Section: Pediatrics

Original Research Article

EFFECT OF EARLY VS DELAYED CORD CLAMPING ON IRON STORES IN SMALL FOR GESTATIONAL AGE BABIES AT 3 MONTHS OF AGE

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Received : *31/03/2023*
Received in revised form : *05/05/2023*
Accepted : *17/05/2023*

Keywords:
ECC, DCC, Iron SGA.

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DOI: 10.47009/jamp.2023.5.3.488

Source of Support: Nil,
Conflict of Interest: None declared

Int J Acad Med Pharm
2023; 5(3); 2495-2500

Abstract

Background: The scientific literature has engaged in a longstanding debate regarding the most advantageous timing for umbilical cord clamping for more than a century. The practise of early clamping of the umbilical cord is commonly implemented as a component of labour management. The practise of early clamping of the umbilical cord emerged as one of the initial standard medical interventions during the process of childbirth. There is evidence to suggest that delaying the clamping of the umbilical cord can provide significant advantages for full-term infants. The practise of delaying umbilical cord clamping has been found to result in elevated haemoglobin levels during birth and enhanced iron reserves in the initial months of an infant's life. These improvements have been associated with positive developmental outcomes. Effect of early vs delayed cord clamping on iron stores in small for gestational age babies at 3 months of age. **Materials and Methods:** A retrospective study was conducted to examine pregnant women who underwent antenatal ultrasonography (USG) starting from the second trimester. Individuals were considered eligible for inclusion in the study if there was observable evidence of foetal growth restriction as determined through antenatal ultrasonography. Clinical care was administered in accordance with the standard unit protocol in both the ECC and DCC groups. The blood samples were obtained from a substantial peripheral vein. Haemoglobin and hematocrit estimation were performed at 2 hours of life. The weight, length, and occipitofrontal circumference (OFC) measurements were obtained using established protocols. The principal measure of interest in our investigation was the level of serum ferritin observed at the age of three months. A total of 100 participants were randomly assigned to either the ECC or DCC group. **Result:** The mean serum ferritin level in the DCC group was 87.50 ± 6.39 ng/ml, whereas in the ECC group it was 51.50 ± 4.19 ng/ml. This difference was statistically significant with a p-value of 0.02. The prevalence of iron deficiency was lower in the DCC group compared to the ECC group, with 12 infants (24%) in the DCC group and 25 infants (50%) in the ECC group exhibiting iron deficiency (p = 0.04). The prevalence of polycythemia in infants was found to be significantly higher in the delayed cord clamping (DCC) group, with 21 (42 %) of infants affected, compared to 10 (20%)in the ECC group. This difference was statistically significant, as indicated by a p-value of 0.02. There was no discernible disparity observed in the proportion of infants exhibiting symptomatic polycythemia or those who underwent partial exchange transfusions. The incidence of polycythemia in infants was found to be significantly higher in the delayed cord clamping (DCC) group. **Conclusion:** Delayed cord clamping (DCC) results in enhanced iron reserves in SGA infants born at or after 35 weeks of gestation when assessed at 3 months of age, without elevating the likelihood of symptomatic polycythemia, requirement for partial exchange transfusions, or associated morbidities.

INTRODUCTION

Iron deficiency and iron deficiency anaemia pose significant public health challenges in young children globally, and are linked to adverse neurodevelopmental outcomes. The practise of delayed umbilical cord clamping has been proposed as a potential strategy for mitigating infant iron deficiency. However, there is a dearth of empirical evidence regarding its efficacy in promoting health benefits and the potential negative consequences, particularly in high-income nations.[1] Young children are particularly susceptible to iron deficiency due to their elevated iron needs during periods of rapid growth, coupled with inadequate iron consumption. On a global scale, approximately 25% of preschool-aged children experience iron deficiency anaemia, which is recognised as the most severe manifestation of iron deficiency. The prevalence of iron deficiency anaemia among young children in Europe ranges from 3% to 7%, while the prevalence of iron deficiency has been documented to reach as high as 26%.[2,3] Iron plays a crucial role in various facets of brain development, encompassing myelination, dendritogenesis, neurotransmitter function, as well as neuronal and glial energy metabolism.[4] The presence of iron deficiency anaemia in young children has been found to be correlated with enduring cognitive and behavioural impairments.[5] There is evidence to suggest that iron deficiency, even in the absence of diagnosed anaemia, is linked to changes in affective responses, hindered motor development, and cognitive delays.[6,7] According to two recent meta-analyses, the administration of iron supplements has been found to enhance psychomotor and cognitive development in infants and children.[8,9] Therefore, based on the existing body of evidence, it can be concluded that the prevention of iron deficiency in infants is crucial for attaining optimal brain development. In the initial moments following birth, the neonate has the potential to receive a significant transfusion of blood from the placenta. During the initial three minutes of life, if a term newborn is positioned 10 cm below the level of the uterus, there is an observed average increase of 32% in its blood volume. Delayed cord clamping refers to the practise of clamping the umbilical cord 2-3 minutes after birth or when cord pulsations cease. This approach leads to a greater volume of blood being transferred from the placenta compared to early cord clamping, which involves clamping the cord immediately after delivery.[10]

