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Effectiveness of nonpharmacological techniques for procedural analgesia in the neonatal intensive care unit

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EFFECTIVENESS OF NONPHARMACOLOGICAL TECHNIQUES FOR PROCEDURAL ANALGESIA IN THE NEONATAL INTENSIVE CARE UNIT

by

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Abstract

The purpose of this thesis is to provide a critical analysis of research findings about nonpharmacological techniques used independently of pharmacological techniques to prevent or reduce procedural pain for infants in the neonatal intensive care unit (NICU). A synthesis of the current research related to nonpharmacological pain relief techniques for infants was conducted for this thesis. Nonpharmacological interventions reviewed in this study include: Kangaroo Care, swaddling, facilitated tucking, positioning, music, non-nutritive sucking and sucrose. An interdisciplinary review of the research was performed using the interdisciplinary databases Cumulative Index of Nursing and Allied Health, PubMED, and PsychINFO. Inclusion criteria for this thesis consists of research focused on preterm neonates (born < 37 weeks gestational age) in the neonatal intensive care unit, the use of nonpharmacological interventions for procedural analgesia, peer reviewed articles, and those written in the English language. This study excludes full term neonates due to the significant number of preterm neonates in the NICU. A total of 18 studies were included in this review. All interventions except for positioning show statistically significant evidence to support their use to reduce procedural pain in preterm neonates. Findings of this thesis may promote further studies and exploration into this field. In addition, this thesis establishes the role of the nurse in providing pain relief for infants in the NICU, as well as provide for enhancement of interdisciplinary care amongst other health care providers.

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Introduction

With advances in health care technology, premature infant survival rates have markedly increased. In the United States, approximately 11% of infants are born 4 or more weeks premature and 1% are born up to 12 weeks premature, or less than 1,250 grams (Stevens et al., 1999). The neonatal intensive care unit (NICU) is a specialized unit in which health care professionals are prepared to care for high risk infants, including those who are born premature and very low birth weight (Blackman et al., 2004). Caring for infants in the NICU has improved morbidity and mortality for these high risk newborns (Blackman et al., 2004). Unfortunately, this highly specialized care comes at a cost. Infants experience an average of 50 potentially painful procedures throughout their stay in the NICU (Maroney, 2003). Consequently, very low birth weight infants are exposed to a high number of procedures in the NICU and are vulnerable to the negative consequences of pain (Stevens et al., 1999).

Pain

Pain is defined by the International Association for the Study of Pain (IASP) as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" (Merskey & Bogduk, 1994, p. 213). Margo McCaffery developed the well-known definition of pain as "whatever the person experiencing the pain says it is, existing whenever the person says it does" (McCaffery & Pasero, 1999, p. 17). Both of these definitions imply that there is a subjective component to pain; however, neonates lack the capacity to self-report their pain verbally and therefore challenge both of these definitions. The ISAP and McCaffery have added to their definitions of pain which includes "the inability to

communicate in no way negates the possibility that an individual is experiencing pain and is in need of appropriate pain-relieving treatment" (Merskey & Bogduk, 1994, p. 213; McCaffery & Pasero, 1999, p. 17). Therefore, health care providers must be able to accurately assess pain in those who rely on others to manage their pain in the absence of a self-report (Lemons et al., 2000).

Physiology of Pain

Pain is an important protective mechanism that alerts individuals of actual or potential harmful events (Ponder, 2002). The first step in the physiological mechanism of pain is transduction. Transduction occurs when free nerve endings, or nociceptors, are stimulated or damaged in the peripheral nervous system (Arnstein, 2010). During the next step, transmission of pain occurs from the site of the stimuli to the spinal cord (Arnstein, 2010). The individual then perceives the character, intensity, and meaning of pain as the process continues from the spinal cord to the brain. This step is called perception and occurs in the thalamus and sensory cortex of the brain (Arnstein, 2010). The final step is modulation. Modulation allows many factors to influence pain by either heightening or dampening its intensity (Arnstein, 2010). When body tissues are damaged, the body releases many chemicals at the site of injury (i.e., prostaglandins, serotonin, bradykinins, norepinephrine, potassium, iron, and substance P). These chemicals trigger the nociceptors and the sympathetic (fight or flight) response is activated (Ponder, 2002). The fight or flight response is a life-sustaining protective mechanism but when prolonged, can lead to many harmful effects on the body (Ponder, 2002). Stress hormones such as epinephrine, norepinephrine, glucagon, cortisol, aldosterone, thyroid stimulating hormone, and growth hormone are all released in response to sympathetic stimulation (Ponder, 2002). These hormones

lead to the breakdown of body tissues, water retention, elevated blood glucose with reduction in glucose utilization, increase in metabolic rate, and impairment of immune function (Ponder, 2002). This causes the initial injury to be exacerbated, wound healing to be delayed, an increase in the risk for infection and overall increase in morbidity (Ponder, 2002). Many people believe that infants and children have an immature central nervous system and therefore they experience pain with less intensity due to the immaturity (Ponder, 2002). However, research has provided evidence to support that pain processing is completely anatomically and functionally intact by middle to late gestation (Ponder, 2002).

At 12 to 16 weeks gestation, substance P, a neurotransmitter involved in the transmission of pain, and its receptors become prevalent in the dorsal root ganglia and dorsal horns of the spinal cord (Ponder, 2002). By 30 weeks gestation, the pain transmitting pathways to the thalamus and to the brainstem are completely myelinated (Ponder, 2002). Finally, by late gestation, all anatomical, neurological, and hormonal mechanisms needed to perceive pain are functional (Ponder, 2002). In contrast to the belief that infants cannot feel pain due to an immature nervous system, neonates actually have an increased sensitivity to pain (Ponder, 2002). Infant's immature nerve fibers have a limited capacity to inhibit modulation of nociception; therefore, they have increased sensitivity to painful stimuli and can develop prolonged periods of hyperalgesia (Ponder, 2002).

