

Insufficient breast milk production (00216): clinical validation

Produção insuficiente de leite materno (00216): validação clínica

Producción insuficiente de leche materna (00216): validación clínica



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RESUMO

Objetivo: Submeter o diagnóstico de enfermagem “Produção insuficiente de leite materno” (00216) à validação clínica.

Método: Estudo transversal de validação clínica de diagnóstico de enfermagem. Foram utilizadas medidas de acurácia diagnóstica (sensibilidade, especificidade, valores preditivos positivo e negativo) para análise, considerando a Classificação dos Diagnósticos de Enfermagem da NANDA International. Os dados foram coletados junto a puérperas e seus filhos, de junho de 2023 a abril de 2024, em setores de alojamento conjunto e ambulatório de neonatologia de um hospital público de ensino.

Resultados: Amostra de 205 díades. A idade das mães variou de 18 a 44 anos. A maioria dos bebês era do sexo masculino ($n=109$; 53,17%), com 2 a 37 dias de vida (média de $3,99+3,41$ dias) e 169 (82,44%) nascidos a termo (entre 37 semanas e 41 semanas e 6 dias). O diagnóstico estava presente em 10 díades (4,88%). A Característica Definidora “Baixo ganho de peso para a faixa etária” mostrou sensibilidade de 60%, especificidade de 96,9% e valor preditivo negativo de 97,9% ($p<0,0001$).

Conclusão: O diagnóstico de enfermagem “Produção insuficiente de leite materno” (00216) foi validado clinicamente. A Característica Definidora “Baixo ganho de peso para a faixa etária” mostrou-se relevante ao diagnóstico estudado.

Descritores: Aleitamento materno; Diagnóstico de enfermagem; Processo de enfermagem; Terminologia padronizada em enfermagem; Estudo de validação.

ABSTRACT

Objective: Submit the nursing diagnosis “Insufficient breast milk production” (00216) for clinical validation.

Methods: Cross-sectional study of a nursing diagnosis clinical validation. Diagnostic accuracy measures (sensitivity, specificity, and positive and negative predictive values) were used for analysis, considering the NANDA International Nursing Diagnosis Classification. Data were collected from postpartum women and their children, from June 2023 to April 2024, in rooming-in and neonatal outpatient departments of a public teaching hospital.

Results: Sample of 205 dyads. Mothers’ ages ranged from 18 to 44 years. Most infants were male ($n=109$; 53.17%), aged 2 to 37 days (mean of $3.99+3.41$ days), and 169 (82.44%) were term babies (between 37 weeks and 41 weeks and 6 days). The diagnosis was present in 10 dyads (4.88%). The defining characteristic “Low weight gain for age group” presented sensitivity of 60%, specificity of 96.9%, and negative predictive value of 97.9% ($p<0.0001$).

Conclusion: The nursing diagnosis “Insufficient breast milk production” (00216) has been clinically validated. The defining characteristic “Low weight gain for age group” was shown to be relevant to the diagnosis studied.

Descriptors: Breastfeeding; Nursing diagnosis; Nursing process; Standardized nursing terminology; Validation study.

RESUMEN

Objetivo: Presentar el diagnóstico de enfermería “Producción insuficiente de leche materna” (00216) para validación clínica.

Método: Estudio transversal de validación clínica de diagnósticos de enfermería. Para el análisis se utilizaron medidas de precisión diagnóstica (sensibilidad, especificidad, y valores predictivos positivos y negativos), considerando la Clasificación de Diagnóstico de Enfermería de NANDA Internacional. Se recolectaron datos de puérperas y sus hijos, de junio de 2023 a abril de 2024, en sectores de alojamiento conjunto y en el ambulatorio de neonatología de un hospital público universitario.

Resultados: Muestra de 205 díadas. Las edades de las madres oscilaron entre 18 y 44 años. La mayoría de los bebés eran varones ($n=109$; 53,17%), con edades de 2 a 37 días (promedio de $3,99+3,41$ días) y 169 (82,44%) nacieron a término (entre 37 semanas y 41 semanas y 6 días). El diagnóstico estuvo presente en 10 díadas (4,88%). La característica definitoria “Bajo aumento de peso para el grupo de edad” resultó con una sensibilidad del 60%, una especificidad del 96,9% y un valor predictivo negativo del 97,9% ($p<0,0001$).

Conclusión: El diagnóstico de enfermería “Producción insuficiente de leche materna” (00216) ha sido validado clinicamente. La característica definitoria “Bajo aumento de peso para el grupo de edad” resultó ser relevante para el diagnóstico estudiado.

