Decreased milk supply during breastfeeding after COVID-19 vaccination

Introduction

To date, the European Medicines Agency (EMA) authorised five COVID-19 vaccines for active immunisation against SARS-CoV-2: BioNTech/Pfizer (Comirnaty®), Moderna (SpikeVax®), AstraZeneca (Vaxzevria®), Janssen and Novavax (Nuvaxovid®) [1]. BioNTech/Pfizer and Moderna are both mRNA vaccines, encoding the viral spike (S) protein while AstraZeneca and Janssen are using an Adenovirus vector and Novavax is a protein-based vaccine. All COVID-19 vaccines are subject to additional monitoring [2-6].

The most widely given vaccine in the Netherlands is the Pfizer/BioNTech vaccine (Comirnaty®) [7]. It is indicated for active immunisation to prevent COVID-19 caused by SARS-CoV-2 virus, in individuals 12 years of age and older [2]. Comirnaty® has been registered in Europe since December 21st, 2020 [2].

The number of live births in the Netherlands in 2020 was about 170.000 [8]. In 2018, 76% of the women in the Netherlands started breastfeeding (partially or fully) their newborn infant [9]. Breast milk contains a lot of nutrition and exclusively breastfeeding is therefore recommended for the first 6 months of life by the World Health Organization (WHO) [10]. Several studies showed the benefits of breastfeeding including neurobehavioral benefits, optimal gastrointestinal function, transfer of antibodies/prevention of illnesses and a decrease in mortality and hospitalization [11].

Low milk supply during breastfeeding is the most common reason for early termination of breastfeeding. Several factors can contribute to a decrease in milk supply, including maternal stress, obesity, preeclampsia, hypertension, diabetes and certain medications [12].

This signal provides an overview of all reports of decreased milk supply during breastfeeding following COVID-19 vaccinations reported to the Netherlands Pharmacovigilance Centre Lareb, up to 31 December 2021.

Reports

Until December 31st, 2021 the Netherlands Pharmacovigilance Centre Lareb received 194 unique individual case reports of suppressed lactation (PT). Table 1 provides an overview of these cases.

Table 1. Overview of reported cases of decreased milk supply during breastfeeding in the Netherlands after COVID-19 vaccines

Brand	**Comirnaty®**	**Vaxzevria®**	**SpikeVax®**	**Janssen vaccine**	**Overall**
N Total	172	3	16	3	194
Other systemic effects reported					
Yes	106	3	13	3	125
No	66	0	3	0	69
Median latency (days)	1.0 (n=168)	1.5 (n=2)	1.0 (n=15)	1.0 (n=3)	1.0 (n=188)
Latency					
< 1 day	43	0	2	1	46
1-2 days	103	2	10	1	116
3-7 days	15	0	2	0	17
> 7 days	7	0	1	1	9
Unknown	4	1	1	0	6
Median duration (days)	4.0 (n=57)	1.0 (n=1)	7.0 (n=5)	10 (n=2)	4.0 (n=65)
Duration*					
1-2 days	8	1	0	0	9
3-6 days	31	0	1	1	33
7-10 days	11	0	4	0	15
11-14 days	7	0	0	1	8
Unknown	115	2	11	1	129
Mean burden	3.9 (n=168)	2.5 (n=2)	4.1 (n=16)	4.0 (n=3)	3.9 (n=189)
Burden					
None at all (=1)	1	0	0	0	1
A little (=2)	14	1	2	1	18
Quite (=3)	46	1	2	0	49

A lot (=4) Very much (=5)	48 59	0 0	4 8	0 2	52 69
Self-reported milk supply after vaccination compared to the pre-vaccination amount <25% 25-50% 50-75% 75-100% Unknown	 28 32 7 0 105	 0 0 0 0 3	 4 0 2 0 10	 0 1 0 0 2	 32 33 9 0 120
Median age of the infant (weeks)	8 (n=87)	-	11 (n=11)	12 (n=1)	8 (n=99)
Mean pregnancy duration (weeks)	39.7 (n=100)	-	40.9 (n=11)	40.4 (n=1)	39.9 (n=112)

* Duration of the reaction is only known for the women who reported to have recovered at the time of the report.

Dutch Pregnancy Drug Register

A total of 163 women, who were enrolled in Moeders van Morgen, the Dutch Pregnancy Drug Register, reported to have received at least one vaccination during breastfeeding. A total of 185 vaccinations were reported during breastfeeding. Twenty-two women reported two vaccinations during breastfeeding. Women were explicitly asked if they noticed an effect on the milk, on their child or noticed no effect of the vaccination in combination with breastfeeding. An effect on the milk was reported seven times (3.8%) by five unique women (two women were vaccinated twice during breastfeeding). In two of these 7 cases, also systemic adverse events like fever, fatigue, myalgia and arthralgia were reported. Only two women commented specific decreased milk supply (in three cases), for the other four cases the effect was not further specified. The median time of the vaccination after birth was 33 days (range: 12-63 days). In 174 cases (94.1%), no effect was noticed.

Table 2: Overview of the women in the Dutch Pregnancy Drug Register who were vaccinated during breastfeeding and reported an effect on the milk

Woman	Vaccine	Timing of the vaccination after delivery (days)	Other adverse events (maternal)	Recovery time
1	2th: Pfizer	18	Fever, myalgia, arthralgia	Unknown
2	1th: Pfizer* 2th: Pfizer*	34 63	No No	24 hours 24 hours
3	2th: Pfizer	12	No	Unknown
4	1th: Pfizer 2th: Pfizer	15 50	Injection site reaction Injection site reaction, fever, fatigue	Unknown
5	2th: Pfizer*	33	No	Unknown

* effect on the milk specified as decreased milk production

Other sources of information

SmPC

Decreased milk supply during breastfeeding is not listed in the SmPC of the COVID-19 vaccines [2-6].

