
**“IMPACT OF CONTINUOUS KANGAROO MOTHER CARE
INITIATED IMMEDIATELY AFTER BIRTH (iKMC)
VERSUS CONVENTIONAL CARE ON NEWBORNS WITH
BIRTH WEIGHT BETWEEN 1.0 TO 1.5KG – A ONE YEAR
RANDOMIZED CONTROL STUDY AT KLE’S DR
PRABHAKAR KORE HOSPITAL & MRC, BELAGAVI”**

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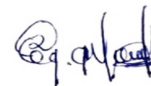
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LIST OF ABBREVIATIONS

KMC	Kangaroo Mother Care
iKMC	Immediate Kangaroo Mother Care
LBW	Low birth Weight
VLBW	Very Low Birth Weight
IUGR	IntraUterine Growth Restriction
NEC	Nectrotizing Entrocolitis
IVH	Intraventricular hemorrhage
RDS	Respiratory distress syndrome
WHO	World Health Organization
SSC	Skin to skin contact
LIC	Low income countries
NICU	Neonatal Intensive Care Unit
CPAP	Continuous Positive Airway Pressure
LSCS	Lower segment caesarean section
NVD	Normal Vaginal delivery
CHD	Congenital Heart Defect
PPH	Postpartum Hemorrhage
SSI	Surgical site infection
CIAB	Cried immediately after birth

CAS	Cried after stimulation
BMV	Bag and mask ventilation
RBS	Random blood sugar
HR	Heart rate
RR	Respiratory rate
DBF	Direct breastfeed
DHM	Donor Human Milk
EBM	Expressed breast milk
RT	Ryle's Tube
SF	Spoon feed
TTNB	Transient Tachypnea of Newborn
ASD	Atrial Septal defect
SCRIP	Stability of the cardiorespiratory system in premature infants

ABSTRACT

BACKGORUND AND OBJECTIVES: Preterm birth, low birth weight, infections and birth complications including birth asphyxia or trauma are the leading causes of neonatal deaths in India. The most effective and evidence-based intervention which is feasible even in a low resource setting is known to be Kangaroo Mother Care (KMC). KMC is known for stabilization of body temperature, improvement of breastfeeding rate, and reducing mortality and chances of sepsis among neonates. However, KMC is ideally recommended to be started after stabilization of the neonate. We intended to study the effect of immediate KMC (iKMC) initiation before the stabilization of the VLBW babies compared with KMC initiated after stabilization of these newborns. Also, we intended to study the effects of iKMC on neonatal mortality, prevention of hypothermia, sepsis, hypoglycemia, RDS and early stabilization of neonates.

MATERIALS AND METHODS: Study group included 60 newborns weighing between 1-1.5kg admitted to the NICU. The newborns were randomized equally into 2 groups-Intervention group: Started with iKMC soon after birth in the labour room even before stabilization of the baby; Control group: Shifted to conventional radiant warmer in the NICU and KMC was initiated after stabilization of the baby. The newborns in the NICU were monitored, and information regarding temperature, heart rate, respiratory rate, capillary blood glucose and oxygen saturation were recorded every 15 mins in the 1st hour and then 6th hourly.

At discharge, the anthropometry, general condition and outcome of the babies were noted and the mothers were explained about the need for continuation of KMC, their benefits and the need for regular follow up in the high-risk baby clinic. After discharge, all infants were regularly followed up until they reach 2.5kgs.

RESULTS: The mean average time of initiation of KMC in intervention group was 18.9 minutes and control group was 4.3 days. The time taken to reach target KMC(8hours/day) was much faster in intervention group. iKMC promoted better physiological stability in the first week of life and also early establishment of enteral feeds as well as exclusive breastfeeding. iKMC had significant impact in prevention of hypothermia, sepsis, need for respiratory support and neonatal mortality. At discharge it was noted that in the intervention group, duration of hospital stay was almost half of control group, the mean average weight gain per day was 15.6 gms/day in the intervention group and 13gms/day in the control group and this difference was statistically significant. It was also observed that the day of consecutive weight gain was almost twice in the control group than the intervention group.

During follow up it, the mean average days taken to reach 2.5kg was 66.9 days in the intervention group and 84.1 days in the control group and this difference was statistically significant. Hence it can be concluded that iKMC promotes better weight gain in neonates.

CONCLUSION: We conclude from our study that the practice of iKMC promotes better compliance to KMC, early stabilization of vital parameters, early enteral feeding, early establishment of breastfeeding, better weight gain. iKMC not only prevents hypothermia but also prevents the need for respiratory support and plays a major role in prevention of sepsis.

KEYWORDS: iKMC(immediate Kangaroo mother care), VLBW(very low birth weight babies), neonatal mortality, weight gain.

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INTRODUCTION

Since 1990, there has been a significant global improvement in child survival. Neonatal fatalities decreased from 5.0 million in 1990 to 2.3 million in 2022 on a global scale. One million infants die prematurely in the first 24 hours of life, making the first week of life the most common time for neonatal mortality 75% (1). Preterm birth, birth complications (birth asphyxia/trauma), newborn infections, and congenital malformations are the primary causes of death among neonates, accounting for nearly 4 out of every 10 fatalities in children under the age of five. It is noteworthy that while rates of the world's primary causes of newborn deaths have decreased, the neonatal mortality rates since 2000 to 2022 were found to have unchanged. For new mothers and babies around the world, having access to the availability of high-quality medical care continues to be a matter of life or death. Majority of the newborn deaths happen in low and middle-income countries (2).

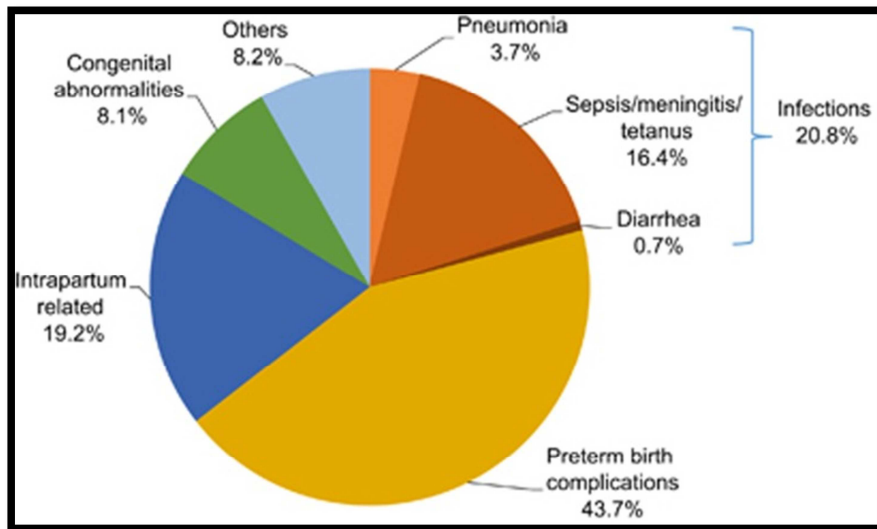
Studies in India has shown similar trends. The rate of newborn mortality in India has decreased from 85.6 [78.5 - 93.3] in 1969 to 19.1 [17.1 - 21.4] in 2021, a change of 66.5 deaths per 1000 live births (3). In 2020, neonatal mortality rate in India was 20 per 1000 live births. More than 25% of newborn fatalities and one-fifth of live births worldwide are attributed by India (4). Majority of the neonatal deaths occur in the first week after birth (75%). One in million newborns die within first 24 hours of life (3).

An infant born less than 2500 gm of weight is considered as low birth weight (LBW) and less than 1500 gm is considered as very low birth weight (VLBW) according to the World Health Organization (9). Prematurity, intrauterine growth restriction, or both might result in low birth weight. It is intimately linked to a number

of adverse health outcomes, including stunted growth and cognitive development, fetal and neonatal mortality and morbidity, and noncommunicable diseases (NCDs) in later life. Compared to heavier infants, low birth weight infants have a about 20 times higher death rate. In poor nations as opposed to rich countries, low birth weight is more prevalent. The lack of reporting of low-birth-weight infants occurs because many deliveries take place in homes or tiny medical facilities, making data on LBW infants in underdeveloped nations scarce. The number of LBW instances may have been significantly underestimated as a result of these cases not being included in official statistics (9).

Around 30% of neonates are born with LBW(<2.5kg) in India. This attributes to 42% of the global burden making India the highest contributor. Among which 60% are term with IUGR(intrauterine growth restriction) and the rest 40% are preterm. The Million Death Study Collaborators conducted a survey which showed three causes contributed to 78% of the neonatal deaths in India: prematurity & low birth weight, neonatal infections and birth asphyxia & trauma. The mortality rate among the preterm babies are 38.8%(1) according to a survey conducted in 2021. Sustainable Development Goal (SDG) target 3.2 is about ending preventable deaths of newborns and children under 5 years of age (5). Preterm birth, low birth weight, infections and birth complications including birth asphyxia or trauma are the leading causes of neonatal deaths in India. If we want to reduce the current neonatal mortality which is one of the important goals of SDG, we will have to reduce the mortality rate especially in preterm. Hence it is necessary to understand why preterm babies are prone for increased mortality and morbidity. In India leading cause of death in preterm babies were found to be Sepsis which accounted for 42.2%, followed by RDS

(21.1%) and other causes such as hypothermia (10%), hypoglycemia(5.3%), delay in initiation of breastfeeding(0.8%) and other causes(20.6%).(5)



Preventive measures, early diagnosis, prompt care seeking, administration of the proper antibiotics, and follow-up can prevent the majority of these deaths. Early identification of clinical signs, symptoms, and syndromes is necessary for an early diagnosis. The most effective and evidence-based intervention which is feasible even in a low resource setting is known to be Kangaroo Mother Care (KMC). KMC is known for stabilization of body temperature, improvement of breastfeeding rate, and reducing mortality and chances of sepsis among neonates. However, KMC is ideally recommended to be started after stabilization of the neonate. Recent studies have shown that immediate KMC (iKMC) which is initiated as soon as possible, even before stabilization of the baby has shown to decrease mortality and that the benefits of KMC can be extended to unstable LBW babies.

Study Rationale

Regarding the impact of starting continuous Kangaroo Mother Care shortly after the child birth before stabilization among low birth weight child is still argumentative. Several studies demonstrated the benefits of KMC in different settings, while there is a limited research comparing the immediate initiation of KMC and its impact on the newborn with a birthweight of (1-1.5kg) in our study settings.

The reasons for limited research in this area might be because of the challenges in conducting the study such as, dedication and willingness of KMC provider, needing of a separate infrastructure to keep both the mother and baby together in NICU and the resources needed for constant monitoring of both mother and the baby.

To reduce this knowledge gap, this study intends to overcome the challenges and estimate the effect of iKMC initiation before the stabilization of the VLBW babies compared with KMC initiated after stabilization of these newborns.

AIMS AND OBJECTIVES

PRIMARY OBJECTIVE: To study the impact of immediate KMC vs Neonatal Intensive Care using warmer in preterm infants weighing (1-1.5kg) on early neonatal mortality, in a tertiary care hospital.

SECONDARY OBJECTIVES: To determine the effect of the intervention on:

1. Time taken for physiological stabilization
2. Hypothermia
3. Time taken to reach full breast feeding
4. Hypoglycemia
5. Clinically suspected sepsis
6. Duration of hospital stay
7. Weight gain of infants

REVIEW OF LITERATURE

Complications of preterm

There are several mechanisms in preterm delivery which causes various complications in the infants. It majorly impacts their health, growth and development. Some of the most important complications leading to early infant mortality and morbidity of preterm birth includes hypothermia, hypoglycemia, RDS, increased duration of hospital stay, delay in breastfeeding and sepsis.

Hypothermia

The WHO classifies 36-36.4 degree Celsius as mild/cold stress, 32-35.9 degree Celsius as moderate and lower than 32 degree Celsius as severe hypothermia. The optimal neonatal body temperature is to be maintained between 36.5-37.5 degree Celsius. There is a sudden drop in temperature immediately after birth especially in preterm neonates due to the stress they undergo during delivery. The main reason for increased risk of hypothermia in preterm babies is attributed to their large surface area-to-body mass ratio and poor thermoregulation. Hypothermia itself can lead to several complications such as NEC, IVH, sepsis and eventually death. Several strategies are being implemented to prevent hypothermia such as use of radiant warmers, using polyethylene films, preheating of elements in contact with the baby etc. One of the interventions which has proved to be the most effective amongst the others is the initiation of early skin to skin contact/iKMC.

A multi-country randomized controlled trial conducted in the tertiary hospitals in five LMICs in South Asia and Sub-Saharan Africa including countries including India, Ghana, Malawi, Nigeria and Tanzania. The study intervention was to provide immediate KMC after the child birth among children with LBW between 1 to 1.8 Kg.

In KMC group the neonatal death was observed as 12%, whereas in control group with conventional therapy, it is 15.7%. A significant reduction in neonatal death was reported (19, 20). The incidence of hypothermia was found to be reduced by 2.7% in the intervention group compared to the control group. Hence this study proves that iKMC have positive role in prevention of hypothermia, but unfortunately due to the high mortality rate in control group this study had to be stopped early as per the recommendation of data and safety monitoring board.

Stabilization

Stabilization of a neonate is defined as the establishment of regular spontaneous breathing, a heart rate of ≥ 100 bpm and oxygen saturation of above 90% while using $F_{iO_2} < 40\%$. Due to the sequence of events during delivery, neonates especially preterm/LBW undergo a lot of physiological stress which are reflected in their need for cardiopulmonary support during their initial stabilization phase. Intervention to promote early stabilization in preterm include, drying, warming, delayed cord clamping, maintenance of strict aseptic precautions in the delivery room and NICU. Studies have shown that iKMC is the cheapest and most effective intervention which helps in early stabilization of neonates.

Two randomized, controlled trials carried out in South Africa and Vietnam assessed the impact of starting kangaroo mother care right after birth on physiological stabilization. Early skin-to-skin contact following delivery in LBW infants led to earlier stabilization than standard care in both trials. A randomized control trial with LBW (1500 to 2500 gm) was Vietnam conducted in over a period of 1 year (December 2010 –to December 2011). 50 babies to intervention (skin to skin contact) and 50 babies to control (separated from mothers and kept in incubators) were randomized. Stabilization of infants were assessed by SCRIP (Stability of cardio

respiratory system in preterm) repeatedly over the first 6 hours of life. This study showed that there was evidence of decreased morbidity in skin-to-skin contact group in relative to the maternal and infant separation group. This study also suggests that early stabilisation period is the key predictor for subsequent clinical course as need for ventilation and iv fluids were higher in control group (16, 17).

Delayed Breastfeeding

In the initial stages of stabilization, especially preterm babies due to their immaturity and absence of suck and swallow reflexes and other risk factors such as NEC, enteral feeds are initiated and increased at an extremely slow rate. Generally breastfeeding is initiated only when the infant's coordination improves after reaching 32-34 weeks approximately. Studies shows that skin to skin contact promotes early initiation of breastfeeding in preterm neonates.

In a systematic review and meta-analysis conducted among newborn children on assessing the impact of iKMC and the neonatal outcomes showed lower mortality by 36% among iKMC group is noted when compared to the conventional care. It also improved exclusive breast feeding among iKMC group on comparison with conventional therapy by 21.2%. Other than these outcomes, newborns who received KMC had lower mean respiratory rate, pain measures, high oxygen saturation, temperature and head circumference growth (18).

Research has indicated that breast milk can have a beneficial effect on parent-child connection by increasing opportunities for bonding through skin-to-skin contact and, consequently, having a long-lasting effect on the child's behavior. Though most research show a positive trend in these categories, the degree of direct influence on

cognitive, language, motor, auditory, and vision impairment has not been constant (21, 22).

Sepsis

Neonatal sepsis is defined as the generalized systemic features of infection, associated with pure growth of bacteria from one or more sites in a neonate. It is one of the leading causes of early neonatal mortality and morbidity in India. It can be categorized in to 2: a) Early onset sepsis(EOS) – Occurs before 72 hours of birth. b)Late onset sepsis(LOS)- Occurs after 72 hours after birth. Blood culture remains the gold standard for diagnosing neonatal sepsis. Clinical sepsis is defined by the presence of changes in lab tests along with the presence of at least 2 of the following signs: hypothermia, apnea, bradycardia, feed intolerance, respiratory distress, hypo/hyperglycemia, lethargy, hemodynamic instability. Most observed complications of sepsis were impaired neurodevelopmental outcome and death. Strategies to reduce the incidence of neonatal sepsis includes, hand hygiene practices, isolation, administration of prophylactic antibiotics whenever necessary, serial monitoring of lab parameters and vitals. iKMC have been observed to reduce the incidence of neonatal sepsis.

A randomized controlled trial was conducted over a 1-year period (November 2001 to November 2002) in Addis Ababa, Ethiopia. This study was conducted to study the efficacy of early KMC (before stabilization) of LBW (less than 2000 gm) infants compared to infants receiving conventional care. 62 infants were enrolled in immediate KMC (iKMC) (started within 24 hours of life) and 61 were enrolled in conventional care. This study concluded that iKMC is safe and feasible in health facility settings and it reduces the neonatal sepsis incidence by 8.5% compared to the infants receiving conventional care (25).

Hypoglycemia

Neonatal hypoglycemia is defined as the disturbance of normal glucose homeostasis, such that the concentration of glucose in the blood does not provide the adequate glucose necessary for a target organ. According to the latest IAP guidelines. Blood sugar less than 40mg/dL in symptomatic infants and in asymptomatic infants , less than 25mg/dL (less than 4 hours of birth), less than 35mg/dL(4-24 hours of birth), less than 45mg/dL(24-48 hours of birth) and less than 60mg/dL(more than 48 hours of birth) is considered as hypoglycemia. Several interplays of mechanisms causing hypoglycemia are, limited glycogen and fat stores, lack of gluconeogenesis, larger demand and inability to mount a counter-regulatory response to hypoglycemia. Hypoglycemia is considered as an emergency in neonates as it can cause permanent neurological damage which may even lead to death. Among the many interventions recommended for the prevention of hypoglycemia, iKMC has been proven to reduce the incidence of hypoglycemia significantly.

RDS (respiratory distress syndrome)

The incidence of RDS is proven to be higher with decreasing gestational age of the baby. RDS can lead to number of fatal complications such as septicemia, BPD (bronchopulmonary dysplasia), PDA, NEC etc. Preventive measures such as antenatal steroids, administration of surfactant had significantly reduced RDS related mortality. iKMC has been proven to have beneficial effects in RDS by causing autonomic stabilization of the rhythm and rate of breathing.

Duration of hospital stay

Initiating early skin to skin contact has shown effects in reducing the time taken for the duration of hospital stay. Studies have shown that the earlier iKMC is initiated and the longer duration it was provided, it had more positive effects on hospital stay and stabilization. In conventional care, the longer duration of hospital stay itself causes increased chances of hospital acquired infections.

A meta-analysis was conducted in the Cochrane database during 2012 assessing 34 randomized control trials comparing early skin to skin contact with conventional care. Statistically significant positive effect of early skin to skin contact on reduction of incidence of hypoglycemia, RDS and reduction of hospital stay were found.

Kangaroo Mother Care (KMC)

One of the most effective strategies for preventing death in low-birth-weight infants is "kangaroo mother care," which is defined as feeding the infant only breast milk and providing constant skin-to-skin contact between the infant and the mother (or a surrogate if skin-to-skin contact is not possible) (10). According to current World Health Organization (WHO) standards, when an infant's condition starts to stabilize, short, intermittent sessions of kangaroo mother care should be started. Once the infant's condition has stabilized, kangaroo mother care should be continued (11) (Figure 1).

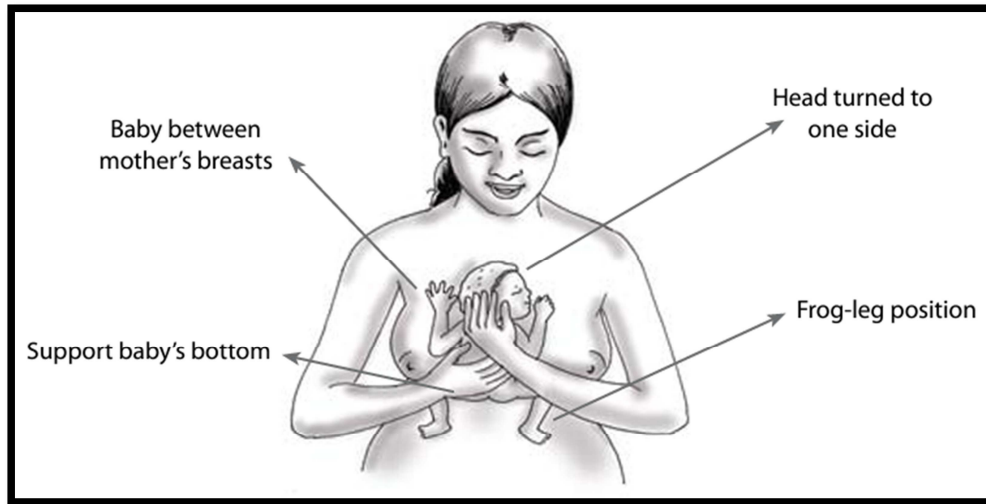


Figure 1: Kangaroo Mother Care (Source: Koreti M, Muntode Gharde P, 2022)

In Bogota, Colombia, Dr. Edgar Rey Sanabria established kangaroo mother care (KMC) in 1978 as a substitute for incubators for LBW children (12). Early, continuous, and sustained skin-to-skin contact (SSC) between the mother and newborn, exclusive breastfeeding, an early release from the medical institution, and close follow-up at home are the components of KMC as defined by the World Health Organization (11). It is hypothesized that KMC improves newborn outcomes by offering the advantages of breastfeeding and by using SSC to regulate the infant's temperature and other vital sign parameters. All newborns are believed to benefit from these benefits, however preterm infants may benefit more than others.

It mainly developed smart ways to make up for the lack of facilities to treat LBW babies. KMC reduces risks of newborn infections and hypothermia while also shortening hospital stays. Since KMC doesn't require energy or technology, it can be offered in environments with low resources. Premature birth and restricted intrauterine growth are the causes of low birth weight. It is associated with rising risks of death for fetuses or newborns, delayed growth or cognitive development, and chronic illnesses in later life. A main objective of "A World Fit for Children" is to

achieve a roughly one-third reduction in the incidence of LBW between 2000 and 2010. In order to promote breastfeeding and bonding, the United Nations General Assembly Special Session on Children established an action plan and statement in 2002. Placing the premature newborn to the mother's chest to encourage bonding and breastfeeding is how KMC is embraced globally. Experts in clinical health also thought that putting KMC into practice would strengthen the emotional ties that mothers had with their babies. Newborns felt safer and moms and their babies were both calmer as a result. Additionally, it was shown that KMC encouraged the babies' growth and development, which strengthened the mother's sense of attachment. Equipment use is not required for KMC. The KMC technique increases the baby's safety and aids in the care of premature infants (14).