Descriptores: Lactancia Materna; Diagnóstico de Enfermería; Proceso de Enfermería; Terminología Normalizada de Enfermería; Estudio de Validación.

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■ INTRODUCTION

The World Health Organization (WHO) considers Exclusive Breastfeeding (EBF) in the first six months as a health indicator⁽¹⁾. This is because human milk is a complete food in the first six months of the life of the infant, reducing their risk of exposure to allergens and contaminated utensils and foods. It also reduces the financial cost with feeding and treatments related to health issues. Owing to its multiple advantages⁽²⁾, it is essential for the promotion and protection of people's health⁽¹⁾. On the other hand, due to the reduction in knowledge and in the culture of breastfeeding in families and societies, mothers and their children have become vulnerable to weaning, and the knowledge and abilities of health workers is essential to prevent that from happening⁽³⁾.

In this stage, in which the contact between baby and the mother is so important to stimulate hormones and develop a bond, the mother may be emotionally affected if they are inexperienced or receive inappropriate guidance about breastfeeding⁽⁴⁾. This may also happen if, for some reason, she needs to be separated from their children after delivery, be it due to a disease of the mother or of the baby. This can lead to the suppression of the hormones necessary for ejecting the milk⁽⁴⁻⁵⁾. On the other hand, the emotional well-being of the woman and the stimuli from the baby through suction, close contact, in addition to the interactions between them, can favor and accelerate milk production⁽⁴⁾.

Serial measures of breast volume showed that milk is continuously produced, and the speed at which it is produced is directly proportional to the amount of milk extracted in the previous breastfeeding⁽⁵⁾. Therefore, when latching and suction are not adequate, the time for feeding is restricted, and complements such as pacifiers and baby bottles are used, which can lead to low milk supply, also known as hypogalactia⁽⁵⁾.

This shows how important it is for the support network of a woman to provide her with appropriate opportunities and strategies to breastfeed her child, in a calm and pleasurable environment that favors the woman's wellbeing⁽⁶⁾, enabling her to establish and continue breastfeeding.

Nurses often provide orientations and clinical management in regard to breastfeeding⁽⁷⁻⁸⁾. In all health care contexts, there are opportunities to apply the Nursing

Process (NP) as a systematized guide of clinical reasoning, to guide dynamic and interrelated actions when providing care⁽⁹⁻¹⁰⁾. Using the NP, nurses can direct their assistance in order to aid in the breastfeeding process of the dyad.

The diagnosis is the stage in which data collected during investigation is gathered and interpreted, culminated in decisions about patient needs and how they should be prioritized⁽⁹⁻¹⁰⁾. Therefore, this study aimed to investigate breastfeeding-related phenomena recognized by NANDA-I, using the nursing diagnoses (ND) as a standardized language.

There are different classifications, as in standardized language systems, which provide a structure to organize nursing diagnoses, results, and interventions⁽¹¹⁻¹²⁾. They include NANDA International's Nursing Diagnoses (NANDA-I)⁽¹¹⁾, according to which the ND is a clinical judgment about a human response to health conditions/life process, or a vulnerability to said response, on the part of an individual, family, group, or community⁽¹¹⁾. Therefore, the NDs related to breastfeeding are essential to name the human responses in this context, in order to orient interventions. This investigation aimed to study, specifically, the ND "Insufficient breast milk production" (00216)⁽¹¹⁾, since it still has a low level of scientific evidence due to the fact that, up to now, the only element included in the classification and submitted was the content analysis^(11,13). Thus, it requires refining and investigations in real clinical contexts.

Due to the relevance of breastfeeding for the health of the population, and considering the standardized language of nursing as the construction of a body of knowledge of the profession, this study aimed to submit the nursing diagnosis "Insufficient breast milk production" (00216) to clinical validation.

■ METHOD

Type of research design.

This is a cross-sectional study derived from a methodological research⁽¹³⁾. At first, a content validation was conducted, and later, a clinical validation of the nursing diagnosis "Insufficient breast milk production" (00216)⁽¹¹⁾.

The validation of the content is a stage that involves careful theoretical analysis of all elements in the ND, from its title to its definition, to ascertain whether the

content is an appropriate description of what the nurse finds in their clinical practice. This process enables a continuous refinement of the diagnosis, helping maintain what is appropriate and proposing changes that are sent to the NANDA-I for evaluation and inclusion, when pertinent. Content validation can use different methods, including literature reviews and specialist consensus, as well as content validity indexes, proportion tests, agreement coefficients, and internal consistency analyses of specialist evaluation. Clinical validation involves an investigation about the diagnosis in clinical practice, as well as the inferences found using its elements with real patients with the diagnosis or at risk of developing it. Then, the elements are once again evaluated for their fitness as descriptions of the nursing phenomenon at hand^(11,14).

