Paternal vs Maternal Kangaroo Care for Procedural Pain in Preterm Neonates

A Randomized Crossover Trial

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**Objective:** To test paternal vs maternal kangaroo care (KC) to reduce pain from heel lance.

**Design:** Randomized crossover design.

**Setting:** Three university-affiliated level III neonatal intensive care units.

**Patients:** Sixty-two preterm neonates at 28 to 36 weeks' gestational age who were expected to stay in the neonatal intensive care unit for at least 2 blood sampling procedures, without major congenital anomalies, grade III or IV intraventricular hemorrhage, or periventricular leukomalacia; without surgical interventions; not receiving parenteral analgesics or sedatives within 72 hours; and with parental consent.

**Intervention:** During 2 separate medically ordered heel lance procedures at least 24 hours apart, infants were held in KC for 30 minutes before and during the procedure with the mother or with the father, and with the other parent in the subsequent session. Which parent came first was randomized.

**Main Outcome Measures:** The Premature Infant Pain Profile and time for heart rate to return to baseline were the primary outcomes.

**Results:** At 30 and 60 seconds after the heel lance, infants in maternal KC displayed significantly lower scores on the Premature Infant Pain Profile than when in paternal KC (30 seconds mean difference, 1.435 [95% confidence interval, 0.232-2.632]; 60 seconds mean difference, 1.548 [95% confidence interval, 0.069-3.027]). At 90 and 120 seconds, there were no differences. The difference in time to return to KC heart rate before the heel lance was significant, with the time in maternal KC being 204 seconds and in paternal KC, 246 seconds (mean difference, 42 seconds [95% confidence interval, 5.16-81.06 seconds]).

**Conclusions:** Mothers were marginally more effective than fathers in decreasing pain response. Future research should address feasibility issues and nonparent providers of KC during painful procedures.

**Trial Registration:** clinicaltrials.gov Identifier: ISRCTN51481987

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**Kin-to-Skin Contact is a caregiving situation in which the mother holds her infant, clad in only a diaper, against her bare chest with a cover wrapped around the pair. This contact is commonly known as kangaroo care (KC) because of its resemblance to marsupial care. Kangaroo care has been promoted around the world for enhancing newborn physiologic stability, breastfeeding, maternal-infant bonding and growth and development.**

Recent reports demonstrate that it has apparent angesic properties for procedural pain. Initially studied as a pain-relieving strategy in full-term infants, it has subsequently been reported in full-term and preterm populations with consistently positive results. There are a sufficient number of studies on KC for procedural pain management that a Cochrane review is under way.

Thus far, most studies have focused on maternal KC. The obvious reason for this is that it is mothers who provide care to newborns, particularly through breastfeeding and holding. Natural physiology of the newly delivered mother provides extrauterine nutrition for the newborn through breastfeeding while also providing warmth to the infant and promoting state regulation. Oxytocin, which is released during breastfeeding, is thought to be the hormone that promotes the maternal bonding to the infant. Another role of oxytocin that has recently been reported is its antinociceptive effect, possibly through potentiating endogenous opioid release. It is released into breast

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milk\textsuperscript{41,45,46} and is one mechanism for the analgesic effect of breastfeeding.\textsuperscript{47,48}

In an effort to make neonatal care more family oriented, fathers have been encouraged to provide KC. Only a few studies have reported on fathers providing KC to their infants. One simply recorded that fathers participated in KC later after birth than mothers,\textsuperscript{49} and another stated that fathers felt more love toward their infants following KC.\textsuperscript{50} Other studies showed that infant body temperature was effectively maintained with fathers doing KC with their preterm infants.\textsuperscript{3,7} More recently, full-term newborns who were randomly assigned to KC with the father following cesarean delivery cried less than those lying in a cot beside the father.\textsuperscript{51}

Nevertheless, there is a unique relationship between a newborn and the mother that is, at the very least, physiological. There are data that support the idea that the infant recognizes the mother at birth. Olfactory memory has been demonstrated in full-term neonates seeking the breast milk scent of their own mothers.\textsuperscript{52-54} Auditory memory for mother’s voice at birth has been well established.\textsuperscript{55,56} On the basis of the unique and powerful relationship the newborn has with the mother, we hypothesized that mothers would be more effective in decreasing pain response to and facilitating recovery from the heel lance procedure in preterm neonates than would fathers.

## METHODS

### SAMPLE

Preterm neonates born between 28 and 36 weeks’ gestation who were expected to stay in the neonatal intensive care unit for at least 2 blood sampling procedures, without major congenital anomalies, grade III or IV intraventricular hemorrhage, or peri-ventricular leukomalacia; without surgical interventions; not receiving parenteral analgesics or sedatives within 72 hours; and for whom both parents gave informed consent and would be available during the daytime when elective blood sampling was done, were eligible for enrollment. Although a sample size of 65 calculated from earlier studies\textsuperscript{31,32} would have been sufficient to have an 80% chance of detecting a 1.5-point difference with an SD of 3 on the pain score outcome (http://bedwigs.mgh.harvard.edu/sample_size/js/js_crossover_quant.html), another 10 infants were enrolled because of the high rate of missing pulse oximeter data for complete analyses. If 1 point on a 10-point rating scale is considered clinically significant, then 2 points on the Premature Infant Pain Profile (PIPP)\textsuperscript{57} would be comparable because the scale ranges from 0 to 21.