KMC entails the mother and child coming into contact with each other's skin. From the moment of birth, the mother and child have skin-to-skin contact, which lasts until the infant is stabilized. KMC typically takes three to seven days and lasts for at least one to three hours each day. For example, there may be little pauses while bathing the baby. The woman must begin breastfeeding an hour after giving birth, and the session may continue for two or three hours. An underweight newborn is too weak to suckle successfully in the first few days of life, therefore the mother needs to learn how to express milk so she may feed the child from paladai. Other family members can also administer KMC to the newborn when the mother is preoccupied with her everyday responsibilities. Because of KMC, the infant gains weight and sleeps for longer periods of time. The infant is placed on the mother's bare chest, typically covered with a warm blanket, in the skin-to-skin contact method (13).

KMC is linked to a lower incidence of serious illnesses in infancy, such as pneumonia. KMC has been shown to be more successful than incubator care for stable newborns in the majority of studies. This is because KMC fosters greater maternal and family involvement in care, offers adequate thermal care, lowers the risk of nosocomial infections, improves exclusive breastfeeding and weight gain, and is less expensive than incubator care.

Time of initiation of KMC

All low-birth-weight newborns should be provided with KMC. However, newborns with less than 2 kg weight should be prioritized. Figure 2 shows the guidelines for time of initiation of KMC based on the birth weight of the newborn.

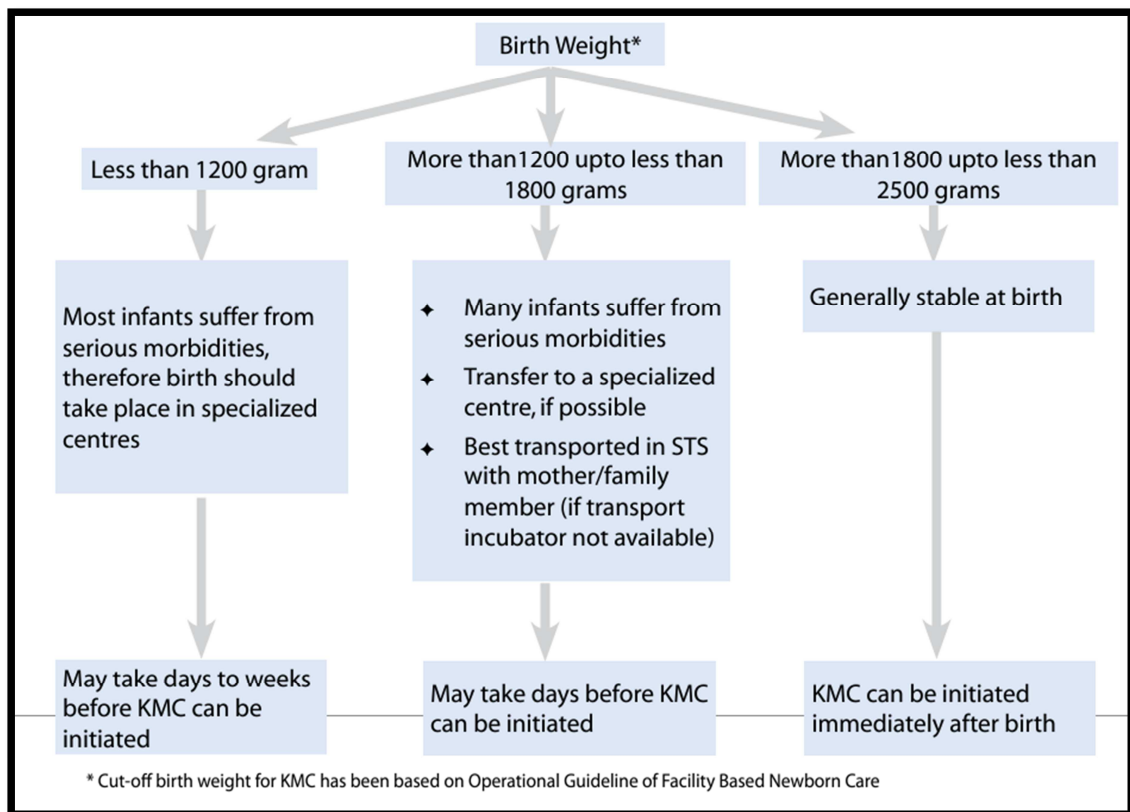


Figure 2: Time of initiation of KMC based on birth weight

Newborns with birth weight of 1.8 to 2.5 Kg are usually stable and KMC can be immediately initiated after birth for these newborns. Newborns with weight 1.2 to 1.8 Kg might have some morbidities and require treatment at a tertiary centre. For newborn with birth weight between 1.2 to 1.8 Kg it may take few days to initiate KMC (to stabilize the newborn). For newborns less than 1.2 Kg birth weight, most of them suffer from serious morbidities and should be transferred to a tertiary care centre if facilities are not available in the birth hospital. For these newborns, it may take a few days to weeks for stabilization of the newborn and hence initiation of KMC (Figure 2).

Who can provide KMC

Fathers, moms, and other adult family members can offer KMC. The KMC provider must be willing, healthy, free from major illnesses, and uphold basic hygienic practices including hand washing, taking a daily bath, cutting fingernails, tying up hair, and dressing in clean clothes. It is advised that jewelry, watches, and holy threads be taken off since they could make it difficult to maintain cleanliness and put the baby in danger (14).

How to provide KMC

Counselling

To overcome socio-cultural hurdles and be concerned in caring for an LBW infant, both the mother and other family members must get effective counselling before beginning KMC. The first counselling session should be scheduled at a time that works for the mother when the baby is ready for KMC. To build a rapport with the mother and allay any fears, the first few sessions are crucial and call for prolonged engagement. She should be shown the KMC process, which explains the proper

position in a patient in a kind and compassionate manner. To ease her fears, her questions ought to be addressed. Urge her to bring her spouse, mother-in-law, or any other family member. It contributes to the family's uplift and guarantees the mother's support, both of which are especially important for home-based KMC after discharge. It is beneficial for the mother and other family members to engage with someone who has experience with KMC for her infant. Family support is vital for a successful KMC.

Clothing for mother and infant

The baby should be dressed with a front-open sleeveless shirt, or "jhabala," made of soft natural fabric, such as cotton, socks, and disposable diapers (Figure 3).

For mother, KMC can be given with any light, front-open clothing appropriate for the community. KMC looks great with a shawl, gown, or sari blouse. An appropriate article of clothing, such as a kangaroo bag, baby bag, sari, or binder, that can hold the child for a long time can be customized locally. No special cloth or dress is required for KMC (Figure 4).

Duration of KMC

Each session should last at least two hours as frequent handling of the newborn may be stressful for them. Duration should be increased gradually based on the mothers ability to provide longer sessions. During changing the diapers and clinical examinations by the physicians and other healthcare nurses, the baby can be removed from KMC (14).

Precautions while providing KMC

Especially in the early phases, infants getting KMC need to be closely observed to make sure their airway is clean, their breathing is regular, their skin is pink, and their body temperature is being maintained. The neonatal case sheet that is used in the unit should accurately document all of the aforementioned clinical observations and the length of KMC. In order for a mother to continue monitoring her child at home, she should be taught to watch for warning indicators such as hypothermia, respiratory issues, feeding difficulties, and color changes during KMC.

Infants who received kangaroo mother care after stabilization had a mortality rate that was 40% lower than those who received conventional care in an incubator or a radiant warmer (3.2% vs. 5.3%; risk ratio, 0.60; 95% CI, 0.39 to 0.92). This was determined by a meta-analysis of eight hospital trials that included a total of 1736 infants. Additionally, this meta-analysis shown that compared to infants who did not receive kangaroo mother care, those who did had greater weight growth, higher rates of exclusive breastfeeding, and fewer infections. The review encompassed studies where the infants' status was deemed stable at randomization, and the mean age at that point varied from 10 hours to 24.5 days of life (15).

A population study of all live births was conducted in England and Wales between January 1st 1993 to December 31st 2011. This study results showed that LBW (1.5 - 2.49 kg) and VLBW (0.5 - 1.49 kg) compared to less than 3kg infants had higher rate of infant and childhood mortality. Around 23% of deaths occurred during 1st year of life. Respiratory distress and sepsis were the major contributing factors followed by congenital malformations and Central nervous system conditions (23).

Low-income nations carried out three published randomised controlled trials (RCTs) contrasting KMC with traditional treatment. The survival rates of the two groups did not differ, according to the findings. In the three trials, almost every death happened before to eligibility, that is, before LBW infants were stabilised and recruited for study. After receiving traditional treatment for an average of 3–14 days, infants weighing less than 2000g were enrolled in urban third-level hospitals. In two of the investigations, the KMC infants were discharged sooner and were subject to a tight ambulatory follow-up; in the third research, however, they stayed in the hospital until they met the standard criteria for discharge, just like the control infants did. One, six, and twelve months were the lengths of the follow-up periods, respectively (21, 26, 27).

In comparison to the control group (18%), KMC infants had a lower rate of severe illness (5%) in the RCT conducted in Ecuador by Sloan and associates ⁽²¹⁾. While there was no discernible difference in severe morbidity, the KMC group had fewer hospital infections and readmissions than the previous controlled trials carried out in low-income nations. Reductions in hospital infections were also reported by Kambarami and co-workers from Zimbabwe ⁽²⁸⁾. There is no difference in morbidity reported by high-income nations. What is noteworthy, though, is that skin-to-skin contact does not appear to carry any greater risk of infection ^(21, 26, 27, 28).

A prospective study of all early neonatal deaths in a tertiary care hospital of Maharashtra over 2 years (between year 2016 to 2018). This study results showed that early neonatal death rate (babies weighing over 1000 gm during 1st 7 days of life) was 36.18 per 1000 live births. About 80% of neonatal death were due to LBW and VLBW among which the leading cause of death was birth asphyxia and respiratory

distress. Hence proper management of LBW and VLBW plays a major role in prevention of early neonatal mortality (24).

Preterm/LBW infants may benefit from KMC in reducing death and morbidity, according to observational studies. Numerators, denominators, and follow-up in the KMC group were distinct from those in the historical control group, making it challenging to evaluate their findings (28).

MATERIALS AND METHODS

Source of data: Preterm newborns with a weight between 1 Kg and 1.5 Kg admitted in Neonatal Intensive Care Unit (NICU) of KLEH Dr Prabhakar Kore Charitable Hospital, Belgaum were included in the study.

Study duration: One year between

Study design: Non-blinded randomized controlled trial

Sample size: The formula used for sample size calculation is,

$$n = \frac{(Z_{\alpha/2} + Z_{\beta})^2 * (p_1(1 - p_1) + p_2(1 - p_2))}{(p_1 - p_2)^2}$$

where p_1 is the proportion of group 1, p_2 is the proportion of group 2. For 95% confidence level, $Z_{\alpha/2}$ value is 1.96 and for 80% power Z_{β} value is 0.8416.

Kangaroo Mother Care (KMC) applied after stabilization of the infant has been shown to reduce mortality by 40% among hospitalized infants with a birth weight of less than 2.0 kg. Mortality in control group is 21% and expected mortality in intervention group is 12.6%.(19). From previous records, it was found that the hospital has about 60 cases in a year. For this population, the minimum sample size required is 27 subjects per group. Total sample size required is $27 \times 2 = 54$ subjects. For this population, the minimum sample size required was 27 subjects per group without considering the dropout rate in each group. With the dropout rate of 15 %, $N=n/(1-(z/100))$, sample size required was 30 subjects approximately in each group with a total of 60 study participants (30 x 2).

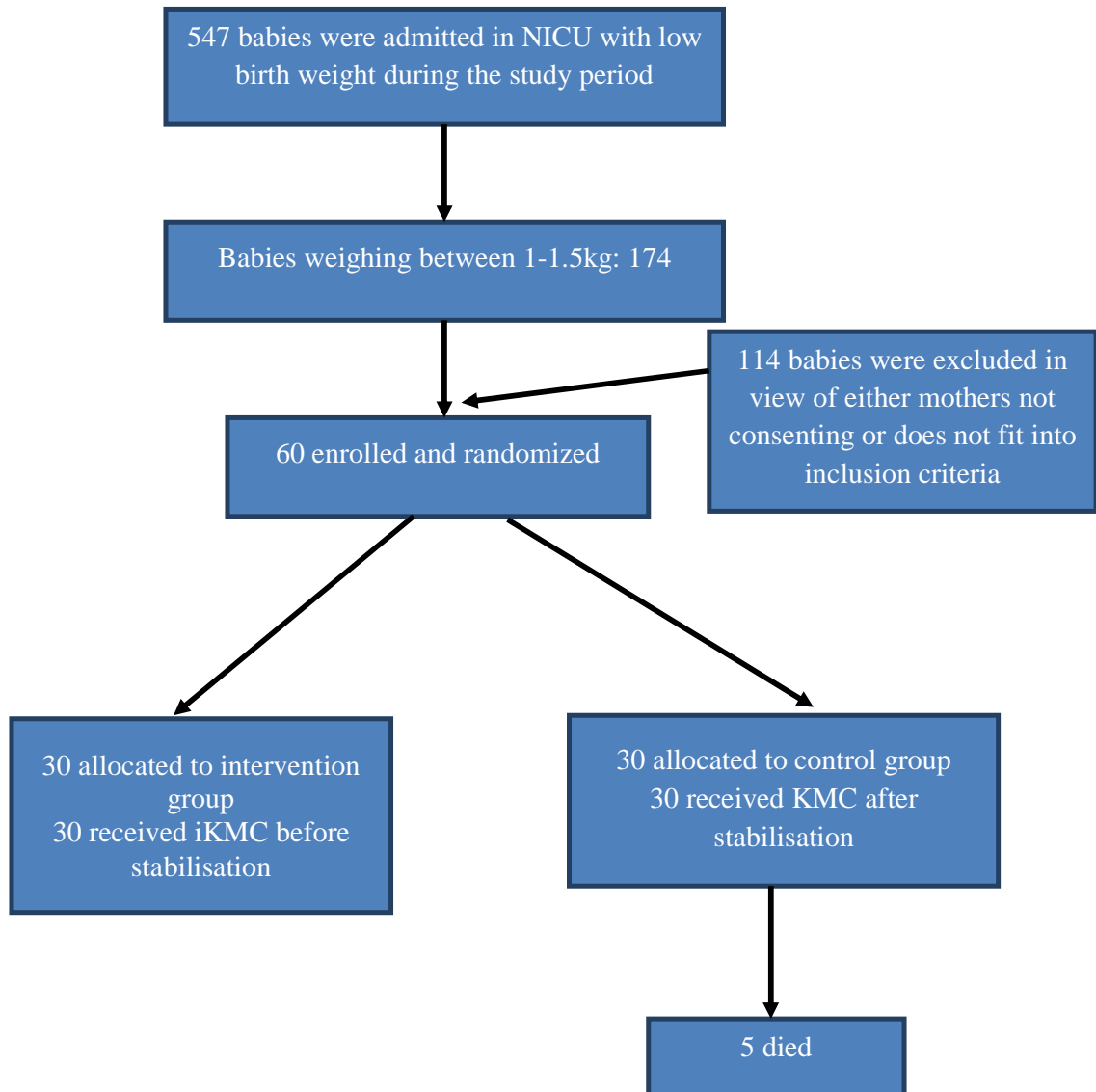




Fig: 5 Pictures of mother providing Kangaroo Mother care to their newborns

Inclusion criteria

- I. All live newborns delivered in the hospital with a birth weight from 1.0 to 1.5 kg, regardless of their gestational age, were eligible.
- II. Only singleton births were included.
- III. The mother–infant dyad was eligible even if the mother experiences some complications during labor and delivery that were expected to be resolved.

Exclusion criteria

- The mother was younger than 15 years of age
- The mother was unable or unwilling to provide consent
- The mother was unlikely to be able to provide KMC initiation within the first 3 days after birth (Eg: eclampsia or shock or has undergone major surgery)
- Baby was unable to breathe spontaneously within 1 hour of birth
- Baby on ventilatory support/CPAP
- Multiple gestation
- Baby had a congenital malformation that interfered with the intervention.
- If for any other reason the mother infant pair cannot be enrolled within 2 hours of delivery.

Study method

Mother-infant dyad who were eligible for the study based on the inclusion and exclusion criteria were enrolled in the study after obtaining informed consent from the pregnant women in the labor room before delivery. Consenting mothers were asked to identify one or two adult relatives or friends of their choice who can act as their surrogates for providing skin-to-skin contact when or if the mother would not be able to provide iKMC. The nominated surrogates were provided with the study details and explained about if the mother-infant dyad were randomly assigned to intervention

group. Soon after delivery, babies were shifted to radiant warmer. Initial steps of resuscitation followed as per protocol.

If the infant was allocated to the intervention group, the nurse who attended the delivery helps to initiate skin to skin contact as soon as possible between the infant and the mother/surrogate in the labor room. Baby's heart rate, saturation and other vital parameters were closely monitored. Skin to skin contact was ensured during the transfer of the baby and the mother/surrogate to NICU by the nurse. In the NICU the researcher ensured the continuation of skin to skin contact by the mother/surrogate.

The infant was kept in skin-to-skin contact for at least 6 hours per day, with the mother/surrogate. However, if mother was not able to provide, the surrogate provided skin-to-skin contact during the absence of mother. During KMC, the infant was put naked on the mother's chest. The infant had a cap, diaper, and socks and was secured firmly to the chest with a binder that ensured a patent airway and a shirt that provides containment in the fetal position. All routine care was provided in skin-to-skin contact. Any interruptions in skin-to-skin contact were documented to determine the duration for which the intervention was provided per day. The nurse also supported the mother in early expression of milk and helped the baby suckle at the breast. Babies who needed ventilator/CPAP support soon after birth were excluded and babies on oxygen support by nasal prongs and on IV fluids were included. Continuous KMC were provided by the mother/surrogate in the NICU next to the warmer and only when the baby is being changed or procedures such as IV line insertion are being carried out or to complete the mother's/surrogate's daily routine activities the babies were kept back on the warmer. Each session was for a minimum of 2 hours such sessions were given as much as possible.

If the infant was allocated to the control group, routine care was provided by the hospital staffs. The infant was transferred to the NICU in a radiant warmer as soon as possible. If they required respiratory support /IV fluids, they were provided with the necessary support. When discharged from the delivery room or operation theatre, the mother was transferred to the postnatal ward and the infant remains in the NICU in accordance with current guidelines. When the infant was ready to be fed, the mother provided milk in the form of expressed breast milk or direct breastfeeds. In case if the mother's milk was not adequate, donor milk/lactogen feeds were provided. After the stabilization of the infant, the mother provided KMC as per the current WHO guidelines. In this context, stabilization of the baby was considered in terms of , able to tolerate feeds, able to take spontaneous breaths without respiratory support and completely off of IV fluids support.

In both the groups, infant in the NICU was monitored, and information regarding temperature, heart rate, respiratory rate, capillary blood glucose and oxygen saturation were recorded every 15 mins in the 1st hour and then 6th hourly. Vital parameters were monitored daily and the trends were observed. Weight was checked every day and other anthropometry such as length and head circumference was measured weekly once. The mode, frequency and type of feeds were also noted. Any issues faced during the hospital stay was recorded along with the duration of interruption of intervention was recorded. Routine nursing care such as monitoring, providing support was same for both the groups. At discharge, the anthropometry, general condition and outcome of the babies were noted and the mothers were explained about the need for continuation of KMC, their benefits and the need for regular follow up in the high-risk baby clinic. After discharge, all infants were regularly followed up until they reach 2.5kgs.

RESULTS

Results of the study: IMPACT OF CONTINUOUS KANGAROO MOTHER CARE INITIATED IMMEDIATELY AFTER BIRTH (iKMC) VERSUS CONVENTIONAL CARE ON NEWBORNS WITH BIRTH WEIGHT BETWEEN 1.0 TO 1.5 KG – A ONE YEAR RANDOMIZED CONTROL TRIAL.

A one year hospital based randomized control trial was conducted at KLES Dr. Prabhakar Kore hospital. All Very low birth weight babies fitting in the inclusion criteria were included in the study. A total of 2024 deliveries were conducted in the labour room from July 2023 to December 2023. Out of this 547 babies were admitted in the NICU. A total of 174 babies weighing between 1-1.5kg were admitted. Out of these 174 babies, 60 babies were selected to be included in the study based on the inclusion criteria and those who gave consent to be a part of study. Newborns selected for this study were enrolled and randomised into 2 groups. Details regarding the birth weight, gestation, parity, mode of delivery, number of hours KMC provided, data were collected.

Statistical methods:

- Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency, and proportion for categorical variables. Data was also represented using appropriate diagrams like bar diagram.
- The association between explanatory variables and categorical outcomes was assessed by cross tabulation and comparison of percentages. Chi square test was used to test statistical significance.

- The association between quantitative explanatory variables and categorical outcomes was assessed by independent sample t-test (2 groups) was used to assess statistical significance.
- P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis. (1)

Randomisation groups:

60 newborns were allocated into 2 groups with each group having 30 subjects each (50%).

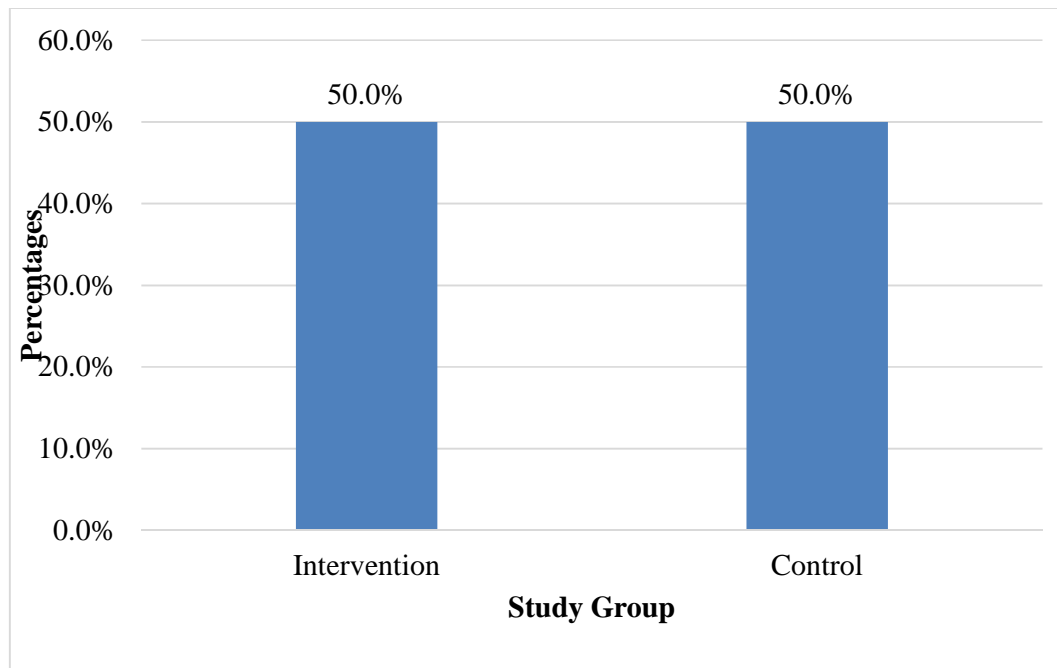
Intervention group: Immediate KMC (iKMC) is initiated immediately after birth even before stabilisation of the infant.

