DELAYED CORD CLAMPING VERSUS UMBILICAL CORD MILKING IN TERM AND NEAR-TERM NEONATES - A RANDOMIZED CONTROLLED TRIAL

THESIS

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DECLARATION

I hereby declare that the thesis titled **"Delayed cord clamping versus Umbilical cord milking in term and near-term neonates- A Randomized Controlled Trial"** embodies the original work carried out by the undersigned in All India Institute of Medical Sciences, Jodhpur.

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CERTIFICATE

This is to certify that the thesis titled **"Delayed cord clamping versus Umbilical cord milking in term and near-term neonates- A Randomized Controlled Trial"** is the bonafide work of Dr. Aashim Garg carried out under our guidance and supervision, in the Department of Obstetrics and Gynecology, All India Institute of Medical Sciences, Jodhpur.

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No one who achieves success does so without acknowledging the help of others. The wise and confident acknowledge this help with gratitude. -Alfred North Whitehead

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LIST OF ABBREVIATIONS

UCM	:	Umbilical Cord Milking
DCC	:	Delayed Cord Clamping
ICC	:	Immediate Cord Clamping
ECC	:	Early Cord Clamping
I-UCM	:	Intact Umbilical Cord Milking
C-UCM	:	Cut Umbilical Cord Milking
IVH	:	Intraventricular Hemorrhage
RBC	:	Red Blood Cell
WHO	:	World Health Organization
NRP	:	Neonatal Resuscitation Program
RCT	:	Randomized Controlled Trial
UC	:	Umbilical Cord
POG	:	Period of Gestation
CI	:	Confidence Interval
LCER	:	Late Clamping Event Rate
NICU	:	Neonatal Intensive Care Unit
ANCs	:	Absolute Neutrophil Counts
BMI	:	Body mass index

Hct	:	Hematocrit
Hb	:	Hemoglobin
NCC	:	Newborn Care Corner
AAP	:	American Academy of Paediatrics
SD	:	Standard Deviation
IQR	:	Interquartile Range
AGA	:	Appropriate for gestational age
SGA	:	Small for gestational age
LGA	:	Large for gestational age

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ABSTRACT

Background: Anemia in infancy is common in developing countries. Delayed cord clamping (DCC) and Umbilical cord milking (UCM) allow the transfer of additional blood volume from the placenta to the newborn infant and thus improve the infant's iron stores. UCM has been endorsed as an alternative to DCC, which is the current standard of care.

Objective: To compare the effect of delayed cord clamping vs milking of umbilical cord on initial haematocrit in term and near-term neonates.

Methods: This randomized controlled trial included 374 pregnant women of more than 34 weeks period of gestation. They were randomized into UCM group and DCC group. In UCM group, 119 underwent vaginal delivery and 68 underwent caesarean section. In DCC group, 117 underwent vaginal delivery and 70 underwent caesarean section. Main outcome measures included hematocrit at birth and at 30±6 hours, requirement of phototherapy and neonatal intensive care unit (NICU) admission. Statistical analysis was done using SPSS software. *P* value less than 0.05 was considered significant.

Results: Mean hematocrit in cord sample was 47.02 ± 7.13% in UCM group and 48.04 ± 8.36% in DCC group and the difference was not statistically significant (p = 0.21). Mean hematocrit at 30 ± 6 hours was 54.48 ± 5.84% in UCM group and 50.9 ± 7.1 in DCC group and the difference was statistically significant (p = 0.01). Requirement of phototherapy in UCM group was 18.18% and in DCC group was 19.25% (p =0.79). Rate of NICU admission was 2.67% in UCM group and 7.49% in DCC group (p=0.034). In newborn born to anemic mothers, mean hematocrit in cord sample was 45.9 ± 6.4% in UCM group and 48.8 ± 8.4% in DCC group which was statistically significant (P value 0.02). However, mean hematocrit at 30 ± 6 hours was not statistically significant (P value 0.11) in newborn born to anemic mothers. In newborn born to non-anemic mothers, mean hematocrit in cord sample was not statistically significant (P value 0.98). However, mean hematocrit at 30 ± 6 hours was 55.0 ± 5.5% in UCM group and 50.5 ± 7.4% in DCC group which was statistically significant (P value 0.0001). In Preterm neonates, mean hematocrit in cord sample as well as at 30±6 hours was not statistically significant. In Term neonates, mean hematocrit in cord sample was not statistically significant (P value 0.23). However, mean hematocrit at 30 ± 6 hours was 54.5 ± 5.7% in UCM group and 50.8 ± 7.1% in DCC group which was statistically significant (P value 0.0001). In Appropriate for Gestational Age (AGA) neonates, mean hematocrit in cord sample was not statistically significant (P value 0.25). However, mean hematocrit at 30 ± 6

hours was 53.8 ± 5.6% in UCM group and 50.3 ± 6.9% in DCC group which was statistically significant (P value 0.0001). In Small for Gestational Age (SGA) neonates, mean hematocrit in cord sample as well as at 30 ± 6 hours was not statistically significant.

Conclusion: UCM lead to significant increase in hematocrit levels without increasing the requirement of phototherapy and NICU admissions. Hence, UCM can be used as an alternative to DCC in both term and near-term neonates.


INTRODUCTION

INTRODUCTION

Anaemia in infancy is common in developing countries. According to National Family Health Survey 2019-21, incidence of anaemia in 6 months to 5 years children in India is 67%[1]. To prevent or decrease the incidence of infant anaemia, the concept of placental transfusion has come into practice[2]. Placental transfusion refers to the transfer of more blood components to the infant during the first few minutes after birth[3]. It leads to decreased mortality in preterm infants and improved developmental outcomes in term infants[4,5]. Different strategies for ensuring placental transfusion to the baby include delayed cord clamping, milking of intact umbilical cord and milking of the cut umbilical cord[3]. Umbilical cord milking (UCM) has been endorsed as an alternative to delayed umbilical cord clamping (DCC), which is the current standard of care[4].

In DCC, the cord is clamped after a short delay after birth and in UCM, cord blood is stripped or milked towards the baby. Both the strategies, prevent anaemia in infants by allowing transfer of additional blood volume and haemoglobin from placenta to the newborn[2,6].

On the contrary, when the umbilical cord is clamped immediately after birth (i.e., immediate cord clamping, ICC), a significant amount of the foetal blood remains in the placenta leading to relatively lower red blood cell (RBC) volume in the newborn[7].

For full-term infants, a Cochrane review of 15 trials involving 3911 women-and-infant pairs showed DCC to improve haemoglobin and haematocrit levels postnatally and reduced iron deficiency at three to six months of age without increasing any maternal complication[3,8]. The only drawback reported was an increased requirement of phototherapy. The reduction of iron deficiency and iron deficiency anaemia can have a significant impact on children's health and long-term neurodevelopment not only for developing countries where iron deficiency is more common but also for high-income countries[9,10].

Physiology

If the umbilical cord is not clamped at birth, the blood flow between the baby and the placenta continues for few minutes[11,12]. This is a part of physiological transition from the foetal circulation to the neonatal circulation[13,14,15].

The infant must move from the foetal circulation to his/her own independent circulation after birth. Therefore, as soon as the baby is born, the umbilical circulation slows and the pulmonary vascular resistance falls, rapidly increasing the pulmonary blood flow. It is a part of physiological mechanisms assisting the baby to make transition from intra-uterine to extrauterine life. These physiological mechanisms are not fully developed in preterm infants, so it might take longer for them to adapt without major consequences[13,16,17,18].

For term infants, the blood flows through the umbilical arteries from the infant to the placenta mainly during the first 20 to 25 seconds after birth but is negligible by about 40 to 45 seconds. On contrary, blood flow in the umbilical vein continues from the placenta to the infant up to at least 3 minutes after delivery, after which blood flow is insignificant[19]. This gives an additional 80 ml to 100 ml of blood volume to the term infant[13,20].

However, for preterm infants, physiology of placental transfusion is not very well understood, but is believed may take longer than the term neonate[13,21,22]. A delay of 30 to 45 seconds leads to an increase in blood volume of approximately 8% to 24%[19].

Classic studies from the 1960s showed that the rate of placental transfusion is rapid at first and then slows down in a stepwise fashion, with approximately 25% of the transfer occurring in the first 15 to 30 seconds after the uterine contractions of birth, 50% to 78% of the transfer by 60 seconds and the remaining transfer by 3 minutes[19].

Foetal haemoglobin has enhanced oxygen-binding capacity which allows sufficient oxygen transfer to the foetus in the absence of gas exchange with the external environment. Since, the intrauterine environment is relatively hypoxic, the haemoglobin level in a near-term foetus or term infant is relatively high. The normal haemoglobin concentration for a term newborn is 19.3±2.2 g/dL (193±220 g/L), with a haematocrit of 61%±7.4% (0.61±0.074), values that continue to rise until they reach a maximum at about 2 hours after birth. Within the first week after delivery, haemoglobin and haematocrit values begin to drop in response to the higher ambient oxygen concentration outside the uterus[19].

Factors affecting placental transfusion:

The rate and amount of transfer can be affected by several factors-

1. **Timing of Clamping**- The optimal timing of umbilical cord clamping has been debated in the scientific literature for over a century.
According to World Health Organisation (WHO), Early cord clamping (ECC) is generally carried out in the first 60 seconds after birth (mostly within the first 15–30 seconds), whereas DCC is carried out more than 1 min after the birth or when cord pulsation has ceased[23].

According to latest Neonatal Resuscitation Guidelines, for term and preterm infants who do not require resuscitation at birth, DCC for longer than 30 seconds is recommended whereas for those who require resuscitation at birth, there is insufficient evidence to recommend ECC versus DCC[24].

2. Uterine Contractions- The uterine contraction that occurs between 1 and 3 minutes after the birth is responsible for last step of placental transfusion. Hence, it can accelerate the rate of transfer of blood volume[23].

3. Uterotonic agents- Ergot alkaloids used intravenously might increase the placental transfusion, but they have been replaced by oxytocin. A study conducted by Farrar and colleagues did not find a significant effect on placental transfusion of intramuscular oxytocin because of small sample size[23].

4. Gravity- Studies performed in the 1960's and 1970's showed that if the infant was held below the level of the uterus, gravity increased the rate of transfer, but did not change the total amount of blood transferred.

On the other hand, if the infant was held high above the uterus (around 50 to 60 cm), placental transfusion was prevented by stopping the blood flow through the umbilical vein. Between 10 cm above or below the level of the uterus, the amount and rate of transfer was approximately similar[23].

5. Mode of delivery- Some studies suggested that placental transfusion was reduced or did not occur in caesarean section because of uterine atony due to the uterine incision, the anaesthesia used for the surgery, or the timing of administration of the uterotonic drug[23].

6. Milking of umbilical cord- also known as cord stripping. The umbilical cord is milked from the placental end towards the infant, forcing the blood in the cord towards the infant, prior to clamping the cord.

It has shown to have similar effects on neonatal outcomes—such as haemoglobin or haematocrit—as delayed clamping in both term and preterm infants[23].

Hence, UCM can be a good alternative to DCC.

Benefits of Delayed Cord Clamping[23]

1. Immediate Benefits:

Term - Provides adequate blood volume and birth iron stores
- Increases haematocrit and haemoglobin levels

Preterm - Decreases risk of:
  - Intra-ventricular haemorrhage (IVH),
  - Necrotizing enterocolitis, and
  - Late-onset sepsis

- Decreases need for:
  - Blood transfusions for anaemia or low blood pressure
  - Surfactant
  - Mechanical ventilation

- Increases:
  - Haematocrit
  - Haemoglobin
  - Blood pressure
  - Cerebral oxygenation
  - Red blood cell flow

2. **Long Term Benefits:**

Term
- Improves haematological status (haemoglobin and haematocrit) at 2 to 4 months of age
- Improves iron status through 6 months of age

Preterm
- Increases haemoglobin at 10 weeks of age
- May be a benefit to neurodevelopmental outcomes in male infants

Concerns Related to DCC

1. Delayed Resuscitation: Neonates which are non-vigorous at birth require resuscitation and hence require ICC. DCC might become a barrier to this resuscitation and may lead to IVH or death of the newborn[3,25].

2. Over-transfusion: Sometimes, DCC may lead to over-transfusion of the foetus through the placenta leading to symptomatic polycythaemia or significant jaundice requiring phototherapy in both term and preterm neonates[3]. However, DCC is recommended if treatment for jaundice requiring phototherapy is available. Increased provision of phototherapy with DCC should be weighed against the reduced incidence of iron deficiency anaemia, which might impact the long-term neurodevelopmental outcomes[3].

3. Placental transfusion in caesarean delivery: There is a limited data indicating whether DCC performed during caesarean deliveries can improve placental transfusion. Hence, as per previous studies there is not much benefit of DCC in caesarean delivery as compared to vaginal delivery with respect to placental transfusion[3,26,27].

Umbilical Cord Milking (UCM)

Two types of UCM methods have been described-

1. Intact UCM (I-UCM)
2. Cut cord milking (C-UCM)

Intact UCM (I-UCM) refers to the milking of the attached cord in which the uncut umbilical cord (UC) is grasped gently between the thumb and the fingers and squeezed three to four times from the placental end towards the infant allowing 1-2 seconds of cord refill time in between each milking manoeuvre. After three or four milkings of the cord, an infant receives

about 17 mL/kg of extra blood volume [30]. It provides similar blood volume to 2 min of DCC in term infants as measured by residual placental blood volume[3, 28].

Cut cord milking (C-UCM) refers to clamping and cutting of a long segment of umbilical cord length attached to the baby, the UC is then untwisted, and entire contents of the UC are milked into the baby[3]. A study by McAdams et al in 2017 demonstrated that the blood volume transferred by I-UCM was more than the C-UCM in term newborns[29].

The main difference between DCC and UCM is the mechanism of cord blood transfer to the newborn. In DCC, there is a passive transfer of blood that occurs at a slow rate, whereas in UCM, there is an active transfer of blood that occurs at a rapid rate within a short time which may or may not be beneficial to neonates, especially preterm neonate[30].

Benefits of UCM[3,13,31]

1. Immediate Benefits:

Term
- Provides adequate blood volume and birth iron stores
- Increases: Haematocrit and Haemoglobin levels
- Minimal delay to resuscitation
- Decrease risk of hypothermia

Preterm
- Decreases risk of-
  - All grades IVH
  - Bronchopulmonary dysplasia
  - Necrotizing enterocolitis
  - Hypothermia
- Decreases need for:
  - Blood transfusions for anaemia or low blood pressure
- Increases:
  - Haematocrit
  - Haemoglobin
  - Blood pressure
  - Urine output
  - Cerebral oxygenation

- Blood volume in caesarean section

- Minimal delay to resuscitation

2. <u>Long Term Benefits:</u>

Preterm - Improves haematological status (haemoglobin and haematocrit) at 6 weeks

- Higher ferritin levels at 6 weeks of age

Concerns related to UCM

The exact physiological impact of UCM on neonatal adaptation is not very clear.

All available clinical data from different trials show no adverse effects of UCM but were limited by small sample size, especially of extremely preterm infants, and lack of sufficient data on long-term neurodevelopmental outcomes[3]. According to latest Neonatal resuscitation guidelines for infants born at less than 28 weeks of gestation, UCM is not recommended because it is associated with brain injury (intraventricular haemorrhage)[24].

Effect of timing of cord clamping on Maternal Outcomes

McDonald et al reviewed all the studies which included the maternal outcomes and came to conclusion that timing of cord clamping has no effect on postpartum haemorrhage, maternal postpartum haemoglobin, need for blood transfusion, need for manual removal of the placenta, or the length of the third stage of labour[8].

Despite numerous studies on UCM, a universal standardized protocol for UCM has not been established. According to Neonatal resuscitation program (NRP) guidelines, ECC can be considered for cases where placental transfusion is unlikely to occur, such as maternal haemorrhage or hemodynamic instability, placental abruption, or placenta previa[24]. In such cases, UCM may prove to be of some benefit[3].

There have been many studies comparing neonatal outcome after ECC vs DCC[8,32,33] and ECC vs UCM[34,35,36,37]. People have also compared I-UCM vs C-UCM[29]. Recent studies have demonstrated that UCM and DCC result in comparable increases in hemoglobin in premature babies[4,31,38]. But there is limited literature available on comparison of DCC vs UCM in term neonates.

Therefore, we decided to do a randomized controlled trial (RCT) comparing neonatal outcomes in UCM and DCC in more than 34 weeks period of gestation in both vaginal as well as caesarean delivery.

AIM & OBJECTIVES

AIM AND OBJECTIVES

AIM OF STUDY:

To compare the effect of delayed cord clamping vs milking of umbilical cord on initial hematocrit in term and near-term neonates.

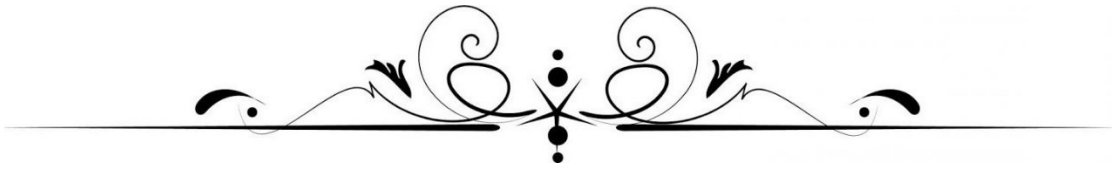
OBJECTIVES:

PRIMARY OBJECTIVE:

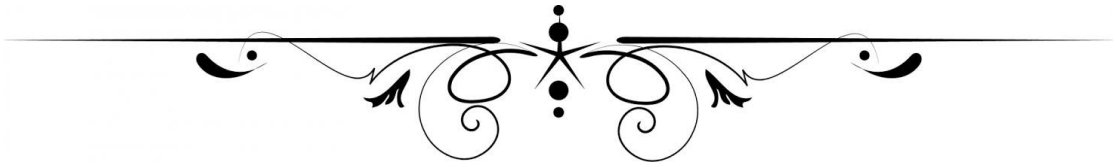
To compare the effect of delayed cord clamping vs milking of umbilical cord on initial hematocrit of cord sample and at 30 +/- 6 hours in term and near-term neonates.

SECONDARY OBJECTIVE:

1. To evaluate hematologic parameters of S. ferritin and Hemoglobin at 14 weeks of age.
2. To evaluate the prevalence of jaundice in neonates requiring phototherapy.
3. To evaluate the need for NICU care.



REVIEW OF LITERATURE



REVIEW OF LITERATURE

In 2007, Baenziger *et al*[39] investigated the effect of placentofetal transfusion on cerebral oxygenation by near-infrared spectroscopy in preterm infants. It was a randomized controlled trial. Total 39 preterm infants with median gestational age of 30.4 weeks were included in the study and were randomly assigned to control group (n=24) and experiment group (n=15). In the experimental group, the delivery of the baby was immediately followed by oxytocin administration to the mother, the infant was then placed 15cm below the placenta and delayed cord clamping was done (60 to 90 seconds). In the control group, baby was delivered conventionally, and early cord clamping was done (<20 seconds). Cerebral hemoglobin concentrations, cerebral blood volume, and regional tissue oxygenation at 4 and 24 hours of life were measured by near-infrared spectroscopy. The cerebral blood volume at 4 hours (6.1 vs 5.8 mL/100 g of tissue) and 24 hours of life (6.2 vs 6.2 mL/100 g of tissue) was not significantly different between the two groups. However, mean regional tissue oxygenation at 4 hours (69.9% vs 65.5%) and 24 hours (71.3% vs 68.1%) of life was significantly higher in the experimental group. They concluded that delayed cord clamping improved cerebral oxygenation in first 24 hours in preterm infants.

In 2010, Ranjit *et al*[33] did a study to compare the effect of DCC and ECC on hematocrit and serum ferritin levels at 6 weeks of life in preterm neonates. It was a randomized controlled trial conducted in delivery room and neonatal intensive care unit of a tertiary hospital. 100 preterm neonates born between 30 0 /7 and 36 6 /7 weeks were randomized to either DCC or ECC group. In DCC group, the cord was clamped 2 min after the baby was delivered and in ECC group, the cord was clamped immediately after the delivery of the baby. The mean serum ferritin (136.9±83.8 ng/mL vs. 178.9±92.8 ng/mL, p value 0.037) and mean hematocrit (27.3±3.8 % vs. 31.8±3.5 %, p value 0.00) were significantly higher in the neonates randomized to DCC group as compared to ECC group. The hematocrit on day 1 was also significantly higher in the DCC group (50.8 ±5.2 % vs. 58.5 ±5.1 %, p value 0.00). The risk of polycythemia and requirement of phototherapy (55.3±40.0 h vs. 36.7±32.6 h, p value 0.016) was significantly higher in DCC group. They concluded that DCC significantly improves the hematocrit value at birth and this beneficial effect continues till at least 2nd month of life.

In 2011, Andersson *et al*[32] investigated the effect of delayed cord clamping and early cord clamping on iron status of the infant at 4 months of age in European setting. It was a

randomized controlled trial done in the setting of Swedish country hospital. It included 400 full term infants born after a low-risk pregnancy. These 400 infants were randomized into DCC group (>180 seconds after delivery) and ECC group (<10 seconds after delivery). The infants showed no significant differences in hemoglobin concentration between the two groups at 4 months of age, but infants with delayed cord clamping had 45% (95% confidence interval [CI] 23% to 71%) higher mean ferritin concentration (117 μg/L v 81 μg/L, P<0.001) and a lower prevalence of iron deficiency (1 (0.6%) v 10 (5.7%), P=0.01, relative risk reduction 0.90; number needed to treat=20 (17 to 67)). The prevalence of neonatal anemia at two days of life (2 (1.2%) v 10 (6.3%), P=0.02, relative risk reduction 0.80, number needed to treat 20 (15 to 111)) was lower in the delayed cord clamping group. Postnatal respiratory symptoms, polycythemia, or hyperbilirubinemia requiring phototherapy showed no significant difference in the two groups. They concluded that delayed cord clamping resulted in improved iron status and reduced prevalence of iron deficiency at 4 months of age, and reduced prevalence of neonatal anemia, as compared to early cord clamping group, without any demonstrable adverse effects. Since iron deficiency in infants is associated with impaired development of the infant, delayed cord clamping benefits full term infants.

