



Medicine consumption during breastfeeding and assessment of infant risk*

Consumo de medicamentos durante a amamentação e avaliação do risco ao lactente

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Objective: to estimate medicine consumption during breastfeeding and the risk to the infant. **Methods:** descriptive study, carried out in a Primary Health Care Unit with 130 infants. The data collection was done through a form with objective questions, analyzed in Epiinfo. **Results:** 73 (56.0%) nursing mothers had used medication during breastfeeding. The most used drugs were antianemics (n=48, 66.0%) and analgesic/antipyretic drugs (n=11, 14.4%). The majority of the drugs consumed were compatible with breastfeeding (n=71, 97.2%), except for Phenobarbital (n=1, 1.4%) and Losartan (n=1, 1.4%). **Conclusion:** it was evidenced that medicine consumption during breastfeeding was high among nursing mothers, but most of the drugs presented low risk, that is, they were drugs compatible with lactation.

Descriptors: Nursing; Breast Feeding; Drug Utilization; Lactation.

Objetivo: estimar o consumo de medicamentos durante a amamentação e o risco para o lactente. **Métodos:** estudo descritivo, realizado em Unidade de Atenção Primária à Saúde com 130 lactantes. A coleta de dados ocorreu por meio de formulário com perguntas objetivas, sendo analisados no *Epiinfo*. **Resultados:** usaram medicação durante a amamentação 73 (56,0%) lactantes. Os medicamentos mais utilizados foram antianêmico (n=48; 66,0%) e analgésico/antipirético (n=11; 14,4%). A maioria dos medicamentos consumidos era de uso compatível com a amamentação (n=71; 97,2%), exceto o Fenobarbital (n=1; 1,4%) e o Losartana (n=1; 1,4%). **Conclusão:** evidenciou-se que o consumo de medicamentos durante a amamentação foi alto entre as lactantes, porém foi visto que a maioria dos medicamentos apresentou baixo risco, ou seja, eram drogas compatíveis com a lactação.

Descritores: Enfermagem; Aleitamento Materno; Uso de Medicamentos; Lactação.

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Introduction

It is estimated that the risk of congenital malformations in the general population is 1 to 2.0%, being the second cause of infant mortality. In Brazil, about 2.0 to 5.0% of the newborns present some type of congenital anomaly⁽¹⁾. About 60.0% of the congenital anomalies have unknown origin, but the others are associated with environmental factors such as physical (radiation), biological (infections), genetic (hereditary) and chemical (exposure to substances) factors⁽²⁾.

As for exposure to substances, the major problem for maternal and child health happens during gestation and lactation, and may cause teratogenic effects for the child. Although knowledge about lactating drugs has expanded, all the side effects for children who are breastfed by women who had used multiple drugs are not yet known. In addition, the effects of new drugs have not yet been adequately studied or literature presents divergences regarding their use during lactation⁽³⁾.

Currently, medicalization during breastfeeding has been frequent, and this prescription is criticized, since the risk-benefit assessment should take into account aspects regarding the benefits of breastfeeding, the impact of the symptoms and the disease on maternal health, as well as the consequences for the newborn⁽⁴⁻⁵⁾.

There is a great lack of information on the safe use of drugs during lactation, which makes it difficult to make decisions at the moment of prescription or guidance by the professionals. Therefore, when the drug use is clinically indicated, professionals should choose an already studied drug that is little excreted in breast milk or that has no apparent risk⁽³⁾.

Research conducted in the Southeast Region of Brazil, which involved 100 women, showed a high number of nursing mothers using medications, all compatible with breastfeeding. The authors emphasized the limited participation of the multidisciplinary team in providing guidance to this clientele⁽⁶⁾.

In this sense, there are still few studies estimating drug use and assessing potential risks to which babies breastfed by mothers using these drugs are exposed. In addition, the effects of many new drugs have not yet been properly studied or are diverging in the literature when used during lactation.