Control group: Conventional care provided in radiant warmer and KMC initiated after stabilisation of the baby.

Table 1: Descriptive analysis of study group in the study population (N=60)

Study Group	Frequency	Percentages
Intervention	30	50.00%
Control	30	50.00%

Figure 1: Bar chart of study group in the study population (N=60)



MATERNAL FACTORS:

Maternal age: The maternal age distribution shows the vast majority of mothers (86.6%) were between 20-30 years old. A smaller proportion 10% were less than 20 years and a very small number (3.4%) were over 30 years old. When compared across the groups, majority of participants in each group are aged between 20-30years, with a slightly higher proportion in control group compared to intervention group. No statistical significant difference was found.

Table 2: Comparison of maternal age (years) between study group (N=60)

Maternal parameter	Study Group		Overall (N=60)	Chi square	P value
	Intervention (N=30)	Control (N=30)			
Maternal Age (Years)					
<20 Years	4 (13.33%)	2 (6.67%)	6 (10%)	0.744	0.689
20-30 Years	25 (83.33%)	27 (90%)	52 (86.67%)		
>30 Years	1 (3.33%)	1 (3.33%)	2 (3.33%)		

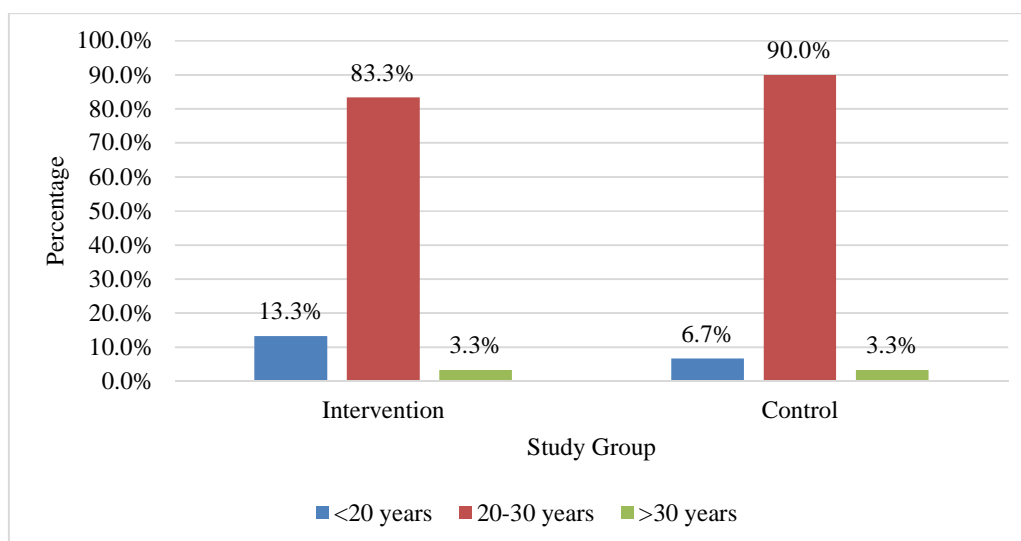


Figure 2: Cluster bar chart of comparison of maternal age (years) between study group (N=60)

Parity: Majority of the mothers (61.6%) were primigravida that were distributed across the groups in similar portion with the control group slightly higher than the intervention group and the remaining mothers were multigravida (38.4%). No statistical significant difference was found.

Table 3: Comparison of parity between study group (N=60)

Parity	Study Group		Overall (N=60)	Chi square	P value
	Intervention (N=30)	Control (N=30)			
Primi	18 (60%)	19 (63.33%)	37 (57.81%)	0.071	0.791
Multi	12 (40%)	11 (36.67%)	27 (42.19%)		

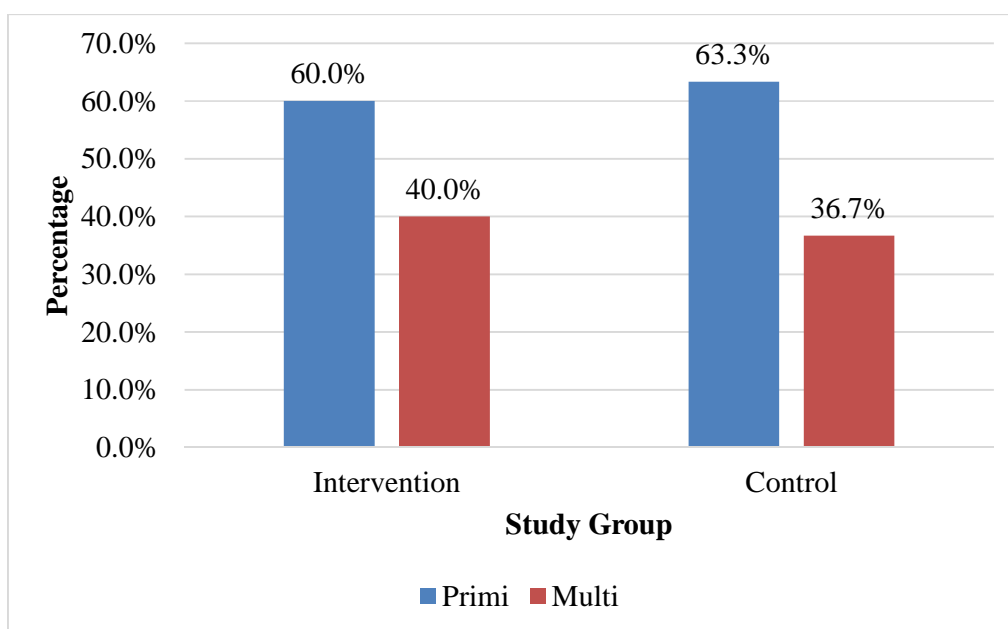


Figure 3: Cluster bar chart of comparison of parity between study group (N=60)

Mode of delivery: The proportion of mothers undergoing Lower segment caesarean section (LSCS) was slightly higher (93.3%) in intervention group when compared to control group (86.6%). Overall 90% of the mode of delivery was LSCS and only a small proportion 10% was Normal vaginal delivery (NVD). No statistical significant difference was found

Table 4: Comparison of mode of delivery between study group (N=60)

Mode of Delivery	Study Group		Overall (N=60)	Chi square	P value
	Intervention (N=30)	Control (N=30)			
LSCS	28 (93.33%)	26 (86.67%)	54 (90%)	0.741	0.671
NVD	2 (6.67%)	4 (13.33%)	6 (10%)		

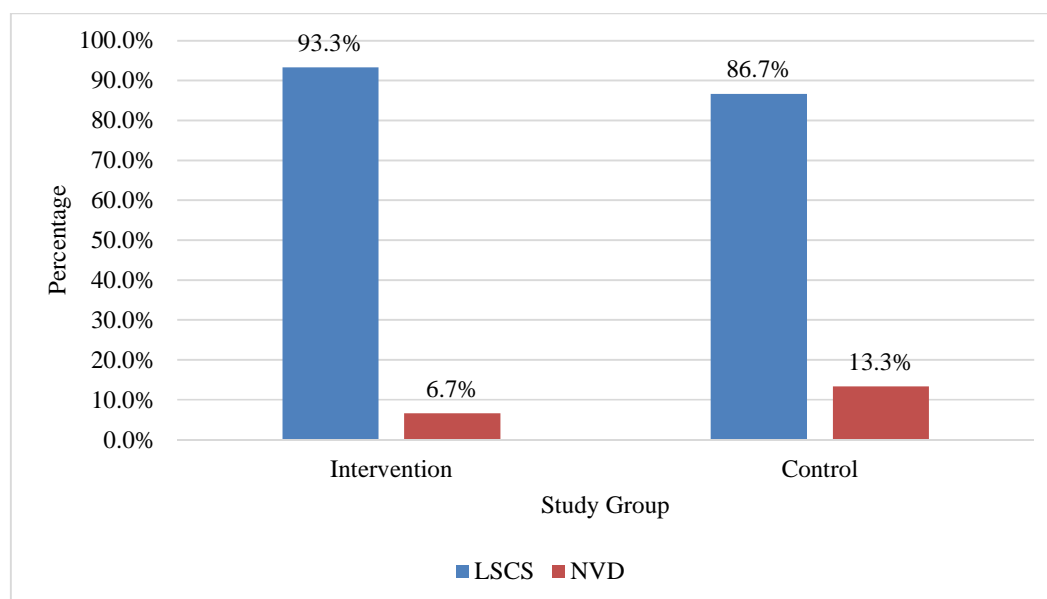


Figure 4: Cluster bar chart of comparison of mode of delivery between study group (N=60)

Maternal problems: The proportion of mothers having surgical site infection (SSI) and Postpartum blues were slightly higher in the intervention group compared to the control group. Other maternal problems like Congenital heart defect (CHD), Eclampsia, Postpartum haemorrhage (PPH) and severe anaemia were distributed almost equally between the 2 groups. No statistical significant difference was found.

Table 5: Comparison of maternal risk factors between study group (N=60)

Parameter	Study Group		Overall (N=60)	Chi square	P value
	Intervention (N=30)	Control (N=30)			
Maternal Risk Factors					
Yes	6 (20%)	4 (13.33%)	10 (16.67%)	0.48	0.488
No	24 (80%)	26 (86.67%)	50 (83.33%)		
Maternal Risk Factors (N=10)					
CHD	0 (0%)	1 (3.33%)	1 (10%)	5.139	0.399
Eclampsia	1 (3.33%)	0 (0%)	1 (10%)		
Postpartum Blues	2 (6.67%)	0 (0%)	2 (20%)		
PPH	1 (3.33%)	1 (3.33%)	2 (20%)		
Severe Anemia	0 (0%)	1 (3.33%)	1 (10%)		
SSI	2 (6.67%)	1 (3.33%)	3 (30%)		

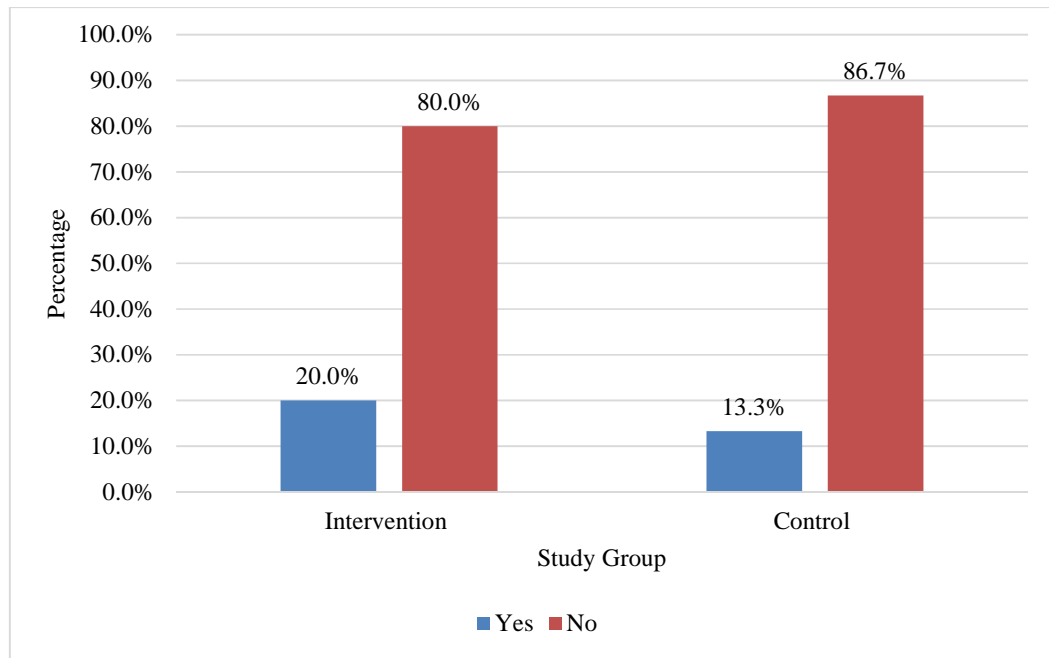


Figure 5: Cluster bar chart of comparison of Maternal Risk Factors between study group (N=60)

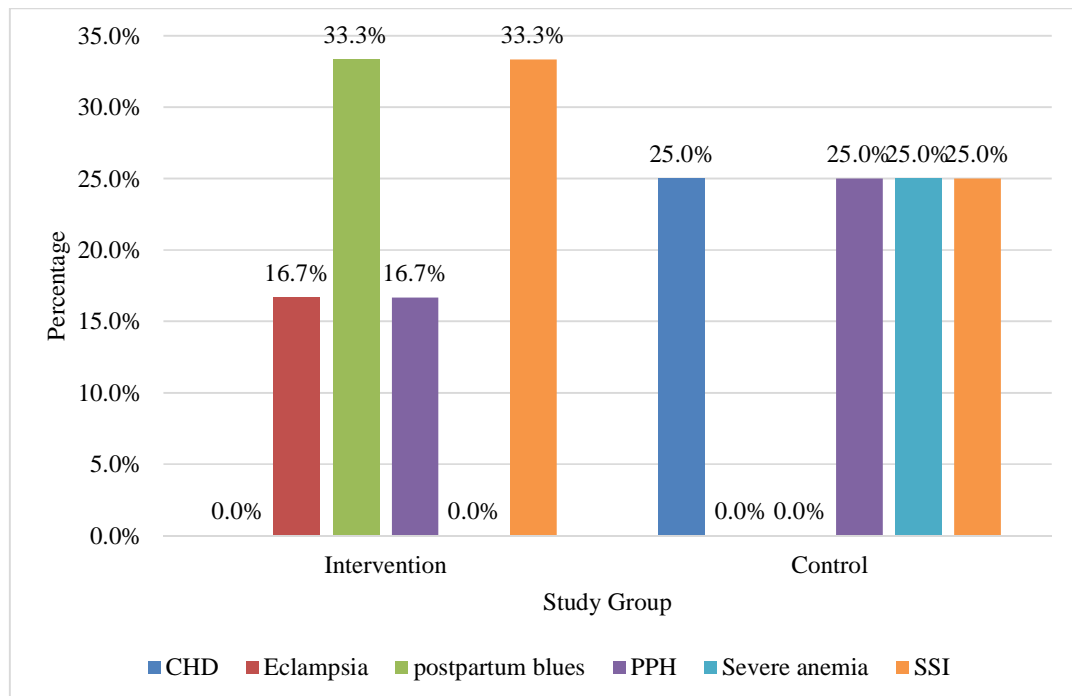


Figure 6: Cluster bar chart of comparison of Maternal Risk Factors between study group (N=60)

Table 6: Comparison of mean of maternal age (years) between study group

(N=60)

Parameter	Study Group (Mean± SD)		P value
	Intervention (N=30)	Control (N=30)	
Maternal age (years)	24.67 ± 3.69	24.5 ± 3.13	0.851

NEONATAL FACTORS:

Gender: The gender distribution in the study population shows a higher proportion of female participants (60%) compared to male participants (40%). No statistical significant difference was found

Table 7: Comparison of gender of neonate between study group (N=60)

Baby's parameter	Study Group		Overall (N=60)	Chi square	P value
	Intervention (N=30)	Control (N=30)			
Gender					
Male	12 (40%)	12 (40%)	24 (40%)	0.000	1.000
Female	18 (60%)	18 (60%)	36 (60%)		

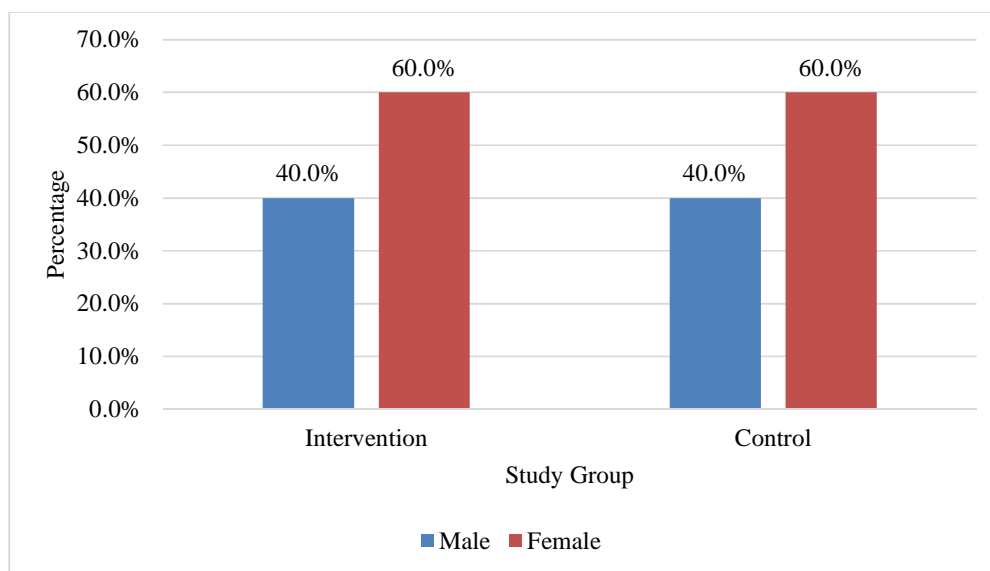


Figure 7: Cluster bar chart of comparison of gender between study group (N=60)

Birth weight: In our study population, birth weight distribution reveals that majority (65%) of the newborns weighed between 1.2 to 1.5kg. Smaller proportions were in the lower weight categories (35 %) babies were between 1 to 1.2kg out of which majority(43.3%) were in the intervention group, whereas, in category of 1.2-1.5kg majority(73.3%) were in control group. No statistical significant difference was found

Table 8: Comparison of birth weight (kg) of neonate between study group

(N=60)

Birth Weight (Kg)	Study Group		Overall (N=60)	Chi square	P value
	Intervention (N=30)	Control (N=30)			
1-1.2 Kg	13 (43.33%)	8 (26.67%)	21 (35%)	1.832	0.176
1.21-1.5 Kg	17 (56.67%)	22 (73.33%)	39 (65%)		

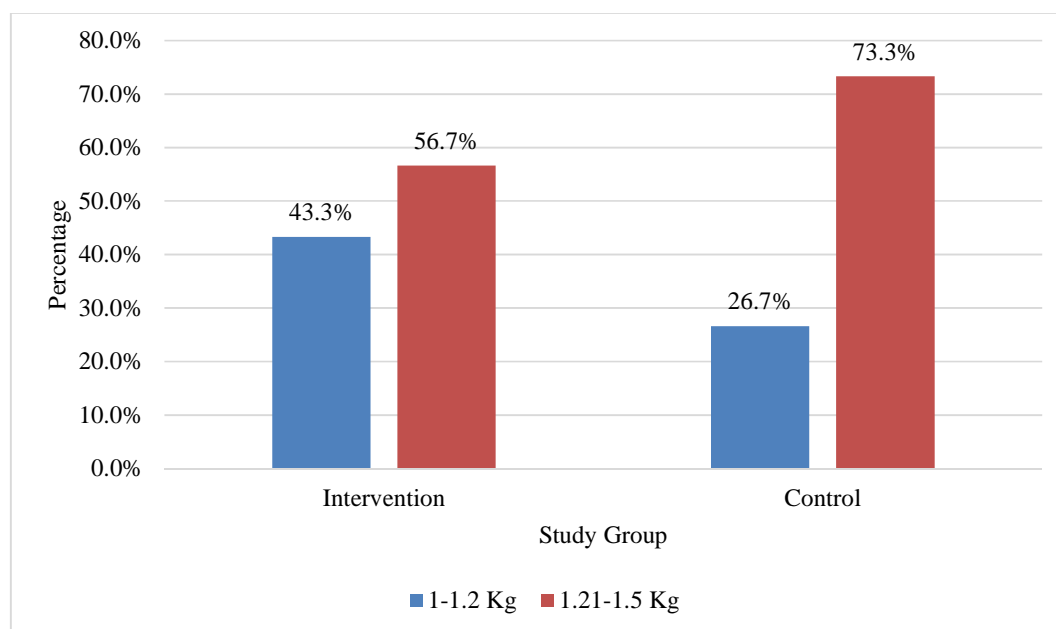


Figure 8: Cluster bar chart of comparison of birth weight (kg) between study group (N=60)

Gestational age: The majority of study population (36.6%) had a gestational age between 34 weeks 1 day and 36 weeks, this was followed by the second highest (33.3%) between 32 weeks 1 day and 34 weeks. When compared across the groups, intervention group has highest number of participants (43.3%) between 34 weeks 1 day and 36 weeks whereas the control group had almost similar distribution of participants among each category except in the category beyond 36 weeks, where all participants were found to be equal in both groups. No statistical significant difference was found

Table 9: Comparison of Gestational Age (Weeks) between study group (N=60)

Gestational Age (Weeks)	Study Group		Overall (N=60)	Chi square	P value
	Intervention (N=30)	Control (N=30)			
28-32 Weeks	6 (20%)	8 (26.67%)	14 (23.33%)	4.484	0.214
32.1-34 Weeks	9 (30%)	11 (36.67%)	20 (33.33%)		
34.1-36 Weeks	11 (36.67%)	11 (36.67%)	22 (36.67%)		
>36.1 Weeks	4 (13.33%)	0 (0%)	4 (6.67%)		

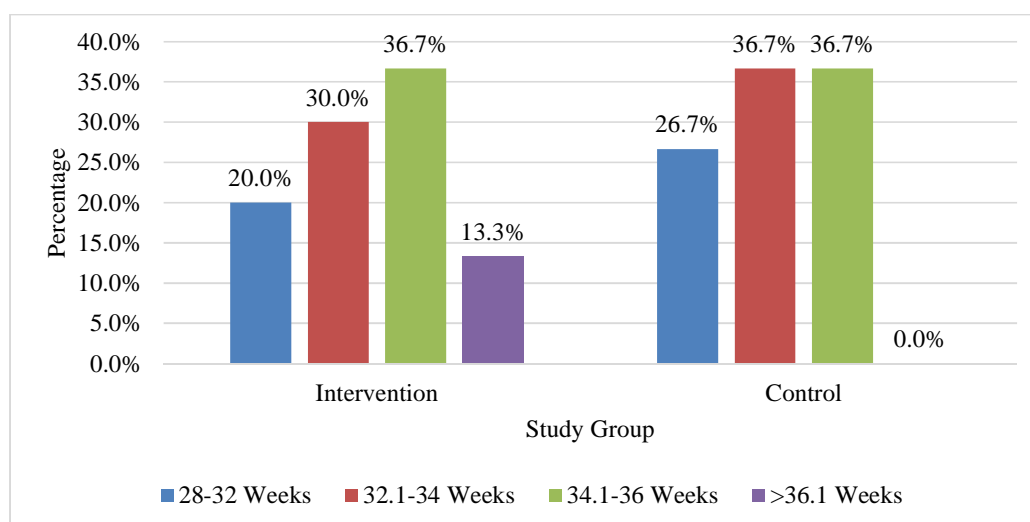


Figure 9: Cluster bar chart of comparison of gestational age (weeks) between study group (N=60)

Resuscitation: Overall, most of the babies (71.6%) in our study group did not need any form of active resuscitative measures. In the control group, 13 babies and 4 babies in the intervention group, required active resuscitation in the form of tactile stimulation or bag and mask ventilation. This difference was statistically significant. (P value-0.036)

Table 10 Comparison of Mode of Resuscitation between study group (N=60)

Resuscitation	Study Group		Overall (N=60)	Chi square	P value
	Intervention (N=30)	Control (N=30)			
BMV	2 (6.67%)	6 (20%)	8 (13.33%)	6.661	0.036
CAS	2 (6.67%)	7 (23.33%)	9 (15%)		
CIAB	26 (86.67%)	17 (56.67%)	43 (71.67%)		

CIAB-Cried immediately after birth

CAS-cried after stimulation

BMV- Bag and mask ventilation

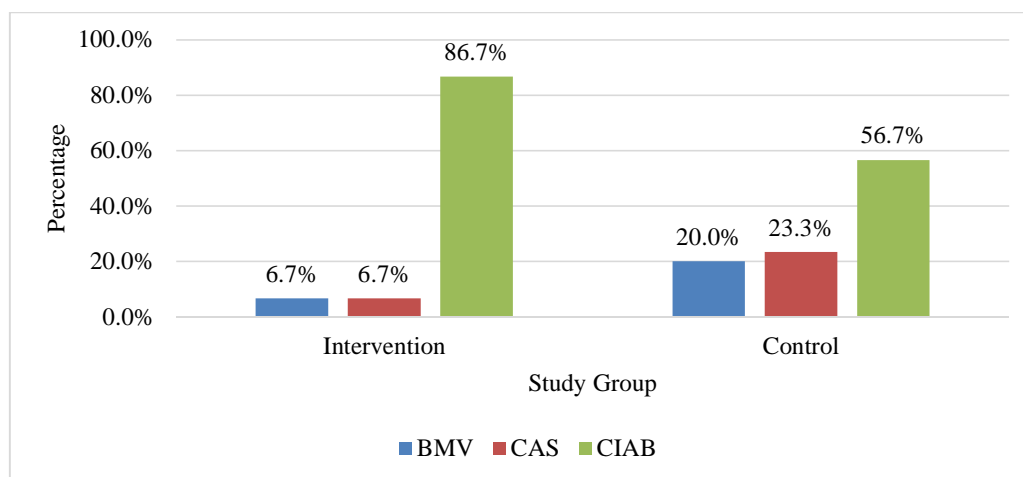


Figure 10: Cluster bar chart of comparison of mode of resuscitation between study group (N=60)

Apgar score @ 1min: 81.6% among overall population had APGAR score of more than 5 at 1 minute of birth. Total of 11 (7 in control and 4 in intervention) out of 60 babies had APGAR score less than 5 at 1 minute. No statistical significant difference was found between the 2 groups.