In 2011, Rabe H *et al*[40] did a randomized controlled trial to compare the effect of UCM and DCC on placenta-fetal blood transfusion in preterm neonates before 33 weeks period of gestation (POG). Women at risk for singleton preterm deliveries were recruited in the study and all of them delivered before 33 completed weeks of gestation. It was a single centre trial in which women were randomized into either UCM (4 times) or DCC (>30 seconds). Out of 58 neonates included in the trial, 27 were allocated to UCM group and remaining 31 were allocated to DCC group. Mean birth weight was 1,235±468 g in the UCM group and 1,263±428 g in the DCC group, with mean gestational age of 29.5±2.7 weeks and 29.2±2.3 weeks, respectively. Mean hemoglobin concentration value at 1 hour of life for UCM group was 17.5 g/L and for DCC group was 17.3 g/L (p value = 0.71). There was no significant difference in number of neonates requiring blood transfusion (UCM group, 17; DCC group, 15; P=.40) or the median number of transfusions required within the first 42 days of life (median [range]: UCM group 0 [0–20]; DCC group 0 [0–7]; P=.76). They concluded that milking the cord four times or DCC for at least 30 seconds achieved a similar amount of placenta-fetal blood transfusion.

In 2012, Erickson *et al*[41] did a study to compare the effect of Umbilical cord miking and immediate cord clamping on hematocrit levels at 36 to 48 hours of life in term infants delivered by caesarean section. It was a randomized controlled trial in which 24 women scheduled for elective caesarean section were included and randomized to either ICC (<10 seconds) or UCM (5 times by obstetrician) at birth. Placental residual blood volume (13.2±5.6 vs 19.2±5.4 ml kg^{-1}, *P*=0.01) was smaller and hematocrit levels at 36 to 48 hours of life (57.5±6.6 vs 50.0±6.4 %, *P*=0.01) were higher in UCM group. Five infants (42%) in the ICC group had hematocrit of ⩽47%, indicative of anemia.

In 2013, Upadhyay *et al*[2] did a study to compare the effect of UCM and ECC on hematological parameters at six weeks of life in term and near-term neonates. It was a randomized controlled trial. The eligible neonates (>35 weeks gestation) were randomized into control and intervention groups of 100 each. Early cord clamping (within 30 seconds) was done in both the groups. In the control group, cord was clamped near (2-3cm) the umbilicus and no milking was done, whereas in the intervention group milking was performed after cutting and clamping the cord at 25cm from the umbilicus. Both the groups received similar routine care thereafter. For statistical analysis, unpaired student t test and fisher exact test was used. Baseline characteristics were comparable in both the groups. Mean hemoglobin concentration (Hb) (11.9 [1.5] g/dL) and mean serum ferritin (355.9 [182.6] μg/L) were significantly higher in the intervention group as compared with the control group (10.8 [0.9] g/dL) and (177.5 [135.8] μg/L), respectively, at 6 weeks of life. Also, the hematocrit and mean hemoglobin at 12 hours and 48 hours of life was significantly higher in the intervention group with *p value* = 0.0001. The mean blood pressure of the neonate at 30 minutes, 12 hours, and 48 hours of life was significantly higher but within the normal range in intervention group. There was no significant difference observed in the respiratory rate, heart rate, polycythemia, serum bilirubin, and the need for phototherapy in the two groups. They concluded that UCM is a safe procedure and it improved hematological parameters at six weeks of life in term and near-term neonates.

In 2013, March *et al*[42] did a randomized controlled study to determine the need for neonatal red blood cell transfusion in extremely preterm neonates in UCM as compared to ICC. Women expected to deliver between 24 to 28 completed weeks in tertiary care centre were randomized into UCM before clamping or ICC. Total 113 women were enrolled in the study and randomized, out of which 56 were allocated to UCM group with 36 remaining eligible

and completing the study and 57 were allocated to the ICC group with 39 remaining eligible and completing the study. Neonates in the UCM group were less likely to receive blood transfusion as compared to the ICC group, though it was not statistically significant (Relative risk: 0.86; 95% CI: 0.73 to 1.0). Neonates in UCM were less likely to develop intraventricular hemorrhage (p=0.0195) and had higher hematocrits at birth (p=0.004). They concluded that UCM of a preterm neonate is an easy intervention with the potential to improve perinatal outcomes.

In 2013, McDonald *et al*[8] did Cochrane review of the randomized controlled trials comparing ECC and DCC. Policies for timing of cord clamping varied, with ECC carried out in the first 60 seconds after birth, whereas DCC usually involved clamping the UC more than one minute after the birth or when cord pulsation ceased. 15 trials involving a total of 3911 women and neonate pairs were included in the study. They determined the effects of ECC and DCC on maternal and neonatal outcomes. There were no significant differences in the maternal outcomes between the two groups. There was no significant difference in the primary outcome of neonatal mortality [Relative Risk 0.37, 95% CI 0.04 to 3.41, two trials, 381 infants with a late clamping event rate (LCER) of ˜1%] in the two groups. Need for phototherapy was less in ECC group as compared to DCC (Relative Risk 0.62, 95% CI 0.41 to 0.96, data from seven trials, 2324 infants with a LCER of 4.36%, I^2 0%). Hemoglobin concentration in neonates at 24 to 48 hours was significantly lower in the ECC group (Mean difference -1.49 g/dL, 95% CI -1.78 to -1.21; 884 infants, I^2 59%). Neonates in the ECC group were twice as likely to be iron deficient at 3 to 6 months as compared to neonates in DCC group (Relative risk- 2.65, 95% CI- 1.04 to 6.73, five trials, 1152 infants, I^2 82%). Mean birthweight was higher in DCC group as compared to ECC group (101 g increase 95% CI 45 to 157, random-effects model, 12 trials, 3139 infants, I^2 62%). There were no significant differences in other neonatal morbidity outcomes like Apgar score less than seven at five minutes or admission to Neonatal Intensive Care Unit (NICU). They concluded that DCC increased early hemoglobin concentrations and iron stores in term neonates, hence it is beneficial if treatment for jaundice requiring phototherapy is available.

In 2015, Wassia *et al*[30] performed a systemic review and meta-analysis to look for efficacy and safety of UCM in full term and preterm neonates. 7 randomized controlled trials involving 501 neonates, which compared the UCM with other methods of umbilical cord management in full term and preterm neonates were included in the study. Neonates of less

than 33 weeks POG allocated to UCM showed no difference in the risk for mortality (risk ratio, 0.75 [95% CI, 0.35 to 1.64]; risk difference, –0.02 [95% CI, –0.09 to 0.04]), hypotension requiring volume expanders (risk ratio, 0.71 [95% CI, 0.41 to 1.25]; risk difference, –0.09 [95% CI, –0.22 to 0.05]), or inotrope support (risk ratio, 0.77 [95% CI, 0.51 to 1.17]; risk difference, –0.10 [95% CI, –0.25 to 0.05]) as compared to the control group. UCM group showed higher initial levels of hemoglobin (mean difference, 2.0 [95% CI, 1.3-2.7] g/dL) and hematocrit (mean difference, 4.5% [95% CI, 1.5%-7.4%]). Reduced oxygen requirement at 36 weeks (risk ratio, 0.42 [95% CI, 0.21 to 0.83]; risk difference, –0.14 [95% CI, –0.25 to –0.04]) and reduced risk for intraventricular hemorrhage of all grades (risk ratio, 0.62 [95% CI, 0.41 to 0.93]; risk difference, –0.12 [95% CI, –0.22 to –0.02]) was identified in the UCM group. Among infants with POG of more than 33 weeks, UCM was associated with higher hemoglobin levels in the first 48 hours of life in 224 neonates (mean difference, 1.2 [95% CI, 0.8-1.5] g/dL) and at 6 weeks of life in 170 neonates (mean difference, 1.1 [95% CI, 0.7-1.5] g/dL). They concluded that UCM was associated with some benefits and no adverse effects in the immediate postnatal period in preterm neonates at POG <33 weeks.

In 2015, Katheria *et al*[31] did a randomized controlled trial on neonates <32 weeks POG born by caesarean section to determine the effect of DCC and UCM on systemic blood flow to the neonates. It was a two-centre trial. Neonates delivered caesarean section were randomly assigned to UCM (4 strippings) or DCC (45-60 seconds) group. Neonates delivered by vaginal delivery were also assigned separately. Total 197 neonates of mean POG 28 ± 2 weeks were enrolled in the study. Out of which 154 neonates were delivered by caesarean section and rest 43 neonates by vaginal delivery. Neonates in the UCM group delivered by caesarean section (n=75) were observed to have higher superior vena cava flow and right ventricular output in first 12 hours of life as compared to DCC group. Neonates in UCM group also had higher delivery room temperature, hemoglobin, blood pressure over the first 15 hours, and urine output in the first 24 hours of life. No significant difference was found in neonates delivered by vaginal delivery. Hence, they concluded that UCM could be an efficient technique to improve blood volume in premature infants especially delivered by caesarean section.

In 2015, Jaiswal *et al*[43,44] did a study to compare the effect of UCM on hematological parameters (serum ferritin and hemoglobin) at 6 weeks of life in term neonates as compared to DCC. It was a randomized controlled trial conducted during 2012 to 2013 in a teaching

hospital in India. Total 200 neonates of more than 36 weeks POG were enrolled in the study and randomized to DCC (60 to 90 seconds) and UCM group (done on 25cm cord length). Baseline characteristics were comparable in both the groups. Mean hemoglobin (11.0 gm/dl [2.4]) and mean serum ferritin (134.0 ng/ml [89.8]) in UCM group was comparable to mean hemoglobin (11.3 gm/dl [2.6]) and mean serum ferritin (142.7 ng/ml [87.1]) in DCC group at 6 weeks of life. There was no difference in cranial Doppler indices, hemodynamic status, and adverse neonatal outcomes among the two groups. They concluded that both UCM and DCC had similar effects on hematological parameters at 6 weeks of life in term neonates.

In 2015, Kilcdag H *et al*[34] did a randomized controlled study to investigate the effect of UCM on the absolute neutrophil counts (ANCs) and the neutropenia frequency of preterm neonates. 58 pregnant women were randomly assigned to one of the UCM and control groups. A total of 54 preterm neonates (gestational age less than or equal to 32 weeks) were enrolled into the study. UCM was performed in 29 neonates before clamping whereas in remaining 25 neonates, UC was clamped immediately after birth. They found that ANCs were statistically significantly lower in the UCM group as compared to the control group on days 1, 3 and 7 of life. The frequency of neutropenia was also higher in the UCM group. They concluded that UCM plays a role on the ANCs of preterm neonates.

In 2017, El-kotb AM *et al*[45] did a study to compare the short-term benefits and risks of DCC and UCM in full term neonate delivered by elective caesarean section. It was a randomized controlled trial done in Ain Shams Maternity teaching hospital, Egypt. A total of 300 patients were enrolled in the study and were randomized into two groups of 150 each. Group 1 was UCM group, in which clamps were applied after milking the UC 5 times towards the neonate and Group 2 was DCC group, in which clamps were applied after 2 minutes of birth of the neonate. On comparing the two groups, mean hemoglobin was 9.95 ± 0.88 mg/dl in group 1 and 9.86 ± 0.71 mg/dl in group 2 with a p value of 0.338 which not significant. In UCM group, 12 neonates were admitted to NICU for jaundice which represents (8%) and in DCC group, 16 neonates were admitted to NICU for jaundice which represents (10.7%) with a p value 0.427 which was not significant. They concluded that both DCC and UCM have similar benefits in improving the hematological parameters at 6 weeks of life without producing any significant adverse effects on neonatal outcomes in initial 6 weeks of life. DCC has been formulated as standard of care in all deliveries by American Academy of Paediatrics, UCM can be recommended in all deliveries in which DCC is not

feasible or not practiced for any reason. UCM can be done in cases where neonate requires resuscitation.

In 2017, McAdams *et al*[29] did a study to determine placental transfusion blood volumes with intact UCM and cut UCM in term neonates. Total 60 women at ≥37 weeks gestation were enrolled in the study. For I-UCM, the cord was milked 3-4 times while attached to the placental circulation. For C-UCM, a 10, 20, or 30 cm cord segment was cut separately and milked four times. Mean blood volume was increased with I-UCM (x4) as compared to 30 cm C-UCM technique (48.5 ± 19.0 vs. 24.8 ± 4.0 mL, P < 0.001). For C-UCM, blood volume increased proportionally to cord length and, by the second milking, 98.1 ± 4.5% of blood volume was delivered. They concluded that I-UCM provides a greater blood volume than C-UCM. With C-UCM, milking the cord more than twice has no additional advantage.

In 2018, Alzaree *et al*[46] did a study to compare the effect of UCM and DCC on hemoglobin at 6 weeks of life among term neonates. It was a randomized controlled study in which participants were allocated into two groups of 125 each. This study was conducted at El-Galaa Teaching Hospital, labour suite, Cairo, Egypt. 250 pregnant women starting from ≥ 37 weeks POG were included in the study. They found that UCM was associated with higher hemoglobin levels at 6 weeks of life as compared to DCC and was statistically significant but clinically there was no difference between the two groups (10.4 ± 0.5 and 10.6 ± 0.5 respectively, P < 0.001). They also found positive correlation between hemoglobin of the mother and the newborn during the first day and after 6 weeks with r = 0.349 and 0.283 respectively and a P value < 0.001. Also, there was a positive correlation between the hemoglobin of the foetus after the first day and foetus at 6 weeks with r = 0.534 and a P value < 0.001. For other outcomes like positive pressure ventilation, APGAR score, poor neonatal outcomes such as respiratory distress syndrome there were no significant differences between the two groups. They concluded that UCM can be recommended in term babies when DCC is not available.

In 2018, Mohan *et al*[35] did a randomized controlled trial to evaluate the effect of UCM on short term morbidity and hematologic parameters at 6 weeks of life in preterm neonates requiring resuscitation. 60 preterm neonates requiring resuscitation were allocated into two groups: UCM group and no milking group. Neonates in UCM group had higher hemoglobin (10.07 g/dl vs 8.9 g/dl; p 0.003) and higher serum ferritin level (244.8ng/ml vs 148.5ng/ml; p 0.04) as compared to no milking group. They concluded that UCM can be used to increase

placental transfusion in preterm neonates requiring resuscitation with no significant side effects.

In 2018, Nagano *et al*[47] did a systemic review and meta- analysis to compare the short- and long-term effects of DCC and UCM on neonates born at less than 37 weeks of POG. They included two trials (255 preterm neonates, 23 0/7 to 32 6/7 weeks of gestation) in the analysis. It was seen that UCM was associated with fewer intraventricular hemorrhages (IVHs) (two trials, 255 preterm neonates; relative risk 0.45, 95% confidence interval [CI] 0.20 to 0.98, low quality of evidence) and also an increased proportion of infants with a Bayley score at 2 years of age (two trials, 174 infants; Cognitive: relative risk 1.14, 95% CI 1.03 to 1.26, Language: relative risk 1.24, 95% CI 1.03 to 1.49, low quality of evidence) as compared to DCC. They concluded that UCM did not reduce mortality or need for transfusion when compared to DCC but lowered the risk of IVH and improved certain neurodevelopmental outcomes.

In 2019, Samantha *et al*[38] did a study to compare the effect of UCM versus DCC on initial hematocrit concentration in preterm neonates, incidence of intraventricular hemorrhage, necrotizing enterocolitis and need for blood transfusion. The study was an unblinded randomized controlled trial of singleton preterm neonates between 23 to 34 weeks 6 days POG assigned randomly into two groups: DCC (>60 seconds) and UCM (4 times). Out of total 204 patients, 104 were allocated to DCC group and 100 to UCM group. No significant difference was found in baseline maternal characteristics between the two groups. The initial hematocrit concentration was higher in UCM group as compared to DCC group, but it was not significant (51.8 [6.2%] vs 49.9 [7.7%]; *P*=.07]. The incidence of blood transfusion (15.5% vs 9.1%; *P*=.24), necrotizing enterocolitis (5.8% vs 3.0%; *P*=.49), and intraventricular hemorrhage (15.5% vs 10.1%; *P*=.35) was lower in UCM group but was not statistically significant. Need for phototherapy and peak serum bilirubin levels were comparable between the two groups. They demonstrated that UCM could be an acceptable alternative to DCC because of the similar effects on hematological parameters and need for neonatal transfusions. Also, there was no increased risk of complications or neonatal morbidity observed in UCM group. So, UCM can offer an efficient and timely method of providing increased blood volume to the neonate.

In 2019, Lago Leal V *et al*[48] assessed the effects of UCM and ECC in neonates born before 37 weeks of gestation. Total 138 neonates at 24 to 36 weeks 6 days POG were included in the

study and was allocated to UCM and ECC groups randomly. Initial hematocrit concentration was significantly higher by 5.36% (p value < 0.05) and initial hemoglobin by 1.675 g/dl (p value < 0.05) in UCM group but there was no difference in the need for blood transfusion in neonate during first 30 days after delivery (relative risk 0.8; 95% CI 0.22–2.85). However, need for phototherapy was also higher in UCM group as compared to ECC group (relative risk 1.62; 95% CI 1.1–2.38). There was no significant difference in platelet transfusion, need for oral iron supplementation, patent ductus arteriosus, intraventricular hemorrhage, respiratory distress syndrome, periventricular leukomalacia, necrotizing enterocolitis, use of surfactant, meconium aspiration syndrome, days of oxygen supplementation, need for vasopressors, length of NICU stay or postpartum hemorrhage. It was concluded that UCM did not reduce the need for phototherapy and red blood cell transfusions in preterm neonates.

In 2019, Balasubramanian *et al*[7] conducted a systemic review and meta-analysis of safety and efficacy of UCM in preterm neonates. All the RCT's that compared UCM with DCC/ICC in preterm infants were identified by searching databases, clinical trial registries and reference list of relevant studies in November 2019. Mortality and morbidities in preterm neonates were the main outcome measures. A total of 19 studies including 2014 preterm neonates were included. Among 19 studies, 14 studies (n=1092) compared UCM with ICC, whereas five studies (n=922) compared UCM with DCC. UCM reduced the need for blood transfusion as compared to ICC (risk ratio: 0.56 (95% CI 0.43 to 0.73), p<0.001). When compared to DCC, UCM significantly increased the risk of intraventricular hemorrhage (grade III or more) (risk ratio:1.95 (95% CI 1.01 to 3.76), p=0.05). Information on long-term neurodevelopmental outcomes was limited. Hence, they concluded that UCM cannot be considered as placental transfusion strategy in preterm infants based on the currently available evidence.

In 2019, Zanardo *et al*[36] did a study to evaluate the effect of intact UCM and ICC in enhancing placental transfusion after elective caesarean delivery. Volume of placental transfusion was assessed by change in hematocrit value between neonatal cord blood sample and capillary heel blood sample at 48 hours of life, corrected for the change in body weight. It was a randomized controlled trial conducted between 1 October 2018 and 31 January 2019. Total 167 women were enrolled in the study. There were no significant differences in cord blood mean hematocrit (Hct) values at birth (UCM, 44.5 ± 4.8 vs. ICC, 44.9 ± 4.2%, p ¼ 0.74) in the two groups. UCM group had higher capillary heel hematocrit values at 48 hours

of life (UCM, 53.7 ± 5.9 vs. ICC, 49.8 ± 4.6%, p < 0.001) which was statistically significant. Hence, UCM group had higher placental transfusion volume (Δ Hct, UCM 9.2 ± 5.2 vs. ICC 4.8 ± 4.7, p < 0.001), despite comparable neonatal body weight decrease (UCM, -7.3 vs. ICC, -6.8%, p = 0.77). They concluded that intact UCM was an efficacious and safe procedure among neonates born via elective caesarean delivery to enhance placental transfusion.

In 2020, Mangla *et al*[49] did a randomized controlled trial to study the effect of intact UCM and DCC on hematocrit concentration at 48 (±6) hours of life in term and late preterm neonates. All term and late preterm neonates of more than 35 weeks POG delivered by either normal delivery or caesarean section were included in the study. They were randomly assigned into either UCM (four times; n=72) or DCC group (more than 60 seconds; n=72). The mean (Standard Deviation) hematocrit at 48 (±6) hours in the UCM group was higher as compared to DCC group [57.7 (4.3) *vs.* 55.9 (4.4); *P*=0.002]. Venous hematocrit at 6 (±1) weeks was higher in UCM group as compared to DCC group [mean (Standard Deviation), 37.7 (4.3) *vs.* 36 (3.4); mean difference 1.75 (95% CI 0.53 to 2.9); *P*=0.005]. Other parameters like incidence of polycythemia requiring partial exchange transfusion, incidence of hyperbilirubinemia requiring phototherapy, and serum ferritin levels at 6 (±1) weeks of age were similar in the two groups. They concluded that venous hematocrit at 48 (±6) hours in late preterm and term neonates is higher in UCM group when compared to DCC.

In 2020, Josephsen *et al*[37] did a single centre randomized controlled trial to assess potential benefits of UCM in extremely preterm infants when compared to ICC. 56 Neonates from 24 0/7 to 27 6/7 weeks' gestation were enrolled in the study. In UCM group, 18 cm of the UC was milked three times. Baseline characteristics were similar in both the groups with a mean gestational age of 26.1 ± 1.2 weeks and a mean birth weight of 815 ± 204 g. There were no differences in the mean initial hemoglobin in the ICC group when compared with the UCM group, 13.8 ± 2.6 g/dL and 13.7 ± 2.0, respectively (p = 0.95). Also, there was no difference in median number of blood transfusions after birth between the ICC group and the UCM group, 2 (interquartile range [IQR]: 1–4) versus 2.5 (IQR: 1–5) (p = 0.40). There was no difference in the rate of severe IVH in two groups. There were no differences in death or disability in the ICC group compared with the UCM group (26 vs 22%; p = 1.0) and no differences in neurodevelopmental outcomes at 15 to 18 months corrected gestational age. They concluded that there was no significant difference between UCM and ICC in extremely preterm infants.

In 2020, Fuwa *et al*[50] did a systemic review and meta-analysis to compare the effects of DCC and UCM on term neonates. They included three trials (650 term neonates). It was seen that UCM was associated with higher hemoglobin levels at 6 weeks of life [neonates, 621; mean difference, 0.17; 95% confidence interval, 0.05–0.29] as compared to DCC. There were no statistical differences in hemoglobin levels at birth, serum bilirubin levels at 48 hours of life, or hematocrit levels at 48 hours of life. They concluded that UCM is as beneficial as DCC in term neonates.

