Journal of Perinatology (2009) 29, 51–56

www.nature.com/jp

ORIGINAL ARTICLE

Enhanced kangaroo mother care for heel lance in preterm neonates: a crossover trial

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Objective: To test if enhancing maternal skin-to-skin contact, or kangaroo mother care (KMC) by adding rocking, singing and sucking is more efficacious than simple KMC for procedural pain in preterm neonates.

Study Design: Preterm neonates ($n = 90$) between 32 0/7 and 36 0/7 weeks' gestational age participated in a single-blind randomized crossover design. The infant was held in KMC with the addition of rocking, singing and sucking or the infant was held in KMC without additional stimulation. The Premature Infant Pain Profile was the primary outcome with time to recover as the secondary outcome. A repeated-measures analysis of covariance was employed for analyses.

Result: There were no significant differences in any of the 30 s time periods over the 2 min of blood sampling nor in time to return to baseline. Compared to historical controls of the same age in incubator, the pain scores were lower and comparable to other studies of KMC. There were site differences related to lower scores with the use of sucrose in one site and higher scores in younger, sicker infants in another site.

Conclusion: The sensorial stimulations from skin-to-skin contact that include tactile, olfactory sensations from the mother are sufficient to decrease pain response in premature neonates. Other studies showing that rocking, sucking and music were efficacious were independent of skin-to-skin contact, which, when used alone has been shown to be effective as reported across studies.
Journal of Perinatology (2009) **29,** 51–56; doi:10.1038/jp.2008.113; published online 4 September 2008

Keywords: pain; kangaroo mother care; preterm neonates; heel lance

Introduction

Kangaroo mother care (KMC) in which the mother has skin-to-skin contact with her baby has been reported to be efficacious in reducing pain in three previous studies, one with full-term neonates[1] and two with preterm neonates.[2,3] KMC minimally involves tactile and olfactory stimulation. In addition, if the mother talks to the infant or rocks the infant, auditory and vestibular systems are added. Furthermore, if the infant sucks, either nonnutritively or breastfeeding, other behaviorally calming mechanisms are invoked. Infants apparently know their mothers through olfactory memory of amniotic fluid, which is similar to breast milk in odour.[4] Furthermore, infants know their mothers' voice from the uterine environment.[5] Rocking is thought to mimic maternal walking and movement when the baby is *in utero*.[6]

Rocking by the mother has been reported to decrease pain response in full-term neonates.[7] Although simulated rocking using waterbeds in preterm neonates promotes quiet state and growth,[6] it was not found to have an analgesic effect.[8] It was possible that the lack of caretaker contact as well as the position of the infant (prone) in that study that contributed to the lack of effect. The analgesic effect of maternal voice previously recorded and played to the infant was not seen in a recent report testing that form of stimulation.[9] Although the volume of the recordings was high in that study and was thought to have interfered with its potential efficacy, it was also in a context without the mother actually being present. In studies of pain response in heel lance in infants, nonnutritive sucking has been shown to have an effect alone or in addition to sweet taste.[10,11]

In a recent comparison of rocking, nonnutritive sucking, sucrose (20%), expressed breast milk and massage against control in full-term neonates, it was reported that rocking and nonnutritive sucking were the most efficacious in decreasing crying.[12] In summary, the use of multiple sensory stimulations to decrease pain response in infants seems to be additive: the combination of tactile, auditory, vestibular, olfactory, gustative and visual stimulation,[13] maintaining visual contact,[14] adding sucking to holding[15] increases efficacy.

The purpose of this study was to determine if by adding other sensory modalities given by the mother during KMC, the previously demonstrated comforting effect of KMC would be enhanced.

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Received 19 February 2008; revised 16 June 2008; accepted 13 July 2008; published online 4 September 2008

Methods

Recruitment

The study took place in three level III units, all of which admitted both inborn infants as well as transfers. The protocol and consent forms were reviewed by the constituted institutional research ethics review board of each participating center, namely, the Montreal Children's Hospital, the IWK Health Centre, and Hôpital Ste Justine. Two of the three committees approved the two KMC conditions without sucrose. The other site required usual use of sucrose but this was not consistent. To accommodate the study, if an infant received sucrose in the first session, then sucrose was administered for the second session and similarly, if sucrose was not administered in the first session, it was withheld in the second.

