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Early versus Delayed Cord-Clamping in Term-Infants Born at Khon Kaen Regional Hospital

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ABSTRACT

Objectives To compare the hematological status of early versus delayed cord clamping on hematocrit, hemoglobin and possible adverse outcomes at 48 hours after birth.

Study design A randomized, controlled trial.

Setting Department of Obstetrics and Gynecology, Khon Kaen Regional Hospital.

Material and methods 94 singleton term pregnancies were eligible for inclusion and randomly assigned to a group for either early cord clamping (ECC at the first 10 sec) or delayed cord clamping (DCC at 120 sec) after vaginal delivery. Infants' hematological status (hematocrit, hemoglobin and total serum bilirubin) and clinicals were evaluated 48 hours after birth.

Results All 94 infants were enrolled into the study, 47 were randomized to receive ECC and 47 DCC. At baseline the groups had similar maternal demographic characteristics. At 48 hrs after delivery, the mean infant hematocrit was statistically significant higher in DCC group (56.2 and 49.6 percent, respectively). The proportion of anemic infants was statistically significant higher in the ECC (15.9 %) vs. the DCC (2.2 %) group. No statistically significant differences were found in the proportion of polycythemic infants, hyperbilirubinemia and the use of phototherapy between groups.

Conclusion DCC 2 minutes after vaginal delivery improved infant hematocrit and hemoglobin within a physiologic range and this intervention is simple, safe and should be implemented in a strategy to prevent early neonatal anemia.

Keywords: Adverse outcomes, Anemia, Cord clamping, Hyperbilirubinemia, Polycythemia

Introduction

Iron deficiency is the most common anemia worldwide, but the prevalence in developing countries is highest among children under five years, ~50%.[1]

The prevalence of iron deficiency anemia among children 6-59 months in Asia is 12-83%.[2] while in Thailand among young infants (4 to 6 months of age) in small survey areas the prevalence is as high as 32-62%.[3]

Iron deficiency early in life may affect neurologic and intellectual functions causing

impaired cognition, impaired motor development and coordination, impaired language development and scholastic achievement, psychological and behavioral effects (i.e., inattention, fatique) and decreased physical activity.[4,5] Infants with low birth weight, consumption of cows' milk early in life, fast growth rate, and poor dietary iron intake are considered the main risk factors of iron deficiency anemia.[6]

Infants who enjoy prolonged and exclusive breast feeding have been found to have good iron status.[7] It has been difficult to implement and promote an exclusive breast feeding program in Thailand. In a 2005 survey, it was found that exclusive breastfeeding at 6 months was 14.5% despite a target of 30% set by the Ninth National Health Development Plan (NHDP).[8]

Some studies have confirmed the benefits of delayed cord clamping,[9-11] which could help prevent iron deficiency anemia in the first year of life, based on the infants' being delivered with a placental transfusion of 80 mL of blood at 1 minute and 100 mL at 3 minutes after birth.[12-15] This volume (75-115 mL/kg) will provide about 50 mg of iron, which might prevent iron deficiency in the first year of life.[9,16,17]

A recent systematic review revealed that the benefit of DCC (at least two minutes post delivery) was that it improved hematologic status such as hematocrit and stored iron over 2 to 6 months of age, while delayed umbilical cord clamping increased infant risk of asymptomatic polycythemia.[18]

Nowadays, the timing of cord clamping is still controversial.[16,19] Cord clamping immediately after birth is the common practice in Thailand plus active management of the third stage of labor[20] (as follows, administration of prophylactic oxytocin before placental delivery, early cord clamping and controlled cord traction) as recommended in the guidelines at Khon Kaen Regional Hospital.

Accordingly, we performed a randomized controlled trial to compare the risk and benefit of timing of umbilical cord clamping. As far as we know, this is the first randomized controlled trial to evaluate the hematological effect of DCC in Thailand. The main objective of this study was to compare of the effect of ECC and DCC in term infants on hematocrit, hemoglobin status and possible adverse outcomes (as follows, anemia, polycythemia and hyperbilirubinemia) at 48 hrs after birth.

