

Kangaroo mother care as compared to standard care for the management of preterm low birth weight babies.

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Abstract- Preterm low birth weight (LBW) babies are unable to control their body temperature and are at greater risk of illness. Conventional neonatal care of LBW babies is expensive and needs both trained personnel and permanent logistic support like the incubator, warmer etc. Kangaroo Mother Care (KMC) is a special way of caring for low birth weight babies has three main components- (a) thermal care through continuous skin to skin contact (b) support for exclusive breastfeeding (c) early recognition and response to complication. This study was conducted to assess the effectiveness of KMC as compared to conventional care. This randomized controlled trial was conducted in the Enam Medical College & Hospital, Dhaka from October 2017 to September 2018. Fifty neonates selected as per inclusion and exclusion criteria. Twenty-five of them were randomly allocated to KMC (Group-I) and 25 of them to Standard Method Care (Group-II). This study was done by χ^2 , t-test etc. with SPSS version 20.0. During hospital stay hypothermia (Group-I 4% vs. Group-II 24%) and hyperthermia (Group-I 8% vs. Group-II 32%) were significantly low in KMC group. 64% of neonates were group-II and 36% were group-I developed late-onset neonatal sepsis (LONS) during the study period and the difference was statistically significant ($p=0.04$). Neonates with KMC care required statistically shorter duration to start direct breastfeeding than standard care group (Group-I 9.6 ± 2.16 days vs. Group-II 20.12 ± 3.82 days; $p=0.04$). Total cost during hospital stay was significantly less in the KMC group (Group-I 9508 ± 4142 takas vs. Group-II 35064 ± 13352 takas; $p=0.01$). At 40 weeks corrected gestational age, KMC infants showed significantly higher daily weight gain than standard care group (Group-I 27.08 ± 3.02 gms vs. Group-II 16.00 ± 2.76 gms; $p=0.002$). In this study, KMC an effective method and provides effective thermal control, helps to achieve full enteral feeding, and birth weight achieving in LBW neonates.

Index Terms- KMC, Low birth weight, Hypothermia, Conventional care.

I. INTRODUCTION

Low birth weight (LBW), defined as weight at birth about < 2500 gm irrespective of gestational age, has an opposing effect on child survival and growth, and may even be a vital risk factor for adult diseases (Outcomes et al.). Preterm LBW is a major problem worldwide. Ten countries account for 60% of worlds preterm birth, among them Bangladesh rank 7 (Blencowe et al.). Approximately 40% of Newborn deaths children under five years of age in developing countries occur in three major causes being birth asphyxia, infections, and complications due to prematurity and low birth weight (Blencowe et al.). It is also notable that, in Bangladesh deaths in the neonatal period account for 60% of all under-five deaths. Developing country like Bangladesh to achieve Millennium Development Goal (MDG-4) must address and reduce the excessively high neonatal mortality rate. Birth weight is a significant determinant of newborn survival (Survey). Worldwide each year at least 15 million babies are born too soon each year before 37 completed weeks of pregnancy that is one out of every 10 babies (Blencowe et al.). LBW infants are about 20 times more probable to die, compared with weightier babies. One-third of LBW babies die in the first 12 hours after delivery. One of the main causes that premature LBW babies are at greater risk of illness and death is that they lack the ability to control their body temperature-i.e., they get cold or hypothermic very quickly. A cold newborn stops feeding and is more susceptible to infection (Lawn et al.). Preterm LBW infants are predisposed to heat loss because they have a high ratio of surface area to body weight, little subcutaneous fat, and reduced glycogen and brown 'fat' stores. In addition, their hypotonic ("frog") posture limits their ability to curl up to reduce the skin area exposed to the cold environment. Conventionally these babies are managed under radiant warmer or incubator which is expensive and needs both trained personnel and permanent logistic support. The baby under warmer has increased the risk of temperature instability, increase the chance of nosocomial infection and increase the insensible loss of water (Thompson). Kangaroo Mother Care (KMC) is a special way of caring for low birth weight babies. In the early 1970s, interested by problems stand up from the lack of incubators and also the impact of mother and newborn partition, Colombian pediatrician Edgar

