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The Relationship between COVID-19 Infection and Breastfeeding: A Randomized Trial

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Abstract

Problem: Currently in the world, 41.0% of children under 6 months are exclusively breastfed.

Background: The COVID-19 pandemic has had a major impact on lactation.

Question, hypothesis or aim: The COVID-19 virus alters the values of prolactin in maternal blood and is correlative with the establishment of lactation in a non-existent way.

Methods: A statistical analysis of linear regression, prolactin analysis in the 3rd trimester of pregnancy and 15 days after delivery was performed in women with Covid-19 infection and healthy, finally the rates of breastfeeding were evaluated. The sample was made up of 680 pregnant women from central region of Spain.

Findings: The sample means of prolactin obtained in the study indicate that the average level of prolactin is significantly higher in women who do not get Covid (195.08 ± 65.00) compared to those who are infected during pregnancy in any of the trimesters.

Discussion: The infection is associated with prolactin in the 3rd trimester and 15 days, with the coefficient of determination r^2 in the 3rd trimester being 0.848, and at 15 days r^2 0.90, indicating that the model explains 84.8% or 90.0% of prolactin variability, respectively.

Conclusion: According to the results obtained, interference of the covid-19 virus in the production of prolactin is evident, as well as low rates of breastfeeding. This study brings important advances to the scientific community, suggesting that support interventions aimed at promoting breastfeeding should be offered in a specialized way to pregnant women with infectious pathologies.

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Introduction

The Covid-19 pandemic has had a major impact on breastfeeding [1], producing significant changes in both the rates of initiation and maintenance of breastfeeding. Ignorance of the mechanisms of transmission [2] and the potential risks of the virus in the health of the mother and newborn, are influential aspects in the low rates of lactation [3,4]. Currently, breastfeeding rates worldwide have been significantly reduced, the World Health Organization (WHO) [5], estimates that the percentage of infants exclusively breastfed up to six months is 41.0% [6,7] Exclusive breastfeeding rates remain low in low-income countries (Nigeria, Colombia, Sierra Leone, Congo...) [8] as in the high income (United Arab Emirates, Germany, Sydney ...) [9]. The WHO recommends that mothers [3,5], feed their children

exclusively breastfed at least the first six months of life [10], as it is scientifically proven to provide benefits for maternal health [11] and infant [12]. The hormone responsible for milk maternal secretion is prolactin [13], its main function is to stimulate lactation (milk production) [14] in women during pregnancy and to maintain milk supply during breastfeeding [15]. The prolactin test measures the level of this hormone in the blood (PRL) [16]. Normal levels of prolactin in pregnant and women who are breastfeeding are 80 to 400 ng/ml [17,18]. Virus by Covid-19 is known to spread through direct person-to-person contact [19,20], this became a concern for mothers-to-be or those who were already breastfeeding due to possible transmission of the virus through breastfeeding [21]. So far there is insufficient scientific evidence that the virus is found in the milk of mothers [22]. The WHO recommend, in cases of confirmed infection [23], maintaining mother-child contact and breastfeeding [24]. The Pan-American Association maintains that according to the latest scientific evidence, [25] if there are specific antibodies against Covid-19 in breast milk [26].

Problem or Issue: Low rates of exclusive breastfeeding globally.
What is Already Known: Human milk is the food of choice in the first six months of the life for all children, therefore, exclusive breastfeeding is recommended for up to six months; however, breastfeeding rates are currently low at 46%, globally.
What this Paper Adds: The significant correlation of virus interference by covid-19 in prolactin values and breastfeeding rates.

Methods

Research question

Previously, the hypotheses existing during the pandemic on the tendency to abondon breastfeeding were analyzed; among them, the most commented was the contagion to the child through breast milk [27,28]. The research question that guided this study was that pregnant women infected by Covid-19 have lower prolactin values than non-infected pregnant women and this fact influences the rates of breastfeeding.

Population and sample of the research

The research population consisted of pregnant women (n=720) from health area. Using the sample formula, the sample size required for this population, which is not in a homogeneous structure, is within the 95% confidence interval, with a sampling error of ±5% n =720 (1. 96) 2 (0. 2) (0. 8) / (0. 05) 2 (720 -1) + (1.96) 2 (0. 2) (0. 8) = 184. The study was conducted between April 13, 2021, and April 20, 2022, with 680 pregnant women who agreed to participate in the study, 318 were infected by Covid-19 (n=26 1st trimester, n= 61 2nd trimester and n=231 3rd trimester) and 362 did not contract the infection.

