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TO STUDY THE EFFECT OF DELIVERING BABIES ON MOTHER'S ABDOMEN WITH REFERENCE TO CORD CLAMPING TIME AND REQUIREMENT OF NEONATAL RESUSCITATION IN TERM BABIES

Paediatrics

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ABSTRACT

Background: Delayed cord clamping is proved to be more efficient in increasing neonatal blood volume as compared to early cord clamping; thereby raising iron status and preventing anemia in term infants. However, the benefits and potential harms of each policy are still debatable. The present study aimed to study the effect of delivering babies on mother's abdomen with reference to cord clamping time (DCC & ECC) and requirement of neonatal resuscitation in term babies. The effect of DCC compared with ECC on infant iron status was also investigated. **Material & Methods:** 200 full term babies who were born after a low-risk pregnancy were assessed. Depending on the timing of cord clamping, infants were randomly categorized into DCC (≥180 seconds after delivery) and ECC (≤10 seconds after delivery) groups. Outcomes were assessed as primary outcomes (Hb & iron status at 4 months of age) and secondary outcomes (neonatal anaemia, polycythaemia, early respiratory symptoms and need for phototherapy). **Results:** A statistically insignificant difference was seen in Hb concentration, but infants subjected to delayed cord clamping had 48% higher mean ferritin levels (P<0.001) and a lower prevalence of iron deficiency (P=0.01). For secondary outcomes, the DCC group showed lower prevalence of neonatal anaemia at 2 days of age (P<0.05). **Conclusions:** DCC as compared to ECC resulted in improved iron status and reduced prevalence of iron deficiency at 4 months of age, and reduced prevalence of neonatal anaemia, without demonstrable adverse effects.

KEYWORDS

Delayed cord clamping, Early cord clamping, infant anemia, late onset sepsis

INTRODUCTION

Timing of umbilical cord clamping has been an issue of debate since past. While few obstetricians still practice early cord clamping, it is now widely accepted that delayed umbilical cord clamping (DCC) is most beneficial to the infant without incurring any risk to the mother.[1] Allowing placental transfusion of blood to run to completion before clamping the umbilical cord can provide the infant with an additional 15–20 mL of blood volume, increasing its total blood volume by an estimated 30%.[1] Keeping baby at the mother's side enables neonatal care with the cord intact and this, along with delayed clamping, may improve outcomes. Umbilical cord milking (UCM) is proposed for increasing placental transfusion when immediate care for the preterm baby is needed.[2]

Iron deficiency and iron deficiency anaemia are major public health problems in young children worldwide, and are associated with poor neurodevelopment. Delayed umbilical cord clamping has been suggested as a measure to prevent infant iron deficiency,[3] but we lack data concerning its health benefits and possible adverse effects, especially in high income countries. Two recent meta-analyses have concluded that iron supplementation improves psychomotor and mental development in infants and children.[4-5] Thus, the available evidence suggests that it is important to prevent iron deficiency in infants in order to achieve optimal brain development.

Delayed cord clamping, usually defined as ligation of the umbilical cord 2–3 minutes after birth or when cord pulsations stop results in a larger placental transfusion than early cord clamping performed immediately after delivery.[6]

Delayed cord clamping seems to drive up mean haematocrit values and serum concentrations of bilirubin, without increasing the number of infants needing treatment for jaundice or polycythaemia. However, some studies suggest that delayed cord clamping may have adverse neonatal effects with increased risk of respiratory symptoms[7], polycythaemia[8], hyperbilirubinaemia[9], and need of phototherapy.[6]

Further there are no available data concerning health effects of delayed cord clamping beyond the neonatal period in term newborn infants for Indian population.

In advent of same we undertook the present study to study the effect of delivering babies on mother's abdomen with reference to cord clamping time (DCC & ECC) and requirement of neonatal resuscitation in term babies. The effect of delayed umbilical cord clamping, compared with early clamping, on infant iron status was also investigated.

MATERIAL & METHODS

After approval from the institutional ethical committee this randomised controlled study was conducted in Department of Pediatrics, SAIMS & PG Institute on 200 infants born to Pregnant females who qualified the inclusion criteria. Written informed consent as obtained, from both parents when possible.

Inclusion Criteria

Pregnant women meeting the below criteria were included

- non-smoking;
- healthy (no haemolytic disease, no treatment with any of the following drugs (anticonvulsants, antidepressants, thyroid hormone, insulin, chemotherapy, or cortisone));
- normal pregnancy (no pre-eclampsia, no diabetes, no prolonged rupture of membranes or signs of infection);
- singleton;
- term pregnancy (gestational age 37+0 to 41+6 weeks);
- expected vaginal delivery with cephalic presentation.
- The mother also had to consent to participate in the study and live close enough to the hospital to be willing to return for follow-up after four months.