Mothers and their preterm neonates were eligible for enrollment in the study if the infants met the following criteria: were born between 32 0/7 and 36 0/7 completed weeks gestational age determined by ultrasound at 16 weeks, had informed parental consent, had Apgar scores >6 at 5 min, were within 10 days of birth, were breathing unassisted, did not have any major congenital anomalies, had not suffered Grade III or IV intraventricular hemorrhage or subsequent periventricular leukomalacia, had not undergone surgery and were not receiving paralytic, analgesic or sedative medications within 48 h of the study time. Mothers had to be willing and able to hold their infant in the KMC position for the study. The protocol was explained to the mother and her cooperation in rocking and singing and offering her choice of finger or pacifier in the assigned enhanced condition and refraining from the above in the control condition was agreed upon. For practical purposes, if the infant was to be discharged before needing two sessions of blood work, mothers were not approached to participate in the study. Using data from an earlier maternal kangaroo care study,[2] we anticipated that the effect size would be smaller between the two KMC conditions than in our earlier study where we were testing KMC vs incubator and found 2 points difference on the primary outcome. Using a mean difference of only 1.5 point, a sample size of 73 was determined for a standard deviation of 4.5 points, a power of 0.8 and a significance level set to 0.05. (PowerSample Size http://biostat.mc.vanderbilt.edu/twiki/bin/view/Main/PowerSampleSize).[16]

Procedure

Employing a single-blind crossover design (Trial Registration (Current Controlled Trials) ISRCTN13550119) each infant was to undergo heel lancing for blood procurement for clinical purposes in either Enhanced KMC (EKMC) position or usual KMC without additional stimuli. Owing to the infrequency of blood sampling that was determined by clinical considerations, we allowed a wider window of post-natal age such that there was a minimum of 24 h and a maximum of 14 days between conditions. Ordering of conditions was determined randomly by a computer-generated program in the study center and assignment was accessed on the website by the site research nurse after consent was obtained. In both KMC conditions, the diaper-clad infant was held upright, at an angle of approximately 60° between the mother's breasts, providing maximal skin-to-skin contact between baby and mother. A blanket and then the mother's clothing were placed over the infant's back and tucked under each side of the mother. In the EKMC condition, the mother sat in a rocking chair, sang/talked 'babytalk' to the baby, and offered her finger or pacifier to the baby to suck. The baby remained in this condition at least 30 min before heel lancing procedure to ensure stability following transfer. The heel lancing procedure includes five phases. One minute of baseline was collected at the end of the 30 min in the assigned condition. The heel-warming phase lasted 1 min. The heel was then swabbed and lanced with spring-loaded lancet (B&D Microtainer). The instant of lancing was the point at which changes from baseline were determined and data were analyzed in 30 s blocks from that instant. An adhesive bandage was applied to the site immediately after all blood was procured. This was the point that indicated the end of the blood sampling procedure. Return to baseline was calculated as time from adhesive bandage application until baseline HR was achieved. There was continuous video, but not audio, recording, ECG monitoring, and pulse oximetry monitoring of the infant throughout each session, both of which always occurred in the morning. The continuous data were analyzed in allocated blocks of time and averaged for each phase of the procedure.

Measures

The primary outcome was the Premature Infant Pain Profile (PIPP).[17,18] The PIPP is a composite measure of pain including physiological (heart rate, transcutaneous oxygen saturation) and behavioral (facial action) indicators and is weighted for younger gestational age and sleep state. Scores can range from 0 to 21, and a difference of two points between conditions can be considered clinically important. The PIPP has been tested for reliability, construct validity and clinical utility, all with results indicating excellent psychometrics.[19]

Heart rate was collected using four ECG leads connected to a data acquisition system (Compumedics E-series) with a sampling rate of 100 Hz averaged on a beat-to-beat basis. Transcutaneous oxygen saturation was collected by infrared oximeter (Massimo Radical) placed on a hand or the unaffected foot of the infant and connected to the data acquisition system. The physiological data were analyzed using the software in the system (Compumedics E-series Profusion PSG II) that allowed minimum, maximum, mean and standard deviation to be calculated. The three facial actions (brow bulge, eye squeeze and nasolabial furrow) of the PIPP were continuously recorded by the research nurse using a digital video camera Panasonic KS162 that allows for close range, high-quality facial images which was directly wired into the data acquisition system. Phases of the heel lancing procedure were

