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Original Article

## Effect of delayed versus early umbilical cord clamping on neonatal outcomes: A prospective randomized comparative study.

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Page | 1

### Abstract

#### Background

The timing of umbilical cord clamping plays an important role in neonatal transition and hematological status. Delayed cord clamping has been proposed to improve neonatal outcomes by enhancing placental transfusion and increasing iron stores.

**Objective:** To compare the effects of delayed versus early umbilical cord clamping on neonatal hematological parameters and clinical outcomes in term neonates.

#### Materials and methods

A prospective randomized comparative study was conducted in the Department of Obstetrics and Gynaecology at CSI Hospital, Bangalore, from August 2014 to May 2016. A total of 400 term pregnant women were randomly allocated into two groups: early cord clamping (ECC, n = 200) performed within 15 seconds of birth, and delayed cord clamping (DCC, n = 200) performed after cessation of cord pulsations. The mean age of participants was  $26.4 \pm 3.2$  years, with the majority being multigravida (62%). Neonatal hemoglobin and hematocrit levels were measured at 48 hours. Secondary outcomes included bilirubin levels, requirement of phototherapy, birth weight, APGAR scores, respiratory distress, polycythemia, and maternal postpartum hemorrhage.

#### Results

Mean neonatal hemoglobin and hematocrit were significantly higher in the DCC group ( $17.6 \pm 1.5$  g/dL and  $52.9 \pm 5.3\%$ ) compared to the ECC group ( $16.8 \pm 1.4$  g/dL and  $50.17 \pm 4.7\%$ ) ( $p < 0.001$ ). Birth weight was also significantly higher in the DCC group ( $p = 0.017$ ). No significant differences were observed between the groups with respect to phototherapy requirement, polycythemia, respiratory distress, APGAR scores, or maternal postpartum hemorrhage.

#### Conclusion

Delayed cord clamping improves neonatal hematological status without increasing maternal or neonatal complications.

#### Recommendations

Delayed cord clamping can be safely recommended as a routine practice in term deliveries.

**Keywords:** Delayed cord clamping, Early cord clamping, Neonatal hemoglobin, Hematocrit, Placental transfusion, Neonatal outcomes, Birth weight, Hyperbilirubinemia, Polycythemia, Postpartum hemorrhage

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### Introduction



The timing of umbilical cord clamping represents a crucial event in the transition from fetal to neonatal life, significantly influencing neonatal hemodynamic stability and hematological status.<sup>[1]</sup> Immediately after birth, the newborn remains physiologically connected to the placenta through the umbilical circulation, allowing continued transfer of oxygenated blood. The duration for which this connection is maintained determines the extent of placental transfusion and has important implications for neonatal adaptation.<sup>[2,3]</sup>

Historically, early cord clamping (ECC), defined as clamping within the first 15–60 seconds after birth, became a routine component of active management of the third stage of labor. This practice was widely adopted to reduce the risk of postpartum hemorrhage and to facilitate prompt neonatal care. However, over the past few decades, accumulating evidence has questioned the universal application of early cord clamping, highlighting its potential to deprive the newborn of a significant portion of placental blood volume.<sup>[4]</sup>

Delayed cord clamping (DCC), typically performed after 1-3 minutes or after cessation of cord pulsations, allows continued placental transfusion to the neonate. It is estimated that delaying cord clamping can result in the transfer of approximately 80-100 mL of additional blood, corresponding to nearly 30-40% of the total neonatal blood volume. This additional blood provides an increased red cell mass and delivers approximately 40-50 mg/kg of elemental iron to the newborn. Consequently, DCC has been associated with higher hemoglobin and hematocrit levels in the early neonatal period and improved iron stores during infancy.<sup>[5]</sup>

Adequate iron stores during early life are essential for optimal neurodevelopment. Iron plays a vital role in myelination, neurotransmitter synthesis, and neuronal metabolism. Iron deficiency during infancy has been linked to impaired cognitive development, behavioral disturbances, and long-term neurodevelopmental deficits.<sup>[6]</sup> In developing countries such as India, where iron deficiency anemia is highly prevalent among women and children, strategies that enhance neonatal iron reserves are of significant public health importance. Delayed cord clamping is a simple, cost-effective, and non-invasive intervention that may help reduce the burden of anemia.<sup>[7]</sup>

