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## Original Research Article

# Delayed cord clamping versus intact umbilical cord-milking and its effects on maternal blood loss: a randomised controlled trial

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## ABSTRACT

**Background:** The ideal timing of cord clamping has been controversial and debated over decades. Delayed cord clamping has many advantages owing to enhanced placental transfusion on neonates but provides limited evidence on maternal postpartum blood loss. The objective of the study was to estimate the maternal blood loss after delayed cord clamping versus umbilical cord milking.

**Methods:** A randomized controlled trial was conducted in KLE's Dr. Prabhakar Kore Hospital, at Belagavi district in Karnataka over 18 months. In the delayed cord clamping (group A- DCC) group, the cord was clamped 60 seconds after the delivery of a newborn. In the intact umbilical cord milking (group B- UCM) group, cord blood was milked 5-8 times for 15-20 seconds towards the neonate. The primary outcome of the study was to estimate the maternal blood loss by comparing the change in hemoglobin and hematocrit values before and after delivery. Furthermore, neonatal outcome was assessed by comparing serum ferritin at third month of life.

**Results:** Maternal blood loss was estimated by a drop in post-delivery hemoglobin, showed a significant difference between the two groups (group A-DCC group= $1.76 \pm 0.1$  gm% and group B-UCM group= $1.73 \pm 0.1$  gm%;  $p < 0.001$ ). Additional administration of uterotonics for medical management of the cases also showed a significant difference ( $p = 0.049$ ) with higher usage among the DCC group.

**Conclusions:** From the present study, it was observed that umbilical cord milking was equally effective and time-saving with the advantages of delayed cord clamping with reduced estimated maternal blood loss.

**Keywords:** Cord clamping, Milking, Maternal blood loss, Postpartum hemorrhage

## INTRODUCTION

Postpartum hemorrhage (PPH) is defined as excessive blood loss after delivery, which poses a significant risk to maternal health. Traditionally, PPH is defined as estimated maternal blood loss of more than 500 ml in vaginal delivery and more than 1000 ml during caesarean delivery.

American College of Obstetrics and Gynecology defines PPH as a cumulative blood loss of more than 1000 ml with signs and symptoms of hypovolemia within 24 hours of delivery irrespective of the mode of delivery.<sup>1</sup> Uterine atony is the most common cause of postpartum hemorrhage. Every year, around 14 million women experience PPH resulting in about 70,000 maternal deaths globally. The third stage of labor begins with the delivery

of the fetus to the complete expulsion of the placenta and membranes. In the past, early cord clamping was practiced to reduce post-partum hemorrhage and the need for blood transfusions in mother.<sup>2</sup> “Placental transfusion” allows physiological transfer of placental blood to the newborn.<sup>3</sup> The placenta transfers about 80 ml of blood in the first minute reaching up to about 100 ml in the next three minutes which gives an extra 40–50 mg/kg of iron to the neonate which is essential as breast milk lacks iron. It helps to prevent iron deficiency anemia in the first year of life.<sup>4</sup> According to the National Family Health Survey (NFHS-5) of 2019-21 system data, the prevalence of anemia, i.e., hemoglobin of <11 gm/dl in pregnant women aged 15-49 years was 52.2%, whereas it was 67.1% among children aged 6-59 months. Children who develop anemia due to iron deficiency are more likely to have delayed psychomotor development. Impairments due to iron deficiency anemia in the early years of life may be lasting, even after the replenishment of iron stores, which highlights the importance of placental transfusion to prevent anemia in the first few years of life.<sup>5</sup> Given this, delayed cord clamping is practiced, which is beneficial for the term neonates, but data on maternal outcomes, particularly after caesarean delivery, are largely sparse.<sup>6</sup> Hence this study was done to assess the maternal blood loss after delayed cord clamping versus umbilical cord milking in vaginal and caesarean deliveries.

