

# RCT of Kangaroo Mother Care for improving the growth outcomes at 40 weeks of gestational age in VLBW infants

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**H O S P I T A L**

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**“K M C”**

**Skin to skin contact**

**Exclusive breast feeding**

**Early discharge**

# Introduction

**KMC is an effective and low cost intervention**

- Thermoregulation**
- Breastfeeding**
- Lower infections**
- Growth**
- Developmental supportive care and**
- Early discharges**

# Introduction

- **Review and metanalysis**
  - KMC is an effective alternative to Conventional care in LBW infants
  - Some quote better growth and breast feeding rates
- **Not a routine in all settings**
- **Safety, Efficacy and Acceptability in VLBW not well studied**

# Study Objective

**To study the effect of Kangaroo mother care (KMC) in the KMC ward in comparison with conventional method of care (CMC) in the NICU on growth and breast feeding in very low birth weight (VLBW) infants at 40 weeks of gestational age**

# Material and Methods

- **Study Design:** Randomized controlled trial
- **Setting:** Level III NICU of a teaching institution in south India
- **Study Period :** April 2009 to February 2011

# Material and Methods

- **Subject** : 140 infants with birth weight <1500 g
- Effect size of 5 g/day weight gain post randomization
- Standard deviation of 10g/day for the total population (from a previous published study), the standardized effect size is 0.5
- Alpha error of 0.05 and power of 80%
- 70 neonates in each group (attrition of 10%)
- **Intervention**: The subjects were randomized into the KMC (n – 71) and CMC groups (n – 69)

# Eligibility

## **Inclusion criteria :**

- **Inborn singleton, VLBW (birth weight <1500gms) infants**
- **Tolerating spoon feeds of 150ml/kg/day**
- **Hemodynamically stable (not on oxygen or respiratory support, no apnea for 72 hrs, not on any intravenous fluids)**



# Eligibility

## **Exclusion criteria :**

- **Major malformations and consent not given by the parents**

# Randomization

- **Random numbers generated using a web based random number generator**
- **Serially numbered, sealed, opaque envelope**
- **Opened after taking informed consent by the research coordinator**
- **Approved by the institutional Ethics Committee**
- **CTRI/2012/04/002599**

# Intervention

| <b>KMC</b>                    | <b>CMC</b>                     |
|-------------------------------|--------------------------------|
| <b>KMC ward/trained nurse</b> | <b>NICU</b>                    |
| <b>Skin to skin contact</b>   | <b>Servo mode incubator</b>    |
| <b>Minimum 8 hrs</b>          | <b>Mothers doing baby care</b> |
| <b>Adlib feeding</b>          | <b>Adlib feed</b>              |

# KMC

## KMC Ward



## KMC Lounge



# KMC

**KMC binder/wrap**



**Dress baby in cap, gloves and socks and nappy**



# KMC

**Keep the baby in KMC position, even when sleeping**



**KMC during routine work**





# Feeding

- **EBM with paladai at 2 hourly intervals**
- **Preterm formula was used when no EBM available**
- **Supplements were used as per the unit protocol**
- **Human milk fortifier in case of poor weight gain (weight gain < 10 g/day for 3 consecutive days)**

# Discharge Criteria

| KMC   | CMC   |
|---|---|
| <b><math>\geq 1300</math>grams</b>  | <b><math>\geq 1300</math> g</b>   |
| <b>Weight gain <math>\geq 10</math>gm/day on 3 consecutive days if weight at randomization was <math>&gt;1300</math>gms</b> | <b>Weight gain of <math>\geq 10</math> g/day for 3 consecutive days if weight at randomization was <math>&gt;1300</math>gms</b> |
| <b>Mother/guardian confident</b>  | <b>Euthermic</b>  |



# Outcome assessment at 40 weeks

## Primary outcome

1. Weight with electronic weighing machine (sensitivity 5gm)
2. Head circumference with a non-stretchable tape
3. Length with an infantometer to the nearest 0.1 cm

## Secondary outcome

1. Type of feeding (exclusive or partial breastfeeding and no breastfeeding)
2. Weight gain from randomization to discharge
3. Weight gain per day after randomization till 40 weeks

