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ORIGINAL ARTICLE

Twelve-month prevalence of breastfeeding among infants born in a Baby-Friendly Hospital

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Abstract

Introduction and Objectives: Baby-Friendly Hospitals' initiative upholds practices that promote and protect breastfeeding. Previous studies reveal high breastfeeding rates at discharge from maternity, with a progressive reduction over the first months of life. The objective of this study is to evaluate the epidemiology of breastfeeding during the first year of life and to identify factors that contribute to its maintenance. **Methods:** An observational, analytical, and cross-sectional study was carried out between February 2020 and March 2021. Data were obtained through a questionnaire carried out during hospitalization after delivery, and periodic telephone contacts during the following months, to assess the maintenance of breastfeeding. **Results:** This study included 201 mother-child dyads. The prevalence of breastfeeding at discharge was 97.5%; all preterm newborns were breastfed and 83.9% of term newborns were exclusively breastfed. The prevalence of breastfeeding at two, four, six, nine and 12 months was 82.6%, 70.6%, 64.7%, 51.2% and 36.3%, respectively. At six months, breastmilk was the only source of milk in more than 50% of cases, and 19.9% were exclusively breastfed, without complementary feeding. Skin-to-skin contact, favorable previous experience and employability were associated with higher breastfeeding rates. **Discussion:** This study highlights the importance of well-established practices in hospitals, such as skin-to-skin contact, to maintain breastfeeding. It also reveals the need to improve maternity support policies for working women. Reducing breastfeeding rates are responsible for adverse health effects, being its promotion a public health priority.

Keywords: Breastfeeding. Baby-Friendly Hospital. Weaning. Risk factors.

Prevalência do aleitamento materno até aos doze meses de vida em lactentes nascidos num Hospital Amigo Dos Bebés

Resumo

Introdução e Objetivos: A iniciativa Hospital Amigo dos Bebés defende práticas que promovem e protegem o aleitamento materno. Estudos prévios mostram taxas de aleitamento materno elevadas na alta da Maternidade, com um declínio progressivo ao longo dos primeiros meses de vida. É objetivo deste trabalho avaliar a epidemiologia do aleitamento materno no primeiro ano de vida e identificar os fatores que contribuem para sua manutenção. **Métodos:** Estudo observacional, analítico e transversal, realizado entre fevereiro de 2020 e março de 2021. Os dados foram obtidos através de um questionário realizado após o parto e contatos telefónicos nos meses seguintes, para avaliar a manutenção do aleitamento materno.

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Resultados: O estudo incluiu 201 díades mãe-filho. A prevalência de aleitamento materno na alta foi 97.5%; todos os recém-nascidos prematuros fizeram aleitamento materno e 83.9% dos recém-nascidos de termo fizeram aleitamento materno exclusivo. A prevalência de aleitamento materno aos dois, quatro, seis, nove e 12 meses foi 82.6%, 70.6%, 64.7%, 51.2% e 36.3%, respetivamente. Aos seis meses o leite materno era a única fonte de leite em mais de 50.0%, e 19.9% dos lactentes eram amamentados exclusivamente, não tendo iniciado diversificação alimentar. O contato pele-a-pele, uma experiência prévia favorável e a empregabilidade foram associados a maiores taxas de aleitamento materno. **Discussão:** Este estudo salienta a importância de práticas nas maternidades, como o contacto pele-a-pele, na manutenção do aleitamento materno. Revela ainda a necessidade de melhoria das políticas de apoio à maternidade das mulheres que trabalham. A redução da taxa de aleitamento materno tem efeitos adversos na saúde, pelo que a sua promoção constitui uma prioridade de saúde pública.

Palavras chave: Aleitamento materno. Hospital Amigo dos Bebés. Desmame. Fatores de risco.

Keypoints

What is known

– Breastfeeding is essential for the promotion and decline, especially after 6 months of life, is still present and reinforces the need for greater involvement of physicians and nurses in supporting breastfeeding.