Materials and Methods

Between October 21, 2005, and February 13, 2006, we recruited 94 infants delivered at the Labor Room, Department of Obstetrics and Gynecology, Khon Kaen Regional Hospital, Thailand. Their mothers were contacted in the hospital while in the first stage of labor. Written informed consent was obtained after explaining to the pregnant women in the research methods. History taking and physical examination were taken and other data were taken via questionnaire to gather demographic and socioeconomic details from mothers. Every subject was assessed for fetal well-being by electrical fetal heart rate monitoring. All subjects met the following inclusion criteria: (1) gestational age 37 to 42 weeks confirmed date by early ultrasound or certain last menstrual period; (2) singleton birth; and, (3) expected birth weight ≥2500 g.

Pregnancy related severe medical disease and complications such as hypertensive disorders, gestational diabetes mellitus, ante partum hemorrhage, renal impairment, heart disease, instrumental delivery, previous cesarean section, congenital malformations, need for neonatal resuscitation, malpresentation, nuchal cord, thick meconium stained amniotic fluid and fetal distress were excluded. Instrumental delivery and nuchal cord were excluded from this study after we enrolled eligibly pregnant women but before the step of randomization into ECC or DCC group.

After delivery of the anterior infant's shoulder by vaginal route, the infants were randomly assigned (using simple randomization opaque sealed envelopes placed in a box from which only one envelope could be drawn at a time by circulating nurse in the labor room) to ECC or DCC.

In the ECC group, clamping was done at 10 seconds after delivery; whereas clamping was done

at 120 seconds after birth in the DCC group. All obstetricians were instructed the sterile technique of cord clamping by using of the two tonsil clamps. The cord was estimated at least 15 centimeters in length from umbilical infant. We applied the first clamps at maternal end then squeezed the cord blood to infant end before using the second clamps. Finally, the cord was cut by sterile scissors. The time was recorded by use of a stopwatch. After vaginal delivery, the infant was placed on the mother's abdomen. We followed the basic steps of the guidelines for neonatal resuscitation (i.e., (1) the infant is placed in a warm environment, (2) next the airway is cleared, (3) the baby dried, stimulated and wrapped in warm towel) as recommended by the American Academy of Pediatrics and the American Heart Association.[21]

The infants' health was assessed every morning especially 48 hours after delivery by a pediatrician. The examinations included clinical assessment of general appearance, vital signs, clinical jaundice, plethora, respiration and sucking ability.

Infant venous blood samples were collected in K3EDTA and serum MiniCollect (Greiner Bio-one GmbH, Bad Haller str. 32, 4550 Kremsmunster, Austria), 1 mL for complete blood count (hematocrit and hemoglobin) and 1 mL for total serum bilirubin, respectively at 48 hours after birth. Complete blood count was done using COULTER-LH 750 ANALYZER (Manufactured by USA, 2002) and total serum bilirubin was estimated by DIMENSION XL (Manufactured by USA, 1995). The recruitment process for the study is shown in Figure 1.

Polycythemia[22] and anemia[23,26] in the newborn were defined as venous Hct >65% and < 45%, respectively. Phototherapy was considered on child by child basis in hospitalized infants of 35 or more weeks' gestation.[24]

This study was approved by the Human Research Ethics Committee of Khon Kaen Regional Hospital, Thailand.

