Effectiveness of Kangaroo Mother Care in Intubated Preterm Neonates 28 to 36 Weeks Gestational Age, Weighing 600 to 2000 Grams at Birth: A Randomized Controlled Trial

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ABSTRACT

Background. Kangaroo Mother Care (KMC) is the standard of care for stable low birth weight infants. Provision of KMC to intubated preterm infants may also be beneficial, but strong evidence is still lacking.

Objective. To determine the effectiveness of KMC in decreasing mortality among intubated preterm neonates.

Study Design. This is a non-blinded, parallel, non-inferiority randomized controlled trial.

Methodology. All intubated, preterm admissions, 28-36 weeks gestation, weighing 600-2000 grams, with respiratory distress were included. They were randomized to the intervention group who received KMC for 2-4 hours daily while intubated and the control group who received care inside an incubator. Participants' physiologic status – before, during, and after the intervention – was recorded. The primary outcome was mortality. Secondary outcomes included comorbidities, days intubated, and hospital stay.

Results. There was a total of 32 patients. The risk of dying in the KMC group (n=16) was significantly reduced by 78% (RR 0.22; 95% CI 0.06 - 0.87 p=0.009). The KMC patients were also less likely to have hypothermia, nosocomial pneumonia, NEC, and late-onset neonatal sepsis (p<0.05). The KMC group had higher blood sugar levels (110 vs. 58, p=0.001) and required fewer days of intubation (3.5 vs.1.5 days, p<0.000) compared to the control group. There was no difference in the duration of the hospital stay.

Conclusion. KMC is effective in decreasing mortality among intubated preterm neonates. Other comorbidities and days of intubation were also reduced.

Key Words: Kangaroo Mother Care, intubated preterm neonates, neonatal mortality, intubation days

INTRODUCTION

The Kangaroo Mother Care (KMC) intervention has three essential components: 1) KMC position described as skin-to-skin contact between the preterm infant and the caregiver's chest in an upright, prone position, 2) breast milk/breastfeedings, and 3) early hospital discharge with outpatient follow-up care. It is now the standard of care for preterm or low birth weight (LBW) infants in many neonatal care units worldwide. In 1978, KMC was conceptualized in Bogotá, Colombia by Dr. Edgar Rey Sanabria and colleagues to address concerns of over-crowding and insufficient resources in the neonatal intensive care unit (NICU), which contribute to neonatal morbidity and mortality among LBW infants. From the 1990s to

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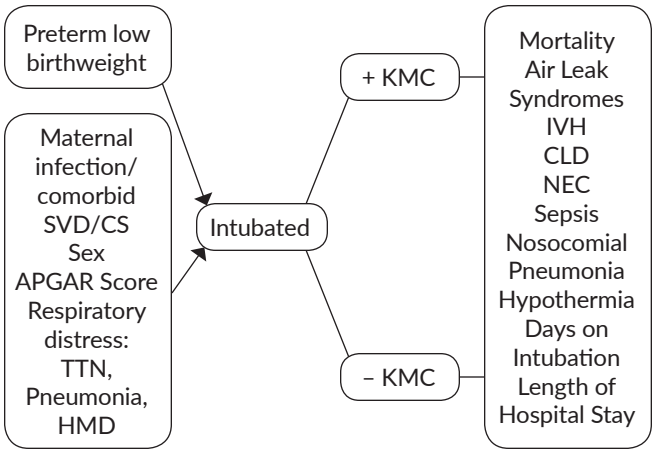

Figure 1. Concept Map of the Study.

the present, the research evidence supporting KMC as an intervention has been overwhelming at 1600 studies to date.[1] Rigorous experiment and meta-analyses provide compelling evidence of the beneficial effects of KMC.