What is added

– Skin-to-skin contact and early onset of protection of child health. The Baby-Friendly brestfeeding had a significant influence on breastfeeding up Hospitals initiative promotes the adoption of good to 12 months of life. A previous positive experience practices to support pregnancy, childbirth and post- and an intention to breastfeed for 12 months or partum. High breastfeeding rates at discharge from more are also associated with greater breastfeed-maternity have been observed in Portugal, with a ing rates. Despite the high rates of breastfeeding progressive reduction over the first months of life. at discharge from the hospital, the progressive.

Introduction

Breastfeeding is essential for the promotion and protection of child health and is recognized as a human right by the United Nations[1]. It has all the nutritional and immunological characteristics that infants need in the first months, being the food of choice in this age group. The World Health Organization (WHO) and the United Nations International Children's Emergency Fund (UNICEF) recommend exclusive breastfeeding (EBF) in the first six months of life and its association with complementary feeding until, at least, two years of age[2]. Together, WHO and UNICEF have promoted, over the years, multiple initiatives, including the Baby-Friendly Hospitals (BFH) initiative. It promotes the training of health professionals and the adoption of good practices related to hospital routines to support pregnancy, childbirth and postpartum, thus enabling mothers and families to breastfeed. There are 15 institutions recognized as BFH in Portugal.

Scientific evidence has demonstrated, over time, numerous advantages of breastmilk for the newborn, both in the short and long term[3]. Breastfeeding reduces infant mortality, sudden infant death syndrome, the incidence of necrotizing enterocolitis and infectious diseases. It also contributes to a reduction in obesity and Type two diabetes mellitus in the long term and is associated with better intellectual and academic performance levels[4]. Breastfeeding also contributes to the establishment of the bond between mother and child[5]. In Portugal there has been a positive evolution in breastfeeding practices and a significant improvement in the rate of EBF, especially at three and four months of life. The prevalence of breastfeeding at six months was much lower (only 30.3% in 2014)[6]. However, there are no recent data on the current breastfeeding prevalence at discharge, as well as its subsequent maintenance.

The aim of this study is to understand the epidemiology of breastfeeding among infants born in a BFH in the first 12 months of life and to analyze the factors that influence its maintenance or abandonment.

Methods

This was an observational, longitudinal, and analytical study that included newborns born in a certified BFH in Portugal. Data were obtained from a survey carried out between February and March 2020, involving all mothers who agreed to participate in the study

during the postpartum period. Subsequent periodic telephone contacts were carried out at two, four, six, nine and 12 months of life (or until cessation of breastfeeding), to assess the continuity of breastfeeding.

Exclusion criteria were gestational age less than 34 weeks, admission to a Neonatal Intensive Care Unit and the presence of contraindication to breastfeeding. All mothers signed an informed consent form.

The survey applied during hospitalization included several sociodemographic variables (mother's age; type of family: nuclear or not; educational level: ≤ 9th grade, 10th to 12th grade or higher education; and mother's professional status: employed or unemployed); variables related to pregnancy and childbirth (adequate pregnancy follow-up; parity: multiparous or not; gestational age: term or premature; type of delivery: vaginal or not; birth weight: more than 2500g or not; breastfeeding in the first hour of life; and skin-to-skin contact); and variables related to breastfeeding (previous positive breastfeeding experience; mother's knowledge about the benefits of breastmilk; and mother's expectation regarding the duration of breastfeeding).

Subsequent telephone contacts included questions such as: type of milk; age and reasons for cessation of breastfeeding and introduction of formula milk; age of introduction of complementary feeding; age of return to work and possibility to express milk in the workplace. The definitions currently recommended by the WHO for breastfeeding were used[7]. EBF was considered only if no formula milk was administered from birth to discharge.

Skin-to-skin contact was defined as the practice of laying the baby on the mother's chest in the first minutes of life and for at least an hour. If the newborn remained at the mother's chest for a period shorter than one hour, it was considered as not having performed skin-to-skin contact. This information was assessed by consulting the infants' clinical records.

