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Original Research Article

Kangaroo mother care verses oral sucrose for pain control in premature neonates on heel prick: a randomized control trial

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ABSTRACT

Background: Preterm Neonates receiving intensive care are subjected to multiple painful procedures as part of their intensive care management. Pain leads to abnormal neurodevelopment, so it is extremely important to treat and reduce pain. Multiple studies have shown to be beneficial in pain control. Objective was to compare the efficacy of Kangaroo Mother Care with oral sucrose for pain management in premature neonates on heel prick.

Methods: A total of 100 preterm neonates (28-36 weeks) who fulfill the inclusion and exclusion criteria were recruited for the study. Randomization was done and fifty participants per study arm were randomly assigned to the KMC and oral sucrose group. Preterm babies in the KMC group were given KMC for 15 minutes uninterrupted prior to heel prick. In oral sucrose group, two minutes prior to the procedure, baby received 0.5ml of 24% oral sucrose solution by syringe onto the tongue. The remainder of the total recommended dose was given as needed in small increments during the procedure. Assessment of pain done using PIPP. The post-procedural PIPP score was compared between KMC and oral sucrose groups.

Results: Analysis of 100 preterm neonates (50 KMC and 50 oral sucrose) were done. Baseline variables were mean±SD gestational age 34.25±1.42 weeks, age 7.15±4.9 days, birth weight 1.72±0.32 kg. Post procedural PIPP score was less in KMC 5.16±1.58 group compared to oral sucrose 5.48±1.81 group but could not achieve statistical significance p=0.35, 95% CI=−0.99,0.35.

Conclusions: KMC and oral sucrose are equally effective for pain management in premature neonates on heel prick but KMC is considered better compared to oral sucrose.

Keywords: Preterm neonates, Pain, KMC, Oral sucrose, PIPP score

INTRODUCTION

Preterm neonates during prolonged stay in NICU, are exposed to many painful procedures & interventions, as well as routine handling that elicit behavioral, physiological, and hormonal responses. The immature peripheral and central nervous system of the very preterm infant responds differently to pain.[1] Repeated pain/stress exposure in very preterm infants takes place at a time of rapid brain development and programming of the hypothalamic-pituitary-adrenal (HPA) axis. Synaptic connections are being formed, activity-dependent selective cell death (apoptosis) shapes the developing brain, and integrated cortical networks will be established during this time.[2] These processes are affected by "developmentally unexpected" stimulation.[3] Exposure to pain can lead to neuronal apoptosis secondary to excitotoxic, free radical, or inflammatory damage.[4] Pain in the neonatal period leads to abnormal neurodevelopment, hence treating and reducing neonatal pain is crucial part of developmental supportive care.[5] Failure to treat pain leads to various short term complications & long term sequele such as altered pain processing, attention deficit disorder, impaired executive

function, impaired visual perceptual ability or visual motor integration. Increased exposure to procedural pain has been associated with poor cognitive & motor score, impairments of growth, reduced white matter & subcortical gray matter maturation & altered corticospinal tract structure.[5-8] There are different methods of non- pharmacological analgesic techniques which can be categorized into sensory stimulation (i.e., positioning/swaddling, non-nutritive sucking, music), nutritive (i.e., breastfeeding, oral sweet solutions), and maternal interventions (i.e., maternal odor and voice, breastfeeding, KMC). KMC provides an analgesic effect by enhancing endogenous opiod activity.[9] In our study KMC and oral sucrose are being used as pain relieving agents during heel prick procedure in preterm neonates. As there are not many studies from India we intend to compare the efficacy of Kangaroo Mother Care (KMC) with oral sucrose for pain management in premature neonates on heel prick.

