


Prelacteal and early formula feeding increase risk of infant hospitalisation: a prospective cohort study

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ABSTRACT

Objective To ascertain the relationship between prelacteal feeding, early formula feeding and adverse health outcomes, especially hospitalisation during the first year of life.

Design Multicentre prospective cohort study.

Setting Six hospitals across three cities in Vietnam.

Patients A total of 2030 pregnant women were recruited at 24–28 weeks of gestation and followed up at hospital discharge, 1, 3, 6 and 12 months post partum.

Main outcome measures Rates of infant hospitalisation, diarrhoea and lower respiratory tract infection during the first 12 months.

Results For the final complete sample (n=1709, 84%), about one-quarter of the infants experienced diarrhoea (25.5%) or were admitted to hospital with at least one episode (24.8%), and almost half (47.6%) the cohort contracted lower respiratory tract infection by 12 months. The prevalence of prelacteal feeding was high (56.5%) while formula feeding was common (79.5%) before hospital discharge, both of which increased the risks of adverse health outcomes particularly hospitalisation by approximately 1.5-fold, with adjusted OR (95% CI) 1.43 (1.09 to 1.88) and 1.48 (1.07 to 2.05), respectively for these infants by 12 months, when compared with others who were exclusively breast fed.

Conclusions Prelacteal feeding and early formula feeding before hospital discharge are associated with higher risks of infection and hospital admission in Vietnamese infants. Support for exclusive breast feeding should be provided to mothers to avoid the adverse consequences of giving formula milk and prelacteal foods.

INTRODUCTION

Respiratory infections and diarrhoea are the most common causes of death in children under 5 years of age, especially in low-income and middle-income countries.^{1–3} In Vietnam, the proportion of deaths among children under 5 years attributable to pneumonia is 10%–14% and diarrhoea is 5%–9%.^{1–4} Current evidence has shown a link between infant feeding types and hospitalisation for infectious diseases including respiratory infections and diarrhoea.^{5–11} For example, a cross-sectional study of Vietnamese infants <5 months in 2011 reported that early initiation and exclusive breast feeding were inversely associated with the prevalence of diarrhoea and acute respiratory infections.¹² Another prospective cohort study of 1049 infants in 2015 concluded that exclusive breast feeding at 6 weeks of age reduced the odds of inpatient

What is already known on this topic?

- Giving prelacteal foods and formula milk to infants soon after birth is a common practice in Vietnam.
- The effects of early feeding method on infant illnesses have been documented in cross-sectional surveys and birth cohort studies, but were mostly limited to 6 months after birth.

What this study adds?

- Prelacteal feeding and formula feeding before hospital discharge are associated with higher risks of infection and hospital admission during the first 12 months of life.
- Interventions to support exclusive breast feeding and to curtail the use of formula milk and prelacteal foods are needed to protect infants against infectious diseases.

admission for suspected pneumonia and diarrhoeal illness.¹³

In Vietnam, high prevalence of prelacteal feeding and formula feeding has been reported in several studies.^{12–14–15} However, the relationships between prelacteal and early formula feeding, infant illness and hospitalisation have not been investigated in detail. Therefore, the present prospective cohort study aimed to ascertain specifically the risk of hospitalisation within 1 year of birth for infants who were given prelacteal or early formula feeds. We hypothesise that infants fed with prelacteal foods or infant formula soon after birth experience higher rates of hospitalisation and childhood illnesses than their exclusively breastfed counterparts.

MATERIALS AND METHODS

Design

A multicentre prospective cohort study was undertaken between August 2015 and December 2017 at six hospitals across three cities of Vietnam.¹⁶ A total of 2030 pregnant women were recruited during their antenatal care visits between 24 and 28 weeks of gestation. After childbirth, participants were followed up at hospital discharge, then at 1, 3, 6 and 12 months post partum.



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Participants

We recruited pregnant women who (1) were permanent residents in the study locations; (2) ≥ 18 years of age; (3) at 24–28 weeks of gestation; (4) had a singleton pregnancy; (5) did not have any serious pre-existing health conditions according to medical records and (6) were able to read the information sheet and sign the consent form.

Main exposures

Breastfeeding practices were defined according to the WHO criteria.¹⁷ Prolactal feeds are any foods (such as water, honey, formula milk and fruit juice) given before the onset of lactogenesis II, that is, the onset of copious breastmilk secretion occurring within 4 days of birth.¹⁸ Early formula feeding refers to a baby receiving any amount of any kind of reconstituted milk products or replacer after birth and before hospital discharge. In this study, prolactal and early formula feeding were not mutually exclusive and recorded as binary variables (yes; no) at hospital discharge using the question “*What was your baby’s first feed after birth?*” and “*How are you feeding your baby?*”, respectively.

