

Early Continuous Kangaroo Mother Care and Physiological Stabilisation of Preterm Infants: A Randomised Controlled Trial in a Tertiary Care Neonatal Unit

Running title: Early continuous KMC and preterm stabilisation

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ABSTRACT

Background: Complications of preterm birth are the leading cause of under-five mortality, and much of this burden follows physiological instability in the first days of life. The study evaluated whether early, continuous kangaroo mother care (KMC) improved physiological stabilisation of preterm infants compared with conventional care. **Methods:** In this single-centre, open-label randomised controlled trial, 180 preterm infants (30+0 to 33+6 weeks; 1200 to 1799 g) received either continuous KMC initiated within 2 hours of birth (target at least 16 hours per day) or incubator or radiant warmer care with KMC deferred until stabilisation. Vital parameters were recorded serially over 72 hours. The primary outcome was hypothermia within 72 hours. **Results:** Overall, 176 infants (88 per group) were analysed. Median daily skin-to-skin duration was 17.5 versus 2.0 hours. Hypothermia occurred in 20.5% of the KMC group and 51.1% of controls (relative risk 0.40, 95% CI 0.25 to 0.63; $p < 0.001$). The 6-hour stabilisation (SCRIP) score was higher with KMC (5.57 ± 0.34 versus 5.18 ± 0.57 ; $p < 0.001$) and median time to stabilisation shorter (8.8 versus 13.2 hours; $p < 0.001$). Group-by-time interactions were significant for temperature, heart rate, respiratory rate and oxygen saturation ($p \leq 0.008$). KMC reduced hypoglycaemia, apnoea, escalation of respiratory support and sepsis, and shortened hospital stay by 4.1 days ($p < 0.001$). Mortality at 28 days did not differ significantly (2.3% versus 5.7%; $p = 0.44$). **Conclusion:** Early continuous KMC achieved faster and more sustained thermal and cardiorespiratory stabilisation of preterm infants than conventional care and should be the default mode of care from birth.

Keywords: Kangaroo mother care; skin-to-skin contact; preterm infant; physiological stability; hypothermia; neonatal intensive care

INTRODUCTION

Preterm birth, defined as birth before 37 completed weeks of gestation, remains one of the most pressing challenges in maternal and child health. An estimated 13.4 million infants were born preterm in 2020, representing nearly one in ten live births worldwide, with southern Asia and sub-Saharan Africa together accounting for approximately 65% of the global burden [1]. Complications of preterm birth are now the single largest cause of death among children younger than five years, responsible for 17.7% of under-five deaths in 2019 [2]. India contributes the largest absolute number of preterm births of any country, and a substantial proportion of these infants weigh less

than 1800 g at birth, placing them at the highest risk of early neonatal death.

The vulnerability of the preterm infant in the first hours and days of life is fundamentally physiological. Immature thermoregulation, limited brown adipose tissue, a high surface area to body mass ratio and thin, permeable skin predispose these infants to rapid heat loss and hypothermia. Immature respiratory control produces periodic breathing, apnoea and oxygen desaturation, while limited glycogen reserves and immature counter-regulatory responses increase the risk of hypoglycaemia. These derangements are interrelated: hypothermia increases oxygen consumption and glucose utilisation, and each episode

of instability can precipitate further deterioration. Conventional care has addressed this vulnerability by placing the infant in a servo-controlled incubator or under a radiant warmer, which necessarily separates the infant from the mother during the period of greatest physiological fragility.

Kangaroo mother care (KMC) was developed in Bogotá, Colombia, as an alternative to incubator care in a resource-constrained setting. In its full form, KMC comprises continuous, prolonged skin-to-skin contact between the mother and the infant, exclusive or near-exclusive breastfeeding, and early discharge with close follow-up. The Cochrane review by Conde-Agudelo and Díaz-Rossello, which included 21 trials and 3042 infants, found that KMC compared with conventional care reduced mortality at discharge or 40 to 41 weeks' postmenstrual age by 40%, reduced nosocomial infection and sepsis by 65%, and reduced hypothermia by 72% [3]. A broader meta-analysis of 124 studies by Boundy and colleagues confirmed a 36% reduction in mortality among low birth weight infants and further reported reductions in sepsis, hypothermia, hypoglycaemia and hospital readmission, together with lower respiratory rates, higher oxygen saturation and higher body temperature among infants receiving KMC [4].

Until recently, however, KMC was recommended only after the infant had been clinically stabilised, a period that frequently lasts several days and during which the majority of preterm deaths occur. The multicentre WHO Immediate KMC trial, conducted in Ghana, India, Malawi, Nigeria and Tanzania, challenged this paradigm by randomising 3211 infants weighing 1.0 to 1.799 kg to KMC initiated immediately after birth or to conventional care with KMC after stabilisation. Immediate KMC reduced neonatal mortality at 28 days by 25% (relative risk 0.75, 95% CI 0.64 to 0.89), and the trial was stopped early for benefit [5]. An updated systematic review of 31 trials involving 15,559 infants subsequently showed that KMC initiated within 24 hours of birth reduced neonatal mortality compared with later initiation, and that mortality benefits were greater when KMC was provided for at least 8 hours per day [6].

The physiological mechanisms that underlie these survival benefits are biologically plausible but less completely characterised. The maternal chest functions as a thermal regulator, adjusting its temperature in response to the thermal needs of the infant, while continuous tactile, olfactory and auditory stimulation from the mother is thought to stabilise autonomic function and reduce the stress response associated with separation. In a small randomised trial from South Africa, Bergman and colleagues demonstrated that skin-to-skin contact from birth in infants weighing 1200 to 2199 g produced superior cardiorespiratory stability, measured by the stabilisation of the cardiorespiratory system in preterm infants (SCRIP) score, compared with servo-controlled incubator care, with

all infants in the skin-to-skin group stable by the sixth hour [7]. A meta-analysis of 23 studies confirmed that skin-to-skin contact increased body temperature, particularly in low-resource settings and colder environments, although it also reported a small reduction in oxygen saturation that warranted further investigation [8]. Longer-term follow-up has shown that early maternal-preterm contact improves autonomic regulation, measured by respiratory sinus arrhythmia, and enhances cognitive control up to ten years of age [9].