MATERIAL & METHODS

MATERIAL AND METHODS

Ethical Consideration:

Prior to the commencement of data collection, the study protocol was reviewed and approved by Institutional Ethics Committee (AIIMS/IEC/2020/2070).

The study is also registered at Clinical Trial Registry of India (CTRI/2020/02/023364).

Study Setting: Study was conducted in the Department of Obstetrics and Gynecology and Department of Neonatology, AIIMS Jodhpur.

Study design: Randomized controlled trial.

Study population: Neonates born at 34 completed weeks or more.

Study Period: This study was conducted from March 2020 to August 2021

INCLUSION CRITERIA:

All singleton infants of more than or equal to 34 weeks of completed gestation, delivered either by caesarean section or by vaginal delivery at AIIMS, Jodhpur.

EXCLUSION CRITERIA:

- Short umbilical cord length (25 cm),
- Limp at birth,
- Non-vigorous babies
- Delivery by caesarean section for fetal compromise,
- Twin pregnancy or higher order gestation
- Instrumental deliveries,
- Delivery to Rh-negative mothers,
- Major congenital anomalies,
- Cord prolapse,
- Hydrops fetalis,
- Placenta previa,
- Placental abruption,

- Cord abnormalities such as true knots.
- Fetal growth restriction.

RANDOMIZATION

All subjects fulfilling the above-mentioned criteria and parents willing to participate were approached for enrolment into the study. Parents were counselled and informed written consent was taken. For randomization, we used computer generated random numbers in the blocks of 10. Computer generated random sequences were generated by online software (https://www.sealedenvelope.com/simple-randomiser/v1/lists) by an individual not involved in enrolment, treatment and follow up of the study. The numbers were written on small slips and placed in serially numbered opaque sealed envelopes. Randomization was stratified based on mode of delivery- Vaginal delivery vs caesarean section. The envelopes for vaginal delivery were kept in the labour room whereas the envelopes for caesarean section were kept in operation theatre.

Immediately after delivery of the baby, the baby was kept on mother's abdomen in both vaginal delivery as well as in caesarean section. If the baby was vigorous and the length of umbilical cord was more than 25cm, then envelopes were opened by the attending nurse who was not involved in the enrolment, treatment and follow up of the study. According to the code written in the envelope, patients were randomized to either of the following groups:

Group 1- Umbilical cord milking (Intervention Group)

Group 2- Delayed cord clamping (Control Group)

Group 1- Umbilical cord milking (Intervention Group)

This group included manual milking or stripping of approximately 20 cm of umbilical cord from the placental end to the infant's umbilicus 4 times by holding the UC in between the thumb and the fingers at the speed of 10cm/sec. Around 1-2 seconds of time was allowed for refill of the UC in between each milking maneuver. After milking the UC four times, early cord clamping (ECC) was done, and the UC was cut. This whole process of UCM took nearly 20-25 seconds from the delivery of the baby. After cutting the UC, the baby was kept under the radiant warmer in the Newborn Care Corner (NCC) of our labour room or operation theatre unless they required admission to NICU for standard indications.

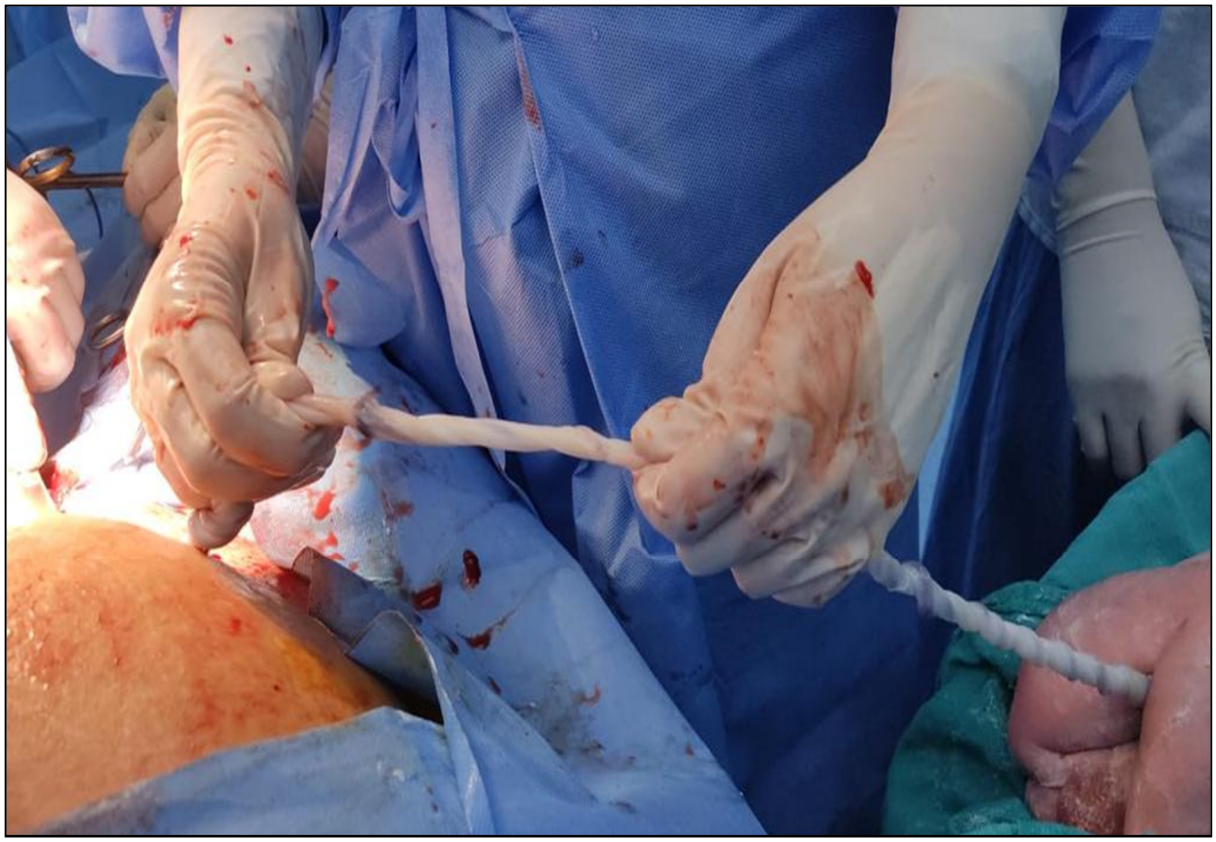


Figure 1: Umbilical Cord Milking

Group 2- Delayed cord clamping (Control Group)

This group included clamping the UC using the clamps after a time lapse of at least 60 seconds or till the cord pulsations ceased. Then the UC was cut, and the baby received routine care similar to the intervention group.

The time to clamping and milking the umbilical cord was measured by wall mounted quartz clocks.

According to our protocol, we used intramuscular oxytocin routinely after vaginal delivery and intravenous oxytocin in caesarean section.

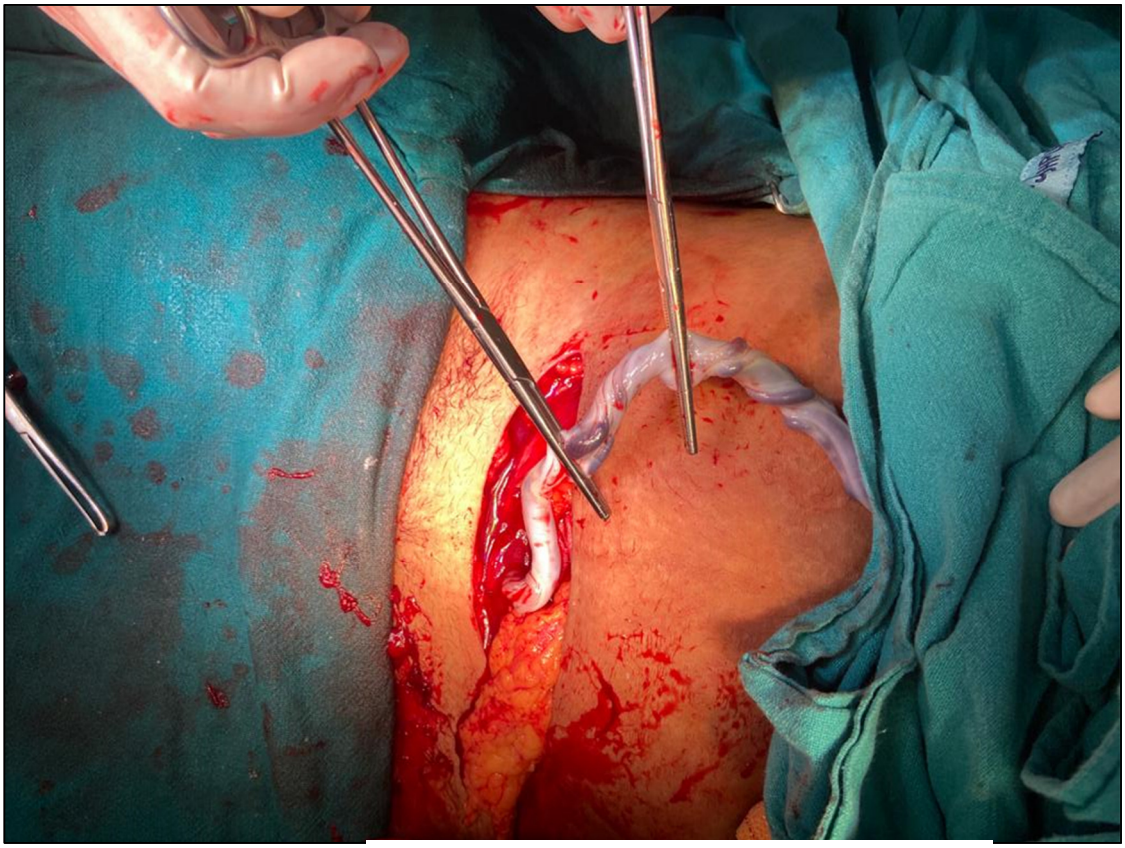


Figure 2: Delayed Cord Clamping

Figure 3: Radiant Warmer In Newborn Care Corner In Our Labour Room

After the umbilical cord was cut, around 2 ml of cord blood was obtained in EDTA vial and sent for the evaluation of the hematocrit to hematology lab. Another sample for hematocrit was obtained at 30 +/- 6 hours of life by the neonatologist. Hematocrit was evaluated using Mindray BC-6200 Automatic Hematology Analyzer.

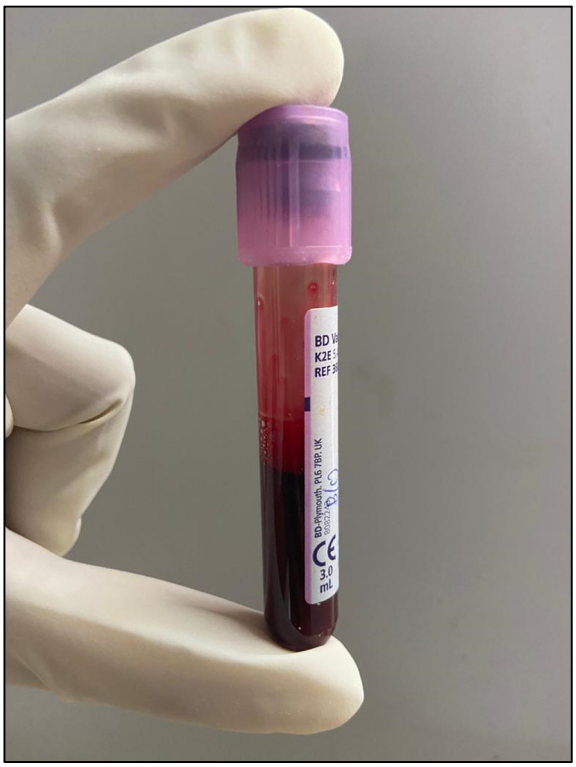


Figure 4: Around 2ml Blood Collected in EDTA Vial

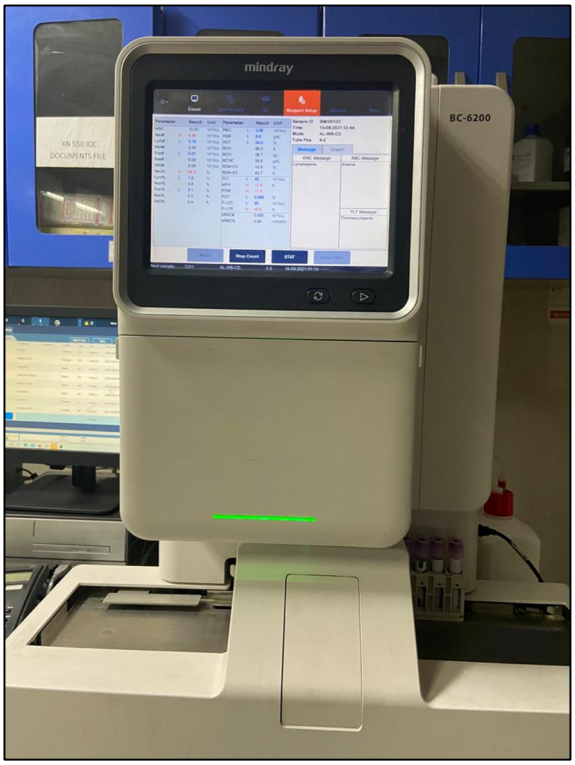


Figure 5: Mindray BC-6200 Automatic Hematology Analyzer

The newborn was evaluated for the development of jaundice and the need for phototherapy. The newborn requiring phototherapy was kept under phototherapy machine emitting light in blue-green spectrum at a wavelength of 460 nm.

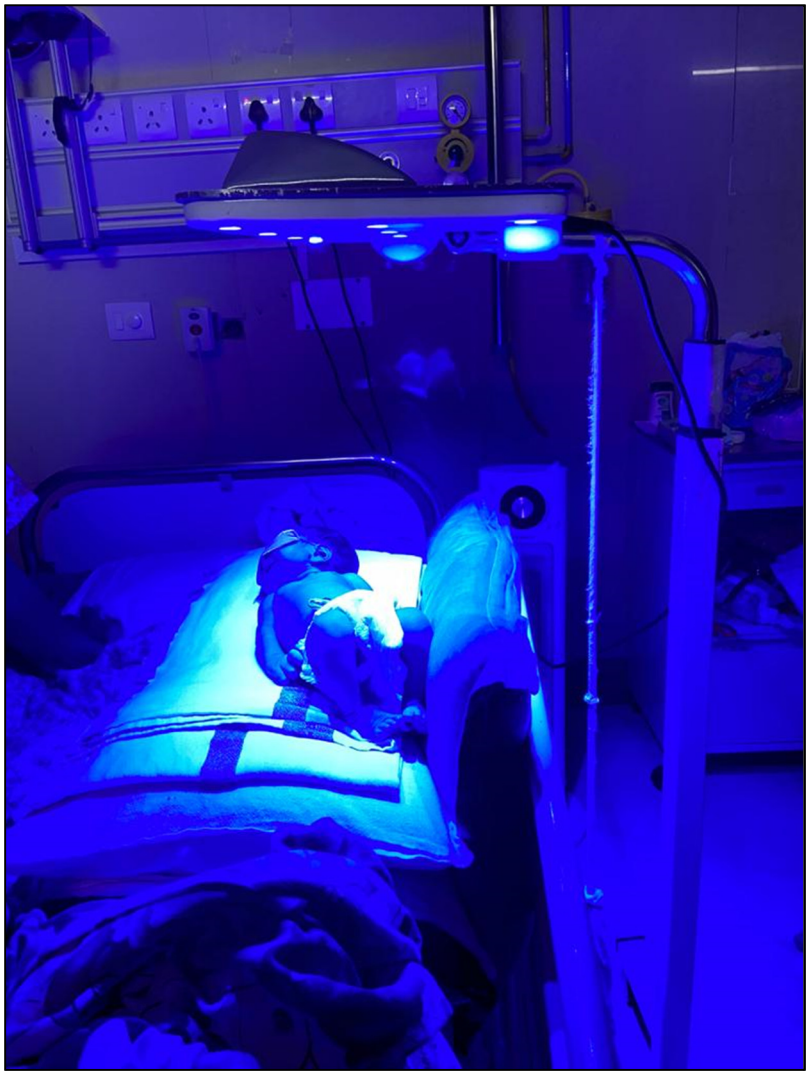


Figure 6: Newborn Receiving Phototherapy

SAMPLE SIZE CALCULATION

Sample size calculation was based on previous study by Katheria et al [3]. In the study by Katheria et al, mean birth hemoglobin in delayed cord clamping group was 15.6 ± 2.2g% and in umbilical cord milking group was 16.3 ± 2.4g%. Based on difference in mean birth hemoglobin in two groups, with alpha error of 5%, power of study set as 80% and assuming an attrition rate of 10%, a total of 374 pregnant women were included in the study, with 187 in each group.

$$N = 2 \times \left(\frac{z_{1-\frac{\alpha}{2}} + z_{1-\beta}}{\delta_0} \right)^2 \times p \times (1-p)$$

STATISTICAL ANALYSIS

Data was entered in Microsoft Excel Sheet. All the analysis was performed by using Statistical package for social sciences (SPSS) software 21. Bell shaped curve and One-sample Kolmogorov- Smirnov test was used to check normal distribution of continuous data. Student *t* test was used to analyze normally distributed and Mann Whitney U test was used for non-normally distributed data. For categorical variables, chi-square test was used at a two-sided significant level of 0.05 for testing the differences between two groups.

RESULTS

RESULTS

During the study period from March 2020 to August 2021, 789 pregnant women were assessed for enrolment out of which a total of 374 cases were enrolled in the study who met the inclusion criteria. They were randomized into UCM group and DCC group. In UCM group, 119 underwent vaginal delivery and 68 underwent caesarean section. In DCC group, 117 underwent vaginal delivery and 70 underwent caesarean section. No patien was lost to follow up for primary outcome analysis and secondary outcome analysis till 72 hrs. However, evaluation of hemoglobin and ferritin at 14 weeks could not be done due to prevailing COVID-19 pandemic. Total 187 participants were analysed in each group.

Flow chart of the study participants is as follows:

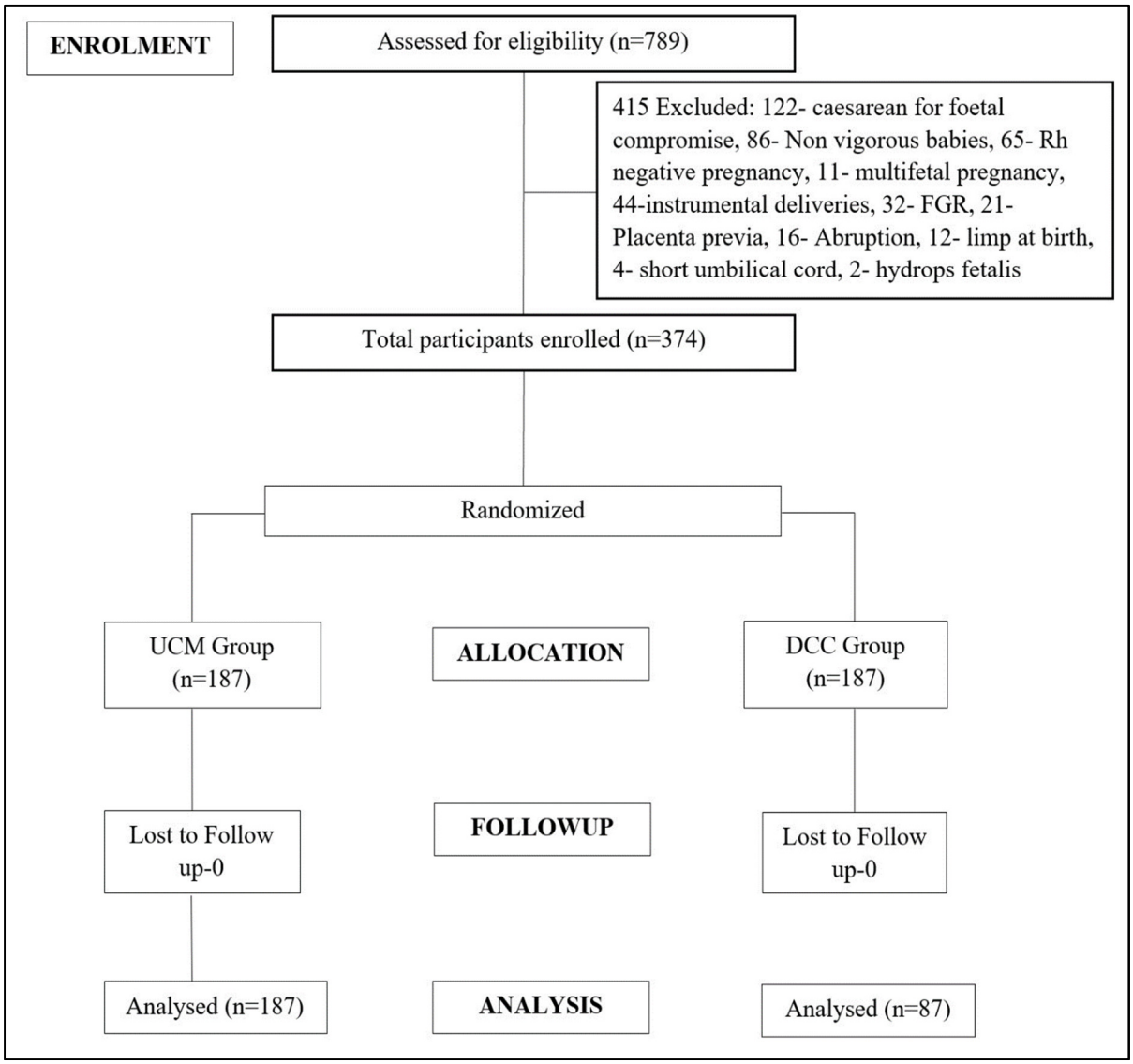


Figure 7: CONSORT FLOW CHART

Table 1: Baseline Maternal Characteristics

	UCM group (n=187)	DCC group (n=187)	P value
Age (years)^	26.7 ± 4.6	26.6 ± 4.2	0.69
Body Mass Index (kg/m2)^	26.2 ± 3.2	26.1 ± 2.9	0.80
Area of Residence# **Rural** **Urban**	 48 (25.67%) 139 (74.33%)	 37 (19.79%) 150 (80.21%)	0.17
Period of Gestation (weeks)^	38.7 ± 1.3	38.7 ± 1.2	0.53
Intake of iron supplements#	177 (94.65%)	175 (93.58%)	0.60
Anemia (Hemoglobin <11g%)#	62 (33.16%)	71 (37.97%)	0.47
Mode of delivery# **Vaginal** **Caesarean section**	 119 (63.64%) 68 (36.36%)	 117 (62.57%) 70 (37.43%)	0.83

DCC-Delayed cord clamping; UCM-Umbilical cord milking
^Data is in Mean ± Standard Deviation
#Data is in n (%)

BASELINE MATERNAL CHARACTERISTICS:

1. Age:

Age distribution in UCM and DCC groups are shown in Figure 8 and 9 respectively. The bell-shaped curves in Figures 8 and 9 denote that age was normally distributed in both groups.

