

Does breastfeeding reduce acute procedural pain in preterm infants in the neonatal intensive care unit? A randomized clinical trial

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ABSTRACT

Managing acute procedural pain effectively in preterm infants in the neonatal intensive care unit remains a significant problem. The objectives of this study were to evaluate the efficacy of breastfeeding for reducing pain and to determine if breastfeeding skills were altered after this treatment. Fifty-seven infants born at 30–36 weeks gestational age were randomized to be breastfed (BF) or to be given a soother during blood collection. Changes in the Behavioral Indicators of Infant Pain (BIIP) and in mean heart rate (HR) across 3 phases of blood collection were measured. In the BF group, the Premature Infant Breastfeeding Behaviors (PIBBS) scale was scored before and 24 hours after blood collection. Longitudinal regression analysis was used to compare changes in Lance/squeeze and Recovery phases of blood collection between groups, with gestational age at birth, baseline BIIP scores, and mean HR included as covariates. Differences in PIBBS scores were assessed using a paired *t*-test. Relationships between PIBBS scores, BIIP scores, and HR were evaluated with Pearson correlations. No differences between treatment groups were found: BIIP ($P = 0.44$, confidence interval [CI] -1.60 – 0.69); HR ($P = 0.73$, CI -7.0 – 10.0). Infants in the BF group showed improved PIBBS scores after the treatment ($P < 0.01$, CI -2.7 to -0.2). Lower BIIP scores during the Lance/squeeze were associated significantly with more mature sucking patterns ($r = -0.39$, $P < 0.05$). Breastfeeding during blood collection did not reduce pain indices or interfere with the acquisition of breastfeeding skills. Exploratory analyses indicate there may be benefit for infants with mature breastfeeding abilities.

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1. Introduction

In the neonatal intensive care unit (NICU), preterm infants repeatedly undergo essential, invasive care-related procedures [9]. For example, a recent Canadian survey showed that during a 1-week period, 580 neonates received over 17,500 painful/stressful procedures, many of which (46–57%) went untreated [27]. Poorly managed pain has serious short and long-term consequences. In these infants, each painful event causes immediate physiological and behavioral instability [25]. In addition, repeated exposure induces long-term changes in pain sensitivity [20,21], in stress-arousal systems such as the hypothalamic–pituitary–adrenal axis [20,26], and in the developing brain [2].

Despite increased efforts to find ways to manage pain, major gaps remain in our knowledge about the most effective ways to relieve procedure-related pain in neonates [1]. Currently, pain associated with such minor procedures as heel lance for blood collection is managed with interventions such as skin-to-skin contact, nonnutritive sucking, and sweet tastes (eg, oral sucrose). These interventions are easy to use and have few associated adverse effects; however, they reduce preterm infant pain responses by only 10–50%, and the results are inconsistent [12,28,29]. Furthermore, some are not recommended for repeated use or for specific populations [22,45]; others appear to be acting as sedatives rather than as analgesics [42,44]; none eliminates preterm infant pain responses completely.

Breastfeeding, a natural, simple alternative, offers simultaneously the pain-reducing components of familiar odor, maternal skin-to-skin contact, sucking, and the ingestion of breast milk. In term-born infants, breastfeeding reduces pain responses to heel lance by 80–90%, has been shown to be superior to sweetening

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Table 1
Characteristics of infants, n = 57.

	Control (n = 29)	Breastfeeding (n = 28)
Mean birth weight (g)	2143 ± 80.7	2114 ± 83.5
Mean gestational age at birth (weeks)	33.9 ± 1.3	34.0 ± 1.5
Sex (% male)	48	53
Ventilation (days)	<1	<1
Other respiratory support (days)	1	1
Time of blood collection (median and 25–75th quartiles) (seconds)	132 (95–199) ^a	108 (80–177)
Pain exposure at testing day (median and 25–75th quartiles) ^a	7 (5–11)	8 (5–11)
Time since last handling before assessment (medians and 25–75th quartiles) (minutes)	45 (34–113)	49 (32–88)
Time since last painful procedure (median and 25–75th quartiles) (minutes)	1690 (1138–2857)	1567 (1464–2933)
Number of breastfeeds in 24 hours before assessment	2	2
Number of primiparous mothers	19	14
Mean maternal age (years)	33 ± 4.0	34 ± 5.4
Mean maternal education (years)	16.7 ± 3.9	16.5 ± 3.5

^a $P < 0.001$.