The relevance of this study is its contribution to knowledge about medicine consumption among breastfeeding mothers and its potential risks, which may help in the planning of specific strategies to reduce this demand, as well as its consequences for the binomial mother-baby.

Therefore, there is a need for constant updates on the use of medications during breastfeeding, in order to rationalize this use, to protect the mother and the baby and to maintain breastfeeding. Thus, the objective of this study was to estimate the consumption of medications during breastfeeding and the risk to the infant.

Methods

This is an exploratory study carried out in a Primary Health Care Unit in the city of Fortaleza-Ceará during the months of June and July 2015. The study population was composed of mothers who were breastfeeding. To select the sample, the following criterion was adopted: being mother of child under the age of two years. The exclusion criterion was being a woman with cognitive and/or mental problems that make it impossible to understand the instruments.

The formula for finite populations was used for the sample calculation based on the number of children enrolled in the Primary Health Care Unit. According to data provided by the unit, there were 320 children followed up at the child care clinic. The variable "breastfeeding prevalence" was considered, estimating a prevalence of exclusive breastfeeding in infants under six months of 41.0%⁽⁷⁾. The confidence level used was 95.0% and a sample error of 5.0%, thus obtaining a sample size of 147. A total of 17 partici-

pants were eliminated for missing data in the collection phase so that the final sample was composed of 130 mothers.

The selection of the sample occurred by means of consecutive sampling in which the entire population was accessible over a period of time. Women were approached before or after childcare consultations in a private setting and were guided about the research procedures. It should be noted that, for women under the age of 18, the legal guardian's signature was requested.

To collect data, a form containing information on socioeconomic data, obstetric history and drug use during breastfeeding was used. The data obtained were compiled in spreadsheets in the program Excel 2010 and, later, the statistical analysis was carried out in Epi Info version 3.5.3. The exploratory analysis of the data consisted of absolute and relative frequencies, means and standard deviations. Nominal variables were analyzed using the Chi-square test and the Fisher's exact test. It was adopted $p < 0.05$ as significance level.

In order to evaluate the risk of drug use during breastfeeding, the Ministry of Health Manual was used: Breastfeeding and use of drugs and other substances, being classified as: compatible use with breastfeeding, careful use during breastfeeding and contraindicated use during breastfeeding⁽³⁾. The data were presented in tables.

The study complied with the formal requirements contained in the national and international regulatory standards for research involving human beings.

Results

The participants' age ranged from 14 to 43 years, with a mean of 26 years ($SD \pm 4.8$). Table 1 presents the socioeconomic profile of mothers regarding the use of medicines.

Table 1 - Socioeconomic characterization of nursing mothers regarding the use of medicines

Variable	Use of medicines	Non-use medicines	p*
	n (%)	n (%)	
Age			
< 20	15 (22.0)	16 (25.0)	0.187*
21-30	34 (51.0)	30 (48.0)	
≥ 31	18 (27.0)	17 (27.0)	
Marital status			
Married/stable union	37 (55.0)	37 (59.0)	0.410**
No partner	30 (45.0)	26 (41.0)	
Schooling (years)			
1 - 4	3 (5.0)	2 (3.0)	1.229*
5 - 8	10 (15.0)	14 (22.0)	
≥ 9	54 (80.0)	47 (75.0)	
Occupation			
Employed	18 (27.0)	16 (25.0)	0.504**
Unemployed/Housewife	49 (73.0)	47 (75.0)	
Monthly income (Minimum wage)			
< 788.00	33 (49.0)	41 (65.0)	0.049**
≥ 788.00	34 (51.0)	22 (35.0)	

*Chi-square test; **Fisher's exact test

It was evidenced that women who did not use drugs had income below a minimum wage ($p = 0.049$). Table 2 presents the obstetric profile of mothers regarding the use of medicines.

