Papers

Effect of bottles, cups, and dummies on breast feeding in preterm infants: a randomised controlled trial

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Abstract

Objective To determine the effect of artificial teats (bottle and dummy) and cups on breast feeding in preterm infants.

Design Randomised controlled trial.

Setting Two large tertiary hospitals, 54 peripheral hospitals.

Participants 319 preterm infants (born at 23-33 weeks' gestation) randomly assigned to one of four groups: cup/no dummy (n = 89), cup/dummy (n = 72), bottle/no dummy (n = 73), bottle/dummy (n = 85). Women with singleton or twin infants < 34 weeks' gestation who wanted to breastfeed were eligible to participate.

Interventions Cup or bottle feeding occurred when the mother was unable to be present to breast feed. Infants randomised to the dummy groups received a dummy on entry into the trial.

Main outcome measures Full breast feeding (compared with partial and none) and any breast feeding (compared with none) on discharge home. Secondary outcomes: prevalence of breast feeding at three and six months after discharge and length of hospital stay.

Results 303 infants (and 278 mothers) were included in the intention to treat analysis. There were no significant differences for any of the study outcomes according to use of a dummy. Infants randomised to cup feeds were more likely to be fully breast fed on discharge home (odds ratio 1.73, 95% confidence interval 1.04 to 2.88, P = 0.03), but had a longer length of stay (hazard ratio 0.71, 0.55 to 0.92, P = 0.01).

Conclusions Dummies do not affect breast feeding in preterm infants. Cup feeding significantly increases the likelihood that the baby will be fully breast fed at discharge home, but has no effect on any breast feeding and increases the length of hospital stay.

Introduction

Although the benefits of breast feeding preterm infants are well established, practical problems in supporting the transition from tube feeding remain. The most common method of supplementing sucking feeds when the mother is not present is by bottle. This may interfere with breast feeding, possibly because of a difference in sucking action.[1][2] An increased prevalence of breast feeding has been reported when bottles were replaced by cups[3] or tubes.[4] However, randomised controlled trials provide conflicting evidence on their effect on breast feeding.[5][6] While the use of dummies is standard practice for preterm infants and is supported by a reduction in length of hospital stay[7] their effect on breast feeding is unknown.

We determined the effect of artificial teats (bottle and dummy) and cups on breast feeding in preterm infants < 34 weeks' gestation at birth.

Methods

Participants—Women with singleton or twin infants < 34 weeks' gestation who wanted to breast feed were eligible for inclusion. We excluded infants with congenital abnormalities precluding enteral feeding. Recruitment occurred at two Australian tertiary referral hospitals from April 1996 to November 1999. A plain language information sheet was given to women and written informed consent was obtained from all participants. We included infants requiring transfer to peripheral hospitals, 54 of which participated.

Randomisation and assignment—Women and their infants were randomised to one of four groups: cup/no dummy, cup/dummy, bottle/no dummy, bottle/dummy. An independent researcher developed a separate randomisation schedule for each recruiting hospital by using a random number table to select balanced blocks of varying size with stratification for gestation (< 28 weeks, 28-< 34 weeks). Assignments were sealed in sequentially numbered, opaque envelopes. Researchers determined allocation by telephoning an independent ward, available 24 hours a day, within the recruiting hospitals. The mother was the unit of randomisation and twins were assigned to the same group.

Intervention—Cup or bottle feeding commenced at the discretion of the attending nurse/midwife or neonatologist and occurred when the mother was unavailable to breast feed or when additional milk, given orally, was required after a breast feed. Small plastic medicine cups were used as described by Lang.[8] Infants randomised to the dummy groups had dummies available on trial entry; their use was encouraged during tube feeds and when the infant was restless. For infants who did not receive a dummy, alternate soothing methods were promoted (for example, facilitation of hand to mouth action promoting self quieting behaviour). Recruiting hospitals received education, written instructions, literature, and one-to-one support. Written instructions, literature, and telephone contact were provided to participating peripheral hospitals.

