Examination of the Effect of Dr. Brown's Natural Flow Baby Bottles on Infant Colic

Marsha L. Cirgin Ellett, DNS, RN, CGRN
Susan M. Perkins, PhD

Thirty-six parents of colicky infants participated in this randomized, placebo-controlled clinical trial conducted via the Internet. Parents recorded a baseline state-of-arousal diary for 3 days using their usual feeding methods, and then they used six study-provided bottles for 2 weeks while recording a second state-of-arousal diary. Infants being fed with placebo bottles significantly spent more time crying ($p = .010$) and fussing ($p = .002$) on average than infants using Dr. Brown's Natural Flow Baby Bottles. Because these bottles decreased the time the infants spent crying and fussing, use of these bottles may be recommended for colicky infants who receive any bottle feedings.

Infant colic, characterized by persistent crying, diminished soothability, and restlessness in an otherwise healthy, well-fed infant, is not a rare occurrence (Keefe & Froese-Fretz, 1991). For example, in a Scandinavian study of 1,400 primiparas, 18% of the mothers reported their infants had "quite a lot of colic" (Rautava, Helenius, & Lehtonen, 1993). Furthermore, several researchers have shown that colic is not related to gender, race, or socioeconomic class (Baildam et al., 1995; Ellett et al., 2003; St. James-Roberts & Halil, 1991; Stahlberg, 1984).

Colic frequently begins in the first 3 weeks of life. Infants usually recover by 3 to 4 months of age, although a few have the symptoms through the fifth month. Caring for a colicky infant is very stressful for parents, and in high-risk families (e.g., those lacking support), colic may have a lasting negative effect on the parent-infant relationship (Mrazek, 1993). The cause of infant colic is likely to be multifactorial because finding one cause has proven to be so elusive (Ellett, 2003). For example, recent literature suggests that infant colic may be related to feeding difficulties (Miller-Loncar, Bigsby, High, Wallach, & Lester, 2004) and to maternal smoking (Shenassa & Borwn, 2004). Regardless of whether the underlying cause(s) of infant colic can be identified, interventions effective in decreasing the severity of colic symptoms are needed.

Studies have been done comparing the physics of bottle-feeding to breastfeeding. When using conventional feeding bottles, negative pressure is generated in the oral cavity, as well as in the bottle when fluid is removed by sucking. In a study by Brown and Magnuson (2000), three types of bottles were tested: fully vented, undervented, and nonvented (see Figure 1). Seven infants were studied using two pressure-sensing transducers: one monitoring the pressure formed in the nipple of the bottle, reflecting pressure in the oropharynx, and the other monitoring the external auditory canal ear pressure (Brown & Magnuson). The nonvented bottle was a solid-walled vessel with a nipple held in place by a cap. An undervented bottle had holes or slits in the flange of the nipple allowing some air to enter the bottle once enough vacuum had formed. A fully vented bottle allowed a direct communication between the outside air and the inside of the bottle through a straw-type conduit connecting the threads of the nipple cap with a cavity at the bottom of the bottle. Any vacuum was thus eliminated because air could pass into the bottom of the bottle without contaminating the feeding liquid with air (Brown & Magnuson). See Brown and Magnuson's article for an explanation of the physics present during feeding infants with the three types of bottles studied.

Many parents report that they wish that their colicky infants would cry and fuss less and sleep more, but no studies comparing the mean crying, fussing, and sleeping time per

Received October 14, 2005; accepted January 12, 2006.

About the authors: Marsha L. Cirgin Ellett, DNS, RN, CGRN, is Associate Professor, School of Nursing.

Susan M. Perkins, PhD, is Associate Professor, Division of Biostatistics, Department of Medicine, Indiana University School, Indianapolis.

Correspondence to: Marsha L. Cirgin Ellett, DNS, RN, CGRN, Indiana University School of Nursing, Family Health, Room 439, 1111 Middle Drive, Indianapolis, IN 46202-5102.

