

Effect of Kangaroo Mother Care Vs Expressed Breast Milk Administration on Pain Associated with Removal of Adhesive Tape in Very Low Birth Weight Neonates: A Randomized Controlled Trial

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Objective: To compare the pain relief effect of Kangaroo Mother Care (KMC) and Expressed Breast Milk (EBM) on the pain associated with adhesive tape removal in very low birth weight (VLBW) neonates.

Design: Randomized Controlled Trial.

Setting: Neonatal intensive care unit of a tertiary care teaching hospital.

Participants: 15 VLBW neonates who needed adhesive tape removal for the first part and 50 VLBW neonates needing adhesive tape removal for the second part.

Methods: In first stage of the study, we studied whether adhesive tape removal in VLBW neonates was painful. In the second stage, eligible VLBW neonates were randomised to compare the efficacy of KMC and EBM in reducing the pain during the

procedure of adhesive tape removal.

Outcome Variables: Premature Infant Pain Profile (PIPP) Score, heart rate, oxygen saturation.

Results: There was significant increase in pain associated with the removal of adhesive tape (Mean pre-procedure PIPP score 3.47 ± 0.74 ; post-procedure mean PIPP score 12.13 ± 2.59 ; $P < 0.0001$). The post intervention mean PIPP pain score was not significantly different between the KMC and EBM groups ($P = 0.62$).

Conclusions: Removal of adhesive tape is a painful procedure for VLBW neonates. There was no difference between KMC and EBM in relieving pain associated with adhesive tape removal.

Key words: Pain, Analgesia, Preterm, Newborn, Adhesive removal.

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Until recently the management of pain in the newborn was hampered by the lack of awareness among the healthcare professionals that the neonate is capable of perceiving pain [1,2]. With increasing awareness of pain in neonates, pain relieving measures are undertaken during NICU procedures like endotracheal intubation, heel-prick, chest drain insertion, etc. but not during many other routinely performed procedures [1]. Adhesive tapes are used in neonates for several procedures like fixing of intravenous cannula, arterial lines, temperature probes and endotracheal tubes. Even a simple procedure such as removal of adhesive tape may cause pain in neonates [1]. Currently no pain relieving measures are undertaken during adhesive tape removal in day-to-day practice.

Clinical studies have shown beneficial effects of pharmacological as well as non-pharmacological interventions in decreasing neonatal pain and stress [1,3-17]. Non-pharmacological interventions are based on the implementation of neurobehaviorally supportive

relationship-based care during the actual procedure [4,5,11,12]. Both provision of KMC and EBM are proved to be non-pharmacological interventions to reduce pain in neonates [1,3,6,16].

We conducted this study in two stages. In first stage of the study, we assessed whether removal of adhesive tape in very low birth weight (VLBW) neonates is a painful procedure or not. After demonstrating that removal of adhesive tape is indeed a painful procedure, in the second stage of the study, we evaluated the comparative efficacy of KMC and EBM in VLBW neonates on pain-relief during removal of adhesive tape.

METHODS

This prospective study was carried out from June to August 2010 in the Neonatal Intensive Care Unit of Department of Neonatology at Seth G S Medical College and KEM Hospital after obtaining approval from the Institutional Ethics Committee. VLBW infants requiring removal of adhesive tape (Micropore Medical Tape, 3M)

during removal of intravenous cannula were enrolled after obtaining informed consent from parents. Neonates with neurological abnormalities and major congenital defects and those receiving sedatives or analgesics were excluded from the study.

Assessment of pain: Pain assessment during removal of adhesive tape was performed by using the Premature Infant Pain Profile (PIPP) score [17,18]. 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.

The behavioral state in the neonate was scored by observing the baby for 15 seconds before the intervention by observing the infant's activity, status of eye (eyes open or closed), and facial movements. The baseline heart rate and oxygen saturation were recorded. A neonatal nurse was then instructed to remove the adhesive tape. The baby was observed for 30 seconds following the intervention and the above-mentioned parameters were recorded again. The heart rate and oxygen saturation were recorded by the investigator. A separate assistant trained to assess the PIPP profile recorded the facial characteristics.