Table 2 - Obstetric characterization of nursing mothers regarding the use of medicines

Variable	Use of medicines	Non-use medicines	p*
	n (%)	n (%)	
History of malformations			
Yes	1 (2.0)	-	0.515
No	66 (98.0)	63 (100.0)	
Planned pregnancy			
Yes	25 (37.0)	30 (48.0)	0.156
No	42 (63.0)	33 (52.0)	
Number of consultations performed during prenatal care			
< 6	15 (23.0)	34 (54.0)	0.001
≥ 6	52 (77.0)	29 (46.0)	
Type of birth			
Vaginal	29 (43.0)	27 (43.0)	0.551
Cesarean section	38 (57.0)	36 (57.0)	
Presence of malformation			
No	67 (100.0)	63 (100.0)	-

*Fisher's exact test

The number of prenatal consultations ranged from 1 to 15 ($M=7$). It was evidenced that among the women who performed more than six prenatal visits, 77.0% had used medicines ($p=0.001$). Of the 130 nursing mothers, 57 (44.0%) had not use any medicines, while 73 (56.0%) had used some type of medicine.

Table 3 shows the medicines used by nursing mothers according to the Ministry of Health's risk classification.

Table 3 - Medicines used during lactation according to the Ministry of Health's risk classification

Medicine	Use compatible with	Careful use during
	breastfeeding	breastfeeding
	n (%)	n (%)
Ferrous sulphate	48 (66.0)	-
Paracetamol	7 (9.0)	-
Dipyron	4 (5.4)	-
Propranolol	1 (1.4)	-
Aluminum hydroxide	1 (1.4)	-
Omeprazole	1 (1.4)	-
Paroxetine	1 (1.4)	-
Cephalexin	1 (1.4)	-
Fexofenadine	1 (1.4)	-
Amoxicillin	1 (1.4)	-
Captopril	1 (1.4)	-
Methyl dopa	1 (1.4)	-
Fluoxetine	1 (1.4)	-
Polyvitamins	1 (1.4)	-
Metformin	1 (1.4)	-
Losartan Potassium	-	1 (1.4)
Phenobarbital	-	1 (1.4)

The most commonly used drugs were antianemics (66.0%) followed by analgesics (14.4%). When asked about indication of drug use, most mothers (95.0%) reported they were prescribed by the health professional and only 5.0% practiced self-medication.

Discussion

This study did not conduct follow-up of children over a period to assess the consequences of long-term drug use. And despite having reached the previously calculated sample, there were data losses due to the need for maternal memory, since it requires the mother to remember a drug exposure that may have occurred months before the collection, which was one of the limitations of the study. Likewise, the data may be underestimated.

Regarding the socioeconomic variables, of the women who had not use drugs, the majority presented income below R\$ 788.00 ($p=0.049$). Low income may be a factor that hinders the purchase of prescribed drugs during follow-up in the pregnancy-puerperal cycle. In a survey involving 1,593 individuals living in the southern region of Brazil, it was pointed out that the low adherence to drug treatment was associated with the fact that the patient had to buy their medication, and this cost was expensive ($p=0.001$)⁽⁸⁻⁹⁾.

It was evidenced that, among women who had performed more than six prenatal consultations, 77.0% had used medicines ($p=0.001$). This fact makes us question what kind of orientation is being provided in prenatal consultations, especially on minimizing the use of medicines and drugs during breastfeeding.

On the other hand, this finding indicates how much nursing mothers have been following the care prescribed during the consultations. This effect is distinct from a research that aimed to evaluate the self-reported therapeutic adherence during gestation in Brazilian women. It showed a low adherence rate to drug treatment, indicating a need for further investigation on the impact of non-adherence during pregnancy and its causes⁽¹⁰⁾.

It was possible to realize that the use of medication during lactation is still a common practice in the present day. A study involving 132 nursing mothers of a basic health unit in the municipality of Caucaia, Ceará, pointed out a prevalence of 80.0% in the use of medicines among nursing mothers. This is something

to be analyzed considering that it can have repercussions for the baby⁽⁴⁾.

