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LONG-TERM BEHAVIORAL CONSEQUENCES OF INFANT FEEDING:

The Limits of Observational Studies

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SUMMARY

Observational (nonexperimental) studies of the association of infant feeding and subsequent child or adult behavior are prone to residual confounding by subtle differences in psychological attributes and interaction styles of mothers who breastfeed vs those who formula-feed. We followed up 13,889 6.5-year-old Belarusian children who participated in a large cluster-randomized trial of a breastfeeding promotion intervention. Behavior was evaluated using the Strengths and Difficulties Questionnaire (SDQ), completed independently by the children's parents and teachers. We compared the results of experimental (intention-to-treat, ITT) and observational analyses (based on feeding actually received), both adjusted for clustering. Observational analyses were additionally adjusted for geographic region and urban vs rural residence; child sex, age at follow-up, and birth weight; and maternal and paternal education. No differences between the randomized experimental vs control groups were observed in ITT analyses. In contrast, small but statistically significant associations with weaning prior to 3 months were observed for parent and teacher SDQ scores on total difficulties, conduct problems, and hyperactivity, even after multivariate adjustment. The absence of associations based on ITT analyses, in contrast with the significant associations based on observed BF duration, strongly suggests that the latter are biased by residual confounding.

INTRODUCTION

Surprisingly few studies have reported on the long-term effects of infant feeding on child behavior, despite the intimate mother-infant physical and emotional contact during the act of breastfeeding.^{1–8} In a recent study based on a large, prospective birth cohort from Western Australia followed to 14 years, Oddy et al reported significant associations between shorter duration of breastfeeding and problematic behavior, as measured by the Child Behavior Checklist administered on 5 occasions during the 14-year follow-up.⁹ In contrast, in our cluster-randomized Promotion of Breastfeeding Intervention Trial (PROBIT) in the Republic of Belarus, despite substantial differences achieved between the two groups in both

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the duration and exclusivity of breastfeeding,¹⁰ we found no difference between the experimental and control groups in parent or teacher evaluations of child behavior at 6.5-year follow-up.^{11, 12}

As we have previously pointed out, observational studies of the associations of infant feeding and subsequent child or adult behavior are prone to residual confounding by subtle differences in the psychological attributes and interactional styles of mothers who breastfeed vs those who formula-feed and even between those who breastfeed for a longer vs shorter duration or more vs less exclusively.¹³ In previous comparisons of observational (according to observed feeding) and experimental (as randomized, usually referred to as intention-to-treat, or ITT) analyses from other randomized trials, we have shown conflicting results of exposure to in-hospital formula supplementation^{14, 15} and to pacifier use¹⁰ on duration of breastfeeding among the same study participants: null results from ITT analyses vs significant adverse effects of exposure when analyzed observationally according to actual exposure. In PROBIT, associations between breastfeeding and infant growth based on ITT vs observational analyses also differed substantially.¹⁶ In this study, we also compare the results of experimental and observational analyses of behavioral outcome data from the same children followed up from the PROBIT trial and in so doing, explore the importance of residual confounding and its potential for bias in observational studies of breastfeeding and subsequent child behavior.

METHODS

The detailed methods of PROBIT and the results of intention-to-treat analyses have been previously published.^{11, 12} The units (clusters) of randomization were maternity hospitals and one affiliated polyclinic (pediatric outpatient clinic for routine well-child and illness care) per hospital, with double randomization based on both a random-numbers table and a coin flip. The experimental intervention was based on the Baby-Friendly Hospital Initiative, which was developed by WHO and UNICEF to promote and support breastfeeding, and particularly to increase breastfeeding duration and exclusivity among mothers who initiate breastfeeding.¹⁷ Control sites continued the practices and policies in effect at the time of randomization. Infants randomized were all born healthy and at term in 1996–97, weighed at least 2500 g at birth, had 5-minute Apgar scores ≥ 5 , were initially breastfed, and were enrolled during their postpartum stay at the maternity hospital.¹¹ Follow-up data on infant feeding, growth, and illnesses were obtained at scheduled study visits at 1, 2, 3, 6, 9, and 12 months of age.¹¹

As previously reported, the two randomized groups were similar in baseline characteristics¹¹ and were also similar at the 6.5-year follow-up.¹² The experimental intervention led to a substantial difference in the duration of any breastfeeding that was maintained throughout the first year of life¹¹ [cluster-adjusted hazard ratio (HR) for weaning 0.70 (95% CI 0.59–0.83)]. In addition, the prevalence of exclusive breastfeeding was 7-fold higher in the experimental group at 3 months (43.3 vs 6.4%; $P < .001$), although low in both groups at 6 months (7.9 vs 0.6%; $P = .01$)¹¹; the cluster-adjusted HR was 0.29 (0.19–0.46) for discontinuation of exclusive breastfeeding.