marked by the research nurse striking keys on the computer and flashing color-coded cards in front of the camera. As both physiological and video data were fed into the same data acquisition system, the time stamps were synchronous. Research assistants, who were blinded to the purpose of the study by being told that the study was about infant facial actions, were trained on video recordings from earlier studies until they reached 90% agreement. As the coders were able to see the rocking, one coder scored the EKMC condition and another coded the KMC condition. Intrarater reliability was checked every 15 sessions and remained over 80%. The selected facial actions were scored on a second-to-second basis. A score based on percentage of time the facial action was present was calculated each 30 s time block throughout each phase of the procedure. The neurobehavioral state component was determined according to Prechtl's categories of quiet sleep, quiet awake, active sleep or active awake[20,21] during the baseline. Gestational age was taken from the chart, based on ultrasound at 16 weeks.

Severity of illness, as a potentially confounding variable, was scored using the Score for Neonatal Acute Physiology Version II (SNAP-II[22]) for the 12 h period after birth and in the 12 h period before each study session. The elements for this score can be found in the medical record and include hemodynamic, respiratory, hematological, metabolic, electrolytic and neurologic parameters. The score has predictive validity for perinatal mortality.

Results

Across the three sites, there were 444 infants admitted during the data collection period (April 2003–December 2006). Of those 330 meeting the selection criteria, 187 were approached and 139 accepted to participate, giving a refusal rate of 26% (Figure 1). The main reasons for refusal were that mothers felt too stressed to participate, did not want to sing in front of research staff, did not want anything extra done to their infant and did not want to see the baby in pain. The primary reason that infants were lost after being enrolled in the study was that the infant was too unstable in the time frame of the study ($n = 8$), discharged from the unit ($n = 27$) or did not require blood work within the time frame of the study ($n = 2$), and there was equipment failure ($n = 5$). Physiological and behavioral data were completed for both EKMC and KMC sessions on 90 infants. Not all infants had complete data at each time block, due to movement artifacts or hand obscuring the face, but there were no more than seven missing data at any point in time and it was not the same infants, so the analyses were conducted with some cases missing. The 90 infants remaining in the study were a mean age of 33.4 weeks (s.d. 7.5 days), at birth weighed 1968 g (s.d. 388 g), had 5-min Apgar scores of 8.6 (s.d. 1.1) and SNAP-PE-II score of 5.5 (s.d. 9.6) (Table 1). There were site differences with one site having infants who were significantly younger by 5 days and who had higher SNAP-II-PE scores. Order of

Table 1 Sample characteristics at both sessions

	*Mean age in gestational days (s.d.)****	*Mean weight in grams (s.d.)**	*Mean SNAP-II scores (s.d.)*
Session 1	239 (7.4)	1850 (356)	2.26 (5.75)
Session 2	241 (7.5)	1872 (343)	2.37 (5.79)

Abbreviation: SNAP, Score for Neonatal Acute Physiology.
$^{*}P<0.05$; $^{***}P<0.001$.

condition, postnatal age, sex or weight had no effect on the pain response. Severity of illness scores measured by the SNAP-II- PE was positively correlated with pain scores but only in the first 30 s block. As gestational age was positively correlated with scores in both conditions and as it was correlated with severity of illness, it was included in the analyses as a covariate. Means for outcomes between sites were significantly different and thus site was an additional factor included in analyses. Thus, a factorial repeated-measures analysis of variance with condition (EKMC vs KMC) as the repeated factor, age as covariate and site as factor was conducted for each 30 s period following heel lance through 2 min when the majority (78%) of the heel lance procedures had been completed. Precisely half ($n = 45$) the infants underwent EKMC before the KMC condition.

Mean pain scores (PIPP; Figure 1) were not significantly different between conditions for any of the 30 s blocks of time. Although there were no significant interaction effects between age and PIPP scores or between site and PIPP scores, age bordered on being a significant covariate ($P = 0.07$) and site as an independent factor was significant at 30, 60 and 90 s, with one site having significantly higher scores than one other site (Figures 2 and 3). The site with lower scores was the one that used sucrose (χ^2 (2) = 6.21, $P<0.05$) and not caffeine, whereas the site with higher scores not only had younger ($F(2,88) = 5.774$, $P<0.01$) more ill infants based on SNAP-II scores at birth ($F(2,88) = 8.238$, $P<0.001$) but also used caffeine more (χ^2 (2) = 7.98, $P<0.05$). PIPP scores were lower with sucrose at 30 ($F(1) = 4.045$, $P<0.05$) and 90 s ($F(1) = 4.98$, $P<0.05$) and higher with caffeine in the first 60 s ($F(1) = 6.522$, $P<0.05$).