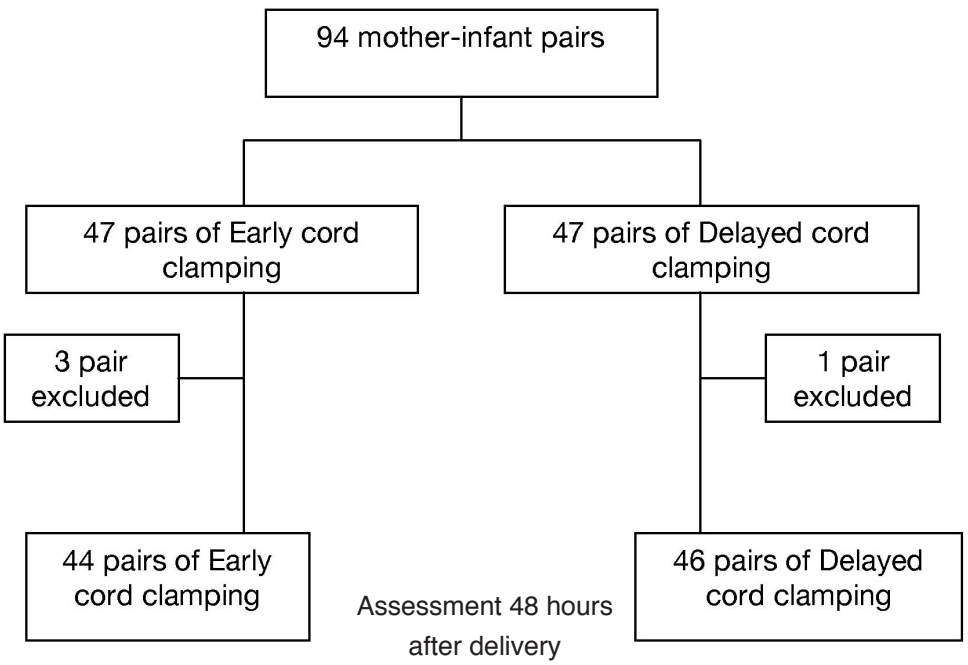

Fig. 1. Recruitment into the study

Exclusion:

1 ECC group

- Two mother-infant pairs were dropped out. They did not allow to give infant blood at 48 hours after delivery.
- One mother-infant pair was excluded. Because of inadequate blood for laboratory test, mothers and infants already went home.

2 DCC group

- One mother-infant pair was excluded. Because of inadequate blood for laboratory test, mothers and infants already went home.

Sample size

Based on the result of the study by Emhamed et al.(23) the difference in mean hematocrit between the ECC (Hct=49.3%) and DCC (Hct=52.9%) group at 24 to 48 hours is 3.6%, and the standard deviation in each group is 5.7 and 6.3 g/dL, respectively. We used a 95% of confidence interval and needed 80% power; therefore, the sample size of infants to be studied needed to be 43 in each group or 94 in total (add 8.5%).

Statistical analysis

Data was analyzed using SPSS version 11. The continuous variables were compared with the independent t-test and categorized variables with the Chi-square or Fisher's exact test as appropriate. Results were reported as means, standard deviations (SD) or percentages. The level of significance used was $p<0.05$.

Results

There were 94 mother-infant pairs enrolled into the study; 47 in the ECC and 47 in the DCC group. Four mother-infant pairs were excluded from the final analysis, reasons for deviations are shown on Figure 1.

Compliance with the allocated intervention was 93.6% (44 of 47) in the ECC and 97.9% (46 of 47) in the DCC group.

Maternal and infant baseline characteristics in the DCC and ECC groups were comparable in maternal age, gestational age, maternal hematocrit at third trimester, antenatal visit, parity, level of education, iron supplement, maternal anemia, estimated blood loss, infant weight, length of stay of infant and infant sex (Table 1,2).

Infant hematological status at 48 hours after birth was significantly higher in the DCC vs. the ECC group; specifically, hemoglobin was 18.73 and 16.82 g/dL and hematocrit 56.16 and 49.65 percent, respectively (Table 3).

There were no significant differences regarding the proportion of polycythemic infants with hematocrit >65% between the DCC and ECC group (8.69% and 2.27%, respectively) (Table 3), two polycythemic infants (4.35%) in the DCC group developed clinical plethora without symptoms (i.e., cyanosis tachypnea, feeding difficulties or neurological depression); consequently they did not need an exchange transfusion.

The proportion of anemic infants with hematocrit <45% was significantly higher in the ECC (15.91%) vs. the DCC group (2.17%) (Table 3), none of the anemic infants developed adverse symptoms, as a result no blood transfusions were required.

The mean serum total bilirubin at 48 hrs in the ECC was slightly higher than the DCC group (11.95 and 11.64 mg/dL, respectively) and the proportion of infant hyperbilirubinemia, indicated by the use of phototherapy in the ECC was higher than the DCC group (9.1 and 6.5 percent, respectively). Both the mean serum total bilirubin and the percentage of infant hyperbilirubinemia that indicated the use of phototherapy were not significantly different (Table 3).