The painful procedures that infants are exposed to in the NICU may have an effect on how they react to pain later in life (Ponder, 2002). Although research has not yet determined whether infants have the capacity to remember painful experiences, their brains are fully developed and are completely functional. It is possible that early painful experiences are stored

in procedural memory which is inaccessible to conscious recall (Ponder, 2002). Even without conscious recall, these children may still develop long-term consequences to pain (Mitchell & Boss, 2002). Infants who have previously been exposed to pain display exaggerated facial expressions and behavioral responses in comparison to infants who have never been exposed to painful stimuli. The frequent painful procedures experienced by preterm infants in the NICU contribute to the tendency of these children to have more somatic and physical complaints later in childhood than children who were born full term (Mitchell & Boss, 2002). Thus, nurses must be able to adequately assess and treat neonatal pain in the NICU.

Pain Assessment

Because infants lack the ability of self report for pain, health care providers must rely on behavioral and physiological indicators to assess pain in this population. Infants display behavioral responses to pain through their facial expressions, body movements, and crying. Physiological indicators of pain may include changes in: heart rate, respiratory rate, blood pressure, oxygen saturation, vagal tone, palmar sweating, and plasma cortisol or catecholamine levels (Lemons et al., 2000). To assist health care providers in accurately assessing pain in the neonate, various pain scales have been developed based on these indicators (Lemons et al., 2000).

Treatment of Pain

In general, pharmacological management is the mainstay of treating acute pain (Arnstein, 2010). Although pharmacological pain relief measures have evidence to support they are safe and effective to treat pain related to procedures in the NICU (Ponder, 2002), nonpharmacological

pain relief measures are also an appropriate alternative for the treatment of mild pain in this population (Kashaninia, Sajedi, Rahgozar, & Noghabi, 2008). In addition, nonpharmacological measures may reduce the dosage of pharmacological analgesia required to relieve pain while also decreasing the potential for dangerous side effects of analgesics, such as respiratory depression (Ersek & Gordon, 2007). Nonpharmacological techniques are recommended to prevent or treat procedural pain because their effects are short term and infants tolerate these techniques well (Lemons et al., 2000).

Nonpharmacological pain relief techniques can be used instead of or as a complement to analgesics to reduce acute pain. These non-drug techniques can grab the attention of the infant and thereby distract them from the pain, decreasing pain perception (Cignacco, Denhaerynck, Nelle, Bührer, & Engberg, 2009). The use of nonpharmacological techniques is important for nursing practice because their use is determined from the nurse's assessment and can be performed independently (Kashaninia et al., 2008).

Problem

This paper will focus on infants receiving care in the neonatal intensive care unit. All infants treated in this unit will at some point become exposed to painful procedures during their care. It is estimated that infants in the NICU will undergo an average of 14 painful procedures each day (D'Apolito, 2006). Despite this number, pain relief measures are used inadequately in the NICU (Cignacco et al., 2009).

Pain can affect the neonate in a variety of ways. Studies performed on animals show that exposure to pain over time can impair normal development (Kashaninia et al., 2008). Pain during infancy affects the normal development of the nociceptive pathways which leads to decreased

pain thresholds during later infancy (Kashaninia et al., 2008). Pain can alter sleep patterns, feeding patterns and impair the neonate's ability for self regulation (Arnstein, 2010). More importantly, the severe stress of pain can increase the neonates' intracranial pressure and eventually lead to intraventricular hemorrhage with permanent brain damage (Mitchell & Boss, 2002). Attention deficit disorders and learning disabilities have also been linked to pain during the neonatal period (Mitchell & Boss, 2002). Therefore, assessment and proper treatment of neonatal pain is important in decreasing neonatal and pediatric morbidity (Lemons et al., 2000).

Purpose

The purpose of this thesis is to provide a critical analysis of research findings about nonpharmacological techniques used independently of pharmacological techniques to prevent or reduce procedural pain for infants in the neonatal intensive care unit. Findings of this thesis may promote further studies and exploration into this field. In addition, this thesis will establish the role of the nurse in providing pain relief for infants in the NICU, as well as provide for enhancement of interdisciplinary care amongst other health care providers.

Method

A synthesis of the current research related to nonpharmacological pain relief techniques for infants was conducted for this thesis. An interdisciplinary review of the research was performed using the interdisciplinary databases Cumulative Index of Nursing and Allied Health, PubMED, and Medline. Inclusion criteria for this thesis consists of research focused on preterm neonates (born < 37 weeks gestational age) in the neonatal intensive care unit, the use of nonpharmacological interventions for procedural analgesia, peer reviewed articles, and those

written in the English language. This study excludes full term neonates due to the significant number of preterm neonates in the NICU.

Background

Description of Interventions

Kangaroo Care, also called skin-to-skin contact, was first used as a means for providing warmth to newborn, low-birth weight infants in 1979 (Johnston et al., 2003). This technique is now used in a variety of ways including promoting mother-infant bonding, encouraging breastfeeding, improving temperature control, and as used in this research, proving procedural pain relief. During Kangaroo Care, the infant remains unclothed except for a diaper and is placed upright between the mother's breasts at a 60 degree angle. A blanket is then placed over the infant and tucked in at the mother's sides. This positioning provides maximum skin-to-skin contact between the parent and child (Johnston et al., 2008). Kangaroo Care provides the infant with multi-sensory stimulation (emotional, tactile, olfactory, auditory, visual, and thermal) that are hypothesized to modulate and inhibit pain perception in a way that reduces the neonate's response to the painful stimuli (Cong et al., 2009).

Swaddling is a comfort measure used for infants of all ages. A blanket or sheet is wrapped tightly around the infant to restrict upper and lower extremity movement (van Sleuwen et al., 2007). Swaddling has traditionally been used to help the newborn maintain body temperature, provide a feeling of safety and security, and to quiet a crying baby by providing easy access to hands for sucking and self-soothing (London et al., 2007). Swaddling has been found to induce sleep, lower heart rate, and promote regularity of respiration in the absence of external stimulation in full term infants (Fearon et al., 1997). The calming effects of swaddling are theorized to occur by mimicking the containment feeling that infants experience in-utero

(Huang et al., 2004) and these effects may be of value for the infant experiencing procedural pain.

Facilitated tucking is a comfort technique that incorporates both touch and position to calm the infant. Facilitated tucking can be performed by the nurse or the technique may be taught to the parent to involve the family in the child's care (Axelin et al., 2005). The nurse or the parent holds the infant in a side-lying, flexed position that is similar to the fetal position in-utero by placing one hand on the infant's head and the other on their feet (Ward-Larsen et al., 2004). This position may increase the infant's ability to control pain by providing the infant the opportunity to control his or her own body. The combination of skin contact and postural support may have a synergistic effect on alleviating procedural pain (Axelin et al., 2005).

