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Research Article

COVID-19 Vaccination Outcomes among Breastfeeding Women and their Children: A Pharmacovigilance Survey Research

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ABSTRACT

Background: The scarcity of data on Covid-19 vaccination among lactating women raises concern about the safety of vaccines in this group of patients. Lactating individuals who decided to get vaccinated participated in our pharmacovigilance survey research. We present a profile of adverse events reported among these women and their children.

Methods: We conducted a cross-sectional survey among breastfeeding women who had received COVID-19 vaccines. Participants were recruited through social media and websites. We examined the frequency of adverse events among breastfeeding women, their children and impact on breastfeeding. Statistical analysis included chi-square tests and logistic regression.

Findings: We included 702 breastfeeding mothers. 486 mothers were vaccinated with Pfizer, 83 with Moderna, 95 with AstraZeneca, and 38 with Johnson and Johnson's Janssen vaccine. 7.1% mothers reported adverse reactions among their children, most of which were mild. 95.9% mothers did not observe any impact on milk supply, 2.4% observed decreased and 1.7% observed increased milk supply. Statistical analysis showed that the occurrence of undesirable symptoms in children had not been related to the number of vaccine doses taken by the mother, the type of vaccine or the age of the child.

Interpretation: Maternal vaccination during lactation might affect some breastfed babies and milk supply in some women, but in most there will be no noticeable effect. These outcomes might not be related to the specific vaccine. Our study supports the statement that the benefits of maternal vaccination during lactation outweigh the risks.

Keywords: COVID-19 vaccine; Breastfeeding; Lactation; Immunization

ABBREVIATIONS

(PEG) Polyethylene Glycol-a polyether compound derived from petroleum, used as an excipient in many pharmaceutical products, a component of Pfizer COVID-19 vaccine; (EMA) European Medicine Agency an agency of the European Union in charge of the evaluation and supervision of medicinal products; (CIOMS) Council for International Organizations of Medical Sciences, organization that created guidelines and forms for reporting adverse events; (AEFIs) Adverse Events Following Immunization any untoward medical event that follows immunization and that does not necessarily have a causal relationship with the usage of the vaccine.

INTRODUCTION

The benefits of breastfeeding are well known. Mothers' milk not only provides an optimal source of nutrition to the newborn, but also impacts the immune system by transferring IgG and secretory IgA antibodies to the infant. Encouraging mothers to breastfeed could help to protect children from Sars-COV-2 infection. Some issues appear when it comes to the terms of COVID-19 vaccination.

Current recommendations developed by professional healthcare organizations and government health authorities state that breastfeeding mothers should be offered COVID-19 vaccines as expected benefits of the vaccination outweigh potential risks for the mother and the baby [1-5].

However, there is still concern about the safety due to limited data. Patients feel insecure and need to know how safe it is to get vaccinated while breastfeeding, in what ways it can affect milk supply, and which vaccine carries the lowest risk for their children.

Since no mRNA has been detected in the breast milk after maternal vaccination with Pfizer or Moderna vaccine, the transfer of vectors to maternal bloodstream and breast milk from AstraZeneca or Johnson and Johnson's Janssen Covid vaccines seems unlikely

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[6,7]; PEG (Polyethylene glycol, a component of Pfizer vaccine) is not absorbed orally and used in a minute amount (the same for polysorbate 80 used in the Johnson and Johnson's Janssen vaccine); no adjuvants or preservatives are added to any of those preparations - the available Covid-19 vaccines are considered low risk during the lactation period [8-12].

Building on previous research, scientists investigated the presence of specific antibodies in breast milk following maternal Covid-19 vaccination. Several antibodies have been found: anti-spike IgA, IgG and IgM, binding and neutralizing antibodies. Research suggests that breast milk of vaccinated mothers could have a protective potential for their children, supporting the recommendation to offer vaccines to lactating individuals [13-19].

So far there have been only few studies on the outcomes in breastfed children following maternal vaccination. Despite that no components of the vaccines have been detected in breast milk, some adverse reactions among children were reported [20-23].