Rey developed a technically simple method later named Kangaroo mother care (Alashetty). KMC has three main mechanisms including thermal care through unremitting skin to skin contact by being tied with a cloth to the front usually of the mother; provision for exclusive breastfeeding; early recognition and response to complication (Charpak et al.). The reported advantages of KMC for neonates are well-maintained skin temperature, reduced incidence of apnea and bradycardia, stable transcutaneous oxygen level (Chia et al.). KMC has been shown to be efficacious in reducing the physiological and behavioral responses to pain in preterm infants 28 to 36 week's gestation (Johnston et al.). KMC is one of the non-pharmacological measures recommended by the Canadian Paediatric Society and the American Academy of Pediatrics for reducing pain associated with bedside procedures in NICU (American Academy of Pediatrics Committee on Fetus and Newborn et al.). A complex process of care named either conventional or modern neonatal care includes interventions already proven to lower the burden of both neonatal morbidities and mortality. Conventional neonatal care of LBW babies is expensive and needs both trained personnel and Permanent logistic support. This complexity is critical mainly during the stabilization period until the infant has adapted to autonomous extrauterine life. The problem of healthiness systems forced by the care of preterm infants in high-income countries is substantial and well documented. Indeed it is estimated that the cost of care for a single LBW infant in the USA is US\$51600. This challenge still largely remains invisible in low-income countries but is actually of greater magnitude as LBW rates are higher and the resources available fewer, characterized by understaffed hospitals with ill-equipped or non-existent neonatal care units which ultimately result in higher neonatal mortality rate (Ruiz-Peláez et al.). This study was conducted to assess the thermal control, cost during hospital stay and effectiveness of KMC as compared to conventional care.

II. METHODOLOGY

This randomized controlled trial study was conducted in low birth weight babies admitted in Enam Medical College & Hospital, Dhaka, Bangladesh from October 2017 to September 2018. Inclusion criteria were neonate with birth weight 1250 to 1800 gm, gestational age >30weeks to <37 weeks and the Hemodynamically stable after birth. A detailed history was taken from the mother/caregiver and from an obstetric record and then entered in the structured questionnaire. Gestational age was determined by best obstetric estimates and new Ballard score. Exclusion criteria were a major life-threatening congenital malformation, severe perinatal asphyxia, babies require a ventilator or ionotropic support, the mother is critically ill or unable to comply with the follow-up schedule, parental refusal for KMC intervention. Eligible subjects were selected as per inclusion and exclusion criteria. The subjects were divided into two groups; Kangaroo Mother Care (Group-I) and Standard Method Care (Group-II). Randomization was achieved by lottery technique and allocation was concealed by sealed envelope technique. Some variables are thermal control, neonatal morbidities: sepsis, hypothermia, and apnea, duration of hospital stay, breastfeeding, and time to achieve full enteral feeding, growth and hospital stay and cost. After enrollment, according to the inclusion and exclusion criteria, the subject was divided into two groups; Kangaroo Mother Care (Group-I) and Standard Method Care (GroupII). Randomization was achieved by simple randomization and allocation was concealed by sealed envelope technique. For the entire eligible neonate, an informed written consent obtained after constructing an informed consent form in easily understandable language and let the caregiver duly informed. In the KMC group mothers were explained detail about KMC adoption in the presence of their family. KMC was initiated as soon as the baby was stable. If the mother is not available initially any of the family members can start KMC. The mother provided skin to skin contact in upright position dressed in a cap, socks, and diaper and supported in the bottom with a sling/binder. Adequate privacy was ensured. Comfortable chairs and beds were provided to the mothers practicing KMC in the nursery. Skin-to-skin contact was given for a minimum of 1 hour at a time and at least for 12 hrs./ day, duration was gradually increased to as long as comfortable to the mother and baby. When the baby is not in KMC, the baby was placed in the cot with adequately clothed and covered. A "KMC" chart was given to the mother to keep a record of the duration of kangaroo care provided. If the mother is unable to fill up the chart, it was done by a close family member. Neonate in the SMC group was managed under a radiant warmer. In both the groups, mothers were allowed to handle their babies at any hour of the day breastfeed the babies by nasogastric tube, cup-spoon or directly. Babies in both the groups were provided feeding, vitamin and minerals supplementation as per protocol. During hospital stay, both the groups were monitored for daily weight gain by electrotonic weighing scale, episodes of hypothermia, apnea, nosocomial sepsis, hyperbilirubinemia, necrotizing enterocolitis, physiological parameters (heart rate, respiratory rate, axillary temperature, and oxygen saturation) were measured by a single observer and duration of stay at hospital was recorded. Gastrointestinal symptoms such as vomiting, abdominal distension, the character of nasogastric aspirate, characteristics of feces and its color were monitored. After assessment by laboratory tests, clinical follow-up and response to treatment, gastrointestinal symptoms categorized as LONS or feeding intolerance. If any of the study neonates in either group, developed features suggestive of sepsis, the following investigations were sent: Blood sample was collected and sent for culture and sensitivity, complete blood count (CBC), CRP, peripheral blood film (PBF) and other supportive investigations as demanded by clinical condition. All existing clinical management's protocols, clinical practices were uninterrupted. The decisions for patient's management were given by the consultant of the NICU. Duration of antibiotic was as per the existing protocol of the unit. The Weight of the baby at admission and thereafter daily and plotted in the weight chart to see the weight gain pattern of two groups and time to achieve birth weight regain. Age at the start of feeding was recorded. Time to reach full enteral feeding was calculated by the difference between the age at the start of feed and the age of effective breastfeeding or getting

