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Effects of Delayed Umbilical Cord Clamping On Maternal and Neonatal Outcomes in IRRUA: A Randomized Controlled (Open Label) Trial

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Abstract

Optimal timing of the clamping and cutting of the umbilical cord is yet to be clearly established, however evidence favours delayed umbilical cord clamping as it is beneficial with potential minimal or no risk to the mother and the baby. The evaluation of this cost effective, easy and practicable procedure especially in our settings where it is highly needed has not been done. Objective of the study is to assess maternal and neonatal outcomes of delayed versus early umbilical cord clamping in Irrua specialist teaching hospital. A prospective, three-armed, single Centre randomized controlled (open label) trials.234 participants were randomized into A, B and C arms, representing ECC within 30 seconds of birth, DCC at 2 minutes and three minutes for A, B and C arms respectively. Data was analyzed with the statistical package for social sciences (SPSS) version 20.0 IBM. Statistical comparison was done using Fisher's exact test for three groups and Student's t- test for two groups that are continuous variables while Chi-Square test was used for categorical variables. The level of significance was accepted when P-value is equal to or less than 0.05 and confident interval of 95%. Primary outcomes were maternal bloodloss post-partum and neonatal PCV, serum ferritin, transcutaneous bilirubin estimation/ serum bilirubin at 48 hours after birth and the infant's packed cell volume and serum ferritinat

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six weeks post-delivery. Secondary outcomes were maternal PPH and neonatal anaemia, jaundice, SBCU admission, phototherapy and EBT. In addition placenta weight and umbilical cord length were compared across groups with maternal satisfaction. 234 mothers-babies pairs were randomized into three groups A, B and C with 6.8% drop out rate, hence 218 mothers-babies pairs were analyzed out of which;75(34.4 %) for group A, 72 (33.0%) for group B and 71(32.6%) for group C. Thebaby's mean PCV and serum ferritins were higher in the DCC than ECC at 48 hours(F=61.0, P= <0.001 and F= 150.0, P= <0.001 respectively) which remained higher in DCC groups as compared to ECC group, at six weeks follow up after delivery (F=7.1, P= 0.001 and F= 379.1, P= <0.001 respectively). All the babies in group A (ECC) had anaemia which was 36 % or less in DCC groups. There was no significant difference between the three groups in respect to maternal blood loss, hyperbilirubinaemia, SCBU admission, and need for phototherapy. Delayed umbilical cord clamping for two minutes is better than ECC and is equally effective as DCC for three minutes. A follow up of cases with hyperbilirubinaemia showed a strong association to ABO incompatibility especially among group O Rh D positive mothers (X2 = 11.7, P = 0.011). It has been concluded that Delayed umbilical cord clamping is beneficial rather than harmful as it ensures higher packed cell volume and serum ferritin to the newborn even up to six weeks after birth at no maternal or neonatal risk. Two minutes of delay in umbilical cord clamping after birth is strongly recommended as an ideal optimal time for cord clamping in our rural setting.

Keywords

Cord clamping, Placenta weight, cord length, maternal- neonatal outcomes.

I. Introduction

Umbilical cord clamping and cutting is one of the most unique parts of the birth processes; however its optimal timing is controversial yet to be clearly established,[1,2] with the different timing approaches having advantages and disadvantages .The clamping and cutting of the umbilical cord is important as it prevent maternal blood loss and allow the newborn to be taken away from mother for resuscitation [2].Routinely as part of the active management of third stage of labour (AMTSL),early cord clamping is done usually within thirty seconds, this is believed to prevent postpartum haemorrhage and may prevent marked placenta transfusion which may predispose to neonatal jaundice [3-8]. Evidence is fast

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growing of the benefits of delayed umbilical cord clamping to the neonate at no or minimal potential risk to the mother and the newborn [1,2-18].

Anaemia is a global public health problem affecting the rich and the poor countries with major consequences for human health as well as social and economic development. Globally it affects 24.8% of the population [19, 20]. Anaemia is most prevalent among pre-school children (47.4%) and pregnant women [19, 20].Iron deficiency anaemia (IDA) contributes 50% of this global burden [19, 20].The World Health Organization (WHO) has risen to this challenge through food fortification with iron, iron supplementation and treatment of hookworm infestation among pre-school children [16]. Delayed Cord Clamping(DCC) results in an increase in birth weight (approximately 100 grams), increase haemoglobin concentration average of 1.5 g/dl with marked reduction in incidence of iron deficiency anaemia of about 61% , though with slightly increased risk of neonatal jaundice that may require phototherapy [1,2,4-10,12]. Recently with good evidence WHO has recommended DCC where possible as a way of improving the newborn iron store; 'What a good start'. However, there are variations in practice, perception and the optimal timing of cord clamping is yet to be established, with the fear that DCC is associated with maternal and fetal risk. The Cochrane review of 15 randomized controlled trials involving a total of 3911 women and infants pairs, showed no significant difference in severe postpartum haemorrhage when ECC and DCC were compared [3].There were however marked benefits of DCC to the neonate such as higher birth weight, haemoglobin concentration and increased iron store [3].This benefits needs however to be weighed against a slight increase in neonatal jaundice requiring phototherapy but not severe one [3]. In a meta-analysis of 15 RCT of full term infants(n=1912), Hutton and Hassan found a significant higher haematocrit among late cord clamping compared to early cord clamping at 48 hours after birth. Also they noted higher serum ferritin among DCC group compared to ECC group; this however was sustained till 2-3months after birth with a 33% risk reduction of deficient iron store at that age [2].At birth, blood flow through the umbilical cord usually continues for a few minutes. This additional volume transfused to the newborn during this time is called "placenta transfusion" [1, 4, 6, 8, 9, 23, 25].For a normal term birth, DCC will allow about 60-240 ml of placenta transfusion (an average of 100mls), this amount to about 20-30% of the new born blood volume and red cell mass[6,7,]. For those vigorous newborn a policy of delayed cord clamping will be recommended [1-18, 23, 27-32].