Nine percent (4 of 44) of the ECC group

required phototherapy, of which 4.6% (2 of 44) had an ABO incompatibility, 2.3% (1 of 44) inconclusive jaundice and 2.3% (1 of 44) G6PD-deficiency anemia. Similarly, 8.7% (4 of 46) of the DCC group required phototherapy, of which 4.3% (2 of 46) had G6PD-deficiency anemia, 2.2% (1 of 46) breast milk jaundice, and 2.2% (1 of 46) physiological jaundice. There was no significant difference between groups regarding clinical jaundice, clinical plethora, respiratory symptoms, sucking ability and length of stay (Table 3).

Table 1. Maternal baseline characteristics

Variables	Early cord clamping (n=44)	Delayed cord clamping (n=46)	p-values
Mean maternal age (year)(±SD)	25.36±6.22	23.85±4.57	0.19
Mean gestational age(±SD)	38.93±0.97	38.71±1.44	0.41
Mean maternal hematocrit at 3rd trimester(%)(±SD)	35.36±3.14	36.52±2.80	0.67
Antenatal visit			0.71
·1 <4 visits (%)	4(9.10)	3(6.50)	
·2 ≥4 visits (%)	40(90.90)	43(93.50)	
Parity			0.54
·3 Nulliparous (%)	20(45.50)	18(39.10)	
·4 Multiparous (%)	24(54.50)	28(60.90)	
Level of maternal education			0.29
·1 Primary (%)	5(11.36)	11(23.91)	
·2 Secondary (%)	28(63.63)	25(54.35)	
·3 Tertiary (%)	11(25.00)	10(21.74)	
Iron supplement in pregnancy (%)	44(100.00)	44(95.65)	0.49
Maternal anemia (Hct <33 %)(%)	7(15.91)	3(6.52)	0.19
Estimated blood loss (mL)(±SD)	153.41±16.69	150.00±25.82	0.46

n=number of mother, Hct=hematocrit, Hb=hemoglobin

Table 2. Infant baseline characteristics

Variables	Early cord clamping (n=44)	Delayed cord clamping (n=46)	p-values
Mean infant weight in gram (±SD)	3,196.82±341.66	3,098.04±354.42	0.18
Mean length of stay (days)(±SD)	2.50±1.17	2.67±0.90	0.43
Infant Sex			0.40
·1 Female (%)	21(47.72)	26(56.52)	
·2 Male (%)	23(52.27)	20(43.48)	

n=number of infant, Hct=hematocrit, Hb=hemoglobin

Table 3. Infant hematological outcomes 48 hours after delivery

Variables	Early cord clamping (n=44)	Delayed cord clamping (n=46)	p-values
Mean Hb in g/dl (±SD)	16.82±1.49	18.73±1.70	<0.001*
Mean Hct in %(±SD)	49.65±4.93	56.16±5.71	<0.001*
Mean Platelet in cell/mm3 (±SD)	296,363.60 ±77,953.80	277,478.30 ±60,589.60	0.20
Polycythemia (Hct>65%)(%)	1(2.27)	4(8.69)	0.36
Anemia (Hct<45%)(%)	7(15.91)	1(2.17)	0.03*
Mean serum TB in mg/dl (±SD)	11.95±3.11	11.64±3.79	0.67
Clinical jaundice (%)	5(11.36)	6(13.04)	0.81
Clinical plethora (%)	0(0)	2(4.35)	0.49
Phototherapy (%)	4(9.09)	4(8.69)	> 0.05

*Significant level was p-values <0.05, n=number of infant
Hct=hematocrit, Hb=hemoglobin, TB=serum total bilirubin

Discussion

The DCC group, over against the ECC group, had a significantly higher mean hematocrit (56.16 vs. 49.65%, respectively) and hemoglobin (18.73 and 16.82 g/dL, respectively). This is similar to other studies on the early hematological effect of DCC showing a higher mean infant hematocrit at 24-48 hrs: Nelle 1993 (59.0% and 43.0%, respectively),[25] Emhamed 2004 (52.9% and 49.3%, respectively)[31] and Ceriani Cernadas 2006 (56.4% and 51.1%, respectively).[26]

The mean infant hemoglobin at 24 to 48 hours is also higher in the DCC group, as also found by Emhamed 2004 (i.e., 18.5 and 17.1 g/dL, respectively),[23] albeit in some trials no significant difference was found in the mean hemoglobin at 2 to 3 months[10,27,28] or 4 to 6 month of age.[29,30] No study has reported ECC higher in the mean infant hematocrit at 24-48 hours after birth.