Table 11: Comparison of APGAR score at 1 Min between study group (N=60)

Apgar At 1 Min	Study Group		Overall (N=60)	Chi square	P value
	Intervention (N=30)	Control (N=30)			
≤5	4 (13.33%)	7 (23.33%)	11 (18.33%)	1.002	0.317
>5	26 (86.67%)	23 (76.67%)	49 (81.67%)		

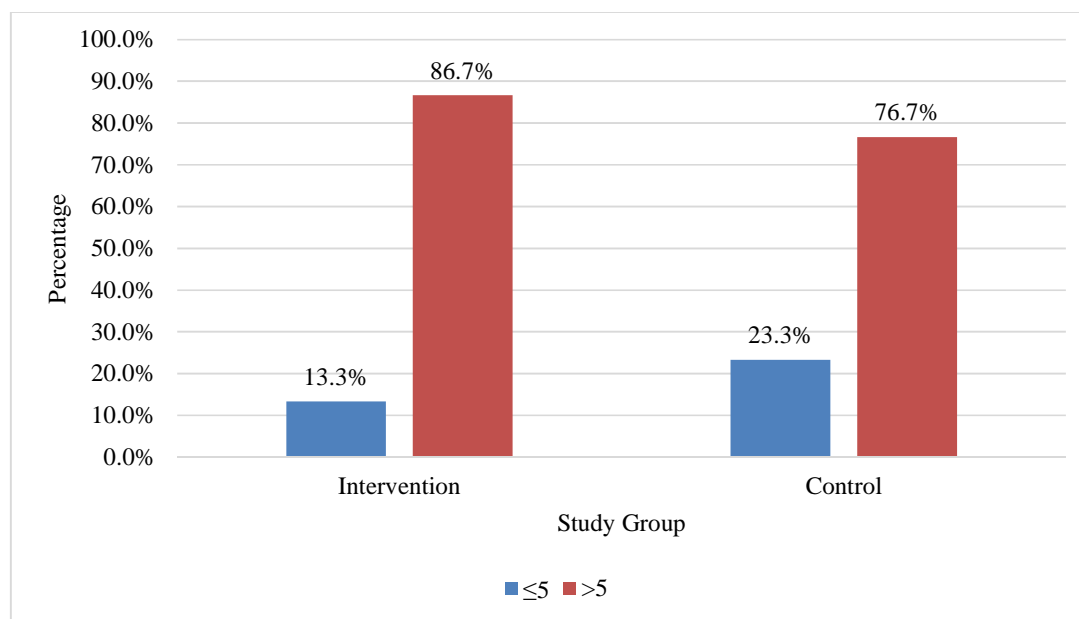


Figure 11: Cluster bar chart of comparison of APGAR score at 1 min between study group (N=60)

**Table 12: Comparison of mean of neonate's parameter on admission to NICU
between study group (N=60)**

Parameter	Study Group (Mean± SD)		P value
	Intervention (N=30)	Control (N=30)	
Gestational age (weeks)	34.1 ± 1.7	33.79 ± 2.06	0.231
Birth weight (kg)	1.29 ± 0.14	1.31 ± 0.15	0.202
Length at birth (cm)	42.27 ± 2.42	41.13 ± 2.59	0.085
Head circumference at birth (cm)	29.1 ± 1.58	28.82 ± 1.64	0.303

The above table is a comparison of parameters of newborns in both the groups at birth. Gestational age, birth weight, length at birth and head circumference are comparable as there was no statistical significant difference between the 2 groups. Hence the data was concluded to be comparable for the study being conducted.

Kangaroo mother care (KMC): Initiation of KMC between control and intervention groups varied as per the protocol of this study. The mean average minutes of iKMC initiation in the intervention group was 18.9 minutes and the initiation of KMC in control group was 4.3days. As KMC was started much earlier in the intervention group, the KMC provider at birth was either grandmother(63.3%) or aunt(36.6%) . In control group, the KMC provider was majorly the mother(90%) due to the delay in the initiation of KMC.

Table 13: Descriptive analysis of initiation of KMC in the study groups (N=30)

Parameter	Mean ± SD	Median	Minimum	Maximum	95% C.I	
					Lower	Upper
Intervention (N=30)						
Initiation KMC (min)	18.97 ± 6.15	20.00	10.00	30.00	16.67	21.26
Control (N=30)						
Initiation KMC (days)	4.3 ± 2.51	3.50	2.00	12.00	3.36	5.24

Table 14: Descriptive analysis of KMC given by Family members during initiation in the study group (N=60)

Parameter	Frequency	Percentages
Intervention (N=30)		
Aunt	11	36.67%
Grandmother	19	63.33%
Control (N=30)		
Aunt	1	3.33%
Grandmother	2	6.67%
Mother	27	90.00%

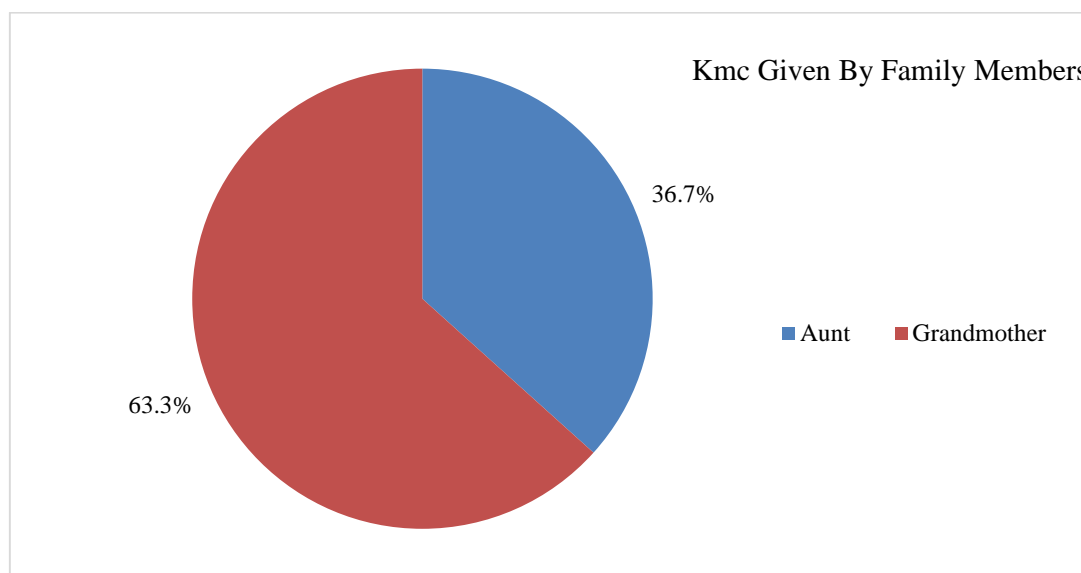


Figure 12: Pie chart of KMC given by family members in the Intervention group (N=30)

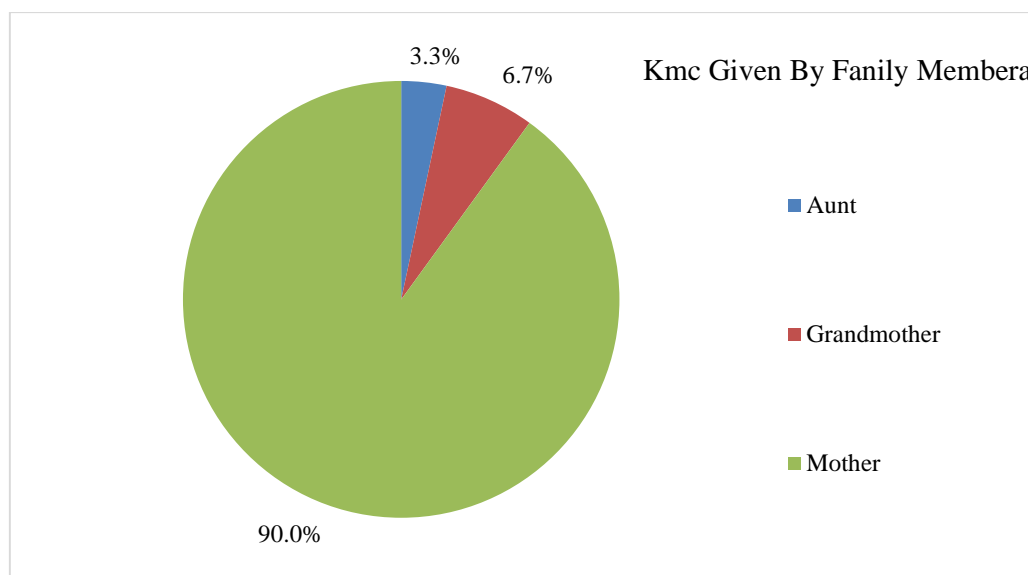


Figure 13: Pie chart of KMC given by family members in the control group (N=30)

When we compared the mean average hours of KMC per day from day 1 to day 7 the difference in the 2 groups was statistically significant (P value-<0.001).

Secondly, the intervention group reached the target KMC (8 hours) much earlier compared to control group. In control group it took almost twice the number of days(8 days) higher to reach the target KMC when compared to intervention group(4 days).This difference was statistically significant (P value-<0.001).

However at discharge the difference in the average number of hours of KMC practiced by mothers was almost equal in both the groups.

Table 15: Comparison of mean of KMC (hours) from Day 2 till discharge across the study group (N=60)

KMC Duration (hours)	Study Group (Mean± SD)		P value
	Intervention (N=30)	Control (N=30)	
At Day 2	4.53 ± 1.94	1.13 ± 2	<0.001
At Day 3	6.03 ± 1.94	2.27 ± 2.26	<0.001
At Day 4	6.9 ± 1.71	2.83 ± 2.48	<0.001
At Day 5	7.17 ± 1.78	3.5 ± 2.91	<0.001
At Day 6	7.4 ± 1.19	3.97 ± 3.12	<0.001
At Day 7	7.55 ± 0.83	4.41 ± 3.12	<0.001
At Discharge	7.93 ± 0.37	7.92 ± 0.4	0.898

Table 16: Comparison of mean of day of reaching target KMC (8 hours/day) between study group (N=56)

Parameter	Study Group (Mean± SD)		P value
	Intervention (N=30)	Control (N=26)	
Day of reaching target KMC	4.23 ± 1.45	8.19 ± 2.95	<0.001

Comparison of Vital parameters in the first hour of life:

Heart rate, Respiratory rate and saturation: The mean average heart rate and respiratory rate was found to be statistically significantly higher in the control group compared to the control group, indicating that they were more stable. The oxygen saturation rise was better in the intervention group.

Random blood sugar (RBS) and Temperature: Although the mean RBS was found to be higher in the control group, the difference in the 2 groups was statistically not significant.

The table shows that the temperature maintenance was better in the intervention group when compared to the control group as early as in the first 15 mins and 30 mins. Whereas the control group took almost 45 mins to reach the normal temperature indicating that intervention group achieved earlier stability. This difference was statistically significant.

Table 17: Comparison of mean of HR, RR and SpO₂ at Day 1 between study group (N=60)

Day 1 Follow-up	Study Group (Mean± SD)		P value
	Intervention (N=30)	Control (N=30)	
At 15 min			
HR	164.37 ± 7.53	165.07 ± 7.22	0.715
RR	59.5 ± 5.02	59.53 ± 4.26	0.978
Spo ₂	94.83 ± 1.26	93.97 ± 1.4	0.015
At 30 min			
HR	160.4 ± 7.81	164.8 ± 6.91	0.024
RR	58.4 ± 5.09	59.7 ± 4.2	0.285
Spo ₂	95.1 ± 1.06	94.1 ± 1.32	0.002
At 45 min			
HR	155.53 ± 6.25	163.13 ± 6.64	<0.001
RR	55.4 ± 2.84	58.27 ± 4.49	0.004
Spo ₂	95.83 ± 0.91	95.13 ± 1.2	0.013
At 60 min			
HR	146.07 ± 6.32	162.77 ± 7.06	<0.001
RR	55.43 ± 3.28	57.57 ± 3.95	0.026
Spo ₂	96.13 ± 0.63	95.07 ± 1.62	0.001

Table 18: Comparison of mean of RBS and Temperature at Day 1 between study group (N=60)

Day 1 Follow-up	Study Group (Mean± SD)		P value
	Intervention (N=30)	Control (N=30)	
At 15 min			
RBS	73.93 ± 13.56	81.77 ± 30.96	0.209
Temperature	36.62 ± 0.07	36.5 ± 0.24	0.013
At 30 min			
RBS	75.07 ± 13.62	80.23 ± 27.89	0.366
Temperature	36.83 ± 0.08	36.67 ± 0.21	<0.001
At 45 min			
RBS	76.03 ± 8.99	80.57 ± 23.69	0.331
Temperature	36.88 ± 0.08	36.85 ± 0.13	0.401
At 60 min			
RBS	81.8 ± 5.44	80.5 ± 17.95	0.706
Temperature	36.97 ± 0.09	36.94 ± 0.15	0.522
KMC Duration (hours)	3.3 ± 0.95	-	-

Vitals during hospital stay: The mean average heart rate and respiratory rate was higher in the control group when compared to the intervention group on all days and this difference was statistically significant.

The oxygen saturation, RBS and temperature were comparable in both the groups on all days. The stability of these 3 parameters were attained in first 30 mins of life. However, it was noted that, the mean temperature was slightly higher in intervention group compared to control group every day. At the time of discharge all parameters were comparable between 2 groups.

This indicates iKMC promotes better physiological stability even in the first week of life.

Table 19: Comparison of mean of HR , RR and SpO2 from Day 2 till discharge between study group (N=60)

Follow-up	Study Group (Mean± SD)		P value
	Intervention (N=30)	Control (N=30)	
At Day 2			
HR	140.17 ± 6.99	155.73 ± 12.81	<0.001
RR	48.8 ± 7.59	54.07 ± 6.64	0.006
Spo2	97.03 ± 1.25	96.9 ± 1.03	0.653
At Day 3			
HR	136.13 ± 7.4	150.13 ± 11.3	<0.001
RR	46.67 ± 5.87	53.03 ± 8.43	0.001
Spo2	97 ± 1.29	96.87 ± 1.04	0.661
At Day 4			
HR	135.77 ± 8.41	148.9 ± 11.91	<0.001

RR	46.27 ± 4.54	51.7 ± 7.21	<0.001
Spo2	97.07 ± 1.17	96.97 ± 1.16	0.741
At Day 5			
HR	133.83 ± 8.89	148.27 ± 15.17	<0.001
RR	45.7 ± 3.99	52.2 ± 8.26	<0.001
Spo2	97.17 ± 1.15	96.83 ± 1.26	0.289
At Day 6			
HR	133.2 ± 10.34	146.7 ± 15.18	<0.001
RR	46.13 ± 4.49	51.33 ± 7.16	0.001
Spo2	97.23 ± 1.25	97.07 ± 1.05	0.578
At Day 7			
HR	128.83 ± 23.61	144.72 ± 14.56	0.003
RR	45.41 ± 4.44	49.66 ± 6.79	0.007
Spo2	97.14 ± 1.25	96.97 ± 1.24	0.599
At Discharge			
HR	129.23 ± 6.93	134.36 ± 11.76	0.050
RR	45.17 ± 2.77	45.48 ± 2.77	0.678
Spo2	97.63 ± 1.19	96.84 ± 1.25	0.019

Table 20: Comparison of mean of RBS and Temperature from Day 2 till discharge at between study group (N=60)

Follow-up	Study Group (Mean± SD)		P value
	Intervention (N=30)	Control (N=30)	
At Day 2			
RBS	93.3 ± 30.96	90.43 ± 31.06	0.722
Temperature	36.86 ± 0.18	36.74 ± 0.27	0.056
At Day 3			
RBS	94.9 ± 24.54	96.63 ± 16.35	0.749
Temperature	36.71 ± 1.59	36.63 ± 1.18	0.827
At Day 4			
RBS	97.43 ± 26.14	99.37 ± 20.88	0.753
Temperature	36.94 ± 0.19	36.82 ± 0.28	0.046
At Day 5			
RBS	96.93 ± 26.27	93.1 ± 18.96	0.519
Temperature	36.94 ± 0.20	36.87 ± 0.31	0.261
At Day 6			
RBS	95.87 ± 22.64	97.17 ± 19.99	0.814
Temperature	36.93 ± 0.19	36.86 ± 0.32	0.315
At Day 7			
RBS	100.07 ± 24.53	92.55 ± 14.19	0.159
Temperature	36.94 ± 0.20	36.86 ± 0.30	0.228
At Discharge			
RBS	94.73 ± 13.93	91.88 ± 15.88	0.481
Temperature	36.78 ± 0.17	36.87 ± 0.18	0.065

Feeding: The average day of starting oral feed in control group was 7.58 days and in intervention group was 2.57 days this difference was statistically significant (P value-<0.001).

The time taken to initiate breastfeeding was significantly faster in intervention group (4.8days) compared to control group(11.3days) and this difference was statistical significant(P value<0.001).

The time taken to reach full breastfeeding was 13.4 days in control and 5.9 days in intervention group and this difference was statistically significant(P-value-<0.001).

Table 21: Comparison of mean of feeding parameters started between study group (N=56)

Parameter	Study Group (Mean± SD)		P value
	Intervention (N=30)	Control (N=26)	
Day of oral feed	2.57 ± 1.99	7.58 ± 4.22	<0.001
Day of DBF started	4.8 ± 2.72	11.31 ± 5.08	<0.001
Time taken to reach full breast feeding	5.93 ± 3.1	13.42 ± 5.44	<0.001

Mode and Type of feed: In intervention group 21 babies required only expressed breast milk(EBM) and 9 babies required donor milk(DHM) and EBM. Whereas in the control group 14 babies required EBM and remaining 16 babies required only DHM or DHM and EBM. This difference was statistically significant(P value=0.047) indicating that mothers in the intervention group had better milk secretion than the control group.

This table shows that in the intervention group oral feeds could be started earlier as more babies received oral feeds when compared to the control group. Total of 8 babies in the control and 19 babies in the intervention group received only spoon feeds. This difference was statistically significant.

