding.^[18-20]

In our study, no adverse effects were noticed in the child after COVID-19 vaccination of mothers. No significant Impact on breastfeeding mother, child and secretion of breastmilk. None of the breastfeeding mother reported negative impact on breastmilk secretion.

Conclusion

Based on our findings in our study vaccine did not produce major adverse effects on breastfeeding mother, child, and breastmilk secretion. Therefore, we recommend COVID-19 vaccine to breastfeeding mother without fear of affecting child and breastmilk Secretion. Our findings may help in guiding the clinician and breastfeeding mother about COVID-19 vaccine administration during lactation.

Limitations

It is a single tertiary centre study with limited sample size and time.

Ethics statement

The study was started only after getting written consent from the patient and approval from the Institute Human Ethical committee no: CARE IHEC-II/0030/21. The patients' details were maintained confidentially and had not been disclosed.

Disclosure Statement

No financial conflicts of interest to disclose.

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