At the age of 6.5 years, children attended a special study interview and examination held at the polyclinic from December 2002 to April 2005. Parents (92% mothers) who accompanied the child to the polyclinic at the follow-up visit consented in writing to the examination and testing procedures at that visit. While awaiting the examination and interview in the polyclinic waiting room, the parent completed the Strengths and Difficulties Questionnaire (SDQ), parent version. The SDQ is a brief scale devised for behavioral screening of children age 3–16 years; it contains 25 items, some positive and others negative.¹⁸ The 25 items are

divided into 5 scales of 5 items each, which generate scores for total difficulties, conduct problems, hyperactivity/inattention, emotional symptoms, peer problems, and prosocial behavior. The SDQ has been used widely in Europe and more recently in North America, and studies have demonstrated its reliability and validity, as well as its cross-cultural validity.^{19–23} It has been translated, validated, and standardized in Russian. The polyclinic pediatricians also distributed the teacher's version of the SDQ (identical to the parent version) to teachers of children who had started formal schooling by the time of their follow-up visit. Teachers' names were reported by the parents at the polyclinic visit. Teachers were blind to the experimental vs control treatment allocation of the children. As previously reported, internal consistency (based on Cronbach's α) of the parent and teacher responses was high, as was test-retest reproducibility of the parent SDQ, based on a random audit of 190 children who were retested at an average of 17.7 months after the initial polyclinic visit.¹²

Cluster-adjusted differences in outcomes from the experimental and control groups in the ITT (as randomized) analyses were ascertained using linear mixed models (the MIXED procedure) in SAS, version 9.1 (SAS Institute, Cary, NC). Observational analyses on the same children were based on the feeding actually received, as reported by the mother, at study visits during the first year, rather than randomized treatment allocation. The regression model used in the observational analyses included random effects to account for clustering by hospital (also included in the ITT analyses) and fixed effects to control for age at the time of follow-up, sex, birth weight, geographic location (East vs West Belarus and urban vs rural), and maternal and paternal educational attainment ascertained at baseline (recruitment). Feeding actually received was categorized according to the duration of any breastfeeding as <3 months, 3 to <6 months, 6 to <9 months, 9 to <12 months, and 12 months. Duration of exclusive breastfeeding was categorized as <3 months, 3 to <6 months, and 6 months. SDQ scores were also dichotomized as "abnormal" (>85th percentile for total difficulties and all subscale scores other than prosocial behavior, <15th percentile for prosocial behavior) vs "normal." The observational analyses of these dichotomized scores were based on the GLIMMIX procedure in SAS, which uses a mixed (multilevel) logistic model.

RESULTS

Table 1 describes the cohort followed up at age 6.5 years according to duration of breastfeeding, duration of exclusive breastfeeding, age, sex, birth weight, geographical location, and maternal and paternal education. As previously reported, these characteristics were similar to those obtained among the 17,046 randomized and were also similar in the experimental and control groups, both at randomization and at the 6.5-year follow-up.^{4, 10}

Of the total 13,889 children (81.5% of those randomized; 80.2% and 82.9% in the experimental and control groups, respectively) who attended the 6.5-year follow-up visit, 13,814 (99.5%) had a completed parent SDQ, while the teacher version was obtained in 12,032 (86.6%). Table 2 shows the results for the parent and teacher SDQ according to the cluster-adjusted ITT analysis, i.e., based on the randomized treatment allocation. As previously reported, no differences were observed in ITT analyses of the parent or teacher SDQ for total difficulties; emotional symptoms; conduct or peer problems; hyperactivity; or prosocial behavior.¹² The results are shown here, however, to 2 decimal places, to facilitate more detailed comparison with the observational results. These results changed very little with respect to either the point estimates or 95% confidence intervals when the models were adjusted for the exact same covariates used in the observational analyses (data not shown, available upon request).

Table 3 shows the associations between the duration of any breastfeeding and the parent and teacher SDQ scores based on the observational (feeding received) analyses, with statistical adjustment for potential imbalances in confounding variables among the observed feeding groups, as well as for clustering. Significant associations were observed between duration of any breastfeeding <3 months and parent and teacher scores on total difficulties, conduct problems, and hyperactivity. Table 4 shows the corresponding results for the duration of exclusive breastfeeding; no significant effects were observed. No significant interactions were observed between duration of any or exclusive breastfeeding and either child sex or maternal education (data not shown).