Our primary goal was to learn about any effects that followed maternal vaccination among mothers and their children. Secondary goal was to define what kind of reactions were observed and tertiary goal was to assess whether vaccination affected milk supply.

METHODS

Based on standard pharmacovigilance application forms: CIOMS and AEFI, a cross sectional web survey that consisted of 28 branched questions was created [24,25]. It included breastfeeding outcomes, infant outcomes and the severity of those outcomes after maternal vaccination. The survey was distributed online through Laktaceuta.pl website and shared by breastfeeding mothers, breastfeeding support organizations, medical specialists on Social Media (Facebook, Instagram).

The surveys were collected between December 2020 and July 2021. The participants were Polish breastfeeding mothers at various stages of lactation.

Study size was determined on the basis of eligibility and exclusion criteria from the total number of completed questionnaires. Eligibility criteria were: mother currently breastfeeding or lactating, having received a COVID-19 vaccine. Exclusion criteria were: the lack of the serial number of the vaccine/expiration date and a lack of consent to use the data from the survey in this paper. The Bioethics Commission of the Medical University of Poznan determined that the study was exempt from the review.

The adverse event of vaccination among mothers was defined as an appreciably harmful or unpleasant reaction resulting from an intervention related to the use of the product that occurred shortly after administration of the vaccine [26].

The outcome of maternal vaccination among breastfed babies was defined as any appreciably harmful or unpleasant reaction (including noticeable change in behaviour) that occurred shortly after maternal vaccination [27].

Maternal vaccination outcomes in breastfed children were ascertained by asking mothers whether they noticed any alarming or different than usual behaviour in their babies after getting vaccinated and what kind of event occurred. The observed events were then assigned to one of 11 categories, meeting our secondary goal. We collected information about the type of vaccine administered to the mother, the time of the onset of the event, the severity of the symptom and following intervention, we asked after which dose it occurred and did the mother think the effect was vaccine related. We also asked if there were adverse events among mothers. The tertiary outcome data was ascertained by asking mothers if they observed any changes in milk production. The questions were formulated in a descriptive way in an attempt to eliminate potential bias.

The data was analysed using SPSS 26.0 software. Frequency analysis, chi-square tests and logistic regression analysis were performed to investigate if and what variables affected the outcomes among children. The level of significance was α=0.05.

RESULTS

The total number of 879 questionnaires has been filled. 138 questionnaires have been excluded due to lack of serial number/expiry date, and 12 due to lack of consent for using data in this paper. 702 surveys were enrolled.

All mothers except one were vaccinated in Poland, one was vaccinated in Ireland.

486 mothers were vaccinated with the Pfizer vaccine (69.2%), 83 got the Moderna vaccine (11.8%), 95 had taken the AstraZeneca vaccine (13.5%) and 38 were given the Johnson and Johnson's Janssen one dose preparation (5.4%) (Table 1).

Table 1: General information about mothers, their children and vaccination.

Type of vaccine	**N**	%
Pfizer	486	69.2
Moderna	83	11.8
AstraZeneca	95	13.5
Johnson & Johnson's Janssen	38	5.4
Total	702	100
Number of doses taken by the mother	**N**	%
1	279	39.7
2	423	60.3
Total	702	100
Child age	**N**	%
<6 months	191	27.2
6-12 months	232	33.0
>12 months	279	39.7
Total	702	100
Adverse events among children	**N**	%
No	652	92.9
Yes	50	7.1
Total	702	100

The average age of children was 12.5 months (SD=9.66, min=0.3 months, max=84 months) (Table 1). 424 women (60.4%) reported having side effects after vaccination (Table 2).

Table 2: Adverse events reported among mothers by specific vaccine.

Did the adverse event occur?								
-	Pfizer		Moderna		AstraZeneca		Johnson & Johnson's Janssen	
	N	%	N	%	N	%	N	%
Yes	262	53.9	69	83.1	73	76.8	26	68.4
No	224	46.1	14	16.9	22	23.4	12	31.6
Total	486	100	83	100	95	100	38	100

50 (7.1%) out of 702 mothers noticed a change in behaviour, harmful or unpleasant reaction among their babies post vaccination. It was a subjective observation, accessed by the mother only.