Positioning is another factor that is thought to alter pain perception in neonates. Positioning provides the infant with physical boundaries while maintaining a flexed position that is similar to in-utero. The thermal and tactile stimulation provided by positioning may modify gate control mechanism and consequently alter pain transmission (Grunau et al., 2004).

Another intervention used to soothe neonates in the NICU is music. Music therapy is a global intervention that is used to alter the general environment for the neonate rather than targeting a specific stressor. Music is used in the NICU to mask adverse environmental stimuli such as bright lights and loud sounds while also soothing infants by modulating their behavioral state (Butt & Kisilevsky, 2000). Music therapy in the NICU may include intrauterine sounds, lullabies, instrumental music, vocal music or a combination (Bo & Callaghan, 2000).

Sucrose and non-nutritive sucking are two interventions that are usually seen together for modulating pain in the NICU. Sucrose may be used with or without a pacifier to provide comfort

to the neonate. The analgesic effect of sucrose is believed to be mediated by endogenous opioid pathways, due to the sweet taste, which results in the production of a natural analgesia (Cignacco et al., 2009). The effects of sucrose are reversible through the administration of the opioid antagonist naloxone, which provides further evidence that sucrose has similar effects to opioid analgesics (Elserafy, Alsaedi, Louwrens, Bin Sadiq, & Mersal, 2009). Non-nutritive sucking consists of the placement of a pacifier in the infant's mouth without the use of sucrose. Non-nutritive sucking does not appear to be mediated by opioid pathways because its effects are not reversed with naloxone and the analgesic effect ceases once sucking has stopped (Gibbins et al., 2002). However, sucking is believed to induce a feeling of calm in the neonate (Stevens et al., 1999). Sucrose and non-nutritive sucking used together may provide a synergistic analgesic effect for procedural pain in neonates.

Pain Assessment Scales

The studies included in this research use various pain scales to objectively determine pain level in neonates. Infants are non-verbal and are unable to self report their pain, therefore, it is important to use objective pain scales to accurately assess neonatal pain. The following pain scales are used most frequently in the findings of this thesis.

The Neonatal Infant Pain Scale (NIPS) uses behavior indicators to determine the level of pain the infant is experiencing (Kashaninia et al., 2008). This tool can be used in both full term and preterm infants (Kashaninia et al., 2008). There are six behavioral indicators of pain that this scale uses including: facial expression, cry, breathing patterns, arm movement, leg movement, and state of arousal. Each variable is scored from 0 to 1, with the exception of cry which is scored from 0 – 2 (Mörelius, Theodorsson, & Nelson, 2005). A total score of a 0-2 indicates mild

to no pain; 3-4 indicates mild to moderate pain; and greater than 4 indicates severe pain (Kashaninia et al., 2008).

Another frequently used scale is the Premature Infant Pain Profile (PIPP) which measures physiological and behavioral pain. The PIPP is validated for use in premature infants only. This scale consists of seven pain indicators including: time of brow bulge, eye squeeze, naso-labial furrow, changes in heart rate and oxygen saturation, gestational age and behavioral state. Each variable is scored from 0 to 3 with total scores ranging from 0-21 (Mörelius et al., 2005).

The Neonatal Facial Coding System (NFCS) was designed specifically for the measurement of neonatal pain-related distress. The NFCS eliminates the potential for bias because it is a purely objective scale that does not allow the researcher to make their own attributions. Facial actions measured by the NFCS include brow bulge, eye squeeze, nasolabial furrow, open lips, horizontal stretch mouth, vertical stretch mouth, lip purse, taut tongue, chin quiver, and tongue protrusion. Scores are calculated by giving 1 point for each facial action that is present, and 0 for actions that are absent (Kohut & Riddell, 2009).

Findings

Kangaroo Care

Johnston et al. (2003) studied the efficacy of Kangaroo Care (KC) for decreasing pain related to heel lancing in preterm infants. A randomized, crossover design was used for this study which consisted of 74 preterm infants, between 32 and 36 weeks gestational age, who were breathing on their own, had 5 minute Apgar scores greater than 6, had not received sedatives or analgesics, and were in level II and level III neonatal intensive care units (NICU). Infants were randomly assigned to either the control or experimental group for the first heel stick and then switched to the opposite group for a second heel stick. During the experimental condition, neonates were held in KC for thirty minutes prior to heel-lancing and during the heel lancing procedure. When crossed over to the control group, neonates were swaddled with a blanket and positioned prone in the isolette for the procedure. Pain was measured using the Premature Infant Pain Profile (PIPP) for the first 90 seconds after heel lancing. Facial actions for the PIPP were video recorded and then analyzed with the cameras aimed directly at the infants face at an angle which blinded whether the infants were in kangaroo position or in the isolette. Heart rate and oxygen saturation levels were also recorded into a computer database for analysis. Results of the PIPP scores throughout the first 90 seconds post heel lance were significantly lower for the neonates in the KC group as compared to the control group ($.002<P<.04$). There were no significant differences in heart rate or oxygen saturation.

The use of Kangaroo Care for decreasing pain from heel lancing in very preterm neonates was studied by Johnston et al. (2008). A single-blind randomized crossover designed was used for this study which consisted of 61 preterm neonates between 28 and 31 weeks gestational age

in level III NICUs. Infants were randomly assigned to either the control group or experimental group for the first heel stick, and were placed in the opposite group for a second heel stick. During the experimental condition, infants were held in KC beginning 15 minutes before and throughout the heel lancing procedure. Infants in the control group were positioned prone and swaddled with a blanket in the isolette. The primary outcome of pain was measured using the PIPP. The PIPP score was obtained at baseline and at 30 second intervals up to 120 seconds after heel lancing. The secondary outcome was the time to recovery, or the time of the infant's heart rate to return to baseline. Results of the PIPP score at 90 seconds post heel lance were significantly lower for the KC group ($p<.001$). There were also non-significant differences in favor of KC at 30, 60, and 120 seconds post heel lance. Time to recovery was also significantly shorter in the KC condition than the isolette condition ($p<.0000$). The average heart rate was significantly lower at 30, 60, and 90 seconds post heel lance ($p<.05$) and the average oxygen saturations were significantly higher at 60 and 90 seconds post heel lance ($p<.05$).