METHODS

This randomized control trial was carried out in the neonatal intensive care unit of the department of pediatrics at MVJ medical college and research hospital, Bangalore from December 2019 to November 2021. 100 stable preterm (28-36 weeks) infants undergoing heel prick procedure were enrolled after obtaining informed consent from parents. Preterm neonates with congenital malformations, neurological impairment (perinatal depression and HIE stage 2 of Sarnat classification, Grade 3/4 IVH, stroke, seizures or congenital malformations of the central nervous system), those who received pain control medications within 12 hours before study interventions, and those with critical illness unstable to undergo study interventions (those requiring mechanical ventilation, inotropes, were excluded.[10]

Sample size

The sample size was calculated by considering the standard deviation (SD) of the premature infant pain profile (PIPP) score of 3.5 from the previous similar study.[11] Considering a 2-point differencein PIPP score as clinically important, a sample of size of 50 was required at 5% alpha error and 80% power. Randomization was performed with the use of WINPEPI software, and the assignment was placed in sealed opaque envelopes. The neonatologist involved in the study opened the sealed opaque envelopes and allocated the intervention. Eligible participants were randomly assigned, in a 1:1 ratio, to KMC and oral Sucrose group.

Pain assessment was performed by using the premature infant pain profile (PIPP) score.[12] PIPP score includes gestational age, Infant's activity, status of eye (open/closed), facial actions like browbulge, eye squeeze, nasolabial furrow, two physiological indicators (baseline heart rate, O2 saturation). The total PIPP score varies for various gestational ages. For all age groups, a total score of ≤6 indicates minimal/no pain while a score of ≥12 indicates moderate to severe pain.[13] Preterm babies in KMC group were given uninterrupted KMC for 15 minutes prior to heel prick. In oral sucrose group, two minutes prior to the procedure, the baby received 0.5ml of 24% oral sucrose solution by syringe onto the tongue. The remainder of the total recommended dose was given as needed in small increments during the procedure. Video recording of the neonate's facial expression and pulse-oximetry monitor which is required for PIPP score calculation was recorded for 5 minutes before and after the intervention. PIPP scoring was done at 30 seconds after the heel prick procedure. In KMC group infant's face was turned to the side; care was taken to capture only the facial expression of the neonate without revealing study interventions, and muted video was taken for blinded PIPP score assessment. The post procedural PIPP score was compared between KMC and oral sucrose groups.

Statistical analysis

Baseline characteristics of the study population were depicted using Descriptive statistics mean±SD, frequency (%). Unpaired student T-test was applied to compare the differences between KMC and oral sucrose groups. The analysis was performed using IBM SPSS version 24, p value (probability that the result is true) of <0.05 was considered as statistically significant.

RESULTS

The baseline characteristics of the study participants like gestational age, birthweight, age, and sex are described in (Table 1) which were comparable in both the study groups. Individual component of PIPP score was compared and analyzed separately. The heart rate, SpO2, browbulge, eye squeeze and nasolabial furrow scores were lower in KMC group while the behavioral state related score was higher in KMC group as compared to the oral sucrose group. Post procedural mean±SD total PIPP score was less in KMC, 5.16±1.58 group compared to oral sucrose 5.48±1.81 but could not achieve statistical significance, p=0.35, 95% CI (−0.99,0.35) (Table 2).

DISCUSSION

Neonates respond to noxious stimulus by release of stress hormones which brings about nonspecific physiological, behavioural & biobehavioural response assessed by premature infant pain profile a well validated pain scoring system for preterm neonates. In our study, we compared the efficacy of Kangaroo mother care with oral sucrose for pain management in preterm neonates on heel prick through a Randomized control trial. According to our study total PIPP score was less in KMC group compared to oral sucrose group but could not achieve a significant difference. Heart rate, SpO2, brow bulge, eye squeeze, and nasolabial furrow related PIPP score

components were found low while behavioral state related score component was found higher in KMC group as compared to oral sucrose group.

Table 1: Baseline characteristics of study population.

Characters	KMC, mean (SD)	Oral sucrose, mean (SD)	Overall, mean (SD)
Gestationalage (weeks)	34.3 (1.44)	34.2 (1.40)	34.26 (1.42)
Birth weight(kg)	1.72 (0.30)	1.78 (0.34)	1.75 (0.32)
Age (days)	8.1 (5.12)	6.2 (4.60)	7.15 (4.92)
Female, N (%)	19 (38)	17 (34)	36 (36)
Male, N (%)	31 (62)	33 (66)	64 (64)

Table 2: Comparison of individual components of PIPP score across group.