As a result, this is a cross-sectional study including the clinical validation of the nursing diagnosis at hand, using diagnostic accuracy measures (sensitivity, specificity, and positive and negative predictive values)⁽¹⁴⁾ and considering the Classification of Nursing Diagnosis in NANDA International⁽¹¹⁾.

Place

This study was carried out in a high-complexity public hospital that provides health care, teaching, and research, being a reference for more than 40 municipalities. This hospital is accredited as a Baby-Friendly Hospital and is in Campinas, São Paulo, Brazil.

The participants and their children were being cared for in the Joint Accommodations (JA) and the neonate outpatient clinic. In AC, they usually stay for 48 to 72 hours, or longer if necessary. The outpatient clinic attends all babies discharged from the JA, who need evaluation from two to three days after hospital discharge. The patient is discharged from the outpatient clinic after breastfeeding is adequately established and they gain weight.

Population

This study included, sequentially, by convenience, dyads in the process of breastfeeding, who were being followed up in the JA for 48h or more, or in outpatient follow-up.

Were excluded babies with medical diagnoses of neonate anoxia or genetic syndromes, cardiopathies, and any malformations that make breastfeeding unfeasible after discharge, according to medical records and discharge reports; mothers with multiple gestation; women under 18; or women that, for any reason, have any impediments caused by clinical or cognitive conditions that prevent them from breastfeeding, according to the assessments and records of the health team in their records.

Sample size calculation

Data was collected from 205 dyads. The sample size was calculated considering the sample calculation method, whose goal is estimating a proportion. In the sample calculation, we considered a proportion of $p=0.50$, a value that represents the maximum variability of the binomial distribution. Thus, it generates an estimate with the highest sample size possible.

The sample size (n) for a proportion, considering a finite population, can be estimated using the following formula:

$$n = \frac{Np(1 - p)}{p(1 - p) + (N - 1)D^2}$$

In this formula, “N” represents the study population. “D” represents the precision of the estimating variable to be measured, which can be described as “B/Z”, where “B” is the sampling error and “Z” a percentile of the standard normal distribution^(15,16). The population considered for the sample calculation included 403 patients. This population size was based on the mean number of patients received in the service from January to May 2022. A period of three months was considered for data collection. Additionally, sampling error of 5% was considered, as well as a significance level of 5%.

Instruments and data collection

Data was collected over 10 months, from June 2023 to April 2024, using a structured instrument specifically developed for this study. This instrument was analyzed by the researchers and by members of the research team they form. The content of the instrument was

used to create a form in Google Forms®, being organized in three steps.

The first included nursing records based on NANDA-I domains, such as nutrition, elimination and exchange, comfort, activity/rest, and safety/protection. Its content included information about the identification of the dyad, characteristics of mother and child, and aspects to be investigated regarding their health status, according with the domains mentioned.

The second part of the instrument was an observation of the breastfeeding itself using the original version of a form developed in 2003⁽¹⁷⁾. This form included signs that breastfeeding is adequate and potential signs of issues, including the position of mother and baby, the answers of the dyad, affection, anatomy of the breasts, and suction, which helped reaching a systematic validation. The score contemplates behaviors and signs considered to be negative in the context of breastfeeding, and the lower it is, the better. There is a different score for each behavior, and their sum is classified as good, regular, or bad. This information subsidized an evaluation about which Defining Characteristics (DCs) were pertinent in each case. The content of the breastfeeding observation form is similar to that of some DCs and was used to confirm whether the score that indicates issues was also present when the diagnosis was stated.

The third part of the instrument was formed by NDs related to Breastfeeding, (Insufficient breast milk production, Interrupted breastfeeding, Readiness for enhanced breastfeeding), presenting their title, defining characteristics, related factors, risk populations, and associated conditions. Their content was reviewed and validated in another study, which will soon be published. This study only used data about the ND "Insufficient breast milk production" (00216)⁽¹¹⁾. There was a meeting between researchers to decide whether each dyad had this diagnosis. Based on the data collected in parts 1 and 2 of the instrument, we considered the prevalence of the elements of the ND and the context provided by the clinical history.

