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Clinical Research

Minimizing the Relationship Between Early Formula Use and Breastfeeding Cessation by Limiting Formula Volume

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Abstract

Objective: Early exposure to formula can interfere with successful long-term breastfeeding. The objective of this study was to determine whether limiting the volume of formula used in the first month attenuates formula's detrimental impact on long-term breastfeeding success.
Materials and Methods: Using detailed data on dietary intake from a randomized clinical trial, we conducted a secondary analysis of the association between volume of formula received in the first month and breastfeeding cessation before 6 and 12 months of age. We used descriptive statistics and multivariable logistic regression, respectively, to explore this association without and with adjustment for demographic and clinical predictors of infant feeding.
Results: Among 199 breastfeeding infants, 80 (40%) received formula daily at 1 month of age, and breastfeeding cessation before 6 and 12 months of age was higher for these infants (46% and 67%) than for those breastfed exclusively (6% and 27%) ($p < 0.0005$ for each). The risk of cessation did not differ between those who received ≤4 fl oz daily in the first month (11%) and those who did not receive formula in the first month (6%) ($p = 0.42$). Adjusting for gestational age, race/ethnicity, income, and intention to breastfeed exclusively, the odds ratio for the outcome of cessation before 6 months was 1.15 (95% confidence interval = 0.20–6.67) for infants who received ≤4 fl oz daily compared with those who breastfed exclusively.
Conclusion: Limiting formula volumes to ≤4 fl oz daily may attenuate the deleterious association between early formula use and subsequent successful breastfeeding.

Keywords: breastfeeding, infant formula, newborn

Introduction

Breastfeeding provides protection against childhood diseases including asthma, gastroenteritis, and sudden infant death syndrome.[1–4] Although the benefits of breastfeeding begin at its initiation, the most substantial health benefits are achieved by sustained breastfeeding. For these reasons, breastfeeding through 6 and 12 months are *Healthy People 2020* goals.[5–8] However, despite the well-documented benefits of sustained breastfeeding, only 52% of U.S. infants breastfeed through 6 months, and only 30% achieve breastfeeding through 12 months.[9] Thus, ~2 million babies each year in the U.S. breastfeed without attaining the recommended duration. Effective strategies for improving breastfeeding duration through 12 months might therefore provide substantial public health benefit.

Exclusive breastfeeding during the first month after birth has been shown to reduce the risk of breastfeeding cessation before 12 months and is recommended by numerous guidelines including those of the World Health Organization and the American Academy of Pediatrics.[6,10–14] However, many breastfed neonates receive some formula, either because of parental preference or to prevent or treat neonatal morbidity from hypoglycemia, hyperbilirubinemia, or dehydration. For such neonates, minimizing the potentially deleterious impact of formula on breastfeeding duration could be beneficial, but little scientific evidence exists to guide practice in this area. Such evidence may be especially important because recent

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research suggests that many breastfeeding mothers use formula for only brief periods, returning intermittently to breastfeeding without formula.[15] Developing better evidence to guide practices to sustain breastfeeding when formula is used could potentially allow more neonates to resume breastfeeding without supplementation. To contribute to the evidence in this area, we analyzed existing data collected during a randomized controlled trial of infant probiotics to determine the relationship between the volume of formula used in the first month after birth and subsequent breastfeeding duration through 12 months of age.

Materials and Methods

Study design

This study consisted of a secondary analysis of data collected in the Trial of Infant Probiotic Supplementation (TIPS) study and the Development of Infant Microbial Evolution Study (DIMES). TIPS was a randomized, controlled trial designed to measure the effect of probiotic use in the first 6 months on the incidence of eczema in infants born with at least one parent with asthma. The TIPS study protocol has been previously published.[13] DIMES was a prospective cohort partner study to TIPS that enrolled healthy controls whose parents did not have a previous diagnosis of allergic diseases. Both TIPS and DIMES received approval from the University of California, San Francisco (UCSF) Committee on Human Research before enrolling the first participant.