Outcome measures

The main outcomes were the presence (yes; no) of hospitalisation, diarrhoea and lower respiratory tract infection during the first 6 months and the first year of life. Hospitalisation refers to any inpatient admission of the infant due to illness or medical problems. Information on hospital admission (for any reason such as fever, jaundice, ear infection, diarrhoea and lower respiratory tract infection) was collected at the 1, 3, 6 and 12 months follow-up interviews using the question “*Has your baby had any inpatient admission since the last interview?*” Medical records were used to confirm such illness outcomes and hospital admission whenever feasible. All mothers were able to provide documentary evidence of admission to hospital and/or diagnosis from their medical invoices and infant health record books. A diarrhoea was defined as ‘the passage of three or more loose or liquid stools per day, or more frequently than is normal for the individual’.¹⁹ Symptoms for a lower respiratory tract infection were ‘at least one specific lower respiratory tract sign (fast or difficulty breathing, chest wall indrawing) and/or abnormal auscultatory findings (crackles/crepitations or bronchial breath sounds)’.²⁰ Although these two outcomes might overlap with the hospitalisation outcome for some cases, specific information on each admission episode was not collected, so that subcategorisation of the hospitalisation outcome was not feasible.

Other variables

Information on confounding factors such as maternal and socio-demographic characteristics, as suggested in the literature,^{8 9 11 21} was collected at the baseline interview. Gestational diabetes was diagnosed following the criteria from the International Association of the Diabetes and Pregnancy Study Groups, with at least one glucose value above the threshold: fasting plasma glucose ≥ 5.1 mmol/L, 1 hour plasma glucose ≥ 10.0 mmol/L, 2 hours plasma glucose ≥ 8.5 mmol/L.²² Variables related to birth were retrieved from medical records at hospital discharge, which included gestational age, gestational weight gain, caesarean section, infant gender, birth weight and admission to neonatal intensive care unit. Infant feeding methods after discharge were assessed through the question “*How are you feeding your baby?*” at the postpartum interviews. Any breastfeeding duration (weeks) was recorded at the interviews by asking “*How old was your baby when you stopped breast feeding?*”

Statistical analysis

In addition to descriptive statistics, group comparisons were made between infants with and without hospital admission during the first year, using χ^2 test for categorical variables and t-test for continuous variables. Cumulative prevalence of the outcomes were computed at the four follow-up time points. Separate logistic regression analyses were then performed to determine the associations between prolactal feeding, early formula feeding and the risks of hospitalisation, diarrhoea and lower respiratory tract infection during the first 6 months and the first year of life, with adjusted OR (AOR) and associated 95% CIs to account for the effects of plausible confounding factors. Covariates included in the 12 logistic regression models were maternal age (years), occupation (working; not working), education level (secondary school or lower; high school graduate; college, university or above), parity (0; 1; ≥ 2), prepregnancy body mass index (kg/m^2), gestational diabetes status (yes; no), gestational age (preterm < 37 weeks; not preterm ≥ 37 weeks), gestational weight gain (kg), caesarean section (yes; no), birth weight (g), infant gender (boy; girl) and newborn admission to neonatal intensive care unit (yes; no). To accommodate the potential effect of feeding practice after discharge, an additional covariate ‘any breast feeding at 6 months (yes; no)’ was included in the models for 6 months, whereas adjustment for the continuous ‘any breastfeeding duration (weeks)’ was made in the models for 12 months. All statistical analyses were undertaken using the SPSS package V.22 (IBM, Armonk, New York, USA).

RESULTS

Of the total 2030 pregnant women recruited at baseline,¹⁶ 297 were lost-to-follow up and 24 mothers who experienced serious medical problems (HIV positive, $n=2$; prepregnancy diabetes, $n=6$; stillbirth, $n=8$; termination of pregnancy, $n=1$; infant death, $n=7$) were subsequently excluded, leaving $n=1709$ for data analysis (retention rate 84%). No differences were found in maternal and sociodemographic characteristics between the final participants and the dropouts, except for maternal education ($p<0.05$).