This study was performed in two stages. In first stage of study, we used PIPP score, heart rate, and oxygen saturations to assess whether removal of adhesive tape in VLBW neonates is a painful procedure or not. In this study the PIPP pain scores, heart rate and oxygen saturations were recorded before and after the removal of adhesive tape and compared.

In the second stage of the study, the effect of KMC and EBM on pain during removal of adhesive tape in VLBW neonates was assessed. The babies were randomized to receive either KMC or EBM. A computer-generated randomization sequence was used to assign infants to two treatment groups in 1:1 ratio. Randomisation was balanced in variable random blocks of two or four patients. Treatment allocations were inserted in sequentially numbered opaque envelopes and were sealed. Just prior to adhesive tape removal, a neonatal research nurse opened the sequentially numbered envelopes. This neonatal nurse was responsible for adhesive tape removal.

In KMC group, the baby was kept in Kangaroo Mother Care for 15 minutes before the removal of the adhesive tape. In EBM group, a swab soaked in EBM was kept in the baby's mouth for 2 minutes before the removal of the adhesive tape and continued during the intervention.

Sample size for first stage of the study was calculated

by using formula for hypothesis of one sample mean. Hypothesizing a pre-procedure score of 5 and post procedure pain score of 7 with allowable difference of 0.1 and expected variance of 0.01 (α error of 0.05 and β error of 0.10 and power of 90%), the estimated sample size was 11 subjects. Sample size calculation for the second stage of the study was calculated by the formula for hypothesis of two parallel sample means. Allowable difference of 0.08 (8%) and expected variance of 0.01 (α error of 0.05, β error of 0.20 and power of 80%) the estimated sample size was 25 subjects in each group.

Statistical analysis: The mean and standard deviation of the total pain score as well as that of each of the indicator of the PIPP scale were calculated. In first stage of the study PIPP score, heart rate and oxygen saturations results were analyzed using two-tailed paired *t* test. In second stage of the study, baseline characteristics of enrolled infants were compared by chi-square test for categorical variables and unpaired *t* test or Mann Whitney U test for continuous variables as appropriate. In second stage of the study, post-procedure PIPP score and its components were compared by two-tailed unpaired *t* test or Mann Whitney U test as appropriate. Statistical significance was accepted for values $P < 0.05$. All the statistical tests were performed by using the Minitab (version 15) statistical software for Windows.

RESULTS

In first stage of this study, 15 VLBW babies were enrolled (birth weight in grams, mean \pm SD, 1254.67 \pm 135.43; gestational age in weeks, mean \pm SD, 32.33 \pm 1.35). Results of this part of study are summarized in **Table I**. There was a significant increase in PIPP score with the removal of adhesive tape ($P < 0.0001$).

In the second part of the study, 66 VLBW neonates were deemed to be eligible for enrollment in the study. Sixteen infants were excluded for various reasons (**Fig. 1**). The final analysis included 50 babies. The baseline characteristics of infants at randomization were similar in two groups except the infants in KMC group were slightly heavier in weight than those in EBM group (**Table II**).

The post-intervention PIPP pain score in the KMC group and EBM group indicated minor or no pain. The difference between the post-intervention mean PIPP pain score was not significantly different between the KMC and EBM groups (**Table III**). These mean PIPP pain scores during adhesive tape removal in both the groups (KMC and EBM) were significantly lower as compared to the post-procedure PIPP scores that were observed in infants enrolled in first stage of the study. The various indicator components of PIPP scores, except for