Positive previous experience was defined as breastfeeding of a previous child for a period equal to or greater than 4 months. Mothers' knowledge about breastfeeding was considered positive if they could list two benefits of breastfeeding/breastmilk.

Univariate analysis was performed using the Chisquare/Fisher test for categorical variables; odds ratio (OR) and respective 95% confidence interval (95% CI) were calculated. Adjustment by logistic regression (RL) was performed in variables with statistical significance. The quality of fit was verified by the Hosmer and Lemeshow test and the model was verified by the Omnibus test. Statistical analysis was performed with IBM SPSS Statistics® version 26. The level of significance adopted in the study was $p < 0.05$.

This study was conducted according to the principles included in the Helsinki Declaration and was approved by the ethics committee of the institution where it was conducted.

Results

A total of 201 valid responses were obtained. The sociodemographic characterization of the studied cohort is shown in Table 1. Median maternal age was 32 years (minimum 14; maximum 47), mother's educational level was higher education in 46.8%, and 80.6% were employed. Among multiparous women (n = 93), 61.3% reported a positive previous experience in breastfeeding. 91.0% of all the mothers knew about the benefits of breastfeeding and the average expected breastfeeding time was 11.5 ± 7.2 months.

Among the newborns, 7.5% were premature (gestational between 34 and 37 weeks).

Skin-to-skin contact was performed in 61.7% of newborns (65.1% of term and 20.0% of preterm newborns), and all of these were breastfed within the first hour of life.

Breastfeeding was maintained throughout the maternity stay in 97.5% of newborns and EBF in 79.6% (83.9% of the full-term and 26.7% of the preterm newborns – Fig. 1). Formula milk was offered to 20.4% of newborns.

During the first 12 months of life, there was a progressive decline in the prevalence of breastfeeding (Fig. 2). At two and four months, respectively, 82.6% and 70.6% of mothers continued to breastfeed (59.7% and 57.2% EBF). At five months, 67.7% of mothers were still breastfeeding, 59.2% exclusively. At six months, breastmilk was the only source of milk offered in 54.2% of cases, and 19.9% of infants were exclusively breastfed and had not started complementary feeding. Breastfeeding rates at nine and 12 months were, respectively, 51.2% and 36.3%.

The median age of introduction of complementary feeding was five months. The median time of return to work was five months after delivery and 78.9% of the mothers reported being able to extract milk at the workplace.

Factors influencing the maintenance and cessation of breastfeeding

After applying the chi-square test, which identified several factors associated with higher rates of

Table 1. Characterization of sociodemographic, pregnancy and birth and breastfeeding data

Sociodemographic characteristics	n (%)
Education level ≤ 9th grade 10-12th grade Higher education	 33 (16.4) 74 (36.8) 94 (46.8)
Type of family: nuclear	195 (97.0)
Job: employed	162 (80.6)
Gestation and birth	**n (%)**
Adequate pregnancy follow-up	99.5%
Gestational age 34-37 weeks ≥ 37 weeks	 15 (7.5) 186 (92.5)
Parity: multiparous	93 (46.3)
Type of delivery: vaginal	158 (78.6)
Birth weight ≤ 2500g > 2500g	 15 (7.5) 186 (92.5)
Breastfeeding	**n (%)**
Previous positive experience (≥ 4 months)	57 (61.3*)
Knowledge about breastfeeding: knows two advantages	183 (91.0)
Intention to breastfeed 0-6 months 6-12 months 12-36 months	 85 (42.3) 77 (38.3) 39 (19.4)
Skin-to-skin contact: yes	124 (61.7)
Breastfeeding in the first hour of life: yes	124 (61.7)

*Among multiparous women; g: grams.