There is a limited number of controlled trials that have examined the impact of delayed cord clamping on the health of infants beyond the neonatal period. All of these studies were conducted in populations characterised by low and middle income, where there is a significant occurrence of iron deficiency anaemia.[11] Two meta-analytic studies have reached the consensus that delayed cord clamping leads to elevated serum ferritin levels during the period of 3 to 6 months after birth.[11,12] Nevertheless, there is a lack of accessible data regarding the potential health consequences of delayed cord clamping in term newborn infants beyond the neonatal period within high-income nations.

MATERIALS AND METHODS

A retrospective study was conducted to examine pregnant women who underwent antenatal ultrasonography (USG) starting from the second trimester. The determination of gestational age was obtained either through the utilisation of first trimester ultrasound, if accessible, or through the assessment of the last menstrual period. The weight of the foetus was estimated and then graphed on the Hadlockchart.[13] Individuals were considered eligible for inclusion in the study if there was observable evidence of foetal growth restriction as determined through antenatal ultrasonography. The unique identification numbers of eligible pregnant women were recorded in a specialised software system. Upon admission to the hospital for the purpose of safe confinement, an automated notification was transmitted to the principal investigator, who subsequently monitored the individuals involved to determine their continued eligibility. The exclusion criteria encompassed infants who were born to mothers with placental abruption or previa, those who had major congenital malformations diagnosed during the antenatal period, infants affected by Rh isoimmunisation, and infants from multiple pregnancies. The exclusion criteria for post-randomization included infants who were born at or above the 10th centile and those who required resuscitation. If pregnant women had a gestational age at delivery of 35 weeks or more, they were randomly assigned to either the early or delayed cord clamping groups. Prior to delivery, written informed consent was obtained from either parent for participation in the study.

The generation of a computer based variable block random sequence was conducted by an independent researcher utilising a random number table. The allocation sequence was concealed within sealed opaque envelopes. The independent staff member sequentially numbered the opaque envelopes, which were then stored in the Neonatal Intensive Care Unit (NICU). All deliveries were attended by either a neonatology fellow or an on-call consultant. Before the commencement of the delivery process, the neonatologist in attendance initiated communication with the Neonatal Intensive Care Unit (NICU) helpline and established contact with the nurse responsible for overseeing the proceedings. Subsequently, the nurse proceeded to unseal the opaque envelope and divulged the nature of the intervention, specifically Delayed Cord Clamping (DCC) or Early Cord Clamping (ECC). The inherent characteristics of the intervention precluded the possibility of implementing blinding.

In the context of an ECC group, the obstetrician promptly applied clamping to the umbilical cord following the delivery of the infant. In the DCC (Delayed Cord Clamping) group, the umbilical cord was clamped after a duration of 60 seconds. The stopwatch was initiated upon the emergence of the infant's buttocks from the vaginal canal. In order to facilitate delayed cord clamping (DCC), the attending neonatologist audibly counted the elapsed time in 10-second intervals. The precise timing of cord clamping was recorded for both experimental groups. During this period, the newborn was placed on linen at the introitus level during vaginal delivery or on the legs during a caesarean section. Precautions were taken to avoid applying tension to the cord. The act of milking the cord was not performed. Following the clamping of the umbilical cord, the attending neonatologist provided care for the infant in accordance with the guidelines outlined in the NRP of 2010. The birth weight was inputted into the Fenton gestation and sex-specific online calculator in 2013, and the infant was categorised as SGA if the birth weight fell below the 10th percentile. The study excluded infants whose birth weight fell within or above the 10th centile, as well as those who required resuscitation. Clinical care was administered in accordance with the standard unit protocol in both the ECC and DCC groups.

