

Effect of Delayed versus Early Cord Clamping on Neonatal Outcomes and Iron Status at 4 Months

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Abstract

Background: The optimal timing of umbilical cord clamping has been debated in the scientific literature for over a century. Early clamping of the umbilical cord is widely practised as part of the management of labour. Early clamping of the cord was one of the first routine medical interventions in labour. Its place in modern births was guaranteed by its incorporation into the triad of interventions that make up the active management of the third stage of labour. Babies who have immediate cord clamping have also been shown to be more likely to be anaemic, have decreased fine motor skills, and have decreased social skills during their first few years of age. Delayed umbilical cord clamping appears to have clear benefit for term infants. Delayed umbilical cord clamping increases hemoglobin levels at birth and improves iron stores in the first few months of life, which improve the developmental outcomes. There is growing evidence that delayed cord clamping is beneficial and can improve the infant's iron status for up to 6 months after birth. For the first few minutes after birth, there is still circulation from the placenta to the infant. Waiting to clamp the umbilical cord for 2 - 3 min, or until cord pulsations cease, allows a physiological transfer of placental blood to the infant (placental transfusion), the majority of which occurs within 3 min. This placental transfusion provides sufficient iron reserves for the first 6 - 8 months of life, preventing or delaying the development of iron deficiency until other interventions. WHO's findings suggest that late cord clamping (one to three minutes after delivery or longer) is recommended for all births. **Aim of the study:** 1) To evaluate the benefit of delayed cord clamping on the infant's health status. 2) To assess hemoglobin, iron and ferritin at birth and at 4 months of age in infants who underwent early cord clamping (at 30 seconds) as compared with infants who underwent delayed cord clamping (at

60 seconds). **Methods:** A randomized controlled trial was conducted in Benghazi Medical Center and Elmgharif Hospital at Ejdabia. Study population was 256 women. The participants were randomized to delayed cord clamping or early cord clamping study groups. The data were checked manually for completeness, coded and analyzed by using Statistical Package for Social Sciences (SPSS). The incidence, relative risk, risk reduction, frequency percentage, mean, and standard deviation were used. Also t-test and chi square test (to test difference between means and proportions respectively) were used to compare between early and late cord clamping groups. **Results:** Two hundred forty seven participants completed the study (the attrition rate was 3.5%); 121 (49%) were control group (early cord clamping) and 126 (51%) were study group (delayed cord clamping) group. At birth no significant difference between two groups regarding the level of hemoglobin, iron and ferritin. At 4th month of age delayed cord clamping was associated with improved hemoglobin, iron and ferritin and that the incidence of anemia among infants who exposed to delayed cord clamping was 0.07, while the incidence of anemia among the infants who exposed to early cord clamping was 0.5. **Conclusion:** There was strong association between delayed umbilical cord clamping and improvement of iron indices and developmental milestones in infants at 4th month of age.

Keywords

Early Umbilical Cord Clamping, Umbilical Cord Clamping, Anaemia, Hemoglobin Ferritin, Polycythemia, APGAR Score

1. Introduction

The optimal timing of umbilical cord clamping has been debated in the scientific literatures for over a century. Early cord clamping is generally carried out in the first 60 seconds after birth [within the first 15 - 30 seconds], whereas delayed umbilical cord clamping is carried out more than one minute after birth [1]. In early 19th century the English physician Erasmus Darwin mentioned [another thing very injurious to child is the tying & cutting of the navel string too soon, which should always be left till the child has not only repeatedly breathed but till all pulsations in the cord ceases, as otherwise the child is much weaker than it ought to be, a portion of blood being left in the placenta which ought to have been in the child] [2] [3]. Many studies do not include actual timing of the delayed cord clamping; however it can range from 30 seconds to 180 seconds; some say there are no benefit of waiting beyond 60 seconds [4] [5].

In Queensland center the average time for delayed cord clamping is approximately 3 minutes [6]. The National Institute for Health and Care Excellence (NICE) recommends that the cord is not clamped in first 60 seconds except where there are concerns about the cord integrity or the baby's heart rate [7].