Before data collection, the researcher explained the goals of the research to the mothers and asked them to sign an informed consent (one copy of this document was left with them). An available office was used to collect outpatient clinic data. In the JA sector, data was collected in the room of the patient. Data was collected on a single occasion, by a researcher who is a

consultant accredited in breastfeeding, and a specialist in neonate nursing.

Data was collected using a tablet that had the instrument, which was also inserted in the Google Forms® app. After the baby was validated, the researcher observed one breastfeeding, from start to finish, after the mother and the health team allowed it. Later, the data was complemented via a consultation to the records.

NDs accuracy was assessed by calculating measures of sensitivity, specificity, and positive and negative predictive values⁽¹⁴⁾. Sensitivity (SE) is the proportion of subjects with the nursing diagnosis in whom a clinical element is present; Specificity (SP) is the proportion of subjects without the diagnosis in whom the diagnostic element is absent; Positive Predictive Value (PPV) is the percentage of people who present the clinical element and actually have the diagnosis of interest; and Negative Predictive Value (NPV) is the percentage of people who do not present the clinical indicator and do not present the diagnosis of interest. We assumed, empirically, that values above 50% (0.500) already show a relevant discrimination power regarding the accuracy measures of the diagnostic elements. This value was also used by other authors⁽¹⁸⁾.

Comparisons involving this ND and quantitative variables, such as days of life, weight, gestational age, and others, were carried out using the unpaired Student's t test, or Mann-Whitney's, depending on data distribution. Data distribution was assessed using the Shapiro-Wilk test. To evaluate the associations between the diagnosis and the qualitative characterization variables, such as data collection place, mother risk factors, gestational age classification, and others, we applied Pearson's chi-squared test. In cases that did not meet the requirements to use the chi-squared test, we applied Fisher's exact. The analyses were conducted using the software Statistical Analysis System (SAS), version 9.4, considering a significance level of 5%.

Ethical aspects

This research complied with Resolution 466/2012 of the National Health Council⁽¹⁹⁾ and was approved by the Research Ethics Committee (CEP) of the State University of Campinas (UNICAMP), under opinion number 5.155.642/2021, CAAE: 47578821.0.0000.5404. All participants signed two copies of the consent form and kept one of them.

■ RESULTS

The study included 205 dyads, 136 (66.34%) of which were in the JA, while 69 (33.66%) were receiving care in the neonate outpatient clinic. The mothers were aged from 18 to 44 (mean: 28.73; SD+6.04). Considering the 138 (67.32%) who described their marital status as “cohabiting”, the length of their relationship varied from 1 month to 22 years, with a median of 5.00 years (Table 1).

Women had from 1 to 13 pregnancies (median: 2; SD+1.54). Regarding the type of their last delivery, 90 (43.91%) had a vaginal delivery, while 115 (56.10%) had a cesarean section. When asked about pregnancy complications, 37 (18.05%) of them had had hypertensive diseases; and 34 (16.59%), decompensation of diabetes mellitus. Regarding their comorbidities, 31 (15.12%) were obese; 36 (17.56%) hypertensive; 18 (8.78%) had diabetes mellitus; and 21 (10.24%) other

Table 1. Characterization of mothers and babies. Campinas, São Paulo, Brazil, 2024. (n = 205).

Variable		n	%	
Mothers				
City of residence	Campinas	95	46.34	
	Other cities in the region	110	53.66	
Self-declared skin color	White	89	43.41	
	Brown	91	44.39	
	Black	24	11.71	
	Indigenous (native)	1	0.49	
Educational level	Incomplete elementary school	11	5.37	
	Complete elementary school	19	9.27	
	Incomplete high school	24	11.71	
	Completed high school	116	56.59	
	Incomplete higher education	10	4.88	
	Complete higher education	24	11.71	
	Post-graduation	1	0.49	
Marital status	No cohabitation	67	32.68	
	Cohabitation	138	67.32	

Table 1. Cont.

Variable		n	%
Family income	< 1 minimum wage	4	1.95
	From 1 to 2 minimum wages	48	23.41
	From 2 to 3 minimum wages	70	34.15
	From 3 to 4 minimum wages	39	19.02
	≥ 5 minimum wages	25	12.2
	Does not know	19	9.27
Babies			
Sex	Female	96	46.83
	Male	109	53.17
Classification by gestational age	Preterm newborn	36	17.56
	Full-term newborn	169	82.44
Classification by weight and gestational age	Adequate for gestational age	190	92.68
	Small for gestational age	5	2.44
	Large for gestational age	10	4.88

Source: Study data, 2024.

endocrine diseases. Regarding the babies, most were male (n=109; 53.17%), from 2 to 37 days of life, with an average of 3.99 days.