In the KMC position, the baby is placed prone, skin-to-skin, in a vertical position between the mother's breasts. The baby is clothed only with a diaper, cap, and socks and secured with a blanket or tube blouse on the mother's chest. The mother is the primary source of warmth, nutrition, and stimulation for the baby. Any other person, however, can share the role of the KMC provider. Beneficial outcomes reported not only include decreased mortality and nosocomial infections.[2-4] There is also improvement of physiologic stability such as prevention of hypothermia, reduced heart rate variability, and pain perception.[5-11] Physiologic stability has been documented during inter-facility transport in KMC.[12] These studies on the physiologic effects of KMC have included very small (<1000 grams), very preterm (<28 weeks GA, ≤30 weeks postmenstrual age when studied), and very sick infants, as well as more mature, older, and relatively stable preterm infants.[13-16] These studies showed that the physiological effects of KMC, for most variables, were better or similar to other premature infants under different forms of care. However, body temperature and weight gain significantly increased. A meta-analysis showed that the KMC position increases the uptake and duration of breastfeeding. Behavioral effects of KMC on the neonate showed rapid quiescence and improved sleeping patterns.[17] The psychosocial impact of KMC include reduced stress, enhancement of mother-infant bonding, and positive effects on the family environment and the infant's cognitive development.[18,19]

After an extensive literature search, a research gap has been identified in the use of KMC among intubated preterm neonates. The volume of publications on KMC for intubated infants did not provide enough data to support or contradict caregivers' concerns about infants' physiological conditions during this intervention.

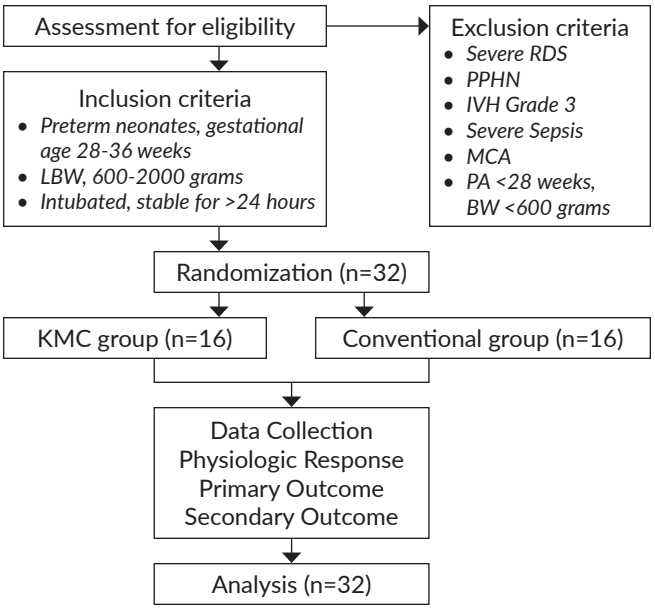

Figure 2. Flow Chart of the Study.

Research Question

Among intubated and ventilated preterm neonates 28 to 36 weeks gestational age with a weight between 600-2000 grams, will KMC effectively decrease mortality compared to conventional care?

OBJECTIVE

The main objective of this investigation is to determine the effectiveness of KMC in decreasing the mortality rate among intubated preterm neonates at 28 to 36 weeks gestational age and weight between 600 to 2000 grams compared to those on conventional care.

METHODOLOGY

Figures 1 and 2 illustrate the concept map and flow chart of the study, respectively.

Study Design

This study is a prospective, non-blinded, parallel, two-arm, non-inferiority randomized controlled trial conducted at the Philippine General Hospital (PGH) NICU.

Study Population

Eligible participants included all preterm neonates admitted at the NICU aged 28 to 36 weeks gestational age, weighing 600 to 2000 grams, requiring intubation and mechanical ventilation due to respiratory distress, but with a stable heart rate of 120 to 160, BP within the normal range for weight and age of gestation, oxygen saturation > 90% and no adverse respiratory events requiring emergent interventions during the previous 12 hours.

Exclusion criteria include severe respiratory distress (FiO_2 >50%), persistent pulmonary hypertension, intraventricular hemorrhage ≥ grade 3, shock state as seen in severe sepsis, and significant congenital abnormalities especially facial and gastrointestinal anomalies. The study did not include preterm neonates with pediatric aging below 28 weeks and birth weight less than 600 grams.