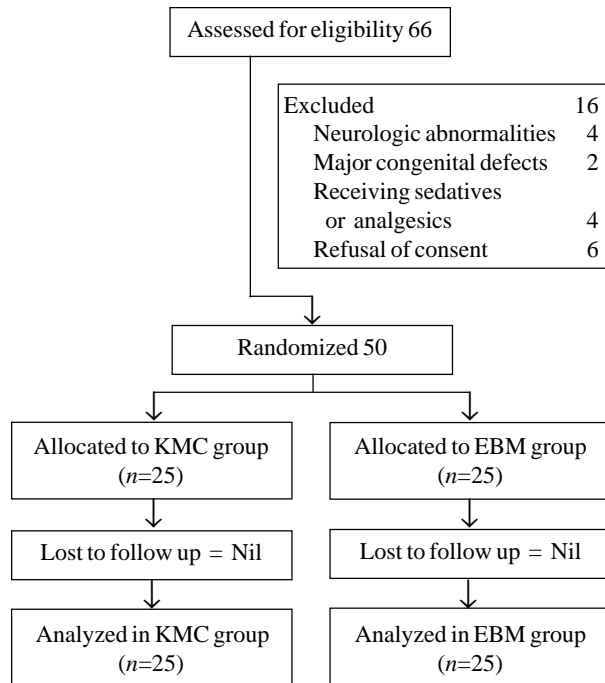


FIG. 1 Flowchart of infants enrolled in second part of the study.

exception of Behavioral state points, were statistically not different between the two groups.

DISCUSSION

This study demonstrated that removal of adhesive tape is a painful procedure. This study also established that both

KMC and EBM can provide pain relief in babies (whose adhesive tapes are being removed) as assessed by PIPP score. There was no statistically significant difference between KMC and EBM in relieving the pain associated with adhesive tape removal.

The babies in the KMC group may score higher in the behavioral component of the PIPP profile for physiological reasons; this was observed in our study. It is imperative to note that the behavioral component under the PIPP scale is graded from 0-3 points with active alert state scoring less on the pain scale (0 points) and sleepy state being given the highest points (3 points) [17]. It is a well-known fact that skin-to-skin contact with KMC is known to induce sleep state.

Strengths of our study were: robust randomized controlled trial design, sufficient sample size with adequate power to detect a difference if there was one, and use of PIPP score for assessment of pain. This is the only study to date which evaluated the pain reducing interventions during adhesive tape removal in neonates. There are no studies in literature that have evaluated the effect of any intervention in amelioration of pain associated with removal of adhesive tape. Limitations of our study are: lack of blinding of outcome measures, use of PIPP in real time as opposed to videotaping for subsequent analysis, and single assessor with no inter-rater reliability checks. Additional limitation of our study was that we have only assessed short term outcomes.

In our study, with the provision of KMC during the removal of adhesive tape, we found a significant decrease

TABLE I CHANGE IN VARIOUS PARAMETERS DURING ADHESIVE TAPE REMOVAL (N=15)

Variable	Pre-procedure (n=15)	Post-procedure (n=15)	Mean difference (95% CI)
PIPP score	3.47 (0.74)	12.13 (2.59)	-8.66 (-9.91 to -7.42)
Heart rate	140.80 (11.48)	152.53 (10.92)	-11.73 (15.78 to -7.69)
Oxygen saturation	94.53 (1.73)	90.33 (3.46)	4.20 (2.54 to 5.86)

*All values in mean (SD); All P<0.0001.

TABLE II BASELINE CHARACTERISTICS OF THE INFANTS ENROLLED IN SECOND STAGE OF THE STUDY

Baseline Characteristics	KMC Group (n=25)	EBM Group (n=25)	P value
Male	13.00	13.00	1.00
Birth weight (g)	1352.76 (150.12)	1235.48 (169.12)	0.01
Gestational age (weeks)	32.72 (2.03)	32.40 (2.16)	0.59
Postnatal age (d)	7.12 (6.64)	5.40 (3.65)	0.26
Oxygen saturation (%)	95.04 (2.50)	96.04 (2.89)	0.19
Heart rate per minute	149.68 (13.78)	148.20 (15.48)	0.72

KMC: Kangaroo mother care; EBM: Expressed breast milk; all values in mean (SD).