Gestational age ranged from 34.28 to 41.85 weeks, with a mean of 38.20 weeks according to ultrasound and 38.37 (SD±1.38) considering the Capurro method (SD±1.38). Birth weight ranged from 2040g to 4820g, with a median of 3077g (SD±477.25). Most babies did not need resuscitation maneuvers in the delivery room (n=176; 85.85%), did not receive formula at any time (n=188; 91.71%), did not use pacifiers (n=185; 90.24%), were never hospitalized (n=188; 91.71%), and were on exclusive breastfeeding (n=191; 93.17%).

As for the results of the application of the breast-feeding observation form, most of the dyads showed signs considered good for all items evaluated: mother/baby position (n=184; 89.76%); responses of the dyad (n=191; 93.17%); affection of the dyad (n=201; 98.05%); anatomy of the breasts (n=136; 66.34%); and sucking (n=176; 85.85%).

Table 2 shows the frequency with which elements of the studied diagnosis were identified in the sample. It stands out that identifying these elements does not mean confirming the diagnosis itself. Only 10 (4.88%) of the 205 dyads presented the ND “Insufficient breast milk production” (00216).

Table 2. Frequency of the elements of the diagnosis “Insufficient breast milk production” (00216) in the sample. Campinas, São Paulo, Brazil, 2024. (n = 205).

Insufficient breast milk production (00216)	n	%
Defining characteristics		
Absence or decrease in breast signs and symptoms or low milk production even with stimulation of the nipple-areola complex		
No	203	99.02
Yes	2	0.98
Frequent crying episodes even after breastfeeding, during an observation period		
No	200	97.56
Yes	5	2.44
Constipation for age group		
No	205	100.00
Yes	0	0
Low weight gain for age group		
No	193	94.15
Yes	12	5.85

Table 2. Cont.

Insufficient breast milk production (00216)	n	%
Infant seeks to suckle at the breast in short intervals, feeding more than 12 times in 24 hours		
No	202	98.54
Yes	3	1.46
Infant eliminates small amounts of concentrated urine, with less than six to eight eliminations per day		
No	203	99.02
Yes	2	0.98
Infant shows resistance or refusal to suckle at breast		
No	204	99.51
Yes	1	0.49
Breast milk expressed from the breast is less than prescribed volume for hospitalized infant		
No	199	97.07
Yes	6	2.93
Delayed secretory activation of milk		
No	204	99.51
Yes	1	0.49
Prolonged breastfeeding time in several feedings over 24 hours		
No	200	97.56
Yes	5	2.44
Related factors		
Unsustained suckling at breast		
No	200	97.56
Yes	5	2.44

Table 2. Cont.

Insufficient breast milk production (00216)	n	%
Maternal malnutrition		
No	205	100.00
Insufficient frequency of breast stimulation by sucking or expressing		
No	203	99.02
Yes	2	0.98
Ineffective latching on to breast		
No	199	97.07
Yes	6	2.93
Infant's refusal to breastfeed		
No	204	99.51
Yes	1	0.49
Ineffective sucking reflex		
No	204	99.51
Yes	1	0.49
Maternal smoking		
No	204	99.51
Yes	1	0.49
Maternal dehydration		
No	205	100.00
Yes	0	0
Perception of insufficient breast milk production		
No	199	97.07
Yes	6	2.93
Associated conditions		

Table 2. Cont.

Insufficient breast milk production (00216)	n	%
Maternal alcoholism		
No	205	100.00
Yes	0	0
Maternal treatment regimen with medications that reduce milk production		
No	205	100.00
Yes	0	0
Pathophysiological changes that reduce or prevent lactogenesis		
No	205	100.00
Yes	0	0
Psychic changes that reduce or prevent lactogenesis		
No	203	99.02
Yes	2	0.98
Populations at risk		
Women who become pregnant while breastfeeding		
No	205	100.00
Yes	0	0
Women with multiple pregnancies		
No	205	100.00
Yes	0	0
Women with insufficient professional, family, and/or social support regarding breastfeeding		
No	205	100.00
Yes	0	0

Table 2. Cont.

Insufficient breast milk production (00216)	n	%
Mothers of premature infants		
No	198	96.59
Yes	7	3.41
PRESENCE OF THE DIAGNOSIS		
No	195	95.12
Yes	10	4.88

Source: Study data, 2024.