Exclusion Criteria

- Serious congenital malformations, syndromes, or other congenital diseases that could affect the outcome measures.
- Patients who did not consented for the study.

Method

Depending on the timing of cord clamping, infants were randomly categorized into DCC (≥180 seconds after delivery) and ECC (≤10 seconds after delivery) groups. In both interventions, the nurse was instructed to hold the newborn infant at a level about 20 cm below the vulva for 30 seconds and then place the baby on the mother's abdomen (20 cm was chosen as a practically obtainable level because of the facility to fold down the lower part of the delivery bed). Babies born by caesarean section were placed in the mother's lap before clamping in accordance with clinical routines. Oxytocin (10 IU) was administered intravenously immediately after cord clamping. The time from complete delivery of the baby to the first clamp on the umbilical cord was measured with a stopwatch by the nurse's assistant.

Venous and arterial cord blood samples for assessment of acid-base status were taken within 30 seconds from the unclamped cord in the delayed cord clamping group and within 10 minutes from the double clamped segment of the umbilical cord in the early clamping group. Study samples were taken from the clamped umbilical cord in both groups.

Follow-up

The infant was assessed at 1 and 6 hours and it was recorded if the baby had been breast fed and the presence of respiratory symptoms (that is,

respiratory rate >60 breaths/minute, presence of nostril flaring, grunting, or intercostal retractions). All neonatal diagnoses were reported in the study protocol. At 48–72 hours after birth, study samples were taken in conjunction with routine venous blood sampling for metabolic screening. At 4 months of age, infants were scheduled for a follow-up visit including blood sampling and weight and length measurements. Before the visit, parents were questioned about the feeding protocol followed (exclusive breastfeeding or formula feed). Maternal health records were assessed for history of any reported illness, medication, parity, weight, height, body mass index, smoking habits, blood group Rh factor status, and haemoglobin concentration at the time of admission to antenatal care.

Investigations

Umbilical cord blood was analysed for CBC (haemoglobin, packed cell volume, mean cell volume, mean cell haemoglobin concentration, reticulocyte count, and reticulocyte haemoglobin); iron status (serum iron & serum ferritin); and C reactive protein. At 2 days of age and 4 months, venous blood was analysed for CBC, iron status, C reactive protein, and bilirubin.

We used the following definitions:

At 2 days

- Anaemia—haemoglobin <145 g/L[10]
- Polycythaemia—packed cell volume >0.6530[11]
- Hyperbilirubinaemia—bilirubin>257 µmol/L (corresponding to 15 mg/dL)

At 4 months

- Anaemia—haemoglobin <105 g/L[12]
- Iron deficiency—≥2 indicators of iron status outside reference range (ferritin <20 µg/L, mean cell volume <73 fL).

Primary Outcome

Infant haemoglobin and iron status (measured as serum ferritin, reticulocyte haemoglobin, mean cell volume, mean cell haemoglobin concentration) was measured at 4 months of age.

Secondary outcomes

Neonatal morbidity (including anaemia, polycythaemia, need for phototherapy, and respiratory symptoms) was assessed.

Statistical Analysis

The raw data was entered into the computer database. All statistical analyses were performed using IBM SPSS Statistics for Windows, Version 22.0. Armonk, NY: IBM Corp. Descriptive statistics were used to show the feature and characteristics of the collected data. For group comparisons of continuous variables, we used Student's t test for variables with normal distribution. For variables with skewed distribution, we used Mann-Whitney U test for group comparisons. A P value <0.05 was considered significant.

RESULTS

200 mother-infant dyads participated in the study. Participants were recruited for 18 months from May 2021 to September 2022; with a four-month follow-up. In total, 191 infants constituted the study population, and their data were analysed according to intention to treat. Of these infants, 167 (87%) received the allocated intervention (87 for delayed clamping, 80 for early clamping), and 175 (92%) were evaluated for the main outcome at 4 months of age.

Baseline Data

A statistically insignificant difference was found (P>0.05) between the delayed cord clamping and early clamping groups with respect to maternal characteristics or neonatal baseline data. Infants in the delayed clamping group had higher birth weights, but, since birth weight was measured after the intervention, this was regarded as an outcome variable.

Primary Outcome

175 children (92%) with mean age of 120 ± 5 days reported for follow up. A statistically insignificant difference was found (P>0.05) in hemoglobin concentration between the two groups. A 30% difference in the ferritin concentration and a 45% higher geometric mean serum ferritin concentration in the delayed cord clamping group (119 µg/L with delayed clamping v 83 µg/L with early clamping, P<0.001).

