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Original Research Article

The impact of maternal influenza vaccination on reducing morbidity in postpartum mothers and their infants: A prospective cohort study

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Abstract

Background: Influenza during pregnancy poses risks to both mothers and infants, leading to increased morbidity. Maternal vaccination is recommended to reduce these risks, but its impact on postpartum health has not been fully explored. This study evaluates the effect of maternal influenza vaccination on the incidence of influenza-like illnesses in mothers and their infants during the first three months postpartum.
Aim and Objective: To Assess the impact of maternal influenza vaccination in reducing the incidence of influenza-related morbidity among mothers and their infants during initial three months.
Materials and Methods: This prospective cohort study was conducted on postpartum mothers at Yashwantrao Chavan Memorial Hospital in Pimpri, Pune between October 2019 and May 2020. These women, either vaccinated with the seasonal influenza vaccine during pregnancy or not, were observed for three months after birth to assess the occurrence of influenza-like illnesses in both the mothers and their infants collected through during clinic visit or weekly telephonic interview.
Results: Out of 542 women initially participated, 160 vaccinated participants and 172 unvaccinated participants completed three months follow up. No significant differences in the influenza related morbidity observed between the two groups. In infants, after employing Poisson regression models, adjusting for prematurity, birth weight, and maternal ILI, the adjusted incidence rate ratios (IRRs) revealed that maternal influenza vaccination significantly reduced hospitalization incidence (IRR: -3.38, 95% CI: -1.97, p=0.001) and the clinician encounters (IRR: -2.18, 95% CI: -0.92, p=0.03). However, effects on ILI incidence (IRR: -1.48, 95% CI: -0.84 to 0.12) were not statistically significant. Maternal ILI emerged as a crucial predictor for infant ILI incidence (IRR: 4.16, 95% CI: 0.49-1.38, p<0.001), clinician encounters (IRR: 3.44, 95% CI: 0.31 to 1.15, p<0.001), and hospitalization (IRR: 4.22, 95% CI: 0.53-1.45, p<0.001).
Conclusion: Maternal influenza vaccination significantly lowers the risk of hospitalizations and clinician visits due to ILI in infants. Also, maternal ILI noted as a significant predictor of the Infant influenza related morbidity, underscoring the indirect benefits of vaccinating pregnant women beyond the direct protection offered to the infants.

Keywords: Influenza vaccine, Postnatal morbidity, Maternal immunization, Influenza like illness.

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1. Introduction

Influenza, characterized by its highly contagious nature, is a respiratory illness caused by influenza viruses and presents considerable health risks, particularly to vulnerable groups such as pregnant women and infants.[1] Globally, the last few decades have witnessed several severe influenza outbreaks and pandemics, each posing significant challenges to public health and healthcare systems worldwide.[2] Specifically, in

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India, the city of Pune has been a critical focal point for influenza infections. This was particularly evident during the 2009 H1N1 pandemic, where Pune emerged as a major hotspot, highlighting the city's susceptibility to influenza virus outbreaks.[3] Evidence from both seasonal flu epidemics and pandemics shows that pregnant women face a higher risk of experiencing severe complications from influenza, significantly more than the general population.[4] Additionally, newborns are especially vulnerable to severe influenza infections due to their underdeveloped immune systems and the limited number of antibodies they have to fight off the influenza virus.[5] The most effective way to prevent influenza virus infection and its associated health issues is through yearly vaccination.[6] The influenza vaccine is generally recommended for everyone 6 months of age or older. Infants younger than six months are typically not candidates for the influenza vaccine, leaving them at risk for infection. Therefore, immunizing women during their pregnancy is recommended as a prime strategy to protect both the mother and the newborn.[7] However there are varied opinion for the safety of maternal influenza vaccine on birth outcome[8] and little evidence for proving effectiveness of influenza vaccine in mother and newborn during postnatal period in Indian setting. Furthermore, despite recommendations from the WHO and initiatives by the State Health Authorities in Maharashtra for maternal influenza vaccination, the acceptance of the influenza vaccine among pregnant women has been notably low.[9]

Understanding whether the maternal influenza vaccine provides protection against influenza-related morbidity for both infants and mothers in the initial period after birth is of paramount importance, especially considering the heightened vulnerability of this demographic. The evidence gathered from such studies is essential for gaining acceptance of the maternal influenza vaccine among healthcare professionals and pregnant women. This research could play a crucial role in informing healthcare policies and practices, thereby potentially increasing vaccine uptake and enhancing maternal and infant health outcomes.

