The impact of teat and bottle design on nipple confusion: a double-blind randomized controlled trial

Pharuhas Chanprapaph (pharuhasc@gmail.com)
Breastfeeding Unit, Department of Obstetrics and Gynaecology, Faculty of Medicine Siriraj Hospital, Mahidol University

Sureelak Sutchritpongsa
Division of Developmental and Behavioral Pediatrics, Department of Pediatrics, Faculty of Medicine Siriraj Hospital, Mahidol University

Pat Rojmahamongkol
Division of Developmental and Behavioral Pediatrics, Department of Pediatrics, Faculty of Medicine Siriraj Hospital, Mahidol University

Siripan Chuchoang
Division of Developmental and Behavioral Pediatrics, Department of Pediatrics, Faculty of Medicine Siriraj Hospital, Mahidol University

Jenjira Arthan
Breastfeeding Unit, Department of Obstetrics and Gynaecology, Faculty of Medicine Siriraj Hospital, Mahidol University

Chulaluk Komoltri
Clinical Epidemiology Unit, Department of Research and Development, Faculty of Medicine Siriraj Hospital, Mahidol University

Research Article

Keywords: bottle refusal, breast refusal, design, nipple confusion, randomized controlled trial

Posted Date: April 4th, 2022

DOI: https://doi.org/10.21203/rs.3.rs-1494783/v1

Abstract

Background: Nipple confusion has been reported in some infants who receive both breastfeeding and bottle feeding at early stage. Two types of nipple confusion including breast refusal (type A) and bottle refusal (type B) are described. Breast refusal may decrease maternal breast stimulation and result in low breast milk production while bottle refusal could create stress and prevent mothers from resuming their normal lives. This study aimed to explore whether the design of teat and bottle could influence the nipple confusion incidence, infant growth, feeding type and infant behaviors.

Method: A double-blind randomized controlled trial study has been conducted during June 2016 and September 2019. Forty normal eligible exclusively breastfed newborn-mother dyads with given informed consent were prospectively enrolled for 8 weeks of mixed feeding due to maternal return to work or study. They were randomly allocated into group A (Pigeon, Peristaltic Plus^{TM} nipple, SS size) and group B (Philips, Avent Natural^{TM} Slow Flow nipple, SS size). All data including feeding type, milk intake, nipple confusion rate and infant behavior were collected for statistical analysis.

Result: Between 21 pairs of group A and 19 pairs of group B, nipple confusion was increasing from 22.5% to 50% during the study. Initially, bottle refusal was found 22.5% while breast refusal was more detected (32.5%) lately. Infant growth and development including weight, length, and head circumference were comparable in both groups. Infants in group A seemed to have lower breast refusal rate than infants in group B (28.6% vs 36.8%). Nevertheless, the bottle refusal rate was rather higher in group A than group B (23.8% vs 10.5%). The earlier the mixed feeding (< 5 weeks), the higher the nipple confusion rate (15% vs 7.5% at 4 weeks; 15% vs 35% at 12 weeks). Infant aerophagia, crying, abnormal latch-on and milk aspiration could be observed in both groups with no statistical difference while constipation was only observed in group B (5.3-15.8 %).

Conclusion: Nipple confusion could be found in exclusive breastfed infants after switching to mixed feeding. In Phillips' group, nipple confusion rate was about 2 times higher than Pigeon's group at 4 weeks, then, the rate was increasing to approximately 50% in both groups by 12 weeks. Aerophagia was more observed in Pigeon's group while constipation was commonly found in Philips' group. Early infant mixed feeding before 5 weeks could cause the higher nipple confusion rate and should be discouraged. As each product has both pros and cons, it has to be thoughtful to choose the proper design to achieve the infant's need.

