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Maternal and Child Outcomes Reported by Breastfeeding Women Following Messenger RNA COVID-19 Vaccination

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Abstract

Background: In December 2020, two novel messenger RNA (mRNA) vaccines for severe acute respiratory syndrome coronavirus-2 received emergency use authorization from the U.S. Food and Drug Administration; however, the early trials excluded lactating women.
Methods: Breastfeeding women residing in the United States who received either of the two mRNA vaccines were enrolled into the Mommy's Milk Human Milk Research Biorepository at the University of California, San Diego. From December 14, 2020 to February 1, 2021, 180 women who received two doses of either mRNA vaccine were recruited into the study.
Results: Similar proportions of women reported any one or more symptoms following vaccination with either mRNA vaccine. In addition, the frequency by specific type of symptom did not differ by brand. However, following the second dose of vaccine, women who received the Moderna brand were significantly more likely to report symptoms. A small proportion of women following the first dose of either vaccine brand reported a reduction in milk supply, and significantly, more women reported a reduction in milk supply following the second dose of Moderna. Few infant events were reported for either vaccine brand following either dose, and no serious adverse events were reported.
Conclusions: These data are reassuring regarding the safety of vaccination in breastfeeding women and their breastfed children with either of the mRNA COVID-19 vaccines.

Keywords: human milk, lactation, breastfeeding, COVID-19, mRNA vaccine, vaccination, SARS-CoV-2

Introduction

Clinical trials for both the Pfizer-BioNTech BNT162b2 and Moderna messenger RNA (mRNA)-1273 COVID-19 vaccines demonstrated ability to prevent infection and severe disease, leading to emergency use authorization by the U.S. Food and Drug Administration in December 2020.[1,2]

The American College of Obstetrics and Gynecology and The Society for Maternal Fetal Medicine have recommended that these mRNA vaccines be made available for lactating women. However, initial trials excluded breastfeeding women, leading to questions about their safety in this special population.[3] One small study of 31 breastfeeding women who received an mRNA vaccine found that >60% reported vaccine-related side effects.[4] However, no data were provided on infant outcomes or milk supply. In addition, another small study of 84 breastfeeding women from Israel reported similar frequencies of vaccine-related symptoms following their first and second doses of the Pfizer-BioNTech vaccine (55% and 61%, respectively).[5] This study did not report any serious adverse events in the infants, but they did report that four infants had fevers and symptoms of upper respiratory infections during the study period following vaccination.[5]

We sought to evaluate a larger sample of vaccinated breastfeeding women for vaccine-related symptoms and their breastfed children for any nonserious and serious adverse events.

Materials and Methods

Breastfeeding women residing anywhere in the United States who received both doses of an mRNA vaccine were selected from those enrolled into the established Mommy's Milk Human Milk Research Biorepository (HMB) at the University of California, San Diego. The structure and design of the HMB have been described elsewhere.[6] Women who only received one dose of the vaccine were excluded from this analysis. Women who volunteered for the study were recruited

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into HMB through a variety of sources, including self-referral, through their health care providers, direct to consumer ads, and social media. Demographics, health history, vaccine brand, and maternal symptoms and child events were collected by maternal interview and questionnaire for 7 days following each dose of the vaccine. The study was approved by the UC San Diego Institutional Review Board; written consent was obtained from participants.

Maternal and child characteristics and outcomes were compared by brand for each dose using Student's *t* test for continuous and Fisher's exact test for categorical variables. Missing values were excluded. R version 25 4.0.3 was used for analyses.