MAYBORN 2041
NANOBEBE v. MAYBORN
IPR2023-00467

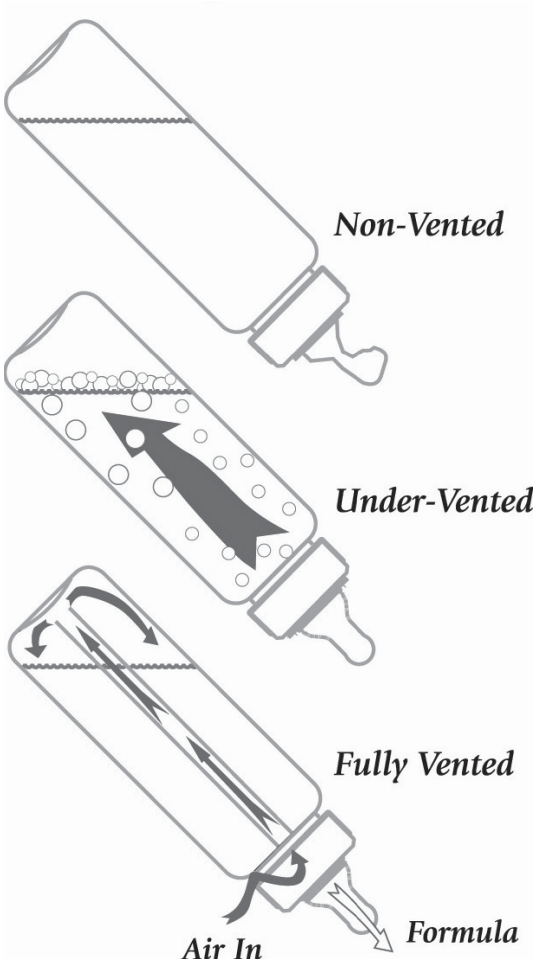

FIGURE 1. Three Types of Bottles. Reprinted from "On the physics of the infant feeding bottle and middle ear sequela: Ear disease in infants can be associated with bottle feeding," by C. E. Brown & B. Magnuson, 2000, *International Journal of Pediatric Otorhinolaryngology, 54*(1), pp.13–20. Copyright 2000, with permission from Elsevier.

day of colicky versus noncolicky infants have been published to date. Therefore, the objective of this study was to examine the effect of using Dr. Brown's Natural Flow Baby Bottles (Handi-craft, Inc.) to feed the colicky infant on the mean time per day the infant spent crying, fussing, and sleeping. Our hypothesis was that the use of Dr. Brown's Natural Flow Baby Bottles would reduce crying and fussing and increase sleeping on average because there would be less mixing of air with formula and a reduced chance for ear pain or discomfort due to the elimination of the negative pressure generated in the oral cavity when using conventional bottles.

Methods

Sample

Parents of 91 colicky infants accessed the Infant Colic Study Web site by typing "infant colic" on any of 1,500 search engines worldwide. On the Web site, infant colic was defined as prolonged crying for no apparent reason in an otherwise healthy infant, and the study was explained briefly along with what study participation would entail. To be eligible, all infants had to be 7 months old or less and receive the majority of their feedings by bottle. For the purposes of this research, parents decided whether or not their infant had colic. If parents were interested in participating in the study, they clicked on the informed consent, read it and, if they remained interested in participating, clicked on the "I agree to participate" button. The investigator then responded by e-mail within 48 hours, offering to answer questions about study participation and requesting that the parents print a hard copy of the consent form, sign it, and fax or mail it to the investigator.

Procedure

Prior to beginning this study, approval was obtained by the appropriate institutional review board. After returning the signed written consent form and thus agreeing to participate in this study, the caregiver who provided most of the infant's care during the episodes of colic completed the online Infant Colic Scale (ICS) (Ellett et al., 2003). This instrument is a 22-item multidimensional Likert-type scale with items addressing each of five current theoretical explanations for infant colic (Ellett, 2003; Ellett et al.). These explanations include cow's milk/soy protein allergy/intolerance, immature gastrointestinal (GI) system, immature central nervous system, difficult infant temperament, and parent-infant interaction problem.

The Scale and the accompanying demographic data form use information from parents to determine the first and second most likely explanations for the colic in each infant. In a previous sample of 254 primary caregivers of colicky infants, content- and criterion-related validity of the ICS were demonstrated (Ellett et al., 2003). Internal consistency reliability for the total scale was 0.73, and that of the five subscales ranged from 0.45 to 0.91 in this previous study.