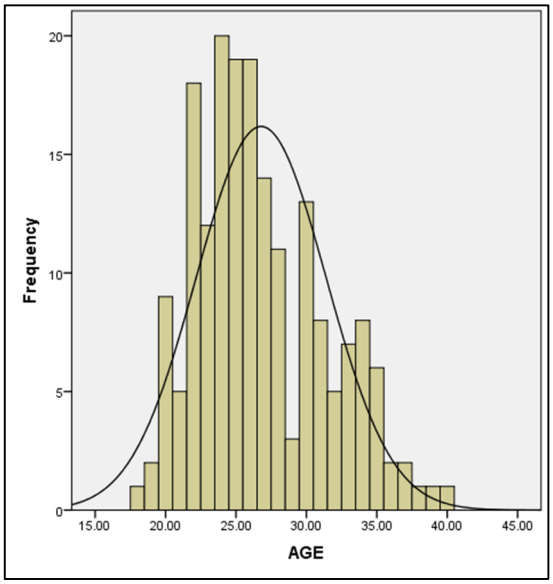


Figure 8: Age Distribution In UCM Group

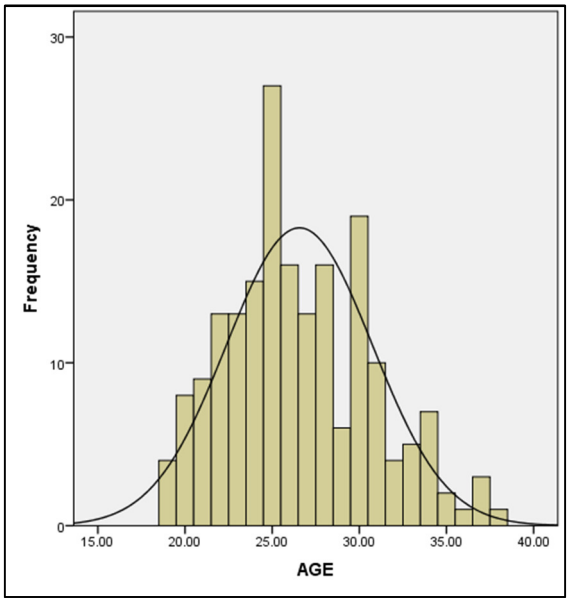


Figure 9: Age Distribution In DCC Group

Table 2: Comparison Of Age In Both Groups

Age group (years)	UCM group (n=187)	DCC group (n=187)	P value
Mean ± Standard Deviation	26.7 ± 4.6	26.6 ± 4.2	0.69

DCC-Delayed cord clamping; UCM-Umbilical cord milking

Table 2 shows that Mean age was 26.7 years with standard deviation of 4.6 in UCM group, and Mean age was 26.6 years with standard deviation of 4.2 in DCC group.

Age in both groups was compared by Unpaired t test. P value was 0.69 which was > 0.05, thus both groups are comparable in terms of age.

2. Body Mass Index (BMI):

The distribution of BMI in UCM and DCC group is given in Figure 10 and 11 respectively. The bell-shaped curves in Figures 10 and 11 denote that BMI was normally distributed in both study groups.

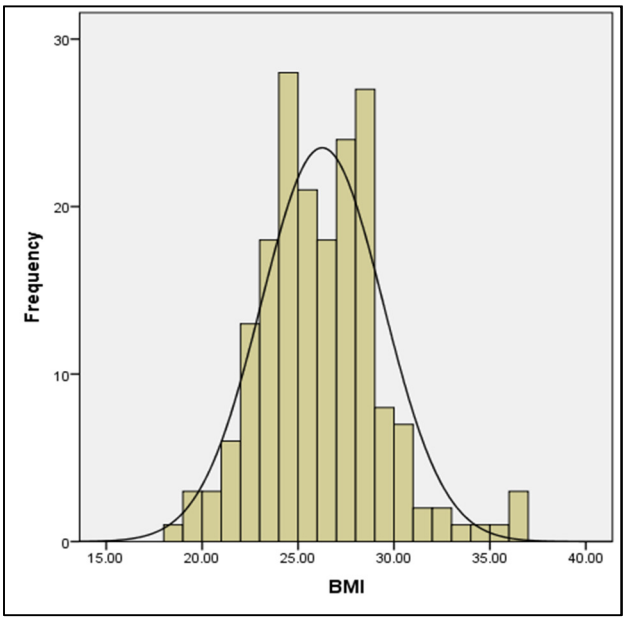


Figure 10: BMI Distribution In UCM Group

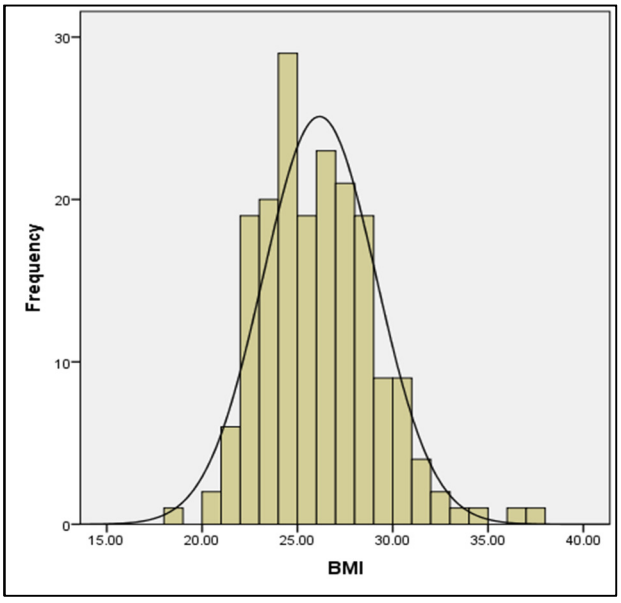


Figure 11: BMI Distribution In DCC Group

Table 3: Comparison Of BMI In Both Groups

Body Mass Index (BMI) kg/m^2	UCM group (n=187)	DCC group (n=187)	P value
Mean ± Standard Deviation	26.2 ± 3.2	26.1 ± 2.9	0.80

DCC-Delayed cord clamping; UCM-Umbilical cord milking

Table 3 shows that mean BMI in UCM group was 26.2 ± 3.2 kg/m^2 and in DCC group was 26.1 ± 2.9 kg/m^2. Figure 12 shows that normal BMI was seen in 13.37% pregnant women in UCM group and 14.97% pregnant women in DCC group, whereas obesity was present in 61.5% pregnant women in UCM group and 58.82% in DCC group respectively.

Both the groups are comparable with respect to BMI with p value 0.80.

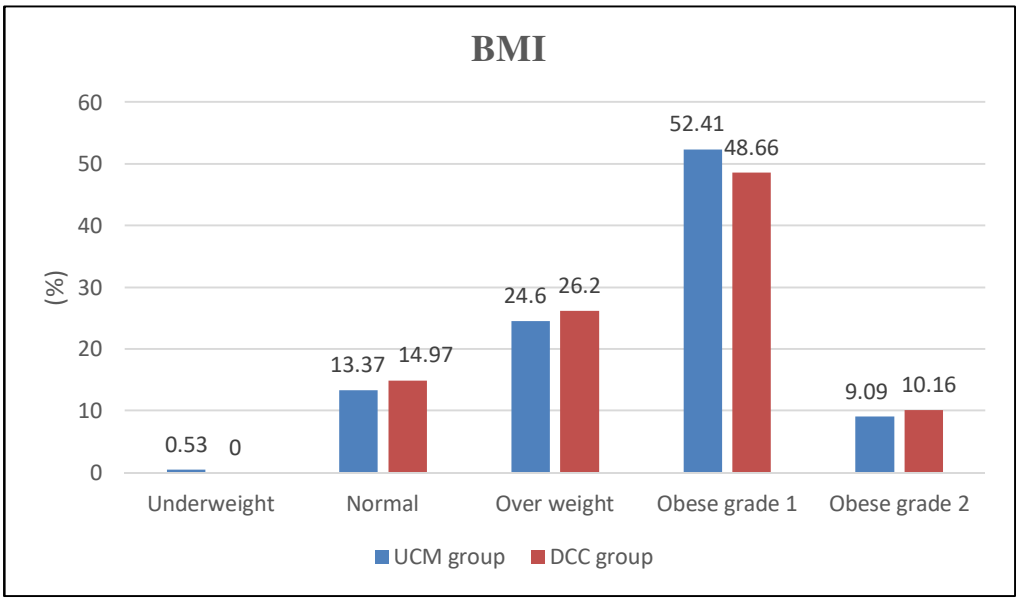


Figure 12: Comparison Of BMI In Both Groups

3. Area of Residence:

Table 4 and Figure 13 shows that in DCC group, 19.79% (37) pregnant women belonged to rural area and 80.21% (150) pregnant women belonged to urban area. In UCM group, 25.67% (48) pregnant women belonged to rural area and 74.33% (139) pregnant women belonged to urban area. Hence, in both the groups majority population lived in urban areas of Rajasthan**.**

Table 4: Comparison Of Residential Status In Both Groups

	UCM group (n=187)	DCC group (n=187)	P value
Rural	48 (25.67%)	37 (19.79%)	0.17
Urban	139 (74.33%)	150 (80.21%)	

DCC-Delayed cord clamping; UCM-Umbilical cord milking

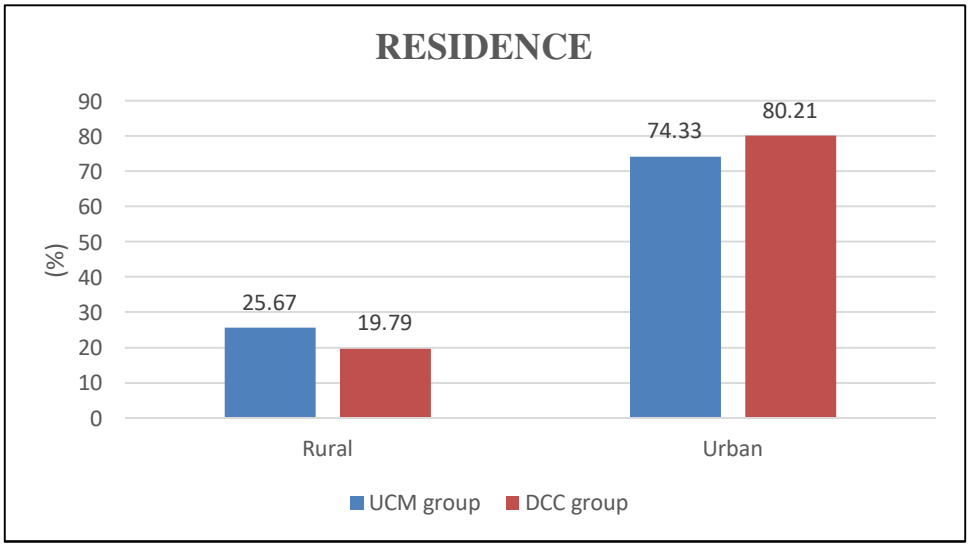


Figure 13: Comparison Of Residential Status In Both Groups

Both the groups were comparable to each other with respect to residence with p value 0.17.

4. Educational Qualification:

Table 5 and Figure 14 shows that in UCM group most of the pregnant women were high school pass outs (27.27%), 20.32% were graduates and 18.72% were educated till middle school level. In DCC group, most of the pregnant women were graduates (28.88%), 24.6% were educated till high school and middle school level.

Table 5: Comparison Of Educational Qualification In Both Groups

	UCM group (n=187)	DCC group (n=187)	P value
Illiterate	7 (3.74%)	5 (2.67%)	0.07
Primary School	25 (13.37%)	20 (10.7%)	
Middle School	35 (18.72%)	46 (24.6%)	
High School	51 (27.27%)	46 (24.6%)	
Graduate	38 (20.32%)	54 (28.88%)	

DCC-Delayed cord clamping; UCM-Umbilical cord milking

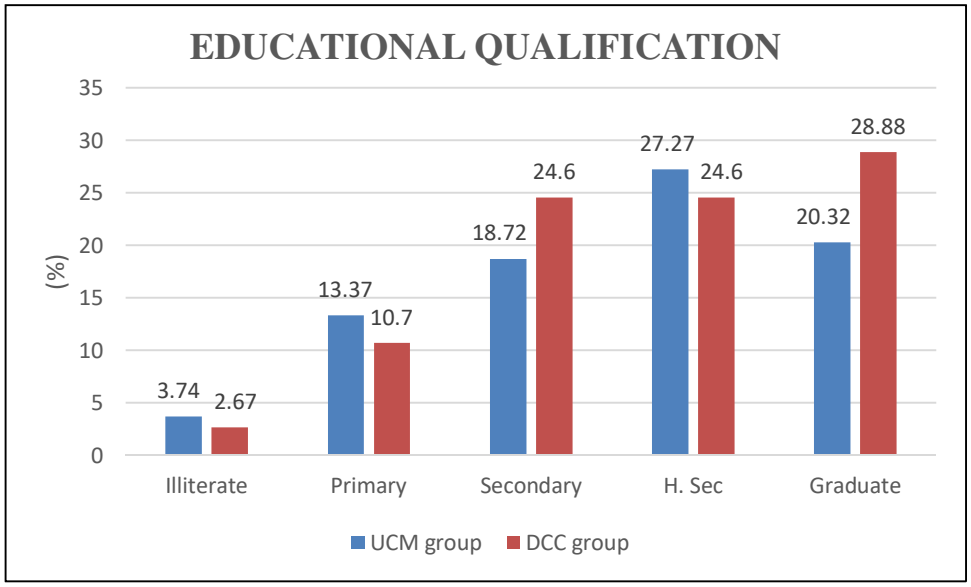


Figure 14: Comparison Of Educational Qualification In Both Groups

Both the groups were comparable to each other with respect to educational qualification with p value 0.07.

5. Occupation:

Table 6 and Figure 15 shows that in DCC group 90.37% of pregnant women and in UCM group 91.44% pregnant women were homemakers. Hence, majority of pregnant women in both groups were homemakers. Both groups were comparable to each other with p value of 0.52.

Table 6: Comparison Of Occupation In Both Groups

	UCM group (n=187)	DCC group (n=187)	P value
Homemaker	171 (91.44%)	169 (90.37%)	0.52
Working	15 (8.02%)	18 (9.63%)	
Student	1 (0.53%)	0 (0%)	

DCC-Delayed cord clamping; UCM-Umbilical cord milking

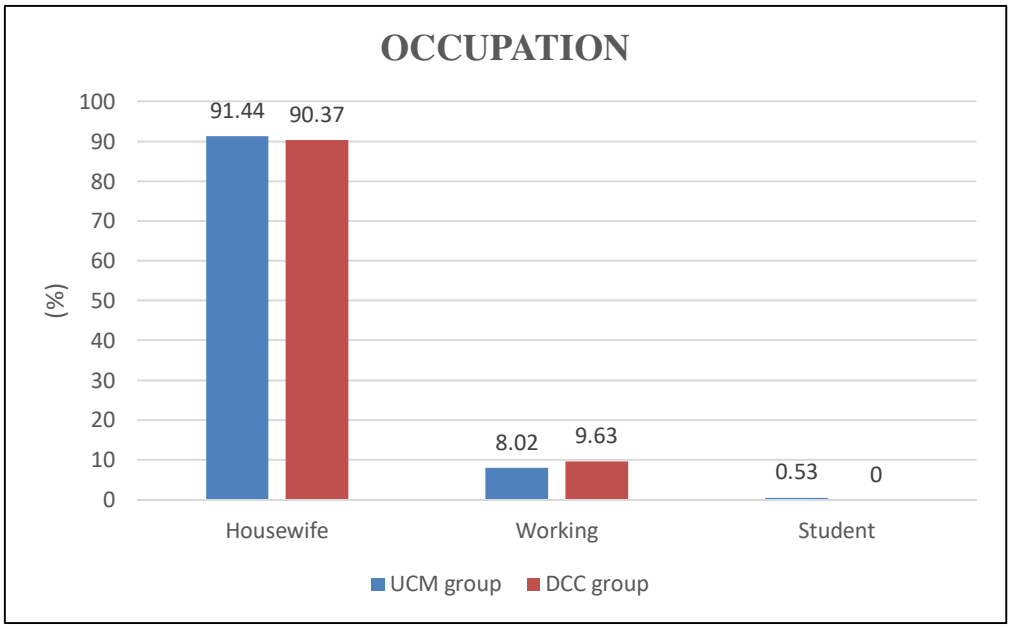


Figure 15: Comparison Of Occupation In Both Groups

6. Parity of patients:

Table 7 and figure 16 shows that in DCC group majority of pregnant women were primigravida 50.8%, In UCM group majority of pregnant women were multigravida 54.9%. Both the groups were comparable to each other as p value was 0.15.

Table 7: Comparison Of Parity In Both Groups

	UCM group (n=187)	DCC group (n=187)	P value
Primi	79 (42.25%)	95 (50.8%)	0.15
Multi	106 (56.68%)	88 (47.06%)	
Grand multi	2 (1.07%)	4 (2.14%)	

DCC-Delayed cord clamping; UCM-Umbilical cord milking

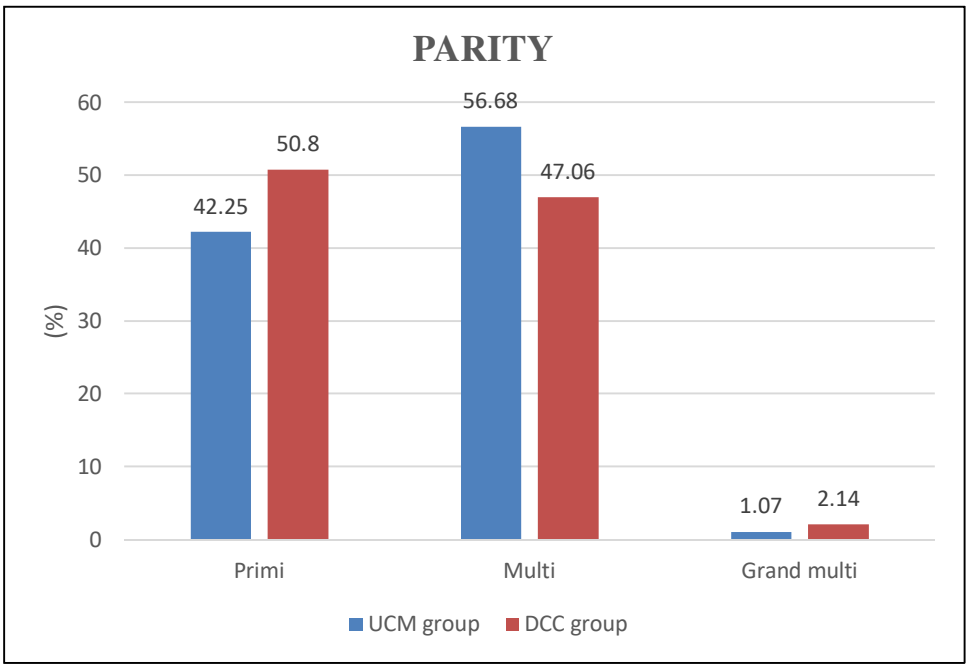


Figure 16: Comparison Of Parity In Both Groups

7. Period of Gestation (POG):

Table 8 and Figure 17 shows that Mean POG was 38.7 with standard deviation of ± 1.3 in UCM group, and Mean POG was 38.7 with standard deviation of ± 1.2 in DCC group.

Table 8: Comparison Of POG In Both Groups

Period of Gestation	UCM group (n=187)	DCC group (n=187)	P value
Mean ± Standard Deviation	38.7 ± 1.3	38.7 ± 1.2	0.53

DCC-Delayed cord clamping; UCM-Umbilical cord milking

On applying unpaired student t test, both the groups were comparable to each other with p value of 0.53 which was non-significant.

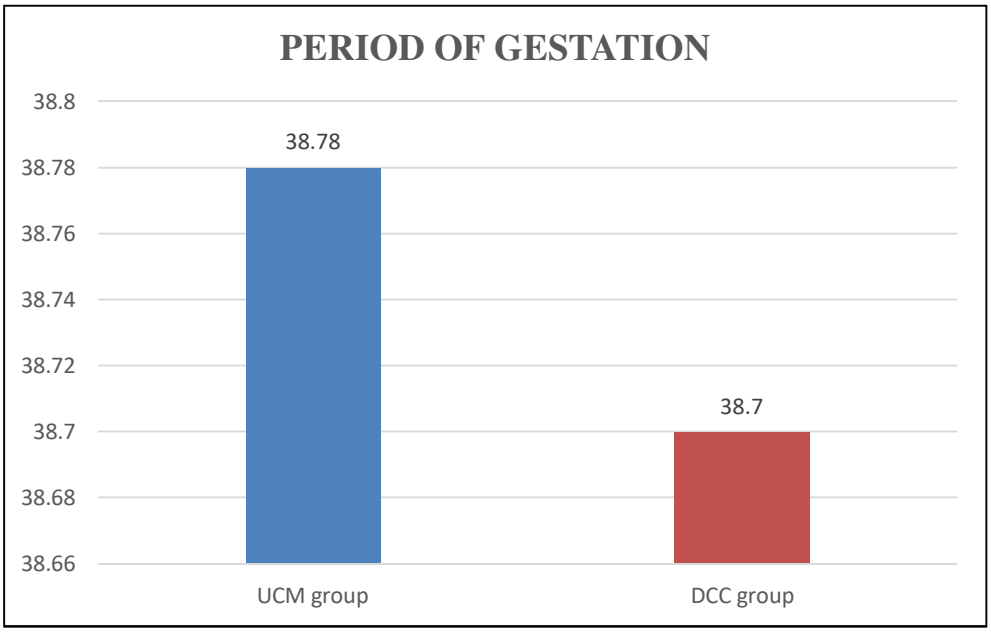


Figure 17: Comparison Of POG In Both Groups

8. Intake of Iron Supplements:

Table 9 and Figure 18 shows that 94.65% women in UCM group and 93.58% women in DCC group took iron supplements regularly throughout the pregnancy.