Results

Between December 14, 2020 and February 1, 2021, 180 women who received both doses of either mRNA vaccine were

Table 1. Characteristics of Breastfeeding Women Who Received Either Messenger RNA COVID-19 Vaccine and Their Breastfed Children, *N* = 180

	Pfizer/BioNTech (n = *128*)	*Moderna* (n = *52*)	*All* (N = *180*)
Maternal age (years)	34.92 (3.67)	34.50 (3.24)	34.80 (3.54)
Race			
White	119 (93.7)	39 (75.0)	159 (88.3)**
Black	0 (0.0)	1 (1.9)	1 (0.6)
Asian	7 (5.5)	12 (23.1)	19 (10.6)
Native American/Alaska Native	1 (0.8)	0 (0.0)	1 (0.6)
Ethnicity			
Non-Hispanic	123 (96.9)	51 (98.1)	174 (96.7)
Hispanic	4 (3.1)	1 (1.9)	6 (3.3)
Education			
Some college	1 (0.8)	0 (0.0)	1 (0.6)
College graduate	33 (26.2)	12 (23.5)	45 (25.3)
Post-graduate	92 (73.0)	39 (76.5)	132 (74.2)
Income per year			
$10,001–$49,999	0 (0.0)	1 (2.0)	1 (0.6)
$50,000–$59,999	0 (0.0)	0 (0.0)	0 (0.0)
>$60,000	127 (100.0)	50 (98.0)	178 (99.4)
Full time employment	89 (71.8)	34 (66.7)	124 (70.5)
Maternal comorbidities			
BMI >30	16 (12.6)	4 (7.8)	20 (11.2)
Hypertension	2 (1.6)	0 (0.0)	2 (1.1)
Diabetes	0 (0.0)	0 (0.0)	0 (0.0)
Asthma	20 (15.7)	6 (11.5)	26 (14.4)
Prior COVID-19 infection	4 (3.1)	4 (7.7)	8 (4.4)
Child age in months at enrollment in months (SD, range)	7.60 (5.54, 0.39–27.45)	7.16 (5.26, 0.10–23.45)	7.47 (5.44, 0.09–27.45)
Child age in months at dose 1 of vaccine (SD, range)	7.57 (6.05, 0.35–47.97)	7.37 (5.27, 0.06–30.74)	7.50 (5.77, 0.06–47.97)
Child age in months at dose 2 of vaccine (SD, range)	8.23 (6.05, 0.21–48.68)	8.21 (5.11, 0.97–31.67)	8.22 (5.72, 0.21–48.68)
Child sex			
Female	75 (59.5)	25 (49.0)	100 (56.7)
Male	51 (40.5)	26 (51.0)	77 (43.3)
Preterm delivery	5 (3.9)	4 (7.7)	9 (5.0)
Infant feeding status			
Exclusive breastfeeding[a]	56 (25.7)	34 (28.1)	90 (26.5)
Breast milk only with complementary solids[b]	125 (57.3)	71 (58.7)	196 (57.8)
Frequency of breast milk consumption			
1–2 feeds per day	14 (6.6)	4 (3.4)	18 (5.5)
3–5 feeds per day	40 (18.9)	29 (24.6)	69 (20.9)
6–7 feeds per day	62 (29.2)	29 (24.6)	91 (27.6)
≥8 feeds per day	96 (45.3)	56 (47.5)	152 (46.1)

Continuous variables were summarized by mean (SD), and group comparisons were made using a *t* test. Categorical variables were summarized by count (%), and group comparisons were made using Fisher's Exact test.

[a]Exclusive breastfeeding is defined as consumption of breast milk only.

[b]Breast milk only with complementary solids is defined as consumption of breast milk only, never any formula, and complementary solid foods.

**$p < 0.005$.

BMI, body mass index; SD, standard deviation.

enrolled. As shown in Table 1, 128 women (71.1%) received both doses of the Pfizer vaccine and 52 (28.9%) received both doses of the Moderna brand. Child age at enrollment averaged 7.47 months (standard deviation 5.44, range 0.09–27.45 months). More than one quarter of children (26.5%) were exclusively breastfed (defined as consumption of breast milk only—no formula or solid foods), almost half (45.9%) of children were breastfed eight or more times per day, and all women continued to breastfeed during the follow-up period.