*\*Weekly follow-up till the gestational age of 40 weeks*

# Statistics

- **For discrete variables – Chi-square or Fisher's exact test**
- **Continuous variables – Student's *t* test or nonparametric tests, when appropriate**
- **Intention to treat analysis was done**

# Results

**Enrolment**

No of Eligible babies (n = 342)  
(April 2009 – Feb 2011)

Infants exclude  
N= 50 refused consent  
N= 15 major malformation  
N= 61 pair of twins  
N= 5 sets of triplets

Eligible infants for  
randomization n = 140

**Allocation**

71 infants randomized to KMC  
3 infants lost to follow up

69 infants randomized to CMC  
1 infant lost to follow up

**Analysis**

68 infants completed (40wks) follow up

68 infants completed (40 wks)

Babies for analysis in  
KMC group n = 68

Babies for analysis in  
CMC group n = 68

**Study flow chart**

# Baseline Characteristics

| Variable                        | KMC (N-71)<br>n (%) | CMC (N-69)<br>n (%) | P value |
|---------------------------------|---------------------|---------------------|---------|
| GA (Wks) (mean $\pm$ SD)        | 30.8 $\pm$ 2.1      | 30.7 $\pm$ 2.1      | 0.82    |
| Birth wt (g) (mean $\pm$ SD)    | 1170 $\pm$ 191      | 1198 $\pm$ 194      | 0.38    |
| Male sex                        | 39 (54.9)           | 39 (56.5)           | 0.59    |
| IUGR                            | 21 (29.6)           | 22 (31.9)           | 0.85    |
| Caserean delivery               | 66 (93)             | 55 (79.7)           | 0.02    |
| Mothers Education<br>(graduate) | 41 (57.7)           | 40 (57.9)           | 0.93    |

# Baseline Characteristics

| Variable                      | KMC (N-71)<br>n (%) | CMC (N-69)<br>n (%) | P value |
|-------------------------------|---------------------|---------------------|---------|
| Morbidities                   |                     |                     |         |
| Respiratory distress syndrome | 26 (36.6)           | 30 (43.5)           | 0.49    |
| PDA                           | 13 (18.3)           | 13 (18.8)           | 0.39    |
| Sepsis                        | 13 (18.3)           | 11 (15.9)           | 0.82    |
| NEC                           | 8 (11.3)            | 4 (5.8)             | 0.36    |
| Apnea                         | 18 (25.5)           | 21 (30.4)           | 0.57    |

# Nutritional Data

| Variable   | KMC<br>(n-71)  | CMC<br>(n-69)  | P<br>value |
|--|----------------|----------------|------------|
| Time To Full Feed (Days) (mean $\pm$ SD)           | 9.7 $\pm$ 6.4  | 11 $\pm$ 8.1   | 0.29       |
| Total parenteral nutrition n(%)                    | 15 (21.1)      | 13 (18.8)      | 0.73       |
| Human milk fortifier n(%)                          | 5 (7)          | 7 (10.1)       | 0.51       |
| Time to regain Birth Weight (Days) (mean $\pm$ SD) | 12.3 $\pm$ 6.1 | 11.9 $\pm$ 5   | 0.67       |
| Wt. at randomisation (g) (mean $\pm$ SD)           | 1191 $\pm$ 131 | 1223 $\pm$ 125 | 0.13       |