Regarding the accuracy of the ND elements, values above 50% were considered significant, with sensitivity being considered as the most relevant element (Table 3). The DC “Low weight gain for age group” was the only element that stood out in terms of sensitivity (60%), with $p < 0.0001$.

Despite their low sensitivity, most DCs show relevant values of specificity, PPV and NPV, including: Absence or decrease in breast signs and symptoms or low milk production even with stimulation of the nipple-areolar complex ($p < 0.0022$); Frequent crying episodes during observation even after breastfeeding ($p < 0.0001$); Low weight gain for age group (< 0.0001); Infant voids small amounts of concentrated urine ($p = 0.0022$); Breast milk extracted from the breast is less than the volume prescribed to a hospitalized infant ($p < 0.0001$); and Prolonged breastfeeding time in several feedings over 24 hours ($p < 0.0001$).

Regarding related factors, no elements presented a sensitivity greater than 50%. On the other hand,

however, the values of specificity, PPV, and NPV were significant for: Unsustained suckling at breast ($p = 0.0008$); Insufficient frequency of breast stimulation by sucking or expressing ($p = 0.0022$); Ineffective latching on to breast ($p = 0.0016$); Ineffective sucking reflex ($p = 0.0488$); and Perception of insufficient breast milk production ($p < 0.0001$). Some diagnostic elements could not be tested, as they did not show up in the sample.

A comparison of the quantitative data analyzed showed no statistically significant result. In turn, there was a statistically significant association between several qualitative variables, including diabetes mellitus ($p = 0.0463$), type of delivery: cesarean section ($p = 0.0451$), use of formula ($p < 0.0001$), Recent use of formula ($p < 0.0001$), and Type of breastfeeding: mixed ($p < 0.0001$). Some variables in the breastfeeding observation instrument could also be associated with the diagnosis “Insufficient breast milk production” (002016), including: “Regular position of mother and baby” ($p < 0.0001$), and “Regular breast sucking” ($p = 0.0061$).

Table 3 - Distribution of the accuracy measurement of the elements of the ND “Insufficient breast milk production” (00216). Campinas, São Paulo, Brazil, 2024. (n = 205).

Diagnostic elements	Accuracy measurements*					
	Sens %	Spec %	Prev %	PPV %	NPV %	p-value†
Defining characteristics						
Absence or decrease in breast signs and symptoms or low milk production even with stimulation of the nipple-areola complex	20.0	100.0	4.8	100.0	96.0	<0.0022
Frequent crying episodes even after breastfeeding, during an observation period	40.0	99.4	4.8	80.0	97.0	<0.0001
Constipation for the age group	0.0	100.0	4.8	-	95.1	-
Low weight gain for age group	60.0	96.9	4.8	50.0	97.9	<0.0001
Infant seeks to suckle at the breast in short intervals, feeding more than 12 times in 24 hours	30.0	100.0	4.8	100.0	96.5	<0.0001
Infant eliminates small amounts of concentrated urine, with less than six to eight eliminations per day	20.0	100.0	4.8	100.0	96.0	0.0022
Infant shows resistance or refusal to suckle at breast	0.0	99.4	4.8	0.0	95.1	1.0000
Breast milk expressed from the breast is less than prescribed volume for hospitalized infant	50.0	99.4	4.8	83.3	97.4	<0.0001
Delayed secretory activation of milk	10.0	100.0	4.8	100.0	95.5	0.0488
Prolonged breastfeeding time in several feedings over 24 hours	40.0	99.4	4.8	80.0	97.0	<0.0001
Related factors						
Unsustained suckling at breast	30.0	98.9	4.8	60.0	96.5	0.0008
Maternal malnutrition	0.0	100.0	4.8	-	95.1	-
Insufficient frequency of breast stimulation by sucking or expressing	20.0	100.0	4.8	100.0	96.0	0.0022
Ineffective latching on to breast	30.0	98.4	4.8	50.0	96.4	0.0016
Infant's refusal to breastfeed	0.0	99.4	4.8	0.0	95.1	1.0000
Ineffective sucking reflex	10.0	100.0	4.8	100.0	95.5	0.0488

Table 3. Cont.