Following dose 1, similar proportions of women reported any vaccine symptom by brand (89.4% Pfizer; 98.1% Moderna); frequency by specific symptom did not differ by brand. However, following dose 2, women who received the Moderna brand were significantly more likely to report systemic side effects, including chills, muscle/body aches, fever, and vomiting. They were also more likely to report localized symptoms, including pain, redness, swelling, or itching, at the injection site than women following dose 2 of the Pfizer brand (all p's < 0.05). A small proportion of women following dose 1 of either vaccine reported a reduction in milk supply. There was a significant difference in reduction of milk supply following dose 2 by brand (8.0% versus 23.4% for Pfizer and

Table 2. Symptoms Reported by Breastfeeding Women Who Received Either Messenger RNA COVID-19 Vaccine and Events in Their Breastfed Children

	Within 7 days of dose 1				*Within 7 days of dose 2*			
	Pfizer-BioNTech		*Moderna*		*Pfizer-BioNTech*		*Moderna*	
Symptom	*Women (n = 126)*	*Children (n = 129)*	*Women (n = 52)*	*Children (n = 53)*	*Women (n = 123)*	*Children (n = 126)*	*Women (n = 52)*	*Children (n = 53)*
Any maternal symptoms	110 (89.4)		51 (98.1)		114 (98.3)		50 (100.0)	
Any local symptoms	105 (86.8)		50 (96.2)		102 (87.9)		48 (98.0)*	
Pain at injection site	105 (86.8)		50 (96.2)		102 (87.9)		48 (98.0)	
Redness at injection site	7 (5.9)		5 (9.6)		3 (2.6)		15 (31.9)**	
Swelling at injection site	7 (5.9)		6 (11.5)		7 (6.1)		14 (29.8)**	
Itching at injection site	3 (3.5)		4 (7.7)		5 (4.4)		8 (17.4)*	
Any systemic symptoms	51 (41.5)		28 (53.8)		101 (87.1)		48 (96.0)*	
Chills	8 (6.8)		5 (9.6)		55 (47.8)		36 (75.0)**	
Headache	28 (23.7)		13 (25.0)		74 (64.3)		35 (71.4)	
Joint pain	7 (5.9)		1 (1.9)		31 (27.2)		16 (34.0)	
Muscle/body aches	16 (13.6)		6 (11.5)		71 (61.7)		41 (83.7)*	
Fatigue or tiredness	31 (26.3)		12 (23.1)		82 (71.3)		42 (84.0)	
Fever	1 (0.8)		2 (3.8)		28 (24.3)		23 (46.9)*	
Nausea	5 (4.2)		1 (1.9)		18 (15.7)		13 (27.7)	
Vomiting	0 (0.0)		0 (0.0)		1 (0.9)		4 (8.5)*	
Diarrhea	2 (1.7)		0 (0.0)		3 (2.6)		3 (6.4)	
Abdominal pain	1 (0.8)		0 (0.0)		4 (3.4)		3 (6.4)	
Rash (body)	1 (0.8)		1 (1.9)		1 (0.9)		1 (2.1)	
Other	7 (5.9)		3 (5.8)		7 (6.3)		3 (6.8)	
Change in milk supply								
More milk	4 (3.3)		0 (0.0)		4 (3.6)		3 (6.4)	
Less milk	9 (7.3)		6 (11.5)		9 (8.0)		11 (23.4)*	
Change in milk color	2 (8.0)		1 (7.1)		1 (4.0)		1 (6.2)	
Child events								
Drowsiness		0 (0.0)		1 (2.0)		0 (0.0)		3 (6.4)*
Sedation		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)
Poor feeding		0 (0.0)		0 (0.0)		0 (0.0)		1 (2.1)
Rash		1 (0.8)		0 (0.0)		1 (0.9)		1 (2.1)
Bruising/bleeding		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)
Constipation		0 (0.0)		1 (2.0)		1 (0.9)		1 (2.1)
Diarrhea		1 (0.8)		2 (3.9)		3 (2.6)		1 (2.1)
Stools w/abnormal color		1 (0.8)		2 (3.9)		2 (1.7)		2 (4.2)
Fever		2 (1.7)		0 (0.0)		2 (1.7)		0 (0.0)
Low body temp		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)
Restlessness		1 (0.8)		0 (0.0)		4 (3.4)		2 (4.2)
Irritability		2 (1.7)		2 (3.9)		12 (10.3)		5 (10.4)
Poor sleep		4 (3.4)		3 (5.9)		9 (7.8)		4 (8.3)
High-pitched crying		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)
Abnormal movements		0 (0.0)		0 (0.0)		0 (0.0)		0 (0.0)
Abnormal skin color		1 (0.8)		0 (0.0)		0 (0.0)		0 (0.0)