## METHODS

### *Study design and setting*

It was a double blinded randomized controlled trial conducted in KLE's Dr. Prabhakar Kore Hospital and Medical Research Centre, at Belagavi district of Karnataka from February 2021 to July 2022. The overall sample size of the study was calculated as 600 with 300 in each group at 5% level of significance and to provide 80% power of the study. Randomization was done by computer-generated sequence and allocation concealment was made by the serially numbered opaque sealed envelopes (SNOSE) method by the one of the researchers between the groups. The participants and researchers were blinded from knowing the interventions. The consolidated standards of reporting trials (CONSORT) flowchart were depicted in the Figure 1.

### *Study participants*

Pregnant women admitted in labor room with singleton live gestation of 34 0/7 to 41 6/7 weeks with hemoglobin >9.9 mg/dl were screened for eligibility. Multiple gestations, Rh-sensitized pregnancies, gestational diabetes, gestational hypertension, placenta previa, antepartum hemorrhage, fetal growth restriction, Doppler changes and the presence of meconium-stained liquor were excluded. Eligible women after consenting to the study were enrolled.

### *Ethical approval*

The study was approved by the Institutional Ethics Committee on Human Subjects Research (MDC/DOME/176). The trial was also registered under Clinical Trial Registry of India (Registration number CTRI/2021/08/036094). The study participants were enrolled in the study after obtaining the informed consent to participate in the study.

### *The procedure of data collection*

After delivery, the baby was placed at a lower level or the level of introitus in vaginal deliveries and between the mother's thighs in caesarean section. In the delayed cord clamping (DCC) group A, the cord was clamped 60 seconds after the delivery of newborn whereas, in the intact umbilical cord milking (UCM) group B, cord blood was milked 5-8 times for 15-20 seconds towards the neonate with a speed of 10 cm/second with two-second interval to allow the blood to refill from the placenta towards the cord.

Blood loss in vaginal deliveries was measured by calculating the blood collected in the BRASS V Drape (calibrated) after the delivery of the placenta. In caesarean sections, blood loss was measured by counting the number of mops soaked with blood and by measuring the blood collected in the separate suction canister apparatus. Blood samples were collected from the mother to estimate hemoglobin (by cyanmethemoglobin method) and hematocrit – at the time of admission and 24-48 hours following delivery. Uterotonic drugs were administered as per the active management of third stage of labour (AMTSL) criteria (immediately after the delivery of the baby).

### *Outcomes*

The primary maternal outcome was to estimate maternal blood loss by comparing the change in pre- and post-delivery hemoglobin and hematocrit values. Secondary maternal outcomes included additional use of uterotonics, the need for surgical interventions like Hayman's, B lynch, uterine artery ligation techniques, the incidence of post-partum hemorrhage (>500 ml in vaginal deliveries and >1000 ml in caesarean sections), the need for blood transfusion, and duration of the third stage of labor. Neonatal outcome was assessed by comparing the serum ferritin at 3<sup>rd</sup> month of life.

### *Statistical analysis*

Data was entered into Microsoft excel and analyzed using statistical package for the social sciences (SPSS) software version 21. Significant associations were drawn by tests like the Chi-square test, and t-test, where a p value less than or equal to 0.05 indicated statistical significance.

## RESULTS

In the study period, 600 participants found eligible were enrolled and randomized into 263 participants of DCC group (A) and 272 participants of UCM group (B), with 65 participants on a whole being excluded in the study from both groups. The mean age of the participants in the DCC and UCM groups was comparable with  $25.17 \pm 3.6$  years and  $25.11 \pm 3.7$  years respectively, without any significant difference. Similarly, mean gestational age at delivery and body mass index (BMI) were  $38.74 \pm 2.5$  weeks and  $38.56 \pm 2.5$  weeks, and  $27.56 \pm 2.6$  kg/m<sup>2</sup> and  $27.33 \pm 2.5$  kg/m<sup>2</sup> respectively among the groups without any significant difference ( $p > 0.05$ ). The mean time for cord clamping among the DCC group was 60 seconds and  $17.23 \pm 2.5$  seconds among the UCM group. Other baseline characteristics were presented in Table 1, with most variables comparable between the groups. However, for most, the mode of delivery was vaginal among the DCC group and this difference was statistically significant ( $p < 0.05$ ).