37 (6.5%) out of 569 women who were vaccinated with mRNA vaccines (Pfizer or Moderna) reported adverse events in their children.

13 (10.8%) out of 133 mothers vaccinated with vector vaccines (AstraZeneca or Johnson and Johnson's Janssen) reported adverse effects in their children.

Reported symptoms were assigned to one of 11 categories (Table 3).

A change in behaviour with or without additional symptoms was the most common adverse event noticed. Mothers reported fussiness, crying, sleep pattern changes, difficulties to settle down, less or more frequent feedings (N=26, 52%). The other predominant symptom was fever (either low grade or higher) with or without additional symptoms (N=20, 40%).

Table 3: Adverse events following maternal immunization among breastfed children by categories and frequency of occurrence.

-	Age (months, N)			Total	
	0-6	06-12	>12		
	N	N	N	N	%
Change in behavior	9	6	3	18	36.0
Gastrointestinal problems	3	3	2	8	16.0
Fever	1	1	4	6	12.0
Fever and change in behavior	1	2	1	4	8.0
Skin rash	-	-	3	3	6.0
Low-grade fever and a change in behavior	-	2	1	3	6.0
Fever and gastrointestinal problems	-	-	2	2	4.0
Fever and coughing or sneezing	-	1	1	2	4.0
Low grade fever	-	-	2	2	4.0
Skin rash and gastrointestinal problems	1	-	-	1	2.0
Fever and changes in behavior and coughing and sneezing	-	1	-	1	2.0
Total	15	16	19	50	100

Note: To "Change in behavior" category we classified: fussiness, crying, sleep pattern changes, difficulties to settle down, less or more frequent feedings; to "Gastrointestinal problems" - loose stools, diarrhea, constipation, flatulence, stomach pain, "Low grade fever" means elevated body temperature up to 38.5 degrees Celsius; "Fever" means body temperature higher than 38.6 degrees Celsius.

The need for medication was reported in 17 children (34% of all those with adverse reactions), and 8 cases (16%) required doctor's visit. One child (8%) was hospitalized. Most adverse events were noticed 0-1 days post vaccination (Table 4).

Table 4: Adverse events among breastfed children following maternal vaccination.

-	Pfizer		Moderna		AstraZeneca		Johnson & Johnson's Janssen	
	N	%	N	%	N	%	N	%
Did any adverse event occur in the child?								
No	457	94.0	75	90.4	86	90.5	34	89.5
Yes	29	6.0	8	9.6	9	9.5	4	10.5
Total	486	100	83	100	95	100	38	100
When did the event occur?								
0-1 day after vaccination	20	69.0	2	25.0	6	66.7	4	100
2-4 days after vaccination	6	20.7	4	50.0	3	33.3	-	-
5-7 days after vaccination	3	10.3	1	12.5	-	-	-	-
no data	-	-	1	12.5	-	-	-	-