150ml/kg/day of the requirement of feed by nasogastric tube or dropper. Adequacy of breast milk was assessed by effective suckling of the baby, feeding at least 8 times in day and night, adequate urine output (6 times per day), the baby is getting weight (10-15 gm/kg/day) and mother’s satisfaction and confidence. Length of hospital stay was calculated at the time of discharge. Cost during hospital stay was calculated by bill payment sheet, investigation cost, and medication cost. Data were recorded by standard Questionnaire and checklist. The study protocol was submitted for review by the Institutional Review Board. Informed written consent was taken from each of the parents before taking any interviews. The consent form has clearly described the purpose and methods of the study, confidentiality in this study, their rights to participate voluntarily and to refuse at any point in time without consequences. Data were compiled and analyzed by the chi-square (X^2) test, unpaired student’s ‘t’ test probability (p) value of less than 0.05 with the help of SPSS version 20.0.

Calculation of sample size:

Sample size will be determined using the following formula:

$$n = \frac{P_1(1-P_1)+P_2(1-P_2) \times (Z_\alpha + Z_\beta)^2}{(P_1 - P_2)^2}$$

$$= \frac{0.85(1-0.85)+0.42(1-0.42) \times (1.96 + 1.28)^2}{(0.85 - 0.42)^2}$$

$$= 21 \text{ in each group}$$

P_1 = 0.85 proportion of patients developing outcome in the control group

P_2 =0.42 proportion of patients developing outcome in the intervention group (George et al.).