In addition to improving hematological parameters, delayed cord clamping has been reported to confer several physiological benefits, including improved cardiovascular stability, better pulmonary perfusion, and enhanced transitional circulation. Furthermore, placental transfusion may facilitate the transfer of hematopoietic stem cells and immunologically active components,

which could play a role in tissue repair and immune function.<sup>[8]</sup>

Despite these advantages, concerns have been raised regarding the safety of delayed cord clamping. Theoretical risks include an increased incidence of neonatal hyperbilirubinemia due to higher red blood cell breakdown and polycythemia resulting from increased blood volume. These concerns have led to variability in clinical practice and hesitation in the universal adoption of delayed cord clamping.<sup>[9]</sup>

Given the balance between potential benefits and risks, it is essential to generate robust clinical evidence to guide obstetric and neonatal practice. The present study was therefore undertaken to compare early and delayed cord clamping in term neonates and to evaluate their effects on key neonatal outcomes, including hematological parameters, bilirubin levels, and clinical indicators such as APGAR scores, respiratory status, and maternal postpartum hemorrhage.

## Materials and methods

### Study design and setting

This prospective randomized comparative study was conducted in the Department of Obstetrics and Gynaecology at CSI Hospital, Bangalore, over a period of approximately 22 months from August 2014 to May 2016. The study was designed to evaluate the effect of the timing of umbilical cord clamping on neonatal outcomes in term deliveries.

### Study population

Pregnant women with uncomplicated term pregnancies who delivered at the study center during the study period were considered for inclusion. Written informed consent was obtained from all participants before enrolment.

### Inclusion criteria

- Singleton term pregnancies (gestational age  $\geq 37$  weeks)
- Women undergoing vaginal delivery or lower-segment cesarean section
- Absence of obstetric or medical complications
- Willingness to participate in the study

### Exclusion criteria



- Preterm deliveries (<37 weeks)
- Multiple pregnancies
- Presence of maternal systemic illness (e.g., anemia requiring treatment, hypertension, diabetes)
- Placental abnormalities or antepartum hemorrhage
- Neonates with congenital anomalies
- Need for immediate neonatal resuscitation

### Sample size

The sample size of 400 participants (200 per group) was calculated based on a previous study, assuming a mean difference in neonatal hemoglobin of 0.8 g/dL between groups, with a standard deviation of 1.5 g/dL, 80% power, and a 5% level of significance. The calculation accounted for a 10% attrition rate.

### Randomization

#### Sequence generation

Block randomization was used, and the random allocation sequence was generated using a computer-generated random number table.

#### Allocation concealment mechanism

Sequentially numbered, opaque, sealed envelopes were used to implement the random allocation sequence. The envelopes were opened only after the participant was deemed eligible and just before cord clamping, ensuring concealment until interventions were assigned.

#### Implementation

The random allocation sequence was generated by a biostatistician who was not involved in participant enrolment or intervention assignment. Participants were enrolled by the attending obstetrician. Assignment to interventions was performed by a study coordinator who opened the sequentially numbered envelopes.

#### Blinding

Blinding of participants and care providers was not feasible due to the nature of the intervention. However, the outcome assessor (pediatrician evaluating neonatal outcomes at 48 hours) was blinded to group allocation.

### Study procedure

Following delivery of the neonate, the timing of umbilical cord clamping was carried out according to the allocated group. In the early cord clamping group, the cord was clamped immediately after birth, typically within 15 seconds. In the delayed cord clamping group, clamping was performed after visible cessation of cord pulsations. All deliveries were conducted according to standard obstetric protocols. Neonatal assessment was performed by a pediatrician who was not involved in group allocation.

### Data collection

**Maternal Parameters:** Age, parity, mode of delivery, hemoglobin levels, and occurrence of postpartum hemorrhage.

**Neonatal Parameters:** Hemoglobin and hematocrit at 48 hours (primary); total serum bilirubin, phototherapy requirement, APGAR score, birth weight, polycythemia, respiratory distress syndrome, need for resuscitation (secondary). Blood samples were collected at 48 hours under aseptic conditions and analyzed using standardized automated hematology analyzers. Phototherapy need was determined using Bhutani's nomogram.

### Definitions

**Early Cord Clamping (ECC):** Clamping within 15 seconds of birth

**Delayed Cord Clamping (DCC):** Clamping after cessation of cord pulsations

**Polycythemia:** Hematocrit >65%

**Respiratory Distress Syndrome (RDS):** Presence of tachypnea, retractions, or need for oxygen support

### Statistical analysis

Data were entered into Microsoft Excel and analyzed using appropriate statistical software. Continuous variables were expressed as mean  $\pm$  standard deviation, and categorical variables as percentages. Comparisons were performed using Student's t-test for continuous variables and the chi-square test for categorical variables.

### Ethical considerations



The study was conducted in accordance with ethical principles for biomedical research involving human subjects. Institutional Ethics Committee approval was obtained before commencement of the study (Approval No: IEC/CSI/2014/42, dated 15th July 2014). Confidentiality of patient data was maintained throughout.