Unlike the results for the ITT analyses, the observational analyses of adjusted associations between weaning prior to 3 months and the dichotomized SDQ scores showed significantly increased odds of high hyperactivity on the parent SDQ [OR=1.23 (95% CI 1.09–1.38) vs 1.06 (0.84–1.35) based on ITT], and high emotional symptoms [OR=1.15 (1.01–1.31) vs 0.88 (0.67–1.14) based on ITT] and low prosocial behavior [OR=1.16 (1.02–1.32) vs 0.89 (0.63–1.25) based on ITT] on the teacher SDQ, compared with breastfeeding ≥12 months.

DISCUSSION

Given the positive effects of the PROBIT experimental intervention on cognitive ability at age 6.5 years,²⁴ we were surprised not to have observed beneficial effects on the child's behavior.¹² Yet, despite the absence of effects of the randomized treatment allocation on parent or teacher SDQ scores in the experimental (ITT) analyses, we found statistically significant associations of modest magnitude with breastfeeding based on the duration of breastfeeding actually received. The contrast between these observational results and those based on randomized allocation strongly suggests that the observational results are biased by residual confounding.

The magnitude of the effects obtained in the observational analyses were modest (approximately 0.1% standard deviation on the SDQ scores and 15–20% excess adjusted odds of abnormal scores), considerably smaller than those reported by Oddy et al in their observational cohort study from Western Australia.⁹ These differences in magnitude might be attributable to differences in degree of residual confounding in Belarus vs Australia. Our findings suggest that residual confounding can bias observational analyses of breastfeeding and subsequent behavior, although the magnitude of bias may differ according to setting. If this speculation is correct, the modest magnitude of the effects (due to bias) we observed in Belarus might be larger in settings with larger degrees of residual confounding. Given the significant effects of the PROBIT intervention we have previously reported on gastrointestinal infection, atopic eczema, and growth in infancy^{11, 16} and on cognitive ability at age 6.5 years,²⁴ we believe that the absence of any apparent behavioral effects in ITT analyses is likely to be generalizable to other developed country settings.

Approaches other than randomized treatment allocation can be used to reduce residual confounding due to behavioral characteristics. In ecological designs,²⁵ outcomes are compared among otherwise similar regions with breastfeeding practices that differ substantially because of regional policies, laws, or strong clinical preferences. In instrumental variable analyses,²⁶ outcomes are compared among individual infants exposed to those different breastfeeding practices (the “instruments”). Statistical approaches using propensity scores, such as structural nested models²⁷ and marginal structural models,²⁸ take into account temporal changes in breastfeeding practices and potentially confounding factors. These latter methods, however, require detailed and accurate data over time on changes in breastfeeding behavior, as well as the reasons for those changes.

In previous randomized trials, we have observed a similar contrast between ITT and observational results. In a quasi-randomized study of in-hospital formula supplementation, we found that a policy to restrict formula supplementation on one of two otherwise similar postpartum wards was not associated with age at weaning, whereas observational analyses (even if restricted to the control or the experimental group) showed strong associations between the receipt or nonreceipt of in-hospital formula supplementation and subsequent weaning.^{14, 15} Similarly, a randomized intervention to reduce pacifier use had no discernible effect on early weaning in an ITT analysis, whereas we found a significant observational association between actual pacifier use and age at weaning.¹⁰ These two earlier trials thus involved practices associated with age of weaning, whereas PROBIT examines age at weaning and subsequent child health and development--in this case, parent and teacher evaluations of the child's behavior.

These three trials have several features in common: both the exposure (formula supplementation in the postpartum ward, pacifier use, or duration of breastfeeding) and outcome (age at weaning or subsequent child behavior) are either behaviors themselves or are strongly influenced by behaviors. Potent interventions with large impacts on the exposure behavior of interest are necessary in such trials to detect effects on outcomes that are also behavioral themselves or are strongly influenced by behaviors.