All infants meeting the eligibility criteria were included in the study. Informed consent was obtained from the parents by the principal investigator, the research assistant, or both. Recruitment was at the NICU of the PGH once the baby was intubated and admitted at NICU III.

Randomization

After obtaining informed consent from the mother or father at the NICU, the infant was randomly assigned to either KMC or conventional care. Assignments were placed in opaque brown envelopes. The control group was provided conventional care inside incubators, while the treatment group received the KMC intervention. An analysis is an intention to treat.

Intervention

All parents of participants enrolled in the KMC group underwent KMC orientation. Fathers or mothers were the ones to provide KMC to their infants. They were instructed to hold their babies in a KMC position and were taught how to recognize danger signs such as apnea, cyanosis, and decreased movement. The research assistant (RA), who is a trained KMC nurse, assisted the principal investigator (PI) in the transfer of the intubated baby to the KMC position as well as monitored the babies during KMC sessions (Table 1).[20]

The parents providing KMC had their chest wiped dry with a clean cloth. Application of disinfectant on the parent's skin was avoided to allow the possibility of the infant's recognition of (familiar) maternal odors and initiation of colonization by paternal or maternal flora, which may enhance protection against healthcare-associated infections.[21] After which, they did the prescribed hand washing and wore a KMC tube blouse with the prescribed NICU gown.

The parent was then correctly positioned on a comfortable, lounging chair which placed the parent's back in a slightly inclined position. The preterm neonate, clothed in diaper and cap, with stable vital signs and O_2 saturations ≥ 90%, was briefly disconnected from the ventilator by the RA while being gently placed by the investigator in a vertical, prone position against the father's or mother's chest. The RA immediately reconnected the tube to the ventilator while the investigator pulled up the tube blouse to cover the baby's back. The parents then wore the NICU gown with the opening on the front.

The infant was monitored for 10 to 15 minutes following transfer to assess any physiological disruption that might warrant immediate interruption of the intervention. If physiological disruption persisted 15 minutes after transfer, the intervention (KMC position) would be discontinued, and a second attempt would be made the following day.

KMC was provided to all preterm neonates in the intervention group as soon as the infant demonstrated stable vital signs while on the ventilator. The infant and parent were intermittently kept on the KMC position for 2 to 4 hours daily until extubated. The KMC group recorded baseline heart rate, respiratory rate, blood pressure, and oxygen saturation by pulse oximetry and thermal values by digital thermometer 5 minutes before the intervention. At 15, 30, and 60 minutes during KMC position and every hour for a minimum of 2 hours, until the parent decided to return the baby to the incubator, at any time the neonate showed any signs of destabilization or both. Another set of vital signs were recorded 5 minutes before ending the intervention and 5 minutes after return to incubator.

Control group

The participants in the control group were provided care inside an incubator. Their heart rate, respiratory rate, blood pressure, and oxygen saturation by pulse oximetry and thermal values by digital thermometer were also recorded as per NICU protocol while intubated.

All the preterm neonates in both groups were managed similarly except for the KMC position in the intervention group. Since KMC is the standard of care for all preterm and LBW neonates in this facility, all neonates in both groups were enrolled in the KMC program as soon as they were extubated.

Sample Size Estimation

The proposed number of subjects was 74 preterm neonates at 37 per arm, based on a level of significance of 5%, a power of 80%, a margin of 20% to detect a 50% reduction in neonatal mortality in the KMC group, as noted from the reference article by Lawn, Mwansa-Kambafwile, Horta, et al.[22] This also took into consideration a 10% dropout rate.

Ethical Considerations

The protocol was reviewed and approved by the University of the Philippines Manila Research Ethics Board.