Outcomes—The primary outcomes were the proportion of infants fully breast feeding (compared with partially and not) and the proportion receiving any breast feeding (compared with none) on discharge home. Breast feeding was defined as mother's milk given by direct breast feeding or other feeding device.[9][10] Full breast feeding meant that no other types of milk or solids were given except vitamins and minerals.[11] Secondary outcomes included the length of hospital stay and prevalence of breast feeding at three and six months after discharge.
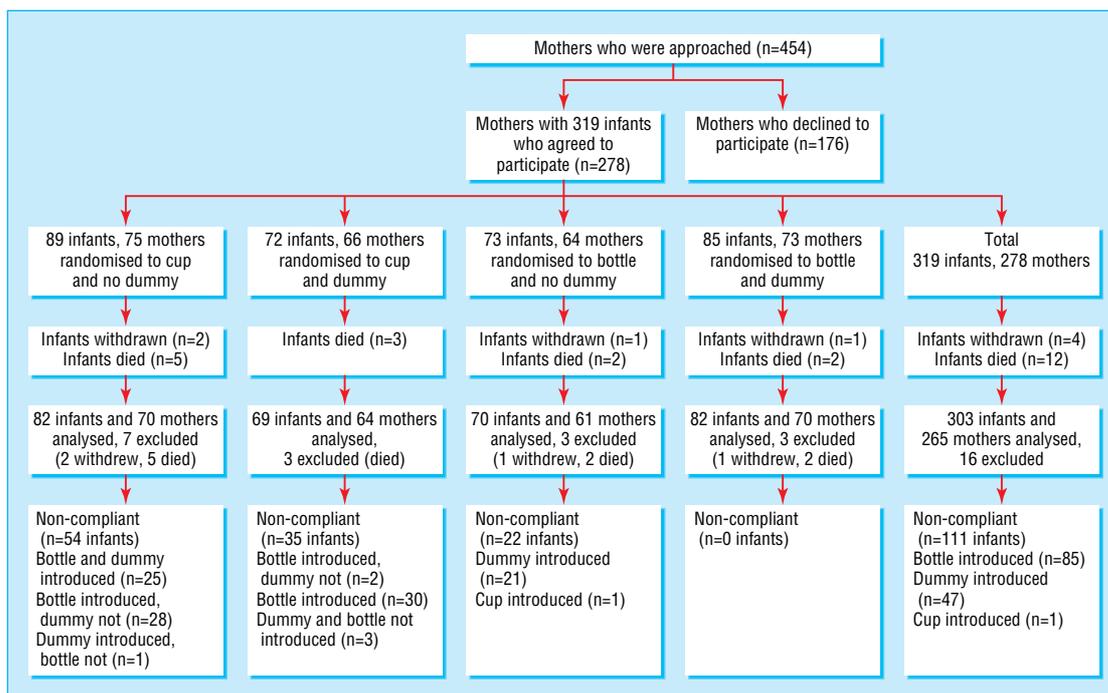
Recruitment and trial participation

Sample size—On the basis of a breast feeding prevalence of 45% (unpublished hospital data) we calculated that a sample size of 310 could detect a 16.5% increase in the proportion full breast feeding on discharge home ($\alpha = 0.05$, 80% power) between use of dummy use and not (irrespective of cup/bottle) and between cup and bottle (irrespective of use of dummy).

Analysis—All analyses were done on an intention to treat basis. We used logistic regression to estimate odds ratios and 95% confidence intervals. The number needed to treat and 95% confidence interval were reported as recommended by Altman.[12] Kaplan Meier curves and Cox proportional hazards models were used to compare time related variables (days). We accounted for the dependence due to inclusion of twins by using robust variance estimates clustering on the mother. Adjustment was made for analyses where there was a $\geq 10\%$ difference in distribution and for prespecified factors known to influence duration of breast feeding in preterm infants: maternal education, previous experience of breast feeding, and gestational age.[13-18]

Masking—Participants, care providers, and researchers were not blinded to treatment allocation; data entry and analysis were undertaken unblinded.

Interaction effect—Initial analyses for the primary outcomes showed that there was no clinically important or significant interaction between use of cups and dummies (odds ratio 1.01 (95% confidence interval 0.36 to 2.79, P = 0.99) for fully versus partially and not breast feeding; 0.94 (0.31 to 2.86, P = 0.91) for any versus not breast feeding). On the basis of these results, we performed further comparisons on the marginal groups: cup versus bottle and no dummy versus dummy.