The effects of Kangaroo Care in the reduction of crying response to pain in preterm neonates was studied by Kostandy et al. (2008). A prospective randomized cross-over study was conducted including 10 preterm neonates between 30 and 32 weeks gestational age. Kangaroo Care in this study consisted of 30 minutes of prone skin contact between maternal breasts while the incubator position required that the infant be inclined 30-40 degrees, nested, and prone in the isolette. Infants were randomly assigned to two groups. Infants in sequence A had heel sticks performed in Kangaroo Care on day 1 and heel sticks in the incubator on day 2. Infants in sequence B were opposite of sequence A. The primary outcome for this study was the presence and length of crying. Crying is defined in this study as either audible or inaudible. Inaudible cry

occurs when infants have depleted energy stores or the presence of an endotracheal tube and display a “cry face” as a characteristic of pain and is called a “silent cry”. Crying time was defined as the number of seconds of inaudible plus audible crying. Crying time was recorded during each phase of the procedure including baseline, heel warming, heel stick, and recovery phase. Results indicated that crying time was less when in Kangaroo Care during the heel stick ($p=.001$) and during recovery ($p=.01$) versus in the incubator.

Johnston et al. (2009) studied whether enhancing skin-to-skin contact by adding rocking, singing and sucking is more effective than simple Kangaroo Care for procedural pain in preterm infants. Study participants included in this study were 90 preterm neonates between 32 and 36 weeks gestational age. Infants were randomly assigned to either the control group or experimental group for the first heel stick, and were placed in the opposite group for a second heel stick. In the experimental condition, infants were placed in KC with the addition of rocking, singing and sucking (mother’s fingers or pacifier) for 30 minutes prior to heel lancing. Infants in the control group were held in traditional KC for 30 minutes prior to heel lancing. The primary outcome for this study was pain as measured by the PIPP. The secondary outcome was time to recovery, or the time in seconds for the infant’s heart rate to return to baseline. Outcome measures were recorded at 30 second intervals for two minutes during heel lance. Results showed no significant differences in PIPP scores during any of the 30 second time intervals. There were also no significant differences in time to recovery.

Cong, Ludington-Hoe, McCain, and Fu (2009) studied the effect of Kangaroo Care on the autonomic nervous system’s response to painful stimuli. A randomized, cross-over trial was used for this study which included 14 preterm infants between 30 and 32 weeks gestational age.

Infants were randomly assigned to either the control group or experimental group for the first heel stick, and were placed in the opposite group for a second heel stick. Kangaroo Care made up the experimental condition for this study. Infants were clothed only in a diaper, placed skin-to-skin with their mother between her breasts and covered with a receiving blanket. Infants were held in this position for 60 minutes prior to initiating heel lance procedures. The control condition for this study consisted of infants positioned prone at 30 – 40 degrees and nested in an incubator without contact for 60 minutes prior to the heel lance procedure. Infants were randomly assigned to two groups. Group A received the control incubator care for the first heel stick and Kangaroo Care for the second. Group B received the opposite treatment. Outcome measures for this study included infant behavioral state, heart rate, and heart rate variability indices including low frequency (LF) power, high frequency (HF) power, and LF/HF ratio. Outcomes were measured over 4 intervals including baseline, heel warming, heel stick, and recovery periods for both Kangaroo Care and incubator care conditions. Heart rate variability is used as a measure of the parasympathetic and sympathetic reactivity of pain in neonates. HF is indicative of the parasympathetic activity while LF is a measure of sympathetic activity. Infant behavioral state was measured using the Anderson Behavioral State Scoring System (ABSS) which gives the infant a numerical score based on the behavior they exhibit from quiet sleep to hard crying. Results showed no significant differences in behavioral states between the two conditions across all time intervals. Heart rate was significantly lower in the KC condition than the incubator care condition at baseline ($p<.05$) and heel stick ($p>.05$). LF was higher in KC at baseline ($p<.01$) and at heel stick ($p<.001$) than incubator care. HF was higher in KC at baseline than in incubator care ($p>.05$). The LF/HF ratio showed less fluctuation across the time intervals

in KC than in incubator care and also was significantly lower during recovery in the KC than in incubator care ($p<.001$). Therefore, infants experienced more balance in response to pain during KC than incubator care as showed by greater autonomic stability during heel sticks.

Swaddling

Huang, Tung, Kuo, and Chang (2004) compared the pain response of premature infants to heel sticks between containment and swaddling. Containment is the standard of nursing care for infants after heel sticks in which the infant is placed in the right lateral position and the nurse gently holds the infant's upper extremities to their chest with one hand and holds the knees to the trunk with the other hand. Swaddling consists of wrapping the infant in a cotton blanket and placing the infant in the right lateral position. A cross-over experimental design was used for this study and consisted of 32 premature infants between 25 and 36 weeks gestational age, birth weight less than 2,500 grams, and without congenital heart diseases, sepsis, or grade 3 intraventricular hemorrhage. Infants were randomly assigned to either containment or swaddling for the first heel stick and then received the opposite intervention for the second heel stick. Infants remained in the assigned position for 11 minutes following the heel stick. Outcomes for this study focused on PIPP scores, heart rate, and oxygen saturation which were obtained at baseline and every minute up to 11 minutes following the heel stick. PIPP score results showed significant differences between the two interventions only at the 3rd and 7th minute ($p<.05$) with lower scores in the swaddling condition than in containment. There were no significant differences between heart rate and oxygen saturation.

Fearon, Kisilevsky, Hains, Muir, and Tranmer (1997) studied the responses of preterm infants to swaddling after heel lance. A crossover experimental design was used for this study

which included 15 preterm infants who were further divided into two age groups. Group 1 consisted of infants between 27 and 30 weeks and Group 2 were infants greater between 31 and 36 weeks gestational age. There were three conditions used in this study: swaddling, standard care, and no-treatment. For each condition, videotaping began with a 10-minute baseline, in which no treatment was conducted, continued throughout the heel lance procedure, and 10 minutes into the recovery period. For the swaddling condition, infants were swaddled immediately after heel lancing and during the 10 minute recovery period. In the standard care condition, the procedure was exactly as the swaddling condition with the exception that infants were not swaddled after but received the same care they would have on a normal day without cameras such as tapping the infants' feet during periods of apnea. In the no-treatment comparison condition, no type of contact was initiated during the 10 minute recovery period. Measures for this study included: respiration rate, heart rate (HR), skin temperature, blood oxygen saturation, and the Neonatal Facial Coding Scale (NFCS). Results showed that facial activity and HR scores decreased more quickly in the swaddling condition than in the standard care condition, however, these results did not meet statistical significance. Both swaddling and standard care showed a significant decrease in facial activity scores than the comparison group ($p<.01$). Results indicated that swaddling had a greater effect in the older group by decreased facial activity and heart rate; however, these results were not statistically significant. All other outcome measures did not show significance.