Large sample sizes may also be required because of the relatively high "noncompliance" with (or resistance to) interventions to change behavior. The large sample size, low values of the intraclass correlation coefficient for within-polyclinic clustering on the parent and teacher SDQ, and large impact of the intervention on breastfeeding duration and exclusivity in the PROBIT trial led to good statistical power and narrow confidence intervals.¹² This power also resulted in our ability to detect modest associations in the observational analyses based on duration of (any) breastfeeding (Table 3). Some of the 95% confidence intervals around the observational estimates included the mean differences observed between the intervention and control groups in the ITT analyses. Others (e.g., total difficulties and hyperactivity on the parent SDQ), however, did not. As shown by the wide confidence intervals in Table 4, our power was limited for detecting associations of similar magnitude with duration of exclusive breastfeeding because of the very small proportion of study infants exclusively breastfed 6 months.

It is possible that the differences in breastfeeding exclusivity and duration achieved between PROBIT's two treatment arms were insufficient to have a measurable impact on later child behavior. But as previously reported, those breastfeeding differences resulted in reduced risks of gastrointestinal infection and atopic eczema¹¹ and different growth trajectories¹⁶ during infancy, and higher overall IQ at 6.5 years.²⁴ Thus the results we report here from PROBIT, added to those from our previous trials,^{10, 14, 15} support the argument that studies in which both the exposure and the outcome are strongly influenced by psychological or behavioral attributes of the study participants are prone to residual confounding. Valid estimates of causal effects from such studies are likely to require randomized intervention and ITT analysis.

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Table 1

Description of PROBIT cohort followed up at age 6.5 years (n=13,889)

Baseline Characteristics	% or Mean $\pm$ SD
Sex (% male)	51.7%
Birth weight, g (mean $\pm$ SD)	3441 $\pm$ 420
Geographic location	
East urban	32.4%
East rural	16.3%
West urban	24.1%
West rural	27.2%
Maternal education	
Incomplete secondary	3.7%
Complete secondary	32.1%
Advanced secondary or partial university	51.0%
Complete university	13.2%
Paternal education	
Incomplete secondary	2.4%
Complete secondary	37.2%
Advanced secondary or partial university	47.5%
Complete university	12.9%

Follow-up Characteristics	% or Mean $\pm$ SD
Duration of any breastfeeding; mo	
<3	34.8%
3 to <6	23.2%
6 to <9	13.2%
9 to <12	7.6%
12	21.2%
Duration of exclusive breastfeeding; mo	
<3	73.1%
3 to <6	23.1%
6	3.8%
Age at planned 6.5-year study visit, yr (mean $\pm$ SD)	6.6 $\pm$ 0.3

Table 2

SDQ results according to intention-to-treat (ITT) analysis

	Experimental Mean $\pm$ SD	Control Mean $\pm$ SD	Cluster-Adjusted Difference* in Means (95% CI)
Parent			
Total difficulties (n = 13,807)	11.45 $\pm$ 5.02	11.58 $\pm$ 4.94	-0.08 (-0.66 to +0.51)
Emotional symptoms (n = 13,811)	2.55 $\pm$ 1.99	2.68 $\pm$ 2.04	-0.13 (-0.32 to +0.06)
Conduct problems (n = 13,811)	1.59 $\pm$ 1.52	1.57 $\pm$ 1.49	+0.02 (-0.10 to +0.14)
Hyperactivity (n = 13,814)	4.78 $\pm$ 2.26	4.74 $\pm$ 2.17	+0.06 (-0.19 to +0.31)
Peer problems (n = 13,813)	2.53 $\pm$ 1.64	2.58 $\pm$ 1.62	-0.03 (-0.25 to +0.19)
Prosocial behavior (13,814)	8.28 $\pm$ 1.67	8.27 $\pm$ 1.63	+0.05 (-0.19 to +0.29)
Teacher			
Total difficulties (n = 12,028)	9.48 $\pm$ 5.79	9.69 $\pm$ 5.77	-0.47 (-1.07 to +0.14)
Emotional symptoms (n = 12,031)	1.93 $\pm$ 1.95	2.02 $\pm$ 1.91	-0.15 (-0.34 to +0.04)
Conduct problems (n = 12,032)	1.36 $\pm$ 1.74	1.38 $\pm$ 1.71	-0.05 (-0.20 to +0.10)
Hyperactivity (n = 12,031)	3.90 $\pm$ 2.70	3.94 $\pm$ 2.62	-0.14 (-0.38 to +0.11)
Peer problems (n = 12,030)	2.29 $\pm$ 1.75	2.36 $\pm$ 1.70	-0.13 (-0.35 to +0.10)
Prosocial behavior (12,031)	7.52 $\pm$ 2.24	7.35 $\pm$ 2.24	+0.14 (-0.21 to +0.49)