Early cord clamping (ECC) was previously recommended as part of active management of third stage labour and was adopted as a way of reducing postpartum haemorrhage (PPH). Post-partum haemorrhage on the other hand is a feared maternal obstetric complication after birth. It is said to have occurred after a blood

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loss of greater than or equal to 500mls from the genital tract following a vaginal delivery [7].It account for 25-30 % of maternal mortality especially in our environment with 576 maternal deaths per 100,000 live births [21].According to World Health Organization, 560 maternal death per 100,000 live births occurs in Nigeria and 510 per 100,000 live births occurs in the whole sub Saharan African (WHO, 2013) [22]. It therefore becomes fearful to allow PPH in an attempt to enhance neonatal haemoglobin through placenta transfusion. Delayed cord clamping (DCC) is claimed to increase the duration of third stage of labour leading to increased risk of PPH. This was not found to be so in that DCC on the other hand encourage drainage of the placenta bed promoting early placenta separation [8, 9]. Andersson O. et al (2011), found no significant difference in PPH between DCC and ECC [9, 35].

The practice of cord clamping and cutting is a routine obstetric procedure. It is easy to learn and can be performed by all skilled birth attendants [11, 15].The timing of this act becomes important especially in our environment with high prevalent of neonatal iron deficiency anaemia viewing the above innumerable benefits at minimal or no risk to the mother or the neonate if delayed to allow for placenta transfusion [4-7, 11-18].The timing of delayed umbilical cord clamping is variable as it is a range from thirty seconds to three hundred seconds or after cessation of cord pulsation. Having a fixed ideal time may be beneficial to allow for uniformity and easy communication. This study therefore aims to compare maternal and neonatal outcomes between early and delayed umbilical cord clamping among low risk women who had vaginal delivery in Irrua Specialist Teaching Hospital, Irrua.

II. Research Questions

1. Is there an ideal time for umbilical cord clamping?
2. Is delayed umbilical cord clamping really harmful than beneficial?
3. Are mothers more satisfied with delayed cord clamping than early cord clamping?

OBJECTIVES AND WORKING HYPOTHESIS

GENERAL OBJECTIVE

To assess the effects of delayed versus early umbilical cord clamping on maternal and neonatal outcomes in Irrua Specialist Teaching Hospital, Irrua, Nigeria.

SPECIFIC OBJECTIVES

To determine the effects of delayed cord clamping compare to early cord clamping on maternal outcome

To determine the effects of delayed cord clamping compare to early cord clamping on neonatal outcome

To determine the effects of placental weight and umbilical cord length on maternal and neonatal outcomes

To assess maternal satisfaction with third stage management between DCC and ECC.

NULL HYPOTHESIS (Ho)

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There is no difference in maternal and neonatal outcomes between early and delayed umbilical cord clamping.

ALTERNATE HYPOTHESIS

Delayed umbilical cord clamping offers favourable neonatal outcomes at no maternal or neonatal risk.

III. Patients and Methods

STUDY AREA

This study was conducted in the antenatal clinic, labour ward, post natal ward, special care baby unit (SCBU) and postnatal clinic of Irrua specialist teaching hospital (ISTH), Irrua from January to December, 2016. The department has a policy of early cord clamping as part of the active management of third stage of labour.

STUDY DESIGN

This was a prospective, three-armed, single centre randomized controlled (open label) trials

STUDY POPULATION

Eligible parturient who consented and met the inclusion criteria were recruited into the study.

SELECTION CRITERIA

INCLUSION CRITERIA:

Women presenting with singleton gestation that delivered vaginally at term and assessed as low risk.

EXCLUSION CRITERIA

Non vigorous live birth requiring urgent resuscitation

Women presenting with antepartum haemorrhage.

Women not stable requiring urgent resuscitation.

Diabetic mothers, retroviral disease patients and Rhesus negative mothers

Pregnant women with multiple gestations

SAMPLE SIZE DETERMINATION

Sample size was calculated from the formula for randomized controlled trial [47], given a significant level of 5% and power of 90%. The mean haematocrit for early umbilical cord clamping (ECC) by Kanwal et al 2012 was 32.8% [44], and the assumption that the use of DCC will improve this to 60%.

$N = [2x (Z\alpha + Z\beta)\ 2x\ P\ x\ (1-P)]/ (P0- P1)2$

P0 = proportion in the control group. = 32.8% = 0.328

P1 = proportion of the participants in the treatment groups. = 60% = 0.60

$P = (P0 + P1)/ 2 = (0.328 + 0.600) /2 = 0.928/2 = 0.464$

N = the desired sample size.

$Z\alpha = 0.05 = 1.96$

$Z\beta = 90\%$ power $= 0.9 = 1.28$

$N = [2 x (Z\alpha + Z\beta)\ 2x\ P\ x\ (1-P)] / (P0- P1)2$

$N = [2x (1.96 + 1.28)2x\ 0.464x\ 0.536]/ (0.328-0.60)2$

$N = 5.223/0.074$

N = 70.6

N = 70.6

To make up for attrition (non-response rate) or proportions of participant who are expected to

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leave the study or loss to follow up at 10% [59].

nS = N / 1-nrr

Where:-

nS = Actual sample size for research

nrr = non response rate (10%)

nS = 70.6 = 70.6 = 78.4
1-0.1 0.9

SAMPLING TECHNIQUE

A simple ballot randomization technique was used. Participants who met the inclusion criteria were recruited after an informed consent in the antenatal clinic and were re-enforced when they present in early labour during the expected period of the study until the desired sample size was achieved.