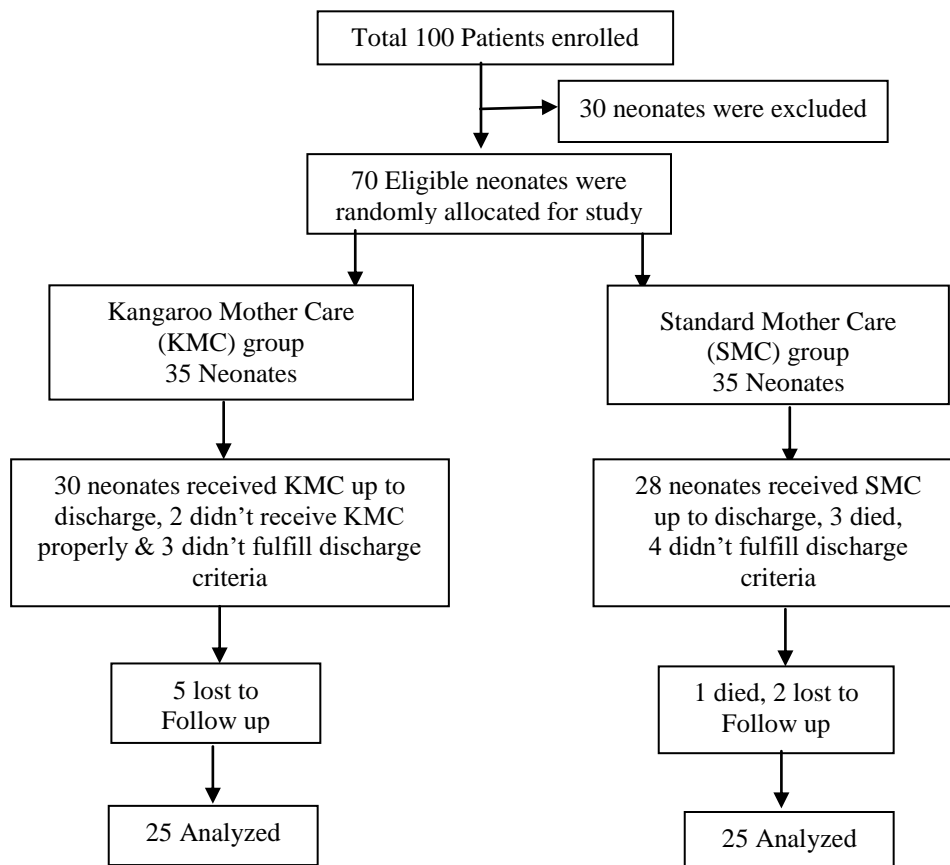
Z_α =Z- value at a definite level of significance.1.96 at 5% level of significance.

Z_β =Z-value at a definite power.1.28 at 90% power.

As the effect size is unpredictable in our population we will increase the sample size to 50.

Intervention group - 25 patients & Control group-25 patient.

Flowchart of selection of case and control



III. RESULTS

This randomized controlled trial was conducted in fifty neonates selected as per inclusion and exclusion criteria. Twenty-five of them were randomly allocated to Kangaroo Mother Care (Group-I) and 25 of them to Standard Method Care (Group-II). There were no differences in birth weight, gestational age, number of male/female neonates, places of delivery and mode of delivery among the two groups. During hospital stay hypothermia (Group-I 4% vs. Group-II 24%) and hyperthermia (Group-I 8% vs. Group-II 32%) were significantly low in the KMC group. 64% of neonates of the standard care group and 36% of KMC group developed late-onset neonatal sepsis (LONS) during the study period and the difference was statistically significant (p=0.04). Neonates with KMC care required statistically shorter duration to start direct breastfeeding than standard care group (Group I 9.6± 2.16 days vs. Group II 20.12 ± 3.82 days; p=0.04). Total cost during hospital stay was significantly less in the KMC group (Group I 9508± 4142 takas vs. Group II 35064± 13352 takas; p=0.01). At 40 weeks corrected gestational age, KMC infants showed significantly higher daily weight gain than standard care group (Group I 27.08± 3.02 gms vs. Group II 16.00± 2.76 gms; p=0.002) (Tables 1-5).

Table-1: Thermal control in two groups.

Variables	Group-I (n-25) n (%)	Group-II (n-25) n (%)	p-value
Hypothermia	1(4%)	6(24%)	0.04
Hyperthermia	2(8%)	8(32%)	0.03

Table-2: Occurrence of sepsis in two groups.

Variables	Group-I (n-25) n (%)	Group-II (n-25) n (%)	p-value
Late onset sepsis	09(36%)	16(64%)	0.04
No sepsis	16(64%)	9(36%)	

Statistical analysis was done by the Pearson Chi-Square test.
 n = Total number of subjects

Table-3: Effect on breastfeeding in two groups.