In examining time for heart rate to return to baseline, there was no difference in condition. There was a difference in sites, but the second site that had not been significantly different in PIPP scores had the significantly lower time to recover ($F(2) = 11.76$, $P<0.001$) by a full minute.

Discussion

The addition of sensory inputs from the mother over and above the tactile and olfactory senses involved in KMC does not appreciably diminish the pain response in preterm neonates. Although studies suggested that rocking,[7,12] hearing music[23] and nonnutritive sucking, especially in combination, can be efficacious in

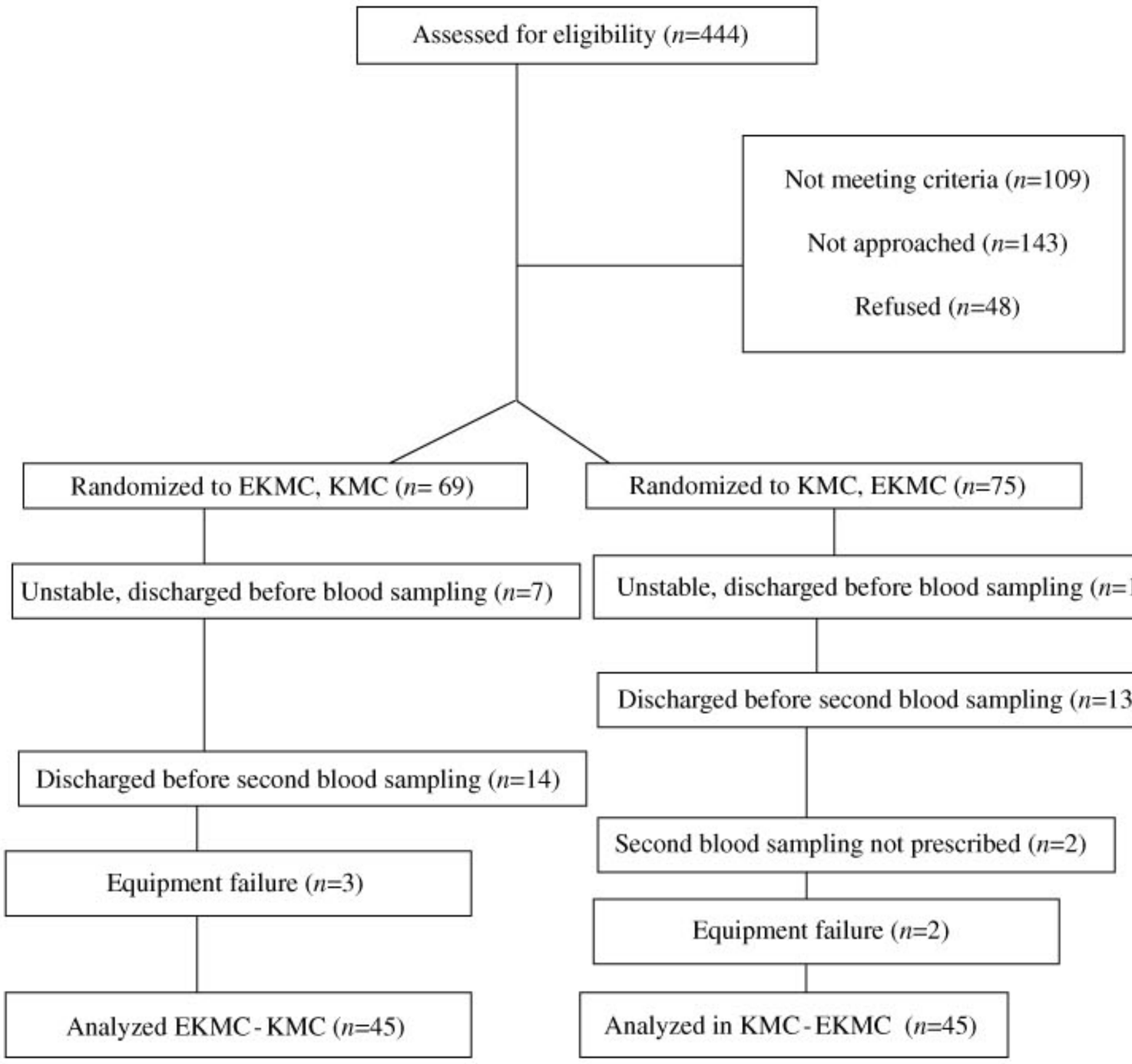

Figure 1 Sample flow.