Randomization.

Intervention starts after allocating eligible candidates into the three study arms - A,B and C. Study arm A was for ECC(within 30seconds of birth) while Study arm B was for DCC which was done at 120 second sand study arm C those who had DCC for 180 seconds after birth while simultaneously basic newborn care was done. The time of birth was noted and with the midwife assistant monitoring time of cord clamping with the stop watch. All babies immediately after birth was placed on the same level with maternal bed while simultaneously basic new born care where done for the groups, while for group A immediate cord clamping and cutting was done and baby taken away from mother for basic new born care. The three groups had intravenous oxytocin 10 IU given and active management of third stage were done as per unit protocol except for the timing of the cord clamping.

Sample collection / data collection

After birth, visual estimation of blood loss (VEBL) was assessed and recorded on the data collection profoma on appendix C.

Maternal blood sample

Pre –labouror pre- partum packed cell volume (PCV) and 48 hours post-partum PCV, sample was collected from the mother's ante-cubital vein through aseptic technique. Five millilitres of blood was withdrawn into a sample bottle containing EDTA anticoagulant and was analysed within 48 hours.

Placenta weight was measured with a weighing scale while the umbilical cord length was measured with a tape rule in centimetre. This was initially measure with a thread of the two segments A and B representing the cord length from the placenta and the one to the baby respectively, and then added up. This was then recorded in the data collection profoma.

Neonatal blood sample

Neonatal blood sample also was collected from the dorsum of the hand or heel prick two capillary tubes were used to collect sample for packed cell volume (PCV) and five milliliters of blood into a plain bottle for serum ferritin. This was done at 48 hour of birth and repeated at 6 weeks postpartum.

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Laboratory Investigations:

Packed cell volume (PCV)

This was measured using the microhaematocrit capillary tube centrifuge – reader method. Sample was collected into capillary tube by capillary action, sealed off at one end with plasticine, and then placed inside the microhaematocrit centrifuge for spinning for five minutes at 1500 revolutions / minutes. Thespun samples were read off with the haematocrit reader in percentage the two values were added up and their averages were taken.

Serum Ferritin is the most important test for IDA [10, 12, 14, 21, 22].Its normal value is about 25-200ng/ml in the neonate [12, 47].The blood was immediately centrifuged and the serum was separated into a sealed tube and was stored in the deep freezer at −20°C till analysis, using ferritin ELISA kit by Calbiotech Inc.

Serum bilirubin; this was assessed with the use of transcutaneous bilirubinometer Dragger JM-103 model at 48 hours of birth. This was placed on the sternum of the neonate and preset to take five readings, and the cumulative average taken. A value greater than or equal to 12.0 mg/dl, is termed hyperbilirubinaemia as per neonatal unit protocol and blood sample collected from the baby into a plain bottle for serum bilirubin estimation using colorimetric method by Randox Laboratory limited, UK.

FOLLOW UP

Mother and babies were closely monitored during their stay in hospital till discharge. Physicians in the postnatal wards took care of the babies as per neonatal unit routines. All babies were discharged after establishment of demand breastfeeding. Residential address and telephone numbers of mothers were collected maintaining confidentiality this was used for follow‑up enquiries and at six weeks postnatal visit.

OUTCOME MEASURES

The patients' labor and delivery outcomes were reviewed after delivery.

The primary outcome measure in the study was;

1. Maternal admitting packed cell volume in labour, visual estimated blood loss after delivery, Postpartum packed cell volume 48 hours after birth.
2. Neonatal birth weight, APGARs core, packed cell volume, Serum ferritin, bilirubin at 48 hours of birth same repeated at six weeks postpartum except serum bilirubin.
3. Placenta weight and length of the umbilical cord.

The secondary outcome measures was

1. Maternal need forresuscitation, post-partum haemorrhage and need for blood transfusion.
2. Neonatal anaemia, hyperbilirubinaemia, polycythaemia, SCBU admission, phototherapy, exchange blood transfusion (EBT).

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Additionally, maternal satisfaction was assessed using a four stems questionnaire with summated rated scale 0-5 and categorized into three groups(poorly, fairly and very satisfied).

Data analysis

Data was collated and entered into SPSS version 20.0 (IBM) for analysis. Analysis involved baseline and hypothesis testing. Baseline analysis involved comparing of the baseline characteristics; mean birth weight, mean packed cell volume (PCV), serum ferritin and bilirubin between the three study arms using Fisher's exact test. Chi- squaretest was used for categorical variables and Student's t-test for comparing two groups means. Results were presented in tables, figures and percentages with 95% confidence intervals and P-value of 0.05.

ETHICAL CONSIDERATIONS

Approval for this study was obtained from the research and ethics committee of the ISTH, Irrua (ISTH/HREC/047). Written Informed consent was obtained from the participants before enlistment into the study and they still had the right to withdraw at any time after initial consent.

IV. Results

There were a total of 1205 deliveries in ISTH, Irrua from 1st January, 2016 to 31st December, 2016. A sample size of 234 mothers was randomized into three groups A, B and C on presentation to labour ward for delivery. A total of 218 mothers and babies pairs were analyzed out of which 75 (34.4%) where in group A, 72 (33.0%) in group B and 71(32.6%) in group C. Three participants were not allocated to intervention; one from group C who opted out after initial consent and two cases from group B which were canceled on account of severe maternal bleeding from extended episiotomy. Also three cases from group A, four cases from group B and six cases from group C defaulted from follow- up as shown in the trial chart of Figure 1.