### DESIGN

A randomized crossover design was used so that each infant served as his or her own control. This design was used to decrease within-subject variability, which is high in this population, especially given the wide age range (28-36 weeks’ gestational age).

### PROCEDURE

Following local research ethics board approval in 3 university-affiliated level III sites, the research nurse identified eligible infants each day, approached parents, explained the study protocol, and obtained signed consent by both parents. Clinical staff taught and supported the parents in providing KC.

Although the policy in the participating units was that infants were to receive oral sucrose analgesia for heel lance, the policy was waived for the study because KC has been shown in earlier studies to have the same magnitude of effect as sucrose.\textsuperscript{21} However, if a physician thought that the infant should have sucrose, the infant was given sucrose with the assurance that it would be given for both conditions.

When clinical care required blood procurement, the research nurse went to the secure computer Web site for the order assignment that had been generated randomly in permuted blocks of 4 and 6. The parents were then contacted by the research nurse, informing them of which one was to provide KC for that procedure. At least 15 minutes before the heel lance, the assigned parent would then place the infant in the KC position and would maintain that position before, during, and at least 15 minutes after the procedure.

Physiologic data of the heart rate at 2 sites were collected using an E-series data acquisition system with a sampling rate of 100 Hz averaged on a beat-to-beat basis (Compumedics Ltd, Abbotsford, Victoria, Australia). At the third site, a Somtech 2.8 (Compumedics) was used. Transcutaneous oxygen saturation was collected at all sites via an infrared oximeter (Masimo Radical; Masimo Corporation, Irvine, California) that was placed on the hand or the unaffected foot of the infant and connected to the data acquisition system. Physiologic data were analyzed using software in the system (Profusion PSG II or Somtech; Compumedics). Close-up video recordings of the infants’ faces were made using a KS162 digital camera (Panasonic; Osaka, Japan) at 2 sites and a webcam (QuickCam Orbit; Logitech, Fremont, California) at the third site. Recordings were made for 1 minute in the incubator for the first baseline, 1 minute before the start of the heel lance procedure while in KC for the second baseline, and during and after the procedure. The instant of the heel lance indicated the invasive part of the procedure, and data were analyzed in 30-second blocks from that point until the application of the bandage to the heel, which indicated the end of the procedure. The point at which the second baseline heart rate was reached after the heel lance indicated recovery. Epochs were marked by the research nurse with colored cards held briefly in front of the camera and a built-in marker in the Compumedics monitor. The neurobehavioral state component of the PIPP was determined according to the Prechtl categories of quiet sleep, quiet awake, active sleep, or active awake\textsuperscript{28} during the baseline. Gestational age was taken from the medical chart on the basis of ultrasound at 16 to 18 weeks.

All data were coded and analyzed in the research laboratory at the off-site university. Faces were coded second-to-second on a stop-frame system. Coders were trained on faces from similar studies and interrater reliability was more than 90%. Coders were from outside the unit and did not know the purpose of the study because the camera was focused on the infant’s face. Coders worked exclusively with tapes of maternal KC or paternal KC. At the end of the coding, 3 infants in maternal KC were coded by the person who had coded the paternal KC, with more than 90% agreement. Intrarater reliability was checked every 3 months, remaining more than 90%. When asked what they thought the study was about, the coders independently stated that it was about facial grimacing when infants were calm or crying.

### MEASURES

The PIPP\textsuperscript{57}, a composite measure developed for procedural pain in preterm neonates, was the primary outcome. A recent review of the PIPP\textsuperscript{57} reports that it has been used in 59 studies, with 14 evaluating the psychometric properties with support for reliability and its validation. The indicators for the PIPP are
RESULTS

From January 16, 2008, through March 24, 2009, there were 185 infants who were determined to be eligible from 3 university-affiliated level III neonatal intensive care units. A major reason for not being eligible was the unavailability of the father in the daytime. The refusal rate was 22%, mostly because one or the other parent did not want to do KC or particularly did not want to be videotaped, even though it was explained that the camera would be focused on the infant’s face. The gestational age and weight were not significantly different in infants of parents who enrolled and those of parents who declined participation in the study (Table 1). There could well have been differences in parents that were not measured. There were no adverse events, such as desaturation, apnea, or bradycardia.