Table 9: Comparison Of Intake Of Iron Supplements In Both Groups

	UCM group (n=187)	DCC group (n=187)	P value
Iron supplements	177 (94.65%)	175 (93.58%)	0.60

DCC-Delayed cord clamping; UCM-Umbilical cord milking

On applying chi square test, both the groups were comparable to each other with p value of 0.6, which was non-significant.

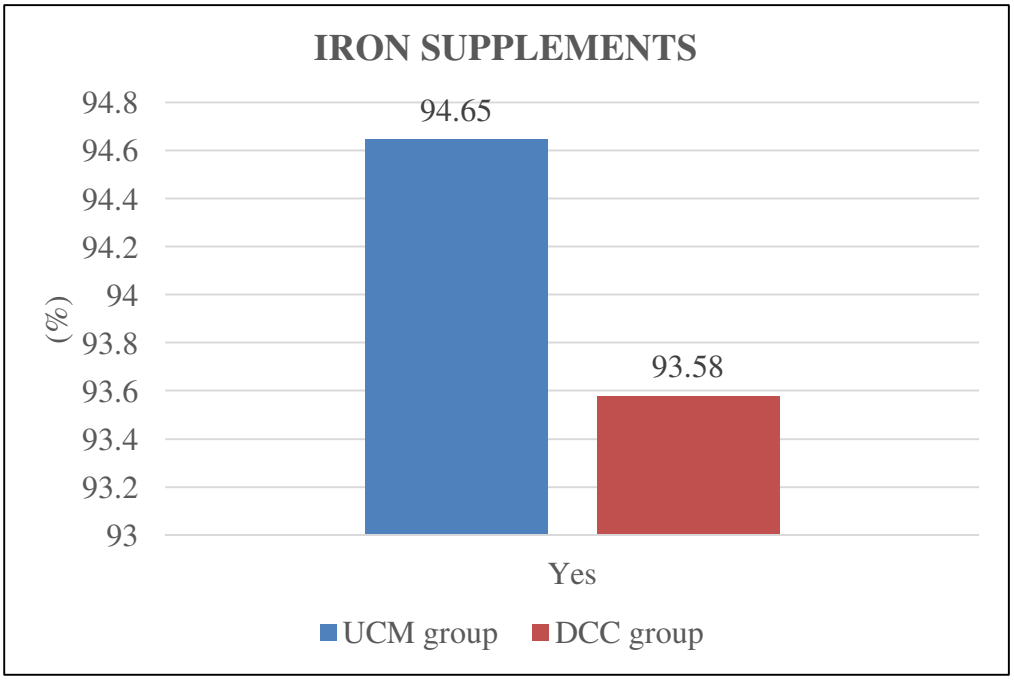


Figure 18: Comparison Of Intake Of Iron Supplements In Both Groups

9. Incidence of Anemia in Pregnancy:

Table 10 and Figure 19 shows that in both groups majority of pregnant women did not have anemia. In UCM group, 66.85% pregnant women did not have anemia, 16.58% had mild anemia and 16.04% had moderate anemia. In DCC group, 62.03% pregnant women did not have anemia, 21.39% had mild anemia and 16.58% had moderate anemia.

Table 10: Comparison Of Incidence Of Anemia In Pregnancy In Both Groups

	UCM group (n=187)	DCC group (n=187)	P value
Non-Anemic	125 (66.84%)	116 (62.03%)	0.47
Mild Anemia (10.0-10.9g%)	31 (16.58%)	40 (21.39%)	
Moderate Anemia (7.0-9.9g%)	30 (16.04%)	31 (16.58%)	
Severe Anemia (<7.0g%)	1 (0.53%)	0 (0%)	

DCC-Delayed cord clamping; UCM-Umbilical cord milking

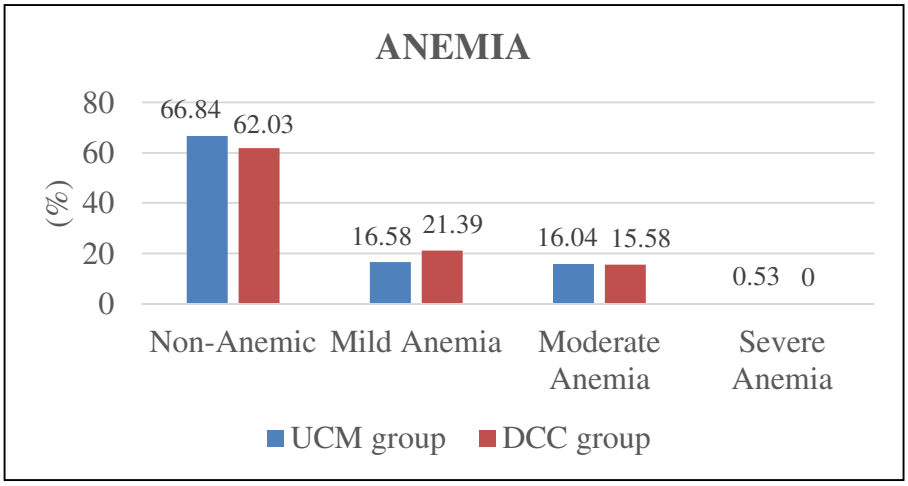


Figure 19: Comparison Of Incidence Of Anemia In Pregnancy In Both Groups

Both the groups were comparable to each other with p value 0.47, which was not significant.

10. Mode of delivery:

Table 11 and Figure 20 shows that in UCM group 63.64% pregnant women underwent vaginal delivery and 36.36% underwent caesarean section. In DCC group, 62.57% pregnant women underwent vaginal delivery and 37.43% underwent caesarean section.

Table 11: Comparison Of Mode Of Delivery In Both Groups

	UCM group (n=187)	DCC group (n=187)	P value
Vaginal Delivery	119 (63.64%)	117 (62.57%)	0.83
Caesarean section	68 (36.36%)	70 (37.43%)	

DCC-Delayed cord clamping; UCM-Umbilical cord milking

On applying chi-square test, both the groups were comparable to each other with p value of 0.83 which was not significant.

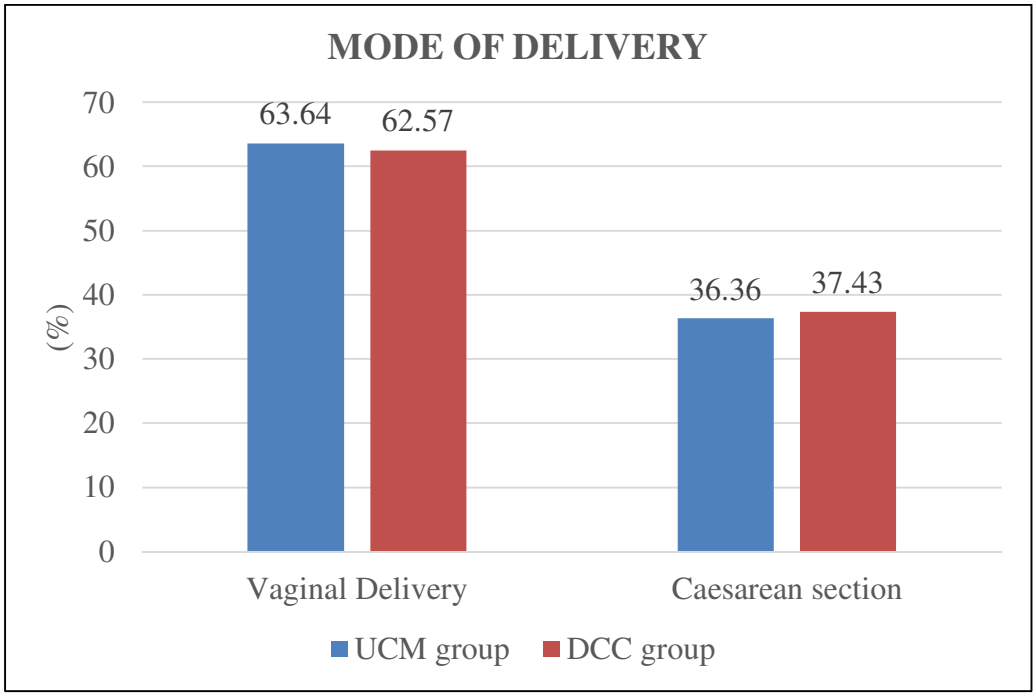


Figure 20: Comparison Of Mode Of Delivery In Both Groups

Table 12: Newborn Characteristics

	UCM group (n=187)	DCC group (n=187)	P value
Birth weight (grams)^	3043.4 ± 426.1	3048.7 ± 390.6	0.90
MATURITY#			
Preterm	7 (3.74%)	10 (5.35%)	0.46
Term	179 (96.26%)	177 (94.65%)	
Apgar at 1min*	8 (8-8)	8 (8-8)	-
Apgar at 5 min*	9 (9-9)	9 (9-9)	-
INTRAUTERINE GROWTH STATUS#			
Appropriate for Gestational Age (AGA)	151 (80.75%)	160 (85.56%)	0.35
Small for Gestational Age (SGA)	33 (17.65%)	26 (13.90%)	

DCC-Delayed cord clamping; UCM-Umbilical cord milking
^Data is in Mean ± Standard deviation
#Data is in n (%)
*Data is in Median (Interquartile range)

NEWBORN CHARACTERISTICS

1. Birth weight:

Table 13 and Figure 21 shows that in UCM group, mean birth weight of neonate was 3043.4 grams with standard deviation of 426.1 grams and in DCC group, mean birth weight of neonate was 3048.7 grams with standard deviation of 390.6 grams.

Table 13: Comparison Of Birth Weight Of Neonate In Both Groups

Birth weight (grams)	UCM group (n=187)	DCC group (n=187)	P value
Mean ± Standard Deviation	3043.4 ± 426.1	3048.7 ± 390.6	0.90

DCC-Delayed cord clamping; UCM-Umbilical cord milking

Birth weight of neonate in both groups was compared using unpaired t test. P value was 0.90 which was non-significant.

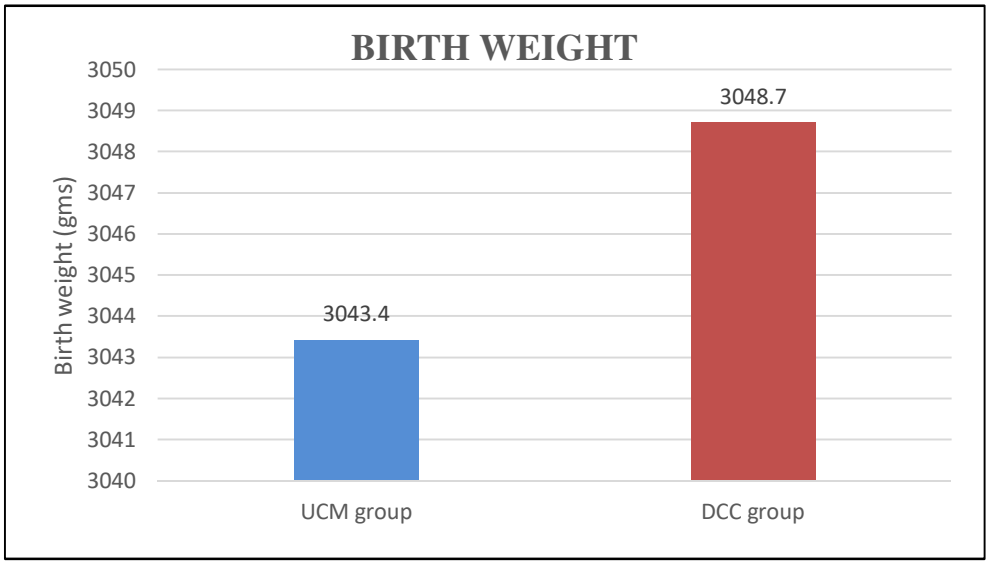


Figure 21: Comparison Of Birth Weight Of Neonate In Both Groups

2. Maturity of neonate:

Table 14 and Figure 22 shows that in UCM group, 96.26% were term deliveries and 3.74% were preterm deliveries and in DCC group, 94.65% were term deliveries and 5.35% were preterm deliveries.

Table 14: Comparison Of Maturity Of Neonate In Both Groups

	UCM group (n=187)	DCC group (n=187)	P value
Preterm	7 (3.74%)	10 (5.35%)	0.46
Term	179 (96.26%)	177 (94.65%)	

DCC-Delayed cord clamping; UCM-Umbilical cord milking

On applying chi-square test, both the groups were comparable to each other with p value 0.46, which was non- significant.

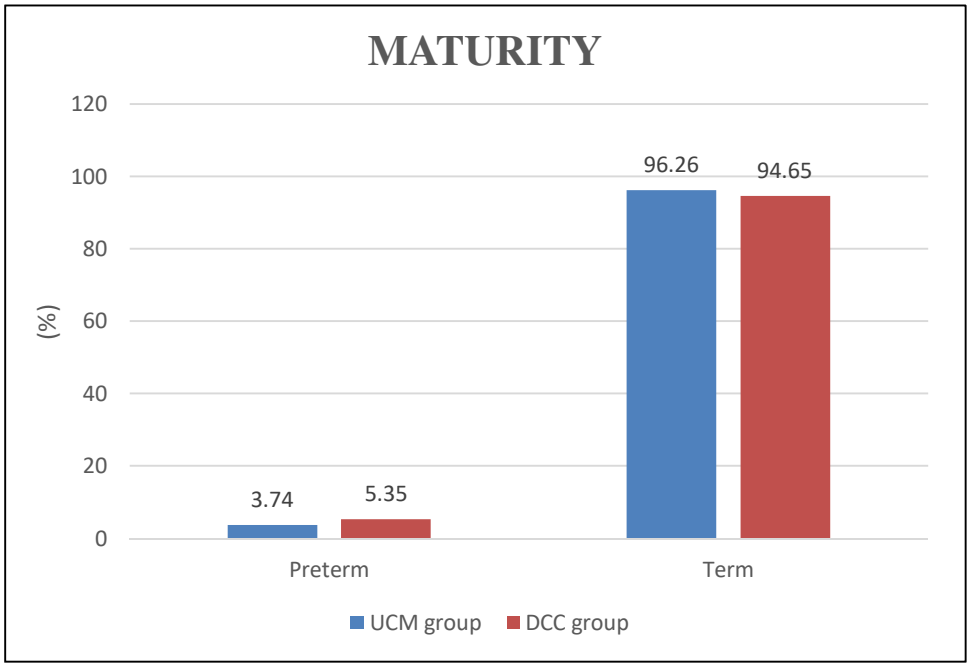


Figure 22: Comparison of Maturity of Neonate in both groups

3. APGAR score:

Table 15 shows that Apgar at 1 min in both UCM group and DCC group was 8 and at 5 min was 9. Hence, both the groups were comparable to each other.

Table 15: Comparison Of Apgar In Both Groups

	UCM group (n=187) Median (IQR)	DCC group (n=187) Median (IQR)
Apgar at 1 min	**8 (8-8)**	**8 (8-8)**
Apgar at 5 min	**9 (9-9)**	**9 (9-9)**

DCC-Delayed cord clamping; IQR- Interquartile range; UCM-Umbilical cord milking

4. Intrauterine growth status

Table 16 and Figure 23 shows that in UCM group, 80.75% neonates were AGA and 17.65% were SGA and in DCC group, 85.56% neonates were AGA, and 13.90% neonates were SGA. On applying chi square test, both groups were comparable to each other (P value 0.35).

Table 16: Comparison Of Intrauterine Growth Status In Both Groups

	UCM group (n=187)	DCC group (n=187)	P value
Appropriate for Gestational Age (AGA)	151 (80.75%)	160 (85.56%)	0.35
Small for Gestational Age (SGA)	33 (17.65%)	26 (13.90%)	
Large for Gestational Age (LGA)	3 (1.60%)	1 (0.53%)	

DCC-Delayed cord clamping; UCM-Umbilical cord milking

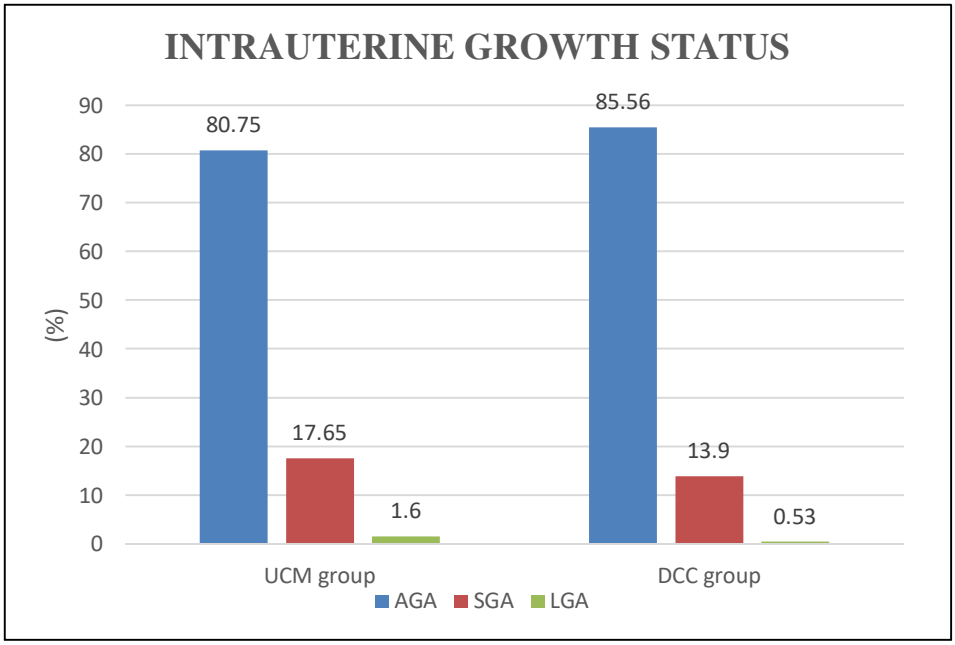


Figure 23: Comparison Of Intrauterine Growth Status In Both Groups

Table 17: STUDY OUTCOMES

	UCM group (n=187)	DCC group (n=187)	P value
Primary Outcome			
Hematocrit in cord sample[^]	47.0 ± 7.1	48.0 ± 8.3	0.21
Hematocrit at 30±6 hours[^]	54.4 ± 5.8	50.9 ± 7.1	<0.01
Secondary Outcomes			
Phototherapy[#]	34 (18.18%)	36 (19.25%)	0.79
NICU admissions[#]	5 (2.67%)	14 (7.49%)	0.03
Polycythemia in cord sample[#]	2 (1.07%)	5 (2.67%)	0.25
Polycythemia at 30±6 hours[#]	4 (2.14%)	3 (1.6%)	0.70

DCC-Delayed cord clamping; NICU- Neonatal intensive care unit; UCM-Umbilical cord milking
[^]Data is in Mean ± Standard deviation
[#]Data is in n (%)

STUDY OUTCOMES

Primary Outcome:

1. Hematocrit of cord blood sample and at 30 ± 6 hours

A. DATA DISTRIBUTION

a) Cord blood hematocrit in UCM group: Bell shaped curve in figure 24 denotes that hematocrit in UCM group at birth was normally distributed.

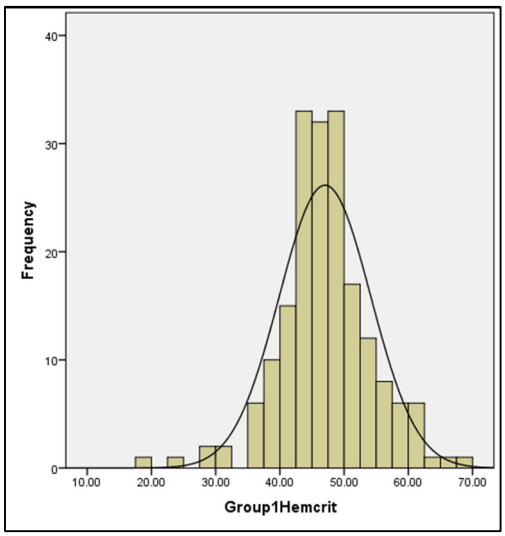


Figure 24: Distribution Of Cord Blood Hematocrit In UCM Group

b) Cord blood hematocrit in DCC group: Bell shaped curve in figure 25 denotes that hematocrit in DCC group at birth was normally distributed.

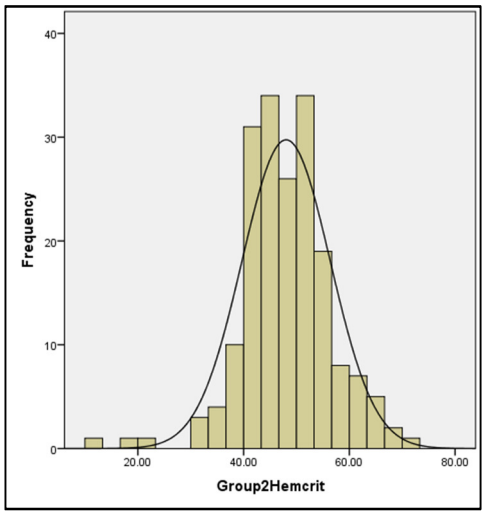


Figure 25: Distribution Of Cord Blood Hematocrit In DCC Group

c) **Hematocrit in UCM group at 30 ± 6 hours:** Bell shaped curve in figure 26 denotes that hematocrit in UCM group at 30 ± 6 hours was normally distributed.