Background

The benefit of breastfeeding to both mothers and neonates has been widely accepted. In term of nourishment, breast milk is customized to match infant necessity. It is full of essential elements required for early neonatal development. Secretory IgA found in breast milk helps enhancing newborns' immune system and prevents them from severe infection. Breastfeeding is also associated with mother-infant bonding and improves both physical and mental development in the offspring. For decades since World

Health Organization (WHO) and United Nations International Children's Emergency Fund (UNICEF) have been supporting 6-month exclusive breastfeeding policy. They had launched "the Baby-friendly hospital Initiative" to encourage health services globally to support breastfeeding by following "Ten steps to successful breastfeeding".[1] Nevertheless, breastfeeding rate still varies substantially between low- and middle-income, and high-income countries. In European region, 6-month exclusive breastfeeding rate varies from 22 % in United Kingdom to 72% in Sweden.[2] The study from Canada revealed that 73.65 % of mothers discontinued breastfeeding before 6 months due to exhaustion (22.6%), uncertainty of adequate milk volume (21.6%), return to work or study (20%) and medical complications.[3] Therefore, several designs of infant feeding bottle and nipple that mimic natural infant suckling have been introduced for breastfeeding contiunation. Thus, the baby can get breast milk through the bottle in day time while the mother can directly breastfed her baby in the night time. However, nipple confusion can be developed in some newborns. Nifert M, et al. has described 2 types including breast refusal (type A) and bottle refusal (type B).[4] Without immediate proper management, infant with breast refusal may decrease maternal breast stimulation and result in breast milk production deterioration. In contrast, infant with bottle refusal if left untreated, it can be very stressful for parents and prevent mother from going back to normal life.

In 2012, an experimental study in 63 exclusively formula-fed term infants found that bottle design (the anti-vacuum infant feeding bottle from Philips Avent ^{TM} vs the internal venting system from Dr Browns ^{TM}) had no significant effects on infant milk intake or growth. However, infants who used the former bottle had significantly less reported fussing than those using the latter.[5] Later on, an observational non-comparative prospective trial of efficacy of using a new design of bottle and nipple (Pigeon Peristaltic PLUS ^{TM}, Japan) for continuation of breast feeding of neonates has been conducted by the researchers from Russia.[6] The trial included 33 breastfed infants (20 full-term and 13 premature newborns), age of 1-10 weeks, having mild or moderate perinatal lesions of central nervous system, with low birth weight and/or premature infants capable of suckling without assistance. All of them required temporary weaning due to supplementary or mixed feeding requirement, prolonged conjugated jaundice. They were all switched to bottle feeding for 14 days before bringing back to breastfeeding. The data revealed that 10 infants (30.3 %) with breast refusal at the beginning were clinically improved and there was no breast refusal found by the end of the study. Furthermore, the number of children receiving primarily breastfeeding was increased from 42.42 % to 78.78 %. Regarding functional digestive disorders which may develop during bottle feeding, the study showed that the rate of aerophagia and colonics were decreased by using this new devices. However, the lack of the control group in this study make the efficacy of this novel design inconclusive and more information is still required. Currently, there are 2 different designs of infant nipples widely used including Pigeon Peristaltic Plus^{TM} and Philips Avent Natural^{TM} Slow Flow.

Methods

Study aims

Theprimarily goal of the study aimed to explore whether the design of infant nipple and bottle could influence the nipple confusion incidence.Secondary, whether or not the nipple and bottle design could affect infant growth, feeding type and behaviors would be explored.

Study design

The randomized controlled study design has been used to evaluate the influence of nipple and bottle design on nipple confusion, infant growth, feeding type and fetal behaviors

Study setting

During June 2016 and September 2019, the study has been conducted and collaborated between Breastfeeding Unit, Department of Obstetrics and Gynaecology and Division of Developmental and Behavioral Pediatrics, Department of Pediatrics, Faculty of Medicine Siriraj Hospital, Mahidol University.

Participants

Healthy normal term singleton infants (37 weeks completed gestation, birthweight >= 2.5 kg), age 15-45 years old were recruited from postpartum ward. Exclusion criteria were: mother with abnormal breasts or nipples, inadequate maternal milk volume, unable to speak Thai, infant with suckling and swallowing disorders. All infants must have exclusively breastfed for at least 4-6 weeks with normal growth and development and switching between breastfeeding and bottle feeding is required due to maternal return to work or study.