Table 1 presents the characteristics of our cohort. Preterm births occurred in 4.2% of the sample, while over one-third (38.2%) experienced caesarean section, and only 44 newborns (2.6%) had been admitted to the neonatal intensive care unit. When comparing infants with and without hospitalisation during the first 12 months, the two groups were significantly different in terms of maternal education, infant gender and early feeding methods. In particular, the hospitalised infants had significantly higher rates of prolactal feeding and formula feeding than their healthy counterparts (61% and 83% vs 55% and 78%, respectively) before hospital discharge. Overall, formula feeding was common (40% at 1 month, 43% at 3 months and 66% at 6 months), but usually in conjunction with breast feeding, even though very few mothers exclusively breast fed their infants (18.8% at discharge and $< 2\%$ at 6 months).

Table 2 summarises the cumulative prevalence of hospitalisation, diarrhoea and lower respiratory tract infection from the four follow-ups of the cohort. About one-quarter of the infants experienced diarrhoea or were admitted to hospital with at least one episode during the first 12 months, while 14.6% of infants had admission(s) during their second 6 months of life. The prevalence of lower respiratory tract infection was very high, with almost half the cohort contracted the disease by 12 months.

Tables 3 and 4 present the associations between prolactal feeding, early formula feeding and the adverse health outcomes

Table 1 Characteristics of participants by hospitalisation status

Variables	Overall	Hospitalisation during the first 12 months		P value*
		Yes	No	
Total, n (%)	1709 (100)	423 (24.8)	1286 (75.2)	
Maternal age (years), mean±SD	27.5±5.3	27.1±5.1	27.6±5.3	0.072
Occupation, n (%)				0.816
Currently not working	533 (31.2)	130 (30.7)	403 (31.3)	
Currently working	1176 (68.8)	293 (69.3)	883 (68.7)	
Education level, n (%)				0.031
Secondary school or lower	574 (33.6)	146 (34.5)	428 (33.3)	
High school graduate	445 (26.0)	127 (30.0)	318 (24.7)	
College/university or above	690 (40.4)	150 (35.5)	540 (42.0)	
Parity, n (%)				0.720
0	655 (38.3)	160 (37.8)	495 (38.5)	
1	636 (37.2)	164 (38.8)	472 (36.7)	
≥2	418 (24.5)	99 (23.4)	319 (24.8)	
Pre pregnancy BMI (kg/m ²), mean±SD	20.1±2.4	20.1±2.5	20.1±2.4	0.945
Gestational diabetes†, n (%)				0.391
Yes	373 (21.8)	86 (20.3)	287 (22.3)	
No	1336 (78.2)	337 (79.7)	999 (77.7)	
Gestational age (weeks), n (%)				0.214
Preterm: <37	71 (4.2)	22 (5.2)	49 (3.8)	
Not preterm: ≥37	1638 (95.8)	401 (94.8)	1237 (96.2)	
Gestational weight gain (kg), mean±SD	13.0±4.0	13.3±3.8	13.0±4.0	0.112
Caesarean section, n (%)				0.784
Yes	653 (38.2)	164 (38.8)	489 (38.0)	
No	1056 (61.8)	259 (61.2)	797 (62.0)	
Infant gender, n (%)				<0.001
Boy	875 (51.2)	249 (58.9)	626 (48.7)	
Girl	834 (48.8)	174 (41.1)	660 (51.3)	
Birth weight (g), mean±SD	3146.2±395.0	3120.3±427.7	3154.7±383.4	0.143
Admission to NICU, n (%)				0.078
Yes	44 (2.6)	16 (3.8)	28 (2.2)	
No	1665 (97.4)	407 (96.2)	1258 (97.8)	
Prelacteal feeding, n (%)	966 (56.5)	258 (61.0)	708 (55.0)	0.033
Early formula feeding, n (%)	1352 (79.1)	350 (82.7)	1002 (77.9)	0.034

*From χ^2 and t-tests.

†Based on International Association of the Diabetes and Pregnancy Study Groups criteria (2010).

BMI, body mass index; NICU, neonatal intensive care unit; SD, Standard deviation.

during the first 6 and 12 months, respectively, after adjusting for plausible confounding factors. The observed rates for all outcomes were higher among prelacteal-fed and early formula-fed infants. Both prelacteal and early formula feeding were apparently associated with hospitalisation and diarrhoea but not lower respiratory tract infection during the first 6 months of life (table 3). By 12 months, their risks of adverse health outcomes were almost 1.5 times higher than the exclusively breastfed infants, particularly for hospitalisation, with AOR (95% CI) 1.43

(1.09 to 1.88) and 1.48 (1.07 to 2.05), respectively (table 4). The online supplementary table shows the detailed results from fitting the 12 multivariable logistic regression models, each with a different set of significant factors and covariates.