Data on usage

The table below provides an overview of number of dose administered per vaccine in the Netherlands.

Table 3. Overview of number of dose administered per vaccine in the Netherlands [13]

	Startdate vaccination	**Number of vaccinations until December 26th, 2021**
Comirnaty®	January 6th, 2021	20.366.466
Vaxzevria®	January 25th, 2021	2.780.112
SpikeVax®	February 12th, 2021	3.816.581
Janssen vaccine	April, 21st, 2021	867.096

Literature

Four papers describe cases of decreased milk supply during breastfeeding after vaccination. It concerns self-reported symptoms.

In Kachikis et al. a total of 339 women reported decreased milk supply for less than 24 hours after the first dose (5.0%) and 434 women experienced this reaction after the second dose (7.2%). Interrupted breastfeeding was reported by 155 women (2.3%) after the first dose and by 130 women (2.2%) after the second dose [14]. Golan et al. describes 50 women who received an mRNA COVID-19 vaccine. A decrease in milk supply was reported by one women (2%) after the first dose and one women (2%) after the second dose [15]. In Bertrand et al. of 180 women who received two doses of a mRNA vaccine, nine women (7.3%) reported decreased milk supply after a first dose with Pfizer and 9 women (8.0%) after the second dose. Six women (11.5%) experienced decreased milk supply after the first dose of Moderna and 11 women (23.4%) after the second dose. Besides, four women (3.3%) reported an increase in milk supply after first Pfizer vaccination and respectively 4 (3.6%) and 3 (6.4%) after first and second Moderna vaccination. The milk supply returned to normal in all cases within 72 hours [16]. In McLaurin-Jiang et al. 258 women (6.0%) reported a decrease in milk supply after COVID-19 vaccination, while 168 (3.9%) reported an increase in milk supply [17]. In another publication with 88 lactating women who received the Pfizer vaccine, no change in milk supply was reported after vaccination [18].

Mechanism

No direct mechanism for the decreased milk supply after COVID-19 vaccination could be found in the literature. Although it is known stress can affect the milk supply. In situations of stress, the hormone cortisol is released, which in turn inhibits prolactin. Prolactin is necessary for the production of milk [19]. Women can experience stress due to concerns about vaccine safety. Also the co-reported systemic adverse events can possibly have an effect on the milk supply, a phenomenon which is also seen in case of other illnesses.

Databases

In the WHO global database of individual case safety reports, VigiBase, a total of 675 cases of decreased milk supply during breastfeeding were found after vaccination with a COVID-19 vaccine (version date dataset: 4-2-2022) [20]. This number includes the reports from the Netherlands. Most reports (513 reports) were related to the Pfizer/BioNTech vaccine (Comirnaty®).

Discussion and conclusion

In the period until December 31th, 2021 the Netherlands Pharmacovigilance Centre Lareb received 194 reports of decreased milk supply during breastfeeding associated with administration of COVID-19 vaccines. Most reports were related to the Pfizer/BioNTech vaccine (Comirnaty®). However, this vaccine has been given to most people by far. Almost all reports were reported by consumers or other non-healthcare professionals (99,5%).

Time to onset of the reaction was in most of the cases in 1-2 days. Of the 65 women that reported to have recovered at the time of the report, the median duration of the reaction was 4 days. This is longer than the duration mentioned in the literature so far. Bertrand et al. mentions that in all cases the milk supply returned to normal within 72 hours. This might be because more severe cases are more likely to be spontaneously reported.

In 74 cases, information about the amount of decrease in milk supply was available, which was objectively determined in 73% of these cases. In 87.8% of the cases the milk supply decreased to less than 50% of the pre-vaccination amount. Twenty women reported to have stopped completely with breastfeeding due to the decreased milk supply. On a 5-point Likert scale, women where asked about the burden of the reaction. Breastfeeding women experienced this reaction with a high burden, with a mean burden of 3.9 and 36.5% of the women scoring the highest score of 5.

In 64.4% of the cases also other systemic adverse events were reported like headache, fatigue, myalgia, malaise, fever, chills, arthralgia and nausea. It is possible the occurrence of the decreased milk supply may be related to the occurrence of systemic adverse events. It is known stress (concern

about vaccines safety) and other illnesses may affect the milk supply so it cannot be ruled out the other systemic reactions play a role in the occurrence.

Several publications in the literature describe a decrease in milk supply after COVID-19 vaccination, ranging from 2-11% after a first dose and 2-23% after a second dose. In the Dutch Pregnancy Drug Register an incidence is found of 3.8%. However, it should be noted not everyone specified the effect on the milk so it's not sure all women experienced a decrease in milk supply.

Based on the reports of decreased milk supply during breastfeeding after COVID-19 vaccination, a causal relationship cannot be ruled out and should be further investigated. This potential adverse reaction may create a substantial burden for lactating women. More knowledge is important for informing lactating women.

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This signal has been raised on March 31, 2022. It is possible that in the meantime other information became available. For the latest information, including the official SmPC's, please refer to website of the MEB www.cbg-meb.nl