"EARLY VS DELAYED UMBILICAL CORD CLAMPING AND ITS IMPACT ON THE POST PARTUM BLOOD LOSS: A RANDOMIZED CONTROLLED TRIAL"

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LIST OF ABBREVIATIONS USED

ANC	Antenatal care
C. I.	Confidence Interval
χ^2	Chi- square
DBP	Diastolic Blood Pressure
DCC	Delayed cord clamping
ECC	Early cord clamping
GA	Gestational Age
Hb	Haemoglobin
Hr	Hour
ID	Identification Digit
IM	Intramuscular
IV	Intravenous
IU	International Units
µg	Microgram
mm Hg	millimetres of Mercury
Min	Minutes
PCV	Packed cell volume (Hematocrit)
PPH	Post partum hemorrhage
RCT	Randomized Controlled Trial
S.D.	Standard Deviation
SBP	Systolic Blood Pressure
Sec	Seconds
WHO	World Health Organization

ABSTRACT

Background

There is no formulated guideline on the timing of umbilical cord clamping after childbirth. Studies on timing of cord clamping have usually assessed infant outcomes. Evidence published to date has not clearly established the impact of the timing of cord clamping on postpartum blood loss and necessitates further research.

Objectives

Primary Objective: To find out the impact of early and delayed cord clamping on the post partum blood loss.

Secondary Objective: To find out the impact of early and delayed cord clamping on infant haemoglobin and hematocrit at 90 ±7 days postpartum.

Methods

A randomized, controlled trial was performed on 183 consenting women fulfilling eligibility criteria in labour ward of a teaching hospital in India. They were randomly assigned into early cord clamping or delayed cord clamping group; other components of active management of third stage of labour being same for all. The duration of third stage of labour was noted. Quantitative assessment of post partum blood loss was done using BRASSS-V drapes and weighing blood soaked pads. Cord blood haemoglobin and hematocrit at birth and infant haemoglobin and hematocrit at 90 ±7 days were estimated. Statistical analysis done using students unpaired ‘t’ test.

Results

Of the 183 recruited (88 in early and 95 in delayed cord clamping), 159 (86.89%) (75 in early and 84 in delayed cord clamping group) completed the follow up at the third month whereas 24 (13.11%) lost to follow up (13 in early and 11 in delayed cord clamping group).

No difference was noted in the mean blood loss (203.52 ±122.74ml versus 200.74±104.07 ml in early and delayed cord clamping respectively) and the duration of third stage of labour (Mean: 296.59± 98.97 seconds versus 281.79±104.59 seconds for early and delayed clamping respectively).

Infant haemoglobin at 90 ±7 days was 11.07 ± 1.27gm/dl versus 12.70± 1.41 gm/dl (p=0.0000) and infant hematocrit at 90 ±7 days was 34.13±3.93% versus 39.33 ±4.88% in early and delayed clamping respectively. (p=0.0000)

Conclusion

The timing of cord clamping has no impact on the mean blood loss and duration of third stage of labour.

Delayed clamping significantly increases mean venous haemoglobin and hematocrit at 90 ±7 days without increasing NICU admissions. Hence, delayed umbilical cord clamping should be implemented to reduce the incidence of anaemia in all term infants who do not require immediate resuscitation.

Key words - Umbilical cord clamping, Delayed cord clamping, Early cord clamping, Post partum blood loss, Neonatal Haemoglobin, Neonatal Hematocrit, Infant Haemoglobin, Infant Hematocrit, Infant anaemia.

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INTRODUCTION

The optimal timing of cord clamping has been a controversial issue for decades. Clamping and cutting of the umbilical cord at birth is by far the oldest and most prevalent intervention in humans. In spite of that, there are no clear-cut guidelines on the clamping of umbilical cord after childbirth. No standard definitions of “early” or “late’’ cord clamping have been formulated. Policies for timing of cord clamping vary, with early cord clamping generally carried out in the first 60 seconds after birth, whereas late cord clamping usually involves clamping the umbilical cord greater than 60 seconds after the birth or when cord pulsation has ceased.[1]

The timing of cord clamping and cutting is frequently regarded as one of the components of active management of the third stage of labour (other components are administration of a prophylactic uterotonic at or after delivery of the baby, controlled cord traction and uterine massage). However, there is no consensus on the precise meaning of the word "early" in this context. Trials evaluating active management of the third stage of labour have used a variety of definitions of early cord clamping and cutting, ranging from immediately after delivery of the baby to up to one minute after birth. The same confusion also exists with regard to the definition of “late” or "delayed" cord clamping. These terms are generally understood to mean a delay of 2–3 minutes after birth, or after the cessation of cord pulsation. However, their exact definition remains unclear.

There are no formal practice guidelines, but most practitioners in western countries clamp and cut the cord immediately after birth, while the practice worldwide is variable. When active management is employed, clamping of the cord may be done immediately after delivery of the infant. Evidence published till the time

of initiating this study has not clearly established the impact of the timing of cord clamping on postpartum blood loss and further investigation is needed. [2]

Early cord clamping is part of active management of the third stage of labour which significantly decreases duration of third stage and postpartum blood loss. It is easy for the obstetrician to clamp the cord immediately after birth. However, the timing of 'early' cord clamping is not consistent in practice.[1, 3, 4]

The disadvantages of early clamping include infant anaemia, increased incidence of acidemia, hypoxic ischemic brain damage, childhood mental disorders, increased risk of hypovolemia, iron loss, several blood disorders, type 2 diabetes and increase in the likelihood of feto-maternal transfusion as a larger volume of blood remains in the placenta. [5, 6, 7]

There is high prevalence of anaemia in India, 79.2% children aged 6-35 months are anaemic.[8] Infant anaemia is associated with increased mortality and impaired mental and motor development. The advantages of delayed cord clamping also include higher haemoglobin levels, additional iron stores, less fall in haemoglobin (by about 1 g/dl) at 3 months and less anaemia later in infancy. Exclusive breast feeding is routine in current practice. Delaying the clamping of the cord helps in early initiation and increased duration of breastfeeding after birth when the baby is in direct contact with the mother. [6, 9, 10]

The reducing effect of late clamping on risk of anaemia at different points within the first 3 months of life appeared to be sustained irrespective of the level of the newborn after delivery. [5] This was demonstrated by the comparable results of the trial, in which newborns were placed on the mother's abdomen, and the trials in which newborns were kept at levels lower than that of the introitus.[10, 11]

Lower rates of iron deficiency anaemia at age 6 months were also reported among infants held at the level of the introitus.[6, 10]

A recent systematic review confirms the benefit of delayed cord clamping.[5] Iron stores at birth is variable and are correlated to each infant at 3months of age. Iron content in the diet is one of the factors influencing the "iron status" during the first year of life. Likewise, another benefit of delayed clamping would be the increase of haematopoietic stem cells transfused to the newborn, which might play a role on different blood disorders and immune conditions.[9]

It was observed in some studies that delayed cord clamping could contribute to preventing iron-deficiency anaemia in the first year of life. [9, 10, 12]

The reason for this effect is based on the fact that after birth the newborn is delivered with a placental transfusion of about 80 ml of blood at 1 minute after birth and about 100 ml at 3 minutes after birth. This volume will supply 40 to 50 mg/kg of extra iron to 75 mg/kg of body iron that newborn term infants have, reaching a total of 115 to 120 mg/kg, which might prevent iron deficiency in the first year of life.[9, 11, 13] Iron deficiency early in life may have pronounced central nervous system effects such as cognitive impairment. Iron deficiency is also the main cause of anaemia, one of the most serious conditions in childhood, especially in developing countries.

Disadvantages of delayed clamping are increased risk of hypervolemia, hyper viscosity, polycythemia, respiratory symptoms and hyperbilirubinemia. Few studies suggest that there may be an increased risk for hyperbilirubinemia, however phototherapy or exchange transfusion are not usually indicated. According to a recent meta analysis, although late clamping is associated with a moderate increase in blood viscosity and increased rates of polycythemia, there is no evidence of any significant

harm as measured by the need for phototherapy to treat jaundice or by admission to the NICU. A Cochrane review suggests delayed cord clamping increases the risk of jaundice requiring phototherapy. [1, 5 , 11, 12]

The implications of different managements of the third stage of labour for developing countries with greater problems of both maternal and childhood mortality and morbidity may be even more important. Whether all the components of full active management are useful should also be investigated. The International Confederation of Midwives and the International Federation of Gynecologists and Obstetricians did not wait for these studies before acting and have removed immediate cord clamping from their recommendations. [14]

There is little agreement among doctors and midwives about the optimal time to clamp the umbilical cord after birth. The most important points of difference relate to maternal and infant safety. Many healthcare workers worldwide tend to clamp the cord and pass the baby off as quickly as possible. Infants in resource poor settings are greatly affected by immediate clamping, as this may prevent a cost-free means of boosting their small iron stores. Delayed clamping of the umbilical cord is a physiological and inexpensive means of enhancing hematologic status, preventing anaemia over the first 3 months of life and enriching iron stores and ferritin levels for as long as 6 months. Although this is of particular importance for developing countries in which anaemia during infancy and childhood is highly prevalent, it is likely to have an important impact on all newborns, regardless of birth setting. However, both maternal and neonatal risks and benefits associated with different timings of umbilical cord clamping require further investigation.

Further research is needed to determine the minimum time required to provide maximum benefit of placental transfusion, advantages and disadvantages of cord clamping by comparing maternal and neonatal outcomes.

OBJECTIVES

Primary objective: To study the impact of early and delayed cord clamping on the post partum blood loss.

Secondary objectives: To study the impact of early and delayed cord clamping on

1. Duration of third stage of labour.
2. Neonatal morbidity (NICU admissions after birth and the incidence of neonatal hyperbilirubinemia requiring photo therapy in both groups).
3. Infant haemoglobin and hematocrit at 90 ±7 Days.

REVIEW OF LITERATURE

There is very little evidence to suggest that the timing of cord clamping has an impact on the incidence of PPH. Because of the benefits to the baby, the cord should not be clamped earlier than is necessary for applying cord traction in the active management of the third stage of labour.[15]

Considerable differences in policies for managing the third stage of labour were observed both between and within countries. It has been shown that many maternity units in most countries do not use the full package of active management but do use some of its components. There are marked differences in policies for managing the third stage of labour are observed both between and within countries. In Europe, 66% of maternity units in the UK and many other countries have policies of clamping and cutting the cord immediately after the birth. 65-74% of units in Austria, Denmark, Finland, Hungary and Norway have policies of waiting until the cord stops pulsating. More than 10% of units in Austria, Hungary, Italy and Switzerland have no stated policy according to the study done by Winter et al.[3]

In Cochrane systematic review of 11 randomized controlled trials including 2989 mother-infant pairs comparing early and late cord clamping, it was concluded that delaying clamping of the cord for at least two to three minutes seems not to increase the risk of postpartum hemorrhage. It can be advantageous for the infant by improving iron status which may be of clinical value particularly in infants where access to good nutrition is poor, although delaying clamping increases the risk of jaundice requiring phototherapy. [1]

A Systematic Review and Meta-analysis of 15 controlled trials including 1912 newborns by Hutton et al concluded that delaying clamping for a minimum of 2 minutes after birth is beneficial to the newborn, extending into infancy. This meta-analysis estimated a significant 47% reduction in risk of anaemia and 33% reduction in risk of having deficient iron stores at ages 2 to 3 months with late clamping. Placental transfusion associated with late compared with early cord clamping resulted in consistently higher hematocrit levels within normal physiologic ranges and in improved markers of iron status over the first months of life without having a significant impact on the absolute values of bilirubin and plasma viscosity during the first week of life. Although late clamping was associated with a moderate increase in blood viscosity and increased rates of polycythemia, there was no evidence of any significant harm as measured by the need for phototherapy to treat jaundice or by admission to the NICU. The risk of polycythemia was not significant when only high-quality studies were considered. In addition, none of the polycythemic infants evaluated in this review were symptomatic (i.e. symptoms of central nervous system, cardiopulmonary, gastrointestinal tract, or renal impairment). There is an increase in polycythemia among infants in whom cord clamping is delayed but it appears to be a benign condition.[5]

Chaparro et al and Cernadas et al reported that maternal blood loss after delivery does not vary significantly between delayed cord clamping and immediate clamping groups. Major limitations of these trials were the differences in the method of measuring blood loss (visual estimation versus measuring jar), the mode of delivery (100% vaginal versus > 25% caesarean section), and the definition of

delayed cord clamping. The risk of postpartum haemorrhage, defined as blood loss of >500 ml, was not different after delayed cord clamping or immediate clamping (363 participants, relative risk 0.89). The Mexican trial did not quantitatively measure maternal blood loss but classified the bleeding as normal, high, or severe, and found no differences between delayed cord clamping and immediate clamping.[6, 11]

In a randomized, controlled trial of 276 mother-infant pairs conducted in Argentina by Cernadas et al, no differences were observed among the groups with respect to postpartum blood-loss volume, postpartum hemorrhage, and maternal hematocrit level 24 hours after birth. The median maternal blood loss was 265 ml in the early-cord-clamping group, 250 ml in the 1-minute cord-clamping group, and 300 ml in the 3-minute cord-clamping group. Postpartum hemorrhage (blood loss>500 ml) was 26.8% in the early-cord-clamping group, 22.2% in the 1-minute cord-clamping group, and 25.4% in the 3-minute cord-clamping group. Severe postpartum hemorrhage (blood loss >1000 ml) was 3.6%, 5.6%, and 3.2% in each group, respectively. The maternal hematocrit at 24 hours postpartum was 29.9% (SD: 3.5) in group 1, 30.9% (SD: 4.5) in group 2, and 30.6% (SD: 3.6) in group 3. Blood loss after delivery and hematocrit variations between delivery and at 24 hours after birth were similar among the 3 groups (umbilical cord clamping within the first 15 seconds after birth, at 1 minute and at 3 minutes after birth). A remarkable increase of anaemia in the group with early cord clamping, both at 6 and 24 to 48 hours of life was noted. It was concluded that delayed cord clamping at birth

increases neonatal mean venous hematocrit within a physiologic range. Neither significant differences nor harmful effects were observed among groups. [11]

A randomized controlled trial of 476 mother-infant pairs done by Chaparro et al. in a large obstetrics hospital in Mexico City, Mexico suggested neonatal benefits of delayed clamping include higher haemoglobin levels, additional iron stores and less anaemia later in infancy. [6]

A partially blinded randomized controlled trial by van Rheenen et al in Mpongwe Mission Hospital, Zambia of 91 mother-infant pairs concluded that delayed cord clamping could help improve the hematological status of term infants living in a malaria-endemic region at 4 months of age. Compared with immediate clamping, a clamping delay of 3 min provides an additional blood volume of 20–35 ml/kg of body weight. However, the beneficial hematological effect disappeared by 6 months. [16]

Delaying the umbilical cord clamping for 1 to 3 minutes after birth appears to increase the infant's hematocrit within a physiological range without harmful effects, leading to lower incidence of anaemia in the first 4 months and higher iron stores for at least 6 months. [11, 17]

A clinical trial from India by Geethanath et al randomized 107 term infants born to non-anemic mothers to either immediate clamping of cord at delivery or clamping delayed till descent of placenta into vagina with neonate placed below the level of the placenta. Three months after delivery the infants in both groups had

similar haemoglobin levels. The serum ferritin was higher but insignificant, in the delayed clamping group. The results of this study did not match with other trials. [18]

Various studies have concluded that delayed cord clamping could help improve the hematological status of term infants at 4 months of age. A clamping delay of 3 minutes provides an additional blood volume of 20–35 ml/kg of body weight, with an additional 30% more blood volume and up to 60% more red blood cells and 40–50 mg/kg body weight extra iron at birth but the beneficial hematological effect disappears by 6 months. [9, 16, 19]

It has been observed that healthy breastfed infants are unlikely to become iron deficient before 6 months of age even though the iron reserves are limited. This is possibly because of the high bioavailability of iron from breast milk and not much increase in utilization of body iron during this period. Between 4-12 months of age, body iron is expected to increase by 70%, thus making this a period vulnerable to iron deficiency anaemia. The recent NFHS survey has reported very high prevalence of anaemia both in mothers and their children in India, with almost a quarter of children of severely anemic mothers being also severely anaemic. Iron stores at birth correlate with iron stores at 6-12 months. Studies have observed that infants of mothers with moderate and severe anaemia had significantly lower cord serum ferritin levels and hence lower iron stores at birth. Iron store at birth is an important determinant of anaemia in infancy. [8, 10]

Delaying cord clamping at birth should be assessed as an effective strategy to combat anaemia in infancy and improve child survival. Studies on timing of cord

clamping have assessed mostly infant outcomes. The beneficial or harmful effects of early or delayed cord clamping on the mother are not well studied.

Hence, the present study is aimed to find out if an association exists between the time of cord clamping (Early clamping ≤ 30seconds versus Delayed clamping at 3 minutes or after cessation of cord pulsation, whichever occurs first) with the post partum blood loss.