* Difference expressed as experimental mean minus control mean

Table 3

Multiple linear regression mixed model results for observational analysis of duration of any breastfeeding (BF) *

	BF Duration, mo			
Parent	<3	3 to >6	6 to <9	9 to <12
Total difficulties	+0.46 (+0.22 to +0.69)	+0.18 (−0.07 to +0.43)	+0.01 (−0.28 to +0.30)	−0.01 (−0.36 to +0.34)
Emotional symptoms	+0.06 (−0.03 to +0.16)	−0.05 (−0.15 to +0.06)	−0.04 (−0.16 to +0.08)	+0.03 (−0.11 to +0.17)
Conduct problems	+0.07 (−0.01 to +0.14)	+0.04 (−0.04 to +0.11)	−0.02 (−0.11 to +0.07)	−0.06 (−0.17 to +0.05)
Hyperactivity	+0.27 (+0.17 to +0.38)	+0.15 (+0.04 to +0.27)	+0.09 (−0.04 to +0.22)	+0.07 (−0.09 to +0.22)
Peer problems	+0.06 (−0.01 to +0.14)	+0.05 (−0.04 to +0.13)	−0.01 (−0.11 to +0.08)	−0.04 (−0.15 to +0.08)
Prosocial behavior	−0.07 (−0.15 to +0.01)	−0.02 (−0.10 to +0.06)	+0.01 (−0.09 to +0.11)	0.00 (−0.11 to +0.12)
Teacher				
Total difficulties	+0.34 (+0.05 to +0.62)	+0.10 (−0.21 to +0.41)	+0.07 (−0.29 to +0.42)	−0.34 (−0.77 to +0.09)
Emotional symptoms	+0.05 (−0.05 to +0.15)	+0.02 (−0.09 to +0.13)	−0.01 (−0.14 to +0.11)	−0.11 (−0.25 to +0.04)
Conduct problems	+0.10 (+0.01 to +0.18)	+0.06 (−0.03 to +0.15)	+0.05 (−0.06 to +0.16)	−0.05 (−0.18 to +0.08)
Hyperactivity	+0.16 (+0.03 to +0.30)	+0.04 (−0.10 to +0.18)	+0.01 (−0.15 to +0.18)	−0.10 (−0.29 to +0.10)
Peer problems	+0.03 (−0.06 to +0.12)	−0.01 (−0.10 to +0.09)	+0.01 (−0.10 to +0.12)	−0.08 (−0.21 to +0.05)
Prosocial behavior	−0.07 (−0.19 to +0.04)	−0.03 (−0.15 to +0.09)	+0.02 (−0.11 to +0.16)	+0.08 (−0.08 to +0.25)

* Results reported as difference (95% confidence interval) from BF duration 12 months, adjusted for clustering, child's age at follow-up, sex, birth weight, geographic location, and maternal and paternal education. Statistically significant results are highlighted in bold font.

Table 4

Multiple linear regression mixed model results for observational analysis of duration of exclusive breastfeeding (EBF)*

	EBF Duration, mo	
Parent	<3	3 to <6
Total difficulties	+0.18 (−0.28 to +0.65)	−0.10 (−0.58 to +0.38)
Emotional symptoms	+0.08 (−0.11 to +0.27)	−0.04 (−0.24 to +0.15)
Conduct problems	+0.03 (−0.11 to +0.17)	0.00 (−0.14 to +0.14)
Hyperactivity	−0.01 (−0.22 to +0.19)	−0.07 (−0.28 to +0.15)
Peer problems	+0.06 (−0.09 to +0.22)	0.00 (−0.16 to +0.15)
Prosocial behavior	−0.14 (−0.30 to +0.01)	−0.06 (−0.21 to +0.10)
Teacher		
Total difficulties	+0.41 (−0.15 to +0.97)	+0.09 (−0.48 to +0.67)
Emotional symptoms	+0.12 (−0.07 to +0.31)	−0.01 (−0.21 to +0.19)
Conduct problems	+0.09 (−0.08 to +0.26)	+0.07 (−0.10 to +0.24)
Hyperactivity	+0.17 (−0.09 to +0.42)	+0.13 (−0.14 to +0.39)
Peer problems	+0.03 (−0.14 to +0.21)	−0.09 (−0.27 to +0.08)
Prosocial behavior	−0.03 (−0.24 to +0.19)	+0.03 (−0.19 to +0.25)

* Results reported as difference (95% confidence interval) from EBF duration 6 months, adjusted for clustering, child's age at follow-up, sex, birth weight, geographic location, and maternal and paternal education