DISCUSSION

This large prospective cohort study confirmed that both prelacteal feeds and early formula feeding before hospital discharge are associated with adverse infant health outcomes during their first year of life. The observed high prevalence of prelacteal feeding and early formula feeding before hospital discharge were consistent with previous cross-sectional studies in Vietnam which reported rates above 50%.^{12 14 23} A recent quasi-experimental study indicated over half the infants received prelacteal feeds, and formula milk was used as the first feed by 65.5% of the control group and 50% overall.²⁴

In Vietnam, respiratory diseases, bacterial and parasitic infections accounted for most hospital admissions in children.²⁵ Compared with the our observed hospitalisation rate of 14.8% for all causes during the first 6 months, a previous cohort study

Table 2 Cumulative prevalence of infant hospitalisation, diarrhoea and lower respiratory tract infection at 1, 3, 6 and 12 months

Adverse health outcome	Prevalence (one or more episodes)			
	≤1 month	≤3 months	≤6 months	≤12 months
Hospital admission, n (%)	55 (3.2)	125 (7.3)	241 (14.1)	423 (24.8)
Diarrhoea, n (%)	45 (2.6)	120 (7.0)	256 (15.0)	435 (25.5)
Lower respiratory tract infection, n (%)	92 (5.4)	242 (14.2)	434 (25.4)	814 (47.6)

Table 3 Association between prelacteal feeding, early formula feeding and adverse health outcomes during the first 6 months of life

Feeding method before hospital discharge	Hospitalisation (0–6 months)			Diarrhoea (0–6 months)			Lower respiratory tract infection (0–6 months)		
	Yes n (%)	No n (%)	AOR* (95% CI)	Yes n (%)	No n (%)	AOR* (95% CI)	Yes n (%)	No n (%)	AOR* (95% CI)
Prelacteal feeding									
Yes	148 (15.3)	818 (84.7)	1.44 (1.02 to 2.03)	166 (17.2)	800 (82.8)	1.73 (1.25 to 2.41)	246 (25.5)	720 (74.5)	0.85 (0.65 to 1.12)
No	93 (12.5)	650 (87.5)	1	90 (12.1)	653 (87.9)	1	188 (25.3)	555 (74.7)	1
Formula feeding									
Yes	197 (14.6)	1155 (85.4)	1.39 (0.92 to 2.10)	215 (15.9)	1137 (84.1)	1.50 (1.02 to 2.21)	350 (25.9)	1002 (74.1)	1.00 (0.74 to 1.37)
No	44 (12.3)	313 (87.7)	1	41 (11.5)	316 (88.5)	1	84 (23.5)	273 (76.5)	1

*Adjusted for maternal age (years), occupation (currently not working; currently working), education level (secondary school or lower; high school graduate; college/university or above), parity (0; 1; ≥2), prepregnancy body mass index (kg/m²), gestational diabetes (yes; no), gestational age (preterm; not preterm), gestational weight gain (kg), caesarean section (yes; no), infant gender (boy; girl), birth weight (g), admission to neonatal intensive care unit (yes; no) and any breastfeeding at 6 months (yes; no). The models only included those with complete follow-up data for 12 months (n=1709).
AOR, adjusted OR; CI, confidence interval.

with 6 months follow-up found 8.8% and 4% of infants required inpatient admission for suspected pneumonia and diarrhoeal illness, respectively.¹³ The prevalence of diarrhoea and acute respiratory infection among infants 0–5 months (during the last 2 weeks) was 5.3% and 24.5%, respectively, from another cross-sectional study in Vietnam.¹² These rates appeared to be comparable to our cumulative data at the 6-month follow-up (15% and 25.4%; table 2). Finding from a cohort study in Maldives also showed a large proportion of infants (35.5%) had diarrhoea and acute respiratory tract infection (30.2%) 6 months after birth.⁹

The present study found prelacteal and early formula feeding before hospital discharge are associated with adverse infant health outcomes, especially hospitalisation and lower respiratory tract infection. Data from a cross-sectional study in Vietnam similarly suggested that babies fed with prelacteal foods are more susceptible to acute respiratory illness.¹² The observed marginal association between early formula feeding and diarrhoea was also consistent with the result from a nationwide longitudinal survey of Japanese children.¹¹ Moreover, formula feeding during the first 3 days after birth was found to be associated with increased infant formula feeding and early breastfeeding cessation.²³ Another study from Brazil concluded that hospitalisation contributed to the interruption of exclusive breast feeding and the introduction of infant formula during hospitalisation.²⁶ Breastmilk is known to have immunological protection against infection. On the other hand, provision of prelacteal foods and formula milk during the first few days of life can

increase the infant's exposure to environmental contaminants from non-breastmilk supplements and change the microbiome as a result,^{27 28} thereby increasing their risk of childhood illnesses.