A significant difference was also observed between all other indicators of iron status i.e., reticulocyte haemoglobin, mean cell volume, and mean cell haemoglobin concentration. A significantly higher prevalence of iron deficiency was observed in the ECC group, but the prevalence of anaemia did not differ between the groups.

Secondary Outcomes

Neonatal blood samples were obtained at a median age of 2.5 days (range 2.0–5) from 179 (94%) newborns. At this time, fewer infants in the delayed cord clamping group were anaemic than in the early cord clamping group (1 (1.2%) v 5 (6.3%), P=0.021). No infant in either group was polycythaemic.

As for treatment with phototherapy, there was no significant difference between groups. Three infants were subjected to phototherapy, one in the delayed cord clamping group and two in the early clamping group.

There were no differences in the prevalence of neonatal respiratory symptoms (respiratory rate >60 breaths/minute, nostril flaring, grunting, or retractions between or under the ribs) between the delayed clamping and the early clamping groups, neither at 1 hour (9 (9.4%) v 6 (6.6%), P=0.42) nor at 6 hours (3 (3.7%) v 4 (5.25%), P=0.6)

The measured amount of blood retained in the placenta was 38% (25% to 50%) lower in the delayed cord clamping group (geometric mean volume 25 mL v 39 mL, P<0.001). There were no group differences in cord blood iron status (not shown), but cord blood haemoglobin and packed cell volume were significantly lower in the delayed clamping group.

There was no difference between the delayed and early cord clamping groups in the proportion of infants who had started breast feeding at 1 hour (68 (75%) v 65 (73%), P=0.90) or at 6 hours (66 (82%) v 66 (85%), P=0.53). In the delayed clamping group 14 newborns (14%) were admitted to the neonatal unit, compared with 6 (6%) in the early cord clamping group (P=0.121).

The indications for admission in the delayed clamping group were transient tachypnoea (n=2), suspected meconium aspiration (n=2), pneumonia (n=2), hypoglycaemia (n=2), feeding difficulties (n=2), need for phototherapy (n=1), seizures (n=1), cleft palate (n=1), and mild asphyxia (n=1). In the early clamping group reasons for admission were transient tachypnoea (n=2), suspected meconium aspiration (n=1), pneumonia (n=1), hypoglycaemia (n=1), and need for phototherapy (n=1).

At a median age of 2.5 days, mean haemoglobin levels and packed cell volume were significantly higher in the delayed cord clamping group, but there were no significant differences in iron status between the two groups. Bilirubin concentrations were similar in the two groups, and no differences were seen in the proportion of infants with hyper-bilirubinaemia (>257 µmol/L) At 4 months of age, infants in the delayed and early cord clamping groups had similar weights (mean 6813 (SD 852) g v 6844 (842) g, P=0.5), and length (64 (2) cm v 64 (2) cm, P=0.4). In the delayed cord clamping group, 47 (56%) infants were exclusively breast fed compared with 42 (51%) in the early clamping group (P=0.44) The proportion of infants exclusively or partially breast fed was 64 (79%) in the delayed clamping group and 75 (87%) in the early clamping group (P=0.087)). There was no significant difference regarding the proportion of iron deficiency: seven (4%) exclusively breastfed infants had iron deficiency compared with four (3%) among those receiving any amount of formula or solid food (P=0.6)

Table 1: Baseline Characteristics Of Mother-infant Dyads Who Participated In Randomised Trial Of Early Umbilical Cord Clamping (≤10 S After Delivery) Versus Delayed Clamping (≥180 S).

	Early (n=80)	Delayed (n=87)	P value
Maternal characteristics			
Age (years)	31.5 (4.1)	30.7 (4.6)	NS
Parity (including study child)	1.77 (0.86)	1.75 (0.72)	NS
Weight at first antenatal visit (kg)	66.5 (12.1)	67.3 (11.8)	NS
Body mass index	23.75 (4.0)	24.1 (3.6)	NS
Haemoglobin at first antenatal visit (g/L)	127 (9)	127 (11)	NS
No (%) with Rh negative blood group	9 (10)	16 (20)	NS
No (%) of vaginal deliveries:			
Non-instrumental	72 (90)	78 (89.6)	NS
Vacuum extraction	6 (7.5)	6 (6.8)	NS