The mean age of the participants was 27.6±7.5, 29.0± 4.8 and 28.1 ± 6.1 for groups A, B and C respectively. Twenty eight (37.3%), 24 (33.3%) and 19 (26.8%) of the participants were primigravida in groups A, B and C respectively while 47 (62.7%), 48 (66.7%) and 52 (73.2%) of the participants were multigravida in groups A, B and C respectively. This was comparable across groups and was not statistically significant (X2=5.160; P=0.269). Thirty one (41.3%), 26 (36.1%) and 30 (42.3%) mothers had secondary level of education while 42 (56.0%), 39 (54.2%) and 38 (53.5%) were unemployed in groups A, B and C respectively. Also the maternal pre-labour packed cell volume (PCV), post-partum PCV and maternal blood groups were similar across groups and was not statistically significant (p=

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0.229, 0.097 and 0.132 respectively) as shown in Table 1.

The mean visual estimated blood loss (VEBL) was 184.93±88.38 for ECC, 166.81±84.11 for DCC at 2 minutes and 195.63±99.45 for DCC at 3 minutes while the mean PCV difference were 1.41 ± 1.43 for ECC , 1.08 ± 0.73 for DCC at 2 minutes and 1.21 ± 0.74 for DCC at 3 minutes. There were no statistically significant difference across groups (P=0.161 and 0.148 respectively) as shown in Table 2.

Immediate neonatal outcomes with respect to birth weight was higher for DCC at 3 minutes than babies in the other group (P= < 0.001). The APGAR score at one minute were similar in the three study arms. The APGAR score at 5 minute of birth was higher for group A, followed by group B and then group C, though statistically significant (P=<0.001) it was not clinically significant as on the average none of the study arms have APGAR score at 5 minutes less than 7. The newborn packed cell volume at 48 hour of birth was higher in delayed groups B and C than group A, this was statistically significant(F=61.0, P <0.001).This was sustained at the six weeks postnatal follow up (F=7.1, P=0.001).The serum ferritin assay at 48 hours of birth was higher in the group B&C than group A (P=<0.001), this again was sustained at the six weeks postnatal follow up (P=<0.001).The transcutaneous bilirubin estimation, was higher in groups B and C than the early cord clamping group and was statistically significant (P=<0.001) as shown in Table 2.

All newborn in the early cord clamping group A had anaemia (using the WHO criteria of packed cell volume less than 45%) compared to group B and C even though none requires treatment, while polycythaemia occurs in 4.2% in group B and 8.5% in group C and non in group A; even though they were not symptomatic requiring treatment and it was statistically significant (P=<0.001) as shown in Table 3A. Amongbabies who developed hyper-bilirubinaemia and had SCBU admissions, they were comparable in the three study arms and was not statistically significant (P=0.715) as shown in Table 3B.Hyperbilirubinaemia was compared among cases with polycythaemia, study arms and maternal blood group, it was found that there was no statistical significant difference with respect to newborn polycythaemia and the study groups, but a statistically significant relationship was found with maternal blood group especially among mother with blood group O Rh D positive(P=0.011) as shown in Table 3C.

Delayed cord clamping at two minutes and three minutes had comparable maternal and fetal outcomes, however the mean placenta weight was higher in group C than group B (P= 0.032).The birth weight was also higher in group C than group B (P= <0.001).The APGAR score at 5 minutes is higher in group B than group C (P=0.001) as shown in Table 4A further analysis was done to compare ECC and DCC at 2minutes it was cleared

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statistically that DCC at two minutes is better than ECC as shown in table 5

Placenta weight and umbilical cord length were also compared across the different study groups, there was a significant reduction in placenta weight with increasing delay in cord clamping (P= <0.001), with no effect on maternal outcomes (P= <0.161 and 0.148 for VEBL and PCV diff. respectively) but had significant indirect effects on the neonatal outcomes. This was not seen with the cord length as it was comparable across the three groups (P= 0.401) as shown in Table 2.
Lastly, maternal satisfaction was compared across groups. Overall remark was fair in 81.2%; none of the participant was dissatisfied while 18.8% had good satisfaction. Maternal satisfaction increased with maternal age and across the study arms but not statistically significant with parity (P=0.004, 0.032 and 0.098for age, study arms and parity respectively) as shown in Table5.

V. Discussion

Umbilical cord clamping is one of the most unique procedures during child birth; however the optimal timing is quite controversial and yet to be clearly established [1,2]. There are evidences of neonatal benefits and potential minimal risk when delayed to allow for placenta transfusion without harm to the mother [1-7].This study clearly showed that delayed umbilical cord clamping is beneficial rather than harmful with no increased maternal or neonatal risk. There is however variation in opinion and practice of delayed cord clamping despite these ample evidences [12].This is not far-fetched as there are still fears of maternal risk of post-partum haemorrhage and neonatal risk of jaundice. Several authors including WHO, RCOG and ACOG have recommended delayed cord clamping for all newborn where possible with readily available facility for phototherapy as it affords greater benefits to the baby than the little risk of neonatal jaundice at no maternal risk [1, 6, 7, 12]. Traditionally cord clamping has been delayed till after cessation of cord pulsation until the era of male midwives and use of oxytocics when early cord clamping was advocated as part of the active management of third stage of labour with the aim to prevent maternal haemorrhage and also for prompt separation of the newborn for resuscitation [, 6, 15].