The proportion of anemic infants (hematocrit < 45%) was significantly higher in the ECC (15.91%) vs. the DCC group (2.17%) similar to Ceriani Cernadas 2006 (16.9 and 2.3 percent, respectively).[26]

Asymptomatic polycythemic infants after DCC at 24 to 48 hours of age were found in some trials.[10,23,26] Similar to our study in which we found four polycythemic infants without hyperviscosity symptoms, two of whom had clinical plethora without clinical jaundice, poor sucking and respiratory distress. They were given intravenous fluid to reduce hematocrit to normal values. Phototherapy was not used and the length of stay was 4 to 5 days after birth.

We found no significant difference between ECC and DCC regarding the mean serum total bilirubin and the use of phototherapy, as did other studies.[23,26] The infants needing phototherapy in the DCC vs. ECC were 9.1 and 8.7 percent, respectively.

The cause of hyperbilirubinemia beyond the phototherapy threshold in the DCC group was G6PD-deficiency anemia (4.3%), while it was ABO incompatibility (4.6%) in the ECC group. Consequently, DCC might not be a risk for hyperbilirubinemia, unless the sample size was too small to adequately detect the difference.

Polycythemia and hyperbilirubinemia are frequently mentioned with regard to the harmful

effects of DCC which were more increased with placental transfusion than ECC. However a placental transfusion was not associated with perinatal complications (i.e., respiratory distress, cyanosis or decreased sucking ability) and the safety of DCC in terms infants has been demonstrated in several trials.[10,13,23,31]

In this study, no significant difference was found between the DCC and ECC groups regarding other clinicals such as the proportion of plethoric skin, clinical jaundice or length of stay.

We were unable to evaluate any hematological effect after 48 hrs such as 5 days, 2, 4 and 6 months after birth. By contrast, previous studies found that the significantly higher mean hematocrit for DCC was further demonstrated at age 5 days and 2 months after birth,[13,25,30] while no significant differences in mean hematocrit were found at age 6 months.[29] Because of their poor socioeconomic status, mothers and their infants in rural areas were unable to re-visit and nor bear the high cost of any laboratory tests. For these reasons, we could not study the infants over a longer follow-up time which might have confirmed whether the DCC is effective in reducing anemia in late infancy.

Since the incidence of polycythemia found among term SGA infants was 15% as compared to 2% in term appropriate for gestational age (AGA) infants,[32] low-birthweight infants who are small-for-gestational age are designated as suffering from fetal growth restriction. It is estimated that 3 to10 percent of infants are growth restricted.[33] SGA infants in developing countries often manifest an increased incidence of polycythemia caused by chronic hypoxemia in utero leading to increased erythropoiesis.[34] We, therefore, suggest DCC should be done in low-risk pregnancy and estimated fetal weight ≥2500 g to prevent risk of polycythem ia in the infant.

Caution should be exercised in the use of oxytocic medications for delivery, since it is liable to increase placental transfusion leading to increased infant blood viscosity too.[35] Relatedly, a limitation of this study is that we assessed maternal blood loss by estimations rather than quantitatively measuring maternal blood loss of the third stage of labor, which may have resulted in a non-significant difference in maternal blood loss between groups. At the Khon Kaen Regional Hospital, ECC is the routine practice and the recommended active management of the third stage of labor to prevent postpartum hemorrhage includes administration of prophylactic oxytocin before delivery placenta, early cord clamping and controlled cord traction.[20] As far as we know, there is no evidence that only ECC does not separately examine each of the three interventions. On the other hand, it was dependent from the active management of the third stage of labor, therefore only ECC might not decrease postpartum hemorrhage. Similar to this study, there were no significant differences between ECC and DCC in maternal blood loss of third stage labor. Accordingly, DCC is not a contraindication for other interventions of active management of the third stage of labor.

Conclusion

DCC at 2 minutes after birth resulted in an increase in infant hemoglobin and hematocrit within a physiologic range. This intervention is simple, safe and should be used as part of a strategy to prevent early neonatal anemia as other programs have not been successful. Longer, follow-up, controlled studies are needed to confirm whether the DCC is effective in reducing anemia in late infancy.