Table 22: Comparison of type and mode of feeds between study group (N=60)

	Study Group		Chi square	P value
	Intervention (N=30)	Control (N=30)		
Type Of Feeds				
DHM	0 (0%)	3 (10%)	5.127	0.047
EBM	21 (70%)	14 (46.67%)		
EBM + DHM	9 (30%)	13 (43.33%)		
Mode Of Feeds				
RT	1 (3.33%)	3 (10%)	8.275	0.016
SF	19 (63.33%)	8 (26.67%)		
RT + SF	10 (33.33%)	19 (63.33%)		

DHM-Donor Human Milk; EBM-Expressed Breast Milk; RT-Ryle’s tube ; SF-Spoon feeds

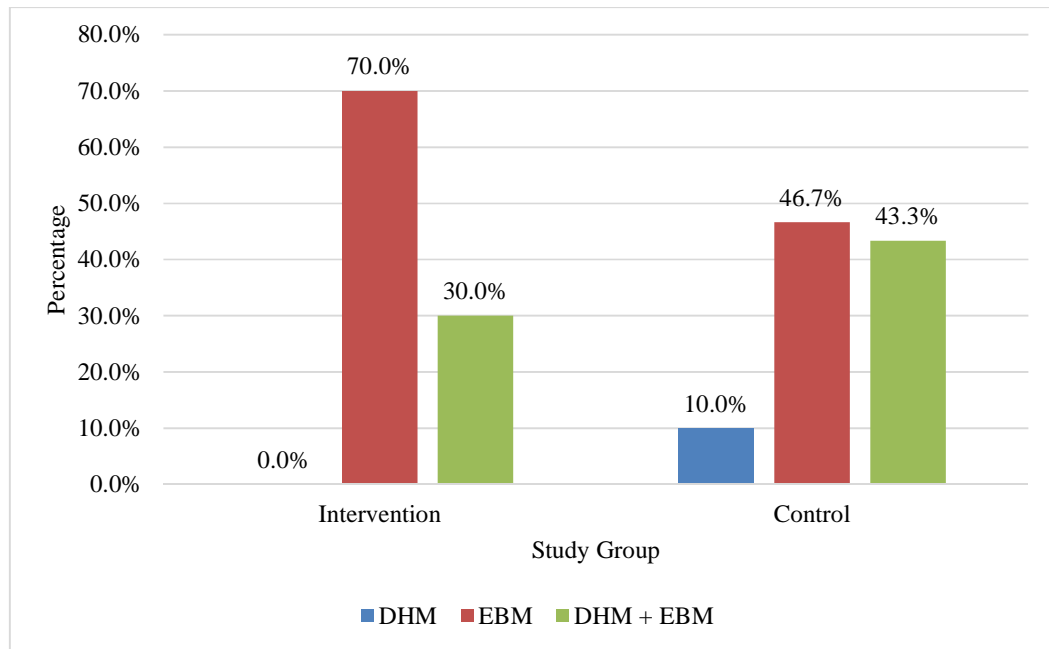


Figure 14: Cluster bar chart of comparison of type of feeds between study group (N=60)

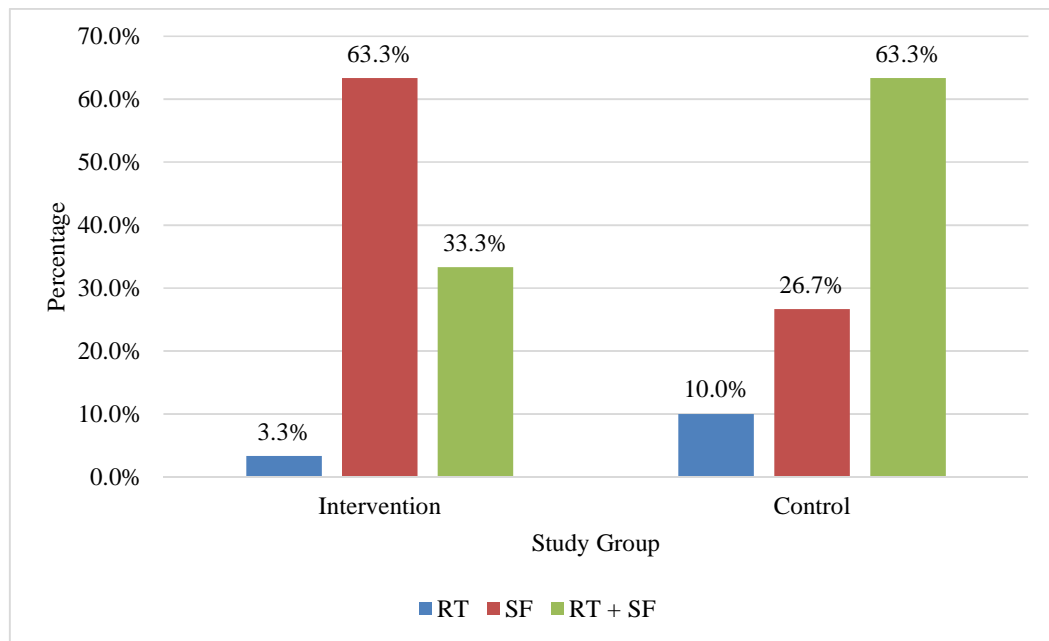


Figure 15: Cluster bar chart of comparison of mode of feeds between study group (N=60)

Problems in the infant during hospital stay:

Hypothermia: At birth during the initial 1 hour, a total of 14 babies out of 60 babies were found to have hypothermia of which 11 were in the control and 3 babies in the intervention group. This difference was statistically significant (P value=0.015). During the duration of hospital stay, total of 5 babies had hypothermia of which 1 was in the intervention group where the temperature recorded was 35 degree Celsius and 4 babies in control group had hypothermia with temperatures of 33.3, 34.3, 34.1, 35.1 degree Celsius. However, this difference was not statistically significant.

Table 23: Comparison of incidence of hypothermia between study group (N=60)

PROBLEMS	Study Group		Chi square	P value
	Intervention (N=30)	Control (N=30)		
Hypothermia At Day 1	3 (10%)	11 (36.67%)	5.963	0.015
Hypothermia During Hospital Stay	1 (3.33%)	4 (13.33%)	1.964	0.353

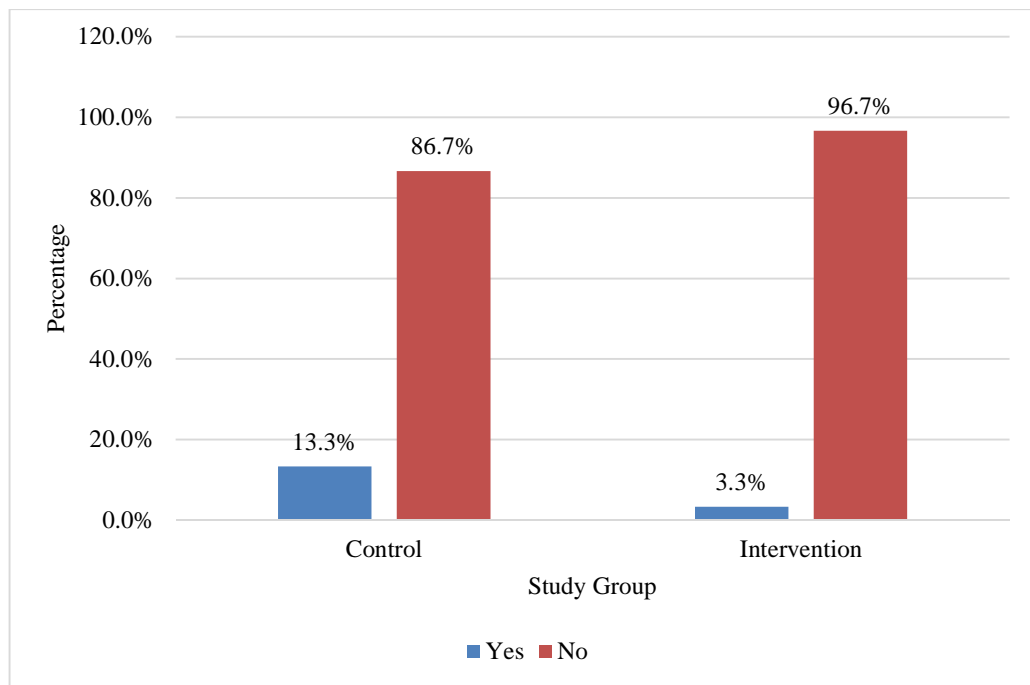


Figure 16: Cluster bar chart of comparison of hypothermia during hospital stay between study group (N=60)

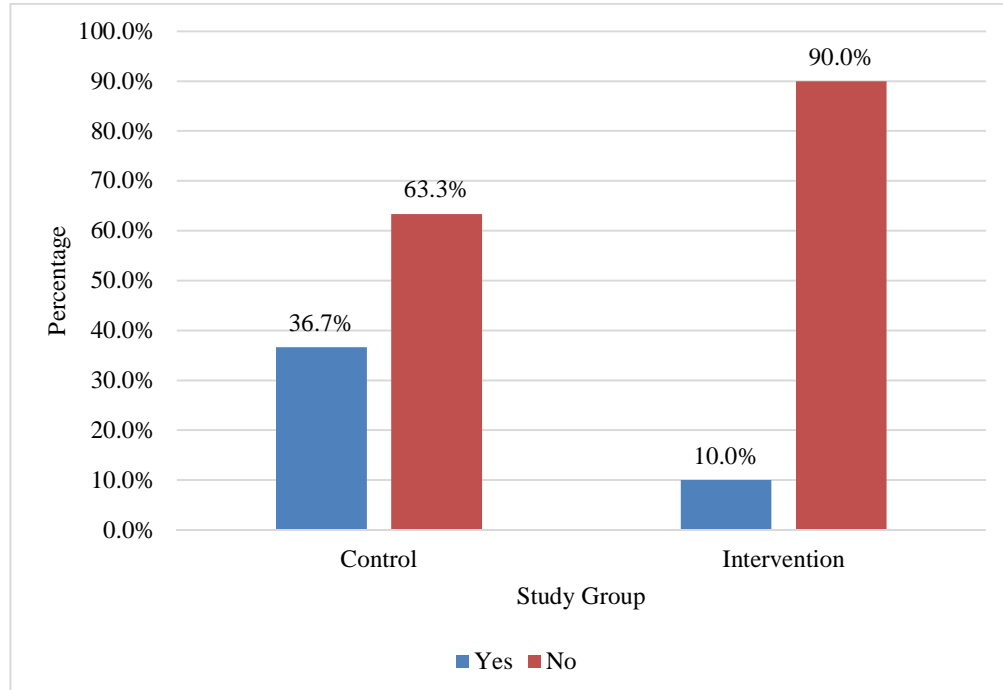


Figure 17: Cluster bar chart of comparison of hypothermia at day 1 between study group (N=60)

Hypoglycemia: Total of 11 babies had hypoglycaemia among which 8 were in control group and 3 were intervention group. However, this difference was statistically insignificant.

Sepsis: Among 60 babies, 11 babies had sepsis out of which 10 babies , were in control group and 1 baby was from intervention group. This difference was statistically significant. (Pvalue=0.003).

Table 24: Comparison of incidence of hypoglycaemia and sepsis between study group (N=60)

PROBLEMS	Study Group		Chi square	P value
	Intervention (N=30)	Control (N=30)		
Hypoglycaemia	3 (10%)	8 (26.67%)	2.783	0.095
Sepsis	1 (3.33%)	10 (33.33%)	9.017	0.003

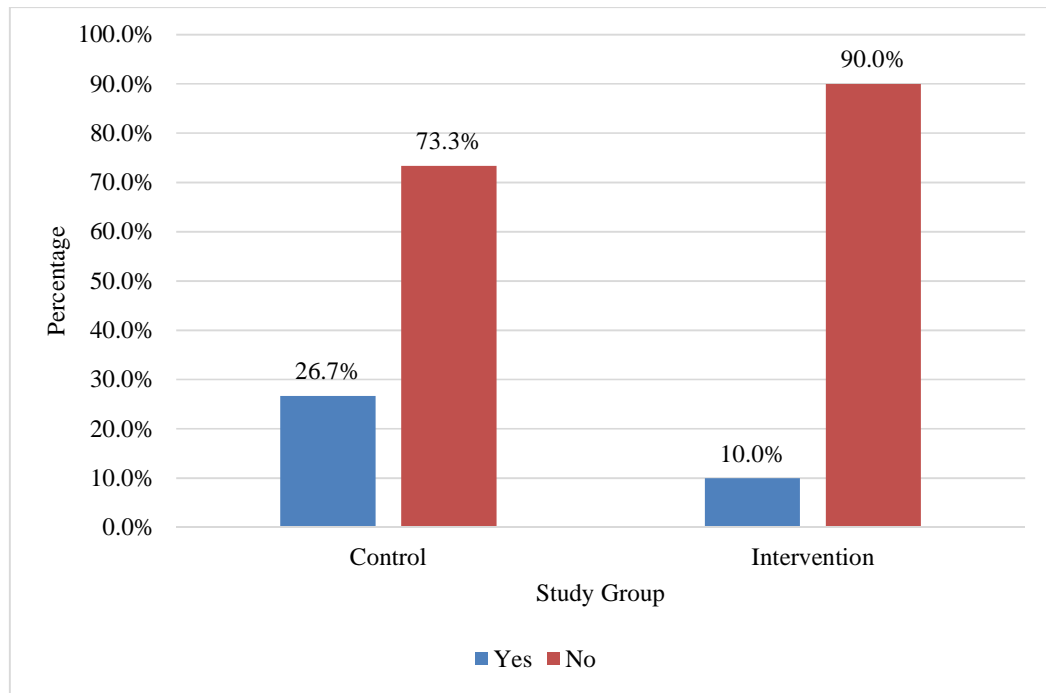


Figure 18: Cluster bar chart of comparison of hypoglycaemia between study group (N=60)

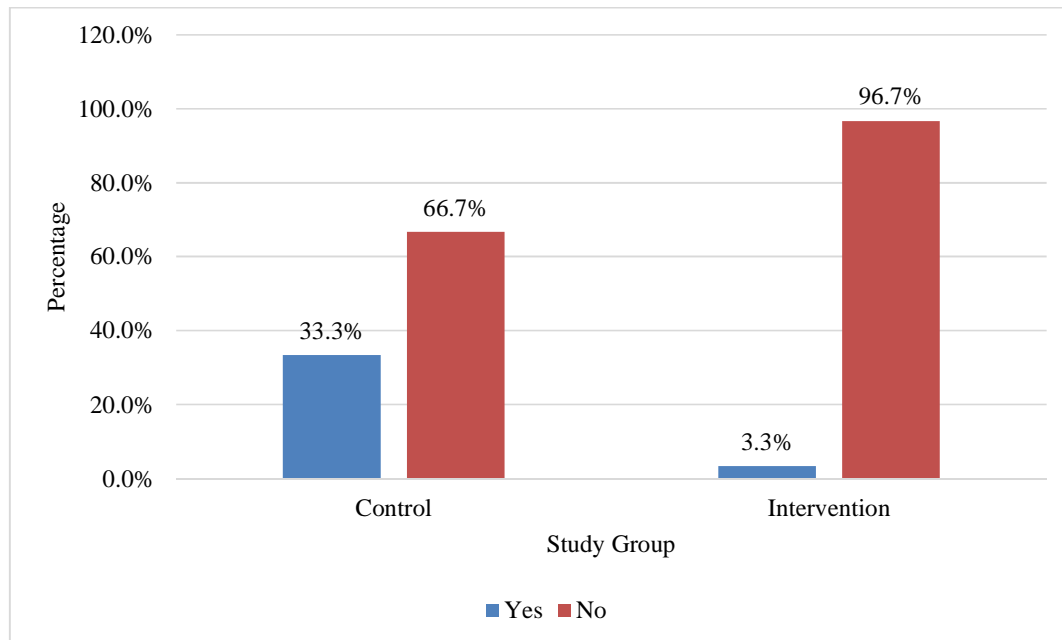


Figure 19: Cluster bar chart of comparison of Sepsis between study group (N=60)

Neonatal jaundice, apnoea and seizure: In our study, out of 60 babies, 42 babies had neonatal jaundice and 20 babies had apnoea. However, the difference across the study group was not statistically significant. A total of 4 babies had seizure and all of them belonged to control group and this difference was statistically significant(P value=0.038).

Table 25: Comparison of incidence of neonatal jaundice, apnoea and seizure between study group (N=60)

PROBLEMS	Study Group		Chi square	P value
	Intervention (N=30)	Control (N=30)		
Neonatal Jaundice	19 (63.33%)	23 (76.67%)	1.27	0.26
Apnoea	8 (26.67%)	12 (40%)	1.2	0.273
Seizure	0 (0%)	4 (13.33%)	4.29	0.038

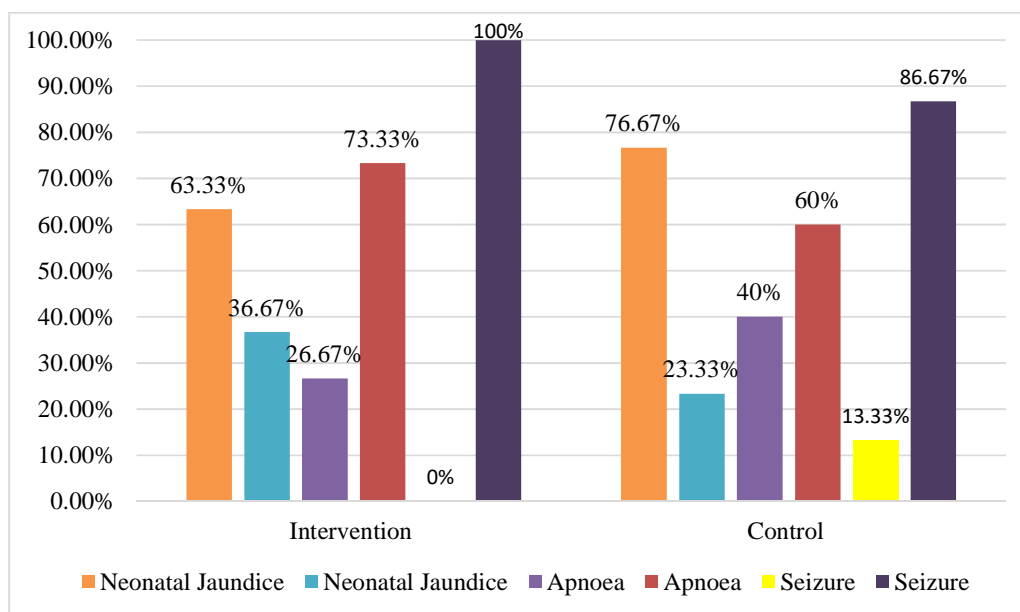


Figure 20: Cluster bar chart of comparison of other problems between study group (N=60)

Need for respiratory support during the hospital stay: Across the study group, 23 babies (76.7%) in control and 9 babies (30%) in intervention group required respiratory support during the hospital stay . 3 babies in the control group needed mechanical ventilation compared to none in the intervention group, 20 babies needed CPAP ventilation out of which 17 babies were in control group and 3 in the intervention. These differences were statistically significant (P value<0.001).

The leading cause of need for respiratory support in both the groups were found to be respiratory distress syndrome (RDS)-5 babies in intervention and 8 babies in control group. This was followed by sepsis where 8 babies in control group and none in the intervention group .Transient tachypnoea of newborn(TTNB) requiring ventilatory support was 3 in intervention group and 4 in control group. 1 baby in intervention group had Atrial septal defect (ASD), 2 babies had anaemia and 1 baby had aspiration pneumonia in the control group requiring ventilation.

Table 26: Comparison of need for ventilatory support between study group

(N=60)

PROBLEMS	Study Group		Chi square	P value
	Intervention (N=30)	Control (N=30)		
Need For Respiratory Support				
	Total=9	Total=23		
Venti	0 (0%)	1 (3.33%)	22.80	<0.001
O2	6 (20%)	2 (6.67%)		
O2 + CPAP	3 (10%)	17 (56.67%)		
O2 + CPAP + Venti	0 (0%)	3 (10%)		
Reason for need of respiratory support (N=32)				
RDS	5 (55.56%)	8 (34.78%)	4.588	0.205
TTNB	3 (33.33%)	4 (17.39%)		
Sepsis	0 (0%)	8(34.78%)		
Others	1(11.11%)	3(13%)		

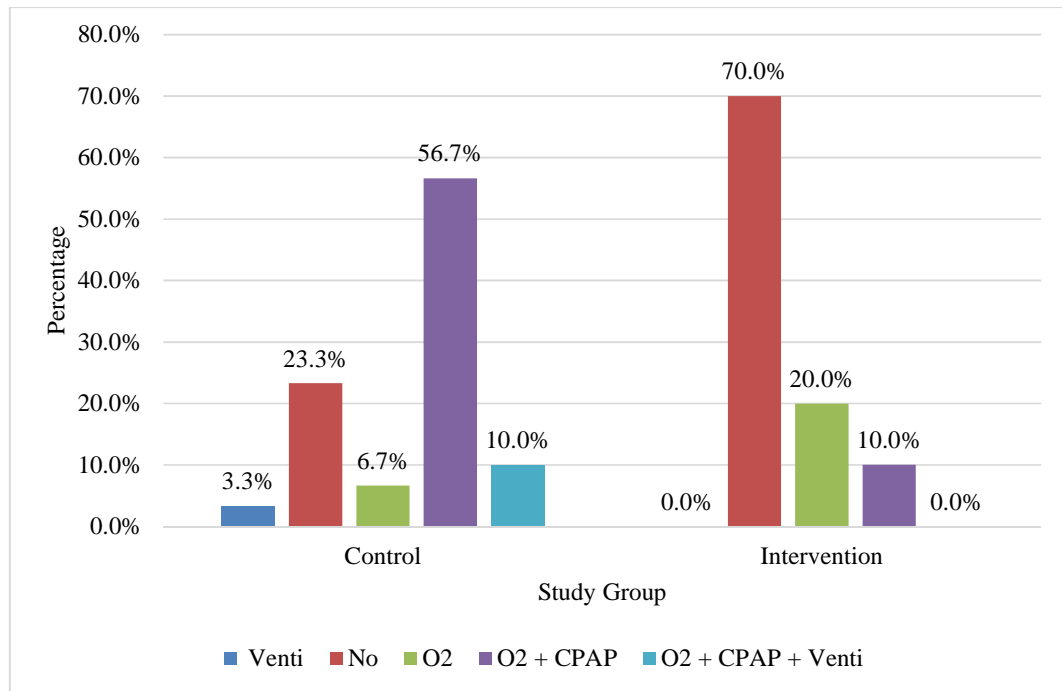


Figure 21: Cluster bar chart of comparison of Need for Respiratory Support between study group (N=60)

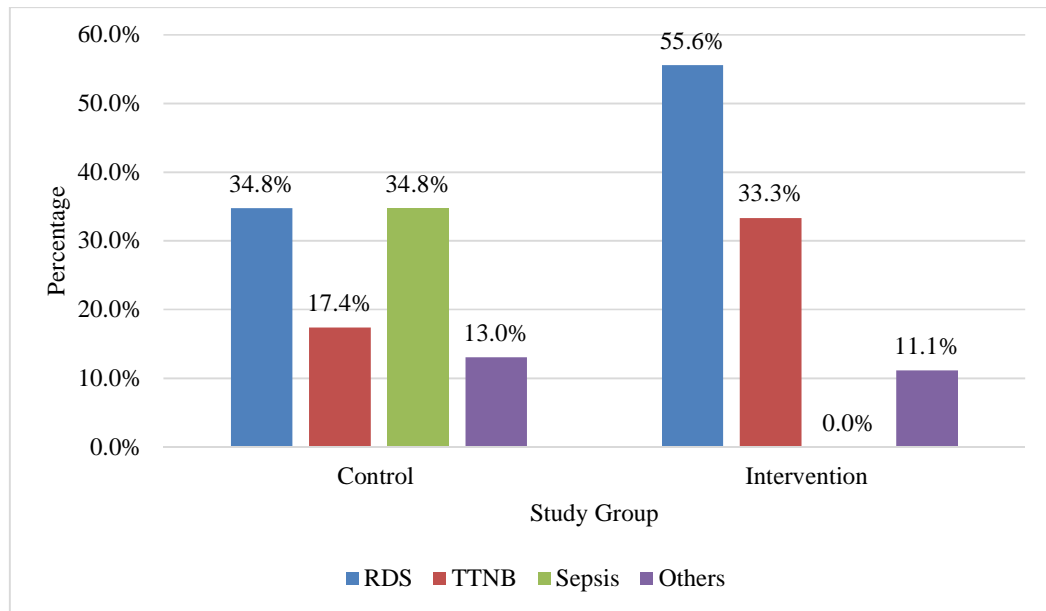


Figure 22: Cluster bar chart of comparison of Reason for need of respiratory support between study group (N=32)

Duration of hospital stay: The duration of hospital stay was significantly prolonged in control group with a mean average of 19.5 days compared to intervention group with a mean average of 11.4 days. This difference was statistically significant (P value<0.001).

Table 27: Comparison of mean of duration of hospital stay between study group (N=60)

Parameter	Study Group (Mean± SD)		P value
	Intervention (N=30)	Control (N=30)	
Duration of hospital stay	11.4 ± 3.28	19.53 ± 6.6	<0.001

Weight gain: In this study, the mean average weight gain were 15.6gms/day in the intervention group and 13gms/day in the control group. This difference was statistically significant (P value=0.038).