Maternal blood loss post-delivery is one of the major concerns of delayed cord clamping and a feared complication because of its contribution to maternal morbidity and mortality especially in our environment where maternal anaemia is prevalent [6, 19, 20]. This study clearly shows that there is no associated increased risk of maternal blood loss or postpartum haemorrhage from delayed clamping of the cord (VEBL: F=1.85, P= 0.161 and PCV difference: F=1.297, P=0.148).This is comparable to other previous findings [1,2, 5, 6, 7-12, 14-16].The Cochrane review by McDonald et al(2013), of 15 randomized controlled trials involving a total of 3911 women and infants pairs, showed no

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significant difference in severe postpartum haemorrhage when ECC and DCC were compared [3]. Andersson et. al., , (2011)found no significant difference in maternal post-partum haemorrhage between ECC and DCC [9].The mean blood loss is comparable across the three study arms with respect to visual estimated blood loss and mean packed cell volume difference. Though VEBL may be said to be subjective, PCV difference was added here to improve objectivity of estimated bloodloss, it however showed also no statistical difference between the study arms [3, 9, 24, 25, 26].

Delayed cord clamping is beneficial to the babies [6--9].Looking at the primary outcome measures of neonatal packed cell volume and serum ferritin, evidence has showed marked increase in packed cell volume and serum ferritin among DCC groups than ECC group[3, 5,6-10,12,15,16,24,35,39]. This study confirmed same with mean PCV of38.93±2.9%, 46.85±5.8% and 48.30±7.15% respectively for study arms A,B and C and this was statistically significant(F= 61.0 & P = <0.001) and at 6weeks post natal follow up, the mean PCV were 35.8±2.5%, 37.8±3.3% and 37.4 ±4.4%for group A,B and C respectively PCV which was also statistically significant(F=7.1, P= 0.001).Higher PCV was found in this study at 6 weeks in DCC groups as compared to that of the ECC group unlike other studies that found no difference in mean PCV when the babies were followed up six weeks post-delivery,[3]his is however similar to the systematic review of Van Rheenen et.al., , 2004 among developing countries[, 45].Ogundeyi MM in 2011 reviewed haematologial profile of apparently healthy term babies at one, three days and six weeks of birth and found out that the mean PCV were 43.3±7.1% and 32.0 ±4.8%on third day and sixth week respectively. This is higher than the PCV for ECC but lower than that for DCC [46].Similar findings was noted also in the serum ferritin level between ECC and DCC groups; mean serum ferritin was higher in study arm C followed by study arm B and lowest in study arm A at 48 hours of life. This was also sustained at the six weeks follow up visits with mean serum ferritin of89.52±13ng/ml, 175.67±17.70 ng/ml and 181.90±33.04 ng/ml for groups A, B and C respectively. This is in keeping with other previous studies [1,4-6] and Krishnan et. al .,(2015) in a RCT of 76 mother infant pairs found a mean serum ferritin level of 299 and 399ng/ml in ECC versus DCC groups at 6 weeks of life respectively[39]

On review of secondary outcomes measures for the new babies, with the World Health Organization cut-off of PCV< 45% for anaemia, all babies in the ECC group had anaemia compared to the delayed groups (36.1% and 32.4% in group B and C respectively).No wonder the raised alarm of Erasmus Dawin (1731–1802) “anything very injurious to the child is tying and cutting the naval string too soon; which should always be left till the child has not only repeatedly breathed but till all pulsation in the cord ceases. As other with the child is much weaker

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than it ought to be, a portion of the blood being left in the placenta which ought to have been in the child" [42].Week et. al., (2007) opined that if ECC was a drug with growing evidence of harm, it would have been withdrawn immediately [30].Anaemia is a major public health concern for the low and middle income countries (LMIC), when compared to the little found in the developed countries as they have access to available iron rich foods and iron supplement [19,20]. Delayed cord clamping will be a major starting point for anaemia prevention in our children; no wonder the WHO has approved it where possible and therefore opined that ECC is contraindicated as part of the AMTSL [19,20].

Another most fear risk of DCC is the increased risk of neonatal jaundice. This is postulated to result from excess blood load and increased risk of polycythaemia. Many studies have looked at this and concluded a slight increase risk that is amenable to phototherapy but not for severe form of hyperbilirubinaemia [3,,4-10,12,15,16,23,35,39].This study clearly showed that the mean transcutaneous bilirubin estimation at 48 hours of birth was higher among group B and C and was statistically significant (F=11.1, P= <0.001); however for cases of hyperbilirubinaemia as reported using the unit protocol of total serum bilirubin of 12mg/dl there was no difference between the study arms(F=0.4,p=0.684). This is very comparable to other studies [3, 5, 6-10, 12, 15, 16, 23, 35, 39].This study went further to follow up cases of hyperbilirubinaemia admitted for clinical jaundice and treated with phototherapy majority of cases in over 80% were attributable to ABO incompatibility especially for mothers with blood group O Rh D positive (x2=11.7, p=0.011).. This is unique to this study as previous studies have not look in to this.

This study also compares maternal and babies outcomes of ECC and DCC at two minutes; it was evidence that DCC at two minutes is better in terms of good fetal outcomes compared to ECC. On further analysis, this study also shows that delayed cord clamping for two minute when compared with that at three minutes of life is equally effective as three minutes delay with respect to fetal outcomes except for birth weight and APGAR score at 5 minute. The average birth weight is higher for group C than for group B, although statistically significant; it may not be clinically significant as the average birth weight in our environment is 3.1kg which is the same for group B. This same argument goes for the difference in APGAR score at 5 minutes; it is not less than seven. It may be justifiable to consider two minutes as the optimal time for delayed cord clamping that can be uniformly communicated as there is no much benefit waiting. Arulkumaran et. al., (2011) stated that most infant complete placenta transfusion in two minutes and a few other later till five minutes[12].Cernadas et. al., (2006) compared DCC at 3minutes, 1minute and ECC in a RCT in two obstetrical units and found that the fetal outcomes at 1 minute and 3 minutes were better than for ECC though he did not compare one and three minutes of

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delay but mean packed cell volume was much higher in the three minutes group[40].Most past studies consider DCC for a minimum of 2 minutes till cessation of cord pulsation however there is still much variation; thus having a unified optimal time is therefore desired to break this long controversies.