Facilitated Tucking

Axelin, Salentera, and Lehtonen (2006) examined the effectiveness of facilitated tucking by parents during endotracheal/pharyngeal suctioning of preterm infants on pain management.

Twenty preterm infants with gestational age between 24 and 33 weeks, no major congenital anomalies, a need for regular endotracheal/pharyngeal suctioning and no analgesics for 4 hours before the procedure were included in this study. Facilitated tucking is a type of containment which consists of the parent holding the infant in the side-lying, flexed fetal-type position which allows the infant to control his/her own body and be stimulated by skin-contact at the same time. Infants in the control group were positioned on their right side and supported by rolled blankets. Each infant in the study participated in each intervention group at separate times; the intervention they received first was randomly assigned. The primary outcome for this intervention was the Neonatal Infant Pain Scale (NIPS). Heart rate and oxygen saturation were also analyzed. Results showed that infants in the facilitated tucking group had a lower average NIPS score during suctioning than infants in the control group ($p< 0.001$). Infants in the facilitated tucking group also returned to baseline more quickly ($p=.0024$).

The efficacy of facilitated tucking for relieving procedural pain of endotracheal suctioning in very low birthweight (VLBW) infants was studied by Ward-Larsen, Horn, and Gosnell (2004). A prospective randomized crossover design was used for this study which included 40 VLBW infants between 23 and 32 weeks gestation and weighing between 500 and 1500 grams with tracheal intubation. Each infant had endotracheal suctioning performed twice, once with facilitated tucking and again with standard nursing care for endotracheal suctioning. Standard care requires all infants to be placed in a “Snuggle Up”. The Snuggle Up is a padded foot roll with soft, adjustable straps that places the infant in proper position with flexion. This provides containment but not support as does facilitated tucking. In this study, facilitated tucking was performed by a research assistant. The infant was placed to the side, back curled gently, legs

flexed greater than 90 degrees and brought to the midline, and shoulders brought to the midline with elbows flexed greater than 90 degrees with hands near the mouth or infant's face. The degree of tucking the infant's chin was dependent on endotracheal tube placement. The primary outcome for this study was the Premature Infant Pain Profile (PIPP). Results showed significantly lower PIPP scores in the facilitated tucking group during suctioning than the non-tucking group ($p<0.001$).

Positioning

Grunau, Linhares, Holsti, Oberlander, and Whitfield (2004) studied whether prone or supine position influences the pain response in preterm infants during heel lancing. A comparison design was used for this study. Participants included 38 preterm infants between 25 and 32 weeks gestational age, with no major congenital anomalies, and no known illicit drug use by the mother during pregnancy. Infants were randomly assigned to be positioned either prone or supine during the first heel lancing and then received the opposite intervention for a second heel lance. Outcomes for pain response were measured using the Neonatal Facial Coding System (NFCS) and heart rate (HR) during continuous ECG monitoring at baseline and during the procedure. The results of the NFCS and HR both showed no statistically significant effect of position between the prone or supine groups during the baseline or heel stick events.

Music

Bo and Callaghan (2000) studied the effect of non-nutritive sucking (NNS), music therapy (MT), and combined NNS and MT, and no intervention (control group) on soothing pain in neonates during heel stick procedures. A within-subjects, counter-balancing, repeated-

measures design was used for this study and 27 neonates both term and preterm gestational ages between 30 and 41 weeks were included. Each neonate was exposed to each of the four interventions. During the non-nutritive sucking condition, each neonate received a standard, hollow, soft latex nipple while gentle pressure was applied to keep the nipple in the neonate's mouth. The MT intervention, involved the use of intrauterine maternal pulse sounds and soothing music played with a cassette recorder near the infant's head with a consistent volume. The combined intervention offered neonates both the latex nipple as well as the intrauterine sounds. During the no intervention period, infants were placed in the supine position. Data was obtained at baseline which was 1 minute before the heel-stick procedure, each minute during the 5 minute intervention, and each minute for 8 minutes following the heel-stick. Outcomes for pain were measured using the Neonatal Infant Pain Scale (NIPS), heart rate and transcutaneous oxygen ($TcPaO_2$) levels were also recorded. Results indicated that each of the three comfort measures significantly reduced the heart rate of neonates ($p<.0001$), improved their $TcPaO_2$ levels ($p<.0001$), and reduced their pain behavior ($p<.0001$). Posthoc scheffe tests determined that combining MT and NNS produced the lowest pain behavior in neonates ($p<.001$) when compared to the NNS group, MT group, and control group. MT in isolation had the most powerful effect on decreasing the neonate's heart rate during painful stimuli at every measurement point post heel stick ($.001<p<.004$).

The use of music during heal lance was studied in premature infants by Butt and Kisilevsky (2000). These researchers studied infants on 2 separate occasions, once with music and once without. Measures were taken at 3 points in care: baseline, during the heal lance, and recovery from the procedure. The study participants ($n = 14$) were divided by age into those less

than 31 weeks and those greater than 31 weeks gestational age. Measures for this study included a modified Brazelton's categories of state-of-arousal, the Neonatal Facial Coding System, heart rate, and oxygen saturation. Two types of music were used, which were vocal and instrumental. Data analysis concluded there was no effect of the type of music on any of the outcome variables except the behavioral state score. The overall data analysis indicated that all participants were stressed by the procedure and responded to the heel lance with decreased oxygen saturation ($p<.01$), increased heart rate ($p<.01$), state-of-arousal, and number of facial expressions of pain ($p <.01$), with the older infants showing increased signs of stress when compared to the younger infants, regardless of the use of music or no music.