2. Materials and Methods

Setting: This study was carried out at Yashwantrao Chavan Memorial Hospital (YCMH) in Pune, a tertiary care civic hospital well-equipped to manage high-risk pregnancies, including a neonatal ICU. Pregnant women attending Antenatal Care (ANC) at YCMH were offered Trivalent Inactivated Influenza Vaccine (TIV) at no charge by the government. Most of the women visiting ANC clinics opted to deliver in the same hospital.

2.1. Design

This was a prospective, observational cohort study included the mothers who were admitted in hospital's delivery ward conducted from October 2019 to March 2020.

2.2. Enrolment

After obtaining written informed consent from the mothers, we investigated their medical records and collected information about their social and health status. Consent was also obtained from the participants for 3 months follow up of the mothers and their babies either by catching them at clinic or calling them over telephone. This follow-up lasted from October 2019 to May 2020.

The study received approval from the Institutional Ethics Committee of KEM Hospital Research Centre, Pune, and adhered to the ICMR's Ethical Guidelines for Biomedical and Health Research on Human Participants (2017).[10]

2.3. Data collection

Participation of mother and infants in the study begun after delivery. The case report forms were filled by study-staff at study enrollment to collect information on demographics, and influenza vaccination status of all participants. The mother's medical records were reviewed for the duration from first prenatal care visit to delivery for information on prenatal visits, illnesses, birth information, and the administration and timing of an influenza vaccine.

The follow-up for all medically attended illnesses in enrolled infants was conducted at YCM hospital and nearby private facilities, until the child reached 12 weeks of age. The primary outcome of interest was influenza like illness (ILI) in both mothers and infants. This outcome was defined as a physician/clinic visit with at least 1 of the following signs or symptoms reported: fever of 38.0°C or higher, or respiratory symptoms (including cough, runny nose, nasal congestion or breathing difficulty).

The follow-up for ILI episodes included review of the clinic, emergency department, and inpatient IPD/pediatric neonatal ward documents for 12 weeks after delivery in both mothers and infants if participants were admitted in YCMH. Participants were asked to contact study-staff whenever they or their child had a medical visit for a respiratory, or febrile illness. Medical record reviews were conducted to identify missed episodes. When an ILI was documented in mothers (post-natal period) and/or in infant's chart, information was collected on demographics, clinical symptoms.

2.4. Exposure

In this study, influenza vaccination was defined as receiving the vaccine anytime from the last menstrual period to the end of pregnancy, serving as a crucial exposure for analysis. Participants' vaccination status was verified by the stamp on their Antenatal Care (ANC) card, with the vaccination date and gestational age at the time of administration recorded.

2.5. Outcomes

The study primarily focused on evaluating the incidence of ILI in the participants (mothers and infants). This included

tracking any instances where the mothers and infants experienced symptoms consistent with influenza. The study also monitored the number of clinic visits and hospitalizations that occurred due to ILI. This aspect was crucial in understanding the healthcare burden associated with ILI among the study participants. The study also noted cases where individual participants experienced more than one episode of ILI during the assessment period, providing further insight into the recurring nature of the illness in the postnatal period.

2.6. Covariates

Information regarding socio-demographics, age, education, smoking, medical and obstetric history, complications during pregnancy, and vaccination status for the influenza vaccine was collected using hospital records and through a questionnaire-based interview.