From Table 2, the change in Hb% post-delivery had significant differences between the DCC and UCM groups, with the mean being  $1.76 \pm 0.1$  gm/dl and  $1.73 \pm 0.1$  gm/dl respectively. Furthermore, the utilization of

uterotonics was significantly more common among the DCC group ( $p < 0.05$ ). Other maternal outcomes were comparable between the DCC and UCM groups. When comparing the maternal outcomes, the mean blood loss in DCC was  $312.59 \pm 133.1$  ml, and in the UCM group  $311.36 \pm 124.9$  ml, shows no significant difference in blood loss between the two groups ( $p = 0.913$ ). The serum ferritin levels measured at the third month of neonatal life was  $258.07 \pm 133.7$  ng/ml and  $248.44 \pm 141.7$  ng/ml respectively. These values showed no significant differences between two groups ( $p = 0.720$ ).

Upon sub-group analysis on Table 3, of maternal outcomes between DCC and UCM groups concerning the mode of delivery, none of the hematological parameters, as well as the duration of third stage of labor, showed no significant differences within the vaginal and caesarean groups. A sub-analysis comparing the groups concerning mode of delivery showed 269 subjects underwent vaginal deliveries, with the mean blood loss in DCC  $243.63 \pm 109.1$  ml and UCM  $217.54 \pm 90.3$  ml and was not significant ( $p = 0.086$ ). Likewise, 256 subjects underwent caesarean delivery and the estimated maternal blood loss after caesarean delivery between two groups DCC and UCM with mean blood loss of  $402 \pm 107$  ml, and  $387 \pm 93$  ml ( $p = 0.315$ ) respectively showed no significant difference.

**Table 1: Comparison of baseline characteristics between groups (n=535).**

Variables	Intervention group		P value
	Group A, DCC (n=263)	Group B, UCM (n=272)	
<b>Age in years</b>			
18-20	17 (6.5)	25 (9.2)	0.503
21-29	209 (79.5)	210 (77.2)	
30 and above	37 (14.1)	37 (13.6)	
<b>BMI</b>	$27.56 \pm 2.61$	$27.33 \pm 2.5$	0.145
<b>Gestational age at delivery (weeks)</b>	$38.74 \pm 2.45$	$38.56 \pm 2.51$	0.407
<b>Gravida</b>			
Primigravida	122 (46.4)	105 (38.6)	0.069
Multigravida	141 (53.6)	167 (61.4)	
<b>Mode of delivery</b>			
Vaginal	148 (56.3)	121 (44.5)	<0.001*
Caesarean	115 (43.7)	151 (55.5)	
<b>Pre-delivery Hb%</b>	$12.49 \pm 1.1$	$12.41 \pm 1.1$	0.396
<b>Pre-delivery haematocrit</b>	$36.84 \pm 3.2$	$37.18 \pm 2.6$	0.173

Data are represented as mean  $\pm$  standard deviation, \* $p < 0.05$  is statistically significant

**Table 2: Comparison of maternal and neonatal outcomes between groups (n=535).**

Variables	Intervention group		P value
	Group A, DCC (n=263)	Group B, UCM (n=272)	
<b>Post-delivery Hb%</b>	$10.73 \pm 1.0$	$10.68 \pm 0.9$	0.564
<b>Change in Hb%</b>	$1.76 \pm 0.1$	$1.73 \pm 0.1$	<0.001*
<b>Post-delivery hematocrit</b>	$32.29 \pm 2.5$	$32.32 \pm 2.3$	0.870
<b>Change in hematocrit</b>	$4.55 \pm 0.6$	$4.86 \pm 0.2$	0.193
<b>Blood loss (in ml)</b>	$312.59 \pm 133.1$	$311.36 \pm 124.9$	0.913
<b>Duration of labor (minutes)</b>	$3.03 \pm 1.1$	$2.84 \pm 1.1$	0.75
<b>Postpartum hemorrhage N (%)</b>	3 (1.1)	1 (0.3)	0.592

Continued.