Variables	Group-I (n-25)	Group-II (n-25)	p-value
Time of starting breastfeeding (days) (mean± SD)	9.6±2.16	20.12±3.82	0.04
Adequacy of breast milk production n (%)	22(88%)	16(64%)	0.04
Exclusive breastfeeding rate up to follow up n (%)	25(100%)	23(92%)	0.14

Statistical analysis was done by unpaired 't' test and Pearson Chi-Square test.

Table-4: Distribution of the study patients according to cost.

Study group	Cost (Taka) mean± SD	p-value
Group-I	9,508 ± 4,142	0.01
Group-II	35,064 ± 13,352	

Statistical analysis was done by unpaired 't' test.

Table-5: Effect of growth in two groups at 40 weeks corrected gestational age.

Variables	Group-I (n=25) mean± SD	Group-II (n=25) mean± SD	p-value
Weight gain (gm/day)	27.08±3.02	16.00±2.76	0.002
Head circumference gain (cm/wk.)	0.86±0.09	0.81±0.09	0.07
Length gain (cm/wk.)	0.99±0.16	0.92±0.10	0.08

Statistical analysis was done by unpaired 't' test.

IV. DISCUSSION

Low birth weight (LBW) has an adverse effect on child survival and development. Preterm LBW neonates are predisposed to heat loss. Conventionally these babies are managed under radiant warmer or incubator which is expensive and needs both trained personnel and permanent logistic support. The baby under warmer has increased the risk of temperature instability, increase the chance of nosocomial infection and increase the insensible loss of water. KMC is a special way of caring for the preterm or low birth weight infants where the baby is kept in skin-to-skin contact with the mother and breastfed exclusively. The reported advantages of KMC for the infant are well maintained of skin temperature, reduce the incidence of apnea and bradycardia, stable transcutaneous oxygen level, long quiet sleep periods, shorter hospital stay and therefore have the potential for considerable cost savings. It is observed that KMC decrease the incidence of nosocomial infection, reduce severe morbidity, and avoid hospital readmission and helps in increasing weight gain in comparison to the conventional care group. KMC has also been found to be related to higher breastfeeding rate improved maternal confidence and bonded better to their infant (Conde-Agudelo et al.) to evaluate the efficacy of KMC as compared to standard care for the management of preterm low birth weight babies this randomized controlled trial was conducted in Enam Medical College & Hospital, Dhaka, Bangladesh, from October 2017 to September 2018.

This interventional study included 50 preterm low birth weight neonates based on inclusion and exclusion criteria. Twenty-five of them were assigned to the KMC group (Group-I) and 25 in the standard care group (Group-II). During the hospital stay, higher incidence of hypothermia (4% vs. 24%) occurred in the KMC group and Standard care group respectively, which was statistically significant (Table-1). This finding was comparable to another study (Suman et al.). Hypothermia was found significantly lower in the KMC group (6% vs.37%, p<0.001). Episodes of hypothermia were significantly reduced in the KMC group and higher rectal temperature was recorded (Ali et al.);(Outcomes et al.);(Ludington-Hoe et al.).(Ibe et al.) also found the same results in their studies. In another RCT states that hypothermia was significantly less common (13.5 vs. 31.5 episodes/100 infants) in KMC infants (Cattaneo et al.). The incidence of hyperthermia was also found higher and statistically significant in the standard care group in this study (32% vs. 8%). Similarly higher incidence of hyperthermia was also found in another study (Suman et al.). A large proportion (64%) of neonates in the standard care group developed sepsis during the study period (Table-2). In the KMC group, the rate of sepsis was 36% (9 out of 25). The difference in the rate of sepsis in the two groups was statistically significant (p<0.05). In another prospective RCT on 114 preterm LBW neonates, statistically significant sepsis was found in the conventional care group that