Diagnostic elements	Accuracy measurements*					
	Sens %	Spec %	Prev %	PPV %	NPV %	p-value†
Maternal smoking	0.0	99.4	4.8	0.0	95.1	1.0000
Maternal dehydration	0.0	100.0	4.8	-	95.1	-
Perception of insufficient breast milk production	50.0	99.4	4.8	83.3	97.4	<0.0001
Associated conditions						
Maternal alcoholism	0.0	100.0	4.8	-	95.1	-
Maternal treatment regimen with medications that reduce milk production	0.0	100.0	4.8	-	95.1	-
Pathophysiological changes that reduce or prevent lactogenesis	0.0	100.0	4.8	-	95.1	-
Psychic changes that reduce or prevent lactogenesis	20.0	100.0	4.8	100.0	96.0	0.0022
Populations at risk						
Women who become pregnant while breastfeeding	0.0	100.0	4.8	-	95.1	-
Women with multiple pregnancies	0.0	100.0	4.8	-	95.1	-
Women with insufficient professional, family, and/or social support regarding breastfeeding	0.0	100.0	4.8	-	95.1	-
Mothers and premature babies	20.0	97.4	4.8	28.5	95.9	0.0396

Source: Study data, 2024.

*Abbreviations: Sens = sensitivity; Spec = specificity; Prev = prevalence; PPV = positive predictive value; NPV = negative predictive value; †p-value obtained using Fisher's exact test.

■ DISCUSSION

Considering the characteristics of the total sample, the participants are young women, with partners, previous experience breastfeeding, and an educational level that allows them to have access to information about self-care and breastfeeding, which has been pointed out in literature as factors that facilitate this activity⁽²⁰⁾. Owing to the fact it is a reference for women in over 40 cities, this hospital receives women with comorbidities who need a cesarean section, and these factors can have an impact on breastfeeding⁽²¹⁾.

6 (60%) of the mothers that presented the ND "Insufficient breast milk production" (00216) presented the DC "Low weight gain for age group", with a specificity level considered to be predictive of this diagnosis. The lack of this DC was relevant, in the total sample, to indicate the absence of the ND (NPV = 97.9%).

Seen as low milk production reduces the appropriate weight gain of the baby, and considering that a newborn is expected to gain 25 to 30 grams a day or 700 grams a month in their first trimester, the DC "Low weight gain for age group" can be considered a relevant sign of this diagnosis. This became clear in

the sample studied, as it reached a sensitivity of 60%, specificity of 96.9%, and NPV of 97.9% ($p < 0.0001$). We considered this DC to be present when the newborn lost more than 10% of their weight at birth, or did not gain as much weight as expected for their age group⁽⁵⁾.

An important predictor for successful breastfeeding is the lactogenesis II stage, which starts after the placenta is no longer present and reaches its peak from 24 to 72 hours after delivery. After 72 hours have passed, the lactation is already considered to be delayed⁽⁶⁾. Some studies show that diabetic mothers are less likely to provide exclusive breastfeeding, and provide it for a shorter period than women considered healthy⁽⁶⁾, due to a delay in this stage. Some of the risk factors for delays in lactogenesis II include the stress during delivery and the fear that emerges when a cesarean section shows itself necessary^(6,22). This stress reduces oxytocin and prolactin, reducing the production of milk and delaying lactogenesis II, consequently delaying the start of milk production. The late onset of breastfeeding is a negative consequence of this type of delivery according to some national and international studies, according to which babies born vaginally are more likely to feed in the first hour of life when compared to babies born in c-sections. Thus, in the context of this study, the absence of the DC "Delayed breast milk production" was determinant for the absence of the ND "Insufficient breast milk production" (00216) (NPV= 95.5%)⁽²¹⁾.

This is not in accordance with the association analysis involving the ND "Insufficient breast milk production" (00216), which showed a statistically significant result regarding the dyads with an ND that also showed diabetes and cesarean sections.

Furthermore, studies^(6,22) showed that the early introduction of formula influences the lactogenesis II stage, potentially leading to insufficient breast milk production and, consequently, low child weight gain, with signs that correspond to the DCs of the ND being studied here, such as babies that void little amounts of urine, and the search for sucking in shorter and more frequent intervals every 24 hours. Considering the accuracy tests, the lack of the DCs "Infant seeks to suckle at the breast in short intervals, feeding more than 12 times in 24 hours" and "Infant eliminates small amounts of concentrated urine, with less than six to eight eliminations per day" showed that these are relevant clinical

indicators to determine the lack of the ND, with a NPV of 96.5% and 96%, respectively.