Infant state was conceptualized as the level of arousal or state of consciousness on a continuum ranging from aroused loud crying to deep quiet sleep. Awake states were crying, active alert, quiet alert, and drowsy. In addition, there were two distinct sleep states—active or random eye movement (REM) sleep and quiet or non-REM sleep (Wong, 1999). After providing participants with descriptions of behavior consistent with each of the six states of infant arousal, parents recorded the time their infant spent in each state of arousal in the state-of-arousal diaries during the time they were awake and assumed that their infants were in quiet sleep when the parents were sleeping.

When the investigator received the signed consent form and completed ICS, she sent general information to the participant about infant colic and infant states of arousal and the baseline state-of-arousal diary to be completed for 3 days. The diary was returned by e-mail using the reply function to eliminate errors from retyping e-mail addresses. If infants were exposed to cow's milk or soy protein, through either dairy or soy products in the mother's diet (if breastfeeding) or in the infant formula, a 2-week trial of strict removal of all dairy and soy products in the mother's diet or a 1-week trial of a hypoallergenic formula (Nutramigen, Alimentum, or Progestimil) was suggested to be begun with while completing the baseline diary. Previous research shows that cow's

milk intolerance or allergy is responsible for some infant colic (Oggero, Garbo, Savino, & Mostert, 1994). Parents of three infants who removed cow's milk protein and soy protein from their infants' diet reported to the investigator that the colic resolved within the 3 days, so they withdrew from the study.

When the investigator received the completed baseline state-of-arousal diary, she mailed the participant a 60-minute telephone card as an incentive to continue participation and e-mailed the second state-of-arousal diary to record the infant's states of arousal for 14 days while using only the study bottles provided to feed the infant. She also e-mailed New Vent Designs, Inc. requesting that they mail the participant a set of bottles. A computer-generated random number list was used to assign the participant to either the control (placebo bottles) or the treatment (Dr. Brown's Natural Flow Baby Bottles) group. A set of six Dr. Brown's Natural Flow Baby Bottles or placebo bottles that appeared to be identical were mailed.

Dr. Brown's Natural Flow Baby Bottles were of identical color and shape as the conventional bottles. In addition, the type of ventilation system was not evident in any of the bottles because the normal venting pathway was plugged internally in a nondetectable fashion during the molding process of the control bottles and left open for the treatment bottles. The bottles were provided free of charge to the participants. The investigator was blinded to the participants' treatment group, and New Vent Designs, Inc. saw none of the data.

When the investigator received the second completed state-of-arousal diary, the participant was mailed a second 60-minute telephone card. Participants randomized to the control group also received a set of six real Dr. Brown's Natural Flow Baby Bottles at the end of study participation. Throughout study participation, the investigator responded promptly to participant's questions. Also, when the completed state-of-arousal diaries were not received in a timely manner, a reminder was sent to the participant's e-mail address, up to three times as necessary. If the participants had trouble opening any of the e-mail attachments, a hard copy was mailed. A few of the participants did not have computer access but heard about the study from their friends. They completed the study successfully by mail using the telephone for questions. The participants were also reimbursed for expenses associated with study participation such as postage and fax costs.

Data Analysis

For each of the three baseline days and the following 14-day observation period, the number of minutes the parent reported that the child spent crying, fussing, or sleeping (active or quiet) was calculated. If the total number of minutes reported overall for a day was more than 1,440, the number of minutes reported in each state of arousal was reduced proportionally so that the adjusted total for the day was 1,440. In other words, we assumed that overreporting was proportionally spread across the six states of arousal. If the minutes reported were less than 1,440, no adjustments were made because it was thought that the underreporting of time could have been due to legitimate reasons (e.g., parent left child alone for a minute), and we did not wish to risk incorrectly distorting the time that was reported by assuming proportional amounts of underreporting for each state of arousal. In addition, the times for active and quiet sleep were combined because it was difficult for the participants to distinguish between the two, and sleep (in general) was the variable of interest.

For the baseline data, the mean number of minutes spent in each state of arousal over the 3 days was calculated. For each state, at least 2 of the 3 days had to be completed in order to include the data in analyses. For the following 14-day period, the mean number of minutes spent in each state of arousal over the 14 days was calculated. For any state of arousal, at least 7 of the 14 days had to be completed in order to include the data in analyses.