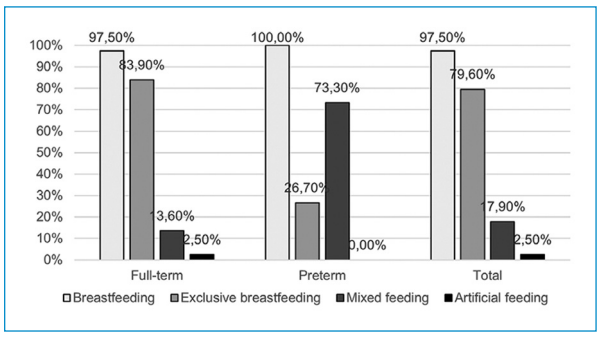

Figure 1. Prevalence of breastfeeding at discharge.

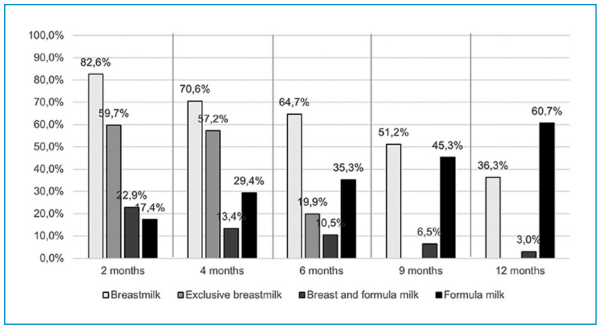

Figure 2. Prevalence of breastfeeding at 2, 4, 6, 9 and 12 months of age.

Availability of data: additional data are not publicly available.

breastfeeding (Tables 2 and 3), a multivariate model was applied to control confounding variables. Adjustment was performed in a logistic regression model of several cofactors: skin-to-skin contact, type of delivery, gestational age and positive previous experience.

After adjusting for logistic regression, the main factors that proved to be favorable to breastfeeding at discharge were (Table 2, adjusted OR): skin-to-skin contact, positive previous experience and gestational age greater than 37 weeks.

Cofactors most associated with breastfeeding and EBF between two and 12 months were breastfeeding expectations above six and 12 months and skin-to-skin contact. Both variables were associated with a two to three times greater likelihood of maintaining breastfeeding and EBF in all periods of the study (two, four, six, nine and 12 months).

No association was found between maternal age, type of family, maternal knowledge of the benefits of breastfeeding and the prevalence of breastfeeding and EBF at discharge or in the following 12 months.

The main factors for cessation of breastfeeding were maternal notion of hypogalactia and other difficulties in breastfeeding perceived by the mother (Table 4).

Discussion

BFH promote good breastfeeding practices by empowering the mother throughout pregnancy, during childbirth and in the first days of the infant's life. The rates of breastfeeding (97.5%) and EBF (greater than 80% in full-term newborns) at discharge are indicative of this investment by the health teams.

Most studies consider prematurity as an exclusion criteria. Considering the negative influence of prematurity on breastfeeding[8-10], the comparison with these studies would not be adequate. In the present study, 7.5% of newborns were premature (gestational age between 34 and 37 weeks).

Table 2. Variables with influence in breastfeeding and exclusive breastfeeding at discharge

	Variables with influence	p value*	OR (CI 95%)	p value†	aOR (CI 95%)
Exclusive BF	Skin-to-skin contact	< 0.001	4.9 (2.33-10.21)	0.003	3.3 (1.48-7.22)
	Gestational age > 37 weeks	< 0.001	14.3 (4.27-47.92)	0.001	9.5 (2.60-34.77)
	Vaginal delivery	0.026	2.3 (1.10-5.01)	NS	NS
	Previous positive experience	0.003	4.6 (1.55-13.53)	0.034	3.5 (1.10-11.01)
	Intention to breastfeed ≥ 6M	0.002	3.0 (1.46-6.05)	-	-
BF	Multiparity	0.020	1.1 (1.01-1.11)	-	-
	FM during hospitalization	< 0.001	1.1 (1.01-1.24)	-	-

*Analysis was performed using the Chi-square test with significance level $p < 0.05$.
†Analysis was performed using logistic regression with significance level $p < 0.05$.
BF: breastfeeding; M: months; FM: formula milk; CI: confidence interval; OR: odds ratio; aOR: adjusted odds ratio; NS: not significant.