Forceps	1 (1.25)	1 (1.1)	NS
No (%) of caesarean sections	1 (1.25)	2 (2.5)	NS
Infant characteristics			
Gestational age (weeks)	40.2 (1.1)	40.1 (1.1)	NS
No (%) of males	40 (50)	86 (45)	NS
No (%) with Apgar score 7–10 at 1 minute	76 (95)	188 (97)	NS
Birth weight (g)	3531 (476)	3628 (460)	0.05*
Birth length (cm)	50.7 (1.8)	50.8 (1.8)	NS
Head circumference (cm)	34.8 (1.4)	34.9 (1.4)	NS
Umbilical cord haemoglobin (g/L)	163 (16)	159 (18)	0.01†
Umbilical cord packed cell volume	0.49 (0.04)	0.47 (0.05)	0.01‡

NS=Not significant (P>0.05).
*Mean difference 96 g (95% CI 0.3 to 191).
†Mean difference −4.7 g/L (95% CI −8.4 to −1.1).
‡Mean difference −0.013 (95% CI −0.024 to −0.003).

Table 2: Measures Of Complete Blood Count And Iron Status At 2 Days And 4 Months Of Age In Infants Who Were Randomised To Early Umbilical Cord Clamping (≤10 S After Delivery) Or Delayed Clamping (≥180 S).

	2 days Cord clamping Difference (95% CI)			4 months Cord clamping Difference (95% CI)		
	Early	Delayed	P value	Early	Delayed	P value
Blood count	(n=80)	(n=87)		(n=86)	(n=89)	
Haemoglobin (g/L)	174 (18)	188 (18)	13.4 (9.5 to 17.4),	114 (7)	114 (8)	0.0 (−1.6 to 1.6), 0.98
Packed cell volume	51 (5)	53 (5)	3.6 (2.5 to 4.7), <0.001	34 (2)	34 (2)	−0.21 (−0.7 to 0.2), 0.28
Mean cell volume (fL)	98.2 (3.8)	98.4 (3.7)	0.1 (−0.7 to 0.9), 0.82	78.1 (3.1)	79.2 (3.1)	1.0 (0.3 to 1.7), 0.004
Mean cell haemoglobin	353 (8)	355 (8)	2.3 (0.7 to 3.8), 0.007	343 (0.8)	345 (0.8)	2.5 (0.9 to 4.3), 0.002
Reticulocyte	32.4 (2.3)	32.6 (2.5)	0.2 (−0.4 to 0.7), 0.54	28.8 (2.1)	29.7 (1.9)	0.6 (0.2 to 1.0), 0.005
Reticulocyte count	170 (48)	168 (44)	−3 (−13 to 7), 0.54	38 (12)	41 (12)	2.4 (0.1 to 4.8), 0.04
Iron status*						
Iron (µmol/L)	9.9 (2.8)	9.9 (2.7)	−0.1 (−0.7 to 0.6),0.88	9.4 (2.8)	10.1 (3.0)	0.9 (0.2 to 1.5), 0.007
Total body iron (mg/kg)	11.7 (2.2)	11.8 (2.1)	0.1 (−0.4 to 0.6), 0.74	8.1 (3.5)	9.6 (2.7)	1.6 (0.9 to 2.3), <0.001

Table 3: Proportion Of Infants Randomised To Early Umbilical Cord Clamping (≤10 S After Delivery) Or Delayed Clamping (≥180 S) Who Had Iron Status Indicators Outside Reference Limits At 4 Months Old.

	Early (n=80)	Delayed (n=87*)	P value	CI)	(95% CI)
Ferritin <20 µg/L	13 (7.4)	0 (0.0)	<0.001	1.0 (0.71-1.00)	14 (14 to 25)
Mean cell volume <73 fL	9 (5.1)	4 (2.4)	0.26	0.54 (-0.39 to 0.85)	NA
Iron deficiency†	10 (5.7)	1 (0.6)	0.01	0.90 (0.38 to 0.98)	20 (17 to 67)
Anaemia (Hb <105 g/L)	21 (1.2)	21 (1.25)	1.0	-0.04 (-0.83 to 0.41)	NA

Table 4. Hyperbilirubinaemia And Need For Phototherapy At 2 Days Old Among Infants Randomised To Early Umbilical Cord Clamping (≤10 S After Delivery) Or Delayed Clamping (≥180 S).

	Early	Delayed	P value	Relative risk reduction (95% CI)
Mean (SD) bilirubin (µmol/L)	144 (62)	145 (67)	0.96†	
Bilirubin >257 µmol/L*	7 (5.4)	4 (2.9)	0.37	0.46 (−0.70 to 0.83)
Treated with phototherapy	2 (1.1)	1 (0.5)	0.62	0.52 (−2.7 to 0.94)

DISCUSSION

Delayed clamping of the umbilical cord is ascertained to be beneficial in term infants born after normal pregnancies and had significant effects on iron status at 4 months with higher serum ferritin concentration, less iron deficiency, and similar effects on all measured indicators of iron status except haemoglobin and packed cell volume.