2.7. Statistical methods for analysis

The statistical analyses were conducted using Stata, a statistical data analysis software (version 16.0, StataCorp). The primary models employed for this analysis included logistic regression and Poisson regression, with a focus on calculating the Incidence rate ratio. Poisson regression models were employed to quantify the associations between maternal influenza vaccination and ILI-related outcomes. These models accounted for the potential influences of prematurity, birth weight, and maternal ILI. Incidence Rate Ratios (IRRs) were calculated as effect measures to estimate the relative changes in ILI-related outcomes for the different exposure categories. The baseline characteristics were estimated or described by exposure and outcome using descriptive statistics. Vaccine effectiveness, mentioned in percentage, was calculated using the formula (1–IRR) x100 which estimated the relative difference in influenza risk among vaccinated group as compared to Non-vaccinated group. The maternal characteristics listed in hospital records and participant files, as well as their possible associations with influenza infection and vaccination, were included in the regression models. As well as the trimester of pregnancy in the group that received the vaccination, the trimester of pregnancy in the other group, and the infant age at influenza infection were also included. The age, educational attainment, parity, and household income of the mothers were observed.

3. Results

Study-participants: In the study, 558 participants were initially enrolled to evaluate the effects on birth outcomes. After collecting demographic, social, and birth outcome data, participants were invited to consent to an additional three-month follow-up. Consent was secured from 542 participants out of which 539 were the enrolled eligible participants who agreed for further follow-up, with 260 having received the vaccination and 279 not vaccinated. At the conclusion of the study, a total of 332 participants had completed the entire three-month follow-up period as explained in **Figure 1**.

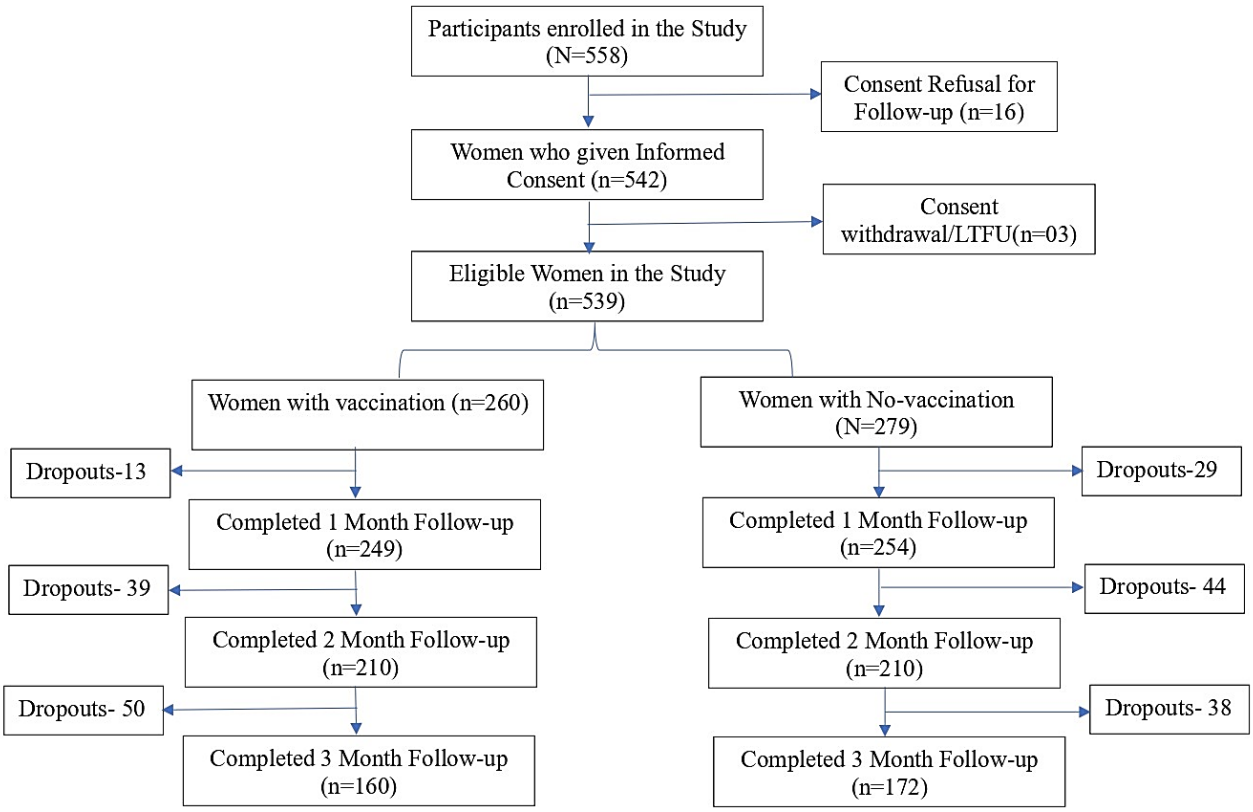

Figure 1: Participant disposition chart (Prospective follow up- effectiveness)