Variables were summarized by count (%), and group comparisons were made using Fisher's Exact test.
The gray columns notate fields that are Not Applicable.
*$p < 0.05$.
**$p < 0.005$.

Moderna, respectively, $p < 0.05$). However, in all cases milk production was reported by the mother to have returned to normal within 72 hours. Three women reported a change in color of milk (blue–green) following dose 1; two reported change in color of milk following dose 2 (Table 2).

Few events were reported for children following maternal vaccination with either brand or either dose. The most common child events following dose 2 were irritability (10.3% and 10.4% for Pfizer and Moderna, respectively), poor sleep (7.8% and 8.3% for Pfizer and Moderna, respectively), with significantly more drowsiness reported for children whose mothers received Moderna versus Pfizer (0% versus 6.4%, $p = 0.02$) (Table 2).

Discussion

We found that >85% of participants reported any symptoms for both the Pfizer-BioNTech and Moderna vaccines following either dose. This is substantially higher than the 61–67% of women who reported any symptom in the Gray et al. article.[4] This could be due to differences in the methods of assessment, including semistructured interviews with a standardized list of symptoms, capture of data for a total of 7 days after each vaccine dose, and number of symptoms specifically queried. However, consistent with adult participants in clinical trials for each vaccine, we noted increased frequencies of most symptoms following the second dose compared to the first.[7,8] We also found significantly greater frequencies of localized pain, redness, swelling, and itching at the injection site, as well as systemic symptoms, including chills, muscle/body aches, fever, and vomiting following dose 2 of the Moderna brand versus Pfizer.

Some participants reported a reduction in milk supply, which in all cases returned to normal within 72 hours of receipt of the vaccine without any intervention. The majority of participants who reported a reduction in milk supply noted the decrease by evaluating their expression of milk output. While this question was subjective and not measured in any quantitative manner, many lactating women use mobile apps to track their breastfeeding patterns (pumping output, frequency of feeds, etc.) and were able to use these data as a reference when answering this study question.

We found low frequencies of any events reported in children, none of which was serious, which is similar to the previous report by Perl et al.[5] Furthermore, although there was no unexposed comparison group used in this analysis, this infant symptom checklist has been in standard use in the HMB since 2014, and before the pandemic, the frequency of reported infant events was similarly low (data not shown).

One limitation of this study was that symptoms postvaccination were captured by self-report. However, all participants completed a semistructured interview guided by trained study staff who prompted for a standardized list of symptoms and events, with the aid of a calendar, for both the breastfeeding women and their child. In addition, women were interviewed within 21 days of their first and second doses of the vaccine to reduce potential for inaccurate recall. A second limitation is that we used a volunteer sample and cannot be sure that these findings are generalizable to the population.

These data are reassuring regarding the safety of vaccination in breastfeeding women and their breastfed children with either of the mRNA COVID-19 vaccines. Additional studies are underway to evaluate milk composition and antibody status in samples obtained from women participating in the current study.

Conclusions

More than 85% of 180 breastfeeding women who received an mRNA COVID-19 vaccine reported local or systemic symptoms, with higher frequency following the second dose. Few nonserious events were reported in their breastfed children, and no serious adverse events were noted. These data are reassuring regarding the safety of vaccination in breastfeeding women and their breastfed children with either of the mRNA COVID-19 vaccines.

Authors' Contributions

C.D.C. and K.B. designed the study and supervised the collection of data used in the study. G.H.-S. performed the statistical analysis. All authors were involved in preparing the article. All authors approved the final article as submitted and agree to be accountable for all aspects of the work.

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