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The