Despite this evidence, uptake of KMC, and particularly of early and continuous KMC, remains low in many health systems. Barriers include concerns among health professionals about the safety of skin-to-skin contact in physiologically unstable infants, the need for continuous monitoring during KMC, limited space for mothers in neonatal units, and cultural and family factors [10]. Much of the evidence on physiological effects derives from intermittent KMC delivered for short sessions to already stable infants, which may not reflect the physiological response to KMC begun immediately after birth and maintained continuously. Detailed, serial physiological data from Indian tertiary care settings, where the burden of preterm birth is greatest, remain scarce.

The present study was therefore designed to evaluate the effect of early, continuous KMC, initiated within 2 hours of birth and maintained for most of the day, on thermal, cardiorespiratory and metabolic stabilisation in preterm infants weighing 1200 to 1799 g, and to compare these effects with conventional care in which KMC was deferred until clinical stability had been achieved.

AIMS AND OBJECTIVES

The primary aim of the study was to compare the incidence of hypothermia during the first 72 hours of life among preterm infants who received early, continuous kangaroo mother care with that among preterm infants who received conventional incubator or radiant warmer care, with kangaroo mother care deferred until stabilisation.

The secondary objectives were to compare the two groups with respect to serial changes in axillary temperature, heart rate, respiratory rate and peripheral oxygen saturation over the first 72 hours, the composite cardiorespiratory stabilisation (SCRIP) score during the first 6 hours, and the time taken to achieve sustained physiological stabilisation. The study also assessed the incidence of hypoglycaemia, apnoea, oxygen desaturation episodes and escalation of respiratory support during the first 72 hours.

Further objectives were to compare in-hospital clinical outcomes, namely clinical or culture-proven sepsis, time to full enteral feeds, time to regain birth weight, daily weight gain, length of hospital stay and exclusive breastfeeding at discharge, as well as mortality within 28 days of birth. In addition, the study examined

whether the effect of early continuous kangaroo mother care on hypothermia was consistent across gestational age and birth weight subgroups, and whether the daily duration of skin-to-skin contact was associated with the time taken to achieve physiological stabilisation.

MATERIALS AND METHODS

Study design and setting

This was a single-centre, open-label, parallel-group randomised controlled trial conducted in the Level III Neonatal Intensive Care Unit (NICU) and the attached Mother-Newborn Care Unit of the Department of Paediatrics, KVG Medical College & Hospital, a tertiary care teaching hospital in Sullia, Karnataka, India. The trial was reported in accordance with the CONSORT 2010 statement.

Ethical considerations

The study protocol was approved by the Institutional Ethics Committee. The study was conducted in accordance with the Declaration of Helsinki and the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017). Written informed consent was obtained from the mother, or from the father when the mother was unable to consent, before randomisation. Wherever feasible, antenatal consent was obtained from mothers admitted in threatened preterm labour and was reconfirmed after delivery.

Study population

Inborn preterm infants with a gestational age of 30+0 to 33+6 weeks, assessed by the first-trimester ultrasound or, when unavailable, the last menstrual period and the New Ballard score, and a birth weight of 1200 to 1799 g were eligible. Infants were included if they were breathing spontaneously, with or without nasal continuous positive airway pressure (CPAP) of up to 6 cmH₂O and a fraction of inspired oxygen of up to 0.40, and if the mother was able and willing to provide skin-to-skin contact.

Infants were excluded if they required invasive mechanical ventilation or had shock requiring inotropic support at the time of screening, had major congenital malformations, hydrops fetalis or a 5-minute Apgar score below 5, or were born of higher-order multiple pregnancies (triplets or more). Infants were also excluded when the mother was critically ill, including mothers with eclampsia, postpartum haemorrhage requiring intensive care, or general anaesthesia from which she had not recovered within 2 hours, and when the mother was unwilling to remain in the unit.

Sample size

The sample size was calculated for the primary outcome. Based on the reported incidence of hypothermia in preterm infants receiving conventional

care in comparable settings [3,4] and on pilot data from the unit, the incidence of hypothermia within 72 hours was assumed to be 40% in the conventional care group. To detect an absolute reduction to 20% in the KMC group, with a two-sided alpha of 0.05 and a power of 80%, 82 infants were required in each group. Allowing for an attrition of approximately 10%, the final sample size was set at 90 infants per group, 180 infants in total.

Randomisation and allocation concealment

Randomisation was performed using a computer-generated sequence in variable blocks of four and six, stratified by gestational age (30+0 to 31+6 weeks and 32+0 to 33+6 weeks). Allocation was concealed in sequentially numbered, opaque, sealed envelopes prepared by a statistician not otherwise involved in the study. Envelopes were opened by the attending resident after eligibility was confirmed and consent obtained, within 60 minutes of birth. Twins were allocated to the same group. Because of the nature of the intervention, neither parents nor caregivers could be blinded; however, the investigator who analysed the data was masked to group allocation.