Data collection

There were 203 infants enrolled in TIPS and 36 in DIMES. TIPS and DIMES assessed breastfeeding prevalence by phone survey monthly using the item, ''How are you feeding your baby?'' Response options included the following: ''breast milk only,'' ''formula only,'' ''combination,'' ''other,'' and ''does not apply.'' Volume of formula used was assessed with the item, ''Please estimate how many ounces your baby drinks (or drank) per day.''

Data analysis

We used chi-square testing to report the association between receipt of formula in the first month after birth and eventual breastfeeding status at 6 and 12 months of age, and to compare other sets of dichotomous variables. We used Student's *t* test to compare continuous demographic and clinical variables between infants who were receiving daily formula at 1 month of age and infants who were not, and between infants who were breastfeeding at 6 and 12 months of age and infants who were not. Multivariable logistic regression explored the association of daily formula use in the first month with breastfeeding status at 6 and 12 months while adjusting for clinical and demographic predictors including infant gestational age and maternal race/ethnicity, age, income, and intention to breastfeed exclusively. All analyses were conducted using STATA statistical software, version 14.2 (StataCorp, College Station, TX).

Results

In this cohort, mean birth weight was $3,439 \pm 482$ g, and mean gestational age was 39.5 ± 1.6 weeks. Among 199 mothers who initiated breastfeeding after birth, 105 (53%) stated a prenatal intention to use formula in the first year. At 1 month of age, all 199 mothers were still breastfeeding; 80 (40%) mothers also reported that their infants received formula daily at 1 month of age. Among those with daily formula use at 1 month of age, 18 (23%) consumed ≤2 fl oz daily, 27 (34%) consumed ≤4 fl oz daily, and 41 (51%) consumed ≤8 fl oz daily. At 6 months of age, breastfeeding status was assessed for 195 (96%) infants, and 151 (77%) were still breastfeeding. At 12 months of age, breastfeeding status was assessed for 187 (93%) infants, and 104 (56%) were still breastfeeding. Table 1 provides clinical and demographic characteristics at enrollment and their association with formula use and breastfeeding duration.

Daily formula use at 1 month of age was associated with a greatly increased risk of breastfeeding cessation. Of the infants who received formula daily at 1 month of age, 37 (46%) had stopped breastfeeding before 6 months, compared with 7 (6%) infants who did not receive formula daily at 1 month ($p < 0.00005$). Comparing these two groups at 12 months of age, 49 (68%) infants who received formula daily at 1 month of age had stopped breastfeeding by 12 months, compared with 33 (29%) who did not receive formula at 1 month of age ($p < 0.00005$).

Infants who used ≤4 fl oz daily in the first month were much less likely to cease breastfeeding than those who used >4 fl oz daily. Among neonates who received ≤4 fl oz daily at 1 month of age, 3 (10%) ceased breastfeeding before 6 months of age compared with 34 (66.7%) of those who received >4 fl oz daily ($p < 0.0005$). By 12 months of age, breastfeeding had ceased for 13 (45%) of those who received ≤4 fl oz daily at 1 month compared with 39 (91.2%) of those who received >4 fl oz daily at 1 month ($p = 0.001$). Among those who used formula daily at 1 month of age, volume of daily formula was 405 ± 310 mL (13.7 ± 10.5 U.S. fl oz) for those who subsequently stopped breastfeeding before 12 months, compared with 159 ± 157 mL (5.4 ± 5.4 fl oz) for those who breastfed through 12 months ($p = 0.0006$). Each additional 1 fl oz formula used daily at 1 month of age was associated with odds ratios (ORs) of 1.41 (1.28–1.54) and 1.27 (1.16–1.39) for the outcomes of breastfeeding cessation by 6 months and breastfeeding cessation by 12 months, respectively.

Eventual breastfeeding duration did not differ between those who received ≤4 fl oz daily at 1 month of age (9.9 ± 2.9 months) and those who did not receive any formula at 1 month of age (10.5 ± 2.6 months) ($p = 0.29$). Compared with those who breastfed exclusively at 1 month of age, the OR for the outcome of breastfeeding cessation before 6 months was 1.64 (0.40–6.67) for those who received ≤4 fl oz daily at 1 month of age but was 33.3 (11.1–100) for those who received >4 fl oz formula daily at 1 month of age. Small-volume usage continued to attenuate the relationship between early formula use and subsequent breastfeeding duration even after adjusting in multivariable analysis for clinical and demographic variables associated with breastfeeding duration (Table 2).