Whipple (2008) studied the effect of music-reinforced non-nutritive sucking on preterm, low birth weight infants undergoing heel sticks. A multiple sample, posttest only design was used for this study which consisted of 40 preterm infants between 32 and 37 weeks gestational age, weighing less than 2500g, had no oral cavity abnormalities, grade 3 intraventicular hemorrhage, or ventilator assistance at the time of the study. The experimental factor in this study used the Pacifier Activated Lullaby (PAL) System to play music to the infants. In this system, a transducer is placed inside a pacifier that measures the strength of the infant sucking. At a measured threshold, infants are rewarded for adequate sucking by playing music. Participants in this study were randomly assigned to either the experimental group (n=14), control group (n=13), or no intervention group (n=13). Infants in the experimental group received the PAL system with a pacifier for 3 minutes prior to, throughout the heel lance procedure, and 3 minutes after the procedure. Pacifiers were held in place by a researcher who gently stroked the infant's mouth to facilitate sucking. Infants in the control group received only

a pacifier for non-nutritive sucking but did not receive the PAL music system. Infants in the no intervention group received no contact during heel lance. Outcomes for this study include behavioral indicators of stress, heart rate, respiratory rate, and oxygen saturation. The behavioral indicators of stress measured in this study are comparable to indicators of pain and include: leg or foot extension, grimace, startle or tremor, whimper, grunting, struggling movements, crying or cry face, intense crying, and intense crying with change of position. Results showed no significant differences between heart rate among each group for the three intervals (pre, during, and post heel lance). Respiratory rate showed statistically significant differences between the no-contact group and both the pacifier only and PAL groups ($p=.03$) with the pacifier only and PALS groups having higher baseline respiratory rates. During heel stick, the pacifier only group had a higher mean respiratory rate compared to the no-contact group ($p=.04$). Oxygen saturation showed no significant differences among the three interventions. Behavioral state and stress level analysis showed significant differences ($p<.05$) for the PAL and pacifier-only groups compared to the no contact group. The greatest differences were between the PAL and no contact group. These differences included: behavior state mean lower during-heel stick, less time in undesirable behavior states, lower stress level means during- and post-heel stick, and smaller behavior state and stress level differences between intervals. Behavior state and stress level were more stable across time for the PAL group than the other groups.

Non-Nutritive Sucking and Sucrose

The variability in pain response in preterm infants who received sucrose during heel lance procedures was studied by Cignacco et al. (2009). A single group, exploratory repeated measures designed was used for this study. Study participants (n=9) were between 28 and 31

weeks gestation, had a need for 5 or more capillary blood samples collected during the study period, and did not have a high-grade intraventicular hemorrhage, a severe congenital malformation, any disease process involving loss of sensitivity, a pH less than 7.00, or any kind of surgery. Each infant received 5 routine heel sticks between day 2 and day 14 postnatal to determine whether their pain response changed over time. Sucrose was administered to the infants 2 -3 minutes before each heel lancing procedure. Outcomes for measuring pain in this study include the Bernese Pain Scale for Neonates (BPSN) and salivary cortisol analysis. The BPSN consists of seven behavioral indicators including alertness, duration of crying, time to calm, skin color, eyebrow bulge with eye squeeze, posture, and breathing pattern. Two physiological indicators including changes of heart rate and oxygen saturation are also included in the BPSN. Each indicator is rated on a four-point scale (0, 1, 2, 3) for a total possible score of 27 (Cignacco, Mueller, Hamers, & Gessler, 2004). Results showed that the variability of pain response within subjects (72 – 94%) was consistently higher than between subjects variability (6 – 28%). The results suggest that individual infants have a high instability in pain response. Interrator agreement in pain scores was high during the first 3 heel sticks but declined during heel sticks 4 -5. This data suggests the possibility of an alteration of pain patterns over time. There were no significant differences in cortisol levels before or after the heel sticks.

Acharya, Annamali and Field (2004) studied the efficacy of oral sucrose as analgesia for preterm infants undergoing venipuncture. A randomized, double blinded, placebo controlled, crossover trial was used for this study and included 39 well infants less than 37 weeks gestational age in the NICU. Infants were given 2 mL of either 25% sucrose solution (S25) or water 4-minutes before two routine venipunctures. The sucrose or water was administered orally with a

syringe over two-minutes. All infants participated in each intervention and were randomly assigned to which intervention they would receive first during venipuncture. One doctor performed all venipuctures during this study. Infant facial actions and cry were recorded using a video camera with mirrors placed inside the isolette in the event that the infant were to turn during the procedure. Outcomes for this study included heart rate, oxygen saturation, duration of cry, and the Neonatal Facial Coding System (NFCS). Outcomes were measured during all three phases of venipucture including pre-procedure, procedure phase, and post-procedure. Results showed there were statistically significant differences in mean heart rate rise during each phase of venipuncture with less heart rate rise with sucrose as opposed to the control ($p<.05$). Total duration of crying was significantly less with sucrose than the control ($p <.001$). The scores of the NFCS were also less with sucrose verses the control ($p <.001$) during each phase of venipucture.

The effectiveness of oral sucrose and a pacifier for procedural pain relief in preterm infants was studied by Elserafy et al. (2009). A randomized, prospective, double blinded, controlled study was used for this research. Study participants (n=36) were less than 37 weeks gestational age, were admitted to the NICU, had no exposure to maternal sedation, had no major neurologic abnormalities, and had Apgar scores greater than 5. There were six regimens used in this study including 0.5 mL sterile water with pacifier, 0.5 mL sterile water without pacifier, 0.5 mL sucrose 24% with pacifier, 0.5 mL sucrose 24% without pacifier, pacifier alone held in the infants mouth , and no treatment (control group). Sucrose and water were administered orally to the infants with a 1 mL syringe without the needle. Each intervention was administered two minutes before the venipucture procedure. The primary outcome of pain from venipuncture was

measured using the Premature Infant Pain Profile (PIPP) which was evaluated at 6 different times during the procedure: prior to procedure, during venipuncture, one minute, three minutes, five minutes, and ten minutes after the procedure. The response time was measured by the crying time for each infant which was assessed during the procedure and at each time interval. The PIPP pain scores were significantly reduced in infants receiving 24% sucrose in combination with a pacifier ($p<.05$).