Randomization

Mothers and newborns were routinely appointed from the postpartum ward to attend “Well Baby Clinic” at the 4^{th} week after delivery. The eligible participants were invited into the study and informed about the research project. After having the written informed consent, a sealed opaque envelope containing a specific code inside was chosen for each participant. The nQuery software was used to randomly generate group A and group B in sequential order. All women will receive a package box filled with devices accordingly (group A: Pigeon Peristaltic PLUS^{TM} nipples (SS size), 160-ml Pigeon milk bottles x 4 sets; group B: Philips, Avent Natural^{TM} Slow Flow nipples (SS size) and 160-ml Avent milk bottlesx 4 sets). Each participant was also given one manual breast pump and breast milk storage bags for3 months. Names and logos on any devices were deleted before giving to the participants. The research assistant will demonstrate how to use and clean all instruments appropriately. Allparticipantsand theirinfantswereasked to revisit at 4 and 12 weeks after enrollment according to their baby’s vaccination

schedule. Each infant underwent physical examination, growth and development assessment, suckling efficacyevaluation by pediatricians specialized in child development and behavior. A log book was given to mother since the first visit for recording her infant feeding type, breast milk intake, type & onset ofnipple confusionand infant behavior twice a week. Finally, all information from log books were collected for statistical analysis.

Definition

Nipple confusion

This term refers to an infant's struggle with or preference for one feeding method over another after exposure to bottle feeding or artificial nipple. Two types of nipple confusion including breast refusal (type A) and bottle refusal (type B) are classified.[4] After bottle feeding exposure, the exclusively breastfed infant who denies breastfeeding will be diagnosed of breast refusal. On the other hand, the infant who refuses bottle feeding will be diagnosed of bottle refusal.

Infant behaviors

Aerophagia is defined as a condition of excessive air swallowing while feeding and can cause subsequent abdominal distention.[7] This functional digestive disorder could be found in premature infants due to immaturity or infants with tongue and possible lip tie.[8] Aerophagia symptoms may include cry at feeding, breast refusal, gastroesophageal reflux disease (GERD)-like symptoms, colics and vomiting.

From maternal observation, all infant behaviors including aerophagia (air swallowing), crying and defecation were observed twice a week. Then, the occurrence of each behavior was graded into 3 levels of none, few (2-3 times a day) and often (1 time in a hour).

From pediatrician observation, all infant behaviors including abnormal latch on, milk aspiration, defecation were observed in every visit. The frequency of each behavior was graded into 3 levels of none, few (2-3 times a day) and often (1 time in a hour).

Data collection

Maternal and infant demographic data such as age, ethnicity, parity, obstetrics history, infant gender, route of delivery and birth weight were recorded. All information from the log book including feeding type, milk intake, type and onset of nipple confusion and infant behavior were collected for statistical analysis using.

Data analysis

Descriptive statistics were used as appropriate, including N (%), mean ± standard deviation (SD). Median, maximum and minimum were used for abnormal distribution data. Either Fisher Exact test or independent samples T-test was used accordingly for the comparison of categorical or non-categorical variables. $P < 0.05$ was considered statistically significant. Statistical analysis was performed using PASW^{Ò} Statistics version 18.0 software (SPSS Inc., Chicago, IL, USA).

Ethic approval

Ethical approval was granted by the Institute of Research Board Committee, Siriraj Hospital Mahidol University No. 318/2558 (EC1). The research project had been approved for registration at Thai Clinical Trial Registry (TCTR20160516001).

Results

Initially, 90 mother-infant couples plus 10% of loss to follow-up cases were required with the total number of 100 dyads were aimed to be enrolled. Due to time strain and mother's work obligation, most of eligible candidates were unable to make multiple visits accordingly. Although sample collection period has been extended from 1.5 year into 3 years, there were finally 40 mother-infants dyads accomplished the protocol. There were 21 cases allocated in group A and 19 cases in group B. Demographic data of all participants in both groups at delivery and enrollment were indifferent. Mean maternal age, gestational age, baby's birth weight and infant age at recruitment were 30.6 ± 6.70 years, 38.70 ± 0.89 weeks, 3,137.5 ± 372.30 gram and 4.67 ± 0.5 weeks, respectively. Infant growth and development including weight, length, and head circumference were comparable observed in both groups during the study. (Table 1)

From Table 2, the nipple confusion rate was increasingly detected from 22.5% to 50% during 8 weeks. At the beginning, only bottle refusal was found 9 out of 40 cases (22.5%). Later on, breast refusal was more detected than bottle refusal (32.5 % vs 17.5%). Infant numbers with mixed feeding decreased from 31 (77.5%) to 20 (50 %) during the study.