3.1. Maternal characteristics

The analysis of maternal characteristics in our study compares 260 vaccinated participants with 279 unvaccinated ones, revealing maternal age, parity, and education level as notable differentiators. Particularly, maternal education emerged as a significant factor, with illiterate women being less likely to be vaccinated (OR 4.02, $p < 0.0001$), and a higher vaccination rate observed among graduates (66.3%). (**Table 1**)

3.2. Influenza vaccination in pregnancy and effectiveness outcomes for women

This study examined the occurrence of Influenza-like illness (ILI), with related clinic visits and hospitalizations, over a three-month period post-childbirth in mothers. During this timeframe, instances where participants experienced one or more ILI episodes were also recorded. The analysis showed that there were no significant differences in the frequency of ILI episodes, clinic visits, or hospitalizations between the vaccinated and non-vaccinated groups. (**Table 2**)

The incidence of the Influenza-like illness (ILI) in Antenatal care period (ANC), clinician Encounters for ILI in ANC, and hospitalization for ILI in ANC among the vaccinated group was 1.02, 1.02 and 0.34 per 1000 weeks of follow-up. The approximate vaccine effectiveness after maternal influenza vaccination against ILI disease in ANC, clinician visits for ILI in ANC, and ILI-hospitalization in ANC was 43%, 43%, and 29%. (**Table 6**)

3.3. Maternal influenza vaccination and effectiveness outcomes for infant

Table 3 denotes the occurrence of Influenza-like illness (ILI), with related clinic visits and hospitalizations, over a three-month period post-childbirth in infants. During this duration, ILI episodes in infants were recorded. The analysis showed that there were significant differences in the clinic visits, or hospitalizations between the vaccinated and non-vaccinated groups.(**Table 3**)

Table 1: Maternal characteristics of vaccinated and unvaccinated pregnant women who delivered at obstetric hospital in Pune

Parameters	**Vaccinated (n = 260)**	**Unvaccinated (n = 279)**	**Total (n = 539)**	***p*-value**
No. of participants	260 (48.2%)	279 (51.8%)	539	
Maternal Age (years)				
Age (yrs)	24.8 ± 4.5	24.6 ± 4.5	24.8 ± 4.4	
<18	2 (0.8%)	6 (2.9%)	8	p = 0.424
18 to 30	224 (86.1%)	239 (85.7%)	463	
>30	34 (13.1%)	34 (12.2%)	68	
Parity				
Primiparous	130 (50%)	122 (43.7%)	252	p = 0.171
Multiparous	130 (50%)	157 (56.3%)	287	
Maternal Education				
Illiterate	24 (9.2%)	80 (28.7%)	104	**p < 0.001**
Primary	116 (44.6%)	116 (41.6%)	232	
Secondary	68 (26.2%)	55 (19.7%)	123	
Graduation	52 (20%)	27 (9.7%)	79	
Post-graduation	0 (0%)	1 (0.3%)	1	
Gestational maturity				
Extremely pre-term	0	1 (0.4%)	1	**p=0.017**
Very-pre-term	17 (6.6%)	21 (7.5%)	38	
Pre-term/late pre-term	17 (6.6%)	36 (12.9%)	53	
Term/mature	219 (84.2%)	214 (76.7%)	433	
Post-term	7 (2.7%)	7 (2.5%)	14	
Influenza vaccine at	**n (%)**	NA		
1st Trimester	4 (1.5%)			
2nd Trimester	105 (40.4%)			
3rd Trimester	151 (58.1%)			
Mean (SD) gest. week of vaccine administration	26.9 ± 6.9	NA	-	

The overall incidence rate of ILI during the first three months of life, Clinician Encounters for ILI, and Hospitalization for ILI were 13.3, 17.98, and 11.61 per 1000 weeks of follow-up during infancy respectively. The incidence of the same among the vaccinated group was 10.65, 13.69, and 6.08 per 1000 weeks of follow-up respectively. The approximate vaccine effectiveness against ILI disease, clinician visits, and hospitalization was 33%, 38%, and 65% respectively.(**Table 4**)