Intervention: early continuous KMC

In the intervention group, KMC was initiated as soon as possible after birth and in all cases within 2 hours. The infant, wearing only a cap and a nappy, was placed prone and upright between the mother's breasts with the head turned to one side and slightly extended, and was secured with a soft binder that allowed free chest movement. The mother wore a front-opening gown and was provided with a reclining bed and chair within the NICU so that skin-to-skin contact could be maintained continuously. The target was at least 16 hours of skin-to-skin contact in every 24 hours, with the father or another designated family member substituting for short periods when the mother needed rest, bathing or toilet use. Interruptions were restricted to essential procedures such as insertion of intravenous lines. Infants requiring CPAP or supplemental oxygen continued to receive respiratory support during KMC, with the circuit secured to the mother's gown. Continuous multiparameter monitoring was maintained throughout. Mothers were supported by trained nurses to express breast milk and initiate breastfeeding as soon as the infant was able.

Control: conventional care

In the control group, infants were nursed in a servo-controlled incubator (skin temperature set point 36.5 °C, humidity adjusted to gestational age) or under a servo-controlled radiant warmer according to unit protocol. Mothers were encouraged to visit and to express breast milk. Intermittent KMC was offered once the infant met the unit's criteria for stability, namely no requirement for respiratory support or intravenous fluids and no episode of apnoea,

bradycardia or hypothermia for at least 24 hours. All other aspects of care, including respiratory support, fluid and nutritional management, infection control and monitoring, followed the same unit protocols in both groups.

Outcome measurements

Axillary temperature was measured with a calibrated digital thermometer. Heart rate, respiratory rate and peripheral oxygen saturation (SpO₂) were obtained from the continuous multiparameter monitor (pulse oximeter probe on the right hand or wrist) by averaging values over a 5-minute period of calm, with the infant not feeding or crying. Measurements were recorded at baseline (at randomisation, before the intervention), and at 1, 6, 24, 48 and 72 hours after randomisation. In the intervention group, measurements were taken with the infant in the KMC position. In addition, all alarms for temperature below 36.5 °C, SpO₂ below 88% for more than 20 seconds, and apnoea of 20 seconds or longer or shorter pauses associated with bradycardia or desaturation were documented by the nursing staff in a standardised event chart.

The SCRIP score was calculated hourly for the first 6 hours as described by Bergman and colleagues [7]. Heart rate, respiratory rate and SpO₂ were each scored 2 when within the normal range, 1 when a mild deviation required no intervention, and 0 when a significant deviation required intervention, giving a maximum score of 6 per observation. The mean of the six hourly scores was used for analysis. Blood glucose was measured by a glucometer at 2, 6, 12, 24, 48 and 72 hours and whenever clinically indicated.

Operational definitions

Hypothermia was defined as an axillary temperature below 36.5 °C and moderate hypothermia as a temperature below 36.0 °C. Physiological stabilisation was defined as the first time point at which temperature (36.5 to 37.5 °C), heart rate (100 to 180 per minute), respiratory rate (30 to 60 per minute) and SpO₂ (90 to 95% on the prescribed support) were all within range on two consecutive hourly recordings without an increase in respiratory support. Hypoglycaemia was defined as a blood glucose below 45 mg/dL. Escalation of respiratory support was defined as initiation of CPAP in an infant not previously on CPAP, an increase in CPAP pressure or FiO₂ above the entry limits, or the need for invasive ventilation. Sepsis was defined as clinical signs of sepsis with a positive blood culture or with a positive sepsis screen treated with antibiotics for at least 5 days. Full enteral feeds were defined as 150 mL/kg/day of enteral milk without intravenous fluids.

Follow-up protocol

All infants were followed until discharge from hospital. Intensive physiological monitoring was

carried out for the first 72 hours, after which vital signs, weight, feeding and morbidity were recorded daily. Infants in both groups were discharged when they were feeding at the breast or by paladai, maintaining temperature in room air or with KMC, and gaining weight for three consecutive days. After discharge, all infants were reviewed in the high-risk newborn follow-up clinic on day 7 after discharge and at 28 days of life, and vital status at 28 days was confirmed by clinic visit or by telephone contact for those who were unable to attend.

Statistical analysis

Data were entered in Microsoft Excel and analysed using IBM SPSS Statistics version 26.0 (IBM Corp., Armonk, NY) and R version 4.3. The analysis followed a modified intention-to-treat principle, including all randomised infants for whom outcome data were available. Normality of continuous variables was assessed with the Shapiro-Wilk test. Normally distributed variables were expressed as mean $\pm$ standard deviation and compared with Welch's independent-samples t-test, and mean differences were reported with 95% confidence intervals (CI). Skewed variables were expressed as median and interquartile range (IQR) and compared with the Mann-Whitney U test. Categorical variables were expressed as frequency and percentage and compared with the chi-square test or Fisher's exact test, as appropriate, and relative risks (RR) were reported with 95% CI.

Serial physiological measurements were analysed with linear mixed-effects models with a random intercept for each infant and fixed effects for group, time and the group-by-time interaction; the interaction term tested whether the trajectory of each parameter differed between groups. Pre-specified subgroup analyses for the primary outcome were performed by gestational age (below 32 weeks and 32 weeks or more) and birth weight (below 1500 g and 1500 g or more), with heterogeneity assessed by a logistic regression interaction term. The association between daily skin-to-skin duration and time to stabilisation within the intervention group was assessed with Spearman's rank correlation. A two-tailed p value below 0.05 was considered statistically significant.

RESULTS

Participant flow and baseline characteristics

During the study period, 214 preterm infants were screened, of whom 34 were excluded (18 did not meet the inclusion criteria, 9 had parents who declined consent and 7 had mothers who were critically ill). A total of 180 infants were randomised, 90 to early continuous KMC and 90 to conventional care. In the KMC group, one infant was transferred to another hospital and consent was withdrawn for one infant; in the control group, one infant was transferred and one family withdrew consent. The final analysis therefore included 176 infants, 88 in each group.