Data analysis

A prospective, cross-sectional, descriptive and linear regression study was carried out, measuring the variable levels of prolactin in pregnant women diagnosed with covid-19 in the 3rd trimester and 15 days after delivery and healthy pregnant women; finally, the breastfeeding rate was evaluated. Description of continuous quantitative random variables: prolactin levels and nominal quality is: Covid-19 infection and breastfeeding.

Data analysis was performed with SPSS 20.0 software. To evaluate the data, frequency, percentage, mean and standard deviation, ANOVA (Test F Welch) and Chi square analysis of variance were used. For the results it was accepted as statistically significant p<05. The results obtained after the application of the ANOVA technique is that in at least two quarters there are significantly different average levels of prolactin. But the typical sample deviations detect that ANOVA does not meet the requirement of homogeneity of variances, therefore, the Test F Welch was applied. A linear regression analysis was also performed.

Intervention

A session was held to present the project to the health teams [29,30], next, telephone contact with pregnant women. Once the patient agreed to participate in the study after giving her informed consent.

The data were collected through all the medical records of pregnant women under the coding of the clinical process of normal pregnancy or diagnosis of Covid-19 infection (1st, 2nd, and 3rd trimester of pregnancy) in the computer registry Medora@ [9,31], under the consent of the Health Directorate, to be able to access the Clinical History for research purposes [9,32].

Likewise, the study is structured in two interventions for each of the individuals in the sample: 1st intervention was performed in 3rd trimester (28-39 weeks): blood prolactin levels and 2nd intervention: Prolactin levels were analyzed 15 days after delivery, and the successful establishment of breastfeeding as exclusive feeding for their baby was evaluated. Due to the current health situation Covid-19 pandemic, blood draws were carried out by appointment in the laboratory, applying and respecting all health safety measures. In such a way that pregnant women infected were received in the "dirty" room through the dirty circuit [33] and healthy pregnant women in the clean room (Figure 1). For the correct collection of the prolactin blood sample, each of the participants was instructed on the ideal conditions to follow do not exercise 2h before [34], advise being relaxed 30 min before, not be subjected to stressful situations, avoid a diet rich in proteins and fats the day before, fasting for 8-10 hours and not taking medications that can raise or lower the values [35]. The extraction technique was performed by venipuncture in veins located in the antecubital area with a 21G butterfly nut with a Vacutainer Safety Lok@ adapter, a 2.5 x 45 cm latex venous compressor and a tube with separating gel (yellow cap) [36].

Ethical approval/informed consent

To carry out the research, the Approval of the Ethics Committee (date: 17.12.2020) of the Ethics Committee was obtained.

Results

The sample means of prolactin obtained in the study indicate that the mean level of prolactin is significantly higher in women who do not get Covid compared to those who are infected during pregnancy at some point, in the 3rd trimester 195.08 ng/ml and 15 days after delivery 329.46 ng/ml. Women who do not get infected have higher levels of prolactin within 15 days of delivery.

Pregnant women who are infected in the 3rd trimester are left with a very low average level of prolactin 6.96 ng/ml and with little variability (all women very similar). However, pregnant women who are infected in the 1st trimester, gives them time to recover a little their average level of prolactin, although far from what would be expected compared to that of women who do not get infected, both in the 3rd trimester and 15 days after childbirth.