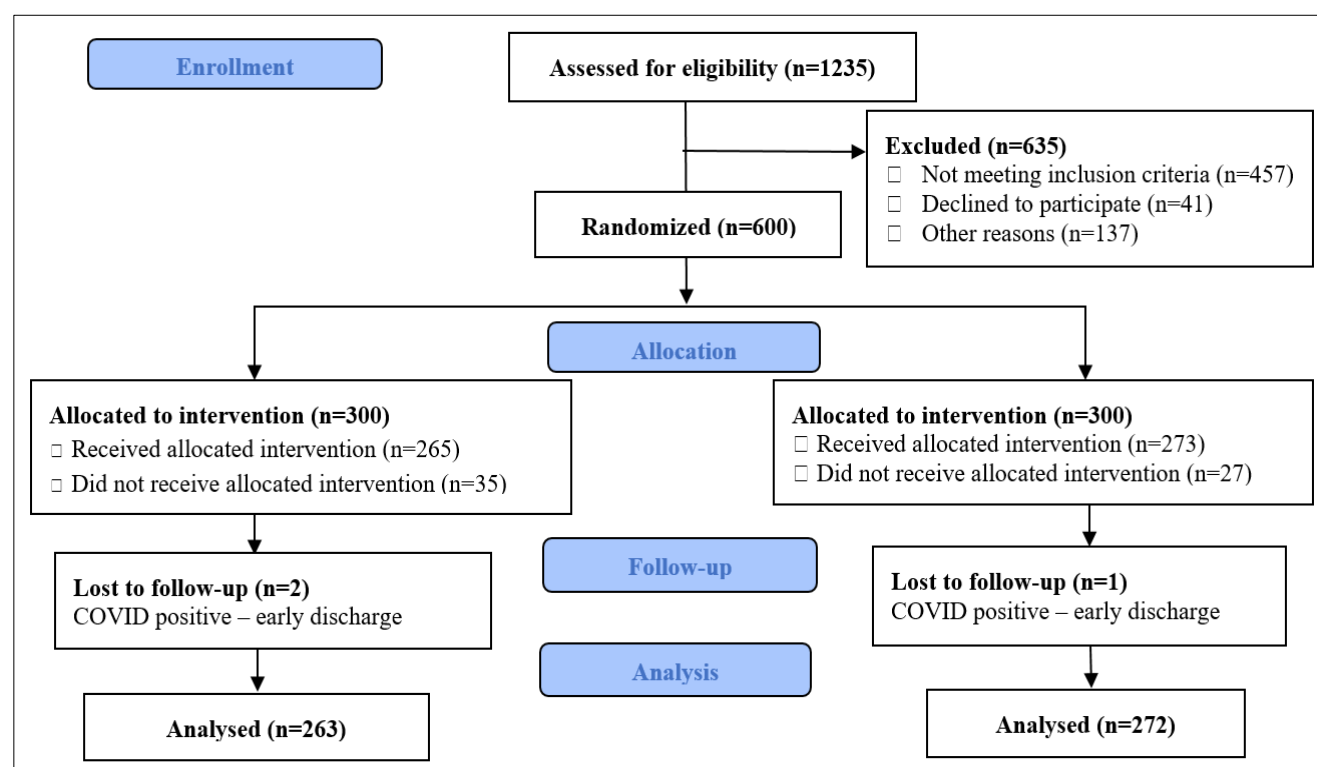
Variables	Intervention group		P value
	Group A, DCC (n=263)	Group B, UCM (n=272)	
Blood transfusion N (%)	7 (2.6)	3 (1.1)	0.183
Uterotonics N (%)	41 (15.5)	27 (9.69)	0.049*
Hayman's stitch	3 (1.1)	5 (1.8)	0.506
B-Lynch	1 (0.3)	1 (0.3)	0.368
Uterine artery ligation	6 (2.2)	6 (2.2)	0.953
Neonatal outcome (n=108)			
Serum ferritin (ng/ml)	258.07±133.7	248.44±141.7	0.720