Participants who completed the study were compared to those who did not with respect to baseline outcomes using two-sample *t* tests. In addition, for those who completed the study, baseline distributions of child and parent characteristics in the treatment and control groups were compared. *t* tests were used for continuous variables and chi-square tests for categorical variables, except when the assumptions for the chi-square test were not met. In this case, Fisher exact tests were used. Treatment and control groups were compared on each of the three outcomes. Treatment effects for average minutes spent per day crying, fussing, and sleeping in the observation period were calculated and adjusted for baseline average minutes spent per day crying, fussing, and sleeping in the analysis of covariance (ANCOVA) models. The treatment effect in an ANCOVA model estimates what the effect of the treatment would be on the outcome if both the treatment and control groups had the same distribution of baseline levels of the outcome. Each of the three outcomes was modeled separately. For all significance tests, a p value of less than .05 was considered statistically significant.

Results

Ninety-one participants were randomized in the study, but three withdrew due to the resolution of colic after removing cow's milk or soy protein from their infants' diet, leaving 88 participants with potential observation data. Thirty-one of 46 participants (67%) who were randomized to the control group did not provide enough data over the study period to use, compared to 21 of 42 (50%) in the treatment group. This difference in noncompletion rate was not statistically significant ($p = .10$); however, although there were no significant differences in the average baseline time spent crying, fussing, or sleeping per day overall or between noncompleters and completers within the treatment group, noncompleters in the control group had infants who tended to spend more time crying per day during the baseline period than completers ($p = .04$, a mean of 150 minutes per day for noncompleters vs. 102 minutes for completers). Information about participants who did not complete the study is presented in Table 1. In most cases, there was no reason given for nonparticipation. Demographic information for the infants of caregivers who completed the study is shown in Table 2. There were no significant differences between the treatment and control groups on any of the demographic characteristics for those infants included in the observation period.

Adjusting for baseline average minutes spent crying, mean minutes spent crying per day in control infants were significantly more than for those in the treatment group ($p = .01$). Similarly, adjusting for baseline average minutes spent fussing, infants in the control group spent significantly more minutes fussing on average per day than those in the treat-

TABLE 1

Participants Who Did Not Complete the Study (n = 52 out of 88)

Action	Reason
Withdrew (n = 7)	Infant would not accept nipple (n = 2)
	Increased choking in infant (n = 1)
	Colic worse (n = 1)
	Notified researcher but gave no reason (n = 3)
Partial data (n = 2)	Only six days of data received for the observation period (n = 1)
	Had observation data but no baseline information (n = 1)
Lost to observation (n = 43)	None given

TABLE 2

Baseline Characteristics of the Study Sample Overall and by Treatment Group for Those Participating in the 14-day Observation Period (n = 33[a])

	Overall	Treatment	Control	p value
Child Characteristics				
Age in weeks[b]	11.3 (6.3)	11.4 (6.5)	11.3 (6.2)	.97
Female	52%	47%	57%	.58
Race				.48
Asian	3%	5%	0%	
Biracial	9%	5%	14%	
Caucasian	88%	89%	86%	
Breastfed[c]	27%	32%	21%	.52
Birth order				.83
First born	43%	47%	36%	
Second born	30%	26%	36%	
Third born	21%	21%	21%	
Fourth born	3%	5%	0%	
Fifth born	3%	0%	7%	
Parent characteristics				
Age in years[b]	30.4 (5.7)	31.1 (6.1)	29.5 (5.1)	.43
Race				1.00
Asian	6%	5%	7%	
Biracial	3%	5%	0%	
Caucasian	91%	89%	93%	
Relationship to infant				1.00
Mom	97%	95%	100%	
Grandmother	3%	5%	0%	
Followed dietary instructions	52%	53%	50%	.88

[a]3/36 (8%) did not complete the demographic information.
[b]Mean (standard deviation).
[c]All breastfed children were both breast and bottle fed.

ment group ($p < .01$). There were no significant differences in the average minutes spent sleeping between the treatment and control groups ($p = .56$). See Table 3 for a summary of baseline, observation, and change scores, along with the ANCOVA treatment effect estimates for each outcome.