Data Analysis

Descriptive statistics were used to summarize the clinical characteristics of the patients. Frequency and proportion were used for nominal variables, median and interquartile range (IQR) for ordinal variables, and mean and standard deviation (SD) for interval/ratio variables. Independent Sample T-test, Mann-Whitney U test, and Fisher's Exact/Chi-square test were used to determine the difference of mean, median, and frequency between groups, respectively. We calculated relative risks with 95% confidence intervals (CI) for adverse events. Last-Observation-Carried-Forward

Table 1. Safe Protocol Care on Transfer to KMC of Mechanically Ventilated Infants

Safe Protocol for Kangaroo Care with Mechanically Ventilated Infants (KC-Vent) (Ludington-Hoe) JOGNN Principle and Practice, September/October 2003[20]
Kangaroo Care is skin-to-skin contact between a preterm infant and a parent, usually mother, chest-to-chest in an upright prone position. The infant is clad in a diaper and has a receiving blanket covering the infant's back. The optimal chair for experiencing kangaroo care is a recliner. Mechanically ventilated infants are intubated or receiving nasal CPAP or oropharyngeal CPAP via a ventilator. The physician will be contacted for approval to kangaroo the infant and confirmation of the infant's hemodynamic stability.
Before transfer
1. Record infant's baseline ventilator parameters (SIMV/IMV, PIP, PEEP, FiO_2) and hemodynamic (HR, RR, SaO_2) and thermal values (axillary temperature). These measures should be carefully monitored during KC-Vent to ascertain the infant's tolerance of this intervention.
2. With the support of a second person, place the infant in a supine position. Note any significant changes in the infant or mechanical ventilator requirements.
3. Auscultate the infant's chest for quality of breath sounds, suction the endotracheal tube and change the infant's diaper as necessary.
4. Suction infant if necessary and drain the vent circuit of condensation. The water condensed in the ventilator tubing will be drained to decrease resistance and maintain flow *(Bhutani & Abbasi, 1992)*.
5. Assess the infant's response to the above actions. Wait up to 15 minutes to allow for physiological adaptation to the above ministrations. Adaptation is defined as all physiological parameters returning to baseline and staying there for 3 minutes. If adaptation has not occurred in 15 minutes, the infant is probably not stable enough to receive KC-Vent on that day.
6. Place a receiving blanket, folded in fourths, underneath the infant (or in the bed but easily accessible to the mother), so the mother picks up her infant by placing her hands underneath the blanket and moving infant and blanket simultaneously.
7. Position and prepare the chair to be used.
Transfer from Incubator to KC-Vent
1. Have two or three staff members assist the mother in the transfer of the infant.
2. Have the mother stand at the side of the incubator/warmer while one staff member gathers all the infant's lines on one side of the infant.
3. A second staff member is responsible for transferring and securing the ventilator tubing. (A third staff member may be needed to assist the mother.)
4. Disconnect the ventilator tubing from the ETT and have the mother lift her infant and place it prone on her chest in one movement.
5. Reconnect the ventilator tubing and have a mother or staff member quickly secure the receiving blanket across the infant's back (if not already placed when the mother picks up her infant as instructed in step 6 above).
6. Disconnect the ventilator tubing and move mother backward to recliner/chair, assisting her in sitting once she feels the recliner against her calf. Reconnect ventilator tubing to ETT.
7. Raise the footrest and reposition the infant, as needed, and make sure the infant is tucked in a slightly flexed or comfortable position underneath the blanket. If the infant is in the fully flexed position, monitor for respiratory compromise and reflux.
8. Drape the ETT circuit securely over the mother's shoulder (ensure adequate circuit tubing length has been provided).
9. Change the incubator/warmer setting to air control and set it at 33.0°C for the duration of KC-Vent.
10. Monitor the infant's condition every 10 minutes during KC-Vent. Allow KC-Vent for a minimum of 1 full hour if the infant's condition remains stable.
Transfer From KC-Vent Back to the Incubator
1. Have one staff member assist the mother in moving to the front edge of the chair, a second staff member handle the lines, and a third staff member disconnect the ventilator tubing.
2. Assist the mother to a standing position, reconnect the ventilator tubing, and give the infant several ventilator breaths.
3. Disconnect the ventilator tubing and replace the infant in the incubator/warming table in one movement.
4. Reconnect the ventilator tubing and make sure all ventilator tubing is stabilized and all lines are placed securely within the incubator/ warming table.
5. Document infant's participation in and tolerance of KC-Vent.