# Post Randomization Morbidities

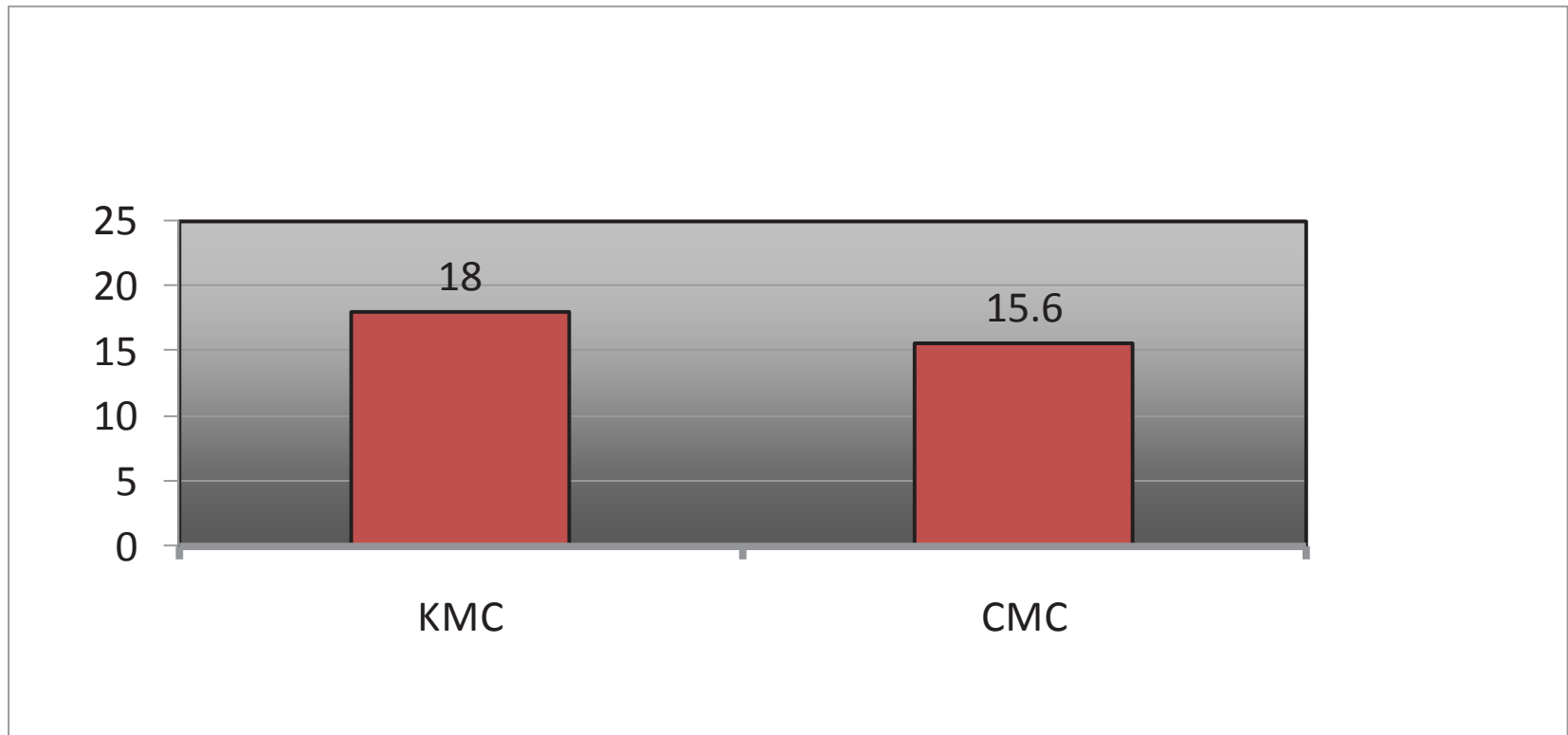
| Variable     | KMC<br>(n-71) | CMC<br>(n-69) | P<br>value |
|--------------|---------------|---------------|------------|
| Sepsis       | 2 (2.8)       | 2 (2.8)       | 0.63       |
| Hypothermia  | 1 (1.4)       | 0             | 0.98       |
| Apnea        | 0             | 2 (2.8)       | 0.46       |
| Hypoglycemia | 0             | 1 (1.4)       | 0.98       |