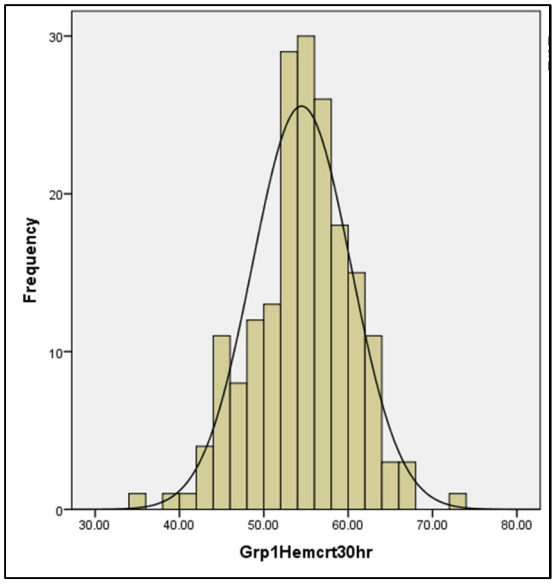


Figure 26: Distribution Of Hematocrit In UCM Group at 30 ± 6 hours

d) **Hematocrit in DCC group at 30 ± 6 hours:** Bell shaped curve in figure 27 denotes that hematocrit in DCC group at 30 ± 6 hours was normally distributed.

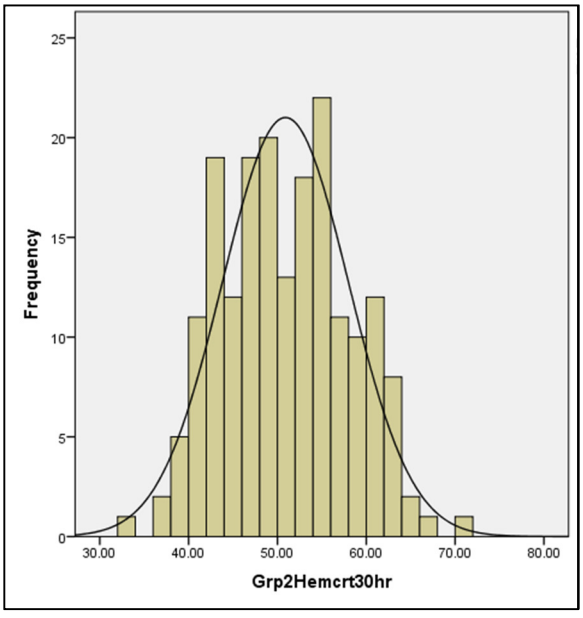


Figure 27: Distribution Of Hematocrit In DCC Group at 30 ± 6 hours

B. Comparison of Hematocrit of cord blood sample and at 30 ± 6 hours:

Table 18 and Figure 28 shows that in UCM group, mean hematocrit in cord sample was 47.0% with standard deviation of 7.1% and in DCC group, mean hematocrit in cord sample was 48.0% with standard deviation of 8.3%. On applying unpaired t test, mean hematocrit in cord sample was comparable to each other in both the groups with P value of 0.21 which was non-significant.

Table 18: Comparison Of Hematocrit In Both Groups In Cord Blood Sample and at 30 ± 6 hours

Hematocrit	UCM group (n=187)	DCC group (n=187)	P value
	Mean ± Standard Deviation	Mean ± Standard Deviation	
Cord sample	47.0 ± 7.1	48.0 ± 8.3	0.21
30±6 hours	54.4 ± 5.8	50.9 ± 7.1	<0.01

DCC-Delayed cord clamping; UCM-Umbilical cord milking

Table 18 and Figure 28 shows that in UCM group, mean hematocrit at 30 ± 6 hours was 54.4% with standard deviation of 5.8% and in DCC group, mean hematocrit at 30 ± 6 hours was 50.9% with standard deviation of 7.1%. Hematocrit in both groups was compared using unpaired t test. p value was 0.01 which was statistically significant.

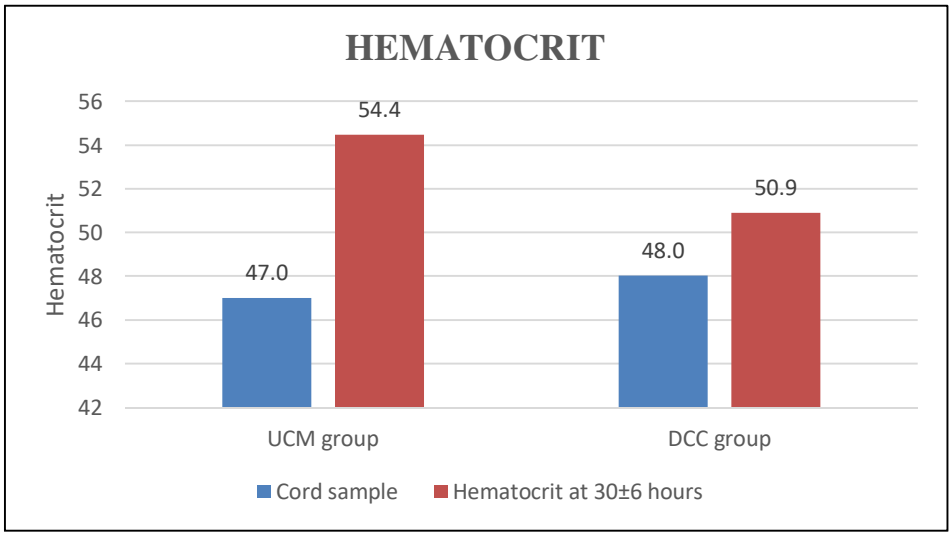


Figure 28: Comparison Of Hematocrit In Both Groups In Cord Sample and at 30 ± 6 hours

Secondary Outcomes:

1. Requirement of Phototherapy:

Table 19 and Figure 29 shows that in UCM group, only 18% of the neonates required phototherapy and in DCC group, 19% of the neonates required phototherapy.

On applying chi-square test, both the groups were comparable to each other with p value of 0.79 which was non-significant.

Table 19: Comparison Of Requirement Of Phototherapy In Both Groups

	UCM group (n=187)	DCC group (n=187)	P value
Phototherapy	34 (18.18%)	36 (19.25%)	0.79

DCC-Delayed cord clamping; UCM-Umbilical cord milking

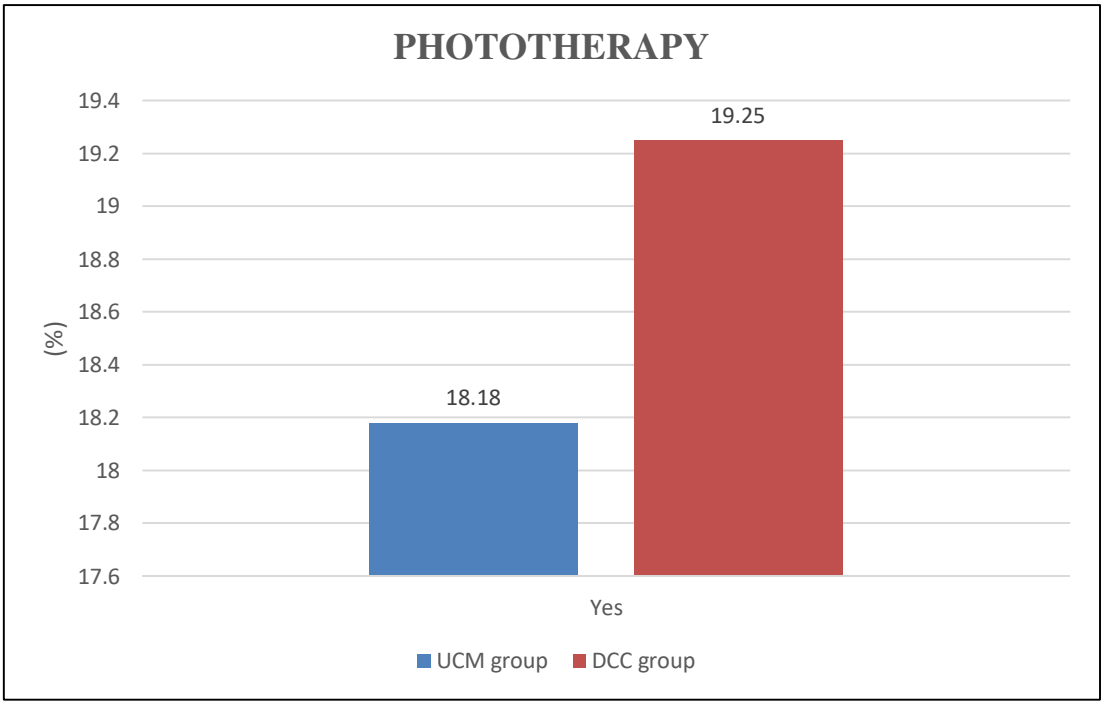


Figure 29: Comparison Of Requirement Of Phototherapy In Both Groups

2. Neonatal Intensive Care Unit (NICU) admission:

Table 20 and Figure 30 shows that in UCM group, only 2.67% of the neonates required NICU admission and in DCC group, 7.49% of the neonates required NICU admission.

On applying chi-square test, p value was 0.034 which was statistically significant.

Table 20: Comparison Of NICU Admissions In Both Groups

	UCM group (n=187)	DCC group (n=187)	P value
NICU admission	5 (2.67%)	14 (7.49%)	0.03

DCC-Delayed cord clamping; NICU-Neonatal Intensive Care Unit; UCM-Umbilical cord milking

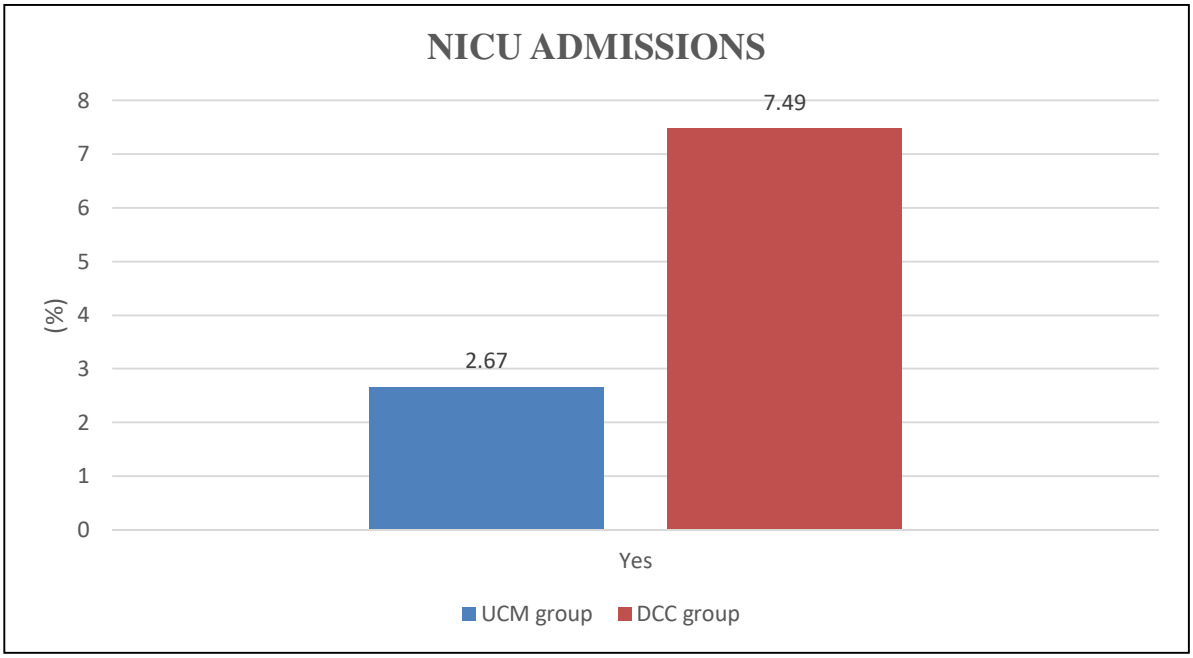


Figure 30: Comparison Of NICU Admissions In Both Groups

3. Incidence of Polycythemia:

Table 21 and Figure 31 shows that in UCM group, incidence of polycythemia at birth was 1.07% and at 30 ± 6 hours was 2.14% whereas in DCC group, incidence of polycythemia at birth was 2.67% and at 30 ± 6 hours was 1.6%.

Both the groups were comparable to each other as on applying chi-square test p value was <0.05 which was non-significant.

Table 21: Comparison Of Incidence Of Polycythemia (Hematocrit >65%) In Both Groups

	UCM group (n=187)	DCC group (n=187)	P value
Cord sample	2 (1.07%)	5 (2.67%)	0.25
At 30±6 hours	4 (2.14%)	3 (1.6%)	0.70

DCC-Delayed cord clamping; UCM-Umbilical cord milking

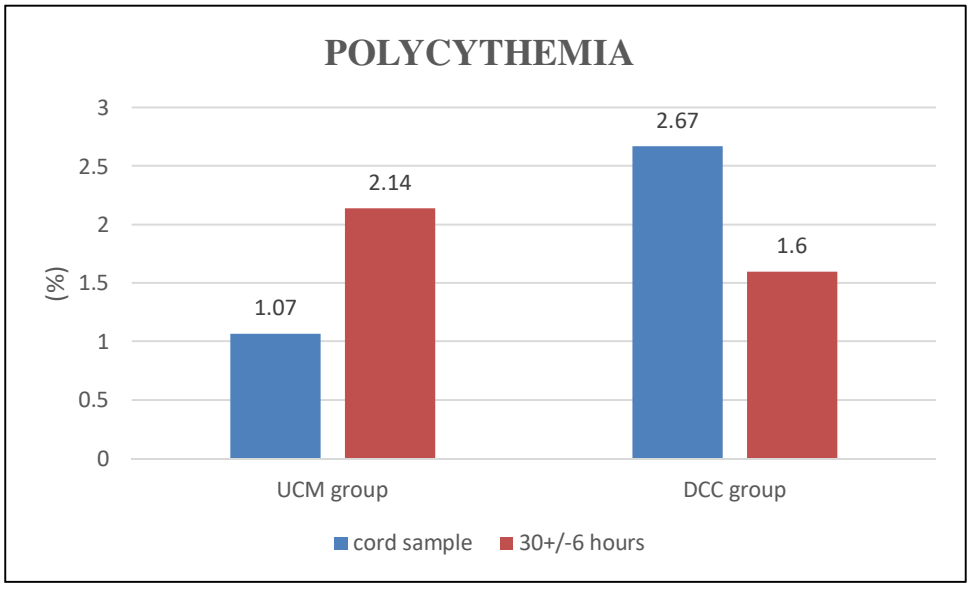


Figure 31: Comparison Of Incidence Of Polycythemia (Hematocrit >65%) In Both Groups

Table 22: SUBGROUP ANALYSIS

ANAEMIC PATIENTS (Hemoglobin <11g%)	**UCM group**	**DCC group**	**P value**
Hematocrit in cord sample	45.9 ± 6.4	48.8 ± 8.4	0.02
Hematocrit at 30±6 hours	53.2 ± 6.1	51.5 ± 6.4	0.11
NON-ANAEMIC PATIENTS (Hemoglobin >11g%)	**UCM group**	**DCC group**	**P value**
Hematocrit in cord sample	47.5 ± 7.4	47.5 ± 8.3	0.98
Hematocrit at 30±6 hours	55.0 ± 5.5	50.5 ± 7.4	< 0.0001
PRETERM (<37 weeks)	**UCM group**	**DCC group**	**P value**
Hematocrit in cord sample	53.5 ± 9.4	51.6 ± 7.5	0.65
Hematocrit at 30±6 hours	55.5 ± 4.3	51.7 ± 6.8	0.22
TERM (>37 weeks)	**UCM group**	**DCC group**	**P value**
Hematocrit in cord sample	46.8 ± 6.7	47.8 ± 8.3	0.23
Hematocrit at 30±6 hours	54.5 ± 5.7	50.8 ± 7.1	< 0.0001
Appropriate for Gestational Age	**UCM group**	**DCC group**	**P value**
Hematocrit in cord sample	46.5 ± 7.0	47.5 ± 8.4	0.25
Hematocrit at 30±6 hours	53.8 ± 5.6	50.3 ± 6.9	< 0.0001
Small for Gestational Age	**UCM group**	**DCC group**	**P value**
Hematocrit in cord sample	49.1 ± 7.4	50.6 ± 6.7	0.44
Hematocrit at 30±6 hours	56.9 ± 6.0	54.0 ± 7.3	0.09

DCC-Delayed cord clamping; UCM-Umbilical cord milking
All data is in Mean ± Standard deviation

SUBGROUP ANALYSIS

1. Comparison of Hematocrit of cord sample and at 30 ± 6 hours in anemic women (Hb<11g%):

Table 23 and Figure 32 shows that in UCM group, mean hematocrit in cord sample was 45.9% with standard deviation of 6.4% and in DCC group, mean hematocrit in cord sample was 48.8% with standard deviation of 8.4%.

Hematocrit in both groups was compared using unpaired t test. P value was 0.02 which was statistically significant.

Table 23: Comparison Of Hematocrit Of Cord Sample and at 30 ± 6 hours In Anemic Women

Hematocrit	UCM group (n=62)	DCC group (n=71)	P value
	Mean ± Standard Deviation	Mean ± Standard Deviation	
Cord sample	45.9 ± 6.4	48.8 ± 8.4	0.02
At 30±6 hours	53.2 ± 6.1	51.5 ± 6.4	0.11

DCC-Delayed cord clamping; UCM-Umbilical cord milking

Table 23 and Figure 32 shows that in UCM group, mean hematocrit at 30 ± 6 hours was 53.2% with standard deviation of 6.1% and in DCC group, mean hematocrit at 30 ± 6 hours was 51.5% with standard deviation of 6.4%. Hematocrit in both groups was compared using unpaired t test. P value was 0.11 which was non-significant.

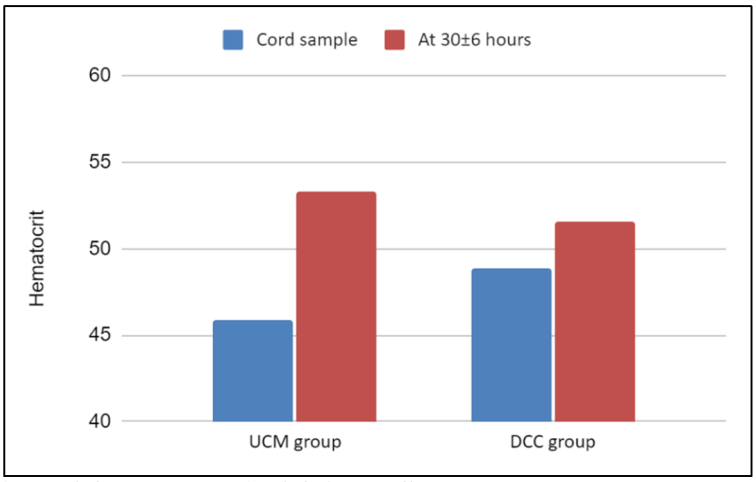


Figure 32: Comparison Of Hematocrit Of Cord Sample and at 30 ± 6 hours In Anemic Women

2. Comparison of Hematocrit of cord sample and at 30 ± 6 hours in non-anemic women (Hb >11g%):

Table 24 and Figure 33 shows that in UCM group, mean hematocrit in cord sample was 47.5% with standard deviation of 7.4% and in DCC group, mean hematocrit in cord sample was 47.5% with standard deviation of 8.3%.

Hematocrit in both groups was compared using unpaired t test. P value was 0.98 which was non-significant.

Table 24: Comparison Of Hematocrit Of Cord Sample and at 30 ± 6 hours In Non-Anemic Women

Hematocrit	UCM group (n=125)	DCC group (n=116)	P value
	Mean ± Standard Deviation	Mean ± Standard Deviation	
Cord sample	47.5 ± 7.4	47.5 ± 8.3	0.98
At 30±6 hours	55.0 ± 5.5	50.5 ± 7.4	< 0.0001

DCC-Delayed cord clamping; UCM-Umbilical cord milking

Table 24 and Figure 33 shows that in UCM group, mean hematocrit at 30 ± 6 hours was 55.0% with standard deviation of 5.5% and in DCC group, mean hematocrit at 30 ± 6 hours was 50.5% with standard deviation of 7.4%.

Hematocrit in both groups was compared using unpaired t test. P value was 0.0001 which was highly significant.

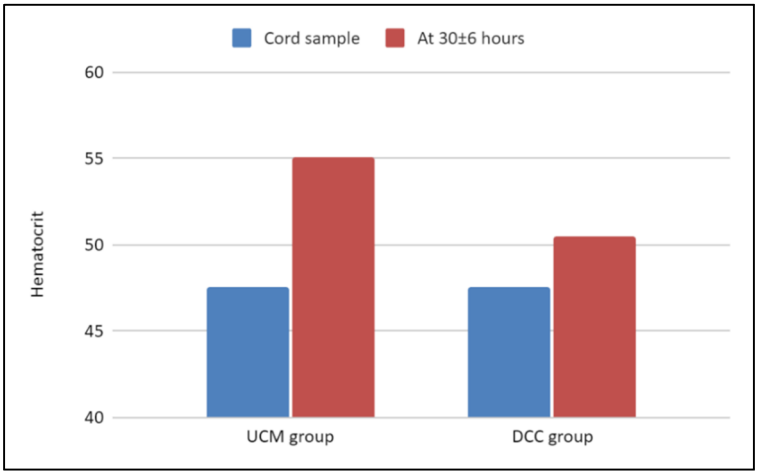


Figure 33: Comparison Of Hematocrit Of Cord Sample and at 30 ± 6 hours In Non-Anemic Women

3. Comparison of Hematocrit of cord sample and at 30 ± 6 hours in preterm neonates (<37 weeks):

Table 25 and Figure 34 shows that in UCM group, mean hematocrit in cord sample was 53.5% with standard deviation of 9.4% and in DCC group, mean hematocrit in cord sample was 51.6% with standard deviation of 7.5%.

Hematocrit in both groups was compared using unpaired t test. P value was 0.65 which was non-significant.