### Informed consent

Written informed consent was obtained from all participants before their inclusion in the study. The participants were informed about the purpose of the study, procedures involved, potential risks and benefits, and their right to withdraw at any time without penalty.

## Results

### Participant flow

A total of 400 mother–neonate pairs were enrolled and randomly assigned: 200 to early cord clamping (ECC) and 200 to delayed cord clamping (DCC). All 400 participants completed the study and were analyzed for the primary

outcome. A diagram is strongly recommended but not reproduced here in text; the authors will provide a CONSORT flow diagram in the final submission.

### Baseline data

The two groups were comparable with respect to baseline maternal and neonatal characteristics. Maternal age: ECC  $26.5 \pm 3.1$  years vs DCC  $26.3 \pm 3.3$  years ( $p = 0.54$ ). Gestational age: ECC  $38.9 \pm 1.1$  weeks vs DCC  $39.0 \pm 1.0$  weeks ( $p = 0.34$ ). Mode of delivery (vaginal/cesarean): ECC 82%/18% vs DCC 84%/16% ( $p = 0.60$ , chi-square = 0.27). No statistically significant differences were observed.

### Neonatal hematological parameters

The mean neonatal hemoglobin and hematocrit levels measured at 48 hours were significantly higher in the DCC group compared to the ECC group. Hemoglobin:  $16.8 \pm 1.4$  g/dL (ECC) vs  $17.6 \pm 1.5$  g/dL (DCC) ( $t = 5.54$ ,  $p < 0.001$ ). Hematocrit:  $50.17 \pm 4.7\%$  (ECC) vs  $52.9 \pm 5.3\%$  (DCC) ( $t = 5.49$ ,  $p < 0.001$ ).

**Table 1: Comparison of neonatal hematological parameters**

Parameter	ECC (n=200)	DCC (n=200)	p-value
Hemoglobin (g/dL)	$16.8 \pm 1.4$	$17.6 \pm 1.5$	<0.001
Hematocrit (%)	$50.17 \pm 4.7$	$52.9 \pm 5.3$	<0.001

### Neonatal clinical outcomes

Birth weight was significantly higher in the DCC group ( $3.04 \pm 0.3$  kg vs  $2.95 \pm 0.4$  kg;  $t = 2.40$ ,  $p = 0.017$ ). Total

bilirubin was slightly higher in DCC ( $11.4 \pm 1.5$  vs  $11.1 \pm 1.4$  mg/dL;  $t = 2.03$ ,  $p = 0.043$ ). Phototherapy requirement (30% vs 29%; chi-square = 0.048,  $p = 0.826$ ). Polycythemia (0% vs 0.5%; chi-square = 1.00,  $p = 0.32$ ). RDS (3% vs 3.5%; chi-square = 0.08,  $p = 0.78$ ).

**Table 2: Comparison of neonatal clinical outcomes**

Outcome	ECC (n=200)	DCC (n=200)	p-value
Birth Weight (kg)	$2.95 \pm 0.4$	$3.04 \pm 0.3$	0.017
Total Bilirubin (mg/dL)	$11.1 \pm 1.4$	$11.4 \pm 1.5$	0.043
Phototherapy (%)	29%	30%	0.826
Polycythemia (%)	0.5%	0%	>0.05
RDS (%)	3.5%	3%	>0.05

### APGAR score

APGAR score  $\geq 9$  at 5 minutes: ECC 86.5% vs DCC 91.5% (chi-square = 2.47,  $p = 0.12$ ).



**Table 3: Comparison of APGAR Scores**

Parameter	ECC (n=200)	DCC (n=200)	p-value
APGAR Score $\geq 9$ at 5 min (%)	86.5%	91.5%	NS

### Maternal outcomes

Page | 5 Postpartum hemorrhage: ECC 4% vs DCC 3.5% (chi-square = 0.07, p = 0.79).