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เปรียบเทียบการหนีบสายสะดือแบบเร็วและช้าในทารกคลอดครบกำหนดในโรงพยาบาลศูนย์ขอนแก่น

สิทธิพงศ์ ถวิลการ, อุษณีย์ สวัสดิ์พาณิชย์, สมศักดิ์ ปฏิภาณวัตร, วรนาฏ จันทร์ขจร

วัตถุประสงค์: *ศึกษาเปรียบเทียบผลทางด้านโลหิตวิทยาของการหนีบสายสะดือแบบเร็วและช้าต่อระดับความเข้มข้นของเลือด ระดับฮีโมโกลบิน และผลเสียที่อาจจะเกิดขึ้นได้ในทารกอายุ 48 ชั่วโมงหลังคลอด*

ชนิดของการวิจัย: *การศึกษาแบบสุ่ม*

สถานที่ทำการวิจัย: *กลุ่มงานสูติ-นรีเวชกรรม โรงพยาบาลศูนย์ขอนแก่น*

วัสดุและวิธีการ: *สตรีตั้งครรภ์เดี่ยวอายุครรภ์ครบกำหนด 94 คน ที่มีคุณสมบัติจะถูกสุ่ม แบ่งเป็น 2 กลุ่ม คือ กลุ่มที่หนีบสายสะดือแบบเร็วโดยหนีบสายสะดือที่ 10 วินาที และกลุ่มที่หนีบสายสะดือแบบช้าโดยหนีบสายสะดือที่ 2 นาทีหลังคลอดปกติทางช่องคลอด ประเมินผลทางด้านโลหิตวิทยาของทารกหลังคลอด ได้แก่ ระดับความเข้มข้นของเลือด ระดับฮีโมโกลบิน ระดับสารเหลืองในเลือดดำ และอาการทางคลินิกในทารกอายุ 48 ชั่วโมงหลังคลอด*

ผลการวิจัย: *ทารกหลังคลอด 94 คน ถูกจัดให้อยู่ในกลุ่มที่หนีบสายสะดือแบบเร็ว 47 คน และแบบช้า 47 คน สตรีตั้งครรภ์ทั้งสองกลุ่มไม่มีความแตกต่างกันของข้อมูลพื้นฐานทั่วไป ผลทางด้านโลหิตวิทยาในทารกอายุ 48 ชั่วโมงหลัง คลอด พบค่าเฉลี่ยความเข้มข้นของเลือด ในกลุ่มที่หนีบสายสะดือแบบช้ามีระดับสูงกว่ากลุ่มที่หนีบสายสะดือแบบเร็วอย่างมีนัยสำคัญทางสถิติคือ ร้อยละ 56.2 และ 49.6 ตามลำดับ สัดส่วนของทารกที่มีภาวะโลหิตจางในกลุ่มที่หนีบสายสะดือแบบเร็วมีระดับสูงกว่ากลุ่มที่หนีบสายสะดือแบบช้าอย่างมีนัยสำคัญทางสถิติคือร้อยละ 15.9 และ 2.2 ตามลำดับ ไม่มีความแตกต่างอย่างมีนัยสำคัญทางสถิติในสัดส่วนของทารกที่มีภาวะเลือดข้น ภาวะสารเหลืองในหลอดเลือดดำสูง และการส่องไฟรักษา*

สรุป: *การหนีบสายสะดือที่ 2 นาทีหลังคลอดปกติทางช่องคลอดสามารถเพิ่มระดับความเข้มข้นของเลือด และระดับฮีโมโกลบิน ซึ่งอยู่ในช่วงของการเปลี่ยนแปลงตามปกติของร่างกาย เป็นวิธีปฏิบัติที่ง่าย ปลอดภัย และสามารถนำไปปฏิบัติเป็นกลยุทธ์เพื่อป้องกันภาวะโลหิตจางในช่วงแรกของทารกหลังคลอด*

คำสำคัญ: *ผลเสียของการหนีบสายสะดือ ภาวะโลหิตจาง การหนีบสายสะดือ ภาวะสารเหลืองในหลอดเลือดสูง ภาวะเลือดหนืด*