^a Number of invasive (skin-breaking) procedures from birth to the test day.

agents, and has no negative side effects [19,49]. In some cases, breastfeeding in human newborn infants completely eliminates pain responses. Work using animal models shows that the pain-modulating effect of breastfeeding is likely mediated by opioid and nonopioid mechanisms (eg, [5,7]). Despite its potentially safe and potent analgesic effects, the efficacy of breastfeeding analgesia has not been studied in preterm infants. In addition, regression in preterm infant feeding behaviors that might result from pairing breastfeeding with a painful procedure is critical to evaluate since infants' health and well-being is contingent upon an infant's ability to feed effectively enough to gain weight adequately. Therefore, in this randomized controlled trial, the primary hypothesis tested was:

1. When breastfed during blood collection, preterm infants in the feeding group would show lower pain scores and lower mean heart rates than infants given a soother.

Two secondary hypotheses were also tested:

2. Following the breastfeeding intervention, no differences would be found in the ratings of the preterm infants' breastfeeding skills within 24 hours of the procedure.
3. Infants with more mature pretest breastfeeding behaviors would have lower pain scores and mean heart rate during blood collection.

2. Patients and methods

2.1. Patients

Between January 2008 and May 2010, 57 preterm infants born between 30 and 36 completed weeks of gestation, admitted to 3 NICUs in the Greater Vancouver Regional District, were studied. Gestational age (GA) was determined on the basis of the first day of the last menstrual period, early gestation ultrasonogram (in most cases), or best estimate based on neonatal examination. Infants were recruited at 30–32 weeks gestation because, as was learned during the pilot study, although babies were not tested before 32 weeks, recruiting them earlier allowed a wider window in which to contact potential mothers to participate. Infant characteristics are presented in Table 1. All infants included in the study were normally breastfeeding infants. A breastfeeding infant was defined as one who had been taken to the breast 2 times or more in the 24 hours before the blood collection. If the mother and/or bedside nurse reported active feeding behaviors during these feeds, including sucking and swallowing, the infant was considered a breastfeeding infant. Infants were studied during a single blood collection required for clinical management on or after Day 3 of life. An additional inclusion criterion was that the mother/infant pairs were medically stable. Mother/infant pairs

were excluded if either was too ill to breastfeed; if the infants had congenital anomalies, had active, ongoing infection, or had undergone surgery; if the infants had received analgesics or sedatives within 72 hours of the assessment; if there was a history of maternal abuse of controlled drugs and substances, or if blood collection occurred beyond the 36th completed week (36 weeks and 6 days) GA. The patient flow diagram is presented in Fig. 1. Of the 995 infants assessed for eligibility, 110 were enrolled in the trial. Fifty-three infants were not studied, the majority of which were transferred out of the NICU before the assessment could be completed (35 infants), leaving 57 randomized to the 2 treatment groups.

The infants were recruited by a NICU-trained research nurse; written informed consent was obtained from the mother or other legal guardian according to a protocol approved by the Clinical Research Ethics Board of the University of British Columbia, the Children's and Women's Health Centre of British Columbia Research Review Committee, the Vancouver Coastal Health Authority, and the Providence Health Authority Ethics Board.

Before participants were recruited for the study, a computer-generated list of 60 infant identification numbers was generated. Then, infants were allocated to the treatment groups as close in time to the blood collection as possible while still allowing time to arrange for the mother to be present for the breastfeeding group. Randomization was done by generating randomly permuted sequential blocks of 4 and 6 allocation numbers by a statistician blind to study hypotheses. Treatment group assignments were placed in sequentially numbered envelopes and sealed. Nine sets of twins were included in this study. For these infants, based on our clinical experience, mothers found 2 assessments in one morning physically too difficult for them; therefore, we randomized the first twin to a treatment group and then assigned the second twin to the other treatment group; that is, twin infants were not assigned to the same treatment group.

With respect to the sample size estimate, based on pilot data for 15 infants (8 Soother, 7 Breastfed), the means for our primary outcomes in the Soother Group were 5.9 for change in behavioral pain scores and 28.7 for change in heart rate, with 2 group pooled SDs of 3.1 and 16, respectively. Gray et al. (2002) report 80% reduction in heart rate and 85% reduction in facial grimacing values in a similar study with full-term infants [19]. Related larger studies in preterm infants had reported reductions in composite pain scores in the order of half an SD [17,43]. As a compromise, we assumed 50% reductions from the Soother Group condition as the basis for calculating the sample size. The number of infants needed to test the primary hypothesis and to provide 80% power for a 2-sided test at (Bonferroni corrected) $\alpha = 0.025$ was approximately 50. Allowing for potential attrition of 5% and for the possible need to covary

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