The blood samples were obtained from a substantial peripheral vein. Haemoglobin and hematocrit estimation were performed at 2 hours of life. The weight, length, and occipitofrontal circumference (OFC) measurements were obtained using established protocols. Haemoglobin and serum ferritin levels were estimated at approximately 3 months of age, with a margin of error of ±7 days. The estimation of hemoglobin/hematocrit was conducted using the Coulter method, while the measurement of ferritin was performed using a two-site immunoenzymatic assay. During the follow-up period, data regarding iron supplementation, type of feeding, any instances of hospitalisation due to illness, and any occurrences of blood transfusion were documented.

The principal measure of interest in our investigation was the level of serum ferritin observed at the age of three months. The secondary outcomes assessed in this study included polycythemia, the necessity for partial exchange transfusion, hypoglycemia, and neonatal hyperbilirubinemia that required phototherapy. Furthermore, additional secondary outcomes included the measurement of haemoglobin levels and anthropometric assessment at the age of three months. Polycythemia is characterised by a venous hematocrit level exceeding 65%. Partial exchange transfusion was performed in asymptomatic infants who had a hematocrit level exceeding 70%, and in symptomatic infants whose hematocrit level exceeded 65%. Symptomatic polycythemia is characterised by a hematocrit level exceeding 65% in conjunction with various symptoms, including respiratory distress, apnea, cyanosis, seizures, necrotizing enterocolitis (NEC), hypoglycemia, renal vein thrombosis, and DIC. Iron deficiency at three months was characterised by a serum ferritin level below 50 ng/ml. The management of hyperbilirubinemia was conducted in accordance with the guidelines established by the American Academy of Paediatrics. A total of 100 participants were randomly assigned to either the ECC or DCC group.

Statistical Analysis

The analysis of the data was conducted utilising the SPSS software, specifically version 25.0. The Fisher exact test or Chi-square test was employed to compare categorical variables. The statistical tests employed to compare continuous variables, as deemed appropriate, included the Student's t-test and the Mann-Whitney test. A two-tailed p-value less than 0.05 was deemed statistically significant.

RESULTS

During the study period, a total of 1157 women received antenatal ultrasonography. Out of the total, 189 foetuses exhibited a weight below the 10th centile as per the Hadlock chart. Prior to the commencement of the delivery process, a total of 161 infants were subjected to a randomization procedure. Subsequently, out of this initial group, 100 infants were selected to undergo definite inclusion in the study. A total of 100 infants, with 50 in the ECC group and 50 in the DCC group, were subjected to analysis at 3 months to assess the primary outcome. The maternal and neonatal characteristics at baseline were comparable between the two groups, with the exception of the timing of cord clamping, which varied based on the design of the study.The provided information is presented in [Table 1].

At the age of 3 months, the serum ferritin levels were found to be significantly higher in the group of infants who received care in a DCC compared to those who received care in an ECC. The mean serum ferritin level in the DCC group was 87.50 ± 6.39 ng/ml, whereas in the ECC group it was 51.50 ± 4.19 ng/ml. This difference was statistically significant with a p-value of 0.02. The prevalence of iron deficiency was lower in the DCC group compared to the ECC group, with 12 infants (24%) in the DCC group and 25 infants (50%) in the ECC group exhibiting iron deficiency (p = 0.04).The prevalence of polycythemia in infants was found to be significantly higher in the delayed cord clamping (DCC) group, with 21 (42%) of infants affected, compared to 10 (20 %) in the ECC group. This difference was statistically significant, as indicated by a p-value of 0.02. There was no discernible disparity observed in the proportion of infants exhibiting symptomatic polycythemia or those who underwent partial exchange transfusions. The clinical outcomes and mortality rates exhibited no significant differences. [Table 2,3].

The incidence of polycythemia in infants was found to be significantly higher in the delayed cord clamping (DCC) group. Nonetheless, there was no discernible disparity observed in the percentage of infants who exhibited symptomatic polycythemia or necessitated partial exchange transfusion. No additional disparities in haematological and clinical outcomes were observed during the neonatal period, as indicated in [Table 3]. The haemoglobin levels and growth parameters at the 3-month mark exhibited comparable results across both groups.