When we compared the babies for consecutive days in weight gain, it was found to be shorter in the intervention group with an average of 7.17 days when compared to the control group where the average was 14.4days. This difference was statistically significant (P-value<0.001).

Anthropometry at discharge: When we compared the gain in length and head circumference though it was higher in the intervention group, the difference was not statistically significant.

Table 28: Comparison of anthropometry parameters at discharge between study group

Parameter	Study Group (Mean± SD)		P value
	Intervention (N=30)	Control (N=27)	
Mean average weight gain per day (gm)	15.67 ± 4.69	13.04 ± 4.62	0.038
Day of consecutive weight gain	7.17 ± 2.73	14.44 ± 5.39	<0.001
Length at discharge (cm)	42.28 ± 2.41	41.44 ± 3.43	0.290
Head circumference at discharge (cm)	30.62 ± 1.5	30.46 ± 2.97	0.801

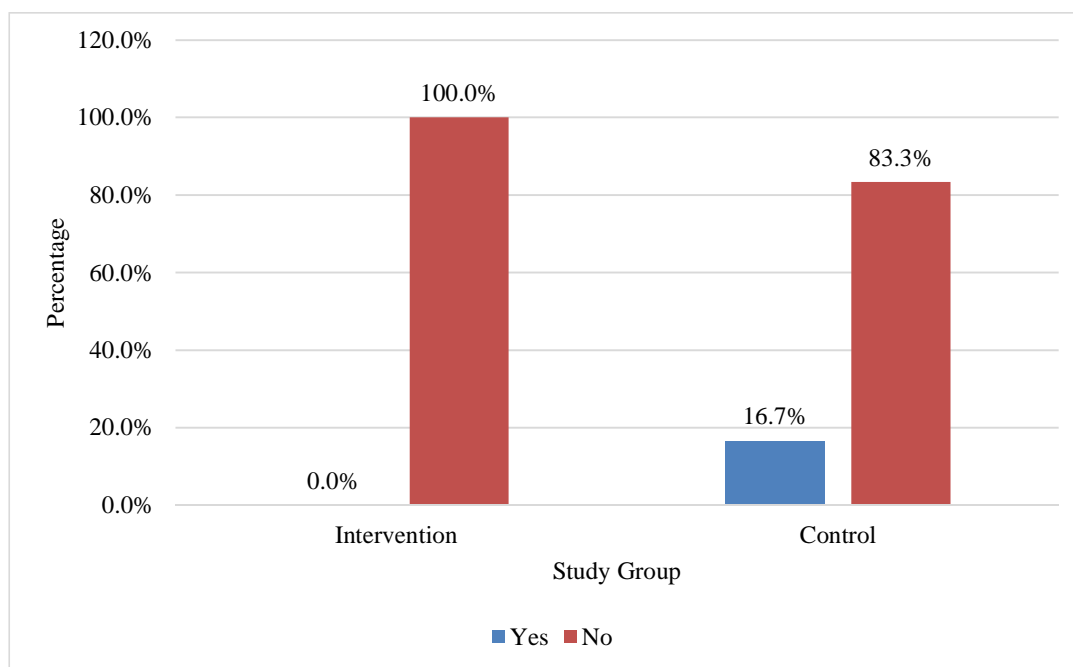
Mortality: Among total of 60 babies, 5 babies expired and all of them belonged to the control group, this difference was statistically significant (P value=0.020). Out of these 5 babies, 4 babies died of sepsis and 1 baby died of aspiration pneumonia.

Table 29: Comparison of incidence of mortality between study group (N=60)

Mortality	Study Group		Chi square	P value
	Intervention (N=30)	Control (N=30)		
Yes	0 (0%)	5 (16.67%)	5.455	0.020
No	30 (100%)	25 (83.33%)		

Figure 23: Cluster bar chart of comparison of Mortality between study group

(N=60)



Time taken to reach 2.5kg on follow up: During follow up it was observed that overall the average number of days taken to reach 2.5kg in the intervention group was 66.9days and in control group was 84.1 days, this difference was statistically significant(P value<0.001).

When they were categorised into 3 groups according to birth weight, in the category of 1-1.2kg, the mean average days was 78.2 days in intervention and 103.4 days in control and this difference was statistically significant(P value<0.001).

In the category of 1.21-1.4kg, the mean average days was 63 days in intervention and 83.4 days in control group, this difference was statistically significant(P value<0.001).

In the category of 1.41-1.5kg, the mean average days was 52.8 days in intervention group and 66 days in control group, this difference was statistically significant(P value<0.001).

Table 30: Comparison of mean of Time Taken to Reach 2.5kg (days) between study group

Parameter	Study Group (Mean± SD)		P value
Overall (N=55)			
	Intervention (N=30)	Control (N=25)	
Time Taken to Reach 2.5kg (days)	66.9 ± 13.21	84.16 ± 15	<0.001
Birth Weight 1-1.2 kg (N=20)			
	Intervention (N=13)	Control (N=7)	
Time Taken to Reach 2.5kg (days)	78.23 ± 11.14	103.43 ± 5.29	<0.001
Birth Weight 1.21-1.4 kg (N=20)			
	Intervention (N=9)	Control (N=11)	
Time Taken to Reach 2.5kg (days)	63 ± 3.87	83.45 ± 4.87	<0.001
Birth Weight 1.41-1.5 kg (N=55)			
	Intervention (N=8)	Control (N=7)	
Time Taken to Reach 2.5kg (days)	52.88 ± 3.18	66 ± 3.7	<0.001

KMC during follow up: The average number of days KMC practiced was 36.6 days in intervention and 34.8 days in control group. Though practice of KMC in the intervention group was higher this difference was not statistically significant. In terms of hours of KMC practiced after discharge, extended hours of KMC was practiced higher in intervention group, though the difference was statistically not significant.

Table 31: Comparison of mean of no. of days of KMC practiced after discharge between study group (N=55)

Parameter	Study Group (Mean± SD)		P value
	Intervention (N=30)	Control (N=25)	
No. of days of KMC practiced after follow-up	36.67 ± 6.19	34.8 ± 7.43	0.314

Table 32: Comparison of compliance to KMC after discharge between study group (N=55)

Compliance To KMC	Study Group		Chi square	P value
	Intervention (N=30)	Control (N=25)		
Short(<5 hours)	11 (36.67%)	14 (56%)	2.056	0.152
Extended(5-8 hours)	19 (63.33%)	11 (44%)		

Complications and feeding during follow up: During follow up it was observed that all babies in intervention group were exclusively breastfed whereas in control group 2 babies were started on lactogen feeds. However, this difference was statistically not significant.

It was also observed that the complications were higher in control group. Out of 25 babies in control group, 1 baby had anaemia of prematurity and 1 baby had failure to thrive. In intervention group no such problems were noted. This difference was statistically not significant.

Table 33: Comparison of compliance to breastfeeding and complications after discharge between the study group

Parameters	Study Group		Chi square	P value
	Intervention (N=30)	Control (N=25)		
Breastfeeding				
On lactogen feeds	0(0%)	2 (6.67%)	1.660	0.197
Exclusive breastfeeding	30(100%)	23 (93.33%)		
Complications after discharge				
Anemia Of Prematurity	0 (0%)	1 (4%)	7.490	0.187
Failure to thrive	0(0%)	1 (4%)		
No Complications	30 (100%)	23 (92%)		

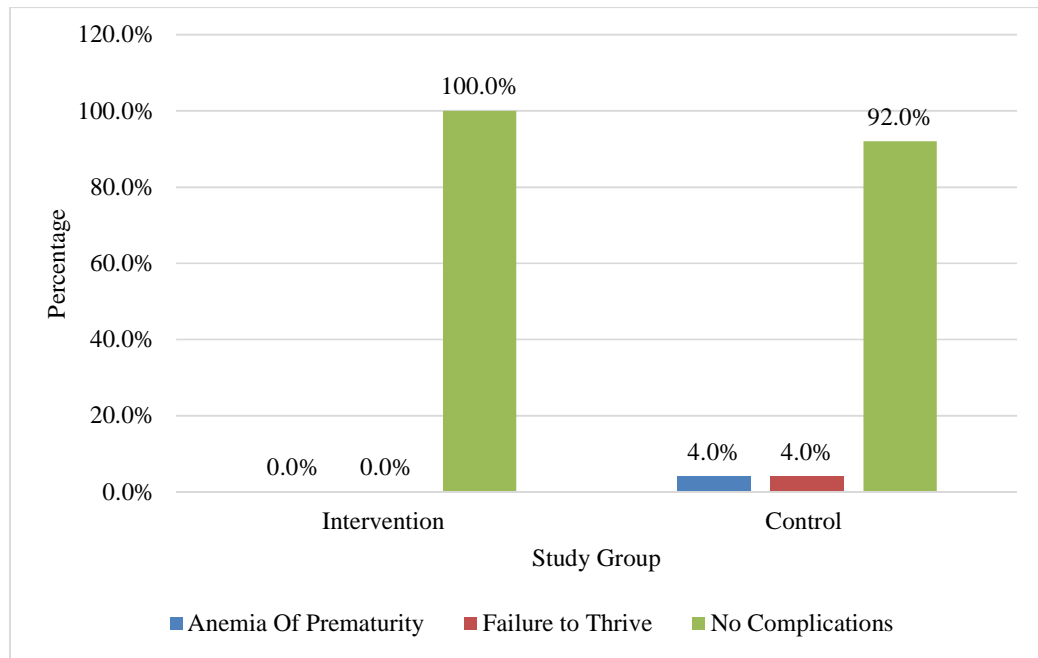


Figure 24: Cluster bar chart of comparison of complications after discharge between study group (N=55)

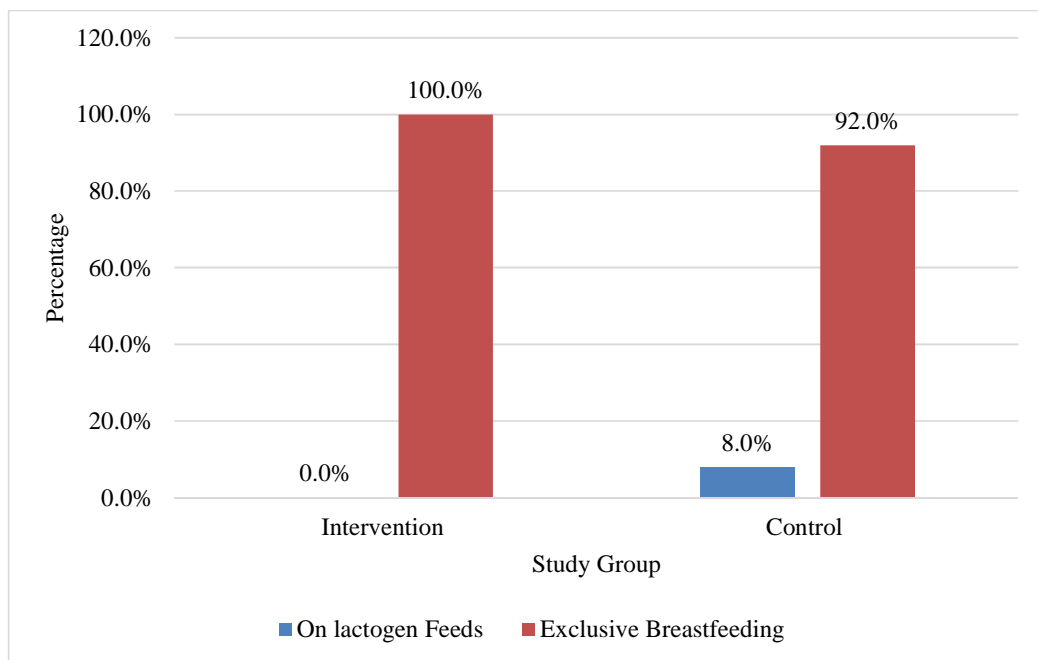


Figure 25: Cluster bar chart of comparison of compliance to breastfeeding after discharge between study group (N=55)

DISCUSSION

Around 30% of neonates are born with LBW (<2.5kg) in India. This attributes to 42% of the global burden making India the highest contributor. Among which 60% are term with IUGR (intrauterine growth restriction) and the rest 40% are preterm. The Million Death Study Collaborators conducted a survey which showed three causes contributed to 78% of the neonatal deaths in India: prematurity & low birth weight, neonatal infections and birth asphyxia & trauma. The mortality rate among the preterm babies are 38.8% (1) according to a survey conducted in 2021. Sustainable Development Goal (SDG) target 3.2 is about ending preventable deaths of newborns and children under 5 years of age (5).

The most effective and evidence-based intervention which is feasible even in a low resource setting is known to be Kangaroo Mother Care (KMC). KMC is known for stabilization of body temperature, improvement of breastfeeding rate, and reducing mortality and chances of sepsis among neonates. However, KMC is ideally recommended to be started after stabilization of the neonate. Recent studies have shown that immediate KMC (iKMC) which is initiated as soon as possible, even before stabilization of the baby has shown to decrease mortality and that the benefits of KMC can be extended to unstable LBW babies.(16)

This study is a non-blinded randomized control trial with an intervention and a control group on VLBW newborns weighing between 1-1.5kg admitted to NICU under KLES Dr. Prabhakar Kore hospital. Intervention group: babies with birth weight of 1-1.5kg in the intervention group were started with immediate skin to skin contact (iKMC) soon after birth in the labour room, even before stabilization of the baby and then continued in the NICU after the babies were shifted to the NICU.

Control group: Babies enrolled in this group were shifted to conventional radiant warmer in the NICU and KMC was initiated after stabilization of the baby. In both the groups, the newborns in the NICU were monitored, and information regarding temperature, heart rate, respiratory rate, capillary blood glucose and oxygen saturation were recorded every 15 mins in the 1st hour and then 6th hourly. Vital parameters were monitored daily 6th hourly and the trends were observed. Weight was checked every day and other anthropometry parameters such as length and head circumference was measured weekly once. The mode, frequency and type of feeds administered to the newborn were also noted. Any problems faced during the hospital stay along with the duration of interruption of intervention was recorded. Routine nursing care such as monitoring, providing support was same for both the groups. At discharge, feeding, anthropometry, general condition and outcome of the babies were noted and the mothers were explained about the need for continuation of KMC, their benefits and the need for regular follow up in the high-risk baby clinic. After discharge, all infants were regularly followed up until they reached 2.5kgs.

RANDOMISATION OF GROUPS: In our study, randomization of participants into 2 groups was executed successfully, with an equal distribution across the groups. Each group comprised of 30 participants, representing 50% of the total study population. This equal distribution was crucial as it ensured that each group had the same potential for receiving the intervention, thereby minimizing bias and enabling a fair comparison of outcomes across the groups.

MATERNAL FACTORS:

MATERNAL AGE: The maternal age distribution showed that vast majority of mothers (86.6%) were between 20- 30 years of age. A smaller proportion 10% were less than 20 years and a very small number were (3.4%) were over 30 years old. When compared across the groups, majority of participants in each group were aged between 20-30 years, with a slightly higher proportion in control group compared to intervention group. This indicates that most of the mothers were within childbearing age and were capable of understanding and taking the challenge of caring for very low birth weight babies.

MODE OF DELIVERY: The proportion of mothers undergoing Lower segment caesarean section (LSCS) was slightly higher (93.3%) in intervention group when compared to control group (86.6%). Overall 90% of the newborns were delivered via LSCS and only a small proportion 10% were delivered normally. There was no statistical significance of distribution across the groups

MATERNAL PROBLEMS: The proportion of mothers having surgical site infection (SSI) and Postpartum blues were slightly higher in the intervention group compared to the control group. Other maternal problems like Congenital heart defect (CHD), Eclampsia, Postpartum haemorrhage (PPH) and severe anaemia were distributed almost equally between the 2 groups. No statistical significant difference was found. However, these factors affected the compliance of mothers while providing KMC and required a surrogate to provide KMC. Since there was no statistical significant difference, confounding bias of these factors on the outcome were minimised.

Maternal factors like maternal age and parity were proportionately distributed across the groups. The differences were minor and were not found to be statistically significant and hence did not affect the outcome.

NEONATAL FACTORS:

GENDER: The gender distribution in the study population shows a higher proportion of female participants (60%) compared to male participants (40%) in both the study groups. However, this was found to be statistically insignificant and did not affect the outcome of the study.

BIRTH WEIGHT: In our study population, birth weight distribution shows that majority (65%) of the newborns weighed between 1.2 to 1.5kg. Smaller proportions were in the lower weight categories (35 %) babies were between 1 to 1.2kg out of which majority(43.3%) were in the intervention group, whereas, in category of 1.2-1.5kg majority(73.3%) were in control group. This difference was not statistically significant. The intervention group had almost equal distribution of babies in the 1-1.2kg (43.3%) and 1.2-1.5kg (56.6%). However, distribution of newborns across the groups were similar and the minor differences were statistically insignificant.

LENGTH: The mean average length at birth was slightly higher in the intervention group (42.2cm) when compared to the control group (41.1cm). This difference was however not statistically significant.

HEAD CIRCUMFERENCE: Participants belonging to the intervention group (29.1cm) had slightly higher head circumference at birth compared to control group (28.8cm). This difference was however not statistically significant.

GESTATIONAL AGE: The majority of study population (36.6%) had a gestational age between 34weeks 1 day and 36 weeks, this was followed by the second highest (33.3%) between 32 weeks 1 day and 34 weeks. When compared across the groups, intervention group has highest number of participants (43.3%) between 34 weeks 1 day and 36 weeks whereas the control group had almost similar distribution of participants among each category except in the category beyond 36 weeks, where all participants were found to be equal in both groups. However, this difference was not statistically significant.

PARAMETERS OF NEONATE ON ADMISSION TO NICU: Gestational age, birth weight, length at birth and head circumference were compared among the groups and showed no difference of statistical significance. Hence the data was concluded to be comparable for the study being conducted.

RESUSCITATION: Overall, most of the babies (71.6%) in our study group did not need any form of active resuscitative measures. Minor of the babies (15%) needed stimulation among which 23.3 % were in control group and 6.6% were in intervention group and even lesser proportion of newborns (13.3%) needed bag and mask ventilation among which 20% were in control group and 6.6% in intervention group. However there was no statistical significant difference and hence did not affect the outcome.

KANGAROO MOTHER CARE (KMC): In the intervention group, KMC was initiated as soon as possible after birth and in the control group, KMC was initiated once the babies were stabilised as per the standard practice in our NICU. Stabilisation is defined in terms of neonate being off IV fluids or oxygen support. The initiation of KMC in the intervention group was done even if the baby was on IV fluids or oxygen support by nasal prongs.

In our study the mean average minutes of immediate KMC (iKMC) was 18.9 minutes in the intervention group whereas in the control group the mean average days of initiating KMC was 4.3 days.

A similar observation was made by a study conducted by WHO, to observe the impact of iKMC in newborns weighing between 1-1.8kg , the mean average time of initiation of iKMC was not mentioned clearly but, the iKMC was initiated within 2 hours of life in the intervention group and in the control group the KMC was initiated after stabilisation which was at 3-7 days of age. (20)

An RCT was conducted by Md Mahbul et al to study the effectiveness of KMC on success of breast feeding in preterm babies weighing between 1.2-1.8kg . It was observed that the mean time of initiation of KMC in the intervention group was 1.8+/-1.09 days (39)

In our study we observed a statistically significant difference in the number of mean average hours of KMC practiced per day from 1 to 7 days of life, being 4-7 hours in the intervention group and 1-4 hours in control group (P value<0.001). Secondly, the number of days taken to reach the target KMC of 8 hours was much earlier in intervention group(4 days), which was half of the time taken in the control group (8 days).This difference was statistically significant(P value<0.001).

Hence our study showed that immediate KMC helps in better compliance to KMC with respect to the number of hours of KMC practiced per day and also reaching the target KMC earlier.

Studies regarding iKMC promoting the compliance of KMC are lacking and further studies are required.

VITAL PARAMETERS: Overall comparison of vital parameters such as heart rate, respiratory rate, Oxygen Saturation, Temperature and Blood glucose were monitored every 15 mins in the initial 1 hour of birth and every 6th hourly till the day of discharge.

In our study, the mean average heart rate and respiratory rate were higher in the control group than intervention group and this difference was statistically significant. It was observed that at 1 hour of life the intervention group attained cardiopulmonary stability whereas the control group took approximately 4 days to attain stability.

Similar observations were made by Bera et al that showcased the effect of KMC in vital parameters. The results showed that mean temperature rose by about 0.4°C, RR by 3 per minute, HR by 5 bpm, and SpO₂ by 5% following KMC sessions. Although modest, these changes were statistically significant on all 3 days.(41)

In terms of temperature, babies the intervention group attained temperature stability at 15 and 30 mins of life whereas in control group temperature stabilisation was attained after 45 mins of life and this difference was found to be statistically significant(P value<0.001).Mean capillary blood glucose was higher in the control group but showed no statistical significance.

During the hospital stay from days 1 to 7, the mean average heart rate and respiratory rate was higher in the control group when compared to the intervention group and this difference was statistically significant.(P value<0.001). However, oxygen saturation and capillary blood sugar were comparable in both the groups. The stability of these 2 parameters were attained in first 30 mins of life. Fluctuations of temperature and hypothermia was observed more in in the control group than in the

intervention group, though not statistically significant. At the time of discharge all parameters were comparable between 2 groups.

Our study shows that iKMC promotes better physiological stability in the first hour of life probably because iKMC causes reduction of stress in the newborn during transition to extrauterine life. Our study also showed that iKMC promotes better physiological stability in the first week of life during hospital stay especially with respect to heart rate and respiratory rate.

There was a significant difference in the two groups' respiratory rate, oxygen saturation, and physiological responses according to SCRIP scores, which showed the effects of KC on physiological stabilization here was a significant difference in the two groups' respiratory rate, oxygen saturation, and physiological responses according to SCRIP scores, which showed the effects of KC on physiological stabilization

Similar to our study, Jihye Lee ,Bang KS authors had reported that KMC promotes better physiological stabilisation as in the neonates receiving KMC , after 10-20 mins of initiation of KMC, the heart rate and respiratory rate began to fall towards normal range and the temperature and oxygen saturation began to rise when compared to the control group who were managed in the warmers and these differences were statistically significant(P value<0.001) .According to SCRIP(Stability of the CardioRespiratory system In Premature infants) scores KMC had beneficial effect on early stabilisation of preterms.(38)

FEEDING: The average day of starting oral feed in the intervention group was 2.57 days and control group was 7.58 days and this difference was statistically significant (P value-<0.001). Our study showed that iKMC promoted early initiation of oral feeding.

When we compared the mode of feeding during the day of initiation of feeds, 19 babies in the intervention group versus 8 babies in the control could be administered spoon feeds. This difference was statistically significant.(P value=0.016)

The time taken to initiate direct breastfeeding was significantly faster in intervention group(4.8days) compared to control group(11.3days) and this difference was statistical significant(P value<0.001).