Chaparro investigated whether a 2 minutes delay in cord clamping (after deli-

very of the infants shoulder) would improve iron stores & hematological status in full term infants at 6 months of age as compared to early cord clamping around 10 seconds after delivery. At 6 months of age infants who were subjected to delayed cord clamping had higher mean cell volume, a higher ferritin levels and higher iron stores [8]. The effects of delayed cord clamping were more pronounced in infants born to mothers with low ferritin at delivery, in breast-fed infants, and in infants with birth weight 2500 - 3000 gm [9] [10].

An extensive comparison of early cord clamping and delayed cord clamping was done by Moss, Monset-couchaard; based on 84 studies and it was concluded that delayed cord clamping was associated with higher hemoglobin and hematocrit levels [11].

At birth placental circulation is cut off and the peripheral resistance suddenly rises. The pressure in the aorta rises until it exceeds that in pulmonary artery; mean while, because of placental circulation has been cut off, the infant becomes increasingly asphyxiated. Finally the infant gasps several times, and the lungs expand. The markedly negative intrapleural pressure during the gasps contributes to the expansion of the lungs, but other factors are likely also involved. The sucking action of first breath plus constriction of umbilical vein squeezes as much as 100 ml of blood from the placenta [placental transfusion] [12]. There is no cut off of placental circulation at birth, although there is steady closure over the first 5 minutes after birth [13]. A sudden rise in pressure has been shown to occur after early cord clamping [14]. A steady rise in the arterial pO₂ and a similar rise in venous pO₂ up to 45 seconds after birth. The statement that the infant gasps because of the asphyxia from the loss of placental circulation is only true after cord clamping but it would not be true in a normal physiological transition [15].

Anemia is one of the common disorders not only among adults, but also in children & infants too. In developing countries prevalence of iron deficiency anemia is highest among children aged less than five years. It is estimated that around 50% of children become anemic by the age of 12 months [16] [17] [18] [19]. Strategies to reduce iron deficiency anemia in infants include iron supplementation and iron fortification, both are either cost-ineffective or difficult to implement, especially in developing countries [8]. Prevention of iron deficiency anemia in infancy is there of priority, a first step towards reducing anemia in infancy can be taken during birth by cost effective intervention by delayed cord clamping [20]. Our study were first time done in Libya and our hospital was conducting about 80 - 100 deliveries per day about 20 - 25 of them are cesareans section early cord clamping are applied for all of them after this study result most of the midwives and doctors started delayed umbilical cord clamping for premature and mature infant.

2. Subjects and Methods

Study period: 15-7-2017 to 15-12-2017.

Reference population: Pregnant women in Benghazi and Ejdabia.

Study area: Bengahazi Medical Center and Elmgharif Hospital at Ejdabia city.

Study design: A randomized controlled trial (parallel design).

Sample size: 256 pregnant women, 247 of them completed this study, 179 were from Ejdabia and 68 from Benghazi, 121 (control group) early cord clamping & 126 (study group) delayed cord clamping.

Calculation of the sample size:

1) The sample size was calculated by using OpenEpi software for epidemiologic statistics. Version 3.01

(<https://www.openepi.com/SampleSize/SSCohort.htm>).

From a previous study in other developing country, the frequency of anemia among infants with early cord clamping (unexposed to delayed cord clamping) was 15.3% and the frequency of anemia among infants with delayed cord clamping (exposed) was 5.5%.

| Sample Size: X-Sectional, Cohort, & Randomized Clinical Trials | | | |
|--|--------|--------|----------------|
| Two-sided significance level(1-alpha): | | | 95 |
| Power(1-beta, % chance of detecting): | | | 80 |
| Ratio of sample size, Unexposed/Exposed: | | | 1 |
| Percent of Unexposed with Outcome: | | | 15 |
| Percent of Exposed with Outcome: | | | 5.5 |
| Odds Ratio: | | | 0.32 |
| Risk/Prevalence Ratio: | | | 0.36 |
| Risk/Prevalence difference: | | | -9.8 |
| | Kelsey | Fleiss | Fleiss with CC |
| Sample Size-Exposed | 151 | 150 | 170 |
| Sample Size-Nonexposed | 151 | 150 | 170 |
| Total sample size: | 302 | 300 | 340 |