Discussion

Our study found that among breastfeeding infants using formula daily at 1 month of age, using smaller formula volumes was associated with improved eventual breastfeeding

Table 1. Maternal and Infant Characteristics, by Status of Formula Use at 1 Month and Status of Breastfeeding at 6 and 12 Months

Variable	*No daily formula use at 1 month of age* (n = *122*)	*Daily formula use at 1 month of age* (n = *80*)	*p*	*Not breastfeeding at 6 months* (n = *44*)	*Breastfeeding at 6 months* (n = *151*)	*p*	*Not breastfeeding at 12 months* (n = *83*)	*Breastfeeding at 12 months* (n = *104*)	*p*
Maternal characteristics									
College grad, *n* (%)	106 (87)	51 (64)	<0.0005	24 (55)	130 (86)	<0.0005	57 (69)	90 (87)	<0.003
Annual income, *n* (%)			0.64			0.33			0.91
<$10,000	3 (2)	3 (4)		3 (7)	3 (2)		2 (2)	2 (2)	
$10,000–$50,000	14 (11)	15 (19)		9 (20)	18 (12)		13 (16)	14 (13)	
$50,001–$100,000	20 (16)	16 (20)		10 (23)	26 (17)		17 (20)	18 (17)	
$100,001–$150,000	31 (25)	14 (18)		7 (16)	37 (25)		17 (20)	26 (25)	
$150,001–$200,000	26 (21)	15 (19)		7 (16)	33 (22)		18 (22)	21 (20)	
>$200,000	23 (19)	15 (19)		7 (16)	30 (20)		15 (18)	19 (18)	
Declined to state	5 (4)	2 (3)		1 (2)	4 (3)		1 (1)	4 (4)	
Age (years), mean (SD)	34.0 (5.0)	33.6 (5.4)	0.64	32.5 (6.2)	34.4 (4.6)	0.06	34.0 (5.0)	33.9 (4.9)	0.93
Race/ethnicity			0.10			0.08			0.56
White non-Hispanic	79 (65)	32 (40)		18 (41)	90 (60)		41 (49)	64 (62)	
Hispanic	3 (2)	6 (8)		4 (9)	4 (3)		3 (4)	5 (5)	
Asian	14 (11)	14 (18)		6 (14)	22 (15)		14 (17)	12 (12)	
Black non-Hispanic	3 (2)	1 (1)		1 (2)	2 (1)		1 (1)	2 (2)	
Other/unknown	23 (19)	27 (34)		14 (32)	26 (17)		24 (29)	21 (20)	
Infant characteristics									
Birth weight (g), mean (SD)	3,516 (488)	3,328 (454)	0.01	3,356 (396)	3,477 (501)	0.17	3,388 (475)	3,502 (486)	0.14
Gestational age (weeks), mean (SD)	39.8 (1.2)	39.1 (1.9)	0.002	39.0 (2.1)	39.6 (1.4)	0.02	39.1 (1.8)	39.8 (1.4)	0.004
Vaginal delivery, *n* (%)	67 (79)	39 (75)	0.60	37 (84)	127 (84)	0.99	42 (72)	61 (84)	0.99
Formula use at 1 month				37 (84)	44 (29)	<0.0005	50 (60)	23 (22)	<0.0005
Formula use 4 fl oz or less daily at 1 month				2 (5)	21 (14)	0.09	10 (12)	12 (12)	0.91

SD, standard deviation.