The two groups were comparable at baseline (Table 1). The mean gestational age was 32.0 ± 1.1 weeks in the KMC group and 32.0 ± 1.0 weeks in the control group ($p = 0.72$), and the mean birth weight was 1515 ± 159 g and 1504 ± 151 g, respectively (mean difference 11.0 g, 95% CI -35.2 to 57.2; $p = 0.64$). There were no significant differences in sex distribution, proportion of small for gestational age infants, mode of delivery,

antenatal corticosteroid exposure, 5-minute Apgar score, maternal age, parity or temperature at admission (all $p > 0.05$). Adherence to the intervention was high: the median daily duration of skin-to-skin contact over the first 72 hours was 17.5 hours (IQR 15.8 to 19.2) in the KMC group compared with 2.0 hours (IQR 1.5 to 3.2) in the control group (Mann-Whitney $U = 7744$; $p < 0.001$).

Table 1. Baseline maternal and neonatal characteristics of the study groups

Characteristic	Early continuous KMC (n = 88)	Conventional care (n = 88)	p value
Gestational age (weeks)	32.0 ± 1.1	32.0 ± 1.0	0.722
Birth weight (g)	1515 ± 159	1504 ± 151	0.638
Male sex	40 (45.5)	41 (46.6)	0.880
Small for gestational age	15 (17.0)	21 (23.9)	0.262
Caesarean delivery	49 (55.7)	49 (55.7)	1.000
Antenatal corticosteroids (complete course)	64 (72.7)	61 (69.3)	0.618
Apgar score at 5 minutes	7.9 ± 0.8	7.9 ± 0.7	0.925
Maternal age (years)	26.1 ± 3.9	26.4 ± 4.7	0.693
Primiparous mother	36 (40.9)	37 (42.0)	0.878
Temperature at admission (°C)	36.13 ± 0.43	36.11 ± 0.40	0.773

Values are mean $\pm$ SD or n (%). p values from Welch's t-test for continuous variables and chi-square test for categorical variables. KMC, kangaroo mother care.

Thermal and oxygenation parameters

Serial temperature and SpO₂ values are shown in Table 2. Baseline axillary temperature was similar in the two groups (36.13 ± 0.43 °C versus 36.11 ± 0.40 °C; $p = 0.77$). Temperature rose more rapidly in the KMC group, which achieved a mean of 36.51 ± 0.48 °C at 1 hour compared with 36.28 ± 0.46 °C in the control group (mean difference 0.23 °C, 95% CI 0.09 to 0.37; $p = 0.001$). The largest difference was observed at 6 hours (36.66 ± 0.46 °C versus 36.38 ± 0.43 °C; mean difference 0.28 °C, 95% CI 0.15 to 0.41; $p < 0.001$), and a significant difference persisted at 72 hours (36.69 ± 0.43 °C versus 36.56 ± 0.43 °C; p

$= 0.040$). The linear mixed-effects model demonstrated a significant group-by-time interaction for temperature ($F = 17.27$; $p < 0.001$).

Baseline SpO₂ did not differ between groups ($93.5 \pm 2.4\%$ versus $93.3 \pm 2.5\%$; $p = 0.60$). From 1 hour onwards, SpO₂ was consistently higher in the KMC group ($95.3 \pm 1.8\%$ versus $94.1 \pm 1.9\%$ at 1 hour; mean difference 1.21%, 95% CI 0.66 to 1.75; $p < 0.001$), and the difference was maintained at 24 hours ($96.3 \pm 1.6\%$ versus $95.1 \pm 1.5\%$; $p < 0.001$) and 72 hours ($96.6 \pm 1.2\%$ versus $95.8 \pm 1.4\%$; $p < 0.001$). The group-by-time interaction for SpO₂ was significant ($F = 3.11$; $p = 0.008$).

Table 2. Serial axillary temperature and peripheral oxygen saturation during the first 72 hours

Parameter / time point	Early continuous KMC (n = 88)	Conventional care (n = 88)	Mean difference (95% CI)	p value
Axillary temperature (°C)				
0 h	36.13 ± 0.43	36.11 ± 0.40	+0.02 (-0.11 to 0.14)	0.773
1 h	36.51 ± 0.48	36.28 ± 0.46	+0.23 (0.09 to 0.37)	0.001
6 h	36.66 ± 0.46	36.38 ± 0.43	+0.28 (0.15 to 0.41)	<0.001
24 h	36.66 ± 0.46	36.46 ± 0.44	+0.20 (0.07 to 0.34)	0.003

Parameter / time point	Early continuous KMC (n = 88)	Conventional care (n = 88)	Mean difference (95% CI)	p value
48 h	36.69 ± 0.47	36.51 ± 0.41	+0.18 (0.05 to 0.31)	0.006
72 h	36.69 ± 0.43	36.56 ± 0.43	+0.13 (0.01 to 0.26)	0.040
Group × time interaction			F = 17.27	<0.001
SpO2 (%)				
0 h	93.5 ± 2.4	93.3 ± 2.5	+0.2 (-0.5 to 0.9)	0.602
1 h	95.3 ± 1.8	94.1 ± 1.9	+1.2 (0.7 to 1.8)	<0.001
6 h	95.9 ± 1.6	94.6 ± 1.5	+1.2 (0.8 to 1.7)	<0.001
24 h	96.3 ± 1.6	95.1 ± 1.5	+1.2 (0.8 to 1.7)	<0.001
48 h	96.7 ± 1.5	95.7 ± 1.3	+1.0 (0.6 to 1.4)	<0.001
72 h	96.6 ± 1.2	95.8 ± 1.4	+0.8 (0.4 to 1.2)	<0.001
Group × time interaction			F = 3.11	0.008

Values are mean ± SD. Time points are hours after randomisation (0 h, baseline before intervention). Between-group comparisons at each time point by Welch's t-test; interaction term from linear mixed-effects model with random intercept per infant.