Results

Participant flow and follow up—We invited 454 women to participate, 176 refused (figure). Reasons for refusal included: wanting to use dummy (45/164, 27%), not wanting to use dummy (23/164, 14%), wanting to use a bottle (16/164, 10%),

study did not appeal (36/164, 22%). Twelve infants died before discharge and four were withdrawn from the study at the mothers' request. Thus, of the 319 infants and 278 mothers enrolled, 303 (95%) and 265 (95%), respectively, were available for the primary analyses (cup/no dummy n=82, cup/dummy n=69, bottle/no dummy n=70, bottle/dummy n=82).

Characteristics of participants—Most maternal and neonatal characteristics were balanced between groups (tables 1 and 2). There was, however, a $\geq 10\%$ difference between dummy and no dummy for primiparity and number who had breast fed before and between cup and bottle for primiparity.

Compliance—Non-compliance was high (figure). Of the infants randomised to cup feeding, 56% (85/151) had a bottle introduced, and of the infants randomised to no dummy 31% (47/152) had a dummy introduced. Reasons for introducing a bottle were available for 91% (77/85) of the infants, and reasons for introducing a dummy were available for 81% (38/47). For 44% (34/77) the mother decided to introduce a bottle; in 33% (25/77) the decision was taken on the advice of the nurse/midwife (some mothers said both of these had occurred). Of the 77 mothers, 39% (30) did not like, or had problems with, cup feeding, including the infant not managing cup feeds, spilling a lot, not being satisfied, or taking too long to feed. 12% (9/77) said the staff refused to cup feed their infant. Dummies were introduced because the baby was unsettled (37%, 14/38) and to teach the baby to suck (29%, 11/38). Primiparous, tertiary educated women, whose household income was from full time work from either partner, and who had a singleton infant >28 weeks' gestation were more likely to have complied with the study protocol.

Breast feeding on discharge home—Not using a dummy had no significant effect on the proportion of infants who were being fully breast fed at discharge (0.84, 0.51 to 1.39, P = 0.50) or partly breast feeding (0.83, 0.45 to 1.05, P = 0.53) (table 3). Cup feeding significantly increased the odds of full breast feeding at discharge (1.73, 1.04 to 2.88, P = 0.03) (table 4). The number needed to

Table 1 Maternal characteristics at trial entry.* Figures are numbers (percentages) unless stated otherwise

	Cup		Bottle	
	No dummy (n=75)	Dummy (n=66)	No dummy (n=64)	Dummy (n=73)
Parity (n=75/66/62/73†):				
Primiparous	34 (45)	40 (61)	22 (35)	36 (49)
Multiparous	41 (55)	26 (39)	40 (65)	37 (51)
Maternal age (years) (n=75/66/62/73†):				
<25	8 (11)	18 (27)	10 (16)	18 (25)
25-34	47 (63)	36 (55)	36 (58)	41 (56)
≥35	20 (27)	12 (18)	16 (26)	14 (19)
Mean (SD, range)	31 (5.4,18-42)	28 (6.0,16-41)	30 (5.5,19-42)	29 (5.9,15-39)
Lives with another adult (n=72/64/63/66†)	70 (97)	58 (91)	60 (95)	60 (91)
Education (n=72/63/62/67†):				
Incomplete high school	21 (29)	22 (35)	21 (34)	29 (43)
Complete high school	19 (26)	24 (38)	26 (42)	17 (25)
Tertiary	32 (44)	17 (27)	15 (24)	21 (31)
Main income source (n=72/63/62/67†):				
Part time work	3 (4)	1 (2)	3 (5)	1 (2)
Full time work	58 (81)	46 (72)	48 (76)	50 (77)
Benefits	11 (15)	17 (27)	12 (19)	14 (22)
During pregnancy had planned to breast feed (n=72/64/63/68†)	70 (97)	60 (94)	59 (94)	65 (96)
Breast fed before (n=72/64/63/68†):				
Yes	32 (44)	20 (31)	31 (49)	25 (37)
No	40 (56)	44 (69)	32 (51)	43 (63)

*Percentages may not sum to 100 because of rounding.
†Numerical data available for cup/no dummy, cup/dummy, bottle/no dummy, and bottle/dummy, respectively.