Table 1: Basic profile of the maternal and neonatal

Parameter	DCC =50		ECC =50		P value
Maternal	**Number /Mean**	**Percentage**	**Number /Mean**	**Percentage**	
Height (cm)	155.41±4.19		155.12±4.15		0.55
BMI (Kg/m2)	22.74±3.64		23.19±3.15		0.34
Prepregnancy weight (kg)	55.15±5.25		56.14±4.15		0.18
Weight gain during pregnancy (kg)	10.01±1.11		10.54±1.31		0.07
Hemoglobin (g/dl)	11.97±1.65		11.11±1.11		0.36
Cesarean section	40	80	34	68	0.22
Time of cord clamping (seconds)	63.14±4.52		13.18±1.95		0.001
Neonatal					
Gestational age (weeks)	37.49±1.58		37.88±1.67		0.22
Male	21	42	28	56	0.27
Length (cm)	46.01±2.64		46.51±2.39		0.67
Birth weight (g)	2194±154		2218±139		0.51
Cord Ferritin (ng/ml)	111.14±3.74		127.15±4.17		0.24
OFC (cm)	31.99±1.85		32.45±1.63		0.37

Table 2: Hematological parameters at 3 months

Parameters	DCC =50		ECC =50		P value
	Number /Mean	**Percentage**	**Number /Mean**	**Percentage**	
Hemoglobin (g/dl)	10.36±1.58		10.69±1.67		0.33
Ferritin (ng/ml)	87.50 ±6.39		51.50±4.19		0.02
Ferritin< 50 ng/ml	12	24	25	50	0.04

Table 3: Clinical and Hematological parameter

Parameters	DCC =50		ECC =50		P value
	Number /Mean	**Percentage**	**Number /Mean**	**Percentage**	
Hematocrit > 70%	4	8	3	6	0.54
Symptomatic polycythemia	2	4	1	2	0.39
Hematocrit at 2 h (%)	64.15±5.85		62.01±4.96		0.06
Polycythemia (Hct> 65%)	21	42	10	20	0.02
Peak bilirubin (mg/dl)	14.03±2.55		16.02±2.39		0.11
Duration of phototherapy (hrs)	30.58±3.57		32.21±3.15		0.27
Partial exchange	6	12	3	6	0.24
Respiratory distress	3	6	2	4	0.41
Hypoglycemia	6	12	7	14	0.37
DIC	1	2	0	0	0.27
Mortality	1	2	0	0	0.22
NEC	1	2	1	2	0.53

Table 4: Anthropometric parameters at 3 months

Parameter	DCC =50		ECC =50		P value
	Number /Mean	**Percentage**	**Number /Mean**	**Percentage**	
Exclusive breast feeding	26	52	25	50	0.37
Exclusive Formula feeding	9	18	8	16	0.49
Weight (g)	4752±259		4901±263		0.33
Length (cm)	55.04±3.68		56.41±3.58		0.19
OFC (cm)	38.11±1.58		38.54±1.63		0.17
Mixed feeding	15	30	17	34	0.22