A major strength of this study was the multicentre prospective cohort study design with a large sample size, which enabled the longitudinal repeated measures of infant health outcomes with follow-up interviews at 1, 3, 6 and 12 months after birth; unlike previous cross-sectional surveys or birth cohort studies in Vietnam with limited follow ups (typically 6 months). Moreover, the final retention rate was high at 84%, and data were collected from six hospitals in both north and south of the country, thus representative of the urban population in Vietnam. To overcome the limitation concerning the self-reported nature of the outcome variables, all reported illness symptoms by the mothers were confirmed with medical records whenever feasible, otherwise the diagnoses were reviewed and assigned by a paediatrician following the standard protocol. Consequently, the observed hospitalisation rates might likely overestimate the actual prevalence of childhood illnesses attributable to the adverse feeding methods, but the same magnitude of bias would also apply to the exclusively breastfed infants. Therefore, additional analyses were undertaken for diarrhoea and lower respiratory tract infection to confirm the effects of prelacteal and early formula feeding. The infant health outcomes were classified as binary variables which did not distinguish infants with single and multiple episodes of illness. The data were analysed using information from participants who completed the 12-month postpartum interview,

Table 4 Association between prelacteal feeding, early formula feeding and adverse health outcomes during the first year of life

Feeding method before hospital discharge	Hospitalisation (0–12 months)			Diarrhoea (0–12 months)			Lower respiratory tract infection (0–12 months)		
	Yes n (%)	No n (%)	AOR* (95% CI)	Yes n (%)	No n (%)	AOR* (95% CI)	Yes n (%)	No n (%)	AOR* (95% CI)
Prelacteal feeding									
Yes	258 (26.7)	708 (73.3)	1.43 (1.09 to 1.88)	271 (28.0)	695 (71.9)	1.56 (1.19 to 2.05)	504 (52.2)	462 (47.8)	1.50 (1.18 to 1.90)
No	165 (22.2)	578 (77.8)	1	164 (22.1)	579 (77.9)	1	310 (41.7)	433 (58.3)	1
Formula feeding									
Yes	350 (25.9)	1002 (74.1)	1.48 (1.07 to 2.05)	357 (26.4)	995 (73.6)	1.37 (1.00 to 1.87)	672 (49.7)	680 (50.3)	1.41 (1.08 to 1.83)
No	73 (20.4)	284 (79.6)	1	78 (21.9)	279 (78.1)	1	142 (39.8)	215 (60.2)	1

*Adjusted for maternal age (years), occupation (currently not working; currently working), education level (secondary school or lower; high school graduate; college/university or above), parity (0; 1; ≥2), prepregnancy body mass index (kg/m²), gestational diabetes (yes; no), gestational age (preterm; not preterm), gestational weight gain (kg), caesarean section (yes; no), infant gender (boy; girl), birth weight (g), admission to neonatal intensive care unit (yes; no) and any breastfeeding duration (weeks). The models only included those with complete follow-up data for 12 months (n=1709).
AOR, adjusted OR; CI, confidence interval.

instead of adjustment of follow-up time for the entire cohort. Information on non-inpatient admission was not recorded, even though it might be a confounding factor for a subsequent inpatient admission. Finally, details of formula milk feeding such as intensity and duration before hospital discharge were not collected to avoid subject burden, which posed as another limitation of our study.

In conclusion, prelacteal feeding and early formula feeding are associated with elevated risks of hospitalisation, diarrhoea and lower respiratory tract infection. Given that relationships have been identified between paediatricians and formula milk companies,²⁹ it is important to promote exclusive breast feeding and to educate women during their pregnancy about the adverse consequences of giving prelacteal foods. Extra support should be available to mothers who have difficulties to initiate breast feeding, and to overcome their reliance on infant formula as a substitute for breastmilk.

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Contributors PN: recruited patients, analysed and interpreted data, drafted the manuscript. CWB and AHL: conceptualised and designed the study, supervised the overall study conduct and analysis. AVVH, TKC, LCN: enrolled patients and interpreted data. DaVD and DuVD: provided technical support, supervised the overall study conduct and analysis. All authors critically revised and approved the final manuscript.

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