In the present study lesser no. of patients presented with anaemia during the early neonatal period in the delayed cord clamping group as compared to early cord clamping. An insignificant difference (P>0.05) with regard to neonatal respiratory symptoms or need for phototherapy was observed between the two groups. We found significant differences between the intervention groups at 4 months of age in all measures of iron status except haemoglobin and packed cell volume, all pointing to an inferior iron status in the early cord clamping group. Lower ferritin concentrations suggest depleted iron stores; and lower mean cell volume, mean cell haemoglobin concentration, and reticulocyte haemoglobin suggest iron deficient erythropoiesis.

In the absence of anaemia, which is the marker of severe iron deficiency, our findings of abnormalities in several of these indicators (as used in our definition of iron deficiency) implies the presence of a moderate rather than a mild iron deficiency. The prevalence of iron deficiency was significantly higher in the early cord clamping group than in the delayed clamping group (6% v 1%), which might have an impact on future neurodevelopment.[4]

The lack of a persisting effect from delayed cord clamping on haemoglobin at 4 months of age can be explained by the physiological and gradual transfer of iron from erythrocytes to iron stores (measured by ferritin) as the haemoglobin concentration decreases and approaches its individual, genetically and environmentally determined "set point" sometime after 2 months of age.

Comparison With Other Studies

The observed effect of delayed cord clamping on ferritin levels at 4 months (48% increase) was concurrent with study done by Chaparro CM et al.[13] & Andersson O et al.[14] McDonald SJ et al.[6] & Hutton EK et al.[15] in their meta-analyses, mainly based on trials in low- and medium-income settings, have shown that delayed cord clamping improves serum ferritin concentration at 3–6 months of age without affecting haemoglobin.[6,15]

It has been postulated that delayed cord clamping may increase the risk of neonatal polycythaemia and respiratory symptoms, but we did not find any group differences in these outcomes, which is also consistent with the Cochrane meta-analysis done by McDonald SJ et al.[6] We found a higher risk of neonatal anaemia in the early cord clamping group, although no infant required treatment which was in concurrence to results from two anecdotal studies done by Ceriani Cernadas JM et al.[16] & Emhamed MO et al.[17]

Seven infants in the DCC group were admitted to the neonatal unit, compared with three in the ECC group which was non-significant statistically, but only three of the admissions in the delayed clamping group and two of those in the early clamping group could reasonably be attributed to the intervention (transient tachypnoea, hypoglycaemia, and need for phototherapy). There have been inconsistent results on the possible association between delayed cord clamping and neonatal jaundice, and the Cochrane review done by McDonald SJ et al.[9] that reported a significant increase in infants needing phototherapy for jaundice relied heavily on unpublished data.[9] In our study there were no group differences in bilirubin concentrations or need for phototherapy even though we observed a relatively large difference in haemoglobin concentration at 2 days of age. Our results therefore strongly suggest that delayed cord clamping is not associated with any increase in the need of phototherapy in term infants, in agreement with the recent meta-analysis done by Hutton EK et al.[18]

An unexpected difference in cord blood haemoglobin concentration was observed in the present study; the delayed cord clamping group had 4.7 g/L lower cord haemoglobin concentration than the early cord clamping group. A similar result was reported in the Cochrane report by McDonald SJ et al.[9], with a mean difference in haemoglobin concentration of 4.2 g/L,16 although this result was not discussed in

the Cochrane report or in the original studies reporting this outcome. However, from the current data, the exact explanation for the difference in cord haemoglobin can't be done. We speculate that the lower umbilical cord haemoglobin level and packed cell volume in the delayed cord clamping group could be due to changes in blood rheology or transendothelial plasma leakage in the umbilical cord after cord clamping, and that the difference does not reflect a true difference in haemoglobin level between the two groups before cord clamping.

CONCLUSION

It can be concluded that delayed cord clamping resulted in improved ferritin levels and reduced the prevalence of iron deficiency at 4 months of age. Delayed clamping also reduced the prevalence of neonatal anaemia at 2 days of age without increasing the rate of respiratory symptoms or need for phototherapy and that this effect is clinically relevant and should lead to a change in practice. Delayed cord clamping also benefits infant health in regions with a relatively low prevalence of iron deficiency and should be considered as standard care for full term deliveries after uncomplicated pregnancies. Further studies are needed to explore long term health effects of delayed and early cord clamping with a larger sample size.

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