Figure in the brackets are percentages



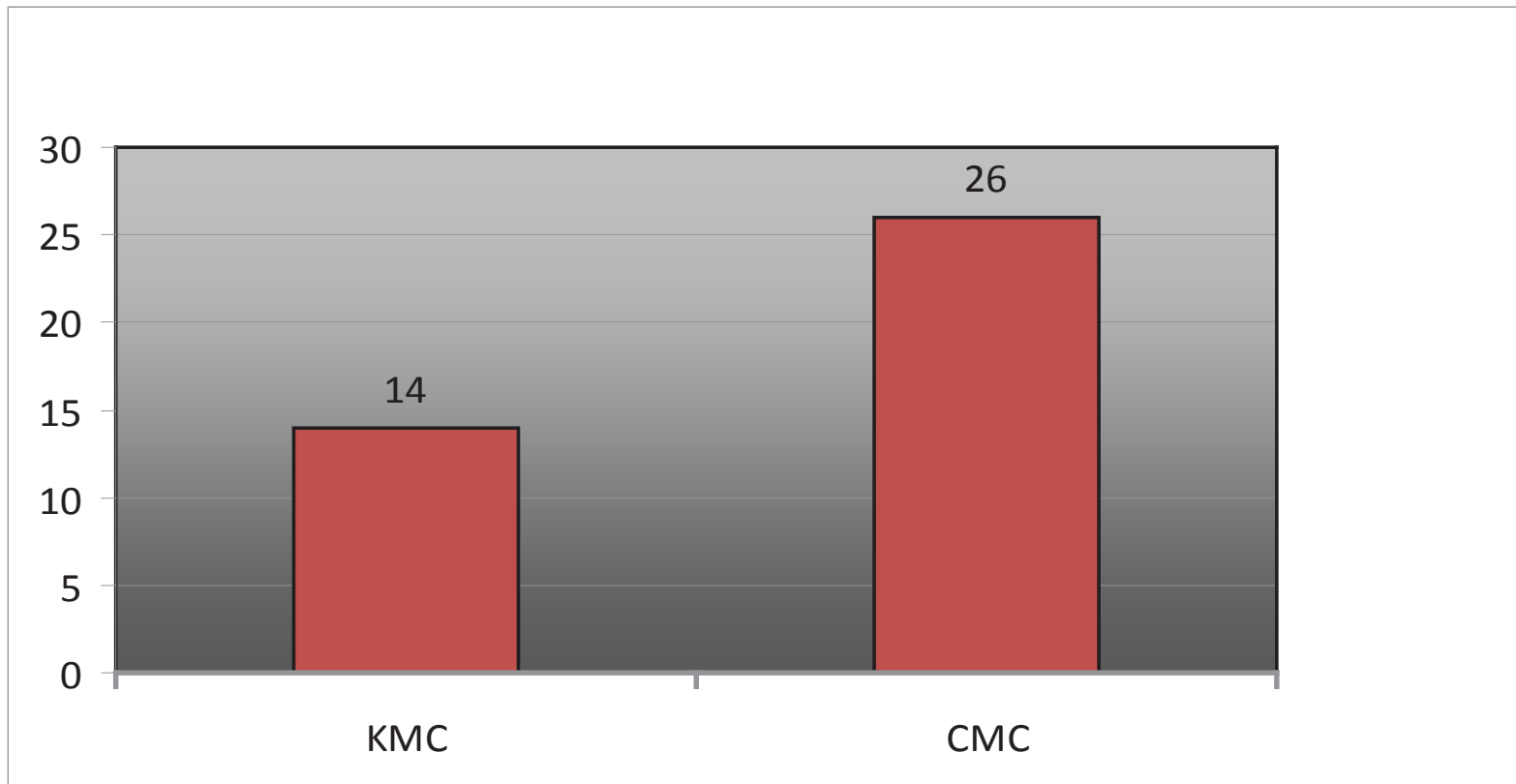
# Randomization to Hospital Discharge

## Weight Gain (gms/kg/day)



**P value-0.12**

# Intensive Care Stay (days)

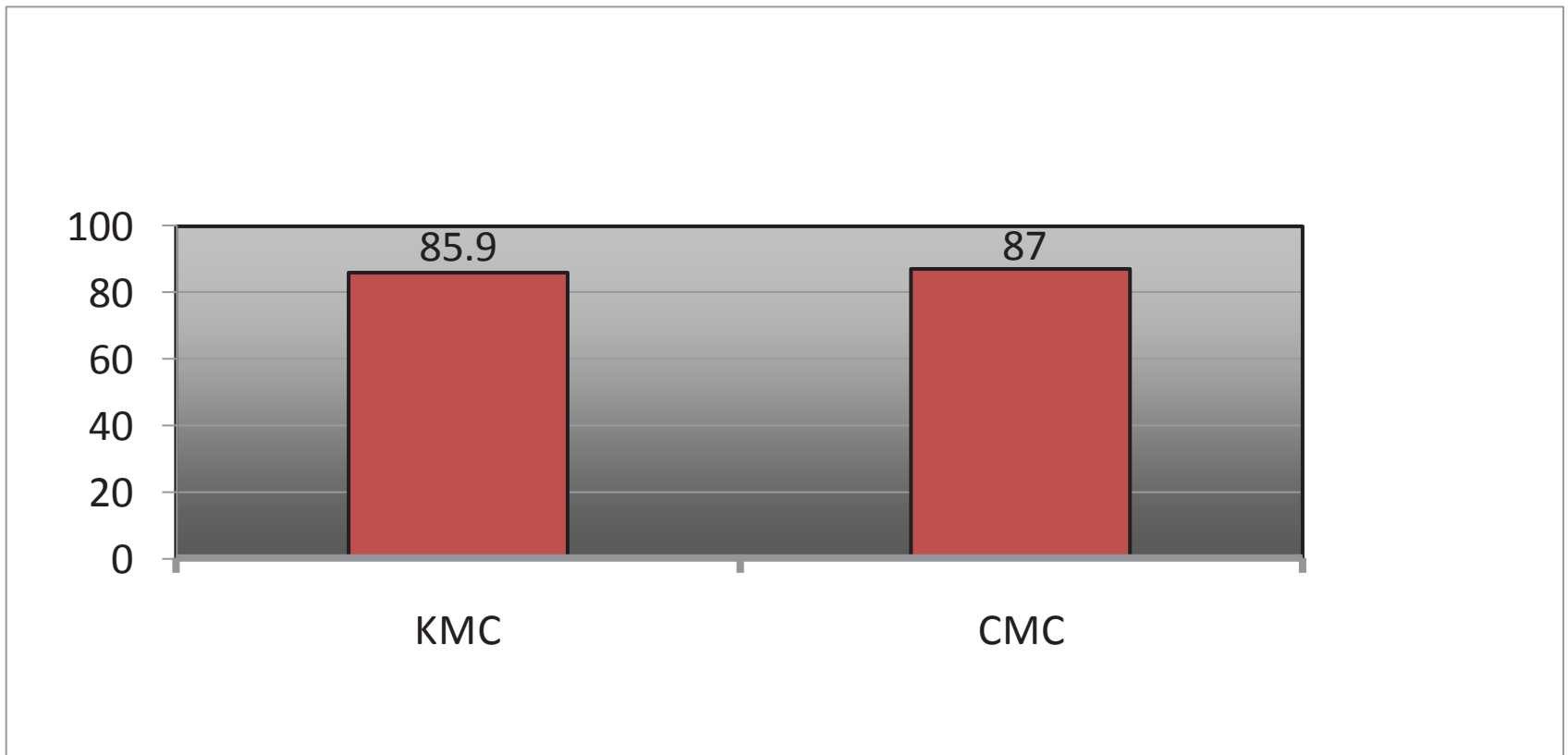


**Intensive care stay was 14 days in KMC group Vs. 26 days in CMC group**

# Outcome variables at 40 wks gestation

| Variable  | KMC<br>(n-68)  | CMC<br>(n-68)  | P<br>value |
|---|----------------|----------------|------------|
| Weight (gms) (mean $\pm$ SD)  | 2449 $\pm$ 456 | 2532 $\pm$ 487 | 0.30       |
| Length (cm) (mean $\pm$ SD)   | 46.5 $\pm$ 2.6 | 47.4 $\pm$ 3.1 | 0.08       |
| Head circumference (cm)<br>(mean $\pm$ SD)                              | 33 $\pm$ 1.3   | 33.3 $\pm$ 1.6 | 0.21       |
| Breast Feeding rate   | 61 (85.9)      | 60 (87)        | 0.68       |
| Wt gain post randomization<br>(g/kg/day) (mean $\pm$ SD) till 40<br>wks | 23.3 $\pm$ 8.7 | 22.6 $\pm$ 9.1 | 0.67       |

# Breast Feeding Rate at Term Gestation



P value-0.68

# Implication for Clinical Practice

- **KMC is an effective and safe alternative to conventional care in the management of stable VLBW infants**
- **KMC care in place of conventional care for stable VLBW infants decreases intensive care stay and hospital cost**

*In affluence,*

*KMC is a useful addition to infant care.*

*In financial constraints,*

*it is a precious gift.*

*In poverty,*

*it may be the only means of survival.*

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