References

Kelsey *et al.*, Methods in Observational Epidemiology 2nd Edition, Tables 12-15

Fleiss, Statistical Methods for Rates and Proportions, Formulas 3.18 & 3.19

CC = Continuity Correction

Results are rounded up to the nearest integer

2) The sample size was 302, by exclusion of women who were not eligible (had at least one exclusion criterion) and who were not agree to participate the sample size became 256 women. The randomization was performed to allocate 128 for delayed cord clamping group and 128 women for early cord clamping. 9 women refused to complete the study the attrition rate was 3.5%.

Study population: Patients at labor who attend Benghazi Medical Center and Elmgharif Hospital obstetric department in the period between 15-7-2017 and 15-8-2017.

Eligibility criteria: Pregnant women at 37 - 42 weeks of gestation, Rh + ve, with single fetus, who was delivered by normal vaginal delivery, and who agreed to participate in the study and signed an informed consent.

Randomization: The process of randomization is carried out to ensure the comparability between the study group and control group; it eliminates the selection bias, balances the groups with respect to many known and unknown confounding or prognostic variables, and forms the basis for statistical tests. As there was a difficulty in contacting the patients before the first stage of labor, the process of randomization carried out at the first stage of labor between every 2 eligible and agreed patient by rolling a fair six sided dice (e.g. below and equal to 3-control, over 3-study).

This procedure was continued until the planned number of the cases was completed.

Blinding: Both, the patient and the person who was conducted the assessment of the infants at birth and at 4th month of age was not know whether the mother belong to study group or control group (The lists of the study and control groups (The lists of the study and control groups according to the randomization will be known by the investigator only).

Procedure and tool of data collection:

An interview with every eligible patient was undertaken by the investigator with aid of an interview performa.

Intervention: The labor conduction and the umbilical cord clamping was undertaken by a midwife at labor room. The infant with early umbilical cord clamping were compared with those delayed umbilical cord clamping (clamping the cord clamping at 1 min). Delivery of infant shoulder was accepted as zero time. The new born baby was put over mother abdomen then umbilical cord was clamped as early or delayed. After clamping the umbilical cord venous blood was obtained from the double clamped umbilical cord of both groups for complete blood count (collected in EDTA tubes) and for serum iron and ferritin (collected in plain tubes), and blood samples was transported to clinical laboratory where they were analyzed.

First medical assessment of the new born was done by the pediatrician at labor room.

Follow up and final assessment: CBC of the newborns done after 48 and before 72 hours of delivery.

The final assessment was undertaken for every infant when he/she at 4 months of age, where the complete medical history, medical examination, assessment of developmental skills, and relevant investigations were performed with aid of follow up sheet.

Data management (coding, entering and analysis): The data were checked manually for completeness, coded and analyzed by using the Statistical Package for the Social Sciences (SPSS) program ver.23.

Measurements and statistics used: Incidence rate of any benefit or complication-relative risk and risk reduction with 95% CI-Descriptive statistics such as;

frequency, percentage, mean, and standard deviation was used. Inferential statistics such as; independent sample T Test, and chi square test to test the differences between means and proportions respectively. $p > 0.05$ will be used to denote statistical significance.

Variables:

At birth:

- Birth weight;
- Apgar score;
- CBC;
- Serum iron;
- Serum ferritin ;

At fourth months:

- Weight;
- CBC;
- Serum iron;
- Serum ferritin;
- Frequency of infections;
- Some milestones.

Ethical consideration:

A formal letter: from department of Obstetrics and Gynaecology at University of Benghazi was send to every hospital requesting the director of hospital as applicable to allow the researcher to conduct the study.