The time taken to reach full breastfeeding was 5.9 days in intervention group and 13.4 days in control group and this difference was statistically significant(P-value-<0.001).

Hence our study showed that iKMC promotes early initiation of breastfeeding and early achievement of full breastfeeding.

In intervention group 21 babies received expressed breast milk from their own mothers and 9 babies required donor milk(DHM) and EBM. Whereas in the control group majority of the babies(16) received donor human milk along with mother's own milk and remaining 14 babies received only Donor human milk. This findings were recorded during the day of initiation of enteral feeds . This difference was statistically significant(P value=0.047) indicating that iKMC promotes better milk production in the mothers participating in the intervention group.

Hence our study shows that iKMC promotes early initiation and acceptance of breastfeeds orally and also promotes early establishment of exclusive breastfeeding.

Similar to our study, Md Mahbulul et al study showed that the meantime to achieve enteral feeding in KMC group was 9.35 ± 3.95 days and in control group was 14.35 ± 6 days which was statistically significant (P value <0.001). Exclusive breastfeeding was significantly higher in KMC group (95%) whereas in control group it was 60% with a P value of <0.001 . (39)

Similarly, Suman RPN et al conducted a study KMC versus conventional care where he found that KMC promotes earlier initiation of breastfeeding and his study showed the mean average days to initiate breastfeeding was (3.76 ± 4.49 days in CMC vs 2.95 ± 3.85 days in KMC group with p value of 0.18). The reason for the difference in time of initiation of breastfeeding can be attributed to the higher incidence of apnea in the control group (29).

Findings correlating with our study was demonstrated in an RCT conducted by Charpak N et al showed that exclusive breastfeeding in intervention and control group was achieved in 46.4% and 45.3% of the study participants respectively. In the study, the intervention group received KMC after stabilization and the control group received traditional conventional care. Partial breastfeeding in the intervention and control group were achieved in 51.6% and 47.2% of the study participants respectively during 40 to 41 weeks of conceptional age (that is gestational age + post-birth age). This difference was statistically significant (P value=0.001)(30). This study shows that KMC promotes exclusive breastfeeding.

PROBLEMS IN THE NEONATE DURING HOSPITAL STAY:

Hypothermia: In our study, during the initial 1 hour, a total of 14 babies out of 60 babies were found to have hypothermia among which 11 and 3 babies were in the control and intervention groups respectively and the difference was statistically significant (P value=0.015). During the first 7 days of hospital stay, total of 5 babies had hypothermia of which 1 was in the intervention group where the temperature recorded was 35 degree Celsius (mild hypothermia) and 4 babies in control group had severe hypothermia with temperatures of 33.3, 34.3, 34.1, 35.1 degree Celsius. Although the incidence and severity was higher in control group, this difference was not statistically significant.

Our study shows that iKMC not only prevents the neonate from developing hypothermia but also prevents the severe hypothermia.

Similar to our observations made, a study conducted by Suman RPN et al, the intervention group received KMC and other group did not receive KMC but a significantly higher percentage of babies had hypothermia during the hospital stay (5.9% in KMC group vs 36.9% in CMC group with $p < 0.001$) (29).

Similar findings were noted in an interventional study conducted by Ahmed MS et al including 50 preterm low birth weight neonates. During the hospital stay, higher incidence of hypothermia was noted in the control group (40%) versus 4% in the intervention group and this difference was statistically significant (P value < 0.001). (40)

Sepsis: A total of 11 babies had sepsis in our study out of which 10 babies, were in control group and 1 baby was from intervention group. Sepsis incidence was much higher in control group and this difference was statistically significant. (P

value=0.003). Thus our study shows that iKMC has an important role in prevention of sepsis.

It is a well known fact that KMC prevents sepsis as reported by other studies , Suman RPN et al reported that sepsis in Kangaroo mother care group was 3.9% compared to 14.8% of sepsis in conventional method of care with statistical significance of $p=0.008$ (29). Overall prevalence of sepsis in newborn was 11% in a study reported by Charpak N et al (30).

A study done by Arya S et al showed that neonatal sepsis was reduced VLBW among newborns who were initiated with iKMC similar to our study (31). Among newborns with birth weight of 1 to 1.5 Kg group, suspected sepsis was reported as 14% lower in intervention group on comparison with control group. Among newborns with birth weight of 1.5 to 1.8 Kg group, a 24% reduction was recorded in the intervention group compared to the control group (31). Other studies conducted in VLBW babies also had similar observations (15, 29, 30). Neonatal sepsis incidence may be decreased by iKMC through a number of potential pathways. Neonates in the intervention group are likely to be colonized by their mother's protective microbiota rather than the NICU environment and hospital staff since immediate KMC is initiated within two hours of birth and then continuous KMC is offered in the mother-newborn care unit. Since each mother in the MNCU attends to her infant alone, there is a lower chance of cross-infection than in the standard NICU, where each nurse attends to 8–10 neonates during a single shift (31). Research has indicated that providing skin-to-skin care to preterm infants results in a unique microbial distribution in the oral cavity (32). Because the mother are constantly present with the child in the mother-newborn care unit, the neonates in the iKMC group received earlier and more frequent breastmilk feeding, which is another protective mechanism by

which KMC may prevent neonatal sepsis (33). In our study, the reasons could be similar as mentioned in the above articles because we observed that the number of newborns with sepsis in the intervention group were considerably less when compared to newborns in the control group. Secondly, the newborns in the intervention group received earlier and more frequent breastfeeding when compared to newborns in the control group.

Need for respiratory support during hospital stay: Across the study group, the need for respiratory support were higher in the control group(76.7%) than in the intervention group(30%). 3 babies in the control group needed mechanical ventilation compared to none in the intervention group, 20 babies needed CPAP ventilation out of which 17 babies were in control group and 3 babies in the intervention. These differences were statistically significant (P value<0.001).

In our study, the leading cause of need for respiratory support in both the groups was found to be respiratory distress syndrome (RDS)-5 babies in intervention and 8 babies in control group. This was followed by sepsis where 8 babies were in the control group versus none in the intervention group. Transient tachypnoea of newborn(TTNB) requiring ventilatory support was 3 in intervention group and 4 in control group. 1 baby in intervention group required oxygen support as it was associated with Atrial septal defect(ASD) with RDS, 3 of the remaining babies in control group required ventilation, 2 babies required ventilation with oxygen by prongs because of severe anaemia and 1 baby required mechanical ventilation due to aspiration pneumonia.

Our study shows that iKMC definitely has a role in preventing the need for respiratory support. Studies are lacking in this area as most of the babies have initiated KMC only after stabilisation.

However only one study which was conducted by Xiaohua Xie et al showed similar observations to our study, Even in this study , KMC was practiced after stabilisation. A total of 145 ELBW infants were included. The mean average day of starting KMC in the intervention group was 4.8 days and KMC was practiced for approximately 3-4 hours a day versus routine care in control group. It was reported that the duration of CPAP ventilation was significantly shorter(20.5 days) in infants receiving KMC compared to(29.5days) infants not receiving KMC (P value=0.001).This study concluded that KMC benefited ELBW by shortening the duration of respiratory support and reducing frequency of apnoeas.(42)

Neonatal mortality:A total of 5 babies(16.6%) expired during the hospital stay and all of them belonged to the control group, this difference was statistically significant (P value=0.020). Out of these 5 babies, 4 babies died of sepsis and 1 baby died of aspiration pneumonia. In our study babies were followed up till they reached 2.5kg and during follow up no mortality was noted in both the study groups.

Hence our study shows that iKMC could prevent early neonatal mortality. Similarly, in a study conducted by WHO, the impact of iKMC on survival of infant(<2kg) was studied. At 28 days of life the neonatal mortality in the intervention group was 12% and in the control group was 15.7% with a P value=0.001 which was statistically significant. The neonatal death in first 72 hours of life was 4.6% in the intervention group and 5.8% in the control group with a P value=0.09 and the difference was not significant.(33)

Similar to our study, in a cohort study from India, it was reported that risk mortality of immediate KMC initiated group was reduced (risk ratio 0.07 (95% CI 0.05 to 0.09)). The mortality rate at 28 days was 6.4% in iKMC group and 74.8% mortality in the control group (34).

A meta-analysis had reported 36% reduction in mortality reduced in neonates in KMC group when compared with conventional care.(18).

Study by Patel D.V et al showed that KMC improved cerebral hemodynamics in preterm infants which in turn led to decreased mortality rates.(44)

Other problems: The other problems observed in our study were hypoglycaemia, neonatal jaundice, apnoea and seizure. Total of 11 babies had hypoglycaemia of which 8 babies were in the control group and 3 were in the intervention group. However, this difference was statistically insignificant. In our study, out of 60 babies, 42 babies had neonatal jaundice and 20 babies had apnoea. However, the difference across the study group was statistically not significant. A total of 4 babies had seizure, among which 3 babies had seizure secondary to sepsis and one baby had seizure due to hypoxia. All 4 of them belonged to control group and this difference was statistically significant (P value=0.038).

Similar observations was made by Gunita Jain et al, in which the study showed that KMC group had no episodes of apnoea and hypoglycaemia as compared to 4 episode of hypoglycaemia and 3 episodes of apnoea in the control group, but this difference was statistically not significant.(43)

DURATION OF HOSPITAL STAY: The duration of hospital stay was significantly prolonged in control group with a mean average of 19.5 days compared to intervention group with a mean average of 11.4 days. Our study shows that iKMC had significantly reduced the number of days of hospital stay. This may be attributed to the fact that iKMC promotes early physiological stabilization and better enteral intake which had ultimately led to earlier discharge of the neonates.

This is contrary to the observations made by Arya S et al. The mean duration of hospital stay in the intervention group was 14.9 days and in the control group was 15.2 days. There was no statistical significance. This could be due to better birth weight babies being included in the study as the study included babies weighing between 1-1.8kg babies, the intervention group was initiated on iKMC and control group was initiated on KMC after stabilization. (31)

This is also in contrary to the observations made by Suman PRN et al. There was no difference in hospital stay between two groups (Hospital stay in KMC group was 12.78 ± 6.27 days vs in conventional method of care (CMC) was 12.86 ± 5.77 with p value of 0.93) (29). There was no difference in the hospital stay in Charpak N et al study (Median days (IQR) in KMC group was 3 (0-11) and in control group was 3 (0-11) days) (30).

ANTHROPOMETRY AT DISCHARGE: In our study ,iKMC promoted statistically significant mean weight gain in the intervention group than the control group. iKMC also had a statistically significant weight gain per day figures during the hospital stay . The mean average weight gain was 15.6gms/day in the intervention group and 13gms/day in the control group .This difference was statistically significant (P value=0.038).

Our study also showed that the duration to attain consecutive weight gain was shorter in the intervention group being 7.17 days when compared to the control group where the average was 14.4days. This difference was statistically significant (P-value<0.001).

When we compared the length and head circumference across the study groups, though both parameters were slightly higher in the intervention group, the difference was not statistically significant.

During follow up it was observed that overall the average number of days taken to reach 2.5kg in the intervention group was 66.9days and in control group was 84.1 days. This difference was statistically significant(P value<0.001). This could be due to the longer duration of KMC practiced by mothers belonging to the intervention group when compared to the control group after discharge. Our study proves that iKMC promotes better growth in VLBW especially with respect to weight gain as the differences in the 2 groups was statistically significant.

A study conducted by Rekha H Udani et al showed that the days taken to reach 2.5kg weight in group practicing KMC for 6 to 12 hrs it was 36.1days(mean weight 1591gm) and 33.3days for the group practicing between 12 to 20hrs(mean weight 1537gm).(48)

Sukrutha Surandran et al observed that infants provided with 4hr/day of KMC had average weight gain of 10.5gm/day compared to 8hr/day of KMC having a gain of 15.02gm/day.(46).Study by Nashwa M Samra et al observed that the average weight gain per day was significantly higher in group providing intermittent KMC where mothers practiced KMC for atleast 1hour twice a day(22.3gms) compared to control group not practicing KMC. (10.3gms).(47)

A study by Suman, Udani et al in western India reported average weight gain per day in the KMC babies practicing KMC for more than 3hours per day of 23.9gm versus 15.8gm in conventional care.(29)

Studies have shown that longer the KMC is practiced per day with respect to number of hours results in better weight gain and also results in lesser number of days to reach target of 2.5kg. This is similar to the observations made in our study.

However in our study, baby's growth in terms of head circumference and length, the differences among 2 groups was not statistically significant.

Contrary to the observations made in our study, a study conducted by Walinjar S et al showed significant change in length and head circumference was noted in KMC group. This study was conducted in 150 babies weighing between 1-1.8kg.(45)

We conclude from our study that the practice of iKMC not only prevents early neonatal mortality but also has several advantages as it promotes better compliance to KMC, early stabilization , early enteral feeding, early establishment of breastfeeding. iKMC also promotes better growth, better weight gain and prevents complications such as hypothermia ,need for respiratory support and sepsis. Hence it should be recommended as a part of routine care of all VLBW babies.

LIMITATIONS:

- The small sample size at a single centre may be insufficient and this might limit the generalizability of the results in other population or settings. Multicenter studies would provide a broader perspective.
- Our study showed that iKMC obligates the need of the surrogate to provide KMC in the labour room at the time of delivery as it may not be possible for the mothers to provide KMC in all babies with VLBW.

- The need for establishment of M-NICU (mother-neonatal intensive care unit) will be essential in all hospital for practice of iKMC to promote the care of both the mother and the neonate.

CONCLUSION

This study aimed to assess the impact of immediate KMC (iKMC) versus conventional care on neonatal mortality in neonates weighing between 1-1.5kg. We divided the 60 newborns into 2 groups: Intervention group, in which KMC was started as soon as possible after birth even before stabilization; and control group in which KMC was started after stabilization.

Maternal factors like maternal age, mode of delivery and maternal problems were comparable across the study groups. Neonatal factors at birth like gender, gestational age, birth weight, mode of resuscitation, APGAR score at 1 min of birth and anthropometry at birth were comparable across the groups.

Our study showed that iKMC helps in achieving better compliance to KMC in respect to number of hours of KMC and early achievement of target KMC(8 hours) and was statistically significant. iKMC also promotes better physiological stability in the first hour of life and also during hospital stay. We observed that it also promotes early initiation of enteral feeding, early establishment of breastfeeding and establishment of lactation earlier and all these observations were statistically significant.

As per our study, iKMC plays an important role in prevention of neonatal mortality, sepsis, hypothermia and the need for respiratory support which subsequently reduced the number of days of hospital stay. These observations were statistically significant. iKMC promoted statistically significant better weight gain and early attainment of target weight of 2.5kg.

We conclude that iKMC has innumerable advantages such as prevention of mortality and morbidity of the VLBW babies and hence it should be implemented in all hospitals taking care of VLBW babies.

SUMMARY

This is a non-blinded randomized control trial conducted in the neonatal intensive care unit and KMC ward under the KLEH DR. Prabhakar Kore Charitable Hospital, department of Pediatrics, Jawaharlal Nehru medical college, Belagavi.

- We included 60 newborns in our study between 1-1.5kg birth weight to assess the impact of iKMC versus conventional care on neonatal mortality.
- The main objective of our study was to observe the impact of iKMC versus KMC implemented after stabilization of VLBW babies on neonatal mortality. Our secondary objectives were to study the other benefits of iKMC on physiological stabilization, breastfeeding, weight gain and prevention of early neonatal problems such as hypothermia, sepsis, hypoglycemia and early discharge.
- We divided the 60 newborns into 2 groups: Intervention group, in which KMC was started as soon as possible after birth even before stabilization ; and control group in which KMC was started after stabilization.
- Data was collected regarding gender, gestational age, birth weight, mode of delivery, maternal problems and neonatal problems at birth and during hospital stay. Vital parameters , anthropometry , feeding along with KMC duration per day were assessed during hospital stay and on followed up until they reached 2.5kgs.
- Maternal factors and neonatal factors at birth were comparable.
- The mean average time of initiation of KMC in intervention group was 18.9 minutes and in control group was 4.3days.
- The mean average hours of KMC practiced per day from 1 to 7 days of life was compared in both the study group and the difference was statistically significant.(P value<0.001)

- The intervention group was able to reach the target KMC(8 hours/day) much faster than the control group and this difference was statistically significant.(P value<0.001).
- Hence our study showed iKMC promotes better compliance to KMC in respect to hours of KMC practiced per day and reaching target KMC.
- We observed that at first hour of life statistically significant difference with respect to heart rate, respiratory rate , temperature but not with oxygen saturation and capillary blood glucose.
- During the hospital stay we found statistically significant differences with respect to heart rate and respiratory rate but no with temperature and capillary blood glucose.
- During the initial 1 hour, more number of babies were found to have hypothermia in the control group compared to the intervention group and this difference was statistically significant(P value=0.015)
- Hence our study shows that iKMC promotes better physiological stability during the first hour of life and also during hospital stay.
- The average day of starting oral feed in the intervention group was 2.57 days and control group was 7.58 days and this difference was statistically significant (P value-<0.001).
- The time taken to initiate direct breastfeeding was significantly faster in intervention group(4.8days) compared to control group(11.3days) and this difference was statistical significant(P value<0.001).
- The time taken to reach full breastfeeding was 5.9 days in intervention group and 13.4 days in control group and this difference was statistically significant(P-value-<0.001).

- We also observed that mothers in the intervention group had better milk production when compared to the mothers in control group and this difference was statistically significant(P value=0.047).
- Hence our study showed that iKMC promotes early initiation of breastfeeding and early achievement of full breastfeeding.
- Incidence of sepsis, was much higher in control group(33.3%) and this difference was statistically significant. (P value=0.003).
- Across the study group, the need for respiratory support were higher in the control group(76.7%) than in the intervention group(30%). (P value<0.001).
- We had a mortality of 16.6%(5 babies) all belonging to the control group and this mortality was during the hospital stay,(P value=0.020). We had no mortality during the follow up indicating that iKMC prevents early neonatal mortality.
- The other problems observed in our study were hypoglycaemia, neonatal jaundice, apnoea and seizure. However, the difference across the study group was statistically not significant though incidence was higher in control group.
- A total of 4 babies had seizure and all 4 of them belonged to control group and this difference was statistically significant(P value=0.038).
- Hence our study showed that iKMC reduces neonatal mortality and prevents sepsis, hypothermia and need for ventilatory support.
- The duration of hospital stay was significantly prolonged in control group with a mean average of 19.5 days compared to intervention group with a mean average of 11.4 days.(P value<0.001)
- There was statistically significant mean average weight gain in the intervention group versus control group being 15.6gms/day and 13gms/day respectively(P value=0.038).

- Our study also showed that the duration to attain consecutive weight gain was shorter in the intervention group being 7.17 days when compared to the control group where the average was 14.4days. (P-value<0.001).
- The mean average time taken to reach 2.5kg was 66.9 days in the intervention group and 84.1 days in the control group and this difference was statistically significant (P value<0.001).
- Hence iKMC promotes better weight gain in babies.
- We conclude from our study that the practice of iKMC prevents early neonatal mortality as it leads to early stabilization of vital parameters, early enteral feeding, early establishment of breastfeeding and promotes better compliance to KMC, better weight gain. iKMC not only prevents hypothermia but also prevents the need for respiratory support and plays a major role in prevention of sepsis.
- We recommend that iKMC should be implemented as a part of routine care of VLBW babies in all tertiary care hospitals for improving the outcomes of the neonates.
- We also recommend the need for establishment of M-NICU(Mother-neonatal intensive care) for the practice of iKMC.
- Further studies are required to study the long term benefits of iKMC on exclusive breastfeeding, promotion of better growth, prevention of mortality and morbidity and neurodevelopmental outcome of infants.

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ANNEXURE I - CONSENT FORM FORMAT

KAHERs JNMC BELAGAVI

INFORMED CONSENT FORM

“IMPACT OF CONTINUOUS KANGAROO MOTHER CARE INITIATED IMMEDIATELY AFTER BIRTH (iKMC) VERSUS CONVENTIONAL CARE ON NEWBORNS WITH BIRTH WEIGHT BETWEEN 1.0 TO 1.5KG”

Name of Student/Principal Investigator:

Name of Guide/Co Investigators:

Objective: To measure the effect of continuous KMC initiated immediately after birth on post-randomization mortality during the first 72h of life and during the neonatal period, compared with continuous KMC initiated after stabilization, in infants with a birth weight of 1.0 to 1.5kg born in a tertiary care hospital

Introduction: You have been asked to involve your child in the said study to be conducted at neonatal care unit of department of paediatrics KLE University's Dr Prabhakar Kore Charitable Hospital, Belagavi by Dr Maanasa G, PG student in department of paediatrics at Jawaharlal Nehru medical College , Belagavi.

Explanation of procedure: Consent will be taken from mother in the labour room before the delivery of the infant and after delivery the infants will be randomized. If the infant is in control group, routine care is provided and infant will be transferred to NICU in a radiant warmer as soon as possible. The infant is closely monitored and will be started on feeds. After stabilisation, mother will be providing KMC as per current WHO guidelines.

If the infant is in intervention group, the infant is kept in SSC as much as possible, preferably with the mother but with a surrogate for the time when the mother cannot provide the intervention. In KMC, the infant is put naked on the mother's chest. The infant has a cap, diaper, and socks and is secured firmly to the chest with a binder that ensures a patent airway and a shirt that provides containment in the fetal position. All routine care is provided in SSC. Any interruptions in SSC are documented to determine the duration for which the intervention was provided per day. The nurse also supports the mother in early expression of milk and to help the baby suckle at the breast

Withdrawal from participation in the study: Participation in this study is voluntary. You will be free to decide whether to participate in this study or continue participation once enrolled. In case you decide to withdraw your participation, you are free to do so. However, please convey the decision to the principal investigator. In case of any complications developed in the infant or the mother this study will be discontinued.

Possible benefits from participating in the study: Participation of your child will help us to assess the impact of immediate KMC care in neonates weighing from 1-1.5kg. Immediate KMC may prevent hypothermia, hypoglycemia, sepsis and improve physiological stabilization and breastfeeding in infants. You are free to discontinue the participation in the study at any time for any reasons and you will not be paid any reimbursement for participation in the research. Hence involving your child in the study is your Voluntary decision, whether or not to participate will not affect your current or future relationship with KLEs Dr. Prabhakar Kore Hospital & Medical research centre, Belagavi.

Possible risks from participating in the study: In both the groups the infants will be closely monitored and measures will be taken for prevention of possible complications such as respiratory distress, hypothermia , etc.

Privacy and confidentiality: The only people who will know that you are a research participant are member of the research team. No information about you or provided by you, during research will be disclosed to others without your written consent. When the results of the research are published or discussed in the conferences, no information will be disclosed that would reveal your identity. Any information obtained in connections with this study and that can be identified with you remain confidential and will be disclosed only with your permission.

Financial incentives: You will not receive any payment for participating in this study.

Authorization for publication of aggregated data: Results obtained after processing of the aggregated data will be published for scientific purposes and or presented to scientific groups. However, your identity will never be revealed.

Questions: In case of any questions with regard to this study, you are free to contact Dr. Harsha Hegde, Chairperson, Ethical committee of JNMC, 0831-2473777 Extension 4052.