Table 25: Comparison Of Hematocrit Of Cord Sample and at 30 ± 6 hours In Preterm Neonates

Hematocrit	UCM group (n=7)	DCC group (n=10)	P value
	Mean ± Standard Deviation	Mean ± Standard Deviation	
Cord sample	53.5 ± 9.4	51.6 ± 7.5	0.65
At 30±6 hours	55.5 ± 4.3	51.7 ± 6.8	0.22

DCC-Delayed cord clamping; UCM-Umbilical cord milking

Table 25 and Figure 34 shows that in UCM group, mean hematocrit at 30±6 hours was 55.5% with standard deviation of 4.3% and in DCC group, mean hematocrit at 30±6 hours was 51.7% with standard deviation of 6.8%.

Hematocrit in both groups was compared using unpaired t test. P value was 0.22 which was non-significant.

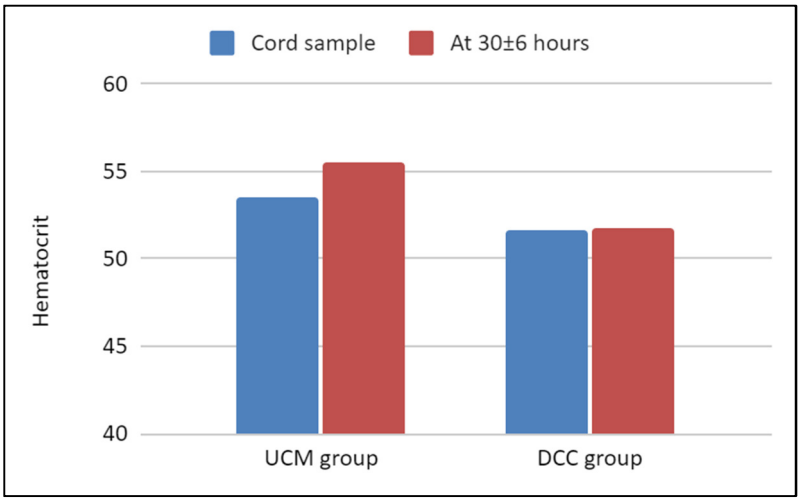


Figure 34: Comparison Of Hematocrit Of Cord Sample and at 30 ± 6 hours In Preterm Neonates

4. Comparison of Hematocrit of cord sample and at 30 ± 6 hours in term neonates (>37 weeks):

Table 26 and Figure 35 shows that in UCM group, mean hematocrit in cord sample was 46.8% with standard deviation of 6.7% and in DCC group, mean hematocrit in cord sample was 47.8% with standard deviation of 8.3%.

Hematocrit in both groups was compared using unpaired t test. P value was 0.23 which was non-significant.

Table 26: Comparison Of Hematocrit Of Cord Sample and at 30 ± 6 hours In Term Neonates

Hematocrit	UCM group (n=180)	DCC group (n=177)	P value
	Mean ± Standard Deviation	Mean ± Standard Deviation	
Cord sample	46.8 ± 6.7	47.8 ± 8.3	0.23
At 30±6 hours	54.5 ± 5.7	50.8 ± 7.1	< 0.0001

DCC-Delayed cord clamping; UCM-Umbilical cord milking

Table 26 and Figure 35 shows that in UCM group, mean hematocrit at 30 ± 6 hours was 54.5% with standard deviation of 5.7% and in DCC group, mean hematocrit at 30 ± 6 hours was 50.8% with standard deviation of 7.1%. Hematocrit in both groups was compared using unpaired t test. P value was <0.0001 which was highly significant.

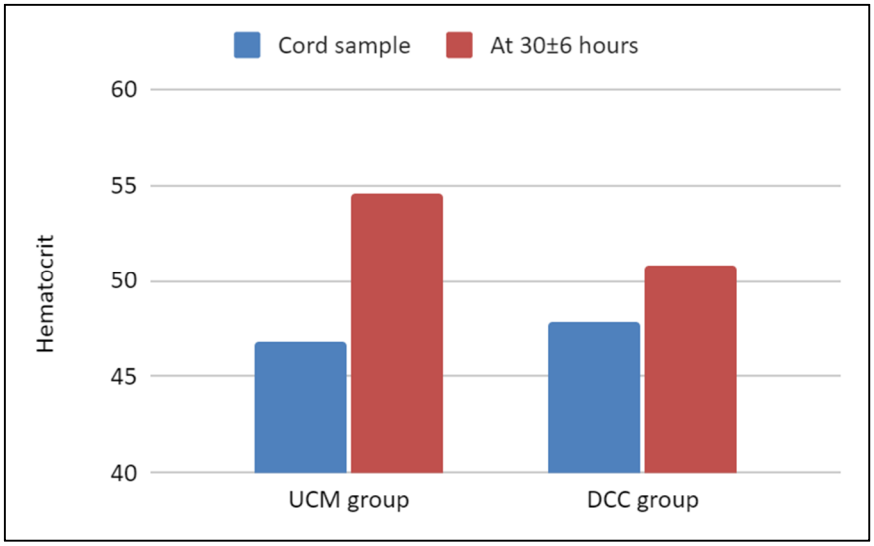


Figure 35: Comparison Of Hematocrit Of Cord Sample and at 30 ± 6 hours In Term Neonates

5. Comparison of Hematocrit of cord sample and at 30 ± 6 hours in AGA neonates:

Table 27 and Figure 36 shows that in UCM group, mean hematocrit in cord sample was 46.5% with standard deviation of 7.0% and in DCC group, mean hematocrit in cord sample was 47.5% with standard deviation of 8.4%.

Hematocrit in both groups was compared using unpaired t test. P value was 0.25 which was non-significant.

Table 27: Comparison Of Hematocrit Of Cord Sample and at 30 ± 6 hours In AGA Neonates

Hematocrit	UCM group (n=151)	DCC group (n=160)	P value
	Mean ± Standard Deviation	Mean ± Standard Deviation	
Cord sample	46.5 ± 7.0	47.5 ± 8.4	0.25
At 30±6 hours	53.8 ± 5.6	50.3 ± 6.9	< 0.0001

DCC-Delayed cord clamping; UCM-Umbilical cord milking

Table 27 and Figure 36 shows that in UCM group, mean hematocrit at 30 ± 6 hours was 53.8% with standard deviation of 5.6% and in DCC group, mean hematocrit at 30 ± 6 hours was 50.3% with standard deviation of 6.9%.

Hematocrit in both groups was compared using unpaired t test. P value was <0.0001 which was highly significant.

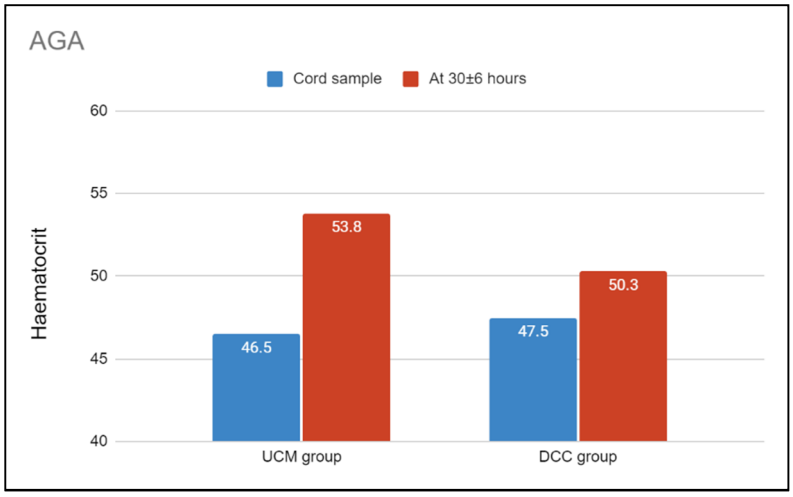


Figure 36: Comparison Of Hematocrit Of Cord Sample and at 30 ± 6 hours In AGA Neonates

6. Comparison of Hematocrit of cord sample and at 30 ± 6 hours in SGA neonates:

Table 28 and Figure 37 shows that in UCM group, mean hematocrit in cord sample was 49.1% with standard deviation of 7.4% and in DCC group, mean hematocrit in cord sample was 50.6% with standard deviation of 6.7%.

Hematocrit in both groups was compared using unpaired t test. P value was 0.44 which was non-significant.

Table 28: Comparison Of Hematocrit Of Cord Sample and at 30 ± 6 hours In SGA Neonates

Hematocrit	UCM group (n=33)	DCC group (n=26)	P value
	Mean ± Standard Deviation	Mean ± Standard Deviation	
Cord sample	49.1 ± 7.4	50.6 ± 6.7	0.44
At 30±6 hours	56.9 ± 6.0	54.0 ± 7.3	0.09

DCC-Delayed cord clamping; UCM-Umbilical cord milking

Table 28 and Figure 37 shows that in UCM group, mean hematocrit at 30 ± 6 hours was 56.9% with standard deviation of 6.0% and in DCC group, mean hematocrit at 30 ± 6 hours was 54.0% with standard deviation of 7.3%.

Hematocrit in both groups was compared using unpaired t test. P value was 0.09 which was non-significant.

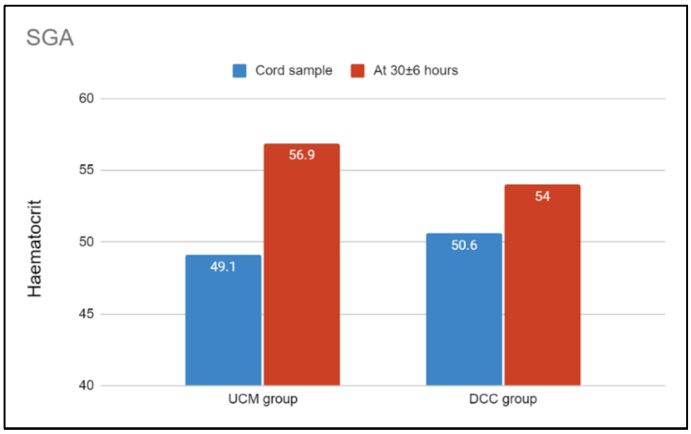


Figure 37: Comparison Of Hematocrit Of Cord Sample and at 30 ± 6 hours In SGA Neonates

DISCUSSION

DISCUSSION

This randomized controlled trial was done to compare the effect of UCM and DCC on various hematological parameters in term as well as near term neonates in both vaginal and caesarean delivery.

The mean age of participants was 26.7 ± 4.6 years in UCM group and 26.6 ± 4.2 years in DCC group which was comparable to most of the previous studies as shown in Table 29.

Table 29: Age Distribution In Various Studies

	UCM group (years)	**DCC group (years)**	**P value**
	Mean age ± Standard Deviation	**Mean age ± Standard Deviation**	
Rabe *et al*[40] (2011)	30.8 ± 6.3	29.1 ± 5.6	0.27
Katheria *et al*[31] (2015)	31 ± 5	30 ± 6	0.26
Alzaree F *et al*[46] (2018)	26.2 ± 4.4	25.6 ± 3.2	0.23
Samantha *et al*[38]# (2019)	28 (22-32)	28 (23-33)	0.33
Mangla *et al*[49] (2020)	29.1 ± 4.2	28.3 ± 3.3	0.20
Index Study	26.7 ± 4.6	26.6 ± 4.2	0.69

DCC-Delayed cord clamping; UCM-Umbilical cord milking
#Data is in Median (Interquartile range)

The mean gestational age was 38.7 ± 1.3 weeks in UCM group and 38.7 ± 1.2 in DCC group which was comparable to studies conducted by Jaiswal *et al*[43], Alzaree F *et al*[46] and Mangla *et al*[49]. However, mean gestational age was lower in studies conducted by Rabe *et al*[40], Katheria *et al*[31] and Samantha *et al*[38]. These studies were conducted only in preterm neonates which contributed to this difference in gestational age. Gestational age can have significant impact on the hematological parameters of the neonate.

Table 30: Gestational Age Distribution In Various Studies

	Mean gestational age in UCM group (weeks)	**Mean gestational age in DCC group (weeks)**	**P value**
Rabe *et al*[40] (2011)	29.5 ± 2.7	29.2 ± 2.3	0.61
Katheria *et al*[31] (2015)	28 ± 2	28 ± 2	1.0
Jaiswal *et al*[43] (2015)	38.3 ± 1.13	38.2 ± 1.1	0.83
Alzaree F *et al*[46] (2018)	38.9 ± 0.9	38.9 ± 0.9	0.606
Samantha *et al*[38]# (2019)	32.1 (29.5-34.0)	32.0 (29.2-34.0)	0.462
Mangla *et al*[49] (2020)	37.9 ± 1.0	37.8 ± 1.6	0.65
Index Study	38.7 ± 1.3	38.7 ± 1.2	0.53

DCC-Delayed cord clamping; UCM-Umbilical cord milking
#Data is in Median (Interquartile range)

Mean birth weight of the neonate in UCM group was 3043.4 ± 426.1 grams and in DCC group was 3048.7 ± 390.6 grams which was comparable to studies conducted by Mangla *et al*[49], Jaiswal *et al*[43] and Upadhyay *et al*[2]. However, mean birth weight was lower in studies conducted by Katheria *et al*[31], Samantha *et al*[38] and Rabe *et al*[40]. This difference was mainly because of the difference in the study population. These studies were conducted in preterm infants, hence mean birth weight was lower in these studies. Birth weight has a significant impact on hematocrit of the newborn.

Table 31: Mean Birth Weight Of Neonate In Various Studies

	Mean birth weight (grams) in UCM group	**Mean birth weight (grams) in DCC group**	**P value**
Rabe *et al*[40] (2011)	1235 ± 468	1263 ± 428	0.81
Upadhyay *et al*[2] (2013)	2750 ± 410	2640 ± 320	0.92
Katheria *et al*[31] (2015)	1255 ± 413	1132 ± 392	0.0598
Jaiswal *et al*[43] (2015)	2760 ± 330	2750 ± 390	0.89
Samantha *et al*[38] (2019)	1620 ± 587	1579 ± 576	0.617
Mangla *et al*[49] (2020)	3038 ± 436	2909 ± 435	0.077
Index Study	3043.4 ± 426.1	3048.7 ± 390.6	0.90

DCC-Delayed cord clamping; UCM-Umbilical cord milking

The primary objective of our study was to compare the effect of UCM and DCC on hematocrit of the neonate in term and near-term neonates. In our study mean hematocrit in cord sample was slightly higher in DCC group (48.0 ± 8.3%) as compared to the UCM group (47.0 ± 7.1%). However, the difference was not statistically significant. Samantha *et al*[38] reported mean hematocrit of 49.9 ± 7.7% at birth in DCC group and 51.8 ± 6.2% in UCM group and the difference was not statistically significant. Rabe *et al*[40] reported mean hematocrit of 51.0 ± 7.0% at birth in DCC group and 52.0 ± 8.0% in UCM group and the difference was not statistically significant. Another study by Jaiswal *et al*[43] reported mean hematocrit of 50.9 ± 6.4% at birth in UCM group and 50.3 ± 6.8% in DCC group which was statistically non-significant (p value 0.46). In study conducted by Katheria et al[31], birth hemoglobin was compared in between the two groups instead of hematocrit. Mean birth hemoglobin in DCC group was reported as 15.6 ± 2.2g% and in UCM group was 16.3 ± 2.4g% which was found to be statistically significant (p <0.05). Thus, this difference could be due to different parameter used for assessment of anemia and difference in the period of gestation and mode of delivery of the study population. The studies which used hematocrit for the assessment of anemia at birth had non-significant results.

Table 32: Comparison Of Mean Hematocrit At Birth In Various Studies

	Mean hematocrit at birth in UCM group	**Mean hematocrit at birth in DCC group**	**P value**
Rabe *et al*[40] (2011)	52.0 ± 8.0%	51.0 ± 7.0%	0.65
Jaiswal *et al*[43] (2015)	50.9 ± 6.4%	50.3 ± 6.8%	0.46
Samantha *et al*[38] (2019)	51.8 ± 6.2%	49.9 ± 7.7%	0.07
Katheria *et al*[31]# (2015)	16.3 ± 2.4g%	15.6 ± 2.2g%	<0.05
Index study	47.0 ± 7.1%	48.0 ± 8.3%	0.21

DCC-Delayed cord clamping; UCM-Umbilical cord milking
#Mean Hemoglobin

In our study mean hematocrit at 30 ± 6 hours in UCM group was higher (54.4 ± 5.8%) as compared to DCC group (50.9 ± 7.1%) and the difference was found to be statistically significant (P value <0.01). The study conducted by Mangla *et al*[49] reported that mean hematocrit at 48±6 hours in UCM group was 57.7 ± 4.3% and in DCC group was 55.9 ± 4.4% and the difference was statistically significant (p value 0.02).

Both the studies showed similar results although there was slight variation in the duration at which hematocrit level was measured.

Another study conducted by Jaiswal *et al*[43] showed mean hematocrit at 48 hours in UCM group was 48.51 ± 6.8% and in DCC group was 48.0 ± 6.8% which was lower than that observed in our study and was statistically non-significant. This difference was probably because of the milking technique. In this study, the umbilical cord was cut and then milked which prevented refilling of the cord from placenta. Also, they milked the cord only three times, whereas we milked the cord four times in our study. This could have led to lower hematocrit values and insignificant results in their study.

Table 33: Comparison Of Mean Hematocrit Beyond 24 Hours In Various Studies

	Mean hematocrit beyond 24 hours in UCM group	**Mean hematocrit beyond 24 hours in DCC group**	**P value**
Jaiswal *et al*[43] (2015) (At 48 hours)	48.5 ± 6.8%	48.0 ± 6.8%	0.60
Mangla *et al*[49] (2020) (At 48±6 hours)	57.7 ± 4.3%	55.9 ± 4.4%	0.02
Index study (At 30±6 hours)	54.4 ± 5.8%	50.9 ± 7.1%	<0.01

DCC-Delayed cord clamping; UCM-Umbilical cord milking

Over-transfusion of the neonate can lead to polycythemia and significant jaundice requiring phototherapy. Hence it is essential to look for the side effects of UCM and DCC.

In our study, slightly higher number of neonates received phototherapy in DCC group (19.25%) as compared to UCM group (18.18%). However, the difference was statistically non-significant (P value 0.79). In a study conducted by Samantha *et al*[38], 88% neonates received phototherapy in DCC group and 85.9% received phototherapy in UCM group with non-significant results (P value 0.65). This huge difference was probably due to the difference in the period of gestation. This study was conducted in neonates of <34 weeks POG whereas our study was conducted in neonates >34 weeks POG. Study by Mangla *et al*[49], showed that only 1.4% neonates in each group required phototherapy. None of the studies showed increased requirement of phototherapy in either of the two groups. Hence, UCM can be a good alternative to DCC without increasing the risk of phototherapy requirement.

Table 34: Comparison Of Phototherapy Requirement In Various Studies

	Phototherapy received in UCM group	**Phototherapy received in DCC group**	**P value**
Samantha *et al*[38] (2019)	85.9%	88%	0.65
Mangla *et al*[49] (2020)	1.4%	1.4%	-
Index study	18.18%	19.25%	0.79

DCC-Delayed cord clamping; UCM-Umbilical cord milking

In our study, NICU admissions were slightly higher in DCC group (7.49%) as compared to UCM group (2.67%). The difference was found to be statistically significant.

In a study conducted by Mangla *et al*[49], NICU admissions were higher in DCC group (2.8%) and lower in UCM group (1.4%), but the result was not statistically significant. Similarly, in study conducted by Jaiswal *et al*[43], 11% neonates were admitted in NICU in DCC group and 6% in UCM group with non-significant results. This could possibly be because there are various factors which might be responsible for NICU admissions which were not included in the study.

Table 35: Comparison Of NICU Admissions In Various Studies

	NICU admissions in UCM group	NICU admissions in DCC group	P value
Mangla *et al*[49] (2020)	1.4%	2.8%	>0.05
Jaiswal *et al*[43] (2015)	6%	11%	0.2
Index study	2.67%	7.49%	0.03

DCC-Delayed cord clamping; NICU- Neonatal intensive care unit; UCM-Umbilical cord milking

In our study, incidence of polycythemia was 1.07% and 2.14% in UCM group as compared to 2.67% and 1.6% in DCC group in cord sample and at 30 ± 6 hours respectively. However, the difference was not statistically significant. In a study by Katheria *et al*[31], polycythemia was seen in 2.66% neonates in UCM group and 5.06% neonates in DCC group and the difference was found to be statistically non-significant. In a study by Mangla *et al*[49], polycythemia was seen only in DCC group (2.8%). Hence, UCM does not increase the risk of polycythemia making it a good alternative to DCC.

Table 36: Comparison Of Polycythemia In Various Studies

	Polycythemia in UCM group	**Polycythemia in DCC group**	**P value**
Katheria *et al*[31] (2015)	2.66%	5.06%	>0.05
Mangla *et al*[49] (2020)	0%	2.8%	>0.05
Index study **Cord sample** **At 30±6 hours**	1.07% 2.14%	2.67% 1.6%	0.25 0.70

DCC-Delayed cord clamping; UCM-Umbilical cord milking

Apart from this we also did subgroup analysis of hematocrit in cord sample and at 30 ± 6 hours of life in anemic and non-anemic mothers, and in term and preterm neonates. Ours is the first study to do this subgroup analysis. None of the previously published studies did this subgroup analysis.

In newborn born to anemic mothers, mean hematocrit in cord sample was 45.9 ± 6.4% in UCM group and 48.8 ± 8.4% in DCC group which was statistically significant (P value 0.02). However, mean hematocrit at 30 ± 6 hours was not statistically significant (P value 0.11) in newborn born to anemic mothers. But the rate of increase of mean hematocrit from cord sample to 30 ± 6 hours was higher in UCM group as compared to DCC group. Therefore, UCM was more beneficial in anemic patients than DCC.

In newborn born to non-anemic mothers, mean hematocrit in cord sample was not statistically significant (P value 0.98). However, mean hematocrit at 30 ± 6 hours was 55.0 ± 5.5% in UCM group and 50.5 ± 7.4% in DCC group which was statistically significant (P value 0.0001). Furthermore, the rate of increase of mean hematocrit from cord sample to 30 ± 6 hours was higher in UCM group as compared to DCC group. Hence, even in non-anemic patients, UCM was more effective than DCC.

In Preterm neonates, mean hematocrit in cord sample as well as at 30±6 hours was statistically non-significant. Since there were limited number of preterm neonates in each group, we could not reach significant results.

