

Effect of bottles, cups, and dummies on breast feeding in preterm infants: 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 cups³ 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. Recruitment occurred at two Australian tertiary referral hospitals from April 1996 to November 1999. 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. Randomisation was done using random number tables, and stratified for gestation (< 28 weeks, 28- < 34 weeks).

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. 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

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Table 1 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.

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.

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 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. We also calculated the number needed to treat for benefits and harms.¹² Kaplan Meier curves and Cox proportional hazards models were used to compare time related variables (days). We accounted for 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 and therefore further comparisons were performed 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 (see bmj.com for full details). Twelve infants died before discharge and four were withdrawn from the study at the mothers' request. Of

the 319 infants and 278 mothers, 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. 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. 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).

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 1). Cup feeding significantly increased the odds of full breast feeding at discharge (1.73, 1.04 to 2.88, $P=0.03$) (table 2). The number needed to treat (where "treatment" means cup feeding) for one extra infant to be discharged home fully breast feeding was seven (4 to 41).

Breast feeding at three and six months after discharge—There were no significant differences between groups

Table 2 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.

(dummy compared with no dummy, and cup compared with bottle) in the prevalence of any breast feeding at three or six months after discharge (table 1 and table 2).

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 remained significant when we stratified results by gestational age (<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, $P=0.01$).

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 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 results of our larger study did not confirm this finding. 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 increase in the likelihood of "any breast feeding."

Two previous randomised controlled trials reported conflicting results.^{5, 6} Kliethermes et al found that tube feeding in preterm infants (compared with bottle feeding) increased the prevalence of breast feeding at discharge home.⁵ But Rocha et al found no significant difference in any breast feeding when they compared cup feeding and bottle feeding in preterm infants.⁶ Questions still 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 It's still unclear how cup feeding delayed discharge among the infants in our study. One of the main criteria for discharge home for stable preterm infants is that they can manage all sucking feeds. It's possible that use of a cup delayed infants' ability to manage all sucking feeds.

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. Compliance differed between recruiting hospitals; the hospital with the better compliance had used

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

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

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

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.

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. Lang²⁰ 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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Infertility among male UK veterans of the 1990-1 Gulf war: reproductive cohort study

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Abstract

Objectives To examine the hypothesis that, theoretically at least, exposure to toxicants of the type present in the Gulf war could affect spermatogenesis, which might be observed as increased levels of infertility.

Design Retrospective reproductive cohort analysis.

Setting Male UK Gulf war veterans and matched comparison group of non-deployed servicemen, surveyed by postal questionnaire.

Participants 42 818 completed questionnaires were returned, representing response rates of 53% for Gulf veterans and 42% for non-Gulf veterans; 10 465 Gulf veterans and 7376 non-Gulf veterans reported fathering or trying to father pregnancies after the Gulf war.

Main outcome measures Failure to achieve conceptions (type I infertility) or live births (type II infertility) after the Gulf war, having tried for at least a year and consulted a doctor; time to conception among pregnancies fathered by men not reporting fertility problems.

Results Risk of reported infertility was higher among Gulf war veterans than among non-Gulf veterans (odds ratio for type I infertility 1.41, 95% confidence interval 1.05 to 1.89; type II 1.50, 1.18 to 1.89). This small effect was constant over time since the war and was observed whether or not the men had fathered pregnancies before the war. Results were similar when analyses were restricted to clinically confirmed diagnoses. Pregnancies fathered by Gulf veterans not reporting fertility problems also took longer to conceive (odds ratio for >1 year 1.18, 1.04 to 1.34).

Conclusions We found some evidence of an association between Gulf war service and reported infertility. Pregnancies fathered by Gulf veterans with

no fertility problems also reportedly took longer to conceive.

Introduction

In late 1990 and early 1991 around 53 000 UK armed service personnel were deployed to the Gulf war. Compared with the many reports on adult health after service in the Gulf, relatively few epidemiological studies have been conducted on reproductive outcomes.¹⁻⁹ Only two small studies specifically examined infertility, with inconsistent results.⁵⁻⁸

We now report findings relating to infertility from the only epidemiological survey of reproductive outcomes among UK Gulf veterans. Analyses of fetal death and congenital malformation have been reported elsewhere.⁹

Methods

Main survey

Detailed information about the study is given elsewhere.^{9 10} This was a retrospective cohort study of the reproductive health of all UK armed forces personnel deployed to the Gulf region between August 1990 and June 1991 (51 581 men, 1230 women) and a comparison group (matched on service, sex, age, fitness to be deployed, serving status, and rank) who were in service at that time (January 1991) but were not deployed (51 688 men, 1236 women). A postal questionnaire, sent from August 1998 (with reminders until early 2001), requested detailed information on reproductive history, including questions on infertility



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