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The Prevalence of Regurgitations in the First 2 Days of Life in Human Milk– and Formula-Fed Term Infants

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ABSTRACT

***Purpose*: Very little is known about the prevalence of regurgitations in human milk–fed infants in the first days of life. The authors aimed to compare the frequency of regurgitations in formula- and breastfed infants in the first 2 days of life. It was hypothesized that human milk–fed infants experience less episodes of regurgitations than their formula-fed counterparts.**

***Design, Sample, and Outcome Variables*: Thirty-two (32) infants were formula fed and 31 were breastfed. In both groups, infants were fed *ad libitum*, as soon as the mother was ready to feed the infant. All regurgitations were noted on a collection form.**

***Results*: The number of regurgitations per infant in the first 48 hours of life was similar in breastfed (range 0 to 7) and formula-fed infants (range 0 to 8). There was also no difference in the number of regurgitations in the first or second 24-hour period. Eighteen of 31 of infants in the breastfed group and 17/32 in the formula fed groups had at least one episode of regurgitation during the 48-hour period.**

***Conclusions*: Contrary to this hypothesis, human milk feeding did not confer a "protection" on regurgitations in these young neonates.**

INTRODUCTION

REGURGITATIONS IN THE FIRST few days of life may theoretically be the early sign of gastroesophageal reflux (GER), food allergy, or anatomic or functional intestinal obstruction. In one recent study of formula-fed infants, the authors showed that such regurgitations are extremely prevalent and benign in the first few days of life, as up to 35% of feeds are followed by a regurgitation episode.[1] Moreover, the authors showed that the frequency of regurgitation may be associated with the type of formula given, or the way formula is administered.[1] Very little is known about the prevalence of regurgitations in human milk–fed infants in the first days of life. Three major textbooks on neonatology or general pediatrics fail to provide such information,[2–4] and the only longitudinal study of regurgita-

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tions in term babies, performed in a cohort of Thai infants, did not address the early neonatal period.[5] The authors and others showed that formula-fed infants are significantly overfed on days 1 and 2 of life as compared with breastfed infants.[6] In older infants, overfeeding has been recognized as a significant cause of regurgitations.[7]

The aim of this pilot study was to evaluate the frequency of regurgitations in two groups of infants fed formula or their mother's breast milk *ad libitum* in the first 2 days of life. The authors hypothesized that human milk–fed infants experience fewer episodes of regurgitations than their formula-fed counterparts.

PATIENTS AND METHODS

The authors recruited 63 healthy, singleton term (38 to 41 weeks gestation), appropriate for gestational age (using the curves of Lubchenco)[8] newborn infants born after uncomplicated pregnancy, labor, and delivery. Maternal analgesia during labor was solely by epidural bupivacaine. All infants had an Apgar score of >7 at 1 and 5 minutes, and were delivered by spontaneous vaginal vertex delivery. Infants with meconium staining of amniotic fluid were not excluded, but infants with meconium aspiration were removed from the study.

By maternal choice, 32 were formula fed and 31 exclusively breastfed; in both groups, infants were fed *ad libitum,* by hospital protocol, as soon as the mother was ready to feed the infant. Formula fed infants received ready-to-feed Similac (20 cal/oz, Ross Laboratories, Columbus OH). All infants were roomed-in together with their mother, and were fed on demand. On the first day they were fed 6 to 13 times per day, and on the second day 6 to 11. Part of the routine nursing education provided to mothers is to hold babies upright after feeding until they pass an eructation, or at least 5 to 10 minutes. Babies cannot be placed on their back before that time. The authors discourage the use of pacifiers in the first few days of life, although they are recommended thereafter, mainly for the prevention of sudden infant death syndrome. In this study, all feeds were provided by the mother. All regurgitations were noted on a collection form by the nurse taking care of the infant and included regurgitations observed by the mother and nurse. Regurgitations were defined as the effortless return of small amounts of the swallowed material, during or shortly after eating.[2] Because infants all roomed-in with their mothers, it was difficult to reliably assess the volume of the regurgitations, which is subjective. Thus, the authors only recorded their frequency.

Statistical analyses

Results are expressed as mean ± SD. Kruskal-Wallis tests were used to compare the number of regurgitation episodes per infant in the two study groups on the first 48 hours of life. Comparability of both groups (in terms of baseline continuous variables such as birthweight, gestational age, or Apgar score) was studied using Kruskal-Wallis tests, whereas the chi-square test was used to determine the difference between the groups for discrete variables (e.g., gender, the presence of meconium staining of amniotic fluid, ethnic origin). This was a pilot study, designed to determine the sample size necessary for a larger, definitive study.

RESULTS

Thirty-three (33) boys and 30 girls were consecutively recruited in the study. All mothers were middle-class, healthy women aged 24 to 43 years with an average parity of 2.4 (range 1 to 6). All infants were Israeli Jews, most of them of mixed Sephardic and Ashkenazi origin. There were no significant differences between the breastfed and formula-fed groups in terms of gestational age, birth weight, or Apgar scores (Table 1).