Gibbins et al. (2002) researched the efficacy and safety of sucrose for procedural pain relief in neonates. A randomized, controlled trial was used in this study which consisted of 190 neonates in a level III NICU with gestational ages between 27 and 43 weeks, less than 7 days of age, had 5 minute Apgar scores greater than or equal to 7, or cord pH greater than or equal to 7.0, and had not undergone surgery. Neonates were stratified into three gestational age groups to control for pain score differences based on age. The first group included neonates between 27-31 weeks, the second 32 and 35 weeks, and the final group 36 and 43 weeks. There were 3 interventions compared in this study including sucrose and non-nutritive sucking (NNS), sucrose alone, and water and NNS. Sterile water and NNS served as the control for this study. The heel lance procedure was divided into 6 phases including: baseline, intervention, warming, lance, squeeze, and return to baseline. Neonates in the sucrose and NNS group were administered 0.5 mL of 24% sucrose with a needleless syringe orally followed by the insertion of a Wee Soothie pacifier 2 minutes before the procedure. The sucrose group was administered 0.5 mL of 24% sucrose with a syringe 2 minutes before the procedure without a pacifier. Neonates in the sterile water and NNS group were offered the same intervention as the sucrose and NNS group except they were administered 0.5 mL of sterile water in place of sucrose. Because the average

gestational age in each intervention group was within 33 weeks, outcomes for pain response were measured using the Premature Infant Pain Profile (PIPP). Results showed that PIPP scores were significantly lower in the sucrose and NNS group compared to sucrose alone ($p < .002$) or sterile water and NNS ($p < .001$). There was no significant difference in PIPP scores between sucrose alone or sterile water and NNS groups.

Multiple Intervention Studies

Stevens et al. (1999) studied the efficacy of a variety of nonpharmacological interventions for relieving procedural pain in very low birth weight (VLBW) infants. A prospective, randomized, crossover trial was used for this study which consisted of 122 VLBW infants between 27 and 31 weeks gestational age, were free of major congenital anomalies or intraventricular hemorrhage greater than level 2, had not received opioid or nonopioid analgesia within 12 hours, and had Apgar scores greater than 6 at 5 minutes. There were four interventions used in this study including: control, prone position, pacifier with water, and pacifier with sucrose. Each infant was assigned to participate in all four interventions in random order. During all four interventions, infants were held with a SnuggleUp device for 30 minutes before heel lancing. SnuggleUp holds the infant in the desired body position and limits large body movements. While in the control situation, infants were positioned in a side-lying or supine position via the SnuggleUp and did not receive a pacifier or any other nursing comfort measures before or during heel lance. In the prone position intervention, neonates were placed prone with the SnuggleUp with knees flexed to the chest, arms at midline, and one foot accessible for heel lance. During the pacifier with water intervention, infants were positioned with the SnuggleUp as in the control intervention and were given a pacifier dipped in approximately 0.1 mL sterile

water 5 minutes prior to heel stick. The pacifier was re-dipped and replaced in the neonates mouth 2 minutes before the procedure and was held in place by a researcher throughout the duration of the heel lance. The pacifier with sucrose intervention was performed in the same way as the pacifier with water intervention, with the exception that the pacifier was dipped in 24% sucrose solution. The heel lance procedure consisted of 5 phases: baseline (1 minute), warming (5 minutes), heel stick (15 seconds), return to baseline (5 minutes), and post-return to baseline (5 minutes). Outcomes for pain were measured using the Premature Infant Pain Profile (PIPP), a video camera and pulse oximeter. Results showed that the pacifier with sucrose ($p < .0001$) and pacifier with sterile water ($p = .003$) significantly reduced pain to heel lancing. The prone positioning intervention did not decrease pain in this study.

Discussion

Kangaroo Care

Five research studies examined the effectiveness of Kangaroo Care on diminishing pain response in preterm neonates to heel lance. Outcomes of pain in the five studies were measured using various tools including the PIPP, crying time, and heart rate variability. The findings of all five studies support Kangaroo Care as an effective non-pharmacologic technique for decreasing procedural pain regardless of how pain was measured.

Johnston et al. (2008) studied very preterm infants (between 28 and 31 weeks gestation) whereas the other four studies included infants greater than 30 weeks. Johnston et al. (2008) compared the results for the younger preterm neonates to a previous study also conducted by Johnson et al. (2003) and determined that while Kangaroo Care was shown to be effective in both studies, it had a more powerful and quicker response in the older neonates than in the younger group. Johnston et al. (2009) compared the use of standard Kangaroo Care to enhanced Kangaroo Care and found no significant differences between the two. Therefore, there is no need to either encourage or discourage mothers from rocking, singing, or allowing their infant to suck during Kangaroo Care.

Swaddling

The analgesic effects of swaddling were analyzed using two research studies. Heel lance was the stimulus for pain used in both research studies. Fearon et al. (1997) suggests that swaddling is only an effective non-pharmacological analgesia in preterm neonates greater than 30 weeks gestational age. Although the results of this study were not statistically significant,

both facial activity and heart rate were decreased in infants greater than 30 weeks in response to swaddling which may be clinically significant. However, Huang et al. (2004) found both containment and swaddling to be of analgesic value for preterm neonates, without one method working more strongly than the other. Further research on the effects of swaddling should be conducted to determine the beneficial effects in preterm neonates based on age.

Facilitated Tucking

Both research articles that examined facilitated tucking as a non-pharmacological analgesia for decreasing procedural pain found statistically significant evidence to support facilitated tucking as a safe and effective technique to reduce pain in preterm infants. However, these two studies varied in how facilitated tucking was performed. Axelin, Salentera, & Lentonen (2005) allowed the parent to hold the infant in the facilitated tucking position while Ward-Larsen, Horn, and Gosnell (2004) used a research assistant. Both techniques offer a safe and effective way to decrease pain in preterm neonates during painful procedures.

Positioning

Although only one research article studied the effects of positioning alone for decreasing procedural pain, the multi-interventional study included positioning as one of the components examined. Grunau et al. (2004) found that prone positioning promotes deep sleep in preterm neonates; however, this effect does not provide a sufficient analgesic effect during painful procedures. Similarly, Stevens et al. (1999) concluded that prone positioning did not decrease pain in neonates. Therefore, neither of the studies provided evidence to support that prone positioning decreases pain response in preterm neonates.