METHODS

Source of data: All women with term, singleton uncomplicated pregnancies undergoing full term vaginal deliveries in labour room at KLES Dr. Prabhakar Kore Hospital & MRC, Belgaum were invited to participate in the trial.

Study design: A hospital based prospective, partially blinded Randomized Controlled Trial (where the neonatal health care providers and laboratory personnel were unaware of the intervention used) was proposed at KLES Dr. Prabhakar Kore Hospital & MRC, Belgaum, Karnataka; a tertiary care teaching hospital in India.

Period of study: Up to completion of sample size from January 2009

Sample size: 106; 53 in each group.

According to a randomized controlled trial, blood loss was 373±366ml in early cord clamping group and 351±327ml had blood loss in delayed cord clamping group. Taking these as the two sample means, the level of significance as 5% and power of the test as 90%; the sample size in early cord clamping and delayed cord clamping group was proposed as **53** in each of the two groups.

$\bar{x}_1 = 373$

$\bar{x}_2 = 351$

$S_1=366$

$S_2=327$

Taking the level of significance as 5% ($\alpha=0.05$)

$Z\alpha=1.96$

Taking the power of the test as 90% ($\beta=0.10$)

$Z\beta=1.28$

The formula for calculating sample size is:

$$N = \frac{2(Z\alpha + Z\beta)^2 S^2}{(\bar{x}_1 - \bar{x}_2)^2}$$

With the above values, N=53 in each group

However, as this was the minimum required size, to get higher effect size for the secondary outcomes also and for better result; larger sample size of 183 was taken.

Study area, enrolment and study population: All women with term, singleton uncomplicated pregnancies undergoing full term vaginal deliveries in labour room at KLES Dr. Prabhakar Kore Hospital & MRC, Belgaum were invited to participate in the trial. All women with full term singleton, uncomplicated pregnancy willing to participate in the trial after informed, written consent were included in the study. Healthy term newborns not requiring resuscitation were included in the study.

Selection criteria

Exclusion Criteria included maternal conditions like

1. Caesarean section(previous or planned in current pregnancy)
2. Instrumental delivery
3. Anaemia (Hb less than 8gm/dl)
4. Preterm labour
5. Known Medical /Surgical disorders
6. All other conditions including obstetric complications requiring early cord clamping (Rh sensitized pregnancy, Multiple pregnancy, Severe pre eclampsia/ eclampsia, Antepartum hemorrhage)

Neonatal exclusion criteria included

1. Need for neonatal resuscitation
2. Major congenital abnormalities
3. Tight nuchal cord necessitating early cord cutting
4. Fetal distress
5. Birth asphyxia

METHOD OF DATA COLLECTION (STUDY PROTOCOL)

The study got ethical approval by Institutional Review Board of Jawaharlal Nehru Medical College, Belgaum, Karnataka, India vide a letter Ref. No. MDC/DOME/2158 dated 07.10. 2008. This was an academic study conducted in accordance with revised CONSORT Guidelines .[20]

We declare that we had no conflict of interest.

Personnel: This trial was conducted by the health care providers in labour room of KLES Dr. Prabhakar Kore Hospital & MRC associated with Jawaharlal Nehru Medical College, Belgaum.

Informed consent: Women who presented to the labour room of KLES Dr. Prabhakar Kore Hospital & MRC, Belgaum were screened for enrollment in the study using inclusion and exclusion criteria. Informed consent was obtained at the time of enrollment into the study in early labor. The health care provider obtained a signature or left hand thumb impression from the consented subject after reading the informed consent document. For illiterate participant, the consent document was read and written confirmation of the same was obtained in the presence of a witness. The written confirmation was obtained with left hand thumb impression in the presence of the woman's relative, who would attest to the process as a witness by signature or left hand thumb impression. (Photograph No.1) The informed consent document was only a small component of the informed consent process. Adequate time was provided for describing the study and fielding questions from the woman and/or immediate family members after equivocally describing the risks and

benefits of participation in the study. No pressure was placed on the woman to enroll in the trial. It was explained that lack of participation would not affect the usual and anticipated standard of care. No monetary benefits were offered to any of the participants enrolled in the study.

Photograph No.1 Taking Written Informed Consent

Randomization: Assignment of the participants to the two groups was done using computer generated randomized number sequence list with block size of 2 into either early or delayed cord clamping groups. The randomization list was concealed and placed in opaque sealed envelopes. These envelopes were opened when a woman was in active labour and fulfilled the inclusion criteria.

For allocation concealment, the randomization instructions were given in sequentially numbered, opaque, sealed envelopes with unpredictable allocation code, which were only opened when a woman had consented to enrol. Randomisation was done on admission to the labour ward, when the women were in

the active first stage of labour. A woman was deemed to be enrolled to the study only when she was randomized to the study in active labour. The eligibility status of the woman could change after initial screening but before randomization. Although study staff did not inform the women of their assignment, the nature of the intervention made it impossible to blind them. If an already randomized woman later became ineligible, the assigned allocation code was not re-used. The women were randomized into two groups: Early cord clamping group and Delayed cord clamping group.

Masking:

Given the characteristics of the intervention, the obstetrician in charge of the intervention (umbilical cord clamping) could not be blinded. However, health professionals who made the neonatal evaluations after birth were not the ones present when infants were delivered and were not aware of the intervention used for the delivery. The personnel in charge of laboratory tests also were not aware of the intervention used.

Procedure:

Informed written consent was taken after fulfilling eligibility criteria.

The screening proforma was completed for every pregnant woman screened for enrollment to the study. A structured survey questionnaire was used to gather obstetrical and medical details of patients. Baseline maternal data with regard to age, medicinal iron intake, parity, socioeconomic status, detailed medical history was noted for all women. Detailed obstetric history was taken from all participants

to recognize any high risk factors for PPH. Menstrual history was noted. A general physical examination and systemic examination including obstetric examination was done for all women. The diagnosis was noted. Delivery outcome of all eligible participants was monitored. Standard care was provided if women refused to participate in the study at any time. Baseline neonatal data with regard to birth weight, sex and gestation were recorded in all cases.

The subject ID assigned to the enrolled women identified all the data. All data pertaining to the enrolled subjects including socio-demographic data, medical/obstetric history, intrapartum and postpartum details, and information regarding primary and secondary outcomes were recorded in the Data Collection Instrument in English. The data was regularly transmitted to the computer in MS Excel database and stored on a CD also. All DCIs and source documents including the laboratory blood reports were stored in a secured file cabinet.

After delivery all neonates were placed approximately 10 cm below the vaginal introitus between the legs of the mother, dried and wrapped in a warm towel. The neonates remained in this position until the cord was clamped. All other treatment including administration of 10 IU oxytocin after delivery of the baby and controlled cord traction for the delivery of placenta were similar for patients in both groups.

Infants were followed up till 3 months of age. No medicinal iron was given to any of these infants till the end of the study. The feeding patterns, weight gain, intervening morbidities like respiratory infections and diarrhoea during this period were carefully recorded.

Any mother or infant requiring treatments that deviated from the study protocol were excluded from the study.

Cord Clamping:

Timing of cord clamping was noted using stopwatch.

Early cord clamping was done within 30 seconds after child birth.

Delayed cord clamping was done at 3 minutes or after cessation of cord pulsation, whichever occurred first.

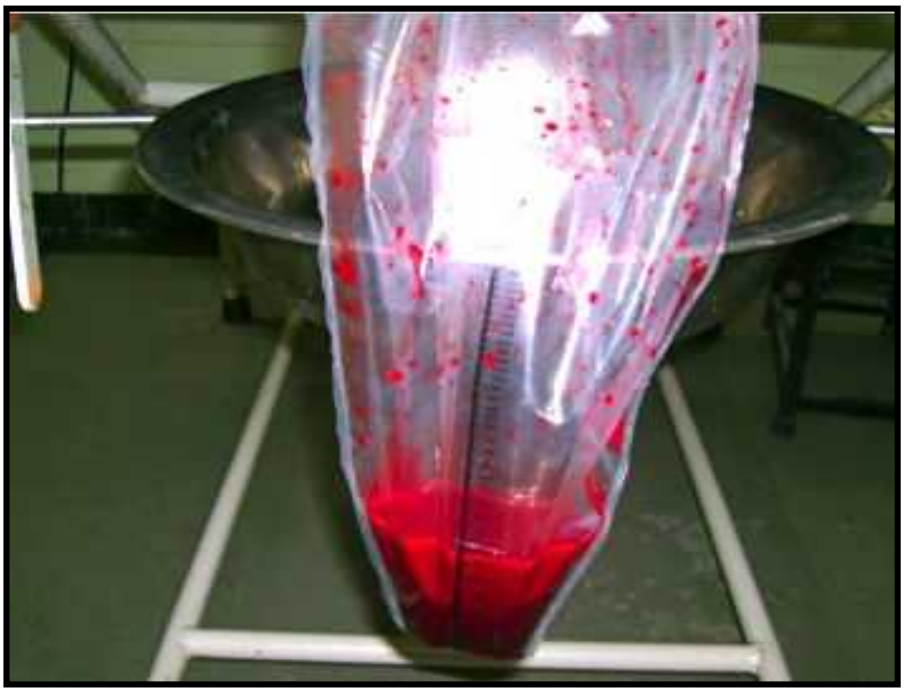
Third stage of labour was timed using stopwatch. (Photograph No.2)

Photograph No.2 Stopwatch to note the cord clamp timing and the duration of third stage of labour

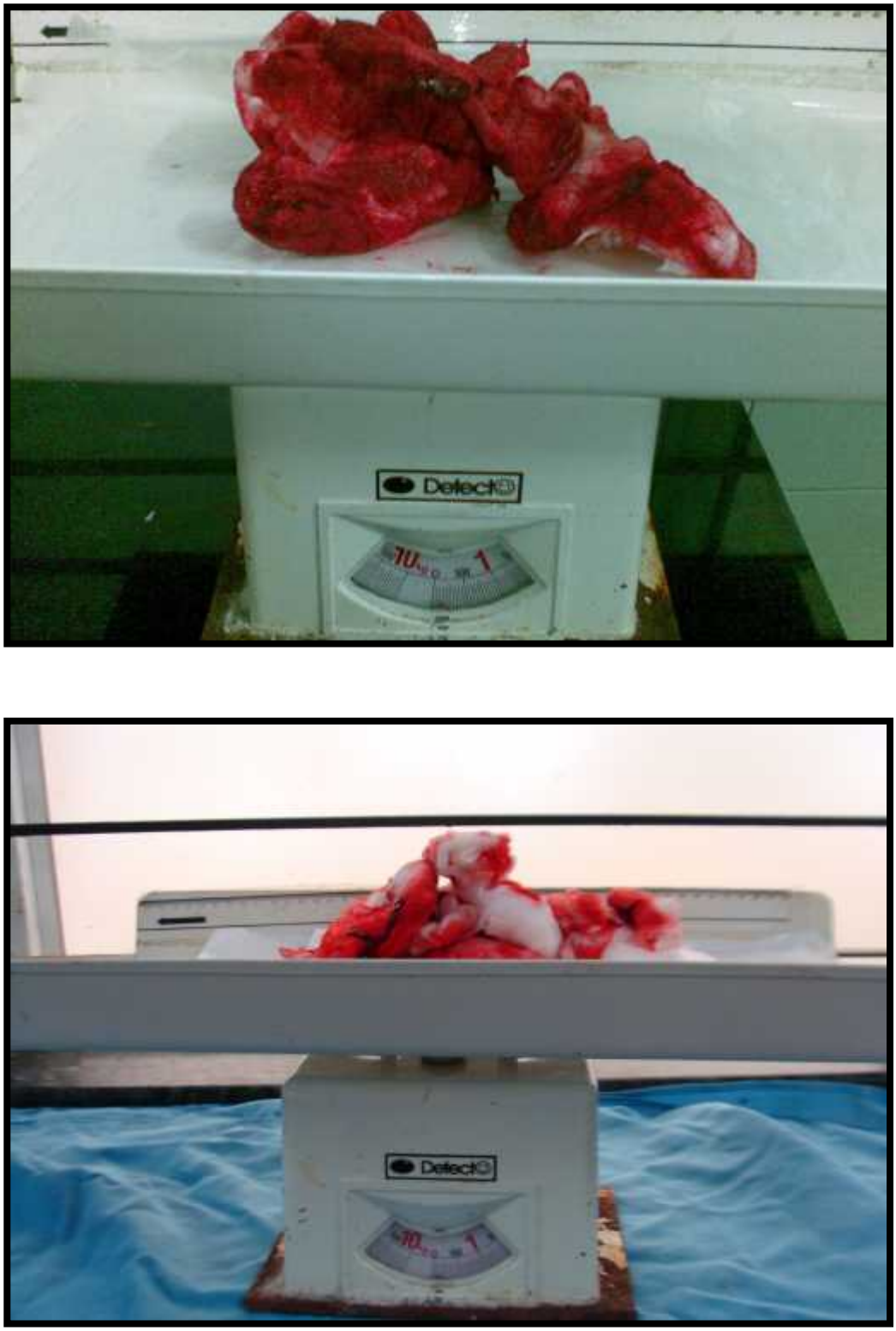
Measurement of blood loss:

Quantitative assessment of post partum blood loss was done using BRASSS-V drapes and estimating weight of blood soaked gauzes and pads. Immediately after clamping and cutting the cord, an under-buttocks BRASSS-V drape with polyurethane plastic receptacle was placed underneath the buttocks of the woman. This was a comfortable and efficient way of collecting all the blood lost after delivery and could be left in place without discomfort even during perineal suturing. This also avoided mixing of amniotic fluid and urine and thus prevented over estimation of blood loss (Photographs No. 3, 4). Blood soaked swabs were weighed in grams, the known dry weight of the swabs was subtracted and calculated volume added to the measured blood volume (1gm=1ml) (Photograph No. 5). This enhanced the quality of total blood loss measurement after delivery. The total post partum blood loss was noted in the drape as well as the swabs/gauzes used. The blood was collected for a maximum of two hours in the drape and the blood loss estimated immediately following the delivery, at the end of 1 hour and total blood loss after 2 hours.

Photograph No.3 BRASSS V Drape for quantitative blood loss measurement



Photograph No.4 BRASSS V Drape under the buttocks for collecting blood after delivery



Photograph No.5 Quantitative estimation of blood loss by BRASSS V- DRAPE and blood soaked pad / gauze weight

Uterine tone, measurement of blood loss, time of delivery of placenta, and other routine parameters were recorded by the health care provider. Placenta and membranes were examined to determine if complete expulsion has occurred. Women were monitored for two hours after delivery.

Care of the newborn was as per prevailing standard practices.

At birth, 2 ml of cord blood was collected in EDTA containing vials for haemoglobin and hematocrit estimation. Secondary outcomes that were noted included possible side effects of delayed cord clamping in newborns including hyperbilirubinemia requiring phototherapy and need for NICU admissions. Infants were followed-up regularly until 3 months of age.

2ml of infant venous blood at 90 ±7 days was collected in EDTA containing vials. Venous haemoglobin and hematocrit in the infant at 90 ±7 days was measured in blood drawn from the antecubital vein.

Investigations:

Estimation of cord blood haemoglobin and hematocrit (PCV) at birth was done using cyanmethaemoglobin method.

Estimation of infant haemoglobin and venous hematocrit (PCV) at 90 ±7 days was done using cyanmethaemoglobin method.

DATA ANALYSIS

Data were collected on standardised forms, and analysed with SPSS version 13.0 statistical software for Windows. Data analysis was performed using students unpaired‘t’ test. Univariate analysis of selected demographic, clinical, and other factors according to group assignment was carried out to ensure that the randomization process was successful in controlling for potential confounding factors. Frequencies and percentages were calculated for categorical variables. All quantitative variables where students unpaired‘t’ test was used were tested for normality using Kolmogorov- Smirnov test. 95% confidence interval was calculated for the difference in the population means. Mann–Whitney U-test was used for the discrete variable number of antenatal visits to compare the two medians.

Student t-tests and chi-square tests were used to compare baseline characteristics between treatment groups and between infants who completed the study and those lost to follow-up. Infants with tight nuchal cord necessitating early cutting, perceived need for neonatal resuscitation and major congenital abnormalities were excluded regardless of group assignment, thus reducing the likelihood of introducing bias.

Baseline imbalances which could influence infant haematological outcome (maternal Hb, parity, age and cord Hb) were controlled for in these analyses. The level of significance used was p value less than 0.05.