The number of regurgitations per infant in the first 48 hours of life were similar in breastfed (range 0 to 7) and formula-fed infants (range 0 to 8) ($p = 0.6$). There was also no difference between breastfed and formula-fed infants in the number of regurgitations in the first or second 24-hour periods (see Table 1).

Table 1. Characteristics and Milk Intake in Breastfed and Formula-Fed Infants

	Breastfed n = *31*	*Formula-fed* n = *32*
Sex (m:f)	18:13	15:17
Birth weight (g)	3201 ± 614	3126 ± 667
Gestational age (wk)	39.2 ± 1.0	39.5 ± 1.0
Parity	2.3 ± 1.3	2.4 ± 0.9
Apgar score 1 min	9.1 ± 0.5	8.9 ± 0.6
Apgar score 5 min	9.9 ± 0.5	9.8 ± 0.3
Weight loss over 2 days (g)	149 ± 96	130 ± 56
Number of regurgitations during first 24 h	1.0 ± 1.1	0.7 ± 1.0
Number of regurgitations during second 24 h	0.5 ± 0.8	0.6 ± 0.9
Number of regurgitations during the study period	1.7 ± 2.3	1.4 ± 2.0

All tested variables were not significantly different (results are mean ± SD or *n*).

Eighteen (18) of 31 (58%) of infants in the breastfed group and 17/32 (53%) in the formula-fed group had at least one episode of regurgitation during the 48-hour period ($p = 0.16$). In infants with regurgitations, there was no significant difference between the numbers of regurgitations of breastfed and formula-fed infants.

Assuming these results are valid, the sample size that would be necessary to demonstrate a significant difference between the two groups was calculated to be approximately 1000 patients per group.

DISCUSSION

The authors hypothesized that human milk–fed infants experience fewer episodes of regurgitations than their formula-fed counterparts. This hypothesis was based on the following facts: (a) human milk feeding at the breast may be slower than bottle feeding (enabling less abrupt gastric distention);[9] (b) formula-fed infants have an intake higher than that of breast-fed infants;[6] and (c) overfeeding is a recognized cause of regurgitations.[7]

Contrary to the present hypothesis, the authors found that regurgitations in the first 2 days of life occurred at very similar rates in human milk–fed and formula-fed infants. In fact, approximately half the infants in both groups had no visible regurgitations at all during the observation period. In all these infants regurgitations were felt to be clinically insignificant by the attending physicians (who were not related to the study) in that they did not cause excessive weight loss, or did not occur in a very abundant or frequent manner, and did not cause a delay in the discharge of the infant on the third day of life. Moreover, the fact that regurgitations are as frequently observed in human milk–fed as in cow milk–based formula-fed infants indicates that food allergy is probably not a frequent cause of such early regurgitations, which do not justify dietary modifications. It is also theoretically possible that some breast-fed infants may be intolerant of the cow milk allergens present in human milk, but this phenomenon probably is rare.[10] Thus, it may appear that most regurgitations in the early newborn period are essentially benign in nature and are related to neither food allergy nor anatomic or functional intestinal obstruction. However, the present study was too short in duration to allow assumptions about the presence or absence of GER, which requires special studies to determine.

A limitation of the present study is that, for obvious ethical reasons, the allocation of infants to the two groups was by maternal choice and not random. However, the authors do not believe that the lack of randomization may have introduced a significant bias that influenced the rate of regurgitations.

Another limitation may have been an insufficient sample size (type II error). Indeed, close to 1000 infants per group would be necessary to prove that the "differences" observed, if true, would be statistically significant. In view of the very little *clinical* difference, such a large, time-consuming study is probably not justified.

Another limitation is that the authors' follow-up lasted only 2 days; thus, these conclusions are only applicable to the early neonatal period, which was the main scope of the study. However, Miyazawa et al. have shown that there was no significant difference in the prevalence of regurgitation or vomiting among breastfed, formula-fed, or mixed-fed infants who were followed up to 1 to 4 months of age.[11]

Another limitation of this study is that maternal diet or family history of milk intolerance was not recorded. However, the authors do not believe that this presents a significant bias to the study because the incidence of true milk allergy in the general adult population is very low.[12]

Finally, the study is limited by the fact that regurgitations were recorded by the mother and not the personnel involved in the study. This may have created a problem of underreporting as well as overreporting, but the authors do not believe that a systematic bias occurred. Also, in these groups of *ad libitum*–fed infants, the decision of how often and how much to feed (or to leave the infant at the breast) was left to the mother based on her impression that the baby was hungry or had reached satiety. Thus, the authors did not record prospectively the number of feeding episodes that may have been different between the two groups and may have affected the number of regurgitation episodes.

Nevertheless, regurgitations were found to be a common phenomenon in the first few days of life, and were very little, if any, affected by the type of infant feeding.

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