Regarding the impact of nipple and bottle design, nipple confusion rate in group A was lower than group B at the beginning (14.3 % vs 31.6 %), then, it became higher in group A at 12 weeks (52.4% vs 47.4%). Breast refusal was more prevalent in group B than group A (36.8 %vs 28.6%). However, there was no significantly difference of infant feeding types observed between 2 groups. (Table 2)

Concerning the onset of mixed feeding, nipple confusion rate in infants with early switching (before 5 weeks) was higher than infants with later switching (24 % vs 20% at 4 weeks and 56% vs 40% at 12 weeks). Nevertheless, there was no statistical significance of infant feeding types found between 2 groups. (Table 2)

From maternal log book's record, aerophagia was more commonly found in infants group A (71.4 % vs 57.9 %), thereafter, it was decreasing in both groups (52.4 % vs 42.1 %). Infant crying was more prevalent in group A than group B (76.1 % vs 68.5 %), however, the number was declining at the end with less prevalence in group A than group B (47.5 % vs 57.9 %). At first, the number of infants with constipation in group A was less than group B (19 % vs 26.3%), then, the number was increasing in both groups (52.4 % vs 52.6%). (Table 4)

From pediatricians' observation, there was only one case of abnormal latch-on observed in group B (5.3%). At first, milk aspiration was not detected in both groups, thereafter, infants developed milk aspiration in group B more than group A (57.9 % vs 47.6%). Constipation was not found in infants group A while in group B it was found increasing from 5.3 % to 15.8 %. (Table 5)

Discussion

In modern world, it is difficult for working mothers to prolong their breastfeeding as long as they need. Although bottle feeding becomes more supportive, the early switching of feeding may be complicated by nipple confusion in infants.[9] Our data confirmed that nipple confusion could be found in exclusively breast-fed infants who switched to mix-fed infants from 22.5% to 50% during 8 weeks of mixed feeding. At the beginning, breast refusal was more prevalent, thereafter, bottle refusal became more detected. Interestingly, the onset of feeding switch seemed to affect the nipple confusion incidence. The change from exclusive breastfeeding to mixed feeding before 5 weeks can cause the higher nipple confusion rate. Therefore, the early feeding switch should be extensively considered to avoid this undesired consequence.

To get success in breastfeeding, infant needs to establish good latch-on to maternal nipple and areola and performs nutritive suckling and breast milk swallowing. Therefore, the design of nipple must replicate maternal nipple both physical and functional features to establish nutritive suckling and minimize nipple confusion. According to product's information, the textured soft silicon surface of Pigeon Peristaltic Plus™ nipple with widened base was designed to ease the baby to latch on, secure the attachment and support peristaltic tongue movement during suckling. On the other hand, the wide breast-shape nipple with a flexible spiral tip and unique petals of Philips Avent Natural Slow Flow™ nipple was applied to make the nipple softer, more flexible to promote latch-on and natural tongue movement.

Apparently, nipple confusion found in both groups were not significantly different. At first, nipple confusion rate in group B (Philips) was about 2 times higher than group A (Pigeon), thereafter, the rate was increasing to approximately 50% in both groups. Finally, the higher number of bottle refusal rate in group A was noted (23.8 % vs 10.5%). According to product's information, the contour and radius of nipple-12mm for SS size in group A are crafted to fit the baby's mouth while its small hole is designed to

make the baby drinking slowly and prevent milk aspiration. On the other hand, group B nipple is designed with 2 small holes that offer a slow flow and features twin anti-colic valves which claimed to reduce colic and discomfort. From maternal records, aerophagia was more commonly found in infants group A than group B. For infant crying, it was initially more prevalent in group A than group B, then, it was declining with the less prevalence in group A than group B later on. There was only one case of abnormal latch-on noted in group B and milk aspiration rate was more observed in group B than group A. Regarding constipation, it was commonly found in group B infants. This finding was unlikely to be associated with nipple design but could possibly relate to the higher rate of breast refusal in this group.

According to Turti TV, et al, infants with breast refusal were clinically corrected after using Pigeon's nipple and bottle for 2 weeks.[6] Our study found that infants using Pigeon's nipple and bottle seemed to have lower breast refusal rate than infants using Philips' products (28.6% vs 36.8%). Nevertheless, the bottle refusal rate was rather higher in Pigeon's group than Philips' group (23.8% vs 10.5%). While aerophagia was more common in Pigeon's group, constipation was prevalent in Philips' group. Considering that each product design has both pros and cons, it has to be thoughtful to choose the proper design to achieve the infant's need.