Another worrying factor regarding this drug exposure is the performance of health professionals, who sometimes discourage women from breastfeeding, preventing the mother and child from enjoying the benefits of breastfeeding, leading to early weaning⁽¹¹⁾.

The present study evidenced that most of the medicines used by the nursing mothers were compatible with the breastfeeding. This finding resembles that of recent research, which also noted that few drugs have been shown to be absolutely contraindicated during breastfeeding, however, clear, safe and reliable information is still lacking for most drugs⁽¹¹⁻¹²⁾.

The use of medicines by nursing mothers depends on the risk/benefit assessment. It is necessary to establish criteria for prescription and, when used, clinical and/or laboratory monitoring of the infant should be carried out, and drugs should be used during the shortest time and in the smallest dose possible by the nursing mothers⁽¹³⁻¹⁴⁾.

The rational use of medications during breastfeeding is justified by the fact that most of the licit and illicit drugs used by the nursing woman can modify the production, volume and composition of breast milk, and can have harmful short- and long-term effects on the breastfeeding child. Thus, the prescribing professional must take into account three fundamental factors: pharmacokinetics, risk assessment for the child and for lactation⁽³⁾.

Corroborating with the findings of this study, a study conducted with a sample of Brazilian women showed that 96.9% of the pregnant women had used some medication during pregnancy, of which the main classes prescribed were: antianemics (55.1%); analgesics, anti-inflammatories and antipyretics (19.0%); and anti-infectives (7.2%)⁽¹⁰⁾. Disagreeing with this finding, a study carried out with 132 nursing mothers of a primary health unit showed a higher prevalence of non-steroidal anti-inflammatory drugs (58.0%), and it was emphasized that most (58.3%) women re-

ported not receiving guidance on the use of medication during lactation⁽⁴⁾.

As for the more restricted drugs during breastfeeding identified in this sample, Losartan is of careful use because there is no data on the transfer of this drug to breast milk and it should be avoided in the neonatal period. Its indication should only be given when no other angiotensin-converting enzyme inhibitor can be used. In the case of Phenobarbital, it may cause rare adverse effects in the infant, such as somnolence⁽³⁾. Thus, the importance of the professional doing rational and judicious use of these medications during lactation is reiterated.

Research conducted in Australia evaluated the provision or counseling on the use of medicines during breastfeeding and showed that community pharmacists discuss the use of medicines during lactation and are confident of their ability to act in that context⁽¹⁵⁾.

A positive aspect of this study was that most of the nursing mothers had used the drug as prescribed by the health professional. These findings corroborate a study conducted in Caucaia, Brazil in which it was evidenced that the majority of nursing mothers (58.0%) received an indication of the use of medicines by health professionals, and only 19.0% practiced self-medication⁽⁴⁾.

The knowledge of health professionals and nursing mothers about the risks of using medicines during lactation is important for the rational use of these substances. In a research that sought to identify the knowledge of medical prescribers and nursing mothers about the use of drugs during breastfeeding, it was pointed out that medical prescribers have knowledge about the use of medicines during breastfeeding, but the knowledge presented by the users on the subject is simple and not very consistent⁽¹⁶⁾. Thus, it is noticed that nursing mothers tend to adhere to health professionals' prescriptions regardless of the risks, since these women lack knowledge on this subject.

This research may raise health professional's awareness about an increasingly conscious prescrip-

tion for nursing mothers in order to reduce risks to the binomial mother-baby.

Conclusion

Medicine consumption during breastfeeding was high among the nursing mothers; however, most of the drugs presented low risk, that is, they were drugs compatible with lactation.

Most of the drugs used were prescribed by health professionals, showing that these prescribers have been evaluating the risk of drugs.

Collaborations

Chaves AFL and Rocha RS contributed to the design, analysis, interpretation of data, writing, critical review of content and final approval of the version to be published. Dias AHM, Dias IKA and Martins JKS contributed to the study design, data collection and interpretation. Oriá MOB contributed to the writing of the article and final approval of the version to be published.

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