Data are represented as mean±standard deviation, \* p<0.05 is statistically significant

**Table 3: Sub-analysis of maternal outcomes between groups among vaginal and caesarean delivery groups (n=535).**

Variables	Intervention group (total-535)		P value
	Group A, DCC (n=263)	Group B, UCM (n=272)	
Vaginal delivery among both groups (n=269)			
Post-delivery Hb%	10.8±1.0	10.7±1.0	0.407
Change in Hb%	1.8±0.8	1.7±0.7	0.294
Post-delivery haematocrit	32.5±2.6	32.4±2.4	0.747
Change in haematocrit	4.6±2.3	4.8±2.3	0.731
Blood loss (in ml)	247.3±113.2	233.9±90.6	0.322
Duration of 3 <sup>rd</sup> stage of labor	3.6±0.9	3.6±1.4	1.000
Caesarean delivery among both groups (n=266)			
Post-delivery Hb%	10.6±1.0	10.7±0.9	0.407
Change in Hb%	1.8±0.9	1.9±0.9	0.294
Post-delivery haematocrit	32.0±2.5	32.2±2.1	0.747
Change in haematocrit	4.9±2.7	4.7±2.0	0.731
Blood loss (in ml)	402.3±105.4	382.0±98.2	0.132
Duration of 3 <sup>rd</sup> stage of labour	2.3±1.0	2.5±0.9	0.112

Data are represented as mean±standard deviation, \* p<0.05 is statistically significant



**Figure 1: CONSORT flow diagram.**

## DISCUSSION

The current randomized controlled trial estimates maternal blood loss by comparing the changes in hemoglobin and hematocrit values before and after delivery. The pre-delivery hemoglobin in DCC (group A) was  $12.49 \pm 1.1$  gm%, and UCM (group B) was  $12.41 \pm 1.1$  gm% ( $p=0.396$ ) and post-delivery mean hemoglobin in DCC was  $10.73 \pm 1.0$  gm% and UCM was  $10.68 \pm 0.9$  gm% ( $p=0.564$ ), which was comparable between two groups. However, the change in hemoglobin following pre- and post-delivery in DCC was  $1.76 \pm 0.1$  gm%, and UCM was  $1.73 \pm 0.1$  gm% which showed significance ( $p<0.001$ ) between the groups.

The present study implies that maternal blood loss was comparatively higher in the delayed cord clamping group than in the cord milking group reflected by the significant drop in hemoglobin following delivery. This can be attributed to a delay of 60 seconds in hysterectomy closure or episiotomy closure leading to increased maternal blood loss. The sub-analysis compared subjects with respect to vaginal and cesarean deliveries individually and it showed no significant difference in change in hemoglobin and hematocrit following either type of delivery in subjects. The mode of delivery had a significant association between the two groups as the participants were randomized before the delivery at the time of admission. A similar study, on cesarean deliveries, showed a significant association in the mode of delivery.<sup>7</sup>

A study by Rhoades et al compared the effect of blood loss before and after the implementation of delayed cord clamping in term patients. The results show no variation in risk of adverse outcomes as well as post-partum hemorrhage.<sup>8</sup> The blood loss in the vaginal deliveries between the cohort groups was not significant ( $p=0.43$ ) whereas there was a comparative difference between the two groups ( $p<0.001$ ) in cesarean deliveries with the post-protocol group showing higher blood loss. Furthermore, several studies comparing early cord clamping and delayed cord clamping reveals insignificant effect on the maternal blood loss.<sup>7,9-11</sup>