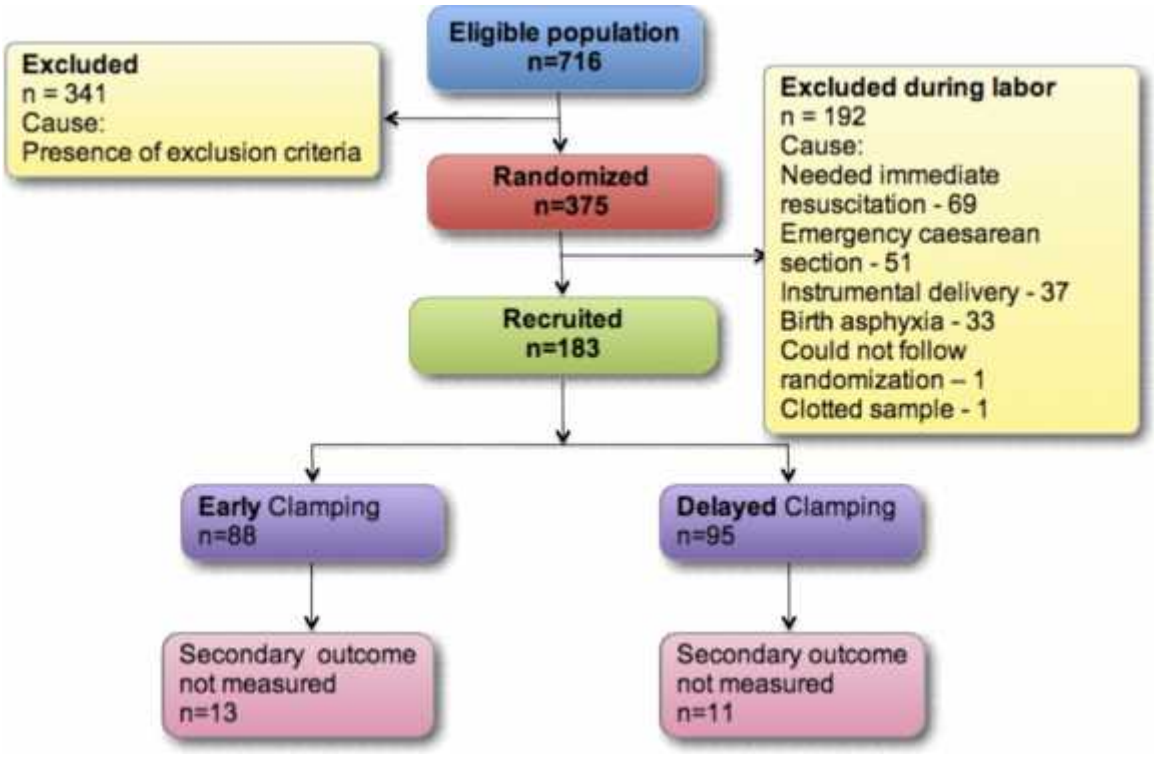
Secondary outcomes like NICU admissions, need for phototherapy, illness and breastfeeding were compared among groups by using the test of proportion. All tests were two-tailed. Analysis was made on an intention-to-treat basis.

RESULTS

Of the 716 women screened, 375 were randomized of which 183 were recruited in the study and included in the data analysis. 88 of the 183 women were randomized in the early cord clamping group and 95 in delayed cord clamping group.

Of the 183 mother- infant pairs, 159 (86.89%) (75 in the early cord clamping group and 84 in delayed cord clamping group) completed the follow up at the third month whereas 24 (13.11%) were lost to follow up (13 in the early cord clamping group and 11 in delayed cord clamping group).

Flow Chart of study population



The 24 mother- infant pairs that were lost to follow up are highlighted in the Master Chart in Annexure III.

Table No.1 provides a comparison of baseline maternal and fetal characteristics between the two groups. The groups were comparable for maternal demographic characteristics like age, religion, parity, education, antenatal care, medicinal iron intake and haemoglobin where no statistically significant difference was noted in the two groups. The systolic and diastolic blood pressure after delivery was also comparable in both groups.

The infant's weight, Apgar score, gestation, sex and breastfeeding pattern at 90 ±7 days, and infant haemoglobin and hematocrit values at birth were comparable with no significant difference between the two groups. Infant's haemoglobin and hematocrit values at 90 ±7 days were significantly lower in early clamping group compared to those in the delayed clamping group.

Table No. 1: Maternal and Infant Demographic characteristics

Maternal Characteristics (Both groups well matched)			
Baseline demographic and clinical characteristics	**Early clamping (N=88)**	**Delayed clamping (N=95)**	**p Value**
Age (yrs) (mean, S.D)	23.30 (3.58)	23.23 (3.56)	0.894
Weight (kg) (mean, S.D)	56.15 (4.61)	55.06 (4.48)	0.108
Gravida (mean, S.D)	1.90 (0.97)	1.73 (0.89)	0.2179
Gravida>3 (%)	02(02.27%)	06(06.32%)	0.1814
Parity (mean, S.D)	0.69 (0.70)	0.62(0.79)	0.5150
Height (mts) (mean, S.D)	1.52 (0.04)	1.51 (0.04)	0.139
BMI(kg/m^2) (mean, S.D)	24.27 (1.67)	24.06 (1.70)	0.412
Antenatal visits (median, range)	6.5 (02 - 14)	7.0 (02 - 14)	0.0775
Haemoglobin (gm/dl) (mean, S.D)	10.68 (1.12)	10.56 (1.01)	0.4588
Regular iron supplements (%)	75(85.23%)	84 (88.42%)	0.5225
SBP@delivery(mm Hg)	120.30 (8.62)	119.87 (7.73)	0.7275
DBP@delivery(mm Hg)	78.23 (6.17)	77.16 (5.26)	0.2076
SBP@1 hour(mm Hg)	119.20 (7.12)	118.59 (6.65)	0.5463
DBP@1 hour (mm Hg)	77.07 (5.07)	77.06 (5.05)	0.9947
SBP@2 hours (mm Hg)	118.16 (6.25)	118.42 (6.02)	0.7730
DBP@2 hours (mm Hg)	77.05 (4.82)	76.36 (5.29)	0.3607

Infant Characteristics (Both groups well matched)			
	Early clamping (N=88)	**Delayed clamping (N=95)**	**p Value**
Clamping time(sec) (mean, S.D)	16.01 (4.19)	101.98 (16.59)	0.0000
Gender of the neonate (Male %)	45 (51.14%)	45 (47.37%)	0.6105
Gestational Age (weeks) (mean, S.D)	39.31 (1.15)	39.23 (1.12)	0.653
Birth weight (kg) (mean, S.D)	2.91 (0.38)	2.87 (0.34)	0.542
Birth weight (kg) less than 2.5 kg(%)	09(10.23%)	09(09.47%)	0.8642
Apgar score at 1 minute (mean, S.D)	7.09(0.88)	7.19(0.84)	0.143
Apgar score at 5 minutes (mean, S.D)	8.72(0.49)	8.69(0.58)	0.152
Cord Haemoglobin at birth (mean, S.D)	15.33 (1.65)	15.85 (1.93)	0.0510
Cord Hematocrit at birth (mean, S.D)	47.63 (5.45)	49.35 (6.29)	0.0501
Illness up to 3 months (%)	21(23.86%)	28(29.47%)	0.3918
Exclusively breastfed at 3 months (%)	63 (71.59)	75 (78.95)	0.1241

The time of cord clamping was 16.01 ±4.19 sec in early cord clamping group and 101.98±16.59sec in delayed cord clamping group which was significantly different (p=0.0000).(Table No.1)

Mean blood loss

No significant difference was found in the mean blood loss in early (203.52 ±122.74ml) and delayed cord clamping (200.74±104.07 ml) groups (p=0.8683) in this study. (95% CI, -30.32-35.88). (Refer Table No.2 and Figure No.1)

Table No. 2: Mean Blood loss during third stage of labour (in ml)

Blood loss during third stage of labour (in ml)				
	Early clamping (N= 88)		**Delayed clamping (N=95)**	
	Mean	S.D	Mean	S.D
Mean Blood Loss(ml)	203.52	122.74	200.74	104.07

Figure No.1: Mean blood loss in early and delayed clamping groups

Mean Duration of third stage of labour

The mean duration of third stage of labour for early clamping group was 296.59± 98.97seconds (4.94± 1.65 minutes) and 281.79±104.59 seconds (4.70±1.74 minutes) for the delayed clamping group. (p=0.3276) as shown in Table No.3. No difference in the duration of third stage of labour was noted between the two groups in the present study. (Figure No.2)

Table No. 3: Mean Duration of third stage of labour (in seconds)

Mean duration of third stage of labour (in seconds)				
	Early clamping (N= 88)		**Delayed clamping (N=95)**	
	Mean	S.D	Mean	S.D
Duration of third stage (seconds)	296.59	98.97	281.79	104.59

Figure No.2: Mean duration of third stage of labour in early and delayed clamping groups in seconds

Cord haemoglobin at birth

At birth the cord haemoglobin in early clamping group was 15.33± 1.65gm/dl and in delayed cord clamp was 15.85±1.93gm/dl which was not significantly different (p=0.0510).

Cord hematocrit at birth

At birth the cord hematocrit in early clamping group was 47.63% ± 5.45 % and in delayed cord clamp was 49.35% ± 6.29% which was not significantly different (p=0.0501).

NICU admissions after birth

There was no significant increase in the need for NICU admissions in the delayed cord clamping group in this study. (Table No.4) NICU admissions after birth were similar in both groups (p=0.4505). 05/88 (5.68%) NICU admissions were noted in early clamping group and 05/95 (5.26%) in delayed cord clamping group. (Figure No.3) Of the 10 NICU admissions, 7admissions were for hyperbilirubinemia and 3 admissions for respiratory distress. None of the neonates were admitted in the NICU for birth asphyxia and they had transient tachypnoea which did not require any ventilatory support. Of the 5 NICU admissions in ECC, 3 admissions were for respiratory distress and 2 for hyperbilirubinemia. All the 5 NICU admissions in DCC were for hyperbilirubinemia.

Table No.4: NICU Admissions after birth

NICU Admissions after birth	Early clamping (N= 88)	Delayed clamping (N=95)
p=0.4505	05 (5.68%)	05 (5.26%)

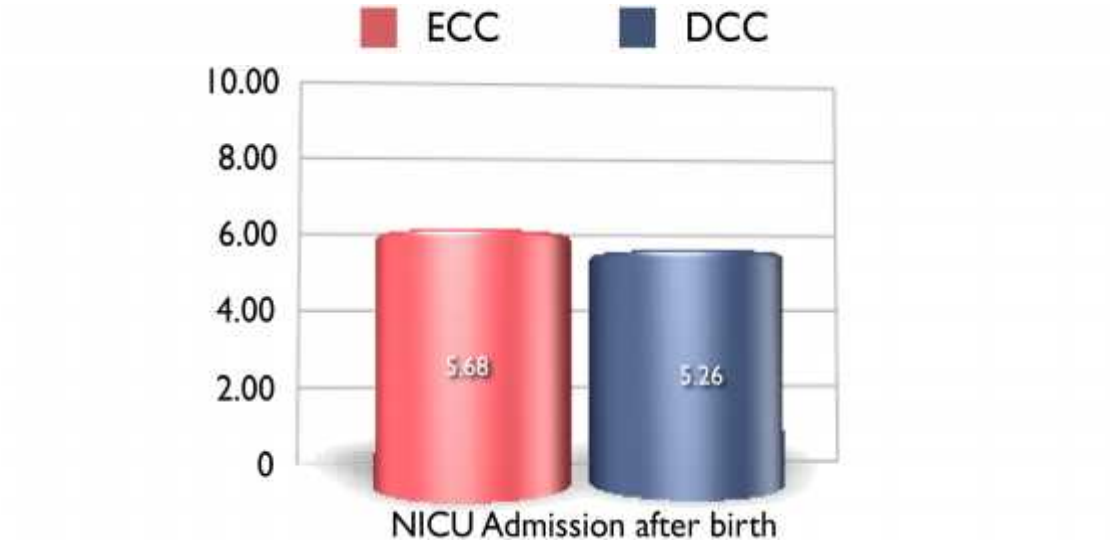


Figure No.3: NICU admissions in early and delayed cord clamping groups

Neonatal hyperbilirubinemia requiring photo therapy

In the present study, 02/88 (2.27%) cases of neonatal hyperbilirubinemia requiring photo therapy were noted in early clamping group and 05/95 (5.26%) in delayed cord clamping group. (Table No.5)

There was no statistically significant difference (p=0.1460) between the two groups for the parameter of neonatal hyperbilirubinemia requiring photo therapy. (Figure No.4)

Table No.5: **Neonatal hyperbilirubinemia requiring photo therapy**

Neonatal hyperbilirubinemia requiring photo therapy	**Early clamping (N= 88)**	**Delayed clamping (N=95)**
p=0.1460	02 (2.27%)	05 (5.26 %)

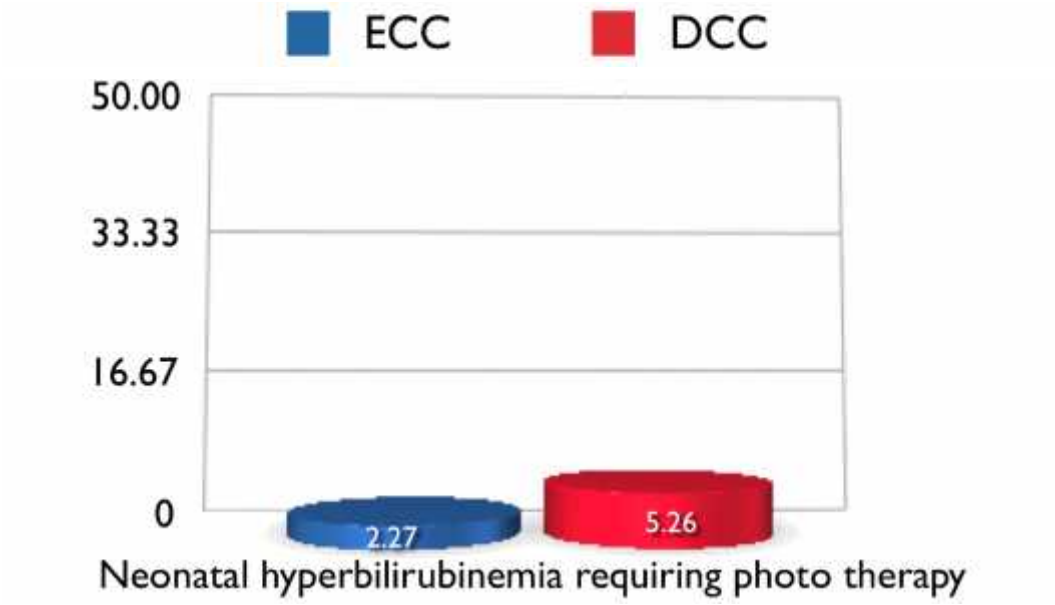


Figure.No.4: Neonatal hyperbilirubinemia requiring photo therapy in early and delayed cord clamping groups

The clinical course after discharge during the first month of life was similar in both groups, and at 90 ±7 days no significant differences in relation to the infant's weight or frequency of exclusive breastfeeding were observed. One neonatal death was observed in the population under study due to respiratory illness after 1 month in the early cord clamping group.