Total	29	100	8	100	9	100	4	100
After which maternal dose did the reported event occur?								
after first	20	69.0	3	37.5	9	100	-	-
after second	4	13.8	4	50.0	-	-	-	-
after both	5	17.2	1	12.5	-	-	-	-
after the dose of one-dose vaccine	-	-	-	-	-	-	4	100
no data	-	-	-	-	-	-	-	-
Total	29	100	8	100	9	100	4	100
Did the event require medication?								
No	20	69.0	5	62.5	7	77.8	1	25.0
Yes	9	31.0	3	37.5	2	22.2	3	75.0
Total	29	100	8	100	9	100	4	100
Did the event require a doctor's visit?								
No	24	82.8	7	87.5	8	88.9	3	75.0
Yes	5	17.2	1	12.5	1	11.1	1	25.0
Total	29	100	8	100	9	100	4	100
Did the event require hospitalization?								
No	28	96.6	8	100	9	100	4	100
Yes	1	3.4	-	-	-	-	-	-
Total	29	100	8	100	9	100	4	100
What type of adverse event was observed?								
change in behavior	12	41.4	4	50.0	1	11.1	1	25.0
gastrointestinal problems	5	17.2	-	-	3	33.3	-	-
fever	3	10.5	-	-	3	33.3	-	-
fever and change in behavior	1	3.4	2	25.0	-	-	1	25.0
skin rash	2	6.9	1	12.5	-	-	-	-
low-grade fever and a change in behavior	2	6.9	-	-	-	-	1	25.0
fever and gastrointestinal problems	-	-	1	12.5	-	-	1	25.0
fever and coughing or sneezing	2	6.9	-	-	-	-	-	-
low grade fever	1	3.4	-	-	1	11.1	-	-
rash and gastrointestinal problems	-	-	-	-	1	11.1	-	-
fever and change in behavior and coughing and sneezing	1	3.4	-	-	-	-	-	-
Total	29	100	8	100	9	100	4	100

24 mothers (48% of the total who had reported adverse events among children) stated that the observed symptoms were probably not related to the vaccination.

The logistic regression model predicting the chances of adverse events in children based on the number of doses of the vaccine received by the mothers, the type of vaccine received and the child's age did not fit the data well: $\chi 2$ (6=6.06; p=0.416; R2 Nagelkerke=0.021).

Chi-square tests showed no relationship between the occurrence of symptoms in children and: the number of doses taken by the mother ($\chi 2$ (1)=3.34, p=0.066), the age of the child ($\chi 2$ (2)=0.21, p=0.899) and the type of vaccine taken by the mother ($\chi 2$ (3)=3.23, p=0.357). The number of vaccine doses taken by the mother also did not affect the type of adverse events that occurred in children chi-square tests were not statistically significant for each type of symptom (the level of significance was α=0.05).

Effect on milk production

29 out of 702 (4.1%) mothers observed changes in lactation (Table 5).

Table 5: Changes in lactation observed among mothers by the type of vaccine.

	Pfizer		Moderna		AstraZeneca		Johnson & Johnson's Janssen	
	N	%	N	%	N	%	N	%
Changes in lactation								
None	466	959	79	95.2	92	96.8	36	94.7

Decreased production	13	2.7	1	1.2	3	3.2	-	-
Increased production	7	1.4	3	3.6	-	-	2	5.3
Total	486	100	83	100	95	100	38	100

12 mothers (1.7%) reported increased milk supply, decreased milk supply was reported by 17 mothers (2.4%).

DISCUSSION

Outcomes among breastfed children following maternal COVID-19 vaccination

Our research confirms that the adverse events among breastfed children after maternal Covid-19 vaccination are infrequent and mild. We had one report of a 24 months old child who needed hospitalization due to relapsing fever 3 days after maternal vaccination. We did not get clear feedback on the cause of the symptom but the mother suggested it had probably not been related to the vaccination.

The frequency of reported adverse reactions is the same as in a cross sectional survey study by McLaurin-Jiang and colleagues. In their research among 4455 nursing mothers who received the Covid-19 vaccine (Either Pfizer or Moderna) 7.1% reported adverse reactions in their breastfed infants [20]. Comparing occurrence of adverse events among children of mothers vaccinated with only mRNA vaccines we observed fewer adverse events (6.5%). We had more reports on adverse reactions in children after maternal vaccination with vector vaccines (10.8%), though there was no correlation between the type of vaccine taken by the mother and occurrence of adverse events in children.

Unlike our research, McLaurin-Jiang and colleagues reported that adverse events among children were more common after the second doses whereas we observed more frequent occurrences after the first dose of maternal vaccination for most preparations, only after Moderna vaccination there have been more reports after the second dose. However the difference was not statistically significant in either.