TABLE III POST PROCEDURE PIPP SCORE AND ITS COMPONENTS IN EBM AND KMC GROUP

<i>Variables</i>	<i>KMC Group (n=25) mean ±SD</i>	<i>EBM Group (n=25) mean ±SD (n=25)</i>	<i>Mean difference (95 % CI)</i>	<i>P value</i>
<i>PIPP Score</i>				
Median	5.92 ± 1.89	6.20 ± 2.10	-0.28 (- 1.42, 0.86)	0.62
interquartile range	6.0 4.5 to 7.0	5.0 5.0 to 7.5		0.98
<i>Components of PIPP Score</i>				
Gestational age points	1.00 ± 0.41	1.28 ± 0.74	-0.28 (-0.62, 0.06)	0.10
Behavioral state points	1.84 ± 0.94	1.20 ± 0.76	0.64 (0.15, 1.13)	0.011
Median (range)	2.0 (0.0 to 3.0)	1.0 (0.0 to 2.0)		0.023
interquartile range	1.0 to 3.0	1.0 to 2.0		
Heart rate points	0.32 ± 0.63	0.16 ± 0.37	0.16 (-0.13, 0.45)	0.28
Oxygen saturation points	0.16 ± 0.47	0.04 ± 0.20	0.12 (-0.90, 0.33)	0.25
Brow bulge points	0.72 ± 0.54	0.92 ± 0.76	-0.20 (-0.58, 0.18)	0.29
Eye squeeze points	0.96 ± 0.89	1.44 ± 0.82	-0.48 (-0.97, 0.01)	0.06
Nasolabial furrow points	0.76 ± 0.72	1.08 ± 0.70	-0.03 (-0.73, 0.09)	0.12

All values in mean (SD) unless stated.

in PIPP pain score. Loss of parental role and the pain the infant experiences in NICU are reported as being the most stressful aspects of having an infant in the intensive care setting. This has led to several studies to explore the means of involving mothers to provide comfort during painful events. Thus for the very preterm group, skin-to-skin maternal contact or KMC would appear to be a method which could decrease pain response and provide mother an opportunity to comfort her infant during painful procedures in a technologically invasive environment. The study conducted to evaluate the effect of skin-to-skin contact of full-term neonates with mothers during heel lance showed significant decrease in crying and heart rate acceleration [7]. Kangaroo care is shown to have positive effects on autonomic behavior and sleep state [9,10,15]. Sleep state has been associated with decreased pain response and KMC increases the amount of time in the sleep state. Facilitated tucking which is similar to provision of KMC is also an effective comfort measure in attenuating premature infants' responses to minor pain [5,11,12].

Recently published studies demonstrated the effectiveness of EBM in providing pain relief [19,20]. In a Cochrane review that assessed the impact of breastfeeding or breast milk for procedural pain, it was noted that neonates in the breastfeeding group had statistically significantly less increase in the heart rate, reduced duration of crying during procedure compared to swaddled group or pacifier group [14]. Components of

breastfeeding that may be responsible include presence of a comforting person (mother), physical sensation (skin-to-skin contact with comforting person), diversion of attention, and sweetness of breastmilk (presence of lactose or other ingredients present in the breast milk). Results from one study indicate that it may be the contact of breast-feeding, as opposed to the breastmilk, which is efficacious [13]. Preterm neonates incapable of direct breastfeeding from the mother may benefit from placement of breast milk on the tongue or administering breast milk via the nasogastric or orogastric route. One study found that rocking or giving a baby a pacifier are more effective non-pharmacological analgesics than EBM, dextrose, sucrose or massage for the pain of heel pricks in neonates [15].

Our study results suggest that neonatal units need to include removal of adhesive tape as one of the procedure that can cause pain in VLBW neonates. KMC or EBM or other pain relief measures should be provided during adhesive tape removal in VLBW neonates.

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WHAT IS ALREADY KNOWN?

- There are no studies on assessment and management of pain associated with adhesive tape removal.

WHAT THIS STUDY ADDS?

- Removal of adhesive tape is a painful procedure for VLBW neonates
- Giving Kangaroo mother care or providing expressed breast-milk during procedure can relieve pain associated with adhesive tape removal.

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