Infant haemoglobin at 90 ±7 days

Infant haemoglobin at 90 ±7 days in early cord clamp group was 11.07 ± 1.27 gm/dl and in delayed cord clamp was 12.70± 1.41 gm/dl and was significantly different. (95% CI, 1.24-2.02). P=0.0000 (HS) (Refer Table No.6 and Figure No.5)

Table No.6: **Infant venous haemoglobin and hematocrit at 90 ± 7 days in early and delayed groups**

Infant venous haemoglobin and hematocrit at 90 ± 7 days				
	Early clamping (N= 88)		**Delayed clamping (N=95)**	
Infant haemoglobin	11.07	1.27	12.70	1.41
Infant hematocrit	34.13%	3.93	39.33%	4.88

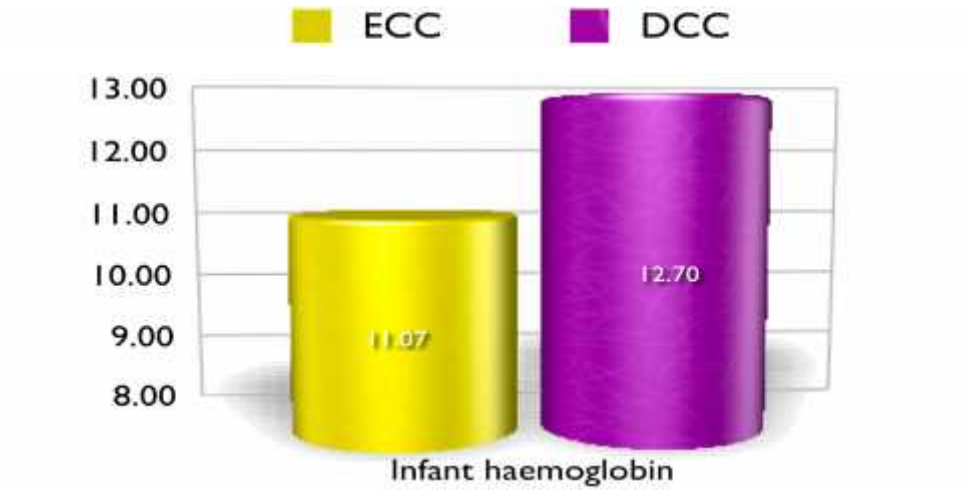


Figure No.5: Infant haemoglobin at 90 ±7 days in early and delayed cord clamping groups

Infant hematocrit at 90 ±7 days

Infant hematocrit at 90 ±7 days in early cord clamp group was 34.13% ± 3.93% and in delayed cord clamp group was 39.33% ± 4.88% and was significantly different. (95% CI, 3.92-6.48). P=0.0000 (HS) (Refer Table No.6 and Figure No.6)

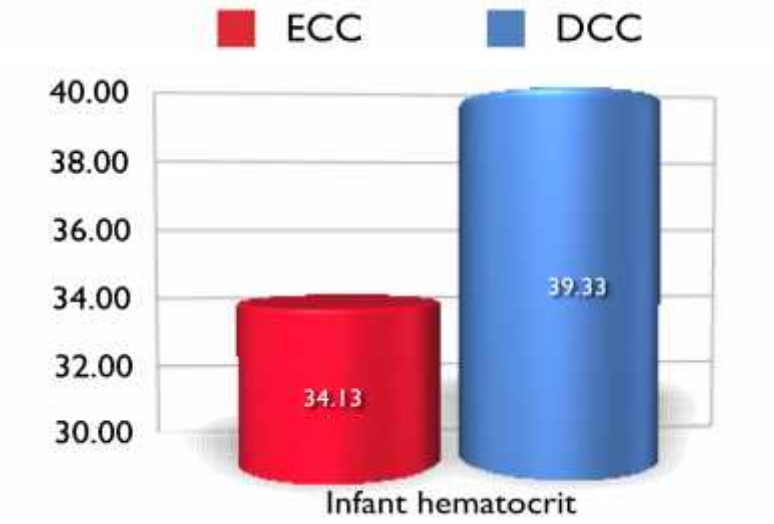


Figure No.6: Infant hematocrit at 90 ±7 days in early and delayed cord clamping groups

Infant haemoglobin and hematocrit at 90 ±7 days in delayed cord clamp group was significantly higher even after intention- to- treat analysis was done as shown in Table No. 3. P=0.0000 (HS) (Table No.7)

Table No.7: Infant venous haemoglobin and hematocrit at 90 ± 7 days (only for mother-infant pairs that completed the follow up)

	Early clamping (N= 75)		**Delayed clamping (N=84)**	
	Mean	S.D	Mean	S.D
Infant haemoglobin	11.0733	1.2673	12.7024	1.4145
Infant hematocrit	34.1267	3.9268	39.3333	4.8801

DISCUSSION

This prospective randomized, controlled study evaluated the potential effects on the post partum blood loss and duration of third stage of labour, the haemoglobin and hematocrit status of the newborn and at 3 months at different cord-clamping time intervals.

Mean blood loss

In the present study, no significant difference (p=0.8683) was found in the mean blood loss in early (203.52 ±122.74ml) and delayed (200.74±104.07 ml) cord clamping groups (95% CI, -30.32-35.88). Blood loss after delivery was similar in both groups. Various studies have reported that late clamping is not associated with greater postpartum bleeding.

There was no significant difference between groups in the midwives' assessment of maternal bleeding, although the sample size was too small to adequately detect modest differences. Manual removal of the placenta was not required for any of the women involved. The difference between antenatal and postnatal maternal Hb levels was small and comparable in both groups (data not shown in the article). A further limitation was inaccurate measurement of maternal blood loss indirectly by comparing maternal haemoglobin levels in the first stage of labour with levels on average 16 hours postpartum and no differences were noted.[16]

No differences were observed among the groups with respect to postpartum blood-loss volume, postpartum hemorrhage, and maternal hematocrit level 24 hours after birth in another RCT. However, this study included both vaginal and caesarean section birth as opposed to the other studies where only vaginal delivery outcome is assessed. For the measurement of maternal blood loss, all vaginal blood was collected immediately after the infant's delivery by placing a pan and pad under the woman's buttocks until she was transferred to the postpartum ward. Collected blood was poured in a graded jar, and blood volume was determined. The median maternal blood loss was 265 ml in the early-cord-clamping group, 250 ml in the 1-minute cord-clamping group, and 300 ml in the 3-minute cord-clamping group. Postpartum hemorrhage (blood loss>500 ml) was 26.8% in the early-cord-clamping group, 22.2% in the 1-minute cord-clamping group, and 25.4% in the 3-minute cord-clamping group. Severe postpartum hemorrhage (blood loss >1000 ml) was 3.6%, 5.6%, and 3.2% in each group, respectively. [11]

Maternal blood loss after delivery does not vary significantly between delayed cord clamping and immediate clamping groups in another study. The risk of postpartum haemorrhage, defined as blood loss of > 500 ml, was not different after delayed cord clamping or immediate clamping (363 participants, relative risk 0.89).This trial did not quantitatively measure maternal blood loss but classified the bleeding as normal, high, or severe, and found no differences between delayed cord clamping and immediate clamping.[6]

The maternal blood loss after delivery did not vary significantly between delayed cord clamping and immediate clamping groups in these trials. However, the

major limitations of these trials were diversity in measuring blood loss (visual estimation vs. measuring jar), diversity in mode of delivery (100% vaginal vs. >25% caesarean section) and in definition of DCC. No differences were found between DCC and immediate clamping with regard to the maternal outcome.

A Cochrane systematic review of 11 randomized trials including 2989 mother-infant pairs suggests that delaying clamping for at least 2-3 minutes seems not to increase the risk of postpartum hemorrhage which is in agreement with the results of the present study.[1]

Mean Duration of third stage of labour

The mean duration for early clamping group was 296.59± 98.97seconds and 281.79±104.59 seconds for the delayed clamping group (p=0.3276) in the present study. No difference in the duration of third stage of labour was noted between the two groups in the present study.

None of the published studies have compared the effect of early and delayed clamping on the duration of third stage of labour. However, an unpublished study by McDonald 1996, quoted in the Cochrane review concluded that instances of third stage greater than 30, nor 60 minutes, were not significantly different between the early and late cord clamping groups.[1]

NICU admissions after birth

There was no significant increase in the need for NICU admissions in the delayed cord clamping group in this study. NICU admissions after birth were similar

in both groups (p=0.4505). 05/88 (5.68%) NICU admissions were noted in early clamping group and 05/95 (5.26%) in delayed cord clamping group.

In a meta analysis by Hutton et al, no significant differences in NICU admissions between late and early cord clamping (RR, 2.02; 95% CI, 0.63 to 6.48) was noted.[5]

Neonatal hyperbilirubinemia requiring photo therapy

In the present study, 02/88 (2.27%) cases of neonatal hyperbilirubinemia requiring photo therapy were noted in early clamping group and 05/95 (5.26%) in delayed cord clamping group which was not significantly different in the two groups (p=0.1460).

The Cochrane review states that delaying clamping improves infant iron status but increases risk of jaundice requiring phototherapy. However, this is largely based upon one 12 year old unpublished trial done by the lead author of the Cochrane Review When that one trial is removed from data, the variable of 'jaundice requiring phototherapy' does not reach significance.[1]

A recent meta-analysis by Hutton et al, did not agree with the outcome that delayed cord clamping (DCC) leads to 'jaundice requiring phototherapy'. A pooled analysis of data from 8 trials (1009 infants) did not show an increased risk of developing neonatal jaundice within the first 24 to 48 hours of life associated with late cord clamping (RR, 1.35; 95% CI, 1.00 to 1.81).When low-quality trials were excluded, findings still showed no significant difference between groups in the risk of jaundice (889 infants) (RR 1.16; 95% CI, 0.85 to 1.58). Similarly, no significant

differences were noted between late and early clamping in risk of jaundice at 3 to 14 days after birth (RR, 1.27; 95% CI, 0.76 to 2.10). In addition, no significant differences were found between groups in the proportions of infants who had elevated bilirubin levels (15 g/dL) that necessitated use of phototherapy (699infants) (RR, 1.78; 95% CI, 0.71 to 4.46). This is in agreement with the results of the present study. [5]

Cord clamping 1 to 3 minutes after delivery of the baby improves the iron status of the infant. Potential adverse effects of delayed cord clamping such as jaundice requiring phototherapy, should be considered. [19]

Few studies suggest that there may be an increased risk for hyperbilirubinemia, however phototherapy or exchange transfusion are not usually indicated. The incidence of hyperbilirubinemia requiring phototherapy was similar in both the groups, which goes along with other authors' observations. [1, 5, 11, 12]

Infant haemoglobin at 90 ±7 days

Infant haemoglobin at 90 ±7 days in early cord clamp group was 11.07 ± 1.27 gm/dl and in delayed cord clamp was 12.70± 1.41 gm/dl and was significantly different in the present study. (95% CI, 1.24-2.02). p=0.0000 (HS)

A clinical trial from India by Geethanath et al randomized 107 term infants born to non-anaemic mothers to either immediate clamping of cord at delivery or clamping delayed till descent of placenta into vagina with neonate placed below the level of the placenta. Three months after delivery the infants in both groups had

similar haemoglobin levels. The serum ferritin was higher but insignificant, in the delayed clamping group. The results of this study did not match with other trials. [18]

In a study conducted by Gupta et al in India, the mean infant ferritin and Hb at 3 months were significantly higher in the delayed clamping group (118.4 µg/L and 99 g/L) than in the early clamping group (73 µg/L and 88 g/L). The mean decrease in Hb (g/L) at 3 months adjusted for co-variates was significantly less in the delayed clamping group compared to the early clamping group (–1.09, 95% CI –1.58 to –0.62, p <0.001).[10]

Infant hematocrit at 90 ±7 days

Infant hematocrit at 90 ±7 days in early cord clamp group was 34.13% ± 3.93% and in delayed cord clamp group was 39.33% ± 4.88% and was significantly different in the present study. (95% CI, 3.92-6.48). p=0.0000 (HS)

Infant haemoglobin and hematocrit at 90 ±7 days in delayed cord clamp group was significantly higher even after intention- to- treat analysis in the present study.

Similar results were also noted in other studies. A recently published trial from Mexico had a follow-up of 6 months, but did not find a difference in Hb, although the iron status at 6 months was significantly higher in the DCC group. This lack of difference in Hb is most likely due to the fact that iron deficiency was relatively uncommon in the Mexican study population. Hb is normally not affected until iron stores are depleted. In another RCT infant Hb levels in the study population continued to decline after the physiological nadir around 3 months. [6, 10, 12]

Delayed cord clamping is compatible with active management of the third stage of labour. Uterotonic agents administered following birth and prior to cord clamping have been shown to increase the rate of placental transfusion and are thus likely to enhance the effect of delayed clamping. A joint statement from the International Federation of Gynaecology and Obstetrics and the International Confederation of Midwives on active management of the third stage of labor already recommends that delayed clamping be incorporated as part of the active management approach to placental delivery. In a recent literature review, similar practice recommendations pertaining to third-stage management were made for providing care in resource-poor settings. [1, 2, 5, 15, 19]

The present study has concluded that delaying clamping of the umbilical cord significantly increased Hb levels at the age of 3 months in term babies. Delayed clamping of the umbilical cord is a physiological and inexpensive means of enhancing haematological status, preventing anaemia over the first 3 months of life. Although this is of particular importance for developing countries in which anaemia during infancy and childhood is highly prevalent, it is likely to have an important impact on all newborns, regardless of birth setting.

Table No.7 Comparison of maternal and neonatal outcomes in various studies

Study	Maternal outcome	Neonatal outcome	Comments
Present study	No difference in mean post partum blood loss. No difference in duration of third stage of labour.	No increase in NICU admissions or hyperbilirubinemia requiring phototherapy in DCC. Higher Hb% and hematocrit at 90 ±7 days in DCC	Quantitative estimation of blood loss. Assessed maternal and neonatal effects of different cord clamping time intervals. DCC recommended for all term babies unless contraindicated
Hutton et al,2007 [5]	Not assessed	DCC (2mins) is beneficial. Benign polycythemia	Meta analysis for neonatal outcome only
P. van Rheenen et al,2007 [16]	No adverse outcome	Higher Hb at 4 months and no hyperbilirubinemia in DCC	Visual blood loss estimation
Cernadas, 2006 [11]	No difference in post partum hemorrhage	Rise in venous hematocrit levels within physiologic limit at 6 hours when cord clamped at 1 or 3 minutes.	Visual blood loss estimation No follow up after 1 month
Chaparro, 2006 [6]	No difference in post partum blood loss	Higher mean corpuscular volume, ferritin and total body iron at 6 months in DCC	Additional iron stores at 6 months in DCC
Gupta et al, 2002 [10]	Not assessed	Higher mean infant ferritin and Hb at 3 months in DCC	Loss to follow up high
Geethanath et al, 1997 [18]	Not assessed	Infants in both groups had similar haemoglobin levels at 3 months. higher serum ferritin but insignificant in DCC	Results did not match with any other study

Strengths of the study

The strengths of this study are its randomized design with block size of two and the low drop-out rate for a rural area for the neonatal follow up.

This is a partially blinded study where the attending neonatologists and personnel in charge of laboratory tests were blinded to the intervention.

Estimation of blood loss in the other studies has been inaccurate as most have done visual estimation of blood loss which under estimates the actual blood loss. In the present study, quantitative assessment of post partum blood loss was done using BRASSS-V drapes and estimating weight of blood soaked gauzes and pads. Immediately after clamping and cutting the cord, an under-buttocks BRASSS-V drape with polyurethane plastic receptacle was placed underneath the buttocks of the woman which avoided mixing of amniotic fluid and urine and thus prevented over estimation.

In the present study, both the groups are well matched in maternal and infant baseline variables along with complementary infant feeding practices as no significant difference ($p =< 0.05$) was noted between the two groups with respect to the baseline maternal and infant characteristics.

Limitations of the study

This study is a partially blinded randomized controlled trial. A limitation of this study is that mothers who were already assigned to a treatment group could later become ineligible. This could not be avoided in view of timing and nature of the intervention. In the present study, infant follow up was done only for 90 ±7 days. However, the long term effects of the intervention (ECC and DCC) on the infants need to be evaluated with an extended follow up.

CONCLUSION

There is no significant difference between mean blood loss and duration of third stage of labour in early or delayed cord clamping groups. Delayed cord clamping significantly increases neonatal mean venous haemoglobin and hematocrit within a physiologic range at the third month of the infant with no significant difference in NICU admissions. Neither significant differences nor harmful effects were observed among groups. Furthermore, this intervention seems to reduce the rate of neonatal anaemia. This practice has been shown to be safe and should be implemented to increase neonatal iron storage at birth.

Delayed cord clamping was associated with increased benefits to the infant (Higher Hb% and hematocrit at 90 ±7 days) without increasing maternal (mean blood loss) or early neonatal morbidity or mortality (NICU admissions, hyperbilirubinemia requiring photo therapy).

Delayed cord clamping is a simple, cost-free and safe delivery procedure that might offer a sustainable strategy to reduce early infant anaemia risk when other interventions are not yet feasible. It should be included in integrated programs aimed at reducing anaemia in young children in developing countries**.**

Recommendations

Delayed umbilical cord clamping is safe for the mother as it does not increase the post partum blood loss and duration of the third stage of labour and beneficial for the neonate also. This practice should be implemented to reduce the incidence of neonatal anaemia in all term infants who have no indications for early cord

clamping, especially in a resource poor country like India. Delayed umbilical cord clamping should be the routine practice in all term babies where it is not contraindicated.

The results of the present study are endorsed by the WHO Reproductive Health Library; World Health Organization, 2009. [19] Thus, delayed cord clamping must be practiced at every delivery where there are no contra indications as it offers various benefits without increasing the risks.

Further research with longer follow up of infants is essential to find out the long-term differences in the infant outcomes.

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SUMMARY

There is no formulated guideline on the clamping of umbilical cord after childbirth. Studies on timing of cord clamping have usually assessed infant outcomes. Evidence published to date has not clearly established the impact of the timing of cord clamping on postpartum blood loss and necessitates further research.

This prospective randomized, controlled study evaluated the potential effects on the post partum blood loss and duration of third stage of labour, the haemoglobin and hematocrit status of the newborn and at 90 ±7 days at different cord-clamping time intervals.

The primary objective of the study was to find out the impact of early and delayed cord clamping on the post partum blood loss. This study aimed to find out if an association exists between the time of cord clamping (Early ≤30sec Vs Delayed at 3 minutes or after cessation of cord pulsation, whichever occurs first) with the post partum blood loss.

Secondary objectives were to study the impact of early and delayed cord clamping on

1. Duration of third stage of labour.
2. Neonatal morbidity (NICU admissions after birth and the incidence of neonatal hyperbilirubinemia requiring photo therapy in both groups).
3. Infant haemoglobin and hematocrit at 90 ±7 Days.