Bhutani, V., & Abbasi, S. (1992). Evaluation of pulmonary function in the neonate. In Polin & Fox (Eds.), Fetal and neonatal physiology (Vol. 2, pp. 853-871). Philadelphia: WB Saunders.

(LOCF) method was used for lost to follow-up patients. All valid data were included in the analysis. Missing variables were neither replaced nor estimated. Null hypotheses were rejected at 0.05α-level of significance. STATA 12.0 was used for data analysis.

RESULTS

On interim analysis of the ethical review board, the recommendation was to stop recruitment already since the primary outcome analysis resulted in statistical significance. As such, there were 32 preterm infants enrolled, with 16 patients in each group. Post-hoc power analysis was 76.6%.

Baseline characteristics between the KMC and the control group were similar in terms of maternal age and educational attainment, parity, mode of delivery, the average number of prenatal consultations, previous medications during pregnancy, and comorbidities except for the presence of maternal cough before delivery (Table 2).

Table 3 shows the clinical characteristics of preterm neonates. The two groups of neonates were similar in terms of sex, gestational age, birth anthropometrics, APGAR scores, type of respiratory disease, and baseline mechanical ventilator settings.

Table 4 displays the average vital signs of the neonates during the intervention. Only two (2) of the neonates in the intervention group did not tolerate the KMC position at first try. However, the second attempt on the following day and the rest of the study period were all without incident. On observation of the mean values of the vital signs, the heart rate and respiratory rate remain the same from baseline to 5 minutes until the end of the KMC. There was a slight increase in heart rate and respiratory rate 5 minutes after the infant was returned to the incubator. Notably, the temperature of the infants tends to increase (still within normal range) until the end of the KMC session and once returned to the incubator. Oxygen saturations also started to increase after one hour of KMC until the end of the session. Systolic and diastolic blood pressure also were increasing while on KMC but were still within the normal range.

This study showed that intubated neonates who received KMC were significantly less likely to have in-hospital mortality (RR = 0.22 (95% CI 0.06 to 0.87, p = 0.009). This indicated a 78% reduction in the risk of dying in the KMC group compared to controls. Similarly, patients in the KMC group were significantly less likely to have hypothermia (RR=0.21), nosocomial pneumonia (RR= 0.36), NEC RR=0.30), and late-onset sepsis (RR = 0.36). The conventional care group's median random blood sugar level was significantly lower than that of the KMC group (58 versus 110, p = 0.001). There were no significant differences in the incidence of air leak syndromes and IVH between the two groups (Table 5).

Table 6 shows that neonates in the KMC group had a lower median number of intubated days than the conventional care group (1.5 versus 3.5 days, p < 0.000). None of the KMC patients had accidental extubations. There was no significant difference in length of hospital stay. After the study period (once the infant is extubated), all parents of either intervention or control group were encouraged to provide KMC to their infants. Eighty-seven percent of the KMC parents continued to provide KMC to their infants compared with 50% of the control. However, this did not reach statistical significance.

DISCUSSION

This is the first randomized controlled trial providing KMC to intubated infants and positive pressure ventilation. In this study, physiologic parameters tend to improve while on KMC, especially for the temperature and the oxygen saturation. In two case studies by Drosten-Brooks, the intubated infants placed on KMC exhibited increased quiet sleep and decreased oxygen requirements during KMC sessions.[23] In the study by Gale, Franck, and Lund (1993), skin-to-skin holding of 25 intubated infants in the NICU

Table 2. Demographic and Clinical Characteristics of Mothers of Intubated Preterm Neonates Born 28 to 36 weeks Admitted at the Philippine General Hospital (n=32)