A similar study done to compare the implementation of DCC for 3 minutes in cesarean deliveries showed no significant difference in maternal blood loss but the change in hemoglobin following delivery in pre-cohort was 0.8 [-1.3 to -0.5] and post cohort was 0.9 [-1.4 to -0.6], which was significantly higher in the post-cohort ( $p=0.01$ ).<sup>12</sup> In contrast, other studies comparing maternal blood loss by a change in hemoglobin pre-and post-delivery did not result in any significant difference.<sup>7,8,10,13,14</sup>

In our study, only 3 cases in DCC (group A) and 1 case in UCM (group B) were reported with blood loss of more than 500 ml ( $p=0.299$ ) in vaginal deliveries. In cesarean deliveries, none of the recruited cases have reported blood loss of >1000 ml in both groups. The additional administration of uterotonics showed a significant association ( $p=0.049$ ) with increased administration in

group A compared to group B. A similar study by Raunkit et al showed that a higher number of cases with post-partum hemorrhage were reported in the early cord clamping group. This can be explained by a higher cesarean section rate in that group.<sup>7</sup> The study hypothesized that patients who underwent cesarean section, on average, tend to lose more blood than those who undergo vaginal delivery.

The mean serum ferritin in DCC was  $258.07 \pm 133.7$  ng/ml and UCM was  $248.44 \pm 141.7$  ng/ml which showed no significant difference between the groups ( $p=0.72$ ). A similar study compared the effect of umbilical cord milking and delayed cord clamping on serum ferritin at 6 weeks of life in term neonates showed insignificant results ( $p=0.49$ ).<sup>15</sup>

When 535 subjects were analyzed, there was a significant drop in hemoglobin following delivery in the delayed cord clamping group. This implies increased maternal blood loss in the delayed cord clamping group but the direct measurement of estimated maternal blood loss was not significant, as it did not include the blood lost in soaked clothes, pads, and gauze used during deliveries.

A plethora of studies are available reporting the effects of delayed cord clamping and umbilical cord milking on maternal and neonatal outcomes. Compiled evidence states that DCC reduced hospital mortality in preterm infants recommending DCC in accordance with the current guidelines.<sup>16</sup> The American College of Obstetrics and gynecologists states that DCC does not increase the risk of postpartum hemorrhage or the need for blood transfusion, reinforcing its safety for maternal outcomes.<sup>17</sup> DCC provided beneficial effects in term and preterm infants with less anemia rate and improved infant neurodevelopment. DCC does not increase the risk of postpartum hemorrhage and need for maternal blood transfusion. DCC was safe and effective procedure but in spite of its advantages controversies remains in time of cord clamping.<sup>18</sup> UCM increases the venous hematocrit at 48 hours in late and preterm infants when compared with DCC.<sup>19</sup> A systematic review on DCC versus UCM alleges that umbilical cord milking significantly increased the risk of severe intraventricular hemorrhage in preterm, particularly at lower gestational ages.<sup>20</sup> This highlights the importance of individualized decision making when choosing between DCC and UCM. This finding highlights the need for further research to establish optimal cord management strategies, particularly in high-risk populations.

### Strengths and limitations

These include: randomized controlled trial involving larger sample size with double blinding; diverse study population with inclusion of both vaginal and caesarean delivery ensures generalizability across different birthing scenarios; using a power of 99% to estimate the sample size makes the study significant; objective measurement of



blood loss using BRASS V Drape for vaginal deliveries provides an objective measurement of maternal blood loss; the estimated maternal blood loss included the blood loss noted in BRASS V Drape in vaginal deliveries but caesarean delivery the blood loss using soaked mops and suction apparatus was an estimate and may not provide precise measurement; and the duration of the third stage of labor was a subjective measurement and further sub-study is necessitated.

## CONCLUSION

This study provides clear evidence that umbilical cord milking is equally effective and time efficient alternative to delayed cord clamping with added advantage of reducing maternal blood loss. Given its comparable neonatal benefits and its potential to minimize postpartum hemorrhage risk, umbilical cord milking can be considered as safe alternative approach of placental transfusion, particularly in clinical settings where rapid stabilization of the neonate and maternal hemostasis are prioritized.

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