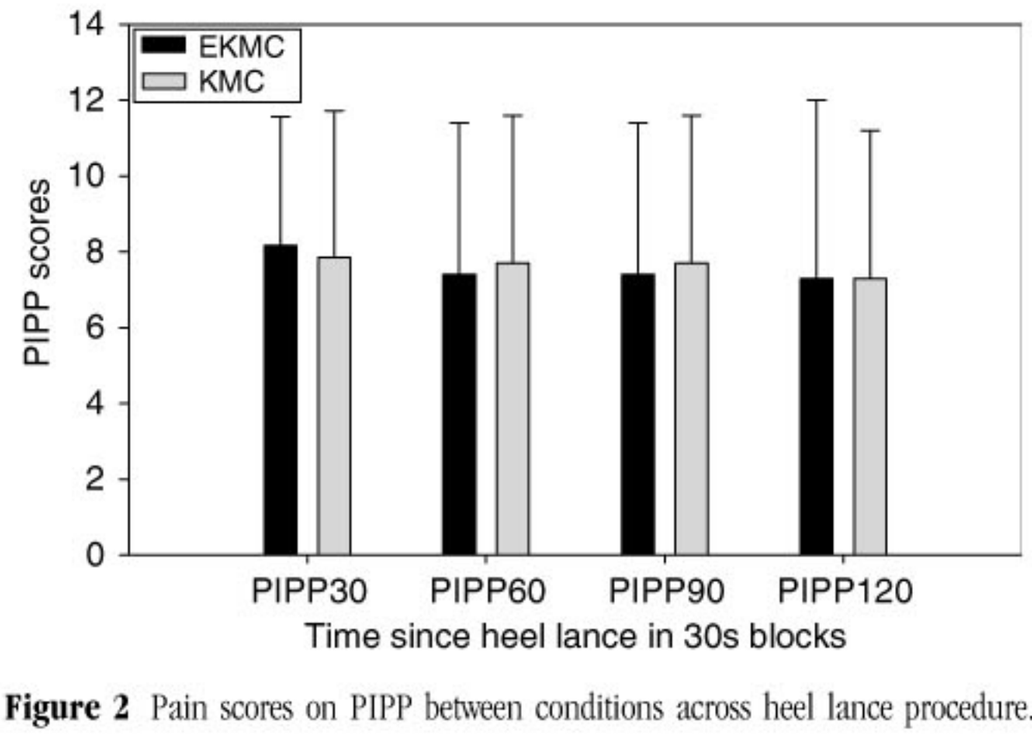

Figure 2 Pain scores on PIPP between conditions across heel lance procedure.