Strength and limitation

To our best knowledge, this is the first prospective experimental study that compares the impact of nipple and bottle design on nipple confusion rate. Owing to the double-blind, randomized controlled study design in which neither the participants nor the evaluators know which group they belonged to. This strongly prevents bias in the research results. In term of data collection, infant physical examination, growth and development assessment, suckling efficacy have been thoroughly evaluated by specialists while infant behavior was observed by both mother and clinicians. As a result, the study has high reliability and validity.

Initially, 100 mother-infant pairs were aimed to recruit for this study. Due to time strain and maternal work obligation, most of eligible candidates were unable to make multiple visits accordingly. Despite sample collection extension, there were only 40 mother-infants dyads accomplished the protocol. In the future, the larger studied population and the longer study period (up to 6 months) should be encouraged.

Conclusion

Nipple confusion could be found in exclusively breast-fed infants from 22.5% to 50% after 12 weeks of mixed feeding. In Phillips' group, nipple confusion rate was about 2 times higher than Pigeon's group at 4 weeks, then, the rate was increasing to approximately 50% in both groups by 12 weeks. Aerophagia was more observed in Pigeon's group while constipation was commonly found in Philips' group. Early infant mixed feeding before 5 weeks can cause the higher nipple confusion rate and should be discouraged.

Declarations

Acknowledgement

None

Author's contributions

P.C. developed research project, analyzed data and wrote the main manuscript.

S.S. developed research project, performed case follow-up, reviewed the manuscript.

P.R. performed case follow-up.

S.C. and J.A. collected all data.

C.K. performed statistical analysis.

Funding

The authors are grateful to Moong Pattana International Public Company Limited, Bangkok, Thailand for funding and the supply of the devices for use in this study.

Availability of data and materials

The datasets generated and/or analysed during the current study are not publicly available due to lack of ethical approval for sharing but may be available from the corresponding author on reasonable request.

Declarations

Ethical approval [No. 318/2558 (EC1)] was granted by the Institute of Research Board Committee, Siriraj Hospital Mahidol University. The research project had been approved for registration at Thai Clinical Trial Registry (TCTR20160516001).

Consent for publication

Not applicable.

Competing interests

The authors have no conflict of interest to declare.

Author details

1. Breastfeeding Unit, Department of Obstetrics and Gynaecology, Faculty of Medicine Siriraj Hospital, Mahidol University, 2 Wanglang Road, Bangkoknoi, Siririaj, Bangkok, Thailand 10700.

2. Division of Developmental and Behavioral Pediatrics, Department of Pediatrics, Faculty of Medicine Siriraj Hospital, Mahidol University, 2 Wanglang Road, Bangkoknoi, Siririaj, Bangkok, Thailand 10700.
3. Clinical Epidemiology unit, Department of Research and Development, Faculty of Medicine Siriraj Hospital, Mahidol University, 2 Wanglang Road, Bangkoknoi, Siririaj, Bangkok, Thailand 10700.

References

1. Baby-Friendly Hospital Initiative: Revised, Updated and Expanded for Integrated Care. Geneva: World Health Organization; 2009.
2. Bartington S, Griffiths LJ, Tate AR, Dezateux C, Millennium Cohort Study Health G. Are breastfeeding rates higher among mothers delivering in Baby Friendly accredited maternity units in the UK? Int J Epidemiol 2006; 35: 1178-86.
3. Brown CR, Dodds L, Legge A, Bryanton J, Semenic S. Factors influencing the reasons why mothers stop breastfeeding. Can J Public Health 2014; 105: e179-85.
4. Neifert M, Lawrence R, Seacat J. Nipple confusion: toward a formal definition. J Pediatr 1995; 126: S125-9.
5. Fewtrell MS, Kennedy K, Nicholl R, Khakoo A, Lucas A. Infant feeding bottle design, growth and behaviour: results from a randomised trial. BMC Res Notes 2012; 5: 150.
6. Turti TV, Namazova-Baranova LS, Belyaeva IA, Zimina EP, Mitish MD, Bakovich EA, et al. Modern methods of breast feeding maintenance in children with intestinal colics. Ped pharmacol 2014; 11: 55-8.
7. Chitkara DK, Bredenoord AJ, Wang M, Rucker MJ, Talley NJ. Aerophagia in children: characterization of a functional gastrointestinal disorder. Neurogastroenterol Motil 2005; 17: 518–22.
8. Siegel S. Aeropohagia induced reflux in breastfeeding infants with ankyloglossia and shortened maxillary labial frenula (tongue and lip tie). Int J Clin Pediatr 2017; 5: 6–8.
9. Zimmerman E, Thompson K. Clarifying nipple confusion. J Perinatol 2015; 35: 895-9.