Music

The effectiveness of music therapy on decreasing neonatal pain in response to painful stimuli was reviewed using 3 research studies. Each of the studies reviewed used different approaches to using music therapy for infants. However, all three studies showed evidence to support the use of music therapy as an effective procedural analgesic intervention. One research study found music therapy to show clinical effectiveness only in infants greater than 31 weeks gestation (Butt & Kisilvskey, 2000). Whereas the other two studies found evidence to support the use of music therapy in combination with non-nutritive sucking to produce the lowest pain behavior in neonates (Bo & Callaghan, 2000; Whipple, 2008)

Non-Nutritive Sucking and Sucrose

A total of 5 research studies examined the use of sucrose and non-nutritive sucking for pain relief during procedures in the NICU, this includes one multi-interventional study. Only one of the studies used venipucture as the pain stimulus whereas the remaining used heel lancing (Acharya, Annamali, & Field, 2004). Results of all five studies support the claim that sucrose and non-nutritive sucking, used together or alone, are safe and effective non-pharmacological analgesics for procedural pain. Three of the five studies found evidence to support that sucrose with non-nutritive sucking provides a synergistic effect and therefore is the strongest technique for reducing neonatal pain as compared to sucrose or NNS alone (Elserafy et al., 2009; Gibbins et al., 2002; Stevens et al., 1999).

Summary

Many non-pharmacological interventions were reviewed and it was found that Kangaroo Care, swaddling, facilitated tucking, music therapy, non-nutritive sucking, and sucrose produced statistically significant results in providing safe and effective nonpharmacological techniques for procedural analgesia in the neonatal intensive care unit. Positioning is the only intervention reviewed that did not have evidence to support its use as an effective technique to decrease procedural pain in preterm infants.

Due to the limitations in the characteristics of the neonates studied for each intervention, it is difficult to generalize these findings for all preterm neonates. However, each of the interventions studied in this review do not discuss any contraindications for using these techniques in infants of higher acuity. Therefore, there is evidence to support the use of nonpharmacological techniques as safe alternatives to pharmacological analgesics and should be implemented when appropriate.

Limitations

This study was limited by the various procedures studied. Heel lancing is the most common routine procedure in the neonatal intensive care unit and therefore was the most often used pain stimulus in the research studied included in this thesis. Only four of the eighteen studies reviewed in this thesis examined an intervention other than heel lancing. It is possible that different medical procedures will alter the effectiveness of these non-pharmacological techniques to reduce pain.

One limitation affecting many of the studies was the difficulty in blinding the person performing the heel lance to which interventional group the infants were in. This may have resulted in alterations in heel lancing techniques. Also, the collectors may not have felt comfortable performing heel lancing in front of the mother's in the Kangaroo Care group which may have also lead to differences in heel lancing.

A limitation to the facilitated tucking studies was the variation in duration of suctioning. Each individual neonate was suctioned for various durations of time based upon their individual needs. Infants that required longer suctioning are likely to have a greater response to pain compared to other neonates.

The studies reviewed using music therapy as the nonpharmacological analgesic technique all used various types of music including intrauterine sounds, vocal, instrumental, and recorded lullabies. The music was also presented to the infants in various ways. There may be differences in the effectiveness of music therapy based upon the type of music and how the music is presented.

Small sample size was another limitation affecting this review. Three of the eighteen studies had sample sizes less than 20 (Konstandy et al., 2008; Cong et al., 2009; & Cignacco et al., 2009). However, the results of these studies were consistent with other related studies containing much larger sample sizes.

The studies included in this thesis focused on infants of relatively low acuity. Further research should be conducted using these non-pharmacological techniques for procedural analgesia in infants with various characteristics such as: age, body weight, various pathologies, and the presence of life sustaining equipment.

Recommendations for Nursing

Research

Future research should be conducted on nonpharmacological interventions for procedural analgesia in the NICU. Because the majority of studies reviewed used heel lancing as the painful stimulus, further studies should include other painful stimuli commonly performed in the neonatal intensive care unit. Additional painful procedures in the NICU include: suctioning, central and peripheral intravenous access, endotracheal intubation, lumbar puncture, intramuscular and subcutaneous injections, chest tube placement, and tape removal. Also, additional studies should include preterm infants of greater prematurity, very low birth weight, higher acuity, various pathologies and congenital anomalies, and the presence of life sustaining equipment. Further research should also be conducted specific to music therapy for neonates. The most effective type of music and presentation of music should be determined. More research is needed to determine other nonpharmacological interventions that may have an impact on decreasing neonatal pain in the NICU. Other nonpharmacological interventions that should be further studied for use in the neonatal population include: heat and cold application, massage, parental presence, breast milk, and decreasing environmental stimuli. Further research should be conducted to determine the limitations of nonpharmacological analgesia for neonates based on individual patient circumstances. For example, non-nutritive sucking would not be an appropriate intervention for an intubated neonate. Larger sample sizes should also be used in additional research and various cultural implications should also be determined.

Education

Nurses should be educated on the negative consequences of pain experience by infants in the NICU. It would be beneficial to incorporate the various nonpharmacological interventions to reduce procedural pain and their effectiveness in nursing education, both in undergraduate education and for nurses already working with this patient population. Nurses working directly with neonates should recognize the nonpharmacological interventions that they may implement in order to advocate for the neonate and decrease their pain experience during their stay in the NICU.

Some of the interventions reviewed require or have the potential for direct parental involvement. Kangaroo Care and facilitated tucking both allow for parental involvement in the care for their child in the NICU. Allowing parents to actively participate in the care of their child has the potential to increase parental satisfaction with care as well as help to reduce stress (Axelin, Salantera, & Lehtonen, 2005). Nurses must be able to educate parents of neonates on how they can participate in their care and help to reduce the pain experienced by their infants.

Practice

Infants in the neonatal intensive care unit are exposed to a number of painful procedures each day that may have detrimental consequences on their growth and development. Nurses have the opportunity to use nonpharmacological techniques as safe and cost effective alternatives or adjuncts to pharmacological analgesia for procedural pain in preterm neonates. These techniques including Kangaroo Care, swaddling, facilitated tucking, music, sucrose, and non-nutritive sucking are simple, feasible, and easily accessible measures that nurses can perform independently to improve pain management in neonates. These techniques are also cost-effective

because they require minimal time and effort and may reduce or prevent the need for pharmacological analgesics. Positioning was the only intervention in the review that showed no clinical benefits in reducing neonatal pain and therefore is not a recommended intervention for nursing practice.

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