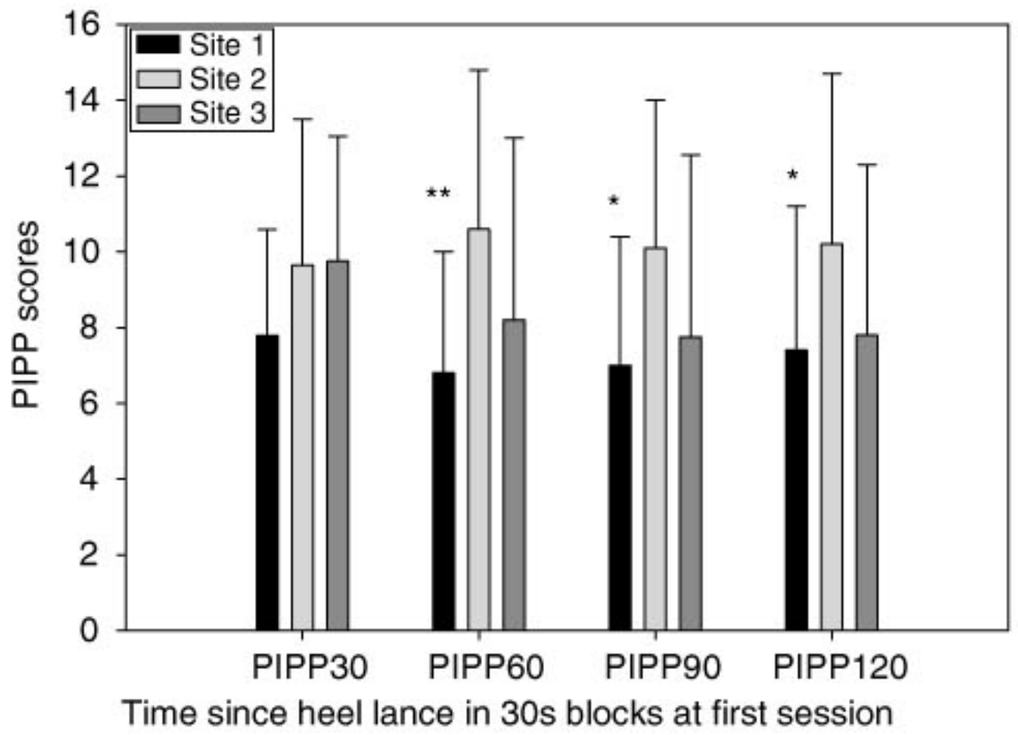

Figure 3 Pain scores on PIPP between sites across heel lance procedure. $^{*}P<0.05$, $^{**}P<0.01$.

decreasing pain, all of these studies were conducted outside the KMC context. Given that tactile and olfactory development occur earlier than other systems,[24] it is not totally surprising that KMC provides enough comfort with these two systems by themselves. Basic studies using animal models clearly show the importance of these two systems over the others[25] and it is paramount to maternal infant interaction (for example, Modrcin-Talbott *et al.*[26]). Recent work on olfactory sensations, evidence of *in utero* olfactory learning and their role in development, has shown that this system has an early role in development.[27] Further, there are studies with full-term neonates that demonstrate that familiar smell by itself, for example from the mother, has analgesic properties.[28]

The site differences were unexpected, given that we have not found site differences in our other KMC studies.[2,29] The fact that the site that used sucrose was lower and the site with the higher scores also was the site with younger sicker infants is the

most likely explanation. The site with the higher scores also used more caffeine, but that could be related to the age and illness of the infants at that site. Caffeine and lower gestational age are both associated with higher heart rates, which could explain why total pain scores were higher and the time to recovery increased.

The clinical implications of this study are clear. In our earlier study in the same sites with the same age range of infants, we compared pain responses when the infant was in KMC to those being in incubator.[2] The scores in this current study are equivalent to the KMC scores in the earlier study and are statistically and clinically significantly lower than in the incubator condition. Although a direct comparison cannot be made as that study took place 5 years ago, it would appear that once again, KMC has been shown to diminish pain response. The results of this study can be interpreted to mean that there is no need to either encourage nor inhibit the mother from rocking, singing to her baby or letting her baby suck. A recent review of KMC[30] summarizes the benefits of KMC for growth,[31] success of breastfeeding,[32] physiological stability[33] as well as family development[34] and maternal mood.[35]

Given the above numerous advantages of KMC, it can perhaps be thought of as an extension of the predelivery relationship between the infant and mother. The close physical contact without interference of clothing is likely releasing endogenous hormones such as endorphins and oxytocin[36] that promote physiological stability even in the face of the stress of acute pain. Issues related to implementing KMC in the neonatal intensive care units are beginning to be addressed.[37] Factors such as staffing, nurse experience and ongoing education play an important role. The evidence in favor of KMC is growing, although there is a need for well-conducted trials that provide high-quality evidence upon which to base practice.[38]

Acknowledgments

This project was sponsored by the Canadian Institutes of Health Research (CIHR; MOP 117475-CHI-CFAA-23682) and additional support from Fonds de la Recherche en Santé du Québec (FRSQ). CJ is a member of the McGill University Health Centre Research Institute that is funded by FRSQ. We thank the babies, parents and staff of the NICUs at Hopital Ste Justine, Montreal, Royal Victoria Hospital, Montreal and IWK Children's Health Centre, Halifax. Canada. We especially thank research nurses Terry Suss and Kim Caddell for the meticulous attention to the protocol and sensitive recruitment of mothers. Thanks also to research assistants Indrayudh Ghoshal and Elaine Tam. We thank the 3M Company for the provision of red dot electrodes, and for the 'puppy dog' electrodes, we thank Tyco Medical Canada.

Authours' contributions. CJ was responsible for all stages of the study. FF, MCY, LB participated in the protocol development, oversaw data collection from one site, participated in data analysis and paper preparation and review. CG participated in study design, and KM, JB trained and oversaw data coding, data entry and verification, literature review update and paper preparation.

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