- Patients were informed about the purpose of the study before conducting the interview and were told that participation will be voluntary.
- Before participation in the study every patient signed an informed consent.

Operational definition of variables:

Early cord clamping: is defined as clamping of umbilical cord at 30 seconds of birth.

Delayed cord clamping: is defined as clamping of umbilical cord at 60 seconds of birth.

Normal maternal hemoglobin: is 11 - 13.8 gm/dl.

Normal infant hemoglobin at birth: mean 16.5 gm/dl (-2SD: 13.5 gm/dl).

Normal infant hemoglobin at the 4th month: mean 11.5 gm/dl (-2SD: 9.5 gm/dl).

Average infant weight at birth: 2.5 Kg - 4.0 Kg.

Normal infant weight gain in first 3 - 6 months is 150 - 200 grams per week.

Normal infant serum ferritin: is 20 - 350 ng/ml.

Normal infant serum iron: is 59 - 158 mcg/dl.

Polycythemia: is defined as hematocrit increased to >65% of normal level.

APGAR score: is determined by evaluating the new born baby on 5 simple criteria (Apperance, Pulse, Grimace, Activity, Respiratory effort) on a scale from zero to two, then summing up the 5 values, the resulting score range from 0 - 10.

3. Results

Out of 256 women, 247 pregnant women completed this study; the attrition rate was 3.5%. One hundred seventy nine (72.5%) of the 247 women were from Ej-dabia and 68 (27.5%) were from Benghazi (Figure 1).

150 women were randomly allocated as a control group (early cord clamping) and 150 women as a study group (delayed cord clamping), at the end of the study 121 (49%) women of the control (early cord clamping group), and 126 (51%) women of the study group (delayed cord clamping) completed the study (Figure 2).

Table 1 shows that no significant difference between females with early cord clamping and females with delayed cord clamping regarding their age, gestational age, hemoglobin level, parity, number of pregnancies and abortions.

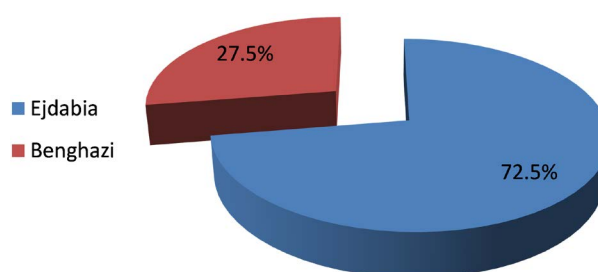


Figure 1. Distribution of the women according to their place of residence.

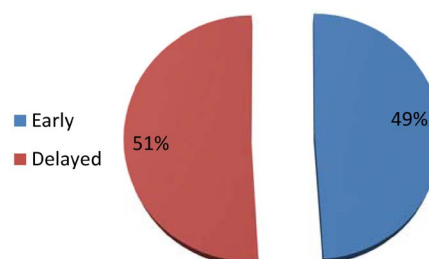


Figure 2. Distribution of the women according to time of cord clamping.

Table 1. Characteristics of women with early cord clamping versus women with delayed cord clamping.

| Maternal characteristics | Study groups | | t | p-value |
|--------------------------|--------------------------------------|--|--------|---------|
| | Early cord clamping group N = 121 | Delayed cord clamping group N = 126 | | |
| Age | 28.50 (±5.8) | 29.50 (±5.5) | 1.831 | 0.167 |
| Gestational age | 39.23 (1.11) | 39.19 (0.98) | 0.246 | 0.806 |
| Hemoglobin level | 10.41 (±1.10) | 10.31 (±1.12) | 0.672 | 0.502 |
| Parity | 2.17 (±1.80) | 2.55 (±1.70) | 1.662 | 0.98 |
| Gravid | 3.80 (±2) | 3.68 (±2.08) | 0.489 | 0.626 |
| Abortion | 0.30 (±0.5) | 0.38 (±0.6) | 0.0937 | 0.350 |

Table 2 shows the frequency of anemia among infants at birth, where 100 (40.49%) were anemic, there was no significant difference (chi square = 0.066, p-value = 0.798) in occurrence of anemia between the infants in both early and delayed cord clamping groups.