Employing Poisson regression models, we evaluated how maternal influenza vaccination during pregnancy associates with ILI-related outcomes while adjusting for prematurity, birth weight, and maternal ILI. Adjusted IRRs revealed that maternal influenza vaccination significantly reduced hospitalization incidence (IRR: -3.38, 95% CI: -1.97, p=0.001) and the clinician encounters (IRR: -2.18, 95% CI: -0.92, p=0.03). However, effects on ILI incidence (IRR: -1.48, 95% CI: -0.84 to 0.12) were not statistically significant. Maternal ILI emerged as a crucial predictor for infant ILI incidence (IRR: 4.16, 95% CI: 0.49-1.38, p<0.001), clinician encounters (IRR: 3.44, 95% CI: 0.31 to 1.15, p<0.001), and hospitalization (IRR: 4.22, 95% CI: 0.53-1.45, p<0.001). (**Table 5**)

Table 2: Influenza related morbidity in mothers during post-natal period (3 Months)

S. No.	Parameter	Not Vaccinated (n = 279)	Vaccinated (n = 260)	Total (n = 539)	Crude OR	95% CI	*p*-value	Adjusted OR	95% CI	*p*-value
1	**ILI- First Episode after delivery (post-natal duration till 12 weeks)**	**25**	**18**	**43**	0.76	0.40 to 1.43	0.39	0.72	0.38 to 1.39	0.33
	New Symptom (in first 10 days)	25	18	43	0.75	0.40 to 1.43	0.39	0.72	0.38 to 1.39	0.33
	Cough	35	42	77	1.34	0.83 to 2.18	0.22	1.35	0.82 to 2.22	0.24
	Fever	34	37	71	1.2	0.73 to 1.98	0.47	1.24	0.74 to 2.08	0.41
	Temp>38C	25	19	44	0.8	0.43 to 1.49	0.49	0.78	0.41 to 1.49	0.46
	Hospitalization for ILI	1	1	2	1.07	0.06 to 17.3	0.96	1.21	0.70 to 20.88	0.89
	Clinic Visit for ILI	18	23	41	1.41	0.74 to 2.68	0.29	1.37	0.71 to 2.66	0.35
2	**ILI-Second Episode after delivery (post-natal duration till 12 weeks)**	**2**	**2**	**4**	1.07	0.15 to 7.70	0.94	1.09	0.15 to 7.96	0.93
	New Symptom (in first 10 days)	2	2	4	1.07	0.15 to 7.70	0.94	1.09	0.15 to 7.96	0.93
	Cough	4	2	6	0.53	0.97 to 2.93	0.47	0.51	0.09 to 2.91	0.45
	Fever	3	2	5	0.71	0.12 to 4.30	0.71	0.75	0.12 to 4.61	0.76
	Temp>38C	2	2	4	1.07	0.15 to 7.68	0.94	1.08	0.15 to 7.89	0.93
	Hospitalization for ILI	0	0	0						
	Clinic Visit for ILI	1	2	3	2.16	0.19 to 23.98	0.53	2.51	0.22 to 28.0	0.45

Table 3: Influenza like illness in Infants after birth (till 12 weeks of age)

S. No.	Points	Not Vaccinated (n = 279)	Vaccinated (n = 260)	Total (n = 539)	Crude OR	95% CI	p-value	Adjusted OR	95% CI	*p*-value
1	**ILI-First Episode in Infants**	**34**	**22**	**56**	0.67	0.38 to 1.18	0.16	0.67	0.38 to 1.18	0.16
	New Symptom (in 10 days)	34	24	58	0.73	0.42 to 1.27	0.28	0.71	0.40 to 1.27	0.25
	Cough	35	31	66	0.94	0.56 to 1.58	0.83	0.93	0.54 to 1.59	0.79
	Fever	52	40	92	0.79	0.51 to 1.25	0.32	0.8	0.50 to 1.28	0.35
	Temp>38C	51	29	80	0.56	0.34 to 0.92	**0.02**	0.56	0.34 to 0.93	**0.02**