Table 2 Neonatal characteristics at birth.* Figures are numbers (percentages) unless stated otherwise

	Cup		Bottle	
	No dummy (n=89)	Dummy (n=72)	No dummy (n=73)	Dummy (n=85)
Twins	28 (31)	12 (17)	18 (25)	24 (28)
Method of delivery (n=89/72/72/84†):				
Vaginal	29 (33)	26 (36)	24 (33)	23 (27)
Instrument	10 (11)	1 (1)	5 (7)	7 (8)
Caesarean, no labour	7 (8)	9 (13)	10 (14)	14 (17)
Caesarean with labour	43 (48)	36 (50)	33 (46)	40 (48)
Mean (SD, range) birth weight (g) (n=89/72/72/85†)	1325 (453, 552-2520)	1344 (488, 609-2560)	1508 (463, 720-2530)	1382 (469, 500-2580)
Gestational age at birth (weeks) (n=89/72/73/85†):				
<28 weeks	25 (28)	17 (24)	14 (19)	20 (24)
28 to <34 weeks	64 (72)	55 (76)	59 (81)	65 (76)
Mean (SD, range)	29.2 (2.7, 24-33)	29.5 (2.7, 23-33)	30.3 (2.6, 25-33)	29.6 (2.6, 24-33)
Outcome (n=89/72/73/85†):				
Discharged directly home	35 (39)	27 (38)	23 (32)	32 (38)
Transferred to peripheral hospital	47 (53)	42 (58)	48 (66)	50 (59)
Died in hospital	5 (6)	3 (4)	2 (3)	2 (2)
No details available (withdrew from study)	2 (2)	0	1 (1)	1 (1)
Respiratory support:				
IPPV	62 (71)	48 (67)	40 (56)	57 (67)
Days of IPPV‡ (n=62/48/40/57†)	5 (2, 19)	6 (3,22)	3 (2, 19)	5 (2, 19)
CPAP (n=87/72/72/85†)	50 (57)	44 (61)	34 (47)	48 (56)
Days of CPAP‡	6 (2, 16)	5 (2, 13)	3 (1, 11)	4 (2, 11)
Home oxygen (n=89/72/73/85†)	11 (12)	8 (11)	4 (5)	8 (9)
Central nervous system:				
PV/IVH, any grade (n=89/72/72/85†)	16 (18)	8 (11)	5 (7)	12 (14)
PVLE (n=89/72/72/85†)	4 (4)	2 (3)	1 (1)	1 (1)
Necrotising enterocolitis (n=89/72/72/85†)	1 (1)	3 (4)	1 (1)	4 (5)

IPPV=intermittent positive pressure ventilation; CPAP=continuous positive airway pressure; PV/IVH=periventricular/intraventricular haemorrhage; PVLE=periventricular leucoencephalopathy.
*Percentages may not sum to 100 because of rounding.
†Numerical data available for cup/no dummy, cup/dummy, bottle/no dummy, and bottle/dummy, respectively.
‡Median (25th, 75th centile).

Table 3 Comparison of prevalence of breast feeding at discharge, 3 months, and 6 months between groups randomised to dummy and no dummy

	No (%) with no dummy	No (%) with dummy	Odds ratio (95% CI); P value	NNTB*/NNTH† (95% CI)
Discharge:				
Fully‡	79/152 (52)	85/151 (56)	0.84 (0.51 to 1.39); 0.50	NNTH 23 (NNTH 6 to ∞ to NNTB 15)
Any§	107/152 (70)	108/151 (72)	0.83 (0.45 to 1.50); 0.53	NNTH 89 (NNTH 9 to ∞ to NNTB 11)
Any breast feeding 3 months after discharge§	58/142 (41)	53/141 (38)	0.99 (0.56 to 1.77); 0.98	NNTB 31 (NNTH 12 to ∞ to NNTB 7)
Any breast feeding 6 months after discharge§	43/141 (30)	34/140 (24)	1.23 (0.66 to 2.30); 0.51	NNTB 16 (NNTH 24 to ∞ to NNTB 6)

*No of patients needed to be treated for one additional patient to benefit.
†No of patients needed to be treated for one additional patient to be harmed.
‡Fully breast fed v combined partially breast fed and not breast fed.
§Combined fully breast fed and partially breast fed v not breast fed.

treat (where "treatment" means cup feeding) for one extra infant to be discharged home fully breast feeding was seven (95% CI 4 to 41). Infants randomised to cups were more likely to have any breast feeding, but this was not significant (1.37, 0.78 to 2.38, P = 0.27) (table 3). In total 6/265 (2%) women with 7/303 (2%) infants chose to express breast milk and bottle feed on discharge home.