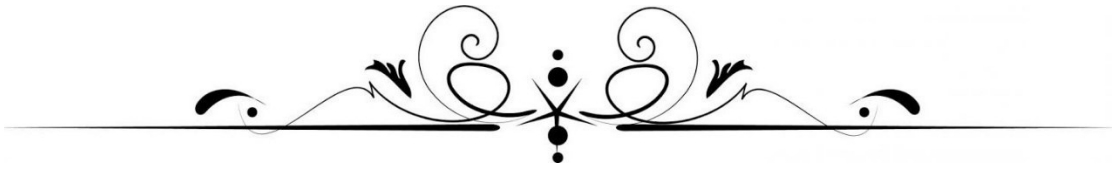
In Term neonates, mean hematocrit in cord sample was statistically non-significant (P value 0.23). However, mean hematocrit at 30 ± 6 hours was 54.5 ± 5.7% in UCM group and 50.8 ± 7.1% in DCC group which was statistically significant (P value 0.0001). Hence, for term neonates, UCM can be a good alternative with improved hematological outcomes as compared to DCC.

In AGA neonates, mean hematocrit in cord sample was statistically non-significant (P value 0.25). However, mean hematocrit at 30 ± 6 hours was 53.8 ± 5.6% in UCM group and 50.3 ± 6.9% in DCC group which was statistically significant (P value 0.0001). Hence, UCM can be a good substitute to DCC in AGA neonates.

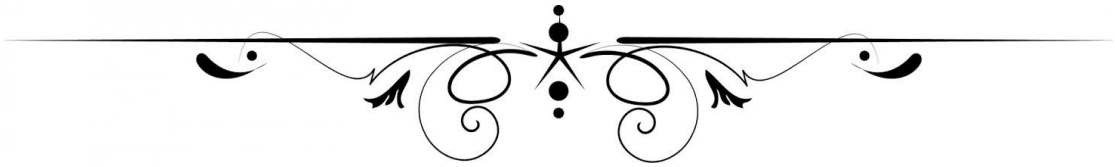
In SGA neonates, mean hematocrit in cord sample as well as at 30 ± 6 hours was statistically non-significant. Since the number of SGA neonates in each group was less, we could not reach conclusive results.

STRENGTHS AND LIMITATIONS

- Main strength of our study was that it was a randomized controlled trial conducted in both term and near-term neonates. There are very few studies comparing the effect of UCM and DCC in both term and near-term neonates. Previous studies published by Katheria *et al*[31], Samantha *et al*[38] and Rabe *et al*[40] were all conducted only in preterm neonates.
- Also, our randomization was stratified into vaginal delivery and caesarean section which was not done by any other study.
- Another strength of our study was large sample size of 374. Large sample size provides more accurate mean values and hence the data is more reliable. Most of the previously published studies have modest sample size of less than two hundred; Katheria *et al*[31] had 154, Rabe *et al*[40] had 58, Upadhyay *et al*[2] had 200, Mangla *et al*[49] had 144 and Jaiswal *et al*[43] had 200.
- Another high point of our study was the technique which was utilized for umbilical cord milking. We did intact-UCM four times which allowed refilling of the cord from the placenta in between each milking maneuver, which might have led to higher hematocrit values. Previous study published by Jaiswal *et al*[43] did UCM after cutting the umbilical cord.
- Another very strong point of our study was that we did subgroup analysis of hematocrit in cord sample and at 30 ± 6 hours of life in anemic and non-anemic mothers; in term and preterm neonates and in AGA and SGA neonates which was not done by any other study published so far.
- Our study had few limitations too. Our follow up included evaluation of S. ferritin and hemoglobin at 14 weeks of life which we were not able to complete because of prevailing COVID-19 pandemic. Long term follow up is desired to establish whether initial increase in hematocrit sustains later in infancy and early childhood. Also, this study was not powered to assess the side effects of each method conclusively.



SUMMARY & CONCLUSION



SUMMARY AND CONCLUSION

- This was a Randomized controlled trial to compare the effect of Delayed cord clamping and Umbilical cord milking in term and near-term neonates.
- It was conducted in the Department of Obstetrics and Gynecology and Department of Neonatology, AIIMS Jodhpur from March 2020 to August 2021.
- A total of 789 women were assessed for enrolment out of which 374 cases were enrolled in the study who met the inclusion criteria. They were randomized into UCM group and DCC group.
- In UCM group, 119 underwent vaginal delivery and 68 underwent caesarean section. In DCC group, 117 underwent vaginal delivery and 70 underwent caesarean section. All the neonates born at 34 completed weeks or more were included in the study.
- The mean age of mother in UCM group was 26.7 ± 4.6 years and in DCC group was 26.6 ± 4.2 years. Mean BMI in UCM group was 26.2 ± 3.2 kg/m^2 and in DCC group was 26.1 ± 2.9 kg/m^2. Hence, mean age and mean BMI were comparable to each other in two groups.
- Mean gestational age in UCM group was 38.7 ± 1.3 weeks and in DCC group was 38.7 ± 1.2 weeks, which was comparable in both groups.
- Mean birth weight of neonates was also comparable between two groups. Mean birth weight in UCM group was 3043.4 ± 426.1 grams and in DCC group was 3048.7 ± 390.6 grams.
- Mean hematocrit in cord sample in UCM group was 47.0 ± 7.1% and in DCC group was 48.0 ± 8.3, which was comparable in both groups.
- Mean hematocrit at 30 ± 6 hours in UCM group was 54.4 ± 5.8% and in DCC group was 50.9 ± 7.1%. Hence, mean hematocrit at 30 ± 6 hours was higher in UCM group as compared to DCC group and was statistically significant ($p<0.01$).
- In UCM group, 18.18% neonates required phototherapy and in DCC group, 19.25% neonates required phototherapy. Requirement of phototherapy was comparable in both the groups with non-significant results (p value 0.79).
- In UCM group, 2.67% neonates required NICU admission and in DCC group, 7.49% neonates required NICU admission. Hence, NICU admissions were slightly more in DCC group as compared to UCM group which was statistically significant (p value 0.034).
- Incidence of polycythemia in cord sample in UCM group was 1.07% and in DCC group was 2.67% and incidence of polycythemia at 30 ± 6 hours in UCM group was 2.14% and

in DCC group was 1.6%. Both the groups were comparable to each other with non-significant results.

- In newborn born to anemic mothers, mean hematocrit in cord sample was 45.9 ± 6.4% in UCM group and 48.8 ± 8.4% in DCC group which was statistically significant (P value 0.02). Mean hematocrit at 30 ± 6 hours was 53.2 ± 6.1% in UCM group and 51.5 ± 6.4% in DCC group which was statistically non-significant (P value 0.11). However, the rate of increase of mean hematocrit from cord sample to 30±6 hours was higher in UCM group as compared to DCC group.
- In newborn born to non-anemic mothers, mean hematocrit in cord sample was 47.5 ± 7.4% in UCM group and 47.5 ± 8.3% in DCC group which was statistically non-significant (P value 0.98). Mean hematocrit at 30 ± 6 hours was 55.0 ± 5.5% in UCM group and 50.5 ± 7.4% in DCC group which was statistically significant (P value 0.0001). Also, the rate of increase of mean hematocrit from cord sample to 30±6 hours was higher in UCM group as compared to DCC group.
- In Preterm neonates, mean hematocrit in cord sample was 53.5 ± 9.4% in UCM group and 51.6 ± 7.5% in DCC group which was statistically non-significant (P value 0.65). Mean hematocrit at 30 ± 6 hours was 55.5 ± 4.3% in UCM group and 51.7 ± 6.8% in DCC group which was statistically non-significant (P value 0.22).
- In Term neonates, mean hematocrit in cord sample was 46.8 ± 6.7% in UCM group and 47.8 ± 8.3% in DCC group which was statistically non-significant (P value 0.23). Mean hematocrit at 30 ± 6 hours was 54.5 ± 5.7% in UCM group and 50.8 ± 7.1% in DCC group which was statistically significant (P value 0.0001).
- In AGA neonates, mean hematocrit in cord sample was statistically non-significant (P value 0.25). However, mean hematocrit at 30 ± 6 hours was 53.8 ± 5.6% in UCM group and 50.3 ± 6.9% in DCC group which was statistically significant (P value 0.0001).
- In SGA neonates, mean hematocrit in cord sample as well as at 30 ± 6 hours was statistically non-significant.
- It can be concluded from our study that UCM lead to significant increase in hematocrit levels at 30 ± 6 hours without increasing the side effects like jaundice requiring phototherapy, polycythemia and NICU admissions in term and near term neonates. UCM lead to significant increase in hematocrit in AGA neonates as compared to DCC. Additionally, the rate of increase of hematocrit from cord sample to 30 ± 6 hours was higher in UCM group as compared to DCC in newborn born to both anemic and non-

anemic mothers. Another benefit of UCM is that it does not interfere with resuscitation as it can be performed in lesser time unlike DCC. As DCC has been accepted as standard of care by AAP, UCM can be recommended as an alternative to DCC in all deliveries where DCC is not possible or could not be practiced for any reason.

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ANNEXURES

ANNEXURES

List of Annexures

ANNEXURE NO.	:	TITLE
1	:	IEC Certificate
2	:	Patient Information sheet in English
3	:	Patient Information sheet in Hindi
4	:	Consent form in English
5	:	Consent From in Hindi
6	:	Case record form
7	:	Master chart

ANNEXURE - I

अखिल भारतीय आयुर्विज्ञान संस्थान, जोधपुर
All India Institute of Medical Sciences, Jodhpur
संस्थागत नैतिकता समिति
Institutional Ethics Committee

No. AIIMS/IEC/2020/2070 **Date: 01/01/2020**

ETHICAL CLEARANCE CERTIFICATE

Certificate Reference Number: **AIIMS/IEC/2019-20/950**

Project title: **"Delayed cord clamping versus umbilical cord milking in term and near term neonates - A randomized controlled trial"**

Nature of Project:	**Research Project**
Submitted as:	**M.D. Dissertation**
Student Name:	**Dr.Aashim Garg**
Guide:	**Dr.Shashank Shekhar**
Co-Guide:	**Dr.Neeraj Gupta, Dr.Pratibha Singh, Dr.Manu Goyal, Dr.Manisha Jhirwal & Dr. Prasenjit Mitra**

This is to inform that members of Institutional Ethics Committee (Annexure attached) met on **23-12-2019** and after through consideration accorded its approval on above project. Further, should any other methodology be used, would require separate authorization.

The investigator may therefore commence the research from the date of this certificate, using the reference number indicated above.

Please note that the AIIMS IEC must be informed immediately of:

- Any material change in the conditions or undertakings mentioned in the document.
- Any material breaches of ethical undertakings or events that impact upon the ethical conduct of the research.
- In case of any issue related to compensation, the responsibility lies with the Investigator and Co-Investigators.

The Principal Investigator must report to the AIIMS IEC in the prescribed format, where applicable, bi-annually, and at the end of the project, in respect of ethical compliance.

AIIMS IEC retains the right to withdraw or amend this if:

- Any unethical principle or practices are revealed or suspected
- Relevant information has been withheld or misrepresented

AIIMS IEC shall have an access to any information or data at any time during the course or after completion of the project.

On behalf of Ethics Committee, I wish you success in your research.

Dr. Praveen Sharma
Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

Enclose:
1. Annexure I

Page 1 of 2

Basni Phase-2, Jodhpur, Rajasthan-342005, **Website:** www.aiimsjodhpur.edu.in, **Phone:** 0291-2740741 Extn. 3109
Email: ethicscommittee@aiimsjodhpur.edu.in

Annexure I

Institutional Ethics Committee
All India Institution of Medical Sciences, Jodhpur

Meeting of Institutional Ethics committee held on **23-12-2019 at 10:00** AM at Committee Room, Admin Block AIIMS Jodhpur.

Following members were participated in the meeting:-

S/No.	Name of Member	Qualification	Role/Designation in Ethics Committee
1.	Dr. F.S.K Barar	MBBS, MD (Pharmacology)	**Chairman**
2.	Justice N.N Mathur	LLB	Legal Expert
3.	Dr. Varsha Sharma	M.A (Sociology)	Social Scientist
4.	Mr. B.S.Yadav	B.Sc., M.Sc. (Physics), B.Ed.	Lay Person
5.	Dr. K.R.Haldiya	MD (General Medicine)	Clinician
6.	Dr. Arvind Mathur	MBBS, MS (General Medicine)	Clinician
7.	Dr. Surajit Ghatak	MBBS, MS (Anatomy)	Basic Medical Scientist
8.	Dr. Vijaya Lakshmi Nag	MBBS, MD (Microbiology)	Basic Medical Scientist
9.	Dr. Sneha Ambwani	MBBS, MD (Pharmacology)	Basic Medical Scientist
10.	Dr. Kuldeep Singh	MBBS, MD (Paediatric), DM (General Medicine)	Clinician
11.	Dr. Abhinav Dixit	MBBS, MD (Physiology), DNB (Physiology)	Basic Medical Scientist
12.	Dr. Pradeep Kumar Bhatia	MBBS, MD (Anaesthesiology)	Clinician
13.	Dr. Tanuj Kanchan	MBBS, MD (Forensic Medicine)	Basic Medical Scientist
14.	Dr. Pankaj Bhardwaj	MBBS, MD (CM&FM)	Clinician
15.	Dr. Praveen Sharma	M.Sc., Ph.D. (Biochemistry)	Member Secretary

Dr. Praveen Sharma
Member secretary
Institutional Ethics Committee
AIIMS,Jodhpur

ANNEXURE 2

Patient Information sheet (PIS)

You are invited to take part in this study entitled "Delayed cord clamping versus Umbilical cord milking in term and near-term neonates- A Randomized Controlled Trial"

It is informed that it is entirely voluntary, and you may refuse to take part or discontinue at any time without losing your right to adequate gynecological care.

The research is aimed at comparing hematocrit in cord sample and at 30+/-6 hours, hematologic parameters at 14 weeks and need for phototherapy and NICU care in the baby following delivery. Consent will be taken from you, then just after delivery, your babies will be divided into two groups. In group 1, umbilical cord milking will be done 4 times while in group 2, delayed cord clamping will be done. Even if you refuse to participate in this study the investigations and the appropriate treatment will be carried out as a regular protocol.

The expected duration of your participation in this study is 14 weeks. There is no specific complication due to the study.

All the records will be kept confidential.

You have the right to ask for any further information that you require.

In case of any doubt regarding the study you are welcome to contact the undersigned personally or by telephone.

Primary Investigator- Dr Aashim Garg

Phone no- 8860346840

ANNEXURE 3

रोगी सूचना पत्र (पीआईएस)

आपको इस □ ध्ययन में भाग लेने के लिए आमंत्रित किया गया है जिसका शीर्षक है " टर्म में और टर्म के निकट नवजात शिशुओं में विलंबित कॉर्ड क्लैम्पिंग बनाम गर्भनाल की दुहना - एक यादृच्छिक नियंत्रित परीक्षण। "

यह सूचित किया जाता है कि यह पूरी तरह से स्वैच्छिक है और आप पर्याप्त स्त्रीरोग संबंधी देखभाल के □ धिकार को खोए बिना किसी भी समय हिस्सा लेने या बंद करने से इनकार कर सकते हैं। □ नुसंधान का उद्देश्य प्रसव के बाद बच्चे में हेमटोक्रिट, 14 सप्ताह में हेमाटोलॉजिक पैरामीटर और फोटोथेरेपी और NICU में देखभाल की जरुरत की तुलना करना है। पहले आपसे सहमति ली जाएगी, फिर डिलीवरी के तुरंत बाद, आपके शिशुओं को दो समूहों में विभाजित किया जाएगा। समूह 1 में, गर्भनाल की दुहना 4 बार की जाएगी जबकि समूह 2 में, विलंबित कॉर्ड क्लैंपिंग की जाएगी। यहां तक कि □ गर आप इस □ ध्ययन में भाग लेने से इनकार करते हैं तो जांच और उचित उपचार नियमित प्रोटोकॉल के रूप में किया जाएगा। इस □ ध्ययन में आपकी भागीदारी की □ पेक्षित □ वधि 14 सप्ताह है। □ ध्ययन के कारण कोई विशिष्ट जटिलता नहीं है।

सभी रिकॉर्ड गोपनीय रखे जाएंगे। आपके पास कोई और जानकारी मांगने का □ धिकार है, जिसकी आपको आवश्यकता है।

□ ध्ययन के संबंध में किसी भी संदेह के मामले में, आपका व्यक्तिगत रूप से या टेलीफोन द्वारा संपर्क करने के लिए स्वागत है।

प्राथमिक जांचकर्ता- डॉ आशिम गर्ग

फोन नंबर- 8860346840

ANNEXURE 4

All India Institute of Medical Sciences

Jodhpur, Rajasthan

Informed Consent Form

Title of Thesis/Dissertation: Delayed cord clamping versus Umbilical cord milking in term and near-term neonates- A Randomized Controlled Trial

Name of PG Student: Dr. Aashim Garg Tel. No.: 8860346840

Patient/Volunteer Identification No.: _____

I, _____ W/o or D/o _____

R/o _____

give my full, free, voluntary consent to be a part of the study "A randomized controlled study of Delayed cord clamping versus Umbilical cord milking in term and near term neonates "The procedure and nature of which has been explained to me in my own language to my full satisfaction. I confirm that I have had the opportunity to ask questions. I fully understand that any of the above mentioned observation can be given to me, still I want to be a part of trial. I understand that my participation is voluntary and am aware of my right to opt out of the study at any time without giving any reason. I understand that the information collected about me and any of my medical records may be looked at by responsible individual from AIIMS, Jodhpur or from regulatory authorities. I give permission for these individuals to have access to my records.

Date: _____

Place: _____ Signature/Left thumb impression

This to certify that the above consent has been obtained in my presence.

Date: _____

Place: _____ Signature of PG Student

Witness 1_____ 2. Witness _____

Signature Signature

Name_____ Name: _____

Address: _____ Address: _____

ANNEXURE 5

ऑल इंडिया इंस्टिट्यूट ऑफ मैडिकल साईंसिस

जोधपुर, राजस्थान

सूचित सहमति प्रपत्र

थीसिस / शोध प्रबंध का शीर्षक: टर्म में और टर्म के निकट नवजात शिशुओं में विलंबित कॉर्ड क्लैम्पिंग बनाम गर्भनाल की दुहना - एक यादृच्छिक नियंत्रित परीक्षण।

पीजी छात्र का नाम: डॉ आशिम गर्ग फोन नंबर: 8860346840

रोगी / स्वयंसेवक पहचान संख्या: _____

मैं _____ पति / पिता _____

पता _____

□ ध्ययन का एक हिस्सा बनने के लिए मेरी पूर्ण, स्वतंत्र, स्वैच्छिक सहमति दें "विलंबित कॉर्ड क्लैम्पिंग बनाम गर्भनाल की दुहना में एक यादृच्छिक नियंत्रित □ ध्ययन, टर्म में और टर्म के निकट नवजात शिशुओं में " जिसकी प्रक्रिया और प्रकृति मुझे □ पनी भाषा में व्याख्या की गई है। मैं पुष्टि करता/करती हूं कि मुझे सवाल पूछने का □ वसर मिला है। मैं पूरी तरह से समझता/समझती हूं कि उपर्युक्त □ वलोकन में से कोई भी मुझे दिया जा सकता है, फिर भी मैं परीक्षण का हिस्सा बनना चाहता/चाहती हूं। मैं समझता/समझती हूं कि मेरी भागीदारी स्वैच्छिक है और बिना किसी कारण के किसी भी समय □ ध्ययन से बाहर निकलने के मेरे □ धिकार से □ वगत हूं। मैं समझता/समझती हूं कि मेरे और मेरे किसी भी मेडिकल रिकॉर्ड के बारे में एकत्रित जानकारी को एम्स, जोधपुर के जिम्मेदार व्यक्ति या नियामक □ धिकारियों से देखा जा सकता है। मैं इन व्यक्तियों को □ पने रिकॉर्ड तक पहुंचने की □ नुमति देता/देती हूँ।

दिनांक: _____

स्थान: _____ हस्ताक्षर / बाएं □ंगूठे का निशान

यह प्रमाणित करने के लिए कि मेरी उपस्थिति में उपरोक्त सहमति प्राप्त हुई है।

जगह: _____ पीजी छात्र के हस्ताक्षर

गवाह 1_____ गवाह 2_____

हस्ताक्षर हस्ताक्षर

नाम: _____ नाम: _____

पता: _____ पता: _____

ANNEXURE 6

CASE RECORD SHEET:-

NAME: REG. ID:

AGE: QUALIFICATION:

OCCUPATION: RESIDENCE:

PHONE NO-

- Chief complaint-

- HOPP

	Yes	No
Iron supplements		
Anemia		
Chronic Hypertension		
Pre-eclampsia		
Diabetes Mellitus		
Fetal Growth Restriction		
Preterm labour		
PPROM		
Circlage		
Placental/cord abnormality		

- Menstrual History:

Menstrual cycle

LMP- EDD- POG-

- Obstetric History:

- Past History:
- Personal History:

On Examination:

- General condition
- Pulse- rate /min
- Blood pressure- mmHg
- Respiratory rate- /min
- Temperature-
- Pallor- Icterus- Cyanosis- Clubbing- Lymphadenopathy- Edema-
- Weight (Kg): Height(cm): Body Mass Index (Kg/m2):
- Central Nervous System:
- Respiratory System:
- Cardio-Vascular System:
- Per-Abdomen:

Final Diagnosis:

Investigations-

	Date-
Blood Group	
CBC- Hb TLC- Plt	

CASE RECORD SHEET OF NEONATE:-

Baby of..... (Name of Mother) REG. ID:_____

• Name of Father _____

• Date and Time of Birth _____

• Sex (male/ Female/ Ambiguous) _____

Birth weight- Apgar Score- Mode of delivery:

Liquor:

Study group- Umbilical cord milking/delayed cord clamping

Neonatal Parameters:

Hematocrit in % Cord Sample At 30+/-6 hours	

	YES	NO
Jaundice requiring phototherapy		
Need for NICU care		

Follow Up

S. ferritin at 14 weeks	
Hemoglobin at 14 weeks