The EBF rate at discharge is higher in our study, compared to 76.6% in national health inquiries from the Portuguese Directorate-General of Health/Direção-Geral da Saúde[11]. In the same study, higher rates of EBF were present in the group of BFH (78.8%). Another study carried out in a portuguese BFH[12] presented exclusive breastfeeding rates at maternity discharge higher than our study (88.0%). However, in addition to not mentioning the included gestational ages, they used a different definition of EBF in this period (EBF in the previous 24 hours).

There was a significant difference between breastfeeding rates of term and preterm newborns at discharge. All preterm newborns included in our study (n = 15) were being breastfed at the time of discharge, with 26.7% being exclusively breastfed. Support to these babies and their mothers could lead to better breastfeeding rates, although it may lead to longer hospital stays.

Almost 62% of mothers made skin-to-skin contact and breastfed within the first hour of life, as recommended in step four of the "Ten Steps to Successful Breastfeeding". This number was below the 80% target set by WHO/UNICEF and the BFH initiative[13]. Skin-to-skin contact was made in many cesarean deliveries, but for periods shorter than one hour, and, therefore, not included in this study.

Skin-to-skin contact was associated with higher breastfeeding rates at discharge and throughout the first 12 months of life, as described in previous literature[13-17]. The proportion of newborns who were offered formula milk (20.4%) was similar to that described among BFH in Portuguese national health inquiries (21.2%)[11]. The use of formula milk during hospitalization has been described as having a negative influence on breastfeeding[12,18,19], which also happened in the present study ($p < 0.001$ in breastfeeding rates at discharge and at 2, 4 and 6 months).

Adequate pregnancy follow-up was recorded in 99.5% of the cases, and the health literacy levels of the sample were high, reflecting the effort made by health professionals. The positive previous experience and mother's expectation of breastfeeding proved to be factors that favor breastfeeding at discharge and in the first months of life, as mentioned in other studies[12,16,19-22].

High educational level has been identified as a factor that promotes breastfeeding[22-24]. In our study, there was an association between the level of education and the rate of breastfeeding at six and nine months.

Returning to work was mentioned in several studies[12,22,25,26] as a reason for abandoning breastfeeding, but there has been a positive trend in recent years[19,21,27]. In our study, almost the entire sample reported being able to express breastmilk at the workplace, and professionally active mothers had higher breastfeeding rates at six months.

There was a progressive decline in the prevalence of breastfeeding and EBF over the 12 months of the study, a finding consistent with other studies carried out in Portugal and other countries in the last twenty years[6,11,14,20,22,23,25,27-29].

EBF rates at two and four months showed higher percentages than other studies described in Portugal[11]. The rate decrease of EBF at two months (59.7%) represents a significant loss in comparison with discharge rates. The major difficulties with breastfeeding maintenance present themselves during the first month of life, as mentioned in previous studies[14,28],

Table 3. Variables with influence in breastfeeding at 2, 4, 6, 9 and 12 months of life