A randomized, controlled trial (computer generated, randomized number sequence, block size of 2) was performed on 183 consenting women fulfilling eligibility criteria (term, singleton uncomplicated pregnancies undergoing non-instrumental vaginal deliveries) in labour ward at KLES Dr. Prabhakar Kore Hospital & MRC, Belgaum.

The mean post partum blood loss and duration of third stage of labour was noted. Quantitative assessment of post partum blood loss was done using BRASSS V drapes and weighing blood soaked pads. Cord blood haemoglobin and hematocrit at birth and infant haemoglobin and hematocrit at 90 ±7 days were estimated. Statistical analysis done using students unpaired‘t’ test.

Of the 716 screened, 375 randomized, 183 recruited of which 88 were in early and 95 in delayed cord clamping and 159 (86.89%) (75 in the early and 84 in delayed cord clamping group) completed the follow up at the third month whereas 24 (13.11%) lost to follow up (13 in the early and 11 in delayed cord clamping group).

No difference was found in the mean blood loss (203.52 ±122.74ml versus 200.74±104.07 ml), duration of third stage of labour (296.59± 98.97 seconds versus 281.79±104.59 seconds), NICU admissions after birth (5.68% versus 5.26%) and neonatal hyperbilirubinemia requiring photo therapy (2.27% versus 5.26%) in early and delayed cord clamping respectively.

Infant haemoglobin at 90 ±7 days was 11.07 ± 1.27gm/dl and 12.70± 1.41 gm/dl in early and delayed clamping respectively (p=0.0000)

Infant hematocrit at 90 ±7 days was 34.13±3.93% and 39.33 ±4.88% early and delayed clamping respectively. (p=0.0000)

Infant haemoglobin and hematocrit at 90 ±7 days in delayed cord clamp group was significantly higher even after intention- to- treat analysis was done.

This study proved that delayed umbilical cord clamping was associated with increased benefits to the infant (Higher Hb% and hematocrit at 90 ±7 days) without increasing maternal (mean blood loss) or early neonatal morbidity or mortality (NICU admissions, hyperbilirubinemia requiring photo therapy).

Hence, delayed umbilical cord clamping should be routinely implemented to reduce the incidence of anaemia in all term infants who do not require immediate resuscitation.

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ANNEXURE-I

INFORMED CONSENT FORM

ID.NO :- | | | | | |

EARLY VS DELAYED UMBILICAL CORD CLAMPING AND ITS IMPACT ON THE POST PARTUM BLOOD LOSS: A RANDOMIZED CONTROLLED TRIAL

There is no fixed protocol regarding the optimal timing of cord clamping. Various studies suggest that delayed cord clamping can be advantageous for the infant by improving iron status, especially in our country where the prevalence of anaemia is 79.2% in children aged 6-35months. We intend to study the impact of early and delayed cord clamping on the mother and the iron status of the baby.

You are invited to participate in a research study being conducted under the guidance of Dr. XXXX, Professor, Department of Obstetrics & Gynaecology, J. N. Medical College, Belgaum.

Your participation in the study is voluntary. You should be willing to answer the questions about your pregnancy and child birth to the best of your knowledge. By agreeing to participate in this study, you will be a valuable contributor towards understanding more about the optimal timing of cord clamping and its impact on the mother and the infant. Your participation in this study is not likely to have any adverse effects. This study may not benefit you, but may be beneficial to the other patients. Standard care will be provided even if you refuse to participate in this study. You are free to stop participation in this study at any time and for any reason.

Every effort will be made to protect the confidentiality of the information you provide. You will be given an ID number and the same will be used for study purpose preventing your identification; confidentiality of the data collected will be maintained. Results of this study may be published for scientific purposes, but you will not be identified. You will not be paid anything for participating in this study.

In case of emergency, you may please call Dr. XXXX, P.G., Department of Obstetrics and Gynaecology, or Dr. XXXX, Professor, Department of Obstetrics and Gynaecology, J.N.M.C. Belgaum.

If you have any questions about this study, you may please call, visit or write to Dr. XXXX, Post Graduate (Obstetrics and Gynaecology), or Dr. XXXX, Professor, Department of Obstetrics and Gynaecology, J.N.M.C, Belgaum-590010.

If you have any questions regarding your rights as a study participant, you may contact Dr. XXXX, Principal & Chairman of Ethical Committee, J. N. Medical College, Belgaum.

Statement of Consent: I volunteer and consent to participate in this study. I have read the consent document or it has been read to me in my vernacular language. I accept to participate in this study. All the information regarding this study has been provided to me and I have understood the same. I have been given an opportunity to ask questions and obtain appropriate answers.

Signature or left thumb print of the participant or legally authorized representative.

Participant's Name: _____

Signature or left thumb print :_____

Address : _____

Telephone No. : _____

Witness's Name: _____

Signature or left thumb print :_____

Investigator's Name: _____

Signature:_____

Date : | | | | | | | | |

ANNEXURE – I

INFORMED CONSENT FORM

ID.NO :- | | | | | |

EARLY VS DELAYED UMBILICAL CORD CLAMPING AND ITS IMPACT ON THE POST PARTUM BLOOD LOSS: A RANDOMIZED CONTROLLED TRIAL

There is no fixed protocol regarding the optimal timing of cord clamping. Various studies suggest that delayed cord clamping can be advantageous for the infant by improving iron status, especially in our country where the prevalence of anaemia is 79.2% in children aged 6-35months. We intend to study the impact of early and delayed cord clamping on the mother and the iron status of the baby.

You are invited to participate in a research study being conducted under the guidance of Dr. M.B. Bellad, Professor, Department of Obstetrics & Gynaecology, J. N. Medical College, Belgaum.

Your participation in the study is voluntary. You should be willing to answer the questions about your pregnancy and child birth to the best of your knowledge. By agreeing to participate in this study, you will be a valuable contributor towards understanding more about the optimal timing of cord clamping and its impact on the mother and the infant. Your participation in this study is not likely to have any adverse effects. This study may not benefit you, but may be beneficial to the other patients. Standard care will be provided even if you refuse to participate in this study. You are free to stop participation in this study at any time and for any reason.

Every effort will be made to protect the confidentiality of the information you provide. You will be given an ID number and the same will be used for study purpose preventing your identification; confidentiality of the data collected will be maintained. Results of this study may be published for scientific purposes, but you will not be identified. You will not be paid anything for participating in this study.

In case of emergency, you may please call Dr. Arveen Vohra, P.G., Department of Obstetrics and Gynaecology, Tel. No. 9844001553 or Dr. M.B. Bellad, Professor, Department of Obstetrics and Gynaecology, J.N.M.C. Belgaum. Tel. No. 0831- 24091537.

If you have any questions about this study, you may please call, visit or write to Dr. Arveen Vohra, Post Graduate (Obstetrics and Gynaecology), Tel. No. 9844001553 or Dr. M.B. Bellad, Professor, Department of Obstetrics and Gynaecology, J.N.M.C, Belgaum- 590010, Tel. No. 0831- 24091537.

If you have any questions regarding your rights as a study participant, you may contact Dr. V.D. Patil, Principal & Chairman of Ethical Committee, J. N. Medical College, Belgaum, Tel. No.0831-2471530

Statement of Consent: I volunteer and consent to participate in this study. I have read the consent document or it has been read to me in my vernacular language. I accept to participate in this study. All the information regarding this study has been provided to me and I have understood the same. I have been given an opportunity to ask questions and obtain appropriate answers.

Signature or left thumb print of the participant or legally authorized representative.

Participant's Name: _____

Signature or left thumb print :_____

Address : _____

Telephone No. : _____

Witness's Name: _____

Signature or left thumb print :_____

Investigator's Name: _____

Signature:_____

Date : | | | | | | | | |

PROFORMA

"EARLY VS DELAYED UMBILICAL CORD CLAMPING AND ITS IMPACT ON THE POST PARTUM BLOOD LOSS: A RANDOMIZED CONTROLLED TRIAL"

TO BE COMPLETED BY HEALTHCARE PROVIDER FOR EVERY WOMAN SCREENED FOR ENROLMENT IN THE STUDY.

SL. NO. ☐☐☐ **IP NO.** ☐☐☐☐☐☐☐

SCREENING AND RECRUITMENT FORM

I. SUBJECT INFORMATION

1. **Name:** First _____ Middle_____Last_____
2. **Age:** ☐☐ **yrs**
3. **Address**: _____

II. SCREENING

1. Has this pregnancy completed 37 weeks of gestation? Yes=1 No=2 ☐
2. Is this pregnancy live Single gestation=1 Multiple gestation=2 ☐
3. Is this pregnancy vertex presentation? Yes=1 No=2 ☐
4. Did the woman have previous caesarean delivery? No=1 Yes=2 ☐
5. Is this woman for an elective caesarean delivery? No=1 Yes=2 ☐
6. Is the woman anaemic (Hb less than 8gm/dl)? No=1 Yes=2 ☐
7. Is the woman's blood group Rh negative? No=1 Yes=2 ☐
8. Did/ Does the woman have high blood pressure? No=1 Yes=2 ☐
9. Did the woman have any obstetrical complications during this pregnancy? No=1 Yes=2 ☐
   1. Antepartum hemorrhage 2. IUGR 3. Malpresentation 4. Fetopelvic Disproportion
   5. Others-specify_____ ☐
10. Did the woman suffer from any of the following conditions? No =1 Yes=2 ☐
    1. Heart Disease 2. Diabetes 3. TB 4. Renal disease 5. Gynecological conditions
    6. Stroke 7. Epilepsy 8. Acute abdomen 9. Acute or chronic infections
    10. Other medical/surgical conditions ☐
11. Did the woman enter active labour? No = 1 Yes=2 ☐

12. Did the woman have febrile illness at time of delivery? No = 1 Yes=2 ☐

13. Is this term singleton, uncomplicated pregnancy? No = 1 Yes=2 ☐

14. Is consent obtained? No=1 Yes=2 ☐

III. FINAL SCREENING RESULT

1. Ineligible 2. Eligible, refusing 3. Eligible, participating ☐

DATE

DATA COLLECTION FORM

PARTICIPANT RECORD

ID.NO ☐☐☐☐☐ IP.NO ☐☐☐☐☐☐☐

I. SUBJECT INFORMATION

1. **Name:** First _____ Middle_____Last_____
2. **Age:** ☐☐ **yrs**
3. **Address**: **House no** : _____ **Street** : _____ **Taluka** :_____
   ___

   District: _____ **Tel No:** _____
4. **Occupation:** 1. Housewife 2. Labourer 3. Others specify ☐
5. **Education:** 1. Illiterate 2**.** Read/Write 3**.** Primary 4. Secondary 5. Graduate 6**.** Post-Graduate 7. Others specify ☐
6. **Monthly Income (Rs.):** Below poverty line =1 Above poverty line =2 ☐
7. **Religion: 1.** Hindu **2.** Muslim **3.** Sikh **4.** Christian **5.** Others specify ☐

CURRENT PREGNANCY

Gravida Para Living Abortion

1. L.M.P. DATE: ☐☐☐☐☐☐
2. EDD: ☐☐☐☐☐☐
3. Gestational age : ☐☐ weeks ☐ days
4. Did the woman receive antenatal care? Yes=1 No=2 ☐
5. If Yes, how many visits ☐ Date of Last visit:
6. Did the woman receive tetanus toxoid vaccination? Yes=1 No=2 ☐
7. If Yes, how many TT Injections ☐
8. Did the woman take iron / folic acid supplements for atleast 100 days? Yes=1 No=2 ☐
9. Did the patient receive any anti malarial drugs? Yes=1 No=2 ☐

GENERAL EXAMINATION

Height (Mtrs) : Weight (Kgs) : BMI :

Vitals

Fundal height (cms) =

PROM No=1 Yes=2 ☐

Pulse rate : ☐☐☐ / min. BP : ☐☐☐ / ☐☐☐ mm Hg. Fœtal ☐☐☐

Heart Rate :

Pallor : Yes=1 No=2 ☐ Icterus : Yes=1 No=2 ☐ Oedema: Yes=1 No=2 ☐

Investigations

Blood Group : Hemoglobin (gm/dl):

INFORMATION ON LABOUR

1. Date & Time when labour pains started ☐☐☐☐☐☐ : ☐☐☐☐ AM/ PM

2. Date & Time of Delivery ☐☐☐☐☐☐ : ☐☐☐☐ AM/ PM

3. Name of Duty Doctor and Signature:

4. What was the Type of Delivery? 1. Spontaneous 2. Induced ☐

5. Was episiotomy given? Yes=1 No=2 ☐

6. Was the case randomized? Yes=1 No=2 ☐

If No, why?

If Yes, ID No of envelope ☐☐☐☐☐

Early cord clamp=1 **Delayed cord clamp=2** ☐

7. Was there post randomization exclusion? No=1 Yes=2 ☐

If Yes, why? ☐

1. Birth asphyxia 2. Instrumental delivery 3. Emergency caesarean section

4. Needed immediate resuscitation 5. Could not follow randomization 6. Others specify

8. Time of cord clamping ☐☐☐ Secs

9. Was there any perineal/cervical tear? Yes=1 No=2 ☐

10. What was the uterine tone? 1. Hard 2. Firm 3. Soft ☐

11. Date and time of delivery of Placenta ☐☐☐☐☐☐ : ☐☐☐☐ AM/PM

12. Was the placenta intact? Yes=1 No=2 ☐

13. Duration of 3rd stage of labour. ☐☐☐ Secs ☐

14. What was the Complication of 3rd stage of labour?

1. None 2. Postpartum hemorrhage 3. Retained placenta 4. Others specify

15. PR after delivery ☐☐☐ bpm

16. BP after delivery ☐☐☐ / ☐☐☐ mm Hg

17. Were Swabs / Mops used? Yes = 1 No=2 ☐

If Yes, Weight of Mops

Blood loss in Mops (ml)

Blood loss in drape (ml)

18. Immediate blood loss after delivery ☐☐☐ ml

19. PR after one hour of delivery ☐☐☐ bpm

20. BP after one hour of delivery ☐☐☐ ☐☐☐ mm Hg

21. Blood Loss after one hour of delivery ☐☐☐ ml

22. PR after two hour of delivery ☐☐☐ bpm

23. BP after two hour of delivery ☐☐☐ ☐☐☐ mm Hg

24. Blood Loss after two hour of delivery ☐☐☐ ml

25. Any oxytocics given ? Yes = 1 No = 2 ☐

yes, Misoprostol (mcg)

Oxytocin (IU)

Others

When was it given? After delivery of baby = 1 ; After delivery of placenta = 2; ☐

Others specify = 3

INFORMATION ABOUT THE BABY

1. Gestational age _____
2. Time of birth ☐☐☐☐☐☐ ☐☐☐☐
3. Sex : Male=1 Female=2 ☐
4. Weight in kgs : ☐
5. Did the baby cry immediately after birth? Yes=1 No=2 ☐
6. Did the baby require resuscitation? Yes=1 No=2 ☐
7. Apgar Score at 1 minute ☐ / ☐ At 5 Minutes ☐ / ☐
8. Did the baby have any congenital malformations? Yes=1 No=2 ☐
9. Did the baby require NICU admission? Yes=1 No=2 ☐
10. Did the baby breast feed after delivery? Yes=1 No=2 ☐
11. Cord Hb at Birth : _____ mg/dl Cord PCV at birth ☐☐ %
12. Did the baby develop jaundice before discharge? Yes=1 No=2 ☐

    If yes, was serum bilirubin level done Yes =1 No=2 ☐

    If Yes, serum bilirubin levels _____mg/dl

13. Did the baby require NICU admission for jaundice / other reasons? Yes = 1 No = 2 ☐
14. Did the baby require photo therapy? Yes=1 No=2 ☐

    If yes, how many times ☐

15. Did the baby require exchange transfusion? Yes=1 No=2 ☐

INFORMATION ABOUT THE BABY AT 3RD MONTH

1. Weight (kgs)_____
2. Length (cms) _____
3. Has the baby been exclusively breast feed ? Yes=1 No=2 ☐
4. Was the baby given top feeds? Yes=1 No=2 ☐
5. Did the baby receive any iron supplements? Yes=1 No=2 ☐
6. Did the baby have any illnesses in last 3 months ? Yes=1 No=2 ☐

If yes, then specify_____

7. Investigations Hb : _____mg/dl PC☐☐ %

8. Was there post randomization exclusion? No=1 Yes=2 ☐

If Yes, why?