Before conducting the hypothesis testing, potential confounders on the outcome measure of the PIPP were examined through either bivariate correlations for continuous variables or 1-way analysis of variance for dichotomous variables. Correlational analyses between PIPP scores at each time point were conducted for gestational age, number of previous KC sessions, and number of painful procedures. Although mothers had provided KC an average of 2 times before the testing and fathers an average of only 0.6 times, none of the correlations were significant. Through analysis of variance, order of condition, sex, and whether they received sucrose for the procedure were tested for effect on PIPP scores; none were significant. Therefore, no covariates were included. Similar tests were conducted for time for heart rate to return to baseline. In preliminary univariate analyses, males recovered more quickly to pre–heel stick baseline, and receiving sucrose lengthened time to recovery, and thus sex and sucrose were included in the analysis of recovery.

The repeated-measures analysis of variance for PIPP scores was conducted in 30-second blocks at 30, 60, 90, and 120 seconds after lancing of the heel. Not all PIPP variables were available at each time point because of infant movements, which results in different df. Because the missing data were randomly scattered among infants across the 30-second blocks, repeated-measures analysis of variance at each time point of the PIPP were performed to keep the maximum number of cases. Furthermore, the PIPP score is based on baseline.

There were significant results only at 30 (mean difference, 1.435 [95% confidence interval, 0.232-2.632]) and 60 (mean difference, 1.548 [95% confidence interval, 0.069-3.027]) seconds, with higher PIPP scores in paternal KC (Table 2). Order was univariately significant at both 30 and 60 seconds, but in opposite directions: at 30 seconds, if the order was maternal KC/paternal KC, the PIPP scores were higher (mean difference, 1.230 [95% confidence interval, 0.006-2.454]), but at 60 seconds, the reverse was true (mean difference, 1.248 [95% confidence interval, 0.242-2.719]). However, there was no interaction effect of order and which parent provided KC at either of these times. Between the different direction of order 30 seconds apart and the lack of an interaction effect, it was concluded that order was not a significant systematic factor.

Time to recovery was analyzed in the repeated-measures analysis of variance, including sex and receipt of sucrose as independent variables. These were conducted separately because only 7 infants received sucrose, which led to violation of homogeneity tests. The difference in time to return to incubator heart rate between conditions was not significant, and sex was not a significant factor. The difference in time to return to KC heart rate prior to heel lance was significant, with the time in maternal KC being 204 seconds and in paternal KC, 246 seconds (mean difference, 42 seconds).
Mothers provide marginally more comfort when providing KC to their preterm neonates than do fathers. Although the effect size was not large, the difference was statistically significant. This supports the hypothesis that there is something unique about the comfort of a mother’s contact over and above that of another caring adult. Although mothers had more experience with KC before the heel lance procedure in the study, this was not a significant factor in our data set. If we had had a larger sample, the previous number of hours of providing KC could have been tested.

The actual scores on the PIPP in both KC conditions are lower than PIPP scores for the incubator condition reported in other studies. For example, in a study of infants aged 32 to 36 gestational weeks, the PIPP scores for the incubator condition were 11.6, 12.9, and 12.1 at 30, 60, and 90 seconds, respectively, whereas in this study even the higher scores with the fathers were 8.5, 8.6, and 7.6. In another study with infants aged 28 to 32 gestational weeks, the scores for the incubator condition ranged between 10 and 11. Thus, both parents seemed to blunt the pain response typically seen without intervention.

It was interesting that sucrose did not further decrease the pain scores, because that has been studied repeatedly with strong evidence for its analgesic effect. Surprisingly, it increased time to recovery during paternal KC. One study found that KC was more analgesic than receiving glucose or laying in the prone position. It could be that KC is indeed more potent as an analgesic and that the addition of sucrose was overpowered by it. However, there were only 7 infants receiving sucrose and it was not being tested per se, and finding 1 significant effect with fathers may have been spurious.

There are some limitations to this study. The scheduling of blood work for clinical purposes at a time that the selected parent could provide KC was challenging and resulted in losing many cases. Although the coders were masked to the intervention, neither the parent nor the staff caring for the infant were masked. However, this is a realistic issue in clinical interventions with visible physical or environmental attributes. The way in which the analyses were conducted, necessary because of sporadic loss of data across the session, may have resulted in the few significant results by chance. Finally, there remain some controversies regarding pain assessment in this nonverbal population, with conflicting results depending on parameters used.

There are also strengths to the study, including that the coders and person conducting the analyses were masked to group assignment. A well-established outcome measure was used that also allowed indirect comparisons to be made to other studies.

Another strength was asking the parents their perceptions of the experience. Although the sample is biased positively, before participating in the study they did not know what it would be like to hold their infant during a painful procedure and had been apprehensive. Afterward, that they all felt positively about it, that they would do it again, and that they would recommend it to other parents implies acceptability.

This study offers some support for the uniqueness of the mother providing the close contact of KC. The difference in the male physique, especially the chest, may be perceived by the infant to be not that of a natural caregiver. Future research should address feasibility issues and non-parent providers of KC during painful procedures.

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