	Kangaroo care (n=16)	Conventional care (n=16)	P-value
	Frequency (%); Mean ± SD; Median (Range)		
Maternal Age (Years)	31.75 ± 7.54	29.19 ± 7.30	0.336‡
Educational attainment			0.587
High school	6 (37.5)	9 (56.25)	
College	8 (50)	6 (37.5)	
N/A	2 (12.5)	1 (6.25)	
Parity			0.083
Primiparous	3 (18.75)	8 (50)	
Multiparous	8 (50)	7 (43.75)	
Grand multipara	5 (31.25)	1 (6.25)	
Mode of delivery			1.000*
Spontaneous vaginal delivery	5 (31.25)	5 (31.25)	
Cesarean section	11 (68.75)	11 (68.75)	
Number of prenatal check-ups	4.85 ± 2.19	5 ± 2.41	0.871‡
Comorbidities*			
Hypertension	7 (43.75)	7 (43.75)	1.000*
Urinary tract infection	5 (31.25)	6 (37.5)	0.710*
Premature rupture of membranes	5 (31.25)	7 (43.75)	0.465*
Others	3 (18.75)	3 (18.75)	1.000
Diabetes	0	1 (6.25)	1.000
Cough	0	5 (31.25)	0.043
Receiving antibiotic treatment	2 (12.50)	4 (25)	0.645
Receiving steroids treatment	11 (68.75)	13 (81.25)	0.685
Dose of steroids (n=24)	1 (1 to 4)	1 (1 to 4)	0.420†

*Statistical Tests Used: Fisher's Exact test; * – Chi-Square test; ‡ – Independent Sample T-test; † – Mann-Whitney U test*
*** – Multiple Responses*

Table 3. Clinical Characteristics of Intubated Preterm Neonates Born 28 to 36 weeks Admitted at the Philippine General Hospital (n=32)

	Kangaroo care (n=16)	Conventional care (n=16)	P-value
	Frequency (%); Mean ± SD; Median (Range)		
Sex			0.476*
Male	8 (50)	6 (36.5)	
Female	8 (50)	10 (62.5)	
Gestational Age (weeks)	30.63 ± 2.16	30.13 ± 2.03	0.505‡
Gestational Age			1.000
Appropriate for Gestational Age	14 (87.5)	14 (87.5)	
Small for Gestational Age	1 (6.25)	2 (12.5)	
Large for Gestational Age	1 (6.25)	0	
Birthweight (grams)	1441.88 ± 361.56	1262.81 ± 345.24	0.162‡
Birth Length (cm)	38.69 ± 4.21	38.25 ± 3.64	0.755‡
APGAR score			
1 minute	4.69 ± 2.02	5.06 ± 2.21	0.620‡
5 minutes	7.31 ± 1.66	7.38 ± 1.41	0.909‡
Respiratory Disease			0.326
Hyaline Membrane Disease	7 (43.75)	10 (62.5)	
Transient Tachypnea of the Newborn	6 (37.5)	2 (12.5)	
Neonatal Pneumonia	3 (18.75)	4 (25)	
Mechanical Ventilator Setting			
FIO_2	32.31 ± 8.17	33.06 ± 8.45	0.800‡
PIP	16 (14 to 20)	16 (12 to 30)	0.079§
Positive End-Expiratory Pressure	5 (4 to 6)	5 (4 to 7)	0.862§
Respiratory Rate	33.5 ± 10.99	35.71 ± 12.26	0.596‡
iTime	0.4 (0 to 0.4)	0.4 (0.3 to 0.4)	0.279§

*Statistical Tests Used: Fisher's Exact test; * – Chi-Square test; ‡ – Independent Sample T-test; § – Mann-Whitney U test*

Table 4. Physiological Characteristics of the Neonates in Kangaroo Care (n=16)