Cardiorespiratory parameters

Heart rate and respiratory rate values are presented in Table 3. Baseline heart rate was comparable (150.7 ± 9.2 versus 151.4 ± 11.6 beats per minute; $p = 0.64$). Within the first hour, heart rate fell in the KMC group to 145.9 ± 8.3 beats per minute, while it rose transiently in the control group to 154.6 ± 8.8 beats per minute (mean difference -8.77, 95% CI -11.32 to -6.22; $p < 0.001$). Heart rate remained significantly lower in the KMC group at every subsequent time point, including 72 hours (141.7 ± 7.3 versus 145.9 ± 7.8 beats per minute; $p < 0.001$), with a significant group-by-time interaction ($F = 5.98$; $p < 0.001$).

Respiratory rate at baseline was 57.4 ± 6.1 per minute in the KMC group and 56.2 ± 7.0 per minute in the control group ($p = 0.25$). The respiratory rate declined steadily in the KMC group, reaching 51.6 ± 5.8 per minute at 6 hours compared with 56.4 ± 5.1 per minute in the control group (mean difference -4.81, 95% CI -6.44 to -3.19; $p < 0.001$). The largest difference was observed at 48 hours (49.1 ± 5.0 versus 55.4 ± 5.2 per minute; mean difference -6.25, 95% CI -7.76 to -4.73; $p < 0.001$). The group-by-time interaction was highly significant ($F = 11.46$; $p < 0.001$).

Table 3. Serial heart rate and respiratory rate during the first 72 hours

Parameter / time point	Early continuous KMC (n = 88)	Conventional care (n = 88)	Mean difference (95% CI)	p value
Heart rate (beats/min)				
0 h	150.7 ± 9.2	151.4 ± 11.6	-0.7 (-3.9 to 2.4)	0.642
1 h	145.9 ± 8.3	154.6 ± 8.8	-8.8 (-11.3 to -6.2)	<0.001
6 h	145.0 ± 8.6	151.5 ± 7.7	-6.5 (-8.9 to -4.1)	<0.001
24 h	143.0 ± 8.2	149.0 ± 8.6	-6.0 (-8.6 to -3.5)	<0.001
48 h	141.4 ± 7.4	148.1 ± 7.6	-6.7 (-9.0 to -4.5)	<0.001
72 h	141.7 ± 7.3	145.9 ± 7.8	-4.1 (-6.4 to -1.9)	<0.001
Group × time interaction			F = 5.98	<0.001
Respiratory rate (breaths/min)				

Parameter / time point	Early continuous KMC (n = 88)	Conventional care (n = 88)	Mean difference (95% CI)	p value
0 h	57.4 ± 6.1	56.2 ± 7.0	+1.1 (-0.8 to 3.1)	0.247
1 h	54.9 ± 6.5	58.4 ± 6.1	-3.5 (-5.4 to -1.6)	<0.001
6 h	51.6 ± 5.8	56.4 ± 5.1	-4.8 (-6.4 to -3.2)	<0.001
24 h	50.7 ± 5.5	55.7 ± 5.5	-5.0 (-6.7 to -3.4)	<0.001
48 h	49.1 ± 5.0	55.4 ± 5.2	-6.2 (-7.8 to -4.7)	<0.001
72 h	49.2 ± 4.9	52.8 ± 4.6	-3.6 (-5.0 to -2.2)	<0.001
Group × time interaction			F = 11.46	<0.001

Values are mean ± SD. Time points are hours after randomisation (0 h, baseline before intervention). Between-group comparisons at each time point by Welch's t-test; interaction term from linear mixed-effects model with random intercept per infant.

Physiological stabilisation and early morbidity

Stabilisation outcomes are summarised in Table 4. The primary outcome, hypothermia within 72 hours, occurred in 18 infants (20.5%) in the KMC group and 45 infants (51.1%) in the control group ($\chi^2 = 18.02$; RR 0.40, 95% CI 0.25 to 0.63; $p < 0.001$). Moderate hypothermia below 36.0 °C occurred in 2 infants (2.3%) and 10 infants (11.4%), respectively (RR 0.20, 95% CI 0.05 to 0.89; Fisher's exact $p = 0.032$). The mean SCRIP score over the first 6 hours was significantly higher in the KMC group (5.57 ± 0.34 versus 5.18 ± 0.57 ; mean difference 0.39, 95% CI 0.25 to 0.53; $p < 0.001$), and the median time to physiological stabilisation was 8.8 hours (IQR 6.0 to 12.1) compared with 13.2 hours (IQR 9.8 to 21.4) in the control group ($U = 1877$; $p < 0.001$).

Hypoglycaemia was less frequent with early continuous KMC (5.7% versus 20.5%; RR 0.28, 95% CI 0.11 to 0.72; $p = 0.004$), as was apnoea requiring stimulation (10.2% versus 23.9%; RR 0.43, 95% CI 0.21 to 0.88; $p = 0.016$). Infants in the KMC group experienced fewer episodes of desaturation below 88% during the first 72 hours (1.4 ± 1.2 versus 3.3 ± 2.0 episodes per infant; mean difference -1.87, 95% CI -2.37 to -1.38; $p < 0.001$), and fewer required escalation of respiratory support (5.7% versus 19.3%; RR 0.29, 95% CI 0.11 to 0.76; $p = 0.006$). No infant in the KMC group experienced accidental extubation, dislodgement of the CPAP interface resulting in clinical deterioration, or a fall during KMC.