On the other hand, according to the data obtained, women who breastfeed have significantly higher prolactin values than women who do not breastfeed, both in the 3rd trimester of pregnancy and 15 days after delivery, is presented in Table 1. Women who do not get infected have more prolactin in the 3rd trimester than those who do, but prolactin is not related to breastfeeding, women who breastfeed have lower levels of prolactin in the 3rd trimester than those who do not breastfeed. Those who are infected in the three trimesters and do not breastfeed, have more prolactin than those who do breastfeed. In addition, the data show that there is a statistically significant relationship between the contagion of pregnant women and breastfeeding rates; likewise, pregnant women who do not get infected breastfeed more than women who do get it (p<.05). If the rates of breastfeeding in infected women are analyzed, pregnant women who are infected in the 1st trimester of gestation, have higher rates, however, those who are infected in the 3rd trimester, the rates are non-existent (Table 2). In addition, we investigated whether Covid infection and lactation (independent variables) have a linear influence on prolactin (dependent variable) at two times: 3rd trimester and 15 days after delivery. Both in the 3rd trimester and at 15 days, the p-value provided by the Snedecor F test for this contrast is p<.05; therefore, the hypothesis is rejected, and it is concluded that at least one of the independent variables has a linear association with the prolactin of 3rd trimester and 15 days, the coefficient of determination r^2, in 3rd trimester is 0. 848, and at 15 days r^2 is 0.90, indicating that the model explains the 84.8% of the variability of the variable prolactin 3rd trimester and 90.0% at 15 days (Table 3). Pregnant women who do breastfeed and are not infected are expected to have more levels of prolactin both in the 3rd trimester and at 15 days; on the contrary, a higher average value of prolactin at the 3rd trimester is expected in pregnant women who are infected in the 2nd trimester (54.77 ng/ml); but the mean value of prolactin at 15 days is expected to be higher in pregnant women infected in the 3rd trimester (214.88 ng/ml). If we study the collinearity in the two contrast tests of hypothesis the p<.05 in both, it is concluded that there is a linear relationship is significant (Figure 2).

Table 1: Sample means of prolactin in the 3rd trimester (28-39 weeks of pregnancy) and at 15 days postpartum in relation to the variable contagion by Covid-19 and breastfeeding variable (n=680). ANOVA.

Covid-19 contagion		Time of analytical determination	Mean prolactin values (ng/ml) SD
No		3rd Quarter	195.08 ± 65.00 n=362
		15 days postpartum	329.46 ± 97.09 n=362
Yes	1st Quarter	3rd Quarter	77.04 ± 4.25 n=26
		15 days postpartum	67.65 ± 4.14 n=26
	2nd Quarter	3rd Quarter	35.39 ± 4.67 n= 61
		15 days postpartum	73.42 ± 5.90 n= 61
	3rd Quarter	3rd Quarter	6.96 ± 2.24 n= 231
		15 days postpartum	72.53 ± 7.98 n= 231
Breastfeeding		**Moment of analytical determination**	**Mean prolactin values**
No		3rd Quarter	25.82 ± 35.48 n= 339
		15 days postpartum	82.11 ± 45.15 n= 339
Yes		3rd Quarter	198, 34 ± 65.90 n=341
		15 days postpartum	335.53 ± 94.06 n=341

SD: Standard Deviation; 1st: 1º Trimester; 2nd: 2º trimester; 3rd: 3º Trimester.

Table 2: Breastfeeding rates and mean prolactin values in relation to Covid-19 infection. ANOVA and Chi-Square (n=680).

Covid-19 contagion		Mean prolactin values 3rd trimester (ng/ml)	
		No	**Yes**
No		31.94	55.78
Yes	1st Quarter	NA	4.24
	2nd Quarter	4.69	2.31
	3rd Quarter	2.24	NA
Covid-19 contagion		Mean prolactin values 15 days postpartum (ng/ml)	
		No	Yes
No		136.18	360.42
Yes	1st Quarter	NA	67.65
	2nd Quarter	73.67	68.40
	3rd Quarter	72.53	NA

Covid-19 Contagion		Breastfeeding	
		No	Yes
No		50 (7.3%)	312 (45.8%)
Yes	1st Quarter	0 (0.0%)	26 (3.8%)
	2nd Quarter	58 (8.5%)	3 (0.4%)
	3rd Quarter	231 (33.9%)	0 (0.0%)

1st: 1º Trimester; 2nd= 2º trimester, 3rd: 3º Trimester.

Table 3: Linear regresion. Independient variable Covid-19 and dependent variable prolactin (n=680).

Prolactin 3rd trimester	**SD**	**Error**	**T value**	***p*-value**
Intercept	-24.37	9.699	-2.513	0.011
Covid 2T	54.77	10.790	5.077	<.001
Covid 3T	31.33	10.042	3.120	0.002
No covid	132,05	8.065	16.374	<2e-16
Breastfeeding	101,41	5.831	17.393	<2e-16
Residual estándar error: 39.52 Multiple R-squard: 0.848 F-statistic: 945.9 Adjusted R-squared: 0.847				
Prolactin 15 days postpartum	**SD**	**Error**	**T value**	**p-value**
Intercept	-142.34	11.152	-12.76	<2e-16
Covid 2T	205.43	12.406	16.56	<2e-16
Covid 3T	214.88	11.546	18.61	<2e-16
No covid	290.81	9.273	31.36	<2e-16
Breastfeeding	209.99	6.704	31.32	<2e-16
Residual standar error: 45.44				
Multiple R-squard: 0.904 F-statistic: 1601		Adjusted R-squared: 0.904		

SD: standard deviation; Covid 2T: 2º Trimester; Covid 3T: 3º Trimester.

