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Is Kangaroo Care Effective in Reducing Procedural Pain in Neonates?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

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Abstract

Objective: The objective of this systematic review is to determine whether Kangaroo Care is effective in reducing procedural pain in neonates.

Study Design: Review of three English language single-blind randomized, controlled trials from 2008.

Data Sources: Randomized, single-blind control trials comparing Kangaroo Care to standard Incubator Care as analgesia for neonates during routine medical procedures. All studies were located using the OVID, Medline, and Cochrane databases.

Outcomes Measured: Neonate pain to minimally invasive routine medical procedures including vitamin K injection and heel stick. Neonate pain includes parameters of both audible and inaudible crying. All three of the studies utilized standardized scoring systems to rate facial cues and behavioral indicators of neonate pain and distress. These scoring systems include the Andersen Behavioral State Scoring System, the Neonatal Infant Pain Scale, and the Premature Infant Pain Profile.

Results: Mean crying times and facial indicators of distress were significantly decreased in neonates receiving Kangaroo Care versus the standard Incubator Care. No adverse events or effects were reported from implementation of the KC intervention.

Conclusion: All of the studies reviewed demonstrate that Kangaroo Care is effective in reducing neonate pain and distress during routine minimally invasive medical procedures. Further research is needed to determine the optimal amount of Kangaroo Care time needed for individual procedures. Likewise, further research should examine paternal and/or surrogate caregivers as the bonding partner. The easy availability, cost effectiveness, and natural bonding of Kangaroo Care make it a promising addition to the nonpharmacologic interventions available for alleviating neonate pain and distress.

Key Words: Kangaroo Care, Skin to Skin Contact, pain, infant, neonate

Introduction

Neonates undergo multiple stressors from the time of birth to discharge from the hospital setting. Most of these processes-APGAR scoring, heel sticks, vitamin K injections and the like are required to ensure the health of a newborn or to determine cause of current or future illness. The pain and distress experienced by the neonate and by proxy the caregivers from such procedures make it desirable to have an arsenal of both pharmacologic and nonpharmacologic interventions available to minimize this distress; especially for those procedures that are invasive in nature such as venipuncture and injections.

Currently, many of the aforementioned procedures are performed while the neonate is within the confines of an incubator. Incubator care (IC) is therefore the current standard for early observation of the neonate as incubators are well equipped with warming mechanisms, and monitoring devices. Additionally, incubators can be isolated if need be for the fragile preterm or seriously ill neonate. In the studies reviewed, standard IC involves placing the neonate prone in the incubator surrounded or "nested" in blankets at incline of 30-45°.[1] When oral glucose (OG) is implemented for analgesia, the neonate is administered oral sugar solution prior to the painful stimulus in addition to being placed per standard IC measures. Caregiver-neonate interaction is limited with the use of IC, due to the inherent isolation of the incubator module. This interaction is further minimized during procedures as incubators are often limited to designated areas of the healthcare facility, and workable space comes at a premium in most nursery settings.

With the conception of Kangaroo Care ("Skin to Skin Contact") the neonate and caregiver are in direct physical contact with each other, thus allowing for the comfort, familiarity, and scent of the caregiver to soothe the neonate whilst the procedure is being performed. Kangaroo Care (KC) is a nonpharmacologic intervention being used in some medical

settings to allay neonate pain and distress during minor invasive procedures. The KC procedure involves placing an undressed, diapered infant upon the mother's bare chest "skin to skin" as she sits comfortably at a 45-60° angle.[1,2,3] The neonate's back is covered with a blanket, and the mother holds the child in position with a firm grip. For the studies, the caregiver is to remain in this position with the neonate undisturbed for the duration of the intervention period. Other parent-child interaction is discouraged and outside stimulus is minimized throughout the study period.

Pain inflicted from procedures such as heel sticks-for blood glucose checks and the newborn screening, and vitamin K injections are some of the first invasive procedures experienced by term and preterm neonates in the hospital setting. Both healthy and ill neonates undergo a number of these tests in the first few hours and days of life. Preterm and ill neonates may experience an exponentially greater number of such procedures. Evidence shows that repeated painful stimuli can provoke physiologic and hormonal changes thus affecting the neurobiology and CNS development of the neonate.[1] Moreover, research demonstrates that preterm infants may lack the pain inhibition abilities of their full term cohorts, leaving them more sensitive to pain and at greater risk for developing maladaptive pain responses.[1,3]

If proven effective, Kangaroo Care offers a promising new intervention to decrease neonate procedural pain. KC affords many advantages over other interventions. It is cost effective, requiring little to no additional overhead. KC can be utilized in any setting that serves neonates; such that hospitals, clinics, ERs and Urgent Care facilities may benefit from its use. As a nonpharmacologic intervention, midlevel providers such as Physician Assistants and Nurse Practitioners as well as other designated medical staff may initiate KC without requiring a Physician's signature. Availability and ability of the caregiver and neonate are essentially

the only prerequisites needed for implementation of the KC intervention.