Table 4. Physiological stabilisation and early morbidity within the first 72 hours

Outcome	Early continuous KMC (n = 88)	Conventional care (n = 88)	Effect estimate (95% CI)	p value
Mean SCRIP score, first 6 h	5.57 ± 0.34	5.18 ± 0.57	MD 0.39 (0.25 to 0.53)	<0.001
Time to physiological stabilisation (h)†	8.8 (6.0-12.1)	13.2 (9.8-21.4)	$U = 1877$	<0.001
Hypothermia (<36.5 °C), any episode within 72 h (primary outcome)	18 (20.5)	45 (51.1)	RR 0.40 (0.25 to 0.63)	<0.001
Moderate hypothermia (<36.0 °C)	2 (2.3)	10 (11.4)	RR 0.20 (0.05 to 0.89)	0.032*
Hypoglycaemia (<45 mg/dL)	5 (5.7)	18 (20.5)	RR 0.28 (0.11 to 0.72)	0.004
Apnoea requiring stimulation	9 (10.2)	21 (23.9)	RR 0.43 (0.21 to 0.88)	0.016
Desaturation episodes (SpO2 <88%) per infant, 72 h	1.4 ± 1.2	3.3 ± 2.0	MD -1.87 (-2.37 to -1.38)	<0.001
Escalation of respiratory	5 (5.7)	17 (19.3)	RR 0.29 (0.11 to 0.76)	0.006

Outcome	Early continuous KMC (n = 88)	Conventional care (n = 88)	Effect estimate (95% CI)	p value
support			0.76)	

Values are mean $\pm$ SD, median (IQR)[†] or n (%). SCRIP, stabilisation of the cardio-respiratory system in preterm infants (maximum 6). MD, mean difference; RR, relative risk. *Fisher's exact test; other categorical outcomes by chi-square test; continuous outcomes by Welch's t-test or Mann-Whitney U test[†].

In-hospital clinical outcomes and mortality

Secondary clinical outcomes are shown in Table 5. Sepsis occurred in 5 infants (5.7%) in the KMC group and 14 infants (15.9%) in the control group (RR 0.36, 95% CI 0.13 to 0.95; $p = 0.029$). Infants receiving early continuous KMC reached full enteral feeds 1.03 days earlier (6.6 ± 2.1 versus 7.7 ± 2.7 days; 95% CI -1.75 to -0.32; $p = 0.005$) and regained birth weight 2.16 days earlier (9.7 ± 2.8 versus 11.8 ± 3.5 days; 95% CI -3.11 to -1.22; $p < 0.001$). Mean daily weight gain was higher in the KMC group (16.5 ± 3.7 versus

12.9 ± 3.6 g/kg/day; mean difference 3.62, 95% CI 2.54 to 4.71; $p < 0.001$), and length of hospital stay was shorter by 4.13 days (14.1 ± 4.4 versus 18.2 ± 5.6 days; 95% CI -5.63 to -2.64; $p < 0.001$). Exclusive breastfeeding at discharge was more common in the KMC group (80.7% versus 58.0%; RR 1.39, 95% CI 1.13 to 1.71; $p = 0.001$). Death within 28 days occurred in 2 infants (2.3%) in the KMC group and 5 infants (5.7%) in the control group; this difference was not statistically significant (RR 0.40, 95% CI 0.08 to 2.01; Fisher's exact $p = 0.44$).

Table 5. Intervention adherence, in-hospital clinical outcomes and 28-day mortality

Outcome	Early continuous KMC (n = 88)	Conventional care (n = 88)	Effect estimate (95% CI)	p value
Daily skin-to-skin duration, first 72 h (h/day) [†]	17.5 (15.8-19.2)	2.0 (1.5-3.2)	U = 7744	<0.001
Clinical or culture-proven sepsis	5 (5.7)	14 (15.9)	RR 0.36 (0.13 to 0.95)	0.029
Time to full enteral feeds (days)	6.6 ± 2.1	7.7 ± 2.7	MD -1.03 (-1.75 to -0.32)	0.005
Time to regain birth weight (days)	9.7 ± 2.8	11.8 ± 3.5	MD -2.16 (-3.11 to -1.22)	<0.001
Weight gain (g/kg/day)	16.5 ± 3.7	12.9 ± 3.6	MD 3.62 (2.54 to 4.71)	<0.001
Length of hospital stay (days)	14.1 ± 4.4	18.2 ± 5.6	MD -4.13 (-5.63 to -2.64)	<0.001
Exclusive breastfeeding at discharge	71 (80.7)	51 (58.0)	RR 1.39 (1.13 to 1.71)	0.001
Death within 28 days	2 (2.3)	5 (5.7)	RR 0.40 (0.08 to 2.01)	0.444*

Values are mean $\pm$ SD, median (IQR)[†] or n (%). MD, mean difference; RR, relative risk. *Fisher's exact test.

Subgroup and dose-response analyses

The reduction in hypothermia with early continuous KMC was consistent across pre-specified subgroups (Table 6). Among infants born at 30 to below 32 weeks, hypothermia occurred in 31.1% of the KMC group and 71.1% of the control group (RR 0.44, 95% CI 0.27 to 0.70; $p < 0.001$), and among infants born at 32 to below 34 weeks the corresponding figures were 9.3% and 30.2% (RR 0.31, 95% CI 0.11 to 0.87; $p = 0.028$). There was no significant heterogeneity of effect by gestational age (p for interaction = 0.74). The

effect was also present in both birth weight strata, being RR 0.55 (95% CI 0.34 to 0.89; $p = 0.008$) in infants weighing 1200 to 1499 g and RR 0.23 (95% CI 0.08 to 0.64; $p = 0.003$) in those weighing 1500 to 1799 g. Within the KMC group, a longer daily duration of skin-to-skin contact was associated with a shorter time to physiological stabilisation (Spearman's $\rho = -0.38$; $p < 0.001$).

