The Effect of Kangaroo Care on Behavioral Responses to Pain of an Intramuscular Injection in Neonates

Zahra Kashaninia, Firoozeh Sajedi, Mehdi Rahgozar, and Fariba Asadi Noghabi

PURPOSE. *This study aims to assess the efficacy of Kangaroo Care (KC) on behavioral responses of term neonates to the pain of an intramuscular injection.*

DESIGN AND METHODS. *One hundred healthy term neonates were enrolled and randomly assigned to intervention and control groups. In the intervention group, the neonate was held in KC for 10 min before the injection and remained in KC for the duration of the procedure. The primary outcome measure was the cumulative Neonatal Infant Pain Scale (NIPS) score immediately after injection.*

RESULTS. *The cumulative NIPS score immediately after injection in the intervention group was significantly lower ($p < .001$) than in the control group.*

PRACTICE IMPLICATIONS. *KC given before injection seems to effectively decrease pain and should be considered for minor invasive procedures in neonates.*

Search terms: *Behavioral responses, Kangaroo Care, intramuscular injection, pain, term neonates*

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Zahra Kashaninia, MSN, is Lecturer, Nursing Department, University of Welfare & Rehabilitation, Tehran, Iran; Firoozeh Sajedi, MD, is Associate Professor of Pediatrics, Clinical Sciences Department, University of Welfare & Rehabilitation, Tehran, Iran; Mehdi Rahgozar, PHD, is Assistant Professor, Biostatistics & Computer Department, University of Welfare & Rehabilitation, Tehran, Iran; and Fariba Asadi Noghabi, MSN, is Lecturer, Nursing Department, University of Bandar Abbas, Bandar Abbas, Iran.

Pain can have direct and long-term consequences on the neurologic and behavior-oriented development of neonates (Anand, 2000; Anand & Carr, 1989; Gagnon, Leung, & Macnab, 1999; Grunau, 2002; Grunau, Whitfield, & Petrie, 1998; Grunau, Whitfield, Petrie, & Fryer, 1994; Oberlander et al., 2000; Peters et al., 2005). Data from animal models confirm that prolonged exposure to pain is harmful to development. It affects the normal development of the nociceptive neural circuits and leads to an altered development of the pain system, characterized by lowered pain thresholds during later infancy (Anand, Coskun, Thrivikraman, Nemeroff, & Plotsky, 1999; Bhutta et al., 2001; Ruda, Qing-Dong, Hohmann, Peng, & Tachibana, 2000) and both hypoalgia after puberty and hyperalgia in adulthood (Ren et al., 2004). Therefore, strategies for stress reduction, such as the concept of developmental care (Als, Duff, & McAnulty, 1996; Sizun, Ansquer, Browne, Tordjman, & Morin, 2002), and systematic pain management are central issues in neonatal care to promote well-being and unimpeded development of the neonate. In particular, the use of nonpharmacologic interventions is of great importance because they are based on a nurse's clinical assessment of pain and can be carried out by nursing staff without instructions by physicians.

Nonpharmacologic methods are suitable to counteract procedural pain because of their short-term efficacy and good tolerance; therefore, they are increasingly being recommended for pain prevention and pain management. In order to achieve optimum efficacy, both pharmacologic

and nonpharmacologic interventions require reduction of external stimuli, such as loud noise and bright light (Franck & Lawhon, 1998; Stevens, Gibbins, & Franck, 2000). The initiation of nonpharmacologic treatment is recommended for mild pain (American and Canadian Academy of Pediatrics, 2000; Anand & the International Evidence-Based Group for Neonatal Pain, 2001).

One such nonpharmacologic intervention is Kangaroo Care (KC). KC involves the neonate being taken out of the incubator and laid vertically on the bare skin of the chest of the mother and the mother wraps her clothing around the infant. A study of 30 term, healthy neonates showed that crying and grimacing were reduced by 82% and 65%, respectively, from infant control's levels of crying and grimacing when KC was used during the heel-lance procedure (Gray, Watt, & Blass, 2000). Heart rate also was reduced substantially by contact. This study confirmed that skin-to-skin contact is a remarkably potent intervention against the pain experienced during heel stick in newborns (Gray et al.).

A literature search (Cignacco et al., 2007) was conducted via the MEDLINE, CINAHL, and Cochrane Library databases covering the period from 1984 to 2004. Twelve randomized control studies and two meta-analyses were considered with regard to the question of current nursing practice of nonpharmacologic pain management methods. The selected interventions were "nonnutritive sucking," "music," "swaddling," "positioning," "olfactory and multisensorial stimulation," "kangaroo care," and "maternal touch." Eleven studies examined the routine intervention heel stick, and one study focused on the relief of pain during endotracheal suctioning. The two meta-analyses were likewise restricted to the heel stick. All interventions have been shown to be effective for reducing pain responses to heel puncture, but the effectiveness during intramuscular injection has not been studied. Therefore, we conducted an experimental study to measure the effect of KC on behavioral (behavioral state and crying time) measures of pain before, during, and after an intramuscular injection of vitamin K.

Methods

Subjects

Following approval by the ethics committee of the University of Welfare and Rehabilitation Sciences and receipt of informed consent from the parents, data were collected from 100 healthy newborns delivered at a hospital in Bandar Abbas City, Iran. Inclusion criteria were as follows: (a) birth weight of between 2,500 and 4,000 grams; (b) approximately 2 hr of age (because vitamin K is injected routinely into all neonates within a few hours of birth); (c) unfed; (d) Apgar scores of at least 7 at 1 min; (e) estimated gestational age of at least 37 weeks; (f) heart rate between 100 and 160 beats per minute; (g) blood O_2 saturation ≥ 95%; and (h) no known congenital anomalies. Exclusion criteria were as follows: (a) born by cesarean section; (b) administration of a vaccine or any injection; (c) birth trauma; and (d) drug abuse by the mother during pregnancy. The neonates were randomly assigned to intervention and control groups by using randomized permuted blocks. Randomization was done by a well-trained nurse using a random numbers table. The purpose was to insure random assignment of the neonates to two groups with gender-matching in each group. The number of neonates in each group was 50 (22 males and 28 females in both the intervention and control groups).

Protocol

Infants who had been assigned to receive contact were brought to their mothers' rooms. The mothers changed into hospital gowns that buttoned in the front and returned to their beds that had been adjusted to a 45° angle to provide a comfortable, reclining position. The infants, wearing only diapers, were then positioned on their mothers so that skin-to-skin contact was maintained through the open gowns. This arrangement left the infants' faces visible for filming from the side of the beds. Two receiving blankets were placed over the infants' backs. The mothers then were asked to lock their fingers, place their hands over the blankets, and apply a slight pressure on their infants' backs to stabilize the infant for both procedural ease and to facilitate video recording. The mothers were asked not to rub their infants' heads, speak with, jiggle, or touch them before, during, or after the injection. At this point, the researchers left the room for 10 min so that mother and infant could settle into a relaxed contact position. Control infants were brought into a quiet room in the nursery, repositioned, and left for 10 min. Upon return, infants in both groups were found to be in a relaxed and quiet state. The sequence of phases were as follows:

1. The pulse oximeter (NTB195) probe was attached to the neonate, and the heart rate and blood O_2 saturation levels were obtained before intervention by a trained nurse (first research assistant).
2. The control infants were brought to a quiet room, repositioned, and left for 10 min. The Kangaroo-held infants were brought to their mothers' rooms, and the intervention (KC) was done 10 min before the injection.
3. Infants in both groups were brought to a quiet–alert state.
4. While KC was continued, the vastus lateralis muscle was grasped, swabbed, and injected with a 30-gauge syringe (SUPA Medical Device, Tehran, Iran), and 0.5 mL of vitamin K was introduced into the vastus lateralis muscle; pressure was held at the site of injection with a sterile gauze pad. This procedure took 2 min. To minimize variability of the stimulus, the same nurse performed all of the injections. This nurse was the second research assistant and was not aware of either the purpose of the study or the different groups.
5. The Neonatal Infant Pain Scale (NIPS) was used during the first minute after the injection. Assessments of facial expression, cry, breathing pattern, arm and leg movements, and state of arousal were collected for purposes of NIPS scoring.
6. The third research assistant (a nurse) began videotaping immediately after the injection. The camera filmed only the face of the neonate for evaluation of the duration of crying, and videotaping was continued until the infant stopped crying for the first time.

Measurements

An experienced nurse (fourth research assistant) used the NIPS to score each neonate in real time (not from the videotapes). She scored each category of the NIPS separately and also gave a total score. The NIPS is a behavioral scale and can be utilized with both full-term and preterm infants. The tool uses the behaviors that nurses have described as being indicative of infant pain or distress. It is composed of six indicators: *facial expression* (relaxed, 0; grimace, 1), *cry* (no cry, 0; whimper, 1; vigorous, 2), *breathing patterns* (relaxed, 0; changed, 1; which means just different from baseline), *arm movement* (relaxed, 0; extended/flexed, 1), *leg movement* (relaxed, 0; extended/flexed, 1), and *state of arousal* (sleeping/awake, 0; irritable, 1). Each behavioral indicator is scored with a 0 or a 1, except *cry*, which has three possible descriptors. Infants were observed for 1 min in order to fully assess each indicator. The total pain score ranged from 0 to 7. The pain levels were as follows: 0–2 = mild to no pain; 3–4 = mild to moderate pain; and greater than 4 = severe pain.

Data analysis. Data were analyzed using SPSS 11.5. There were no missing data. An independent *t*-test was used for comparing means. The Mann–Whitney test is a nonparametric substitute for the independent *t*-test when a normality assumption does not hold for data in groups, and the chi-square test was used to test the homogeneity or quality of proportions of behavioral responses and the NIPS score in the two groups.

Results

Background Variables

One hundred neonates were randomized during the 2-month observation period; similar demographic characteristics were demonstrated between the two groups (see Table 1). The numbers of females in the intervention and control groups were 28 (56%).

NIPS Score

The behavioral responses immediately after injection in the control group were significantly more severe than in the intervention group ($p < .001$, Table 2). The NIPS scores immediately after the injection in the control group were markedly higher than in the intervention group ($p < .001$, Table 3).

The duration of crying after the injection in the control group was significantly longer than in the intervention group ($p = .001$, Table 4). Unexpectedly, 36 neonates (30 in the intervention and 6 in the control group) did not cry at all during the KC intramuscular injection.

Discussion

In this study, we assessed the efficacy of 10 min of KC for relieving pain in healthy, term neonates following an intramuscular injection of vitamin K, as measured by cumulative NIPS scored immediately. The results of this study showed that there were significant differences between the two groups ($p < .001$) in pain expression after a minor painful procedure.

Table 1. Comparing Means of Background Variables in Two Groups

Variables	Groups	*M* ± *SD*	*M* Rank	Statistics test	*df*	*p*
Apgar, 1 (min)	Intervention (*n* = 50)	8.64 ± 0.63	51.74	1188.00*	—	.598
	Control (*n* = 50)	8.6 = 0.60	49.26			
Gestational age (weeks)	Intervention (*n* = 50)	39.36 = 1.45	52.78	1136.00*	—	.415
	Control (*n* = 50)	39.12 = 1.42	48.22			
Birth weight (grams)	Intervention (*n* = 50)	3083.2 = 258.33	—	–1.178**	98	.242
	Control (*n* = 50)	3142.2 = 242.3	—			
Mother age (years)	Intervention (*n* = 50)	23.7 ± 4.79	—	–1.410**	98	.162
	Control (*n* = 50)	25.04 ± 4.70	—			

*Mann–Whitney, **Independent *t*-test.
Note: *M* and *SD* were calculated separately.

Table 2. Behavioral Responses Immediately After Injection in Two Groups

Behavioral reactions		Intervention *N* = 50 (%)	Control *N* = 50 (%)	χ^2	*df*	*p*
Facial expression	Relaxed	50	3	29.937	1	< .001
	Grimace	50	96			
Breathing pattern	Relaxed	86	22	44.222	1	< .001
	Changed	14	78			
State of arousal	Sleeping/Awake	94	60	16.318	1	< .001
	Fussy	6	40			
Arm movements	Relaxed	94	56	19.813	1	< .001
	Extended/Flexed	6	44			
Leg movements	Relaxed	50	10	30.069	1	< .001
	Extended/Flexed	50	90			
Cry	No Cry	54	12	33.969	2	< .001
	Whimper	40	32			
	Vigorous	6	56			

Table 3. Analysis of NIPS Score in Two Groups Immediately After Intramuscular Injection

Pain score	Intervention (*n* = 50) *N* (%)	Control (*n* = 50) *N* (%)
No pain to mild (0–2)	31(62%)	1(2%)
Moderate Pain (3–4)	16(32%)	19(38%)
Severe pain (> 4)	3(6%)	30(60%)
Total	50(100%)	50(100%)

$PV < 0.001$, $df = 2$, $\chi^2 = 50.47$.

For this procedure to be effective, the mother must hold her infant close and apply a light but firm pressure to the infant's back. In our experience, the key to insuring success was the 10 min of privacy the mother had with the infant in the ventral–ventral position. We should note, however, that we have not explored the range of time or the intensity of the mother's grasp on the infant. Nonetheless, it was not the quiet ambiance or the lack of activity per se that caused analgesia because the control infants who had been resting undisturbed did not benefit from the interlude.

In this regard, KC differs from how a sweet taste or sucking relieves pain in newborns (Gray et al., 2000) because it is context-dependent. The influence of taste or sucking seems to be context-independent. Sucrose delivered via a syringe by a stranger to infants who are not being held markedly reduces crying and grimacing to heel stick, as does sucking a pacifier in the same circumstances. In contrast, contact effectiveness is very much dependent on contact with a relaxed individual who is holding the infant comfortably, yet firmly, against her skin. An additional difference between contact-based analgesia and those induced by oral stimulation is the time course of induction. Both sucking and taste-induced

Table 4. The Duration of Crying After Injection in Two Groups

Group	*M** (sec)	*SD**	*M* Rank	Sum of ranks	Man–Whitney test	*p*
Intervention ($n = 20$)	14.55	19.98	20.83	416.50	206.5	.001
Control ($n = 44$)	24.61	16.39	37.81	1663.50		

**M* and *SD* calculated separately.

analgesics have a rapid onset. In contrast, contact-induced analgesia is of a gradual onset; in our study, a time period of 10 min of holding was used to prevent excessive crying and grimacing. These contextual considerations are important in our view because holding as a source of analgesia persists well into childhood and is a source of comfort for adults as well.

For this procedure to be effective, the mother must hold her infant close and apply a light but firm pressure to the infant's back. In our experience, the key to insuring success was the 10 min of privacy the mother had with the infant in the ventral–ventral position.

It is of therapeutic relevance to study pain therapy for minor painful procedures. Ten to 15 min of KC was effective in reducing the crying time (by 82%) during a heel stick versus an incubator heel stick in 15 full-term infants (Gray et al., 2000). In our study, 10 min of KC was also effective in reducing crying time during a different minor painful procedure (intramuscular injection), which may be more painful than heel stick, in 50 full-term neonates.

A study involving KC in the reduction of premature infant heel stick pain (Johnston et al., 2003) showed that KC given for 30 min effectively reduced the pain score by 2 points, a value that reached statistical and clinical significance. The mean Premature Infant Pain Profile score was calculated for each 30-s period for 2 min following completion of the heel stick. The study concluded that determination of multiple indicators or composite responses is required for valid and reliable pain assessment in neonates. In our study, we calculated the behavioral pain score immediately after injection with the NIPS; it may be more helpful to determine multiple indicators in future studies. In the Johnston et al. study, there was no measure of the number of previous invasive procedures performed. In our study, the neonates had no previous injections, minimizing the possible influence of previous painful experiences on the pain response (Grunau, Oberlander, Whitfield, Fitzgerald, & Lee, 2001; Johnston, Stevens, Yang, & Horton, 1996, 1999). The more previous painful experiences an infant has had, the more likely the infant is to have hypersensitization to pain (Andrews & Fitzgerald, 1994; Fitzgerald & de Lima, 2001).

The data presented here should be viewed with caution because manual recording of data is subject to error. Furthermore, the observer was not blinded to the intervention and control groups because she gave the score immediately postprocedure; thus, she saw which neonates were in contact with their mothers.

In summary, skin-to-skin contact is an effective, easily implemented, and safe intervention against pain in human newborns. The high rate of cooperation from the mothers in this study suggests that this procedure can be implemented readily in standard hospital settings.

How Do I Apply These Findings to Nursing Practice?

Nurses have positive attitudes about relieving pain and using behavioral interventions to do so (Van Hulle Vincent, 2005) and these results support the implementation of KC to avert procedural pain. KC is a nonpharmacologic intervention to manage neonatal procedural pain, and it can be easily implemented. This is the first finding of a possible effect of KC in reducing

pain responses during intramuscular injection of vitamin K. Further studies should compare term neonates and other age populations of infants receiving KC to those receiving traditional holding or other treatments during intramuscular injection of vitamin K, to determine which treatments are most effective.

Author contact: fisajedi@uswr.ac.ir, with a copy to the Editor: roxie.foster@UCDenver.edu

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