	5 mins before start	15 mins during	30 mins during	60 mins during	2nd hour	3rd hour	5 mins prior to end	5 mins back in incubator
	Mean ± SD; Median (Range)							
HR	144.13 ± 17.66	141.69 ± 15.97	141 ± 14.54	141.81 ± 14.47	142.38 ± 14.10	141.81 ± 13.75	140.69 ± 12.86	148.13 ± 10.75
RR	44.5 (38,62)	46 (40,60)	43 (40,58)	42 (38,60)	42 (36,60)	41.5 (36,60)	42 (38,60)	52 (43,65)
Temp	36.34 ± 0.38	36.63 ± 0.49	36.73 ± 0.51	36.88 ± 0.39	36.95 ± 0.37	36.98 ± 0.40	36.97 ± 0.38	36.85 ± 0.32
O_2 Sat	96 (83,99)	96.5 (85,100)	96 (88,99)	97 (89,100)	97 (90, 99)	97.5 (90, 99)	98 (92,99)	96 (90,98)
BP								
Systolic	61.5 ± 9.71	64.19 ± 10.60	64.88 ± 8.88	66.81 ± 8.28	66.06 ± 7.29	67.06 ± 7.44	67.06 ± 6.60	63.38 ± 6.06
Diastolic	35.81 ± 7.45	38.31 ± 7.96	39.25 ± 7.66	39.63 ± 6.12	38.31 ± 8.68	39.44 ± 6.58	40.13 ± 4.87	36.81 ± 5.38

weighing 0.7 to 1.3 kg, 28-33 weeks postconceptional age with a diagnosis of respiratory distress syndrome at the time of study and received ad libitum amounts (15 minutes to >20 hours over one or more sessions) of KMC, also showed better thermoregulation during KMC compared when they were inside an incubator.[24] In addition, once an infant settled on the mother's chest, their oxygen saturation rose, and they tended to have 15-20 minutes of quiet comfort before "becoming wriggly." Although one accidental extubation occurred in the study of Gale, this infant was returned to the incubator and was re-intubated without complications. In another observational study by Azevedo, KMC for preterm neonates on mechanical ventilation were assessed for 90 minutes (15 min before, 60 min during KMC, and 15 min after).[3] These periods demonstrated that the heart rate, oxygen saturation (SpO_2), axillary temperature, and mean arterial blood pressure were more stable during KMC ($p<0.05$). In another observational study by Carbasse of 141 SSC sessions in 96 preterm infants (18% - intubated, 52% - nasal CPAP, 30% - on room air), there was increased oxygen saturation ($P<0.005$); decreased FiO_2 requirement ($P=0.043$); greater heart rate stability ($P<0.001$).[25] During transfer into SSC, mean axillary temperature dropped moderately but transiently ($P<0.05$). No extubations occurred. Apnea and bradycardia requiring minor intervention occurred in 13% of SSC sessions, but none required SSC termination. Carbasse concluded that SSC was safe and beneficial for clinically stable preterm infants, including those ventilated

Table 5. Mortality and Other Neonatal Complications of Intubated Preterm Neonates Born 28 to 36 weeks from Admission to Discharge (n=32)

	Kangaroo care (n=16)	Conventional care (n=16)	Relative Risk* (95% CI)	P-Value
	No. (%)			
Mortality	2 (12.5)	9 (56.25)	0.22 (0.06, 0.87)	0.009
Air Leak Syndromes	1 (6.25)	3 (18.75)	0.33 (0.04, 2.87)	0.285
Intraventricular Hemorrhage	1 (6.25)	1 (6.25)	1 (0.07, 14.64)	1.000
Chronic Lung Disease	1 (6.25)	0	–	0.310
Hypothermia	3 (18.75)	14 (87.5)	0.21 (0.08, 0.60)	<0.000
Nosocomial Pneumonia	4 (25)	11 (68.75)	0.36 (0.15, 0.90)	0.013
Necrotizing Enterocolitis	3 (18.75)	10 (62.5)	0.3 (0.10, 0.89)	0.012
Late-Onset Neonatal Sepsis	5 (31.25)	14 (87.5)	0.36 (0.17, 0.76)	0.001
Random Blood Sugar [Mean Range]	110 (70-200)	58.34 (50-150)		0.001§

**For nominal variables only. Statistical Tests Used: § – Independent Sample T-test; Chi-Square test*

Table 6. Clinical Outcomes on Intubation and Hospital Stay of Intubated Preterm Neonates Born 28 to 36 weeks Admitted at the Philippine General Hospital (n=32)