Breast feeding at three and six months after discharge—There were no significant differences in the prevalence of any breast feeding in infants randomised to no dummy compared with dummy at three (0.99, 0.56 to 1.77, P = 0.98) and six (1.23, 0.66 to 2.30, P = 0.51) months after discharge (table 3). There were minor, non-significant increases in the prevalence of any breast feeding in infants randomised to cup feeds compared with bottle at three (1.31, 0.77 to 2.23, P = 0.33) and six (1.44, 0.81 to 2.57, P = 0.22) months after discharge (table 4).

Length of hospital stay—There was no significant difference (median days, interquartile range) in the length of stay between those randomised to no dummy (53, 35-74) or to dummy (50, 33-78) (hazard ratio 0.98, 0.76 to 1.26, P = 0.87). Discharge from hospital was significantly delayed for those randomised to cup feeds (cup 59, 37-85; bottle 48, 33-65; 0.71, 0.55 to 0.92, P = 0.01). The differences by gestational age remained significant (<28 weeks: cup 93, 86-113; bottle 93, 72-100; 0.55, 0.32 to 0.94, P = 0.03; 28-<34 weeks: cup 45, 32-66; bottle 40, 32-55; 0.69, 0.52 to 0.93, P = 0.01).

Adverse events—No adverse events were associated with any of the interventions.

Discussion

The results of our study contribute to the small number of randomised controlled trials that have evaluated the effect of bottle feeding on breast feeding in preterm infants. This study is also the first to evaluate the effect of dummies on breast feeding in this population.

We found no significant differences on any of the study outcomes between those randomised to dummy versus no dummy.

Our study provides no evidence for withholding dummies from infants <34 weeks' gestation as a strategy to increase the success of breast feeding. A Cochrane review on the use of dummies in preterm infants showed a significant reduction in hospital stay,[7] but the two trials included were small. Our trial is the largest to evaluate the effect of dummies and provides evidence that the use of dummies does not reduce length of hospital stay. Infants randomised to cup feeds were significantly more likely to be fully breast fed on discharge home, but also had a longer hospital stay with no significant difference in any breast feeding.

Two previous randomised controlled trials reported conflicting results.[5 6] Kliethermes et al found a significant increase in breast feeding on discharge home when they compared tube feeding (n = 47) with bottle feeding (n = 52) for preterm infants (birth weight 1000-2500 g).[5] Infants randomised to tube feeds were significantly more likely to be breast feeding (odds ratio 4.5, 1.4 to 15, P = 0.001, for any breast feeding; 9.4, 3.1 to 28.4, for full breast feeding). In contrast, Rocha et al found no significant difference in any breast feeding when they compared cup feeding and bottle feeding in infants of 32-36 weeks' gestation (cup 36/44, 82%; bottle 27/34, 79%) (full breast feeding was not reported in their study).[6] Given the strength of the findings of Kliethermes et al,[5] the significant effect on full breast feeding but not any breast feeding we observed in our study, and the negative findings of Rocha et al,[6] questions remain as to whether the use of bottles during the transition to breast feeding interferes with a preterm infant's ability to breast feed.

Kliethermes et al found no significant difference in length of stay.[5] One of the main criteria for discharge home for stable preterm infants is that they can manage all sucking feeds. As the infants matured some became less satisfied with cup feeds and more difficult to feed by this method. The feed was then given by tube, thus delaying the onset of all sucking feeds. As we have few data on this, it is not known how much this may have contributed to the increased length of stay.