Table 6. Subgroup analysis of the primary outcome (hypothermia within 72 hours)

Subgroup	Early continuous KMC, n/N (%)	Conventional care, n/N (%)	Relative risk (95% CI)	p value
Gestational age 30 to <32 weeks	14/45 (31.1)	32/45 (71.1)	0.44 (0.27 to 0.70)	<0.001
Gestational age 32 to <34 weeks	4/43 (9.3)	13/43 (30.2)	0.31 (0.11 to 0.87)	0.028
Birth weight 1200 to 1499 g	14/42 (33.3)	31/51 (60.8)	0.55 (0.34 to 0.89)	0.008
Birth weight 1500 to 1799 g	4/46 (8.7)	14/37 (37.8)	0.23 (0.08 to 0.64)	0.003
Interaction (treatment × gestational age)				0.742

Pre-specified subgroups. p values from chi-square or Fisher's exact test; interaction p value from logistic regression.

DISCUSSION

This randomised controlled trial demonstrated that early, continuous KMC initiated within 2 hours of birth and maintained for a median of 17.5 hours per day produced faster and more sustained physiological stabilisation in preterm infants weighing 1200 to 1799 g than conventional incubator or radiant warmer care. Early continuous KMC more than halved the incidence of hypothermia in the first 72 hours, improved the composite SCRP score, shortened the time to stabilisation by more than 4 hours, and was associated with significantly more favourable trajectories of temperature, heart rate, respiratory rate and oxygen saturation. These physiological gains were accompanied by reductions in hypoglycaemia, apnoea, desaturation, escalation of respiratory support and sepsis, faster attainment of full enteral feeds, better weight gain, higher rates of exclusive breastfeeding and a shorter hospital stay.

The thermal benefit of KMC observed in the present study is consistent with the wider literature. The 72% reduction in hypothermia reported in the Cochrane review [3] and the 78% reduction reported by Boundy and colleagues [4] are larger than the 60% relative reduction observed here, which probably reflects the fact that the comparison group in the present trial received servo-controlled incubator or radiant warmer care rather than the less controlled cot nursing used in several older trials. The pattern of temperature change closely resembles that reported by Bera and colleagues in 265 low birth weight infants in Kolkata, who documented a mean rise of about 0.4 °C during KMC sessions, together with the correction of individual episodes of hypothermia [11]. The meta-analysis by Mori and colleagues similarly showed that skin-to-skin contact increased body temperature and that the effect was greatest in middle- and low-income settings [8].

The oxygen saturation findings merit particular comment because the literature on this parameter is inconsistent. The present study found that SpO₂ was higher by approximately 1% throughout the KMC period, and that desaturation episodes were fewer. This

agrees with the meta-analysis by Boundy and colleagues, which reported higher oxygen saturation with KMC [4], with the trial by Parsa and colleagues in Iran, which found significant improvements in all physiological indices after KMC [12], and with the meta-analysis by Zengin and colleagues, which found positive effects of KMC on both temperature and SpO₂ in preterm neonates in the NICU [13]. In contrast, the earlier meta-analysis by Mori and colleagues reported a small decline in saturation during skin-to-skin care, especially in cold environments [8], and the meta-analysis of randomised trials by Cristóbal Cañadas and colleagues found higher SpO₂ with KMC that did not reach statistical significance [14]. Differences in the timing of initiation, in the duration of individual sessions, in positioning and in the respiratory status of enrolled infants probably explain much of this heterogeneity. Short sessions to already stable infants involve transfers from the incubator that may themselves cause transient desaturation, whereas continuous KMC from birth avoids repeated handling and may therefore preserve oxygenation.

The lower heart rate and respiratory rate observed with early continuous KMC are best interpreted as markers of reduced physiological stress rather than as deviations from normality, since both parameters remained well within the normal range in the KMC group. The transient rise in heart rate in the control group during the first hour, in contrast to the fall observed with KMC, is consistent with the observations of Bergman and colleagues, who interpreted cardiorespiratory instability in separated infants as a biological protest response to maternal separation and found that all infants receiving skin-to-skin contact from birth were stable by the sixth hour, compared with fewer than half of those in incubators [7]. The significant reduction in respiratory rate is also in keeping with the meta-analysis by Cristóbal Cañadas and colleagues, which identified respiratory rate as the physiological stress parameter most clearly reduced by KMC [14]. Zengin and colleagues, however, found insufficient evidence for an effect on

heart rate or respiratory rate [13], and Srinath and colleagues found no significant changes in heart rate, temperature or oxygen saturation in stable preterm infants after single 1-hour sessions of either maternal or paternal kangaroo care [15]. These contrasting results suggest that the magnitude of the cardiorespiratory response depends on both the physiological status of the infant at initiation and the continuity of contact, and that short sessions in stable infants may underestimate the effect of continuous KMC begun during the transitional period.

An important finding of the present study was that early continuous KMC was safe in infants receiving CPAP or supplemental oxygen. This agrees with the observational non-inferiority study by Lorenz and colleagues in 40 infants with a median gestation of 27.6 weeks receiving respiratory support, in which cerebral oxygenation, heart rate, SpO₂, FiO₂ and temperature did not differ between skin-to-skin care and incubator care [16], and with the study by Blomqvist and colleagues using near-infrared spectroscopy, which found no differences in cerebral or somatic tissue oxygenation during skin-to-skin contact in very preterm infants on CPAP or mechanical ventilation, together with a rise in body temperature [17]. The lower rate of escalation of respiratory support in the KMC group in the present study suggests that KMC may actively support respiratory stability rather than merely being tolerated. At a biochemical level, Forde and colleagues demonstrated that preterm infants receiving KMC had lower urinary allantoin, a marker of oxidative stress, than those receiving incubator care [18], providing a plausible mechanism by which reduced physiological stress may translate into improved clinical outcomes.