Name of Investigator

Signature of Investigator

MASTER CHART

				Labour information									Baby information													
				Post randomization exclusion			Time of cord clamping (Sec)	3rd Stage of labour	Post partum blood loss				At Birth						Follow up at 90 ± 7 days					
		POG (Weeks)	No. of ANCs	Early / Delayed	Yes/No	Reason		Duration (sec)	Blood loss after delivery(ml)	Blood loss @1hr(ml)	Blood loss@2hrs (ml)	Sex	Weight (Kg)	Cord Hb (g/dl)	Cord PCV (%)	Jaundice	Bilirubin	NICU Admission	Photo therapy	Breast feed	Top feed	Iron	Illness	Hb (g/dl)	PCV(%)
P001	302184	40	2	D	2	4	12	360	250	300	300	2	2.25												
P002	302365	40	6	E	2	6 Cl	19	180	50	100	150	1	3.10	Cl	Cl	2									
P003	302587	38	10	D	1	-	79	180	50	100	150	1	2.60	12	37	2		2	N	1	2	2	2	10.5	31
P004	302615	40	6	E	2	4	20	180	150	200	300	1	2.30												
P005	302850	39	4	D	1	-	80	240	50	100	120	2	2.50	15	47	2		2	N	1	2	2	2	12.0	36
P006	303024	39	4	E	1	-	27	360	75	100	125	1	2.70	16	49	2		2	N	1	2	2	2	11.0	34
P007	303178	38	6	D	1	-	79	360	100	150	175	1	2.60	16	50	2		2	N	1	2	2	LRTI	11.5	36
P008	303240	44	4	E	2	1	5	360	250	250	300	1	3.00												
B0001	303535	40	3	D	2	3	6	240	300	350	350	2	2.75												
B0002	303489	39	3	D	2	2	10	420	150	200	200	2	2.75												
A0003	303705	40	5	E	1	-	16	600	200	250	275	2	2.90	15	46	2		2	N	1	2	2	2	11.5	41
B0004	303924	41	4	D	2	2	6	360	150	150	200	2	3.20												
A0005	304045	39	4	E	1	-	14	300	50	200	400	2	3.25	15	47	2		2	N	1	2	2	2	10.5	32
B0006	304158	39	3	D	1	-	80	180	150	160	180	2	2.80	15.5	48	2		2	N	1	2	2	LRTI	13.0	42
A0007	304123	39	3	E	1	-	19	180	50	75	100	1	3.20	15	42	2		2	N						
A0008	304317	41	2	E	1	-	14	240	200	225	250	1	3.10	15	47	2		2	N	1	2	2	2	10.5	32
B0009	304655	39	6	D	1	-	75	420	50	50	100	2	2.96	12	38	2		2	N						
A0010	304639	40	3	E	2	2	10	300	250	250	250	2	3.00												
A0011	304672	38	4	E	2	2	10	180	200	250	250	1	2.90												
A0012	304771	37	3	E	2	3	7	180	300	400	400	1	2.25												
A0013	305011	39	5	E	2	3	5	120	350	400	400	1	3.00												
A0014	305000	37	7	E	1	-	16	240	100	150	150	1	2.98	17	53	2		2	N						
B0015	305162	40	4	D	1	-	64	240	50	50	50	2	2.80	16	49	2		2	N	1	2	2	2	12.0	34
A0016	305276	42	3	E	2	4	5	300	200	250	250	1	2.90												
B0017	305005	40	7	D	1	-	76	240	100	100	150	1	2.70	15	46	2		2	N	1	2	2	2	12.0	36
A0018	305264	41	3	E	1	-	21	180	100	150	200	1	2.75	14	44	2		2	N	2	1	2	2	10.5	30
A0019	303756	39	2	E	1	-	18	240	100	150	200	2	3.20	15	47	2		2	N	2	1	2	2	11.5	34
A0020	305375	39	12	E	1	-	16	240	100	150	250	2	3.40	13	40	2		2	N	1	1	2	2	10.5	33

MASTER CHART

				Labour information								Baby information													
				Post randomization exclusion			Time of cord clamping (Sec)	3rd Stage of labour	Post partum blood loss					At Birth						Follow up at 90 ± 7 days					
		POG (Weeks)	No. of ANCs	Early / Delayed	Yes/No	Reason		Duration (sec)	Blood loss after delivery(ml)	Blood loss @1hr(ml)	Blood loss@2hrs (ml)	Sex	Weight (Kg)	Cord Hb (g/dl)	Cord PCV (%)	Jaundice	Bilirubin	NICU Admission	Photo therapy	Breast feed	Top feed	Iron	Illness	Hb (g/dl)	PCV(%)
A0021	305423	39	3	E	2	3	6	120	300	400	400	2	3.10												
A0022	305457	40	6	E	2	3	7	120	350	400	400	1	2.75												
A0023	305206	40	6	E	1	-	18	300	100	150	150	1	2.75	15	46	2		2	N	2	1	2	2	11.5	36
B0024	305622	39	4	D	2	3	7	120	375	400	400	1	2.75												
B0025	305669	41	2	D	2	2	16	300	200	250	250	1	3.00												
B0026	305738	50	7	D	2	1	2	240	250	300	400	2	3.20												
B0027	305691	40	4	D	1	-	102	360	200	300	300	1	3.00	14.0	41	2		2	N	2	1	2	LRTI	11.0	32
B0028	305794	39	4	D	2	3	7	180	400	400	450	1	2.50												
A0029	305776	39	4	E	1	-	24	120	150	150	200	1	3.20	12.5	38	2		2	N	2	1	2	2	10.0	30
B0030	305868	39	7	D	2	1	6	300	100	125	150	1	3.00												
A0031	305920	38	13	E	1	-	26	180	100	150	175	2	3.22	15.0	46	2		2	N	1	1	2	Diar	10.0	32
A0032	305992	44	9	E	1	-	16	240	200	200	250	2	2.70	14.0	43	2		2	N	1	2	2	LRTI	10.0	32
A0033	306026	39	4	E	1	-	20	420	200	300	400	1	2.50	13.0	41	2		2	N						
A0034	306117	37	6	E	2	2	15	180	250	250	300	2	2.90												
B0035	306283	39	5	D	1	-	79	190	100	150	150	1	2.80	13.0	40	2		2	N	1	2	2	2	10.5	33
A0036	306493	40	5	E	1	-	16	180	150	200	250	1	4.00	17.0	49	2		2	N	1	2	2	2	11.5	34
A0037	306514	39	4	E	1	-	18	240	150	150	200	1	2.80	13.5	43	2		2	N						
A0038	306518	40	2	E	1	-	25	240	150	150	200	1	3.18	13.5	42	2		2	N						
B0039	306787	38	3	D	1	-	74	300	150	200	250	2	3.20	15.0	46	2		2	N	1	2	2	2	12.5	36
B0040	306801	41	4	D	1	-	90	360	200	300	350	1	3.70	14.0	43	2		2	N	1	2	2	LRTI	10.0	31
B0041	306919	39	7	D	1	-	86	240	200	250	300	1	2.75	15	44	2		2	N	2	1	2	2	12.5	36
B0042	306920	38	7	D	1	-	90	420	250	300	350	1	3.50	15.5	48	2		2	N						
A0043	306932	39	8	E	1	-	21	180	200	250	250	2	2.50	15	46	2		2	N	1	2	2	2	12.5	38
A0044	306242	39	3	E	1	-	16	240	200	250	300	1	2.75	14	44	2		2	N	1	2	2	LRTI	12.0	36
B0045	306957	41	4	D	1	-	82	240	100	100	150	2	2.70	17	52	2		2	N	1	2	2	2	13.0	38
B0046	307054	40	9	D	1	-	78	180	150	150	200	1	3.50	16	50	2		2	N	1	2	2	2	12.0	36
B0047	307116	40	3	D	2	1	15	240	300	300	300	1	3.20												
A0048	307117	38	12	E	1	-	18	180	100	150	200	1	3.00	13.5	40	2		2	N	1	2	2	Diar	10.0	31

MASTER CHART

				Labour information								Baby information													
				Post randomization exclusion			Time of cord clamping (Sec)	3rd Stage of labour	Post partum blood loss					At Birth						Follow up at 90 ± 7 days					
		POG (Weeks)	No. of ANCs	Early / Delayed	Yes/No	Reason		Duration (sec)	Blood loss after delivery(ml)	Blood loss @1hr(ml)	Blood loss@2hrs (ml)	Sex	Weight (Kg)	Cord Hb (g/dl)	Cord PCV (%)	Jaundice	Bilirubin	NICU Admission	Photo therapy	Breast feed	Top feed	Iron	Illness	Hb (g/dl)	PCV(%)
B0049	307145	39	9	D	1	-	96	180	200	200	250	1	2.80	16	48	1	15.75	1	1	1	2	2	2	10.5	32
B0050	307381	38	7	D	1	-	89	240	120	120	120	1	3.10	18	54	2		2	N						
B0051	307393	40	5	D	1	-	78	300	300	300	350	1	3.25	16	50	2		2	N	1	2	2	2	14.0	42
B0052	307520	38	8	D	2	3	12	180	400	450	450	1	3.00												
B0053	307509	39	6	D	1	-	90	300	200	200	250	1	3.00	16.5	48	2		2	N	1	2	2	2	14.0	40
A0054	307598	41	10	E	2	3	10	120	350	400	400	2	3.30												
B0055	307602	37	2	D	2	3	11	240	300	350	350	1	3.17												
A0056	307890	38	2	E	1	-	16	240	250	300	300	2	2.60	16.0	48	2		2	N	1	2	2	2	11.0	35
A0057	307907	40	8	E	2	2	18	360	100	100	150	1	2.75												
B0058	307968	39	10	D	1	-	98	360	150	150	150	2	3.30	15.0	46	2		2	N	2	1	2	LRTI	10.5	33
A0059	307995	39	6	E	1	-	22	120	50	50	50	2	2.28	16.0	48	2		2	N	2	1	2	Pn, Dia	10.0	31
A0060	308047	40	3	E	2	3	5	360	350	400	400	1	2.00												
A0061	307977	38	4	E	2	3	7	180	400	450	450	2	2.25												
A0062	308047	40	6	E	2	3	9	240	300	350	350	2	2.00												
B0063	308049	39	9	D	1	-	102	240	100	100	100	2	3.00	14.0	46	2		2	N	1	2	2	2	11.5	34
A0064	308046	42	3	E	2	4	10	300	250	300	350	2	3.20												
A0065	308079	40	5	E	1	-	16	240	150	150	200	2	2.80	16.5	51	2		2	N	2	1	2	2	15.5	46
B0066	308053	38	5	D	1	-	72	360	350	350	400	2	3.24	14	43	2		2	N	2	2	2	2	12.5	38
A0067	308062	41	4	E	2	2	10	300	150	150	200	1	3.00												
A0068	308130	41	7	E	1	-	15	180	150	200	250	2	2.70	12.5	38	2		2	N	1	2	2	2	10.0	31
A0069	308528	39	4	E	2	2	16	300	200	200	250	1	2.75												
A0070	308266	39	9	E	1	-	16	360	50	50	50	2	3.00	13.5	42	2		2	N	1	2	2	2	15.0	45
A0071	308394	41	6	E	1	-	20	300	50	50	100	2	3.10	14.0	44	2		2	N	1	2	2	2	10.0	32
B0072	308314	39	9	D	2	1	5	300	75	75	100	2	3.30												
B0073	308402	40	6	D	1	-	90	360	100	100	100	2	3.10	14.5	45	2		2	N	2	1	2	2	10.5	33
B0074	308454	38	6	D	2	2	16	360	250	250	300	1	2.50												
A0075	308439	39	7	E	1	-	14	360	50	350	900	1	2.90	15.0	46	2		2	N						
B0076	308516	38	10	D	1	-	96	420	300	300	350	1	2.50	14.5	46	2		2	N						

MASTER CHART

				Labour information								Baby information													
				Post randomization exclusion			Time of cord clamping (Sec)	3rd Stage of labour	Post partum blood loss					At Birth						Follow up at 90 ± 7 days					
		POG (Weeks)	No. of ANCs	Early / Delayed	Yes/No	Reason		Duration (sec)	Blood loss after delivery(ml)	Blood loss @1hr(ml)	Blood loss@2hrs (ml)	Sex	Weight (Kg)	Cord Hb (g/dl)	Cord PCV (%)	Jaundice	Bilirubin	NICU Admission	Photo therapy	Breast feed	Top feed	Iron	Illness	Hb (g/dl)	PCV(%)
B0077	308579	40	5	D	1	-	98	540	200	200	250	1	2.90	15.0	46	2		2	N						
B0078	308567	37	9	D	1	-	102	420	250	275	300	1	3.50	12.0	38	1	16.85	1	2	1	2	2	2	10.5	34
A0079	308573	39	12	E	1	-	19	300	250	250	300	2	3.00	15	48	2		2	N	1	1	2	2	14.0	42
B0080	308588	40	4	D	2	1	6	360	100	100	100	2	2.25												
B0081	308577	40	5	D	2	3	9	240	450	450	450	1	2.40												
B0082	308602	40	8	D	1	-	108	480	200	200	200	1	3.50	14.0	43	1	19.10	1	4	2	1	2	2	12.0	36
A0083	308707	40	6	E	2	3	10	300	450	450	500	1	4.10												
A0084	308784	39	10	E	1	-	15	480	50	50	150	1	3.20	14.0	44	2		2	N	1	2	2	2	10.5	34
B0085	302772	39	7	D	1	-	100	420	150	150	150	2	2.29	16.0	58	2		2	N						
A0086	308701	40	7	E	1	-	20	600	300	300	350	2	2.80	15.0	48	2		2	N	2	1	2	2	10.0	32
B0087	302791	39	10	D	1	-	100	480	300	300	350	2	2.60	14.0	44	2		2	N						
A0088	308786	40	5	E	2	3	9	240	350	400	400	1	3.30												
B0089	308703	39	8	D	1	-	90	360	200	225	250	2	2.75	18.0	58	2		2	N	1	2	2	2	14.5	44
A0090	308525	41	8	E	2	4	5	300	250	250	250	1	3.20												
B0091	308635	41	4	D	1	-	98	420	300	300	300	2	2.75	14.0	44	2		2	N						
A0092	308815	39	9	E	2	3	9	240	300	350	350	2	2.60												
B0093	308824	39	7	D	2	4	15	300	200	200	250	1	2.70												
B0094	308850	40	11	D	2	4	5	360	450	600	600	1	2.90												
B0095	309006	39	5	D	2	1	6	360	150	150	200	1	2.60												
A0096	308855	40	8	E	2	4	9	600	200	200	200	1	2.80												
A0097	308973	40	5	E	2	3	10	360	350	400	400	1	3.30												
B0098	308666	38	6	D	1	-	102	360	125	125	200	1	2.25	17.0	52	2		2	N	1	2	2	LRTI	13.0	41
B0099	309035	38	5	D	2	4	14	600	150	150	200	1	2.88												
B0100	308932	39	9	D	1	-	109	300	200	250	300	2	2.76	13.5	42	2		2	N	1	2	2	2	14.0	43
A0101	309213	38	4	E	1	-	15	240	300	300	350	1	3.25	15.0	46	2		2	N	1	2	2	2	11.0	35
A0102	309290	40	6	E	2	3	5	180	550	650	400	2	2.60												
A0103	309328	39	9	E	2	3	15	120	200	300	400	1	2.50												
A0104	309332	40	2	E	1	-	18	300	350	400	400	2	3.40	16.5	52	2		2	N	1	2	2	2	15.0	46