	Variables with influence	p value*	OR (CI 95%)	p value†	aOR (CI 95%)
2M - EBF	Skin-to-skin contact	< 0.001	2.9 (1.59-5.19)	0.004	2.5 (1.35-4.72)
	Gestational age > 37 weeks	0.003	3.2 (1.06-9.86)	-	-
	Vaginal delivery	0.019	2.3 (1.13-4.44)	-	-
	Previous positive experience	0.011	2.4 (1.21-4.65)	NS	NS
	Intention to breastfeed ≥ 6M	< 0.001	3.3 (1.81-5.88)	0.001	2.9 (1.57-5.37)
2M - BF	Skin-to-skin contact	0.010	3.4 (1.60-7.29)	0.010	2.8 (1.28-6.12)
	Vaginal delivery	0.010	2.7 (1.21-5.91)	-	-
	FM during hospital stay	< 0.001	0.1 (0.06-0.27)	-	-
	Previous positive experience	0.014	3.6 (1.22-10.83)	NS	NS
	Intention to breastfeed ≥ 6M	0.007	2.8 (1.30-5.88)	0.039	2.3 (1.04-5.02)
4M - EBF	Skin-to-skin contact	0.003	2.4 (1.33-4.27)	0.019	2.1 (1.13-3.90)
	Intention to breastfeed ≥ 6M	0.001	2.7 (1.49-4.75)	0.004	2.4 (1.32-4.47)
	Previous positive experience	0.043	1.9 (1.02-3.70)	NS	NS
	Being employed	0.023	2.3 (1.11-4.60)	NS	NS
4M - BF	Skin-to-skin contact	0.001	2.8 (1.51-5.28)	0.005	2.6 (1.33-5.02)
	Vaginal delivery	0.002	3.0 (1.50-6.07)	-	-
	Multiparity	0.007	0.4 (0.23-0.80)	-	-
	FM during hospital stay	< 0.001	0.2 (0.10-0.39)	-	-
	Intention to breastfeed ≥ 6M	0.005	2.4 (1.31-4.51)	0.024	2.1 (1.11-4.13)
	Being employed	0.010	2.5 (1.23-5.21)	0.025	2.4 (1.12-5.32)
6M - EBF	Skin-to-skin contact	0.006	3.0 (1.30-6.92)	0.047	2.4 (1.01-5.76)
	Higher education	0.004	2.8 (1.37-5.91)	0.009	2.8 (1.29-5.97)
6M - BF	Skin-to-skin contact	0.001	2.7 (1.48-4.89)	0.005	2.5 (1.31-4.66)
	Gestational age > 37 weeks	0.038	3.0 (1.02-8.81)	-	-
	Vaginal delivery	0.014	2.3 (1.17-4.63)	-	-
	Multiparity	0.007	0.5 (0.25-0.80)	-	-
	FM during hospital stay	< 0.001	0.2 (0.08-0.32)	-	-
	Intention to breastfeed ≥ 6M	0.003	2.4 (1.35-4.41)	0.012	2.3 (1.20-4.23)
	Being employed	0.020	2.3 (1.13-4.66)	NS	NS
9M	Skin-to-skin contact	0.002	2.5 (1.37-4.39)	0.007	2.3 (1.26-4.23)
	Gestational age > 37 weeks	0.048	3.1 (0.96-10.19)	-	-
	Vaginal delivery	0.038	2.1 (1.03-4.14)	-	-
	Multiparity	0.014	0.5 (0.28-0.87)	-	-
	Intention to breastfeed ≥ 12M	0.022	2.3 (1.12-4.82)	0.048	2.1 (1.01-4.56)
	Higher education	0.039	1.8 (1.03-3.16)	NS	NS
12M	Skin-to-skin contact	0.016	2.1 (1.14-3.96)	0.019	2.2 (1.14-4.24)
	Multiparity	0.002	0.4 (0.21-0.70)	-	-
	Intention to breastfeed ≥ 12M	0.001	3.4 (1.68-7.02)	0.002	3.2 (1.54-6.77)

*Analysis was performed using the Chi-square test with significance level $p < 0.05$.
†Analysis was performed using logistic regression with significance level $p < 0.05$.
M: months; BF: breastfeeding; EBF: exclusive breastfeeding; FM: formula milk; CI: confidence interval; OR: odds ratio; aOR: adjusted odds ratio; NS: not significant.