Discussion

This study testing the effectiveness of Dr. Brown's Natural Flow Baby Bottles on crying, fussing, and sleeping times was difficult to conduct because colic is a phenomenon that frequently begins abruptly for no known reason and ends just as abruptly. Also, Dr. Brown's bottles were available for sale in stores and on the Internet at the time this study was conducted.

Seven parents notified the investigator that they wished to withdraw from the study; three of these seven did not provide a reason for withdrawal, and 43 withdrew without notification. Two other parents provided only partial information so their data could not be used. Of the four parents who gave a reason for withdrawal, one cited increased infant choking on formula using the bottles provided (control group), one cited worsening of colic (control group), and two cited the reason that their babies would not accept the nipples on the bottles (one in the control group and one in the treatment group). The nipples were different in size or shape than the ones they were used to using. Both the treatment and placebo bottles had the same type of nipples.

No participants complained of seeing any air bubbles in the bottles. Although not specifically reported, some of the parents may have become disheartened because their baby's colic was not improving, and other parents may have decided that completing the state-of-arousal diary for 14 days was too time consuming, regardless of whether or not the bottles helped their infants' colic. Also, the colic probably disappeared of its own accord in some of the infants.

This study was conducted via the Internet. Advantages of Internet research include that participants come from a range of geographical backgrounds (32 states within the United States and 2 foreign countries) and can participate in their own homes at any time of day or night. The racial composition in this study was about the same as would have been expected had the study been conducted locally.

Disadvantages of Internet research include that for the most part, participation is limited to those with Internet access, usually those of a higher educational and socioeconomic level, though this profile is changing with lower cost Internet access through WebTV, public libraries, and retail establishments such as coffee shops and bookstores. Several participants in this study had WebTV or Internet access through friends or family members. Another disadvantage of Internet research is the difficulty in establishing a relationship of trust between the researcher and participant. In this study, the investigator tried to overcome this difficulty by responding to the participants' questions/problems quickly (usually within 24 hours), making inquiries by e-mail when the completed state-of-arousal diaries were not received as expected, and mailing incentives promptly upon receiving completed diaries.

The researcher contemplated the possible connection between the negative pressure formation in the middle ear, induction of air into the formula, and colic. Sucking on a nonvented and undervented bottle results in negative ear pressure. Negative ear pressure also occurs during descent in an airplane; this is commonly known to cause ear pain or discomfort. Induction of air bubbles into the infant formula was seen with the undervented bottles. Transfer of this air into the infant gastrointestinal tract upon feeding could lead to colicky symptoms.

Potential limitations for this study include noncompletion by participants, age of enrolled infants, and parental diagnosis of colic. Although we found no significant differences

TABLE 3

Mean Number of Minutes per Day Spent in Each Activity and Results of ANCOVA Models ($N = 36$)

Group	State-of-Arousal Diary	*n*	Crying	Fussing	Sleeping
Treatment	Baseline	21	184.2 (65.9)	123.8 (69.0)	690.0 (120.7)
	Observation	21	93.7 (84.0)	73.6 (40.2)	715.6 (121.5)
	Change	21	–90.5 (62.6)	–50.2 (57.3)	25.6 (115.9)
Control	Baseline	15	101.6 (63.5)	111.3 (52.7)	747.2 (151.9)
	Observation	15	88.9 (77.1)	116.0 (60.8)	761.6 (87.4)
	Change	15	–12.7 (55.8)	4.7 (45.2)	14.3 (101.1)
Treatment effect from ANCOVA model[a]			66.1	48.2	17.8
p value[b]			0.010	0.002	0.561

[a]A positive value indicates more minutes spent on average in the activity in the control group.
[b]The *p* value is for the test of treatment effect from an ANCOVA model that adjusted for baseline outcome.

TABLE 4

Frequency of First and Second Most Likely Explanations for the Colic in the 21 Infants Who Received Treatment Bottles Based on the Primary Caregiver-Completed Infant Colic Scale

	Cow's Milk Protein Intolerance or Allergy	Immature Gastrointestinal System	Immature Central Nervous System	Difficult Infant Temperament	Parent-Infant Interaction Problem
First	8	3	3	7	0
Second	0	4	5	5	7

between infants of completers and noncompleters of the study with respect to baseline crying, fussing, and sleeping, it is possible that the infants of noncompleters were different from those of completers in ways we could not observe. In addition, the average age of the infants was relatively older and near the age when colic tends to begin resolving itself; however, we found no difference between the treatment and control group with respect to age. In addition, we examined the correlations between change in crying, fussing, and sleeping with age, and there were no significant correlations. Finally, because colic was diagnosed by the parent, some children may not have met some of the more stringent criteria available for colic diagnosis; however, Dr. Brown's Natural Flow Baby Bottles should be of benefit to both children diagnosed with colic and those with only symptoms of colic.