MASTER CHART

				Labour information								Baby information													
				Post randomization exclusion			Time of cord clamping (Sec)	3rd Stage of labour	Post partum blood loss					At Birth						Follow up at 90 ± 7 days					
		POG (Weeks)	No. of ANCs	Early / Delayed	Yes/No	Reason		Duration (sec)	Blood loss after delivery(ml)	Blood loss @1hr(ml)	Blood loss@2hrs (ml)	Sex	Weight (Kg)	Cord Hb (g/dl)	Cord PCV (%)	Jaundice	Bilirubin	NICU Admission	Photo therapy	Breast feed	Top feed	Iron	Illness	Hb (g/dl)	PCV(%)
A0105	309334	41	6	E	2	3	18	120	300	350	350	1	3.00												
A0106	309437	40	4	E	2	4	6	540	250	250	250	2	2.30												
A0107	309566	40	12	E	1	-	19	540	150	150	175	2	2.75	12.4	38	1	18.90	1	3	1	2	2	2	10.0	30
A0108	309382	38	6	E	1	-	30	480	250	250	300	1	2.60	12.0	37	2		2	N						
B0109	309570	41	6	D	2	4	8	240	350	350	400	1	3.50												
B0110	309569	37	4	D	1	-	90	360	50	50	50	2	2.25	13.0	42	2		2	N	1	2	2	2	11.5	36
A0111	309643	40	6	E	2	4	6	480	200	200	225	2	3.25												
B0112	309558	40	6	D	2	3	19	180	80	100	200	2	2.80												
B0113	309503	40	9	D	2	3	10	120	200	200	200	2	3.00												
B0114	309677	39	4	D	2	1	2	360	50	75	75	1	2.70												
A0115	309719	40	14	E	1	-	15	420	50	150	300	2	2.60	15.0	47	2		2	N	1	2	2	2	10.0	30
B0116	309862	39	5	D	1	-	150	480	150	200	250	2	2.80	13.0	40	2		2	N	1	2	2	2	11.0	34
A0117	309871	40	4	E	2	3	5	180	250	300	350	1	3.20												
A0118	309861	39	5	E	2	4	9	240	200	200	250	2	3.00												
B0119	309907	41	8	D	1	-	128	360	250	300	350	1	3.40	18.5	58	2		2	N	1	2	2	2	13.5	39
A0120	309867	41	9	E	1	-	15	240	50	100	300	2	2.40	17.0	53	2		2	N	2	1	2	LRTI	11.0	34
A0121	309937	37	7	E	2	4	3	420	300	300	325	2	2.35												
A0122	309930	38	8	E	1	-	17	240	75	80	80	2	2.60	14.0	45	2		2	N	1	2	2	2	12.0	37
A0123	309947	41	7	E	1	-	20	300	200	200	225	2	3.75	12.0	37	2		2	N	1	2	2	2	10.0	32
B0124	309980	39	8	D	2	4	7	300	250	250	250	2	2.75												
A0125	309602	40	11	E	2	2	5	240	450	550	650	1	3.10												
B0126	309617	40	9	D	2	1	9	240	25	25	50	2	3.20												
B0127	310004	39	7	D	1	-	109	120	125	125	125	2	2.80	13.5	45	2		2	N	1	2	2	2	11.5	36
B0128	309994	39	7	D	1	-	107	180	300	400	425	2	3.00	13.0	41	2		2	N	1	2	2	2	11.0	34
A0129	310083	37	3	E	2	3	5	120	350	400	400	2	2.50												
B0130	310147	40	10	D	1	-	107	180	100	100	250	2	3.00	14.0	44	2		2	N	1	2	2	2	12.5	38
A0131	309793	40	12	E	2	3	7	60	300	350	350	1	3.00												
B0132	310179	40	9	D	1	-	96	180	200	200	225	1	3.35	16.5	50	2		2	N	1	2	2	LRTI	13.5	40

MASTER CHART

				Labour information								Baby information													
				Post randomization exclusion			Time of cord clamping (Sec)	3rd Stage of labour	Post partum blood loss					At Birth						Follow up at 90 ± 7 days					
		POG (Weeks)	No. of ANCs	Early / Delayed	Yes/No	Reason		Duration (sec)	Blood loss after delivery(ml)	Blood loss @1hr(ml)	Blood loss@2hrs (ml)	Sex	Weight (Kg)	Cord Hb (g/dl)	Cord PCV (%)	Jaundice	Bilirubin	NICU Admission	Photo therapy	Breast feed	Top feed	Iron	Illness	Hb (g/dl)	PCV(%)
B0133	310197	40	11	D	1	-	102	180	300	400	450	1	3.10	18.0	58	2		2	N	1	2	2	2	16.0	50
B0134	310177	41	4	D	2	4	6	180	80	80	80	1	3.50												
B0135	310291	41	4	D	2	1	10	300	50	50	50	2	2.90												
B0136	310311	38	9	D	1	-	114	300	50	50	75	1	3.20	14.0	43	2		2	N	1	2	2	2	11.0	34
A0137	310402	38	6	E	2	4	12	300	200	200	250	1	2.50												
B0138	310084	41	8	D	2	2	5	360	350	350	400	1	3.80												
B0139	310089	38	9	D	1	-	110	300	100	125	125	2	2.60	15.0	46	2		2	N	1	2	2	2	13.0	39
A0140	310974	39	5	E	2	2	20	300	150	200	250	1	3.40												
A0141	310627	40	9	E	1	-	14	240	50	100	100	2	2.30	15.0	48	2		2	N	1	2	2	2	13.0	40
B0142	310637	39	8	D	2	2	15	240	150	200	250	1	3.30												
A0143	310640	38	4	E	1	-	15	300	50	75	100	2	3.00	12.0	38	2		2	N	1	2	2	Diar	10.0	30
B0144	310773	40	11	D	1	-	120	240	25	50	50	1	2.90	15.0	46	2		2	N	1	2	2	2	12.5	39
B0145	310842	38	7	D	2	1	2	300	200	250	300	2	3.00												
B0146	310854	37	8	D	1	-	108	300	100	200	200	1	3.00	13.5	42	2		2	N	1	2	2	LRTI	11.0	32
B0147	310689	41	14	D	1	-	98	300	400	425	450	1	3.50	13.0	41	2		2	N	1	2	2	2	12.0	39
A0148	310586	40	6	E	1	-	20	360	50	100	100	1	3.30	14.0	44	2		2	N	1	2	2	2	12.5	39
B0149	311004	39	12	D	2	3	9	120	350	400	400	1	2.75												
A0150	311115	41	8	E	2	3	15	120	300	350	350	1	2.80												
A0151	311179	37	7	E	2	1	8	300	100	150	200	1	2.40												
A0152	311180	38	5	E	1	-	15	360	150	200	200	2	2.50	16.5	50	2		2	N	2	1	2	LRTI	11.0	32
A0153	311193	40	2	E	2	4	10	300	150	200	250	2	3.20												
B0154	311215	40	12	D	1	-	98	240	300	300	300	1	3.30	15.0	46	2		2	N	2	1	2	Pn, GI	11.0	33
A0155	311347	38	10	E	2	1	2	300	150	200	200	1	2.20												
B0156	311352	40	9	D	2	4	5	360	200	250	250	2	3.40												
A0157	311391	39	6	E	1	-	13	300	50	75	75	1	2.60	13.5	42	2		1	N	1	2	2	2	14.5	47
B0158	311413	38	12	D	2	4	7	300	150	200	200	2	3.00												
A0159	311495	39	9	E	2	3	20	120	350	400	400	1	2.60												
A0160	311631	39	6	E	1	-	15	240	200	200	200	2	3.00	17.0	56	2		2	N						

MASTER CHART

				Labour information								Baby information													
				Post randomization exclusion			Time of cord clamping (Sec)	3rd Stage of labour	Post partum blood loss					At Birth						Follow up at 90 ± 7 days					
		POG (Weeks)	No. of ANCs	Early / Delayed	Yes/No	Reason		Duration (sec)	Blood loss after delivery(ml)	Blood loss @1hr(ml)	Blood loss@2hrs (ml)	Sex	Weight (Kg)	Cord Hb (g/dl)	Cord PCV (%)	Jaundice	Bilirubin	NICU Admission	Photo therapy	Breast feed	Top feed	Iron	Illness	Hb (g/dl)	PCV(%)
B0161	311616	40	6	D	2	4	10	300	200	250	200	2	2.75												
B0162	311683	40	12	D	1	-	118	240	150	150	200	2	2.30	17.0	53	2		2	N	1	2	2	Pn, Dia	11.5	34
B0163	311823	40	11	D	1	-	109	240	200	225	250	1	2.50	20.0	61	2		2	N	1	2	2	2	16.0	48
B0164	311791	41	10	D	1	-	120	300	200	200	200	2	2.75	15.0	46	2		2	N	1	2	2	2	14.0	47
A0165	311821	40	9	E	2	2	30	360	150	175	200	2	2.30												
A0166	311844	38	10	E	2	1	4	300	200	200	250	2	3.10												
B0167	311837	41	9	D	1	-	90	240	75	75	75	2	2.80	15.5	48	2		2	N	1	2	2	2	13.5	44
A0168	311834	42	7	E	2	2	15	360	150	150	175	2	3.10												
A0169	311872	39	10	E	2	2	5	240	200	200	250	1	2.75												
B0170	311921	39	8	D	1	-	110	120	150	150	200	2	2.50	19.0	58	2		2	N						
A0171	311909	40	13	E	1	-	12	300	350	400	425	2	3.20	15.0	47	1	18.07	1	2	1	2	2	2	10.0	31
A0172	311982	40	12	E	1	-	10	360	300	325	325	1	3.00	16.0	50	2		2	N	1	2	2	2	10.0	30
B0173	311972	39	9	D	2	2	9	300	400	600	1000	2	3.00												
A0174	311961	42	9	E	1	-	15	420	250	300	380	1	3.00	16.5	52	2		2	N	1	2	2	2	11.5	34
A0175	312040	40	10	E	2	2	8	360	300	300	325	2	3.20												
B0176	312187	38	10	D	2	1	7	300	50	80	80	1	2.60												
A0177	312116	40	9	E	2	3	10	60	350	400	400	1	3.00												
B0178	312320	41	11	D	1	-	98	180	100	150	250	2	2.75	16.0	50	2		2	N	1	2	2	2	15.0	46
A0179	312297	39	10	E	2	4	7	240	150	200	200	2	3.00												
A0180	312503	40	5	E	1	-	14	240	50	75	125	1	2.10	15.0	47	2		2	N						
A0181	312471	39	7	E	2	4	7	300	150	200	250	2	2.75												
A0182	312623	39	10	E	1	-	17	240	100	150	250	1	2.75	16.0	50	2		2	N	1	2	2	2	11.0	34
B0183	311861	40	10	D	1	-	109	120	50	50	100	1	2.75	16.5	52	2		2	N	1	2	2	LRTI	13.0	42
B0184	312756	40	9	D	1	-	111	120	250	250	300	2	3.00	17.0	52	2		2	N	1	2	2	2	14.0	46
A0185	312805	40	11	E	2	2	15	300	300	300	350	1	3.50												
A0186	312826	40	5	E	2	4	7	240	100	150	150	1	3.50												
A0187	312888	40	8	E	2	3	9	120	300	350	350	1	2.50												
B0188	312856	38	9	D	2	3	5	120	400	450	500	1	3.00												

MASTER CHART

				Labour information								Baby information													
				Post randomization exclusion			Time of cord clamping (Sec)	3rd Stage of labour	Post partum blood loss					At Birth						Follow up at 90 ± 7 days					
		POG (Weeks)	No. of ANCs	Early / Delayed	Yes/No	Reason		Duration (sec)	Blood loss after delivery(ml)	Blood loss @1hr(ml)	Blood loss@2hrs (ml)	Sex	Weight (Kg)	Cord Hb (g/dl)	Cord PCV (%)	Jaundice	Bilirubin	NICU Admission	Photo therapy	Breast feed	Top feed	Iron	Illness	Hb (g/dl)	PCV(%)
A0189	312936	39	6	E	1	-	12	240	150	200	250	2	2.90	18.0	54	2		2	N	1	2	2	2	10.0	32
A0190	312874	40	6	E	2	4	7	240	100	150	250	2	3.10												
A0191	312938	38	12	E	1	-	19	300	150	200	200	1	3.00	17.0	52	2		2	N	2	1	2	LRTI	11.0	32
B0192	313210	41	9	D	1	-	106	120	350	450	450	2	3.20	18.0	56	2		2	N	1	2	2	2	15.0	45
B0193	313139	37	8	D	1	-	98	180	150	150	200	2	2.30	16.0	49	2		2	N	1	2	2	2	12.5	39
B0194	313230	39	5	D	1	-	96	180	150	200	200	2	2.50	16.0	50	2		2	N	1	2	2	2	12.0	39
B0195	313232	40	9	D	2	3	5	180	350	400	400	2	2.60												
B0196	313247	40	4	D	2	4	2	240	200	250	250	2	3.25												
B0197	313342	39	4	D	1	-	109	120	100	100	100	2	2.75	18.0	57	2		2	N	1	2	2	2	14.5	47
B0198	313234	40	6	D	2	4	5	240	200	200	200	1	3.10												
B0199	313343	38	8	D	2	3	6	60	375	400	400	1	2.50												
B0200	313418	37	7	D	2	4	5	240	25	50	75	2	1.80												
D0201	313336	38	6	D	1	-	114	180	50	100	150	2	2.75	17.0	52	2		2	N	2	1	2	Diar	13.0	42
D0202	313482	40	7	D	1	-	106	120	150	200	200	2	3.30	16.5	52	2		2	N	1	2	2	Diar	12.0	37
D0203	313547	39	5	D	1	-	120	120	150	200	200	2	2.20	22.0	70	1	12.69	2	N	1	2	2	LRTI	10.0	32
D0204	313566	42	4	D	2	3	7	120	300	400	450	1	2.80												
D0205	313745	40	4	D	2	4	10	240	100	100	125	2	2.50												
D0206	313793	38	9	D	1	-	110	180	50	50	75	2	2.60	14.0	44	2		2	N	1	2	2	2	10.5	32
C0207	314005	40	5	E	1	-	16	300	25	50	100	2	3.30	18.5	58	2		2	N	1	2	2	2	12.0	38
C0208	314072	37	10	E	2	4	9	300	100	150	150	2	2.80												
C0209	314081	40	10	E	1	-	15	240	50	100	150	2	3.10	17.0	52	2		1	N	2	1	2	Diar	12.0	37
C0210	314016	39	6	E	1	-	10	180	75	100	100	1	2.75	16.0	48	2		2	N	1	2	2	Diar	10.0	32
D0211	314090	38	4	D	2	3	5	120	500	550	550	2	2.90												
C0212	314273	41	6	E	1	-	15	300	50	100	100	2	3.50	17.5	56	2		2	N	1	2	2	LRTI	12.0	33
C0213	314307	39	6	E	1	-	15	240	20	50	75	1	1.90	16.0	50	2		2	N	2	1	2	Pn, GI	11.0	33
C0214	314432	38	4	E	2	4	9	360	75	100	100	2	2.75												
C0215	314419	41	5	E	2	3	7	120	400	450	450	2	3.30												
D0216	314180	40	4	D	2	4	9	240	100	125	125	2	2.75												

MASTER CHART

				Labour information								Baby information													
				Post randomization exclusion			Time of cord clamping (Sec)	3rd Stage of labour	Post partum blood loss					At Birth						Follow up at 90 ± 7 days					
		POG (Weeks)	No. of ANCs	Early / Delayed	Yes/No	Reason		Duration (sec)	Blood loss after delivery(ml)	Blood loss @1hr(ml)	Blood loss@2hrs (ml)	Sex	Weight (Kg)	Cord Hb (g/dl)	Cord PCV (%)	Jaundice	Bilirubin	NICU Admission	Photo therapy	Breast feed	Top feed	Iron	Illness	Hb (g/dl)	PCV(%)
C0217	314535	39	4	E	1	-	18	540	150	200	200	1	2.40	19.0	58	2		2	N	1	2	2	LRTI	11.0	33
C0218	314640	40	6	E	2	3	18	180	50	75	75	2	2.50												
C0219	314732	39	9	E	1	-	15	300	70	125	125	2	2.75	17.0	52	2		2	N						
C0220	314726	41	5	E	1	-	15	300	25	75	75	1	3.40	18.0	58	2		2	N	Baby	Died				
C0221	314892	41	9	E	1	-	14	300	100	150	150	1	3.00	14.5	46	2		2	N	1	2	2	2	12.5	39
D0222	314917	40	6	D	2	4	10	300	100	150	200	2	3.70												
C0223	314911	41	9	E	1	-	10	360	50	75	100	2	2.50	14.0	43	2		2	N						
D0224	315195	38	10	D	1	-	112	180	150	250	250	1	3.10	15.0	46	2		2	N	1	2	2	LRTI	13.0	42
C0225	315263	41	9	E	2	2	10	300	300	350	350	2	2.65												
D0226	315284	37	8	D	1	-	84	300	100	150	150	2	2.80	15.0	46	2		2	N	1	2	2	2	13.0	44
D0227	315241	40	5	D	2	3	14	120	350	400	450	2	3.00												
C0228	315425	40	7	E	2	3	10	180	300	350	450	1	3.05												
C0229	315473	38	4	E	1	-	12	300	50	50	50	1	2.50	18.0	55	2		2	N	1	2	2	Diar	10.5	31
C0230	315503	38	6	E	1	-	14	540	75	100	100	1	3.75	12.0	37	2		2	N	1	2	2	2	10.0	31
D0231	315562	38	2	D	1	-	108	360	50	100	100	2	2.70	15.0	46	2		2	N						
D0232	315588	40	6	D	2	4	7	420	50	50	50	2	3.00												
D0233	315611	39	4	D	1	-	101	480	100	100	125	1	2.75	18.0	55	2		2	N	2	1	2	2	13.5	44
D0234	315767	40	7	D	1	-	116	300	50	50	50	1	2.70	14.0	43	2		2	N	1	2	2	2	12.5	39
D0235	315774	40	8	D	2	2	12	300	100	150	150	2	2.75												
D0236	315784	38	7	D	2	4	15	240	50	100	200	1	2.60												
D0237	315763	39	9	D	1	-	109	240	75	100	100	2	2.60	18.5	58	2		2	N	1	2	2	LRTI	14.0	46
D0238	315880	39	8	D	1	-	104	300	50	75	100	1	2.95	18.0	55	2		2	N						
D0239	315907	39	7	D	1	-	92	240	50	100	150	1	2.60	18.0	56	2		2	N	1	2	2	LRTI	14.0	46
D0240	315900	41	7	D	2	3	10	180	250	350	350	1	3.00												
C0241	316005	41	7	E	2	4	10	300	100	150	150	1	2.50												
C0242	316039	39	9	E	2	1	9	360	50	100	100	2	2.60												
D0243	316087	39	7	D	2	3	7	180	350	400	450	1	2.50												
D0244	316152	40	8	D	1	-	102	240	75	100	100	2	2.76	18	55	2		2	N	1	2	2	2	14.5	47