Discussion

Despite the growing number of published studies on Covid-19 in pregnancy [3,7], there are not enough to investigate how the virus affects the physiological process of breastfeeding. Our study found significant findings that confirmed that healthy women had higher levels of prolactin and were breastfeeding their children. An association was found between prolactin values and lactation rates in pregnant women infected with Covid. A recent study [38] that conducted an experiment on breast milk after Covid-19 infection, found a rapid increase in the neutralization of the virus developed in the breast milk of infected subjects; however, in our study prolactin levels decreased in infected women, the more advanced the pregnancy, fewer levels of prolactin had, except for women infected in the first trimester of pregnancy which gave them time to recover. In study [39] evaluating the effect of Covid-19 on pregnancy and neonatal outcomes, significant associations between maternal and fetal mortality and virus infection were recorded, but the impact on breastfeeding was not evaluated. However, recent research on breastfeeding and covid-19 [40], ensures the importance of the implementation and continuity of breastfeeding due to its multiple benefits because there is no scientific evidence of vertical transmission of Covid-19, it also states that breastfeeding should be ensured especially during the pandemic, because there are greater benefits in the relationship, nutrition, immunity and protection against the virus. If a mother with Covid-19 or with suspected infection is asymptomatic or with mild symptoms, it is recommended to continue breastfeeding with strict control measures. However, if you have severe symptoms, the newborn should be fed freshly expressed breast milk, without the need to pasteurize it, as it is not considered as a vehicle of the virus.

Other authors suggest avoiding direct breastfeeding, due to the risk of contagion, with the aim of decreasing the chances of the newborn becoming infected through the mother's droplets [40]. On the other hand, there is a great risk that the mother-child affective bond will be damaged, and breastfeeding will be interrupted, with serious consequences for the child [41]. Another of the [42] investigations carried out in the context of the pandemic carried out a follow-up of the indicators of breastfeeding practices obtaining as results (n=46), at 6 months of age, the average of exclusive breastfeeding was 18.0%. In our study, breastfeeding rates in healthy women were 45.8% (n=680) and 4.2% in infected women.

Limitations

The strengths found in the study include the collection of data for the promotion of breastfeeding in the context of the Covid-19 pandemic. Among the limitations are the women who participated in the study without a previous diagnosis of infection, classified as healthy and were infected between the period of the 3rd trimester and fifteen days after delivery; In this case they were excluded from the sample; the possibility of women who have passed the Covid-19 disease asymptomatically without analytical confirmation was also determined. On the other hand, we found a bias in the sample since the variability that exists in non-infected women is very significant; this suggests that in the sample there are pregnant women with very high levels of prolactin and with very low levels in that same group. It is interesting to note that this group of women with low levels

of prolactin, more typical of women who have passed Covid, could perhaps have passed the disease asymptomatically and not know it.

Conclusions

According to the results obtained, interference of the Covid-19 virus in the production of prolactin is evident, as well as low rates of breastfeeding. Therefore, it should be noted that this research study brings important advances in the field of Public Health, Epidemiology and Health Promotion. The intervention proposed in this study brings important advances to the scientific community in the context of Covid-19 to further catalog pregnant and postpartum women as vulnerable patients in the Promotion of breastfeeding. In order to continue with significant research regarding the relationship of Covid-19 with the physiological process of breastfeeding, we urge researchers to present in the future data of results that include lines of research such as pharmacological interference in the virus so as not to reduce prolactin or how to increase prolactin levels in infected women.

Declarations

Ethical approval and consent: To carry out the research, the Approval of the Ethics Committee (date: 17.12.2020) of the Ethics Committee was obtained.

Data availability: Due to the sensitive nature of the data obtained in this study, participants were assured raw data would remain confidential and would not be shared.

Conflict interest: The authors declare that they have no known competing financial interests or personal relationship that could have appeared to influence the work reported in this paper.

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