Variables	KMC, mean (SD)	Oral sucrose, mean (SD)	P value
Gestational age	1.06 (0.24)	1.08 (0.27)	0.69
Behavioral state	2.40 (0.78)	1.96 (0.83)	0.008
Heart rate	0.96 (0.7)	1.08 (0.72)	0.40
SpO_2	0.02 (0.14)	0.06 (0.24)	0.31
Brow bulge	0.26 (0.53)	0.50 (0.65)	0.04
Eye squeeze	0.24 (0.48)	0.38 (0.53)	0.17
Naso-labial furrow	0.24 (0.48)	0.44 (0.58)	0.20
Total PIPP score	5.16 (1.58)	5.48 (1.81)	0.35

The above results indicate both groups are equally effective for pain relief in preterm neonates but KMC is better compared to oral sucrose group. In a study by Nimbalkar et al the heart rate, behavior, and facial scores were statistically significant and lower in KMC group. But there was no statistically significant difference in oxygen saturation (SpO2). The mean difference of 4.85 in PIPP score was clinically and statistically significant ($p<0.0001$). The findings suggest that short duration KMC (15 min) has stress reducing benefits. Preterm neonatesabove 32 weeks gestational age can benefit from KMC to decrease pain from heel prick procedure.[11] Here mean±SD of total PIPP score of KMC group was similar to our KMC group. In another study by Shukla et al, heart rate,brow bulge, eye squeeze and nasolabial furrow were lower in skin-to-skin care (SSC) group while gestational age and behavioral state related scores were higher in the SSC group as compared to the Sucrose group. The mean±SD total PIPP score was lower in SSC group as compared to Sucrose group but could not achieve statistical significance.[14] which was similar to the findings of our study.

In our study, there is a significant difference in behavioral state scoring between two groups (p value=0.008) indicating the ability of KMC to reduce stress and induce sleep in newborn which helps in better development of the brain. Many studies have documented reduced stress during ophthalmologic examination, and reduced stress during transfer from incubator to skin-to-skin care with the parent.[15] Improved long-term outcome in infant cognitive, motor system and emotional functioning due to KMC in the NICU has also been reported.[3,15] Sleep is one of the primary activities of the brain during early development and plays an important role inhealthy cognitive and psychosocial development in early life.[16] A study by Johnston et al in a RCT involving preterm neonates (born at <31weeks post conceptional age) found that a higher number of doses of Sucrose predicted lower scores on motor development, vigor, alertness and orientation at 36 weeks, lower motor development and vigor at 40 weeks.[17] Marsha Campbell in their study on a theoretical framework of the brain opioid theory of attachment, found that KMC will be a preferred standard of care compared to oral sucrose.[18] There are many other non- pharmacological analgesic methods that include acupuncture, non-nutritive sucking (NNS), breastfeeding (BF), glucose, swaddling, therapeutic massage, musical therapy (MT) and facilitated tucking. Amir Weissman et al in their studies showed that any method of pain control is better than none. Feeding and breastfeeding during heel lancing were found to be the most effective methods of pain relief.[19] Though there are multiple individual studies that have shown the benefits of KMC and oral sucrose on neonatal pain reduction, there were very few randomized control trials comparing the pain reduction between these two methods which was unique in our study.

Limitations

Limitation of this study was small sample size and the use of only short-term hospital-based outcomes were studied. Also, could not study the long-term outcomes of oral sucrose and KMC.

CONCLUSION

KMC and oral sucrose are equally effective for pain management in preterm neonates on heel prick. KMC is

considered better because of its long-term advantages over oral sucrose. Whenever infant is subjected to any procedure/intervention they should be assessed by a valid pain assessment tool. Non pharmacological or pharmacological measures must be optimally utilized to reduce pain & stress of any procedure to prevent short term complications/long term sequel.

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