Table 3 shows that no significant difference ($p > 0.05$) between neonates born to women in both study group and control group regarding health indicators; birth weight and Apgar score. Also there is no significant difference ($p > 0.05$) between them regarding the level of some hematological indicators.

Table 4 shows that the infants who underwent delayed cord clamping have significantly ($p < 0.001$) higher level of hemoglobin, serum iron and serum ferritin.

Table 5 shows that the anemia is significantly more among infants with early cord clamping (Chi square = 69.436 and p-value < 0.001) also from **Table 4** the incidence of anemia among the infants during their 4th. month of age, who exposed to delayed cord clamping is 0.078, while the incidence of anemia among the infants who exposed to early cord clamping is 0.587, the relative risk (R.R) is 0.133, which means there are a negative association between delayed cord clamping and occurrence of anemia and the delayed cord clamping is protective against anemia in infants at age of 4 months. The absolute risk reduction is 49.95%, 95% confidence interval: [39.88%, 60.01%]

Table 2. Distribution of the infants by the time of cord clamping and the level of their hemoglobin at birth.

| Time of cord clamping | Hemoglobin level (gm/dl) | | Total | Chi square = 0.066 p-value = 0.798 |
|-----------------------|--------------------------|--------------|---------------|---------------------------------------|
| | <13.5 | ≥13.5 | | |
| Early | 48 (19.43%) | 73 (29.55%) | 121 (48.89%) | |
| Delayed | 52 (21.06 %) | 74 (29.96%) | 126 (51.02%) | |
| Total | 100 (40.49%) | 147 (59.51%) | 247 (100.00%) | |

Table 3. Health and hematological indicators at birth, for neonates born to early cord clamped group versus neonate born to delayed cord clamped group.

| Neonate health and hematological indicators at birth | Study groups | | t | p-value |
|--|--------------------------------------|--|-------|---------|
| | Early cord clamping group N = 121 | Delayed cord clamping group N = 126 | | |
| Apgar score | 9.72 (±0.56) | 9.74 (±0.64) | 0.246 | 0.806 |
| Hemoglobin | 13.85 (±1.77) | 13.69 (±1.41) | 0.784 | 0.434 |
| Birth weight | 3.37 (±0.45) | 3.34 (±0.40) | 0.677 | 0.499 |
| Serum ferritin | 117.98 (±85.1) | 124.23 (±82.0) | 0.578 | 0.558 |
| Serum iron | 131.33 (±50.05) | 132.33 (±5.38) | 0.144 | 0.885 |

Table 4. Distribution of the infants by the time of cord clamping and their hematological parameters at the 4th month of age.

| Parameter | Time of cord clamping | | t | p-value |
|--------------------------|-----------------------|-----------------------|-------|---------|
| | Early Mean (sd.) | Delayed Mean (sd.) | | |
| Hemoglobin (gm/dl) | 9.47 (0.76) | 10.55 (0.89) | 10.24 | 0.000 |
| Serum ferritin (ng/ml) | 67.51 (44.27) | 114.65 (50.05) | 7.76 | 0.000 |
| Serum iron (μ g/dl) | 84.88 (42.92) | 116.13 (46.26) | 5.45 | 0.000 |

Table 5. Distribution of the infants by the occurrence of anemia at age of 4 months and the time of cord clamping.

| Time of cord clamping | Hemoglobin level at the 4 th month of age | | Total | Chi square = 69.436 p-value < 0.001 |
|-----------------------|--|------------------|-------|--|
| | <9.5 mg/dl | \geq 9.5 mg/dl | | |
| Early | 71 | 50 | 121 | |
| Delayed | 11 | 115 | 126 | |
| Total | 82 | 165 | 247 | |

4. Discussion

The World Health Organization advice delayed cord clamping; however, there is a debate on the optimal time for cord clamping [16]. If the cord clamping is delayed equal to or more than 60 seconds, blood flow between the baby and placenta continues and is usually completed by 120 seconds. This allows the transfusion of 80 - 100 ml of blood which constitute about one third of the newborns total blood volume [15].