was 23.2% vs. 6.9% $p=0.014$ (Ali et al.). Significantly low incidence of sepsis was also reported by another study (Suman et al.). Among 206 LBW babies, a significantly lower incidence of sepsis was found in the KMC group 3.9% vs. 14.8% $p=0.008$. Cochrane review concluded that KMC reduces the incidence of nosocomial infections (Conde-Agudelo et al.) in a prospective observational study also found a low incidence of sepsis (4.7%). This study showed that neonates who got KMC required a statistically significant shorter time to start breastfeeding directly than the standard care group (Table-3). Another study also showed the same type of results (Suman et al.). An Adequate amount of breast milk production was significantly higher in the KMC group mother in this study. Adequacy of breast milk was assessed by daily urine output and weight gain of the baby. KMC is associated with a longer duration of breastfeeding, higher volumes of milk expressed, higher exclusive breastfeeding rates and the higher percentage of breastfeeding at the time that pre-term infants are discharged from hospital (Renfrew et al.);(Hake-Brooks and Anderson). We always try to ensure breast milk for the baby from mother or donor milk, formula feeding is not recommended in our institution. For this reason, though the exclusive breastfeeding rate was higher in the KMC group in this study (100% vs. 92%) but was not statistically significant. A randomized trial carried out with KMC among babies less than 1500 gram which found higher breastfeeding rates (55% vs.28%) at 6 weeks in the KMC group (Whitelaw et al.). The number of mothers exclusively breastfeed their babies at 6-week follow-up was double (12/14 vs. 6/14) in the KMC group than in the control group (George et al.) Another comparative study also found a higher rate of exclusive breastfeeding in the KMC group (Suman et al.). KMC was found to decrease the probability of not exclusively breastfeeding (relative risk 0.41, 95% confidence interval 0.25 to 0.68) at discharge (Conde-Agudelo et al.). Exclusive breastfeeding was found to be more prevalent in the KMC group as compared to the control group (Ali et al.). Proportions of exclusively breastfed neonates was higher at 40 weeks (KMC: 94.4%, control: 72%, $p=0.002$). This study showed that neonates who got KMC required statistically significant less amount of money for treatment purpose than standard care group (Table-4). Total cost during hospital stay was significantly less in the KMC group. (Group I 9508 ± 4142 takas vs. Group II 35064 ± 13352 takas; $p=0.01$). Less morbidity like sepsis and shorter duration of hospital stay may likely decrease the amount of cost in the KMC group. In this study at 40 weeks corrected gestational age, KMC neonates showed significantly higher daily weight gain than standard care group (Table-5) (Group I 27.08 ± 3.02 gms vs. Group II 16.00 ± 2.76 gms; $p=0.002$), head circumference gain (cm/wk.) 0.86 ± 0.09 and 0.81 ± 0.09 and length gain (cm/wk.) was 0.99 ± 0.16 and 0.92 ± 0.10 in KMC group and standard care group respectively and both differences were not significant statistically. Similarly, in another study, it was found that KMC babies accomplished considerably better development. It exposed that KMC babies had better average weight improvement per day (KMC: 23.99 gm vs. CMC: 15.58 gm, $p<0.0001$). The weekly increases in head circumference (KMC: 0.75 cm vs. CMC: 0.49 cm, $p=0.02$) and length (KMC: 0.75 cm vs. CMC: 0.49 cm, $p=0.02$) were higher in the KMC group (Suman et al.). An RCT from India has shown higher increments in weight, length and head circumference in kangaroo infants in the neonatal period (George et al.);(Ali et al.) showed that KMC infants gain larger daily weight, while they were cared in the hospital (control: 10.4 ± 4.8 grams, KMC 19.3 ± 3.8 grams, $p<0.001$). In a meta-analysis by Neonatal Review Group of the Cochrane Collaboration randomized trials comparing KMC and conventional neonatal care in LBW showed KMC neonates had gained more weight per day by discharge than controls (weighted mean difference 3.6 g/day, 95% confidence interval 0.8 to 6.4) and had a larger head circumference at 6 months' corrected age than controls (George et al.).

V. CONCLUSION

From this interventional study, it can be concluded that Kangaroo Mother Care maintain effective thermal control, decrease the incidence of sepsis, reduces feed intolerance, helps to achieve full enteral feeding and birth weight earlier in preterm low birth weight neonates. KMC also found to reduce hospital stay, treatment cost and enhances growth during the postnatal period. With proper implementation, KMC may become a safe and effective method in the management of preterm low birth weight babies.

CONFLICT OF INTEREST

None

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