In spite of the difficulties in conducting this study, the results were encouraging. Adjusting for baseline, Dr. Brown's Natural Flow Baby Bottles decreased the time the infants spent crying by about 66 minutes per day and the time they spent fussing by 48 minutes per day in the 21 treatment group infants who completed both the baseline and observation periods. This gave these families nearly 2 more hours of peace per day on average. Because the average amount of time the infants spent per day sleeping was not significantly different in the two groups, it appears that the infants using Dr. Brown's Natural Flow Baby Bottles spent more time in active or quiet activity or being drowsy rather than in sleeping.

Table 4 presents the first and the second most likely explanations for the colic in the 21 infants who received treatment bottles based on the primary caretaker-completed ICS. As can be seen, Dr. Brown's Natural Flow Baby Bottles helped decrease the time the infants spent crying and fussing for a group of infants with a variety of possible explanations for the colicky behavior. Therefore, results of this study support recommending Dr. Brown's Natural FlowBaby Bottles to colicky infants who receive any bottle feedings.

Acknowledgments

The authors want to thank the 36 participants who completed the study diaries during a very difficult period in their lives. Their attention to the details is greatly appreciated.

References

Baildam, E. M., Hillier, V. F., Ward, B. S., Bannister, R. P., Bamford, F. N., & Moore, W. M. (1995). Duration and pattern of crying in the first year of life. *Developmental Medicine and Child Neurology, 37*(4), 345–353.

Brown, C. E., & Magnuson, B. (2000). On the physics of the infant feeding bottle and middle ear sequela: Ear disease in infants can be associated with bottle feeding. *International Journal of Pediatric Otorhinolaryngology, 54*(1), 13–20.

Ellett, M. L. C. (2003). What is known about infant colic? *Gastroenterology Nursing, 26*(2), 60–65.

Ellett, M. L. C., Murphy, D., Stroud, L., Shelton, R. A., Sullivan, A., Ellett, S. G., et al. (2003). Development and psychometric testing of the infant colic scale. *Gastroenterology Nursing, 26*(3), 96–103.

Keefe, M. R., & Froese-Fretz, A. (1991). Living with an irritable infant: Maternal perspectives. *MCN: The American Journal of Maternal Child Nursing, 16*(5), 255–259.

Miller-Loncar, C., Bigsby, R., High, P., Wallach, M., & Lester, B. (2004). Infant colic and feeding difficulties. *Archives of Diseases in Childhood, 89*(10), 908–912.

Mrazek, P. J. (1993). Maltreatment and infant development. In C. H. Zeanah, Jr. (Ed.), *Handbook of infant mental health* (pp. 159–170). New York: Guilford.

Oggero, R., Garbo, G., Savino, F., & Mostert, M. (1994). Dietary modifications versus dicyclomine hydrochloride in the treatment of severe infantile colic. *Acta Paediatrica, 83*(2), 222–225.

Rautava, P., Helenius, H., & Lehtonen, L. (1993). Psychosocial predisposing factors for infantile colic. *British Medical Journal, 307*(6904), 600–604.

Shenassa, E. D., & Borwn, M. J. (2004). Maternal smoking and infantile gastrointestinal dysregulation: The case of colic. *Pediatrics, 114*(4), 497–505.

St. James-Roberts, I., & Halil, T. (1991). Infant crying patterns in the first year: Normal community and clinical findings. *Journal of Child Psychology and Psychiatry, 32*(6), 951–968.

Stahlberg, M. R. (1984). Infantile colic: Occurrence and risk factors. *European Journal of Pediatrics, 143*(2), 108–111.

Wong, D. (1999). Growth and development of children. *Whaley & Wong's nursing care of infants and children* (pp. 117–167). St. Louis, MO: Mosby.