Table 4. Reasons that led to the cessation of breastfeeding and number of times reported at discharge and 2, 4, 6, 9 and 12 months of age

Reason	Discharge	2M	4M	6M	9M	12M
Hypogalactia*	-	17	11	7	11	6
Other difficulties in BF†	2	6	10	6	4	6
Maternal option	3	1	-	-	1	2
Maternal disease	-	2	3	1	-	2
Work-related reasons	-	-	-	-	4	4

*Hypogalactia was considered whenever the mother reported having little milk and the baby showed signs of hunger or there was associated weight loss confirmed by the attending physician.
†Other difficulties in BF were perceived by the mother.
BF: breastfeeding; M: months.

reinforcing the need for greater involvement of Primary Health Care in supporting breastfeeding. In our study, the EBF rate at four months presented itself higher (around 60%) than referred in national health inquiries performed in 2014 (48,5%)[11], maintaining similar values until the five-month mark. A study that included data from 43 countries found EBF rates at four months of 11 to 66%[28].

At six months, EBF is still far from the WHO target that at least 50.0% of children remain on EBF for up to six months in 2025, increasing to 70.0% in 2030[30,31].

European studies revealed EBF rates lower than 25% at six months[32], alerting to the crucial need of protecting, promoting and supporting breastfeeding as a public health priority.

In our study, the median age at which complementary feeding began was five months. The WHO advocates starting complementary feeding at six months of age[2], while the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition (ESPGHAN) recommends between four and six months[5,33]. This lack of consensus is associated with different recommendations regarding the beginning of diversification. Also, returning to work, despite the possibility of extracting milk, may lead to diversification before six months.

In the present study, breast milk was the only milk given to 54% of babies, but the introduction of complementary foods from five months onwards led to a lower EBF (19,9%). The simultaneity of return to work (five months) with the beginning of diversification supports that the maternal decision to start complementary foods may be related to the mothers' concerns when returning to professional activity. As a result, despite high rates of breastfeeding at six months (> 50%), EBF only occurs in about 20% of women.

More favorable legislation promoting an effective right to maternity leave for at least six months could be a decisive factor in achieving the WHO goals.

Concordant to other studies[25,26,32], prolonged maternity leaves and better flexibility in the workplace may help mothers achieve their breastfeeding goals.

The breastfeeding rate at 12 months was 36.3% in our study, slightly higher than data reported in other high-income countries (median of 29% in a study involving 25 countries). However, the rates varied greatly between countries[28]. This lack of consistency may be due to the different breastfeeding policies adopted in each country.

It was found that, similarly to other studies[14,18,22,25,34,35], the main reasons for abandoning breastfeeding are the notion of hypogalactia and breastfeeding difficulties perceived by mothers.

The limitations of our study are the lack of standardization of the surveys used; sample size (< 10% of births), which conditions methodological differences that limit comparisons with other national or international studies. However, the use of standardized definitions can alleviate this limitation.

Our strengths include the fact that it is a longitudinal study, with contact with mothers over time, allowing the elimination of memory bias.

This study highlights the importance of practices, such as skin-to-skin contact and early onset of breastfeeding, in improving breastfeeding rates. Our study emphasizes that there is still an urgent need to improve policies to support women who work and wish to maintain breastfeeding. It reveals the importance of national and international governmental promotion and protection of breastfeeding, supporting mothers in maternity wards and primary health care, following the BFH initiative and recommended measures. It is mandatory to monitor breastfeeding rates with a standardized methodology, allowing health professionals to obtain reliable information.

Presentations

This study was presented as a poster discussion on the 21st Congresso Nacional de Pediatria, in October 2021, in Braga, Portugal.

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None.

Conflicts of interest

None.

Ethical disclosures

Protection of human and animal subjects. The authors declare that the procedures followed were in accordance with the regulations of the relevant clinical research ethics committee and with those of the Code of Ethics of the World Medical Association (Declaration of Helsinki).

Confidentiality of data. The authors declare that they have followed the protocols of their work center on the publication of patient data.

Right to privacy and informed consent. The authors have obtained the written informed consent of the patients or subjects mentioned in the article. The corresponding author is in possession of this document.

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