Table 2. Univariate and Multivariate Odds Ratios for the Association Between First-Month Clinical and Demographic Variables and Eventual Breastfeeding Through 6 and 12 Months of Age

Predictor	*Univariate OR for the outcome of breastfeeding through 6 months (95% CI)*	*Multivariate OR for the outcome of breastfeeding through 6 months*[a] *(95% CI)*	*Univariate OR for the outcome of breastfeeding through 12 months (95% CI)*	*Multivariate OR for the outcome of breastfeeding through 12 months*[a] *(95% CI)*
Infant characteristics				
Gestational age (weeks)	1.27 (1.03–1.57)	1.04 (0.80–1.36)	1.35 (1.09–1.68)	1.19 (0.93–1.52)
No daily formula use at 1 month	Ref.	Ref.	Ref.	Ref.
Formula use >4 fl oz daily at 1 month	0.03 (0.01–0.09)	0.04 (0.01–0.11)	0.11 (0.05–0.25)	0.14 (0.06–0.31)
Formula use ≤4 fl oz daily at 1 month	0.61 (0.15–2.50)	0.67 (0.15–3.04)	0.46 (0.19–1.14)	0.60 (0.23–1.59)
Maternal characteristics				
Intention to use formula in the first year	0.24 (0.11–0.53)	0.36 (0.13–0.94)	0.32 (0.17–0.58)	0.52 (0.25–1.06)
Race/ethnicity				
White non-Hispanic	Ref.	Ref.	Ref.	Ref.
Hispanic	0.20 (0.05–0.87)	0.96 (0.15–6.25)	1.07 (0.24–4.71)	3.54 (0.61–20.6)
Asian	0.73 (0.26–2.06)	1.22 (0.31–4.83)	0.55	0.84 (0.30–2.36)
Black non-Hispanic	0.40 (0.03–4.65)	0.36 (0.02–7.61)	1.28 (0.11–14.6)	1.51 (0.10–22.5)

[a]Model including infant gestational age, infant formula use at 1 month of age and maternal race/ethnicity and baseline intention to breastfeeding exclusively.

CI, confidence interval; OR, odds ratio.

duration. In our cohort, daily use of ≤4 fl oz formula in the first month did not impact breastfeeding duration, whereas daily use of >4 fl oz formula in the first month was associated with greatly increased risk of breastfeeding cessation. When formula is used in the first month, limiting formula volumes to ≤4 fl oz daily may minimize any impact on long-term breastfeeding.

Our findings may be attributable to the fact that during lactogenesis III, maternal milk supply is controlled by the breast's autocrine system, so that the more milk is removed from the breast, the more milk the breast produces. Using large volumes of formula in the first month may reduce infant breastfeeding demand, leading to a direct deleterious effect on a mother's milk supply. In contrast, using small volumes of formula may not reduce an infant's breastfeeding demand and may therefore minimize any impact on milk supply. Using >4 fl oz of formula daily at 1 month of age may place a mother at risk of developing insufficient milk supply. When this occurs, evaluation by a lactation specialist may be indicated to identify strategies to sustain breastfeeding.

Our study has several important limitations. First, maternal age, income, and educational attainment were high in our cohort, and median duration of breastfeeding was 10 months. Therefore, our results may not be nationally or internationally generalizable. Second, our sample size of 199 breastfed infants had only 80 infants who breastfed with daily formula supplementation at 1 month of age. Therefore, confidence intervals are wide for some effect size estimates. Third, the observational design of this study does not allow us to report whether the observed relationship between higher volume of supplementation and decreased breastfeeding duration was causal. However, of note, the relationship between higher volume of supplementation and decreased breastfeeding duration persisted even after adjusting for potential confounders. Fourth, our study did not collect data on the use of artificial nipples or the reason for formula supplementation. We are therefore unable to report whether the use of artificial nipples or the reason for formula supplementation mediated the observed relationship between early formula intake and subsequent breastfeeding duration. Further research is needed to investigate these important questions.

Conclusion

Findings from this study may inform efforts to improve the proportion of mothers and infants achieving the Healthy People 2020 goal of breastfeeding through 12 months of age. While breastfeeding exclusively without formula for the first 6 months is associated with the greatest success at sustaining breastfeeding through 12 months, many U.S. infants receive formula either because of parental preference or because of medical concerns about weight loss, dehydration, or hyperbilirubinemia. When formula is used, limiting formula volume to <4 fl oz daily might allow more mothers to meet their personal breastfeeding goals and to meet Healthy People 2020 goals for breastfeeding duration.

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Disclaimer

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Disclosure Statement

M.D.C. has served as a paid consultant for Nestle (Glendale, CA) for his work on probiotics. V.J.F., M.M., E.B., and L.R.K. declare no conflicts of interest.

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