Another area unique to this study is the placenta weight and umbilical cord length as it may affect the outcome of delayed cord clamping and early cord clamping. Farrar et. al., has looked at birth weight variation between DCC and ECC with the babies weighed with the placenta intact and found increased birth weight among DCC groups [5]. This study showed a reduced placenta weight among DCC groups B and C compared to ECC group A and was statistically significant (F=64.92, p=<0.001)this reduced placenta weight reflects an indirect relation to the placenta transfusion and fetal outcomes. The umbilical cord length is comparable in the three study arms and was not statistically significant (F=0.919, p=0.401).

This study also uniquely looked at maternal satisfaction of third stage management with respect to the three study arms of ECC versus DCC. The knowledge of the choice of the time for cord clamping among mother for their baby is very poor as majority over 98% are not aware. The overall remark of satisfaction was fair across the three study arms and none had poor satisfaction, this was statistically significant when compared to age and study arms but not to parity. This is an area that still requires more research.

VI. CONCLUSION

This study shows that DCC improves babies packed cell volume and serum ferritin at 48 hours of birth which remained higher in DCC groups as compared to ECC group, six weeks of life with no significant maternal risk of postpartum haemorrhage and neonatal hyperbilirubinaemia / SCBU admission. Delayed cord clamping for two minutes is equally effective as that of three minutes in respect to maternal and fetal outcomes, it is the optimal time in our environment. The hyperbilirubinaemia, thought to be higher with DCC may be attributable to ABO incompatibility. There is significant placenta weight reduction with DCC compared to ECC but no difference with umbilical cord length. Maternal satisfaction is comparable between DCC and ECC however it increases with maternal age but not parity.

RECOMMENDATION

Delayed umbilical cord clamping is more beneficial rather than harmful with two minutes of delay after birth recommended as an ideal optimal time.

LIMITATIONS OF THE STUDY

1. This is a tertiary hospital based study. This result may not reflect the findings in the generality of the different categories of the health facilities in the country because of referral. I ensured that only booked pregnant

women are used for his study and a multi-centered study will also help.

2. This study is a randomized controlled trial, which should have blinding to reduce bias but the intervention is such that it is difficult to blind the Obstetricians/ midwives. The neonatal unit and the laboratory physicians were blinded by means of research coded number for identification to help reduce bias.

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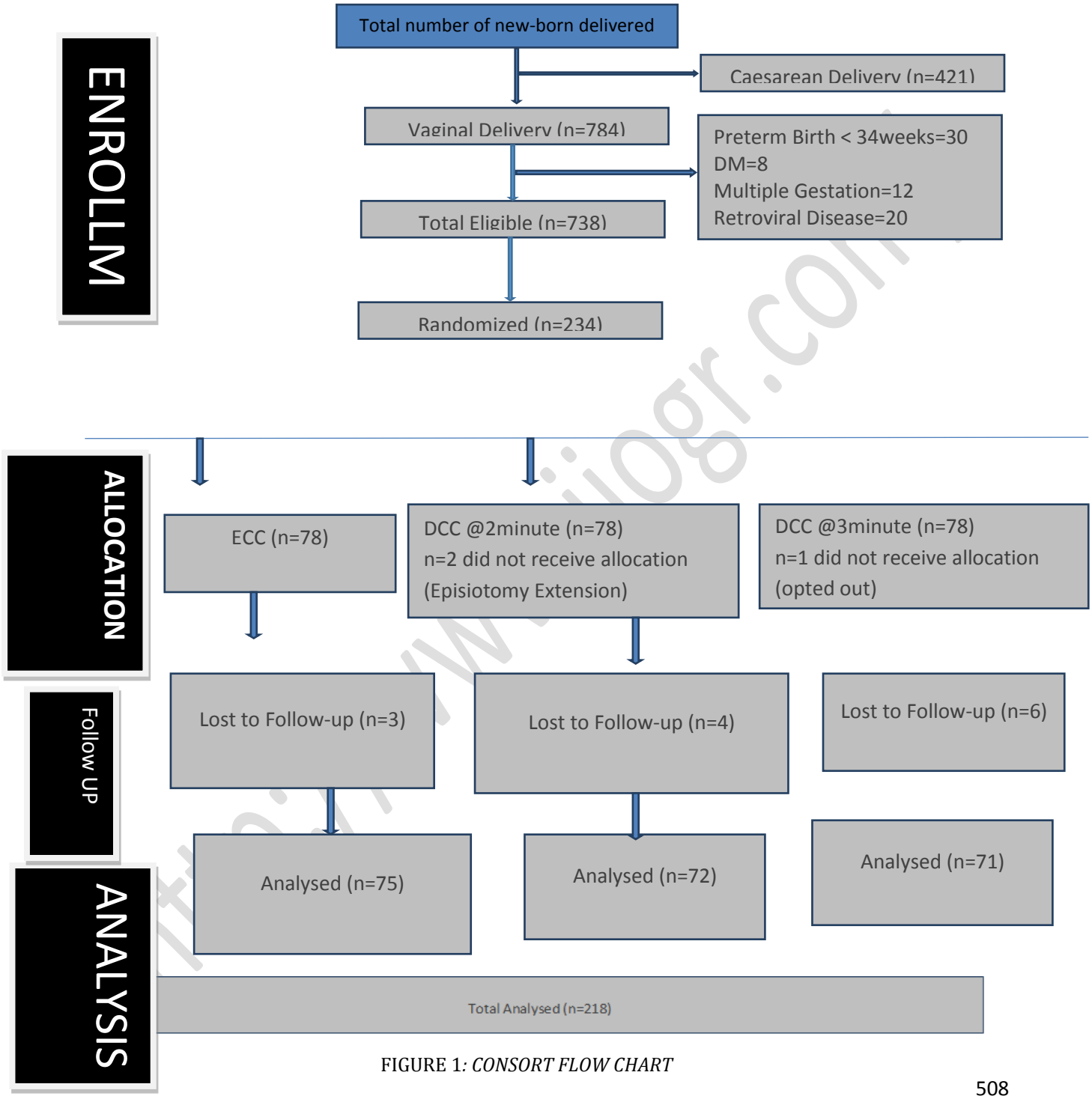