**Table 4: Comparison of maternal outcomes**

Outcome	ECC (n=200)	DCC (n=200)	p-value
Postpartum Hemorrhage (%)	4%	3.5%	NS

### Discussion

The present study evaluated the impact of timing of umbilical cord clamping on neonatal hematological parameters and clinical outcomes in term neonates and demonstrated that delayed cord clamping confers significant hematological benefits without increasing adverse neonatal or maternal outcomes. In this study, neonates in the delayed cord clamping group had significantly higher hemoglobin and hematocrit levels at 48 hours compared to the early cord clamping group. These findings are consistent with the Cochrane review by McDonald et al. (2013)<sup>[10]</sup>, which reported significantly higher hemoglobin concentrations in neonates undergoing delayed cord clamping. Similarly, the randomized controlled trial by Andersson et al. (2011)<sup>[11]</sup> demonstrated improved iron stores and higher hemoglobin levels in infants subjected to delayed cord clamping, with benefits extending up to 4 months of age. The increase in hematocrit observed in the present study is also supported by Jahazi et al. (2008)<sup>[12]</sup>, who reported higher hematocrit values in neonates with delayed cord clamping without associated clinical complications. Furthermore, the study by Dipak et al. (2017)<sup>[13]</sup> in preterm neonates also showed improved hematocrit and hemodynamic stability with delayed cord clamping, reinforcing the physiological advantage of placental transfusion observed in the current study.

The present study also demonstrated a statistically significant increase in birth weight in the delayed cord clamping group, which can be attributed to the additional placental blood volume transferred to the neonate. Although not all studies have focused specifically on birth weight, Mercer et al. (2017)<sup>[14]</sup> reported increased neonatal blood volume and improved hemoglobin levels following delayed cord clamping, supporting the observation that placental transfusion contributes to measurable physiological benefits in the newborn.

With respect to neonatal adaptation, no significant differences were observed in APGAR scores or

respiratory distress between the two groups in the present study. These findings are in agreement with the randomized clinical trial by Kc et al. (2019)<sup>[15]</sup>, which demonstrated that delayed cord clamping does not adversely affect early neonatal parameters such as heart rate, breathing, and oxygen saturation during the first minutes of life. This suggests that delayed cord clamping is safe and does not compromise immediate neonatal transition.

One of the key concerns associated with delayed cord clamping is the risk of hyperbilirubinemia due to increased red cell mass. In the present study, although a slightly higher proportion of neonates in the delayed cord clamping group required phototherapy, the difference was not statistically significant. This finding is consistent with the systematic review and meta-analysis by Hutton and Hassan (2007)<sup>[16]</sup>, which found no significant increase in clinically relevant hyperbilirubinemia in neonates undergoing delayed cord clamping. Similarly, McDonald et al. (2013)<sup>[10]</sup> reported only a slight increase in bilirubin levels without a significant rise in the need for phototherapy, indicating that delayed cord clamping does not pose a major clinical risk in this regard.

The incidence of polycythemia in the present study was minimal and did not differ significantly between the groups, which is in line with findings from previous studies. Jahazi et al. (2008)<sup>[12]</sup> and McDonald et al. (2013)<sup>[10]</sup> have reported that although hematocrit levels may be higher in delayed cord clamping, clinically significant polycythemia is rare and usually asymptomatic, requiring no intervention. Thus, the present study further supports the safety of delayed cord clamping in this aspect.

Maternal outcomes, particularly postpartum hemorrhage, were comparable between the two groups in the present study. This observation aligns with the Cochrane review by McDonald et al. (2013)<sup>[10]</sup>, which found no increase in maternal blood loss with delayed cord clamping. Current clinical guidelines also support this finding; both the World Health Organization (2014)<sup>[17]</sup> and the American





College of Obstetricians and Gynecologists (2020)<sup>[18]</sup> recommend delayed cord clamping as a safe practice that does not increase the risk of postpartum hemorrhage.

Additionally, evidence from Rabe et al. (2012)<sup>[1]</sup> further supports the benefits of delayed cord clamping, particularly in improving neonatal outcomes through enhanced placental transfusion without increasing maternal complications. Although their study focused on preterm infants, the underlying physiological benefits of delayed clamping are consistent across different gestational groups and correlate well with the findings of the present study.