Churn rate (sometimes called attrition rate), is a measure of the number of individuals moving out of a collective group over a specific period of time. Out of 256 women, 247 pregnant women completed this study; the attrition rate was 3.5%. This attrition rate is acceptable and does not affect the validity of the results [17].

The Normal infant hemoglobin at birth: mean 16.5 gm/dl (-2 SD: 13.5 gm/dl) and Normal infant hemoglobin at the 4th month: mean 11.5 gm/dl (-2 SD: 9.5 gm/dl). Anemia, defined as hematocrit (Hct) or hemoglobin (Hb) concentration >2 SD below mean for age. In neonate anemia is not immediately seen as serious or life threatening condition. In our study, at birth there was no significant difference in occurrence of anemia between the infants in both early or delayed cord clamping groups (p-value = 0.7). When compared with study done in India which revealed that the hemoglobin levels was higher in delayed umbilical cord clamping group as compared to early clamping group (p-value < 0.001) [18].

Polycythaemia, usually defined as venous hematocrit above 65%, and increased blood viscosity and risk of hyperbilirubinaemia. In present study, after 2 days of delivery no infant had polycythemia, vast majority (99.6%) of them nei-

ther had respiratory syndrome nor need phototherapy, which is in agreement with previous study done in Sweden [21]. But a study done by Hutton and Hassan did find significantly higher rates of polycythemia associated with delayed cord clamping groups [19] and study done by Macdonald states that delaying clamping the cord increase the risk of jaundice requiring phototherapy [22].

Increased hemoglobin would result in increased iron stores, and thus prevent iron deficiency, and as a consequence also protect infants from iron deficiency anemia and iron deficiency-associated neurodevelopmental and behavioural deficits [23].

At 4th month of age infants who underwent delayed cord clamping have significantly (p-value = 0.001) higher level of hemoglobin, serum iron, serum ferritin. As compared with study done in Pakistan; showed that delayed cord clamping increases term infants hemoglobin, serum iron (p < 0.000, p < 0.02 respectively) and serum ferritin increase but not significantly (p < 0.07) [24]. This means that the results of present study are more significant. But anemia is significantly more among infants aged 4 months who underwent early cord clamping (p-value = 0.001) and the incidence of anemia among infants with delayed cord clamping is 0.07, while the incidence of anemia among the infants who exposed to early cord clamping are 0.58, the relative risk (R.R) is 0.13, which means there are a negative association between delayed cord clamping and occurrence of anemia and delayed cord clamping is protective against anemia in infants at age of 4 months. The absolute risk reduction is 49%, 95% confidence interval: [39%, 60%]. Which is nearly same when compared with study done in Sweden; mean hemoglobin was 0.2 gm/dl (95% CI, 0.1 - 0.4) higher in delayed clamping group, proportion of anemia in early clamping group was 82% out of 270 and that delayed clamping group was 73% out of 270, p value = 0.01, R.R (95% CI) is =0.89 (0.81 - 0.98) with risk reduction of 11% in delayed clamping group [8].

5. Conclusion

Our study proved that: Clamping umbilical cord at 60 seconds in healthy term infants is a physiological, safe, simple, and inexpensive means of enhancing hematological status in low risk pregnancies at 4th months of age. Delayed cord clamping should be incorporated in integrated programs that are aimed at reducing iron deficiency, and iron deficiency anemia in infants, decreasing the incidence of infection and improving developmental mile stones at 4th month of age. Delayed cord clamping decreases the incidence of infection at 4th month of age. Delayed cord clamping improves developmental mile stones at 4th month of age.

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Limitation of the Study

There were some difficulties from some midwives and doctors in acceptance delayed umbilical cord clamping because all of them use to early umbilical cord clamping.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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