Defining and categorizing adverse events among breastfed children after maternal Covid-19 vaccination

McLaurin-Jiang and colleagues described that the most common adverse reactions among children were: sleep less than usual, sleep more than usual, fed more than usual, fed less than usual, fussier than usual, less fussy than usual [20]. Such symptoms we have put in one category: “change in behaviour”. In the cited study fever was observed only in 1.7% of children whereas participants of our research reported that fever (with or without other symptoms) was almost equally frequent as changes in behaviour. Bertrand and colleagues reported irritability as the most common adverse event following the second dose of maternal vaccination with Pfizer (10.4%) or Modena (10.3%) vaccine in 21 of 180 breastfeeding women, poor sleep was reported in 7.8% for Pfizer and 8.3% for Moderna cases and 6.5% mothers reported drowsiness (only after Moderna) [21]. Kelly and colleagues reported 4 cases of fever among breastfed infants following maternal vaccination with Pfizer vaccine in a study of 84 breastfeeding medical health workers but all of them had upper respiratory tract infections [22]. In a study by Baird and colleagues among 18 breastfed infants no adverse event was reported after maternal vaccination with Pfizer vaccine [23].

In summary, there were some adverse reactions reported among children following maternal Covid-19 vaccination in our and other studies, the frequencies are similar.

The frequency of adverse events among children seems to be lower after Covid-19 maternal vaccination compared to flu vaccination. Brady and colleagues have noted adverse events (fussiness) in 45% of babies after maternal inactivated flu vaccine and 60% (also fussiness) after maternal live strain vaccine [28].

The type of maternal vaccine, number of doses and child age did not impact the occurrence and type of side effects among breastfed babies in our study.

Perhaps the reason for those adverse effects among children is not the preparation, but the maternal post vaccination reaction, as proposed by McLaurin-Jiang and colleagues [20]. Breastfeeding is a dyadic behaviour and it seems plausible that when mother experiences fatigue, headache, fever, chills and other effects it might change breastfeeding patterns, daily activities and other factors that influence the baby's mood or behaviour.

Effect on milk supply

McLaurin-Jiang and colleagues reported that after receiving mRNA vaccine decreased milk supply occurred in 6% and increased milk supply in 3.9% of participants [20]. Bertrand and colleagues observed higher frequency: 9.9% cases of decreased supply and 3.11% cases of increased supply [21]. We have observed a lower incidence of both (2.4% mothers reported a decrease in milk production and 1.7% increased production). These discrepancies may arise from individual maternal post vaccination reactions, such as fatigue and flu like symptoms, which are proven to impact milk supply, when mother suffers from illness [29,30]. Though post vaccination symptoms are much less severe than during illness, McLaurin-Jiang and colleagues also think that might be the reason for changes in milk supply [20].

Strengths and limitations

A large number of survey respondents who received one of four COVID-19 vaccines, both mRNA and vector, are strength of this study. Diversity of respondents is another - participants of this study were from different regions in Poland, and the survey was conducted at the time when there were no restrictions in vaccine availability.

Small population of mothers vaccinated with vector vaccines is a limitation in our study. Effects on breastfed children were assessed by the mothers; it was a subjective observation and might have not been unbiased.

CONCLUSION

Maternal vaccination during lactation might affect some breastfed babies and milk supply in some women, but in most there will be no noticeable effect. These outcomes are probably unrelated to the specific vaccine, number of doses and child age and mostly occur within the first day after maternal vaccination. The correlation of maternal post vaccination reaction and side effects among children

needs to be investigated further. Our study supports the statement that the benefits of maternal Covid-19 vaccination during lactation outweigh the potential risks.

CONTRIBUTORS

K.M. devised the study concept, wrote the initial analysis plan, created the survey, wrote the first draft of the manuscript, analysed the data, and prepared text for the final editing and typesetting. A.K verified and analysed the data. All authors contributed to editing and commenting on the final version. S.U.P, A.K, A.A. provided feedback and critically reviewed the manuscript.

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DECLARATION OF INTERESTS

All of the authors have nothing to declare.

DATA SHARING

The data that support the findings of this study are available from the corresponding author, K.M., upon request.

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