The present study demonstrated that delayed cord clamping (DCC) significantly improves neonatal hematological parameters without increasing adverse outcomes. Neonates in the DCC group had significantly higher mean hemoglobin ( $17.6 \pm 1.5$  g/dL vs  $16.8 \pm 1.4$  g/dL; mean difference 0.8 g/dL,  $t = 5.54$ ,  $p < 0.001$ ) and hematocrit ( $52.9 \pm 5.3\%$  vs  $50.17 \pm 4.7\%$ ; mean difference 2.73%,  $t = 5.49$ ,  $p < 0.001$ ) at 48 hours compared to the early cord clamping (ECC) group. Birth weight was also modestly higher in the DCC group ( $3.04 \pm 0.3$  kg vs  $2.95 \pm 0.4$  kg; mean difference 0.09 kg,  $t = 2.40$ ,  $p = 0.017$ ). Although total serum bilirubin was slightly higher in the DCC group ( $11.4 \pm 1.5$  mg/dL vs  $11.1 \pm 1.4$  mg/dL;  $t = 2.03$ ,  $p = 0.043$ ), phototherapy requirement did not differ significantly (30% vs 29%;  $\chi^2 = 0.048$ ,  $p = 0.826$ ). No significant differences were observed in polycythemia (0% vs 0.5%), respiratory distress (3% vs 3.5%), APGAR scores (91.5% vs 86.5%  $\geq 9$  at 5 min), or maternal postpartum hemorrhage (3.5% vs 4%). These findings are consistent with the Cochrane review by McDonald et al. (2013) and the trial by Andersson et al. (2011), which reported improved hemoglobin and iron stores with DCC. The benefits of DCC—enhanced placental transfusion and improved hematological status—are achieved without clinically meaningful harms. The 0.8 g/dL higher hemoglobin delivers approximately 40–50 mg/kg of elemental iron, which is particularly valuable in settings with high iron deficiency anemia prevalence. The slight increase in bilirubin did not translate into increased phototherapy needs, and the absence of increased polycythemia or respiratory distress confirms neonatal safety. Comparable postpartum hemorrhage rates (3.5% vs 4%) align with evidence that uterine contraction, not early clamping, drives hemostasis. Thus, balancing benefits against risks, DCC is a favorable intervention for term neonates.

This study was conducted in a single tertiary care hospital in Bangalore, India, with 400 uncomplicated term pregnancies. Findings are directly applicable to low-risk obstetric populations in low- and middle-income

countries, particularly where iron deficiency is prevalent. However, generalizability to high-risk pregnancies (preterm, multiple gestation, fetal distress, maternal illness) is limited, though other studies suggest benefits extend across gestational groups. The intervention requires no additional equipment or cost, making it highly scalable.

Several limitations should be acknowledged. Blinding of caregivers was not feasible, introducing potential performance bias, though outcome assessors were blinded. The single-center design limits generalizability. Only short-term outcomes (48 hours) were assessed; long-term neurodevelopmental and iron status outcomes were not evaluated. The study may have been underpowered for rare adverse events. The use of "cessation of cord pulsations" rather than a standardized time interval introduces variability. Finally, the study period (2014–2016) predates some recent guidelines, though core findings remain relevant.

## Conclusion

Delayed umbilical cord clamping significantly improves neonatal hemoglobin and hematocrit levels and is associated with a modest increase in birth weight, reflecting enhanced placental transfusion. Importantly, it does not increase the risk of adverse neonatal outcomes such as hyperbilirubinemia requiring phototherapy, polycythemia, or respiratory distress, nor does it increase maternal postpartum hemorrhage. These findings, consistent with existing evidence and international guidelines, support delayed cord clamping as a safe, simple, and effective practice that can be routinely implemented to improve neonatal outcomes, particularly in settings where prevention of iron deficiency anemia is a priority.

## Recommendation

Delayed cord clamping can be safely recommended as a routine practice in term deliveries.

## Acknowledgement

The authors sincerely thank the women who participated in this study, the nursing and medical staff of the Department of Obstetrics and Gynaecology at CSI Hospital, Bangalore, for their support in conducting the study, and the hospital administration for providing the necessary facilities.



## List of abbreviations

**DCC:** Delayed Cord Clamping  
**ECC:** Early Cord Clamping  
**RDS:** Respiratory Distress Syndrome  
**PPH:** Postpartum Hemorrhage  
**Hb:** Hemoglobin  
**Hct:** Hematocrit  
**APGAR:** Appearance, Pulse, Grimace, Activity, Respiration  
**WHO:** World Health Organization  
**ACOG:** American College of Obstetricians and Gynecologists\

## Registration

The study was not registered in a public clinical trials registry.

## Funding

This study received no specific funding from any public, commercial, or not-for-profit agencies. No external support (e.g., drug or equipment supplies) was provided. The funders had no role in study design, data collection, analysis, interpretation, or manuscript preparation.

## Conflict of interest

The authors declare no conflicts of interest.

## Author contributions

**Dr. Parvathaneni Divya:** Conceptualization, study design, data analysis, manuscript writing, corresponding author.

**Dr. Sornalatha C.L.:** Data collection, intervention implementation, manuscript review.

**Dr. Ashmitaa Srikanand:** Data collection, statistical analysis, manuscript editing.

**Dr. Konka Sekar Chaitanya:** Literature review, interpretation of results, manuscript revision.

## Data availability

The data that support the findings of this study are available from the corresponding author upon reasonable request. Due to ethical and privacy considerations, data are not publicly available but can be shared with qualified researchers after approval from the Institutional Ethics Committee.

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Page | 9

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