Considering the dyads with this ND, in addition to the fact that the data was collected from a baby-friendly hospital, the artificial milk was introduced after an evaluation by the health team, considering the perception of insufficient milk production in the joint accommodations and the attempts to recover the weight and glycemic levels of the baby. The sample also included cases in which babies had been hospitalized in a neonate unit beforehand, which may have been an obstacle for the beginning of the formation of a bond and early breastfeeding. The relationship between the use of formula and the presence of the ND "Insufficient breast milk production" (00216) was also statistically significant ($p < 0.0001$). These results corroborate literature, showing the relevance of early feeding, exclusive breastfeeding, and professional support^(6,7) for breastfeeding to be established - especially when the mother and the child must be separated.

The breastfeeding observation form showed that regular and bad results with the items "Positioning of the baby" (p -value < 0.0001) and "Suction" ($p = 0.0061$) also had a significant association with the presence of the ND. Studies have shown that poor latching and positioning, as well as restricted time for breastfeeding, use of complements, and use of pacifiers and baby bottles can contribute to a low production of milk⁽⁵⁾.

A study⁽²³⁾ carried out using Hill and Humenick Lactation Scale to evaluate the perception of maternal milk supply highlighted their insecurity regarding the amount of milk produced for the baby, demonstrating concern about their ability to produce the volume appropriate to the needs of their child. This insecurity, coupled with a lack of professional support, can cause the mother to feel anxious and introduce formula too early^(4,23,24), which will be another factor to reduce milk production. The absence of the associated condition "Psychic changes that reduce or prevent lactogenesis" was also relevant to indicate the absence of the ND (NPV=96%).

Some DCs in this sample were found to be predictors of the ND "Insufficient breast milk production" (00216) despite showing a sensitivity below 50%, namely: "Breast milk expressed from the breast is less than prescribed volume for hospitalized infant" and RF "Perception of

insufficient breast milk production". Both were clinically relevant, had a specificity of 99.4%, PPV of 83.3%, and NPV of 97.4% ($p < 0.0001$).

Nurses must have clinical experience in handling breastfeeding and knowledge about standardized nursing language, so they can better differentiate phenomena related to breastfeeding by identifying them. This study shows that there is no single DC that ensures that the diagnosis being studied can be identified, but there is a set of elements in clinical history that help the reasoning process, to determine which diagnostic elements better describe what is being experienced by the mother and her child, especially differentiating it from other diagnoses, such as "Ineffective breastfeeding".

A limitation of the study includes the fact it was carried out by a single researcher. Despite the expertise of the researcher involved, including more than one breastfeeding expert, with the use of a standardized nursing language, could reduce the clinical reasoning bias throughout the definition of the diagnoses. An attempt was made to lessen this issue by carrying out a consensus meeting, in which other researchers also evaluated clinical history and the final decision about which diagnoses should be identified for each participant.

Another limitation was the long period of data collection and the low number of participants from outpatient clinics in the JA. This was due to the lower number of patients being cared for in the outpatient clinics due to the COVID-19 pandemic and the then ongoing building renovation, which meant that data collection had to be prolonged to reach the necessary sample.

■ CONCLUSION

The ND "Insufficient breast milk production (00216)" was clinically validated and identified in only ten dyads (4,8%). This low prevalence showed how important clinical reasoning is to better identify this phenomenon and differentiate it from others, such as "Ineffective breastfeeding", which precedes it but can take place simultaneously.

Our results show relevant elements to identify the presence of the ND, such as: Low weight gain for age group; Absence or decrease in breast signs and

symptoms or low milk production even with stimulation of the nipple-areola complex; Infant seeks to suckle at the breast in short intervals, feeding more than 12 times in 24 hours; Infant eliminates small amounts of concentrated urine, with less than six to eight eliminations per day; Delayed secretory activation of milk; Insufficient frequency of breast stimulation by sucking or expressing; Ineffective sucking reflex; Psychic changes that reduce or prevent lactogenesis.

The diagnosis studied here was found to be present in clinical practice, despite not being much prevalent in the study sample. Statistical tests showed that no single element from our sample functioned as a predictor of the ND "Insufficient breast milk production" (00216), and instead, there was a set of predictive elements. This requires the nurse to observe the situation with a critical and clinical look, to differentiate this diagnosis from other breastfeeding-related ones.

Future research should investigate this diagnosis in samples with children of other ages, who were breastfeeding for longer, to ascertain whether the ND elements behave the same in these cases. Furthermore, to increase reliability and reduce bias, it is ideal to have more than one researcher collecting data from the same dyad simultaneously and independently, both researchers being experienced and trained in breastfeeding and in the use of standardized nursing language.

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■ Data and material availability

The dataset may be accessed upon request to the corresponding author.

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■ Conflict of interest

The authors declare that there is no conflict of interest.

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