The reduction in hypoglycaemia observed with early continuous KMC is consistent with the 88% reduction reported by Boundy and colleagues [4] and is physiologically coherent, since the prevention of hypothermia reduces non-shivering thermogenesis and glucose consumption, and early skin-to-skin contact facilitates early initiation of breastfeeding. The lower rate of sepsis in the KMC group agrees with the Cochrane review [3] and with the updated meta-analysis by Sivanandan and Sankar [6], and may reflect colonisation of the infant with maternal skin flora, earlier exposure to breast milk and reduced handling by health workers. The shorter time to full enteral feeds, better weight gain and higher rates of exclusive breastfeeding at discharge are in keeping with previous trials [3,4] and with the Indian experience reported by Posan and colleagues, in which KMC improved physiological parameters and weight gain and was perceived by mothers as enhancing bonding and confidence [19].

Mortality within 28 days was lower in the KMC group, but the difference did not reach statistical significance. The present trial was not powered for mortality, and the absolute number of deaths was small. The direction

of the effect is nevertheless consistent with the 25% reduction in neonatal mortality demonstrated in the WHO Immediate KMC trial [5], with the 30% reduction in 28-day mortality reported for community-initiated KMC in Haryana by Mazumder and colleagues [20], and with the pooled estimates of the Cochrane and subsequent reviews [3,6]. The physiological data reported here may help to explain these survival benefits, since hypothermia, hypoglycaemia, apnoea and sepsis are among the principal proximal causes of early preterm death. The finding that longer daily duration of skin-to-skin contact was associated with faster stabilisation also supports the observation by Sivanandan and Sankar that mortality benefits are greater when KMC is provided for at least 8 hours daily [6].

The benefits of early KMC are likely to extend beyond the neonatal period. The 20-year follow-up of the original Colombian trial by Charpak and colleagues showed persistent effects on intelligence quotient, behaviour and brain structure among the most vulnerable participants [21], and Feldman and colleagues showed that maternal-preterm skin-to-skin contact improved autonomic regulation, stress reactivity, sleep organisation and cognitive control through the first decade of life [9]. The early autonomic stabilisation observed in the present study may represent the first step in this developmental trajectory.

From an implementation perspective, the high adherence achieved in the present study shows that continuous KMC for more than 16 hours per day is achievable in an Indian tertiary care unit when mothers are accommodated within the NICU and supported by trained nursing staff. Systematic reviews have identified the lack of space for mothers, concerns among staff about the safety of KMC in unstable infants, and insufficient family support as major barriers to adoption [10,22]. The absence of adverse events during KMC in the present study, including in infants receiving CPAP, should help to address these concerns.

The study has several strengths, including randomised allocation with concealment, stratification by gestational age, high adherence to the intervention, serial measurements at pre-specified time points, and the use of a validated composite stability score. Several limitations should also be acknowledged. It was a single-centre trial, which may limit generalisability. Blinding of parents and caregivers was not possible, and the nursing staff who recorded vital signs were aware of group allocation, which may have introduced observer bias; this was mitigated by the use of monitor-derived values averaged over fixed periods. Infants requiring mechanical ventilation and infants weighing less than 1200 g were excluded, so the findings cannot be extrapolated to the most immature infants. The trial was not powered to detect

differences in mortality, and neurodevelopmental outcomes were not assessed.

In conclusion, the present trial adds robust physiological evidence to the growing body of data on the survival benefits of immediate KMC, and supports a shift in practice from KMC as a step-down intervention to KMC as the primary platform of care for preterm infants from birth.

CONCLUSION

Early, continuous kangaroo mother care initiated within 2 hours of birth and maintained for more than 16 hours per day significantly reduced hypothermia and produced faster and more sustained thermal, cardiorespiratory and metabolic stabilisation in preterm infants weighing 1200 to 1799 g compared with conventional incubator or radiant warmer care. These physiological benefits were accompanied by fewer episodes of hypoglycaemia, apnoea and desaturation, less need for escalation of respiratory support, a lower incidence of sepsis, better growth, higher rates of exclusive breastfeeding and a shorter hospital stay. Early continuous KMC was safe, including in infants receiving non-invasive respiratory support. Neonatal units should therefore reorganise care so that mothers can remain with their preterm infants and provide skin-to-skin contact from birth, and larger multicentre studies are warranted to confirm the effect on mortality and long-term neurodevelopment.

DECLARATIONS

Ethics Approval and Consent to Participate

The study was conducted in accordance with the Declaration of Helsinki and the ICMR National Ethical Guidelines for Biomedical and Health Research Involving Human Participants (2017). Ethical approval was obtained from the Institutional Ethics Committee of KVG Medical College & Hospital, Sullia, Karnataka, India. Written informed consent was obtained from the mother or, when the mother was unable to provide consent, from the father before enrolment.

Consent for Publication

Not applicable. No individually identifiable participant information or images are presented in this manuscript.

Authors' Contributions

Dr. Harshitha N: Conceptualization, study design, participant recruitment, data collection, intervention implementation, data analysis, interpretation of results, literature review, and manuscript drafting.

Dr. Sunita Biradar: Conceptualization, study supervision, methodological guidance, clinical oversight, interpretation of findings, critical revision of the manuscript, and final approval of the version to be published.

Both authors approved the final manuscript and agree to be accountable for all aspects of the work.

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Competing Interests

The authors declare that they have no competing interests or conflicts of interest related to this study.

Data Availability

The datasets generated and/or analysed during the current study are available from the corresponding author on reasonable request, subject to institutional ethical and confidentiality requirements.

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AI Use Disclosure

The authors declare that no generative artificial intelligence tools were used to generate or substantially modify the scientific content of this manuscript.

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