DISCUSSION

The World Health Organisation recommends the practise of delayed cord clamping. Nevertheless, there exists a scholarly discourse regarding the most favourable timing for cord clamping. When the clamping of the cord is postponed for a duration of 60 seconds or longer, the circulation of blood between the infant and placenta persists, typically concluding within 120 seconds. This procedure enables the administration of 80 - 100 ml of blood, which accounts for approximately one third of the neonate's overall blood volume.[14] The prevalence of SGA infants in India is substantial, with approximately 47% of neonates falling into this category.[15] Due to diminished iron reserves at birth, neonates are more susceptible to the subsequent development of iron deficiency and anaemia. The implementation of DCC (Delayed Cord Clamping) has proven to be an effective approach in reducing the prevalence of iron deficiency anaemia during infancy. Nevertheless, the efficacy of this economical intervention has yet to be comprehensively assessed in the susceptible population of SGA individuals. Our study revealed that infants in the DCC group exhibited significantly elevated serum ferritin levels in comparison to the ECC group. The results of our investigation demonstrate a resemblance to the iron accumulation patterns observed in previous studies.[16–18] In a study conducted by Chaparo et al., a total of 476 term infants with AGA were randomly assigned to either the delayed cord clamping (DCC) group, where clamping was performed at 180 seconds, or the early cord clamping (ECC) group.[16] The group receiving delayed cord clamping (DCC) exhibited a statistically significant increase in serum ferritin levels at the 6-month mark. In a similar vein, Gupta et al. conducted a study involving 102 term infants who were born to mothers with anaemia (haemoglobin levels below 10 g/dl). The researchers observed that the group of infants who underwent delayed cord clamping (DCC) exhibited elevated levels of ferritin at the 3-month mark.[17] Nevertheless, the aforementioned studies did not provide specific outcomes pertaining to infants with SGA status. The potential implementation of delayed cord clamping during the birthing process may have contributed to the achievement of a successful placental transfusion, thereby leading to enhanced ferritin levels. In our study, we observed a lower prevalence of iron deficiency among infants at 3 months of age in the group that DCC, despite the fact that their haemoglobin levels were comparable to those in the control group. No significant disparity in haemoglobin levels was detected, which can be attributed to the progressive nature of iron deficiency. Erythropoiesis is affected only after a substantial decrease in bone marrow iron stores and serum ferritin levels.[19] A more extensive follow-up could potentially have identified the disparity in haemoglobin levels. A recent systematic review conducted by Cochrane examined the comparative effects of early and delayed cord clamping strategies in term infants. The findings of this review also indicated a lower occurrence of iron deficiency in the delayed cord clamping group, while the levels of haemoglobin were found to be similar in both groups.[6] The secondary outcomes assessed in our study encompassed the measurement of haemoglobin and hematocrit levels at the 2-hour mark, as well as the evaluation of polycythemia and other clinical outcomes during the neonatal period. An elevation in haemoglobin and hematocrit levels was observed at the 2-hour mark in the DCC group, although this difference did not attain statistical significance. The prevalence of polycythemia was found to be greater in the DCC group, which contradicts the results of a Cochrane systematic review examining the impact of DCC on full-term infants.[6]

The potential cause of this phenomenon may be attributed to a higher inherent risk of polycythemia in SGA infants in comparison to AGA infants.[20] The administration of additional red blood cells (RBCs) in DCC was found to elevate the likelihood of polycythemia in these neonates. Nonetheless, no discernible disparity was observed in the incidence of symptomatic polycythemia or the need for partial exchange transfusions between the two cohorts. Two additional studies comparing delayed cord clamping (DCC) and early cord clamping (ECC) in term AGA infants found no significant variation in partial exchange transfusions.[21,22] Hyperbilirubinemia is a potential complication that may be associated with both polycythemia and delayed cord clamping. There was no statistically significant disparity observed in the proportion of infants who experienced significant hyperbilirubinemia necessitating phototherapy. The peak levels of bilirubin and the duration of phototherapy exhibited similarities as well. The results of previous studies conducted on term infants have shown that a smaller proportion of infants in the early cord clamping (ECC) group required phototherapy for hyperbilirubinemia compared to the delayed cord clamping (DCC) group.[6] The observed phenomenon may be attributed to the accelerated maturation of the liver in SGA infants.[23] Similar clinical outcomes, including hypoglycemia, respiratory distress, necrotizing enterocolitis, renal vein thrombosis, disseminated intravascular coagulation, and mortality, were observed. At the age of 3 months, there were no discernible variations observed in the anthropometric measurements, including weight, length, and occipitofrontal circumference (OFC), as well as feeding patterns, blood transfusions, and hospitalisations, among the different groups. This study represents the inaugural randomised controlled trial that focuses solely on SGA infants, examining the impact of delayed versus early cord clamping on early neonatal outcomes and iron levels at 3 months postpartum. The implications of these findings are significant in the context of developing countries, where a considerable number of infants are born SGA and face a heightened risk of developing iron deficiency.

CONCLUSION

Delayed cord clamping (DCC) results in enhanced iron reserves in SGA infants born at or after 35 weeks of gestation when assessed at 3 months of age, without elevating the likelihood of symptomatic polycythemia, requirement for partial exchange transfusions, or associated morbidities.

ISSN(O): 2687-5365; ISSN(P): 2753-6556

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