FIGURE 1*: CONSORT FLOW CHART*

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TABLE 1. MATERNAL SOCIO-DEMOGRAPHIC CHARACTERISTICS, PRE-LABOUR, POST PARTUM PACKED CELL VOLUME AND BLOOD GROUP ACROSS GROUPS.

Characteristics	Group A	Group B	Group C	F-value	P- value
Mean age	27.6±7.5	29.0±4.8	28.1±6.1	23.721	<0.001
Parity: Primigravida	28 (37.3%)	24(33.3%)	19 (26.8%)		
Multigravida	47 (62.7%)	48 (66.7%)	52 (73.2%)	5.160	0.269

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Level of education:					
No formal education	10 (13.3%)	13 (18.1%)	8 (11.3%)		
Primary	18 (24.1%)	16 (22.2%)	13 (18.3%)		
Secondary	31 (41.3%)	26 (36.1%)	30 (42.3%)		
tertiary	16 (21.3%)	17 (23.6%)	20 (28.1%)		
Occupation: Employed	22 (29.3%)	28 (38.9%)	30 (42.3%)		
Unemployed	42 (56.0%)	39 (54.2%)	38 (53.5%)		
Student	11 (14.7%)	5 (6.9%)	3 (4.2%)		
Maternal blood group:A+	6 (30%)	7 (35%)	7 (35%)		
B+	20 (30.8%)	26 (40%)	19 (29.2%)		
O+	46 (37.4%)	39 (31.7%)	38 (30.9%)		
AB+	3 (30.5%)	0 (0.0%)	7 (70%)	9.642	0.132
Mother Pre-Labour PCV	34.44±4.02	34.50±2.87	35.30±2.92	1.484	0.229
Mother Post-Partum PCV	33.03±3.43	33.42±2.75	34.08±2.63	2.358	0.097

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PCV= Packed cell volume, A = ECC within 30 seconds; B =DCC at 2 minutes; C- DCC at 3 minutes

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TABLE 2: MATERNAL &FETAL OUTCOMES: COMPARISONOF MEANS OFVEBL, PCV DIF, PLACENTA WEIGHT, UC LENGTH, BIRTH WEIGHT, APGAR SCORE, TRANSCUTANEOUS BILIRUBIN, AND SERUM BILIRUBIN, PACKED CELL VOLUMEAND SERUM FERRITIN ACROSS GROUPS.

OUTCOME MEASURE	Group A	Group B	Group C	F-Test	P –Value
PCVdiff. (%)	1.41±1.43	1.08±0.73	1.21±0.74	1.297	0.148
VEBL	184.93±88.38	166.81±84.11	195.63±99.45	1.845	0.161
Placenta weight(kg)	0.85±0.08	0.67±0.12	0.71±0.12	64.92	< 0.001*
Cord length (cm)	54.61±7.04	55.13±11.27	56.49±6.88	0.919	0.401
APGAR Score @ 1min	8.6±0.6	8.6±0.5	8.5±0.5	0.8	
APGAR Score @ 5mins	9.2±0.5	9.2±0.4	8.9±0.7	8.1	<0.001*
Baby PCV at 48 hours (%)	38.9±2.9	46.9±5.8	48.3±7.2	61.0	<0.001*
Serum Ferritin at 48 hours (ng /ml)	53.87±8.65	79.19±11.64	81.38±11.69	150.0	<0.001*
Transcutaneous bilirubin (mg /dl)	4.93±2.93	6.45±3.14	7.24±3.01	11.1	<0.001*
Serum Bilirubin at 48 hrs ifTCB is 12+ (mg/dl)	12.9±0.87	12.6±1.2	12.9±0.9	0.4	0.684
Baby PCV at 6 weeks after birth (%)	35.8±2.5	37.8±3.3	37.4±4.4	7.1	0.001*
Serum Ferritin at 6 weeks (ng/ml)	89.5±13.2	175.7±17.7	181.9±33.0	379.1	<0.001*

***Statistically significant. A = ECC within 30 seconds; B =DCC at 2 minutes; C= DCC at 3 minutes ; TCB= Transcutaneous bilirubin.**

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TABLE 3: SECONDARY FETAL OUTCOMES

TABLE 3A: RELATIONSHIP BETWEEN STUDY GROUPS AND LEVEL OF PCV

	LEVEL OF PACKED CELL VOLUME			X^2	P-Value
GROUPS	**ANAEMIA**	**NORMAL**	**POLYCYTHAEMIA**		
A	75(100.0 %)	0(0.0)	0(0.0)		
B	26(36.1 %)	43(59.7)	3 (4.2)		
C	23(32.4 %)	42 (59.2)	6 (8.5)	**88.353**	**< 0.001***