Tables

Table 1

Patients' demographic data in each group

Group A: Pigeon Peristaltic Plus^{TM} nipple (size SS), 160-ml Pigeon milk bottle

Characteristic Data	Group		Total	P-value
	A (n =21)	B (n = 19)	N = 40	
Maternal age (yr)	30.1 ± 6.69	31.21 ± 6.85	30.63 ± 6.70	0.606
Gestational age at delivery (wk)	38.51 ± 0.99	38.91 ± 0.71	38.70 ± 0.89	0.161
Baby's birth weight (g)	3,144.29 ± 409.90	3,130 ± 336.93	3,137.5 ± 372.30	0.905
At enrollment				
Infant age (wk)	4.68 ± 047	4.66 ± 0.55	4.67 ± 0.5	0.909
Infant weight (g)	4,279.29 ± 480.41	4,346.58 ± 422.39	4,311.25 ± 449.29	0.642
Infant length (cm)	54.02 ± 2.18	54.10 ± 2.38	54.06 ± 2.25	0.916
Infant head circumference (cm)	37.06 ± 0.95	36.64 ± 1.33	36.86 ± 1.15	0.253
4 weeks after enrollment				
Infant age (wk)	8.56 ± 0.6	8.44 ± 0.44	8.47 ± 0.53	0.724
Infant weight (g)	5,208.33 ± 434.68	5,137.37 ± 923.31	5,174.63 ± 701.18	0.754
Infant length (cm)	57.46 ± 2.17	57.24 ± 1.77	57.35 ± 1.97	0.729
Infant head circumference (cm)	38.63 ± 0.85	37.99 ± 1.23	38.33 ± 1.08	0.064
12 weeks after enrollment				
Infant age (wk)	17.10 ± 0.68	17.25 ± 0.51	17.17 ± 0.6	0.427
Infant weight (g)	6,485.48 ± 602.51	6,717.89 ± 678.99	6,595.87 ± 642.95	0.259
Infant length (cm)	62.19 ± 2.73	62.28 ± 1.59	62.23 ± 2.24	0.891
Infant head circumference (cm)	40.77 ± 0.91	40.65 ± 1.05	40.72 ± 0.97	0.704

Group B: Philips, Avent Natural^{TM} Slow Flow nipple (size SS), 160-ml Avent milk bottle

Analysis test: independent samples T-test

Table 2

Infant feeding type in both groups

Duration of study	4 weeks			12 weeks		
Infant feeding type	**A (n =21)**	**B (n =19)**	**P-value**	**A (n =21)**	**B (n =19)**	**P-value**
Exclusive breastfeeding (Bottle refusal or nipple confusion type B)	3 (14.3 %)	6 (31.6 %)	0.265	5 (23.8 %)	2 (10.5 %)	0.583
Mixed feeding	18 (85.7 %)	13 (68.4 %)		10 (47.6 %)	10 (52.6%)	
Bottle feeding only (Breast refusal or nipple confusion type A)	0	0		6 (28.6 %)	7 (36.8 %)	

Group A: Pigeon Peristaltic Plus^{TM} nipple (SS), 160-ml Pigeon milk bottle

Group B: Philips, Avent Natural^{TM} Slow Flow nipple (SS), 160-ml Avent milk bottle

Analysis test: Fischer Exact test

Table 3

Onset of feeding type switching and infant feeding type in 2 groups

Onset of feeding type switching	Infant feeding type	4 weeks after enrollment			12 weeks after enrollment		
		A (n =21)	B (n =19)	P-value	A (n =21)	B (n =19)	P-value
Early (< 5 week)	Exclusive breastfeeding (Bottle refusal or nipple confusion type B)	2 (18.2 %)	4 (28.6 %)	0.661	3 (27.3 %)	1 (7.1%)	0.491
	Mixed feeding	9 (81.8 %)	10 (71.4 %)		4 (36.4 %)	7 (50.0%)	
	Bottle feeding only (Breast refusal or nipple confusion type A)	0	0		4 (36.4%)	6 (42.9%)	
Late (³ 5th week)	Exclusive breastfeeding (Bottle refusal or nipple confusion type B)	1 (10.0 %)	2 (50 %)	0.242	2 (20.0 %)	1 (20.0 %)	1.0
	Mixed feeding	9 (30.0 %)	3 (60 %)		6 (60.0 %)	3 (60.0 %)	
	Bottle feeding only (Breast refusal or nipple confusion type A)	0	0		2 (20.0%)	1 (20.0%)	