Artificial teats may interfere with success of breast feeding because of a difference in sucking action.[1 2] We found no difference in breast feeding outcomes with the use of dummies. In the

Table 4 Comparison of prevalence of breast feeding at discharge, 3 months, and 6 months between groups randomised to cup and bottle

	No (%) given cup	No (%) given bottle	Odds ratio (95% CI); P value	NNTB*/NNTH† (95% CI)
Discharge:				
Fully‡	92/151 (61)	72/152 (47)	1.73 (1.04 to 2.88); 0.03	NNTB 7 (4 to 41)
Any§	112/151 (74)	103/152 (68)	1.37 (0.78 to 2.38); 0.27	NNTB 16 (NNTH 26 to ∞ to NNTB 6)
Any breast feeding 3 months after discharge§	61/144 (42)	50/139 (36)	1.31 (0.77 to 2.23); 0.33	NNTB 16 (NNTH 20 to ∞ to NNTB 6)
Any breast feeding 6 months after discharge§	44/142 (31)	33/139 (24)	1.44 (0.81 to 2.57); 0.22	NNTB 14 (NNTH 32 to ∞ to NNTB 6)

*No of patients needed to be treated for one additional patient to benefit.
†No of patients needed to be treated for one additional patient to be harmed.
‡Fully breast fed v combined partially breast fed and not breast fed.
§Combined fully breast fed and partially breast fed v not breast fed.

trial by Kliethermes et al dummies were available for use in both groups,[5] and it has been shown that infants use the same tongue action (with a different sucking rate) for bottle and dummy teats.[1] A contributing factor as to why bottles may interfere with success of breast feeding is the immediate and consistent availability of milk with bottle feeding[2] and not differences in sucking action between breast and bottle or dummy.

Limitations

A major limitation of our study is the poor compliance, which reduces the power of the trial to identify a real treatment effect.[19] We are unable to determine if the lack of significant benefit of cup feeding on any breast feeding is due to the low compliance with resultant loss of power, or to lack of efficacy of cup feeding. Similarly, the finding of no benefit attributable to not using a dummy must be qualified by the poor compliance. Exploratory analysis of compliance, however, showed no significant differences in full breast feeding (odds ratio 0.60, 0.26 to 1.37, $P = 0.22$), any breastfeeding (0.75, 0.40 to 1.41, $P = 0.37$), or length of stay (hazard ratio 1.08, 0.77 to 1.51, $P = 0.67$) with not using a dummy. Compliance analysis also showed a significant increase in the prevalence of any breast feeding with cup feeding (odds ratio 21.09, 2.62 to 169.75, $P = 0.004$) with no significant difference in length of hospital stay (hazard ratio 0.82, 0.58 to 1.17, $P = 0.27$). Such compliance analyses need to be interpreted with caution and highlight the need for further research. Compliance differed between recruiting hospitals; the hospital with the better compliance had used cup feeding before, in the other it was introduced for the trial. Most peripheral hospitals had not used cup feeding before. Some staff had strong feelings against cup feeding and the withholding of dummies and some parents did not like cup feeding.

Conclusion

From our results we cannot support withholding a dummy in preterm infants <34 weeks' gestation as a strategy to increase the prevalence of breast feeding. Also, using a dummy does not decrease hospital stay.

The use of cups significantly increased the proportion of infants discharged home fully breast feeding even with the high non-compliance. The obvious benefit of this outcome needs to be considered alongside the financial implications for the health system of longer hospital stays and the lack of effect of cup feeding on any breast feeding.

Given the difficulty of getting staff and parents to accept cup feeding in our trial, the lack of effect on any breast feeding, and the increased length of stay, it is difficult to recommend its introduction. Our study adds some support to the theory that avoiding bottles increases the success of breast feeding,[5] though more research is needed. Lang[20] suggests that it may be possible to introduce bottles once breast feeding is well established without interfering with the success of breast feeding. This may be a more acceptable strategy for parents and staff. A sufficiently powered randomised controlled trial is required to test this hypothesis.

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What is already known on this topic

The one small randomised controlled trial on the effect of cup feeding on breast feeding in preterm infants showed no benefit

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Dummies are widely used for preterm infants but their effect on breast feeding is unknown

What this study adds

Cup feeding significantly increased the prevalence of fully breast feeding on discharge home but had no effect on any breast feeding and was associated with longer stays in hospital

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Use of dummies did not affect breast feeding and did not affect length of stay

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