Table 3B: COMPARING HYPERBILIRUBINAEMIA, NEED FOR SCBU ADMISSIONS AND POLYCYTHAEMIA ACROSS GROUPS

GROUP	BILIRUBINAEMIA / SCBU ADMISSION		X^2	P-Value
	HYPER / YES	NORMAL / NO		
A	9 (12.0 %)	66 (88)		
B	10 (13.9 %)	62 (86.1)	0.728	0.715
C	12 (16.9 %)	59(83.1)		

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LEVEL OF PACKED CELL VOLUME	BILIRUBINAEMIA			
	HYPER	NORMAL		
Anaemia	10(32.3 %)	114(61.0)	9.19	0.08
Normal	18(58.1 %)	67(35.8)		
Polycythaemia	3(9.7 %)	6(3.2)		

*Statistically significant. A =ECC within 30 seconds; B =DCC at 2 minutes; C= DCC at 3 minutes.

TABLE 3 C: RELATIONSHIP BETWEEN MATERNAL BLOOD GROUP AND LEVEL OF BILIRUBIN IN THE BABIES

Mother Blood Group	**Bilirubinaemia**	
	Hyper (%)	Normal (%)
A^+	0 (0.0)	20 (10.7)
B^+	4 (12.9%)	61 (32.6)
O^+	26 (83.9%)	97 (51.9)
AB^+	1 (3.2%)	9 (4.8)

$X^2 = 11.7$, P-value = 0.011

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TABLE4: COMPARISONOF MATERNAL AND FETAL OUTCOMES BETWEEN GROUP B (DCC AT 2 MINUTES) AND GROUP C (DCC AT 3 MINUTES).

Outcome measure	Group B	Group C	t- value	P value
VEBL (mls)	166.81±84.11	195.63±99.50	3.506	0.064
PCV DIFF (%)	1.08±0.73	1.21±0.73	1.095	0.297
PLACENTA WT.(Kg)	0.67±0.12	0.71±0.12	4.702	0.032*
UMB. CORD LENGTH(cm)	55.13±11.27	56.49±6.88	0.766	0.383
BIRTH WT (kg)	3.14±0.35	3.43±0.40	19.470	<0.001*
APGAR Score @ 1	8.56±0.50	8.51±0.50	0.334	0.564
APGAR Score @ 5	9.20±0.40	8.90±0.68	12.056	0.001*
BABY PCV (%) @ 48	46.85±5.79	48.30±7.15	1.775	0.185
SERUM FERRITIN (ng/ml) @ 48 hours	79.19±11.64	81.38±11.69	1.255	0.265
TCB ESTIMATE (mg/dl)@ 48 hours	6.45±3.14	7.24±3.01	2.350	0.128
SERUM BILIRUBIN (mg/dl)	12.58±1.19	12.89±0.87	0.506	0.485
BABY PCV @ 6WKS (%)	37.83±3.31	37.37±4.42	0.513	0.475
SERUM FERRITIN (ng/ml)@ 6WKS	175.67±17.70	181.90±33.04	1.986	0.161

***Statistically significant. B =DCC at 2 minutes; C=DCC at 3 minutes; TCB=transcutaneous bilirubin; PCV =packed cell volume.**

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TABLE 5: COMPARISON OF MATERNAL AND FETAL OUTCOMES BETWEEN GROUP A (ECC WITHIN 30 SECONDS) AND GROUP B (DCC AT 2 MINUTES)

OUTCOMES MEASURES	GROUP A	GROUP B	t- test	p- value
VEBL	184.9±88.4	166.8±84.1	1.620	0.205
PCV DIFFERENCE	1.4±1.4	1.1±0.7	3.06	0.82
BIRTH WEIGHT	3.2±0.4	3.1±0.4	0.532	0.467
APGAR SCORE @1	8.6±0.6	8.6±0.5	0.428	0.514
APGAR SCORE @5	9.2±0.5	9.2±0.4	0.231	0.632
NEWBORN PCV @48HRS	38.9±2.9	46.8±5.8	11.54	<0.001*
SERUM FERRITIN@ 48HRS	53.9±8.6	79.2±11.6	225.6	<0.001*
TCB	4.9±2.9	6.4±3.1	9.30	0.003*
SERUM BILIRUBIN	12.9±0.9	12.6±1.2	0.535	0.474
PCV @6WEEKS	35.8±2.5	37.8±3.3	18.153	<0.001*
SERUM FERRITIN@6WEEKS	**89. 5±13.2**	**175.7±17.7**	**367.9**	**<0.001***

***Statistically significant. A = ECC within 30 seconds; B =DCC at 2 minutes TCB =transcutaneous bilirubin**

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TABLE 6: MATERNAL SATISFACTION WITH THIRD STAGEMANAGEMENT IN RELATION TO AGE, PARITY AND ACROSS GROUP.

	Poor	Fair	Good	X^2	P-Value
AGE					
15-24	0 (0%)	43 (71.7)	17 (28.3)		
25-34	0 (0%)	102 (81.0)	24 (19.0)		
35-44	0 (0%)	32 (100.0)	0(0.0)	10.983	0.004*
PARITY					
1	0 (0%)	57(80.3)	14(19.7)		
2-4	0 (0%)	102(79.1)	27(20.9)		
4+	0 (0%)	18(100.0)	0(0.0)	4.589	0.098
GROUPS					
A	0 (0%)	60 (80.0)	15 (20.0)		
B	0 (0%)	65 (90.3)	7 (9.7)		
C	0 (0%)	52 (73.2)	19 (26.8)	6.903	0.032*

***Statistically significant. A =ECC within 30 seconds; B =DCC at 2 minutes; C= DCC at 3 minutes**