Group A: Pigeon Peristaltic Plus™ nipple (SS), 160-ml Pigeon milk bottle

Group B: Philips, Avent Natural™ Slow Flow nipple (SS), 160-ml Avent milk bottle

Analysis test: Fischer Exact test

Table 4

Fetal behavior observed by mother in both groups

Fetal Behavior		4 weeks after enrollment			12 weeks after enrollment		
		A (n =21)	B (n =19)	P-value	A (n =21)	B (n =19)	P-value
Aerophagia	None	6 (28 .6%)	8 (42.1 %)	0.728	10 (47.6 %)	11 (57.9 %)	0.545
	Few (2-3 times a day)	13 (61.9 %)	9 (47.4 %)		11 (52.4 %)	8 (42.1 %)	
	Often (1 time in an hour)	2 (9.5 %)	2 (10.5 %)		0 (0 %)	0 (0 %)	
Crying	None	5 (23.8 %)	6 (31.6 %)	0.480	11 (52.4 %)	8 (42.1 %)	0.897
	Few (2-3 times a day)	12 (57.1 %)	12 (63.2 %)		8 (38.1 %)	9 (47.4 %)	
	Often (>3 times a day)	4 (19.0 %)	1 (5.3 %)		2 (9.5 %)	2 (10.5 %)	
Defecation	None	4 (19 %)	5 (26.3 %)	0.758	11 (52.4 %)	10 (52.6 %)	1.00
	Few (2-3 times a day)	13 (61.9 %)	9 (47.4 %)		8 (38.1 %)	8 (42.1 %)	
	Often (>3 times a day)	4 (19.0 %)	5 (26.3 %)		2 (9.5 %)	1 (5.3 %)	

Group A: Pigeon Peristaltic Plus^{TM} nipple (SS), 160-ml Pigeon milk bottle

Group B: Philips, Avent Natural^{TM} Slow Flow nipple (SS), 160-ml Avent milk bottle

Analysis test: Fischer Exact

Table 5

Fetal behavior observed by pediatrician in both groups.

Fetal Behavior		4 weeks after enrollment			12 weeks after enrollment		
		A (n =21)	B (n =19)	P-value	A (n =21)	B (n =19)	P-value
Abnormal latch on	None	21 (100 %)	18 (94.7 %)	0.475	21 (100 %)	18 (94.7 %)	0.475
	Few	0 (0 %)	1 (5.3 %)		0 (0 %)	1 (5.3 %)	
Milk aspiration	None	21 (100%)	19 (100 %)	0.354	11 (52.4 %)	8 (42.1 %)	0.897
	Few (2-3 times a day)	0 (0 %)	0 (0 %)		8 (38.1 %)	9 (47.4 %)	
	Often (>3 times a day)	0 (0 %)	0 (0 %)		2 (9.5 %)	2 (10.5 %)	
Defecation	None	0 (0 %)	1 (5.3%)	0.098	0 (0 %)	3 (15.8 %)	0.042
	Few (2-3 times a day)	21 (100 %)	16 (84.2 %)		21 (100 %)	15 (78.9 %)	
	Often (>3 times a day)	0 (0 %)	2 (100 %)		0 (0 %)	1 (5.3 %)	

Group A: Pigeon Peristaltic Plus^{TM} nipple (SS), 160-ml Pigeon milk bottle

Group B: Philips, Avent Natural^{TM} Slow Flow nipple (SS), 160-ml Avent milk bottle

Analysis test: Fischer Exact

Figures

Figure 1

A) Pigeon Peristaltic Plus™ nipple (size SS), 160-ml Pigeon milk bottle B) Philips, Avent Natural™ Slow Flow nipple (size SS), 160-ml Avent milk bottle

Figure 2

Study flow