	Kangaroo care (n=16)	Conventional Care (n=16)	P-Value
	Frequency (%); Median (Min, Max)		
Days on Intubation	1.5 (1, 3)	3.5 (2, 12)	<0.000*
Accidental Extubation	0 (0)	0 (0)	–
Length of Hospital Stay (day)	21 (5, 93)	17.5 (3, 145)	0.474*
Growth			
Discharge weight of survivors (gms)	1554.29 ± 151.76	1432.14 ± 228.73	0.158§
Discharge length of survivors (cm)	39.43 ± 3.88	38.43 ± 3.78	0.581§
Compliance to KMC Post-Extubation			0.067§
Yes	14 (87.5)	8 (50)	
No	0	2 (12.50)	
N/A	2 (12.5)	6 (37.5)	

**For nominal variables only. Statistical Tests Used: * – Mann-Whitney U test; § – Fisher's exact test*

and those <1000 gm. The investigators proposed that "earlier and longer" (the practice of SSC) could improve neurodevelopmental outcomes. These observational studies and our study showed safety in providing KMC to intubated babies and showed evidence of a much calmer infant based on the physiologic parameters.

In this study, no accidental extubation occurred during the intervention period or KMC sessions using the described transfer method. Whereas Ludington-Hoe, in 2003, described a detailed protocol on the "standing transfer" for the provision of KMC while being mechanically ventilated, this study found the "sitting transfer" safer and more efficient.[20] Only two participants did not tolerate the initial KMC position, but subsequent attempts were well tolerated. All other intubated babies receiving KMC remained physiologically stable during the initial positioning and the entire KMC sessions, lasting 2-4 hours daily. The safety of KMC among intubated preterm neonats was reinforced in this study.

Provision of KMC to unstable, ventilated infants or both remains controversial. In a case report by Swinth, a 33-week-gestation infant with mild respiratory distress at birth, eventually requiring intubation and mechanical ventilation, placing the preterm neonate in a KMC position was shown to assist in, rather than retard, recovery from respiratory distress.26 In this RCT, the infants also seem to recover faster, as demonstrated by the significantly shorter intubation days among KMC infants. Better physiologic parameters may indicate decreased energy utilization so that energy is used for growth and recovery.

This study demonstrated the effectiveness of KMC in decreasing mortality among intubated preterm neonates. The risk of dying in intubated preterm neonates in the KMC group was reduced by 78% compared with the control group. Co-morbid conditions such as hypothermia, nosocomial pneumonia, necrotizing enterocolitis, and late-onset sepsis were significantly less in the KMC group. In the meta-analysis of Conde-Agudelo5, there was also a significant reduction in comorbidities. The decline in sepsis, a leading cause of neonatal mortality, may have led to significantly lower mortality among the KMC group. Data gathered on these subjects was from the time of admission of these neonates to NICU III up to the time of discharge.

The median random blood sugar levels were also significantly higher (within the normal range) in the

KMC group than those in the control group. Although the mechanism of sugar control has not been well elucidated, Chiruvolu proposes the following reasons.[27] First is that better thermoregulation and brown fat stabilization lead to the prevention of glycogen store depletion. Second, KMC decreases neurosteroids indicating less stress which leads to better energy conservation and blood glucose stabilization. Lastly, KMC is associated with higher colostrum output which has also been shown to stabilize glucose levels.

In the meta-analysis of Conde-Agudelo, KMC has been found to have a dose-response effect in their benefits.[5] The earlier and the longer duration/day KMC is provided, the lower the neonatal mortality rates were seen. In this study, an institution of KMC, even while the infant was still intubated, led to higher compliance after the study period. Though not statistically significant, the continuation of KMC provision among the KMC group may have led to lower comorbidities among these infants. However, growth rates and hospital stay remained the same. Further studies can further elucidate the effects of KMC compliance while in the hospital and after discharge.

CONCLUSION

KMC can be safely provided to intubated preterm neonates. Furthermore, KMC significantly reduced mortality, other comorbidities, and duration of intubation among these infants.

Statement of Authorship

All authors participated in the data collection and analysis and approved the final version submitted.

Author Disclosure

All authors declared no conflicts of interest.

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