Legal rights: By signing this consent form, we are not waving any of your legal rights.

CONSENT STATEMENT

I am making a voluntary decision to participate in the study “IMPACT OF CONTINUOUS KANGAROO MOTHER CARE INITIATED IMMEDIATELY AFTER BIRTH (iKMC) VERSUS CONVENTIONAL CARE ON NEWBORNS WITH BIRTH WEIGHT BETWEEN 1.0 TO 1.5KG”. My signature below indicates that I have decided to participate and I have read the information provided above or the information provided above has been read to me in the language that I understand best. I was given the opportunity to ask questions and that they have been answered to my satisfaction.

Name of the participant:

Signature or left thumb impression of the participant: Name of the witness:

Signature or left thumb impression of the witness: Name of the investigator:

Signature of the investigator:

ANNEXURE II - PROFORMA

[S.No]

PATIENT PARTICULAR'S: -Study group: A B

Name: - Sex:- M/F DOB: - / /

I.P no.

Address: -

Mb. /Phone No: -

LMP: - EDD: - GA: - (a/c LMP)

Birth Weight:

Mode of delivery:

EXAMINATION: -**At Birth:**

General physical	Systemic examination
AF PF Back and spine	R/S: -
Genitals: - Anal opening	CVS: -
Other significant: -	PA: -
Temp RR HR	CNS: -
Pulse CFT	
Weight	
Length	
Head circumference	
Congenital anomaly	

Monitoring of the infant:

KMC started at: _____ hours of life

Daily chart:

Parameters	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 7	Day 8	Day 9	Day 10
Weight										
RBS										
Heart rate										
Respiratory rate										
Temperature										
Saturation										
Type of feeds										
Mode of feeds										
Frequency of feeds										

Problems developed during monitoring:

Hypothermia:

Hypoglycemia:

Sepsis:

Respiratory distress:

Need for ventilatory support: _____, If yes, no of days: _____

Investigations done:

Total hours of KMC provided in a day:

Total no of hospital stay days:

Age at discharge:

Weight of baby at discharge:

Length of baby at discharge:

Head circumference of baby at discharge:

Mode of feeds:

DETAILS OF SURROGATE:

Name:

Age:

Sex:

Relationship to the infant:

STATUS OF THE BABY AT DISCHARGE:

Outcome of the baby:

Follow up at KMC:

	1 st follow up	2 nd follow up	3 rd follow up
Age			
Current weight			
Weight gain			
Length			
Head circumference			
Feeding status			
Clinical examination			
Any complaints/issues			

ANNEXURE III - PHOTOGRAPHS



Photograph 1: iKMC in neonate on IVF and O2 support



Photograph 2: iKMC in labour room



Photograph 3: KMC in NICU

ANNEXURE IV –
MASTER CHART

Name of subject	IP NO	Sex	Maternal age	Parity	Maternal risk factors	GA	Birth weight	Length at birth	HC at birth	Mode of delivery	Resuscitation APGAR @ 1min	Test/control	KMC started at	KMC given by	Day of reaching target KMC	Neonatal jaundice	Need for respiratory support	Reason for need of respiratory support	Time taken for physiological stabilization	Hypothermia during hospital stay	Day of oral feed	Type of feeds	Mode of feeds	Day of DDF started	Time taken to reach full breast feeding	Apnea	Seizure	Hyponatremia	Sepsis	Duration of hospital stay	Day 1 (15 mins)-HR/RR/SpO2/BB S/Temp	Day 1 (30 mins)-HR/RR/SpO2/BB S/Temp	Day 1 (45 mins)-HR/RR/SpO2/BB S/Temp	Day 1 (60 mins)-HR/RR/SpO2/BB S/Temp/KMC	Day 2 -HR/RR/SpO2/BB S/Temp/KMC/ve light	Day 3 -HR/RR/SpO2/BB S/Temp/KMC/ve light	Day 4 -HR/RR/SpO2/BB S/Temp/KMC/ve light	Day 5 -HR/RR/SpO2/BB S/Temp/KMC/ve light	Day 6 -HR/RR/SpO2/BB S/Temp/KMC/ve light	Day 7 -HR/RR/SpO2/BB S/Temp/KMC/ve light	Day of discharge- HR/RR/SpO2/BB S/Temp/KMC	Weight at discharge	Length at discharge	HC at discharge	Day of course weight gain	Mean average weight gain per day	Mortality	Cause of death	Complications after discharge	time taken to reach 2.5kg	Compliance to BF	Compliance to KMC	No of days KMC practiced after follow up
B/O Wajeeda	1185521	M	19	Primi	PPH	30wk 6 d	1.2kg	40cm	29cm	NVD	CIAB	7	Test	20 mins OL	Grandmother	Day 5	yes	O2-3	RDS	3 days	No	Day 5	DHM-2 days, EBM-4 days	RT-4 days, SF-3 days,	Day 8	9 days	yes	no	no	no	12days	172/58/92/88/97.8	168/55/93/84	166/54/95/86/98.4	158/52/96/8/6/98.4/4 hours/1.18kg	155/50/96/98/98.4 hours/1.48kg	150/50/96/9/8/83.6 hours/1.16kg	145/45/96/108/98.3/6 hours/1.15kg	145/49/99/92/9/8.8 hours/1.17kg	145/48/98/10/98.7/8 hours/1.19kg	135/45/97/84/98.8/8 hours	1.14kg	40cm	30cm	Day 6	10gms	no		no	86 days	Good	extended	40 days
B/O Gulnar	1189657	F	22	Multi	no	33wk 3 d	1.5kg	41.5cm	29cm	LSCS	CIAB	8	Control	2 days OL	Mother	Day 4	yes	no		1 day	No	Day 1	EBM-3 days	SF-3 days	Day 3	4 days	no	no	no	15 days	168/55/94/65/97.9	168/57/95/66/98	168/57/96/66/98.3	168/57/96/6/98.4	160/52/97/85/98.2 hours/1.48kg	146/49/97/9/6/98.4/4 hours/1.46kg	148/47/98/91/98.5/6 hours/1.43kg	148/43/97/10/2/98.6/8 hours/1.42kg	145/46/97/100/98.6/8 hours/1.38kg	140/42/97/9/5/98.7/8 hours/1.33kg	140/50/96/10/0/98.1/8 hours	1.45kg	42cm	30cm	Day 8	15gms	no		no	66 days	Good	short	35 days
B/O Sabiya	1190275	F	19	Primi	No	33wk 2 d	1.35kg	40cm	28cm	LSCS	CIAB	7	Test	14mins OL	Aunt	Day 3	no	no		1 day	No	Day 1	DHM-1 day,EBM-3 days	SF-4 days	Day 5	5 days	no	no	no	9 days	166/60/94/78/98	160/58/95/80/98.3	150/54/96/66/98.3	144/54/96/8/98.4/4 hours/1.34kg	148/47/98/10/8/98.4/4 hours/1.34kg	140/45/96/9/9/98.7/8 hours/1.30kg	148/47/96/10/8/8.7 hours/1.26kg	148/47/98/91/9/8.6 hours/1.19kg	148/45/96/9/0/98.6/8 hours/1.2kg	138/47/98/80/98.8/8 hours	1.22kg	40cm	29cm	Day 7	10gms	no		no	70 days	Good	short	38 days	
B/O Shakunthal a	1193138	M	24	primi	No	31wks	1.36kg	41cm	29cm	NVD	CAS	4	Control	3 days OL	Mother	Day 14	yes	O2-1 ; CPAP-3	LOS	12 days	No	Day 12	EBM-10 days	RT-3days,SF-8 days	Day 16	17 days	yes	yes	yes	27 days	160/65/90/10/8/98	160/64/90/10/0/98	160/54/96/66/98.3	160/54/96/2/98.1	172/56/97/45/97.8/0 hours/1.34kg	152/54/97/8/1/98.2/2 hours/1.30kg	168/65/98/102/98.0/2 hours/1.28kg	160/56/99/14/5/98.0/2 hours/1.25kg	152/52/96/85/9/8.2/0 hours/1.24kg	150/50/95/1/25/98.4/3 hours/1.20kg	155/44/95/94/98.4/8 hours	1.43kg	42cm	31cm	Day 22	10gms	no			80 days	Good	extended	23 days
B/O Iaxmi	1194016	M	19	primi	Severe anemia	33wk 5 d	1.4kg	45cm	25cm	LSCS	CIAB	6	Control	5 days OL	Mother	Day 9	yes	O2-3 ; CPAP-1	EOS	6 days	No	Day 15	EBM-9 days	SF-6 days	Day 20	21 days	no	no	yes	30 days	170/57/97/54/97.9	169/58/94/60/98	168/57/96/66/98.4	168/57/96/6/98.5	156/55/97/85/98/0 hours/1.17kg	158/58/97/1/0/98.2/0 hours/1.12kg	160/55/97/168/98.2/0 hours/1.08kg	148/50/97/11/8/8.6 hours/1.02kg	145/49/98/78/9/8.8 hours/1.02kg	146/50/97/8/9/98.5/4 hours/1kg	161/52/95/88/98.3/8 hours	1.5kg	45cm	26.5cm	Day 20	12gms	no		Anemia of prematurity	85 days	Poor(on lactogen)	short	30 days
B/O Kasturi	1195648	F	23	primi	no	30wk 2 d	1.36kg	46cm	27.5cm	LSCS	CIAB	6	Control	9 days OL	Mother	Day 11	yes	O2-2 ; CPAP-6	RDS	9 days	No	Day 13	EBM-10 days	RT-4 days,SF-6 days	Day 18	19 days	yes	no	no	23 days	159/56/93/68/97.1	159/56/93/68/97.4	159/56/93/68/98	158/56/93/8/98.6	155/58/98/11/4/98.3/0 hours/1.34kg	160/50/98/8/98.4/0 hours/1.31kg	154/50/98/77/98.4/0 hours/1.28kg	153/68/99/82/98.4/0 hours/1.25kg	160/62/98/94/9/8.2/0 hours/1.21kg	156/57/98/8/2/98.5/0 hours/1.21kg	143/49/96/78/99.8/8 hours	1.45kg	46cm	28.5cm	Day 15	10gms	no		no	78 days	Good	extended	45 days
B/O Sharadha	1198079	F	28	Multi	No	33wk 2 d	1.2kg	42cm	28.5cm	LSCS	CAS	7	Control	4 days OL	Mother	Day 9	yes	O2-2 ; CPAP-1	RDS	3 days	No	Day 8	DHM-1 day,EBM-11 days	RT-2 days,SF-9 days	Day 12	13 days	yes	no	no	17 days	171/60/95/72/98	171/60/95/72/98	170/60/95/72/98.3	170/60/95/2/98.3	159/50/97/99/9/87/0 hours/1.16kg	160/56/97/9/8/98.7/0 hours/1.13kg	150/50/98/75/98.4/0 hours/1.10kg	148/51/97/10/3/98.6/6 hours/1.07kg	146/47/97/80/9/8.8 hours/1.05kg	149/50/97/7/9/98.8/8 hours/1.02kg	144/49/96/12/2/98.7/8 hours	1.2kg	29.5cm	42cm	Day 9	15gms	no		no	103 days	Good	short	28 days
B/O Anha	1197851	F	24	primi	no	33wk 5 d	1.5kg	43cm	27.5cm	LSCS	CIAB	8	Control	3 days OL	Mother	Day 10	Yes	O2-15 ; CPAP-2 ; venti-3	Anemia, LOS		No		EBM-13 days	RT-13 days			yes	yes	yes	37days	167/71/95/76/97.9	167/71/95/76/98.1	167/71/95/76/98.1	167/71/95/76/98	187/66/97/79/98.2/0hours/1.48kg	168/60/98/8/9/98.4/4 hours/1.44kg	165/56/97/96/98.2/4 hours/1.43kg	180/65/97/88/98/0 hours/1.41kg	177/60/97/179/98.2/0 hours/1.38kg	184/65/97/7/9/98.3/0 hours/1.33kg					Day 25	5gms	yes	?Bone marrow failure,LOS Cholestasis					
B/O Vaishali	1197133	M	30	Multi	PPH	31wk 3 d	1kg	42cm	26cm	NVD	CIAB	8	Control	5 days OL	Mother	Day 10	yes	O2-1 ; CPAP-1	TTNB	6 days	No	Day 10	EBM-5 days	RT-3 days,SF-4 days	Day 12	14 days	no	no	no	18 days	170/56/94/60/98	170/56/94/60/98	170/60/95/72/98.3	170/60/95/2/98.3	168/58/96/91/98/0 hours/980gms	170/62/96/1/04/98/0 hours/950gms	168/58/96/94/98.1/0 hours/940gms	158/48/96/94/98.6/4 hours/920gms	148/48/96/94/9/8.8 hours/900gms	150/50/96/9/4/98.8/4 hours/880gms	149/47/95/87/98.6/8 hours	1.18kg	42cm	27cm	Day 15	15gms	no		no	94 days	Good	extended	48 days
B/O Rohini	1198857	M	22	primi	No	32wk 4 d	1.3kg	42cm	31cm	LSCS	CIAB	7	Test	20mins OL	Aunt	Day 5	yes	O2-2	TTNB	2 days	No	Day 5	EBM-5 days	RT-1 day,SF-2 days	Day 6	7 days	no	no	yes	14 days	156/59/96/64/98	150/53/96/70/98.2	156/56/96/80/98.4	140/52/96/8/6/98.4/4 hours	144/45/95/36/98.6/4 hours/1.48kg	150/50/95/8/98.6/4 hours/1.45kg	140/46/98/81/98.6/4 hours/1.40kg	135/44/96/91/98.8/8 hours/1.38kg	141/48/99/106/98.8/8 hours/1.35kg	138/45/95/1/19/99/8 hours/1.35kg	122/42/98/77/98.1/8 hours	1.39kg	42.5cm	32cm	Day 8	20gms	no		no	63 days	Good	extended	35 days
B/O Bismilla	1200010	M	21	primi	No	30wk 4 d	1.1kg	39cm	32cm	LSCS	CIAB	7	Test	30 mins OL	Grandmother	Day 4	yes	O2-2	RDS	2 days	No	Day 4	DHM-1 day,EBM-6 days	SF-7 days	Day 7	8 days	no	no	no	15 days	149/55/94/71/97.6	144/54/96/78/98.3	145/54/96/78/98.6	134/56/96/7/98.8/2 hours	136/47/98/95/98.4/4 hours/1.08kg	140/45/99/8/7/98.6/6 hours/1.01kg	142/44/98/83/98.8/8 hours/1kg	138/48/98/76/98.6/8 hours/950gms	141/42/98/87/9/8.5 hours/920gms	136/45/98/1/19/99/8 hours/900gms	126/45/99/10/1/98/8 hours	1.09kg	39cm	32cm	Day 9	10gms	no		no	100 days	Good	extended	38 days
B/O Sunita	1202103	M	26	multi	No	34wk 6 d	1.2kg	40cm	32cm	LSCS	CAS	4	Test	12 mins OL	Grandmother	Day 10	yes	O2-5 ; CPAP-1	ASD in the baby	2 days	No	Day 3	EBM-4 days	SF-4 days	Day 6	7 days	yes	no	no	15 days	166/52/95/82/97.9	158/53/95/82/98.4	152/54/96/82/98.6	158/54/96/8/2/98.6/2 hours	160/58/97/89/98.1/0 hours/1.46kg	154/60/95/9/98.4/4 hours/1.42kg	160/58/97/99/98.4/6 hours/1.4kg	162/56/98/85/98.4/6 hours/1.37kg	160/58/97/79/9/8.6 hours/1.33kg	155/60/97/9/8/98.6/8 hours/1.32kg	149/57/98/12/0/97.8/8 hours	1.31kg	40cm	32cm	Day 11	10gms	no		no	68 days	Good	short	30 days
B/O Fakiravva	1202432	F	28	multi	Eclamps ia	37wk 5 d	1.43kg	46cm	33cm	LSCS	CIAB	8	Test	10 mins OL	Grandmother	Day 5	yes	no		1 day	No	Day 3	DHM-3 days, EBM-3 days	RT-2 days,SF-6 days	Day 8	9 days	no	no	yes	14 days	155/50/94/66/97.9	150/50/94/68/98.2	152/54/94/68/98.4	142/56/96/7/4/98.6/4 hours	139/45/98/40/98.6/4 hours/1.41kg	135/42/98/8/98.7/4 hours/1.38kg	143/45/98/82/98.5/6 hours/1.35kg	138/42/98/10/8/7.8 hours/1.31kg	130/44/98/90/9/8.7 hours/1.28kg	135/42/98/1/20/98.5/4 hours/1.25kg	130/40/96/94/98.5/8 hours	1.5kg	46cm	33.5cm	Day 9	20gms	no		no	50 days	Good	extended	41 days
B/O Ansari	1203145	F	27	primi	CHD	34wk 3 d	1.2kg	40cm	29cm	LSCS	CAS	7	Control	4 days OL	Mother		yes	Venti-1	aspiration	4 days	degree farenheit		DHM-2days,EBM-1	RT-2 days,SF-1 day			yes	no	no	6 days	170/57/94/57/97.1	172/57/94/57/97.7	170/60/95/72/98.3	170/60/95/2/98.3	165/62/98/69/98.5/0 hours/1.15kg	155/56/97/7/8/99/0 hours/1.10kg	146/55/98/92/98.3/4 hours/1.04kg	140/50/95/82/98.4/0 hours/1kg	148/50/98/98/9/8.4/2 hours/1kg					yes	2Aspiration pneumonia/LOS								
B/O Bharathi	1204478	M	23	Primi	No	33wk 1 d	1.3kg	36cm	26cm	LSCS	CIAB	8	Control	3 days OL	Grandmother		No	O2-1 ; CPAP-3 ;venti-2	LOS	3 days	degree farenheit		EBM-2 days	RT-2 days			yes	yes	yes	16 days	170/56/94/60/97.8	170/56/94/60/97.9	160/60/95/72/98.3	160/60/95/2/99	167/58/98/86/98.3/0 hours/980gms	141/50/97/10/98.5/4 hours/970gms	149/49/95/151/98.4/4 hours/950gms	156/43/95/88/98.8/0 hours/910gms	180/60/97/100/98.8/0 hours/880gms	177/49/98/1/15/98.4/0 hours/860gms					yes	Sepsis/RDS Cholestasis							
B/O Heena	1206838	F	29	Multi	No	34wk 6 d	1.2kg	49cm	29cm	LSCS	CIAB	6	Test	15 mins OL	Grandmother	Day 4	No	No		1 day	No	Day 1	EBM-2 day	SF-2 days	Day 2	3 days	no	no	no	12 days	168/55/94/65/98	168/55/94/65/98.3	154/55/96/66/98.4	140/54/96/8/2/98.2/2 hours	139/45/98/10/98.5/4 hours/1.48kg	133/42/98/8/98.6/8 hours/1.45kg	139/45/98/92/98.6/8 hours/1.38kg	121/41/98/76/98.9/8 hours/1.35kg	126/45/98/79/9/8.7 hours/1.31kg	125/40/98/1/07/98/8 hours/1.29kg	126/45/99/10/1/98/8 hours	1.1kg	49cm	29cm	Day 8	20gms	no		no	86 days	Good	short	49 days
B/O Savita	1207962	F	20	Primi	no	34wk 6 d	1.3kg	46cm	30cm	LSCS	BMV	3	Control	3 days OL	Mother		No	O2-1 ; CPAP-5;venti-2	LOS	93.5 degree farenheit		EBM-5 days	RT-5 days			yes	no	Yes	Yes	12 days	166/52/95/82/97.9	166/52/95/82/98	166/54/95/86/98.4	166/55/96/8/98.2	160/55/97/19/9/98.0 hours/1kg	150/54/97/8/9/98.4/3 hours/1.23kg	141/55/97/117/98.3/4 hours/1.2kg	170/62/96/90/8/0 hours/1.16kg	161/55/97/83/9/8/0 hours/1.1kg	160/50/97/7/0/98.4/0 hours/1.1kg					yes	Sepsis							
B/O Rani	10001056	F	27	Multi	No	32wk 2 d	1.28kg	47cm	30cm	LSCS	CIAB	7	Test	10mins OL	Grandmother	Day 3	No	No		1 day	No	Day 1	EBM-3 days	SF-3 days	Day 4	4 days	yes	no	no	6 days	155/68/95/80/98	150/68/95/78/98.2	140/64/96/80/98.1	14																			

B/O Vaishnavi	10037815	F	24	Primigravida	No	34wk 3 d	1.46kg	43cm	28cm	NVD	CIAB	7	Test	20mins OL	Aunt	Day 3	yes	no		1 day	no	Day 2	EBM 2 DAYS	RT 1 DAY SF1 DAY	Day 4	5 days	yes	no	no	no	9 days	176/67/97/45/97.8	176/67/97/45/98	170/60/95/72.98	160/60/95/72.98	129/42/98/123/98.2/8 hours/1.44kg	129/42/98/123/98.2/8 hours/1.44kg	129/42/98/123/98.2/8 hours/1.44kg	129/42/98/123/98.2/8 hours/1.44kg	129/42/98/123/98.2/8 hours/1.44kg	129/47/98/120/97.8/8 hours	1.4kg	41cm	31cm	Day 5	20gms	no		no	56 days	Good	extended	38 days	
B/O Soumya	10039184	M	26	Primigravida	No	36wk 2 d	1.39kg	40cm	27.5cm	LSCS	CIAB	8	Control	2 days OL	Mother	Day 4	yes	no		1 day	no	Day 1	EBM2 DAYS	SF2DAYS	Day 2	4 days	no	no	no	no	11 days	170/56/94/60/98.1	170/56/94/60/98.5	164/55/96/66/98.6	154/52/98/78/98.7	159/50/97/99/98/4hours/1.48kg	159/50/97/99/98/4hours/1.48kg	159/50/97/99/98/4hours/1.48kg	159/50/97/99/98/4hours/1.48kg	159/50/97/99/98/4hours/1.48kg	159/50/97/99/98/4hours/1.48kg	130/45/98/109/98/8 hours	1.33kg	44cm	33cm	Day 7	25gms	no		no	79 days	Good	extended	41 days
B/O Vedika	10026456	F	22	Primigravida	No	33wk 1 d	1.3kg	41cm	30.5cm	LSCS	CIAB	7	Control	3 days OL	Mother	Day 6	Yes	O2-1	TTNB	2 days	no	Day 3	EBM 1 DAY	SF1 DAY	Day 4	5 days	no	no	no	12 days	156/59/96/64/97.8	156/59/96/64/98.2	154/54/96/66/99	154/55/97/80/98.8	142/65/95/119/98.6/2 hours/1.1kg	142/65/95/119/98.6/2 hours/1.1kg	142/65/95/119/98.6/2 hours/1.1kg	162/65/95/119/98.6/2 hours/1.1kg	152/65/95/119/98.6/2 hours/1.1kg	152/65/95/119/98.6/2 hours/1.1kg	120/44/98/89/98.4/8 hours	1.26kg	41cm	28cm	Day 8	15gms	no		no	80 days	Good	extended	31 days	