MASTER CHART

				Labour information								Baby information													
				Post randomization exclusion			Time of cord clamping (Sec)	3rd Stage of labour	Post partum blood loss					At Birth						Follow up at 90 ± 7 days					
		POG (Weeks)	No. of ANCs	Early / Delayed	Yes/No	Reason		Duration (sec)	Blood loss after delivery(ml)	Blood loss @1hr(ml)	Blood loss@2hrs (ml)	Sex	Weight (Kg)	Cord Hb (g/dl)	Cord PCV (%)	Jaundice	Bilirubin	NICU Admission	Photo therapy	Breast feed	Top feed	Iron	Illness	Hb (g/dl)	PCV(%)
D0245	316158	38	6	D	2	4	15	480	100	150	150	2	2.75												
D0246	316229	38	7	D	1	-	107	240	50	75	100	1	2.75	15	48	2		2	N	1	2	2	LRTI	12.5	38
C0247	316358	39	7	E	2	4	7	360	100	125	125	1	2.60												
D0248	316476	39	4	D	2	4	6	240	100	100	100	2	3.34												
D0249	316484	41	9	D	2	4	7	240	75	100	100	2	3.00												
D0250	316468	40	7	D	1	-	116	360	50	75	75	1	2.75	14	43	2		2	N	1	2	2	LRTI	11.5	34
C0251	316868	37	5	E	1	-	15	240	50	75	75	2	2.85	14	43	2		2	N	1	2	2	2	10.0	31
C0252	316925	38	10	E	1	-	14	300	75	100	100	1	2.90	15	46	2		2	N	1	2	2	Diar	10.5	33
D0253	317038	40	7	D	1	-	116	420	25	25	25	2	2.80	16	50	2		2	N	1	2	2	2	13.0	40
C0254	317129	38	7	E	1	-	19	480	250	300	350	2	2.60	15	46	2		2	N	1	2	2	LRTI	11.0	34
C0255	317181	40	7	E	2	1	8	360	50	100	100	1	2.75												
D0256	317162	40	9	D	1	-	180	360	50	100	150	1	3.25	20	61	2		2	N	1	2	2	LRTI	15.0	46
C0257	317163	39	9	E	2	2	10	240	50	100	300	2	3.00												
D0258	317367	40	6	D	1	-	101	360	100	100	100	1	2.30	18	55	2		2	N	1	2	2	LRTI	15.0	46
D0259	317380	40	9	D	1	-	96	240	100	100	100	2	3.20	16	50	2		2	N	1	2	2	2	12.0	38
D0260	317382	41	7	D	2	1	11	360	50	75	75	2	2.75												
D0261	317485	38	9	D	1	-	112	300	50	75	75	2	3.00	15	46	2		2	N	1	2	2	2	13.0	40
D0262	317645	41	6	D	2	4	15	300	175	250	250	1	3.00												
D0263	317561	40	7	D	2	4	5	420	150	200	200	1	3.50												
C0264	317661	41	6	E	1	-	11	360	100	150	150	1	3.30	15	50	2		2	N	1	2	2	2	10.5	34
D0265	317647	38	7	D	1	-	98	300	100	150	150	2	2.90	16	49	1	20.10	1	1	1	2	2	Diar	13.5	42
C0266	317782	40	9	E	2	3	11	120	300	350	400	1	2.50												
C0267	317913	39	7	E	1	-	7	300	50	100	300	2	2.30	18	58	2		2	N	1	2	2	LRTI	11.5	36
D0268	317917	39	8	D	2	3	9	180	350	450	500	2	2.70												
D0269	317976	39	7	D	1	-	109	600	250	250	250	1	3.10	17	52	2		2	N	1	2	2	LRTI	13.5	42
C0270	318018	41	7	E	2	4	10	300	50	100	100	2	2.40												
C0271	318030	39	7	E	1	-	14	300	50	100	150	2	2.75	18	56	2		2	N	1	2	2	2	11.5	35
D0272	318248	39	7	D	2	3	5	180	400	450	450	2	2.90												

MASTER CHART

				Labour information								Baby information													
				Post randomization exclusion			Time of cord clamping (Sec)	3rd Stage of labour	Post partum blood loss					At Birth						Follow up at 90 ± 7 days					
		POG (Weeks)	No. of ANCs	Early / Delayed	Yes/No	Reason		Duration (sec)	Blood loss after delivery(ml)	Blood loss @1hr(ml)	Blood loss@2hrs (ml)	Sex	Weight (Kg)	Cord Hb (g/dl)	Cord PCV (%)	Jaundice	Bilirubin	NICU Admission	Photo therapy	Breast feed	Top feed	Iron	Illness	Hb (g/dl)	PCV(%)
C0273	318086	40	6	E	2	1	5	420	75	75	75	2	2.80												
C0274	318276	39	8	E	2	2	10	300	50	100	200	2	2.60												
C0275	317551	41	11	E	2	4	14	300	300	350	375	1	3.40												
C0276	318565	39	7	E	1	-	11	240	200	250	300	1	2.75	15	48	2		2	N	1	2	2	2	10.0	31
D0277	318779	40	9	D	1	-	104	420	50	100	150	2	3.00	18	58	2		2	N	1	2	2	2	14.0	43
C0278	318812	40	6	E	2	3	5	180	350	400	400	2	2.80												
C0279	318844	39	7	E	2	4	5	360	50	200	200	2	2.80												
C0280	318813	41	9	E	2	4	7	300	150	200	200	1	3.40												
D0281	318991	41	7	D	1	-	90	300	250	300	350	2	2.75	18	55	2		2	N	1	2	2	2	14.0	44
C0282	318983	40	8	E	2	2	5	360	50	50	75	2	2.75												
D0283	319034	41	3	D	1	-	115	360	150	200	250	1	3.40	14	45	2		2	N	1	2	2	2	10.5	32
C0284	319159	40	12	E	1	-	17	360	50	50	100	1	3.40	17	58	2		2	N	1	2	2	Diar	11.0	34
C0285	319196	38	10	E	1	-	15	300	50	150	150	1	3.00	16	50	2		2	N	1	2	2	2	10.5	32
C0286	319190	38	9	E	2	4	7	300	75	100	100	1	2.75												
D0287	318553	40	9	D	1	-	105	240	100	200	300	2	3.00	17	57	2		2	N	1	2	2	2	12.5	40
C0288	319124	41	9	E	2	4	7	300	350	400	400	1	3.25												
C0289	319345	41	7	E	1	-	12	240	50	75	75	2	2.75	16	50	2		2	N	1	2	2	2	10.0	32
C0290	319252	37	7	E	2	4	5	240	50	100	100	1	3.05												
D0291	319361	39	9	D	2	2	7	360	50	100	150	2	2.30												
D0292	319372	40	7	D	1	-	98	180	100	150	200	2	3.00	15	45	2		2	N	1	2	2	2	12.5	38
D0293	319490	41	9	D	2	4	7	600	50	100	100	2	2.70												
C0294	319346	39	4	E	2	4	7	360	200	250	250	1	3.40												
C0295	319575	40	7	E	2	3	7	180	400	450	450	2	2.75												
D0296	319523	38	9	D	1	-	103	240	50	100	150	1	3.00	16	48	2		2	N	1	2	2	LRTI	13.5	44
C0297	319778	40	9	E	2	4	5	360	200	200	200	2	2.75												
C0298	319786	40	7	E	2	4	9	240	200	200	250	2	3.35												
D0299	319782	40	7	D	2	4	7	300	200	250	250	1	2.30												
C0300	319844	39	9	E	1	-	10	360	50	80	150	1	3.00	16	54	2		2	N	1	2	2	2	11.0	35

MASTER CHART

				Labour information								Baby information													
				Post randomization exclusion			Time of cord clamping (Sec)	3rd Stage of labour	Post partum blood loss					At Birth						Follow up at 90 ± 7 days					
		POG (Weeks)	No. of ANCs	Early / Delayed	Yes/No	Reason		Duration (sec)	Blood loss after delivery(ml)	Blood loss @1hr(ml)	Blood loss@2hrs (ml)	Sex	Weight (Kg)	Cord Hb (g/dl)	Cord PCV (%)	Jaundice	Bilirubin	NICU Admission	Photo therapy	Breast feed	Top feed	Iron	Illness	Hb (g/dl)	PCV(%)
F0301	319906	37	3	D	2	5	10	300	50	100	200	2	2.70												
E0302	319852	38	5	E	1	-	10	240	150	200	300	2	3.10	14	44	2		2	N	1	2	2	2	10.0	32
E0303	319950	41	6	E	2	4	7	240	100	250	250	2	2.50												
F0304	319953	39	9	D	2	4	16	180	100	125	150	1	2.90												
F0305	320126	39	11	D	2	1	9	180	80	100	100	2	2.90												
F0306	320247	40	9	D	2	3	5	120	550	600	650	1	2.70												
F0307	320255	41	9	D	2	2	11	240	200	250	250	1	2.70												
E0308	320379	38	7	E	2	4	9	240	200	300	300	1	2.70												
F0309	320494	39	9	D	2	1	9	300	400	400	400	2	2.70												
E0310	320649	39	9	E	2	2	10	240	600	600	650	1	2.75												
E0311	310948	39	9	E	2	1	5	240	50	150	150	1	2.60												
F0312	320681	40	8	D	2	4	7	300	300	356	350	2	3.60												
F0313	321069	40	7	D	1	-	110	180	350	400	400	1	2.40	18	58	1	18.56	1	3	1	2	2	LRTI	13.5	44
E0314	321139	39	4	E	2	3	7	120	500	600	600	1	3.50												
F0315	321299	40	9	D	1	-	106	180	80	100	100	2	3.25	16	48	2		2	N	1	2	2	2	13.0	43
F0316	321456	40	7	D	2	1	10	360	300	350	350	2	3.20												
F0317	321575	42	9	D	2	4	7	240	200	200	250	2	2.70												
E0318	321775	41	9	E	2	4	10	300	50	80	120	2	3.20												
F0319	321815	38	7	D	2	2	5	240	480	480	500	1	2.90												
F0320	321945	41	11	D	2	4	9	240	100	120	150	1	2.76												
E0321	322183	41	4	E	2	4	7	240	550	600	600	1	2.60												
F0322	322356	40	9	D	2	4	9	420	250	300	300	2	2.60												
F0323	322497	39	9	D	2	2	6	240	350	400	400	1	2.80												
F0324	322451	41	7	D	2	4	10	300	350	400	400	1	3.40												
E0325	322642	40	4	E	2	1	7	300	350	400	450	2	2.80												
E0326	322839	38	7	E	2	2	9	240	350	400	400	2	2.70												
E0327	323203	40	8	E	2	1	7	180	150	200	200	2	3.15												
E0328	323298	40	11	E	2	4	6	180	200	300	300	1	2.80												

MASTER CHART

				Labour information								Baby information													
				Post randomization exclusion			Time of cord clamping (Sec)	3rd Stage of labour	Post partum blood loss					At Birth						Follow up at 90 ± 7 days					
		POG (Weeks)	No. of ANCs	Early / Delayed	Yes/No	Reason		Duration (sec)	Blood loss after delivery(ml)	Blood loss @1hr(ml)	Blood loss@2hrs (ml)	Sex	Weight (Kg)	Cord Hb (g/dl)	Cord PCV (%)	Jaundice	Bilirubin	NICU Admission	Photo therapy	Breast feed	Top feed	Iron	Illness	Hb (g/dl)	PCV(%)
E0329	323736	39	6	E	1	-	15	240	300	350	350	1	3.00	16	48	2		2	N	1	2	2	2	10.0	31
F0330	323906	39	5	D	2	4	7	240	350	400	400	1	2.90												
E0331	323908	38	9	E	2	4	6	120	100	150	200	1	2.70												
F0332	324534	38	8	D	1	-	109	240	200	200	250	1	2.60	18	58	2		2	N	1	2	2	2	14.0	44
E0333	324586	39	6	E	1	-	11	240	50	100	150	1	3.10	16	48	2		2	N	1	2	2	2	10.5	32
E0334	324429	39	6	E	1	-	20	300	100	150	150	1	3.50	14	46	2		2	N	1	2	2	2	10.0	31
E0335	324700	41	6	E	2	4	9	360	100	150	150	1	2.30												
E0336	324823	37	9	E	2	1	5	300	150	200	200	1	2.70												
F0337	324359	41	7	D	2	2	7	240	200	250	250	1	3.10												
E0338	324848	39	7	E	1	-	9	240	150	175	175	1	3.40	18	55	2		2	N	1	2	2	LRTI	11.5	34
F0339	324857	39	8	D	1	-	115	300	200	20	200	1	3.50	18	58	2		2	N	1	2	2	2	14.5	46
E0340	325321	40	9	E	1	-	15	240	50	100	100	2	2.50	16	48	2		2	N	1	2	2	2	11.0	32
F0341	325413	38	9	D	2	2	9	180	150	200	200	2	2.45												
E0342	305413	41	9	E	2	1	9	180	50	100	100	1	2.80												
F0343	325520	41	9	D	2	3	5	120	300	550	350	1	2.80												
E0344	325840	40	7	E	1	-	9	180	150	250	250	1	3.40	18	58	2		2	N	1	2	2	2	12.0	39
F0345	326348	40	7	D	2	2	5	240	75	75	100	2	2.70												
F0346	326336	41	7	D	2	2	10	300	200	250	300	1	2.70												
E0347	326274	40	6	E	1	-	15	180	200	200	250	2	3.45	15.5	46	2		2	N						
E0348	326453	39	9	E	2	1	5	240	75	100	100	2	2.70												
F0349	326529	38	6	D	1	-	120	180	200	250	300	2	2.50	17.5	58	2		2	N	1	2	2	Diar	13.5	42
E0350	326542	40	7	E	2	2	7	240	75	100	100	1	2.60												
E0351	326568	39	7	E	1	-	20	300	75	100	100	2	2.60	16	48	2		2	N	1	2	2	2	11.0	34
F0352	326569	40	7	D	2	2	10	300	450	500	500	1	2.50												
E0353	326552	37	6	E	1	-	20	300	100	150	150	2	2.40	14.5	43	2		2	N	1	2	2	LRTI,D	10.0	31
E0354	326648	39	8	E	1	-	9	360	250	300	300	2	2.75	15	46	2		2	N	1	2	2	2	10.5	32
E0355	326650	39	9	E	1	-	20	360	150	200	200	1	2.75	15.5	48	2		2	N	1	2	2	2	11.0	34
F0356	326679	40	6	D	1	-	145	240	100	150	150	2	2.30	18	58	2		2	N	1	2	2	Diar	13.5	42

MASTER CHART

				Labour information								Baby information													
				Post randomization exclusion			Time of cord clamping (Sec)	3rd Stage of labour	Post partum blood loss					At Birth						Follow up at 90 ± 7 days					
		POG (Weeks)	No. of ANCs	Early / Delayed	Yes/No	Reason		Duration (sec)	Blood loss after delivery(ml)	Blood loss @1hr(ml)	Blood loss@2hrs (ml)	Sex	Weight (Kg)	Cord Hb (g/dl)	Cord PCV (%)	Jaundice	Bilirubin	NICU Admission	Photo therapy	Breast feed	Top feed	Iron	Illness	Hb (g/dl)	PCV(%)
E0357	326945	39	9	E	2	1	5	420	75	100	150	1	3.00												
E0358	327047	38	6	E	2	3	5	120	350	400	450	2	2.60												
E0359	327339	38	6	E	2	1	5	240	75	100	150	2	2.50												
E0360	327366	41	8	E	2	1	5	240	150	200	200	1	3.00												
E0361	327442	39	7	E	1	-	10	360	100	150	150	1	2.40	16	48	2		1	N	1	2	2	2	10.5	32
E0362	327500	39	7	E	2	1	5	300	600	700	750	2	3.40												
F0363	327519	38	6	D	2	4	9	240	100	150	150	1	2.60												
F0364	327825	40	7	D	1	-	106	360	100	200	250	1	3.00	18	58	2		2	N	1	2	2	LRTI	14.0	42
E0365	327854	39	7	E	1	-	20	240	25	25	25	1	2.55	17.5	58	2		2	N	1	2	2	2	11.0	34
F0366	328081	37	7	D	1	-	106	360	25	50	50	1	2.50	16.5	48	2		2	N	1	2	2	2	13.0	36
F0367	328129	39	6	D	2	1	7	360	200	250	300	1	2.90												