Table 3 Continued…										
	Hospitalization for ILI	39	12	51	0.3	0.15 to 0.58	**0.0001**	0.33	0.16 to 0.65	**0.001**
	Clinic Visit for ILI	51	31	82	0.61	0.37 to 0.98	**0.04**	0.6	0.36 to 0.99	**0.04**
2	**ILI- Second Episode in Infants**	**9**	**6**	**15**	0.71	0.25 to 2.02	0.52	0.83	0.28 to 2.46	0.74
	New Symptom (in 10 days)	10	6	16	0.64	0.23 to 1.78	0.39	0.75	0.26 to 2.18	0.6
	Cough	12	6	18	0.53	0.19 to 1.42	0.21	0.6	0.21 to 1.68	0.33
	Fever	12	6	18	0.53	0.19 to 1.42	0.21	0.6	0.21 to 1.68	0.33
	Temp>38C	10	6	16	0.64	0.23 to 1.77	0.39	0.75	0.26 to 2.18	0.6
	Hospitalization for ILI	7	4	11	0.61	0.18 to 2.10	0.43	0.67	0.18 to 2.46	0.55
	Clinic Visit for ILI	9	5	14	0.59	0.19 to 1.78	0.35	0.74	0.24 to 2.33	0.61

Table 4: Incidence and crude rate ratios of infant ILI-related outcomes by maternal influenza vaccination status

Parameter	**Follow-up in total No. of weeks**	**ILI**	**Clinician encounters**	**Hospitalization**
Unvaccinated group (n=279) Incidence rate (per 1000 weeks)	2708	43	60	46
Incident Rate (1000 Weeks)		15.88	22.16	16.98
Vaccinated group (n=260) Incidence rate (per 1000 weeks)	2630	28	36	16
Incident Rate (1000 Weeks)		10.65	13.69	6.08
Incidence rate ratio (Unadjusted)		0.67	0.62	0.35
Vaccine effectiveness (1-IRR)		33%	38%	65%

Table 5: Maternal influenza immunization during Pregnancy and ILI related outcomes of infant

Parameter	**Coef.**	**Std. Err.**	**z**	**[95% CI]**	***p*-value**
Infant ILI					
Maternal vaccination	-0.36	0.24	-1.48	-0.84 to 0.12	0.14
Birth weight	0.00	0.00	1.78	-0.00004 to 0.0008	0.08
Prematurity	-0.02	0.22	-0.08	-0.45 to 0.42	0.94
Maternal ILI	0.94	0.23	4.16	0.49 to 1.38	<0.001
Clinician encounters for ILI					
Maternal vaccination	-0.46	0.21	-2.18	-0.92	0.03
Birth weight	0.00	0.00	2.72	0.0001 to 0.0009	0.01
Prematurity	0.15	0.18	0.88	-0.19 to 0.50	0.38
Maternal ILI	0.74	0.21	3.44	0.31 to 1.15	<0.001
Hospitalization for ILI					
Maternal vaccination	-0.98	0.29	-3.38	-1.97	0.001
Birth weight	0.00	0.00	1.65	-0.00007 to 0.0008	0.10
Prematurity	-0.02	0.24	-0.10	-0.49 to 0.44	0.92
Maternal ILI	0.99	0.23	4.22	0.53 to 1.45	<0.001

Table 6: Vaccine effectiveness during pregnancy (Ante-natal Care period)

Points	**Follow-up in total No. of weeks**	**ILI in ANC**	**Clinician encounters for ILI in ANC**	**Hospitalization for ILI in ANC**
Unvaccinated group (n=279) **Incidence rate (per 1000 weeks)**	10496	19	19	5
Vaccinated group (n=260) **[03 cases after vaccination]** **Incidence rate (per 1000 weeks)**	2933*	3	3	1
Incidence rate ratio (IRR) **(Unadjusted)**		0.57	0.57	0.71
Vaccine effectiveness **(1-IRR)*100**		43%	43%	29%
***The person-week in Vaccinated group for ANC is estimated as duration from MI-vaccination week till delivery outcome.				

4. Discussion

Infants younger than one year are highly susceptible to severe influenza and its potentially fatal consequences. Consequently, they cannot receive vaccinations, as their immune systems are not fully developed, underscoring the need for alternative protective measures against infectious diseases during this vulnerable period. Numerous research has shown that infants can receive protection against influenza virus infections through antibodies passed from the mother via the placenta after she has naturally contracted influenza.[11,12] Studies like one conducted by Englund et al. have also proved transfers of vaccine-specific IgG antibody across placenta when the pregnant women were vaccinated with Influenza vaccine.[13] Clinical evidence of infant protection via maternal antibodies is crucial for newborn health strategies. Studies on the impact of maternal influenza vaccinations on infant protection present mixed findings. Black et al.[14] did not observe notable benefits, contrasting with Jarvis et al., who documented the vaccine's efficacy.[15] This study shows contribution of maternal influenza vaccination in reducing the risk of influenza-related illnesses in infants, consistent with findings from studies by Zaman et al.[16] and Binowitz.[17] This study highlights the notable decrease in cases of influenza-like illness (ILI), along with fewer clinic visits and hospital admissions among infants born to vaccinated mothers. These findings highlight the critical role of maternal vaccination in safeguarding infants against serious illnesses,

While it is anticipated that maternal influenza vaccination would protect mothers from influenza-like illness (ILI) during the prenatal period, this study did not show significant differences in reduction in ILI cases, clinic visits, or hospitalizations among vaccinated mothers compared to those who were not vaccinated. There are existing evidences those support the effectiveness of maternal influenza vaccination in lowering the risk of laboratory-confirmed influenza infection in pregnant women.[15,18]

This study identified maternal ILI as a crucial predictor for infant influenza-related morbidity, highlighting the secondary benefits of immunizing pregnant women. This finding suggests that vaccinating expectant mothers not only directly shields infants from influenza but also provides indirect protection by reducing the risk of maternal ILI, thereby lowering the chances of infants developing influenza-related health issues. This underscores the broader protective impact of maternal influenza vaccination.

The hesitation around the maternal influenza vaccine in India stems from insufficient data on its safety and efficacy for Indian populations. This uncertainty impacts vaccination policy and the confidence of healthcare providers, pregnant women, and the community, leading to low vaccine uptake. Such evidence demonstrating the effectiveness of vaccines can significantly enhance the confidence of healthcare professionals and the wider community. This support, grounded in solid research findings, plays a crucial role in increasing vaccine uptake and promoting public health initiatives.

5. Limitations and Future Research

The study faced challenges starting from March 2020 due to the COVID-19 lockdown in India.

The restrictions on movement might have altered participants' behavior to assess healthcare for Severe or non-severe conditions and possibly decreased the number of clinician encounters and hospitalization. Additionally, there was a significant loss of follow-up, as many participants became unreachable during lockdown period as some of the participant migrated to different regions. Most follow-up data were collected via telephone interviews, meaning clinical diagnoses were not made through direct examination but were based on participants' self-reported information. The limited sample size and a brief follow-up period of only for three months might not have captured all pertinent occurrences, possibly influencing the study's conclusions. A future study with a longer follow-up period and more regular

clinic visits to monitor symptoms in both mothers and infants along with laboratory confirmation ILI would be crucial for a more accurate assessment of the maternal influenza vaccine's protective benefits.

6. Conclusion

The study found that maternal influenza vaccination during pregnancy significantly reduced hospitalization and clinician encounters related to influenza-like illness (ILI) in both mothers and infants. While vaccination did not show a statistically significant impact on ILI incidence in mothers, it demonstrated effective protection for infants, with reduced rates of clinic visits and hospitalizations. Maternal education played a crucial role in vaccination rates, highlighting the need for targeted educational efforts to improve vaccination uptake. Overall, the findings support the importance of maternal influenza vaccination in enhancing health outcomes for both mothers and their infants.

7. Source of Funding

The authors received no specific funds for this work.

8. Conflict of Interest

The authors declare that they have no conflict of interest.

9. Ethical Approval

The study received approval from the Institutional Ethics Committee of KEM Hospital Research Centre, Pune, under the reference number KEMHRC/RVM/EC/2383 on March 14, 2019.

10. Patient Consent

All the participants gave consent to participate in the study and follow up for three months.

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