Objective

The objective of this systematic review is to determine whether or not, "Is Kangaroo Care effective in reducing procedural pain in neonates?" Previous research has concluded that KC is effective for promoting preterm neonate development, including thermoregulation and respiratory maturation. Other randomized, controlled trials have shown promising results using KC in other avenues of neonate care. However, limited studies are available on the effectiveness of KC in alleviating neonate pain during routine invasive medical procedures.

Methods

For this review, the author performed a detailed search of the Cochrane, Ovid and Medline Databases for Randomized Controlled-Trials and Systematic Reviews. Search criteria included English language, peer reviewed journal articles published from 2005 to present. Key search terms used: "Kangaroo Care," "Skin to skin contact," "pain," "infant," and "neonate." Of those RCTs selected, the subject population included both term and preterm neonates undergoing routine minimally invasive medical procedures. Articles chosen were based on relevance and validity to the objective in question.

The studies selected for this review were all randomized, controlled trials with measures based on patient oriented outcomes (POEMs). Two of the selected studies compared KC with IC.[2,3] A third study compared these and oral glucose (OG) as analgesia as well.[1] Two of the studies enrolled preterm neonates with 28-36 weeks and 30-32 weeks gestational age respectively.[1,3] In contrast, the Kashaninia group studied full term neonates $\geq$ 37 weeks gestational age. The painful stimulus experienced by study subjects was either routine heel stick or intramuscular vitamin K injection.[1,3,2] Studies excluded from this review were those that

involved KC in subjects older than neonate age, or those undergoing medical procedures where piercing of the skin was not involved. Demographics of the studies included in this review can be found in Table 1. All three studies utilized standardized tools for measuring neonate pain/distress. The statistics used in each study are somewhat variable, with results performed by ANOVA and Kruskal-Wallis testing; all studies include *p*-values.

Table 1: Demographics of reviewed studies

Study	Type	# of Pts	Age	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Freire, Brazil, 2008	RCT, Single-blind	105	Preterm 28-36 wks GA	Healthy neonates, Healthy mothers	Congenital anomalies, Maternal drug use, Ventilation support, Intraventricular hemorrhage Chest drain, Tracheotomy, Oxygen therapy, Hemodynamic instability, Analgesia/sedative care within 48 hours	10	Incubator care without analgesia, Glucose as analgesia, Kangaroo care-10 mins prior and during procedure
Kostandy, USA, 2008	RCT, Prospective cross-over	10	Preterm 30-32 wks GA; post-natal age of 2-9 days	Healthy neonates, Healthy English-speaking mothers, NPO or bolus fed over 20 mins	Congenital anomalies, Maternal drug use, Intraventricular hemorrhage, Surgical history, Heel inflammation, Sedative or analgesia treatment within 24 hours	0	Incubator care-30 mins undisturbed, then procedure, then 20 min recovery, Kangaroo care-kept in position 30 mins prior, during and 20 mins after procedure
Kashaninia, Iran, 2008	RCT, Gender-matched	100	Full term 37 wks GA, Approx 2 hr post-natal age	2500-4000g at birth, APGAR $\geq$7 at 1 min old, HR 100-160 bpm, pO2 $\geq$ 95%, Unfed	Congenital anomalies, Maternal drug use Caesarean birth, Administration of any injection of vaccine, Birth trauma	0	Incubator quiet time, Kangaroo care, both for 10 mins prior to procedure

Outcomes Measured

Outcomes measured were based on importance to the patient, and in this case the caregiver as well. The outcomes measured include expressive cues of neonate pain/distress that could be easily read by the caregiver and/or hospital staff. All studies used for the review utilized standardized tools for recognizing and scoring infant pain and distress. One study employed the Neonatal Infant Pain Score (NIPS) to account for infant facial expression, crying indicators, and to compile a cumulative score.[2] The Andersen Behavioral State Scoring System (ABSSS), which calculates both audible and inaudible crying times from relevant facial cues, neonate level of arousal and activity was used by another.[3] The third research group utilized the Premature Infant Pain Profile (PIPP) scoring model to measure eye squeeze, brow bulge, and nasolabial furrowing as signs of neonatal pain.[1] All studies used videotaping and blinded raters for scoring.

Results

Each of the studies presented in this review are randomized, controlled trials with the intention to treat pain experienced by neonates during routine medical procedures. Two of three studies compared Kangaroo Care with standard Incubator Care, while the third also compared oral glucose as an intervention.[2,3,1] The Kashaninia group utilized intramuscular vitamin K injection as the painful stimulus, while both of the other studies used heel stick procedures.[1,3] The Freire et al study began with the most participants at 105, but lost 10 due to blinding errors. Thus the Kashaninia et al study completed with the largest study population at 100. As a pilot study, the Kostandy et al population was limited to 10 subjects. This group also experienced blinding errors as one neonate subject was noncompliant to study conditions.

All studies reviewed here utilize standardized tools for measuring neonate distress. Such measures include the NIPS, ABSSS, and PIPP scoring systems. Although each tool measures

slightly different signs of distress, overlap did occur and such indicators included audible crying times and facial cues like brow bulge, grimacing expression, and eye squeeze.[1,2,3] All data presented amongst the studies is continuous. Only the scales used by the Kashaninia group were convertible to dichotomous data for purposes of this review.

Kashaninia et al utilized the NIPS scoring system for infant pain and distress. Cumulative NIPS scoring was tiered and assessed values:

No to Mild pain (0-2), Moderate pain (3-4), Severe pain (> 4)

For purposes of this review, scores of no to mild pain (0-2) constituted successful interventions whereas scores of moderate to severe pain ($\geq$3) were considered failures. As such, 62% of the KC intervention group experienced no to mild pain, while only 2% of the IC control group scored similarly. Of the 38% of the KC group scoring at a 3 or above only 6% demonstrated indicators of severe pain. Of those in the 98% of IC group failures, 60% scored a 4 or above indicating severe pain. *P*-values for all of the statistics as presented in this research indicated statistical significance ($p < 0.001$). Table 2 highlights the clinical significance and treatment benefit of using KC as compared to IC as presented by Kashaninia et al.

Table 2: Analysis of NIPS Score Outcomes Immediately after Intramuscular Injection

Measured Response	**RBI**	**ABI**	**NNT**	***p*-value**
Cry Response	1.136	0.50	+2	$p < 0.001$
Facial Expression	15.667	0.47	+3	$p < 0.001$
Cumulative NIPS score	30.000	0.60	+2*	$p < 0.001$

RBI=Relative benefit increase, ABI=Absolute benefit increase, NNT=Number needed to treat.
*Based on the cumulative NIPS score analysis the practitioner would need to treat 2 neonates with KC to reduce pain in 1 neonate during IM injection of vitamin K.

The Kostandy group implemented a randomized cross-over study design utilizing either KC or IC as the day 1 intervention and switching to the contrary intervention on day 2. The

ABSS system was used for measuring neonate distress across four phases for each condition on each day. The phases were continuous from 1) baseline, 2) heel warming, 3) heel stick, and 4) recovery. The mean total of audible and inaudible crying time was recorded for each subject. Inaudible crying times were minimal throughout each phase, from 0-1.34 seconds across both groups on both days. A distinct pattern of crying time emerged in that crying was minimal during baseline warming, increased during the heel stick procedure, and then declined during the recovery phase on both days of the study regardless of the intervention used. ANOVA testing was performed and the results are listed in Table 3.

Table 3: Efficacy of Kangaroo Care in Decreasing Mean Crying Time

	Kangaroo	**Care**	**Incubator**	**Care**		
	Mean Crying Time (sec)	**SD**	**Mean Crying Time (sec)**	**SD**	**ANOVA F score**	***p*-value**
Day 1 Recovery phase	5.83	7.63	25.50	41.93	NR	NR
Day 2 Heel stick phase	55.00	55.53	96.17	92.42	F (1,8) = 7.76	$p = 0.001$
Days 1 &2 (combined across phases)	NR	NR	NR	NR	F (1,8) = 10.25	$p < 0.001$

NR=Not Recorded; SD=Standard Deviation

Kostandy et al report that differences were minimal between groups during the baseline and warming phases. In contrast, considerable differences were discovered during the heel stick and recovery phases, with the day 2 heel stick phase showing the most significant difference in crying time between groups [F (1,8) = 7.76; $p = 0.001$]. The KC intervention neonates experienced significantly less crying time during heel stick than the IC group. The ANOVA results show a significant difference in combined crying time between phases on both days [F (1,8) = 10.25; $p < 0.001$].

Freire et al compared three interventions for reduction of heel stick pain in neonates: IC, KC, and OG. Those subjects randomized to the OG group were administered 1 mL of oral glucose solution by syringe 2 seconds prior to heel stick, and were otherwise placed prone at a 30-45° incline similar to those in the IC group. Behavioral indicators were measured for 30 seconds following the painful stimulus using the PIPP scoring model. These parameters included brow bulge, eye squeeze, and nasolabial furrowing.

Kruskal-Wallis statistical tests were performed on each parameter. A significant difference was seen across parameters between groups, with a smaller difference observed between KC and OG groups as compared to the IC group. Moreover, scores were significantly lower in the KC group than either of the other two groups. An abbreviated listing of the results is provided in Table 4. ANOVA tests were also performed in this study for physiologic measures of heart rate and oxygen saturation (p-value ≤ 0.05). However, as these outcomes are difficult to assess by non-medical personnel (i.e. an untrained caregiver), these statistics were excluded from this review.

Table 4: Abbreviated Summary of Behavioral Indicators before and after painful stimulus

Facial Cue	**Incubator Control (n=33)**	**Kangaroo Care (n=31)**	**Oral Glucose (n=31)**	***p*-value**
Brow Bulge	2.33 $\pm$ 0.64	0.96 $\pm$ 0.87	1.48 $\pm$ 0.92	0.0001
Eye Squeeze	1.75 $\pm$ 0.79	0.54 $\pm$ 0.88	1.06 $\pm$ 0.81	0.0001
Nasolabial Furrowing	1.75 $\pm$ 0.75	0.48 $\pm$ 0.85	1.00 $\pm$ 0.81	0.0001

All results listed as mean $\pm$ SD

Discussion

Across all three studies reviewed, Kangaroo Care does appear to be more effective than standard incubator care in treating neonate pain due to minimally invasive procedures. Audible crying times were less in the KC groups versus the IC groups across all studies. Results in the

cross-over study were most profound during heel stick and recovery phases and more so on day 2 of the interventions.[2] It should also be noted that no adverse events were reported with any of the interventions used.

All studies reviewed here encountered limitations. As a pilot study, Kostandy et al had a sample population much too small to establish any correlations. Also, within this study it states that "80% of subjects had previous KC experience."[3] Having a sample population with previous exposure to the intervention in question may skew the results of the current research and must be accounted for. The Freire study was also troublesome, as information on enrollment methods and inclusion criteria was somewhat limited.

All studies had issues with blinding. This caused the majority of withdrawals accounted for in this review. Videotaping was used to assist in rating the NIPS, ABSSS, and PIPP measures. Due to the nature of the KC intervention, only single-blindedness could be achieved. This too was limited as some neonates did move during taping and response rating issues arose. Another limitation in regard to rating, involved those actually scoring the responses. Only one study utilized a multiple rater system and determined inter-rater reliability to score each subject for data purposes.[2] Both of the other studies used a single rater, and did not account for any bias that may have occurred from this practice.

The optimal amount of time for KC to be effective in reducing neonate pain remains to be determined. Of the three studies reviewed, the KC intervention was initiated from 10 to 30 minutes prior to the painful stimulus, and continued from 0 to 20 minutes post-procedure.[1,3,2] Yet, concomitant outcome responses were measured and scored for periods as short as 30 seconds post-procedure.[1] Such a disparity between time frames provokes inquiry as to whether the post-procedure follow up and scoring should be based on a longer review period.

Strengths of the studies were multiple. The Kashaninia group effectively performed a randomized gender-matched trial with a solid population size. The use of standardized measures for scoring neonate pain and distress were well conceived. Kostandy et al benefited from using the ABSS system as it measures both audible and inaudible cry times.

Kangaroo Care shows promise as a nonpharmacologic intervention for use in treating neonate pain and distress during routine minimally invasive medical procedures. It requires low to no overhead costs to implement. It can be initiated by healthcare providers at multiple levels without a physician's authorization. The requirements to carry out the intervention are minimal, and depend on the ability and availability of the neonate and caregiver involved.

Conclusion

The studies reviewed demonstrate that Kangaroo Care is effective in reducing procedural pain in neonates; and that it is more effective than standard incubator care in doing so. Further research should focus on specific painful procedures and optimal periods of KC as intervention. KC research should be expanded to include similar medical procedures in those infants beyond neonate age, say up to 12 months old. Likewise, research should also be conducted with KC and the paternal caregiver and/or a designated surrogate. Modern family situations are complex, maternal caregivers may fall ill or die from complications of labor and delivery; yet Kangaroo Care offers an intervention with potentially few limitations. As long as a willing bonding partner is available to the neonate, and that partner is comfortable and able to perform the procedure, it is expected to be successful. The neonate will sense stress from the bonding partner whether mother, father or surrogate if that partner is anxious about the intervention. Perhaps, further researchers should also survey the caregiver to assess his/her level of anxiety about participating

in the Kangaroo Care intervention and about observing the neonate in pain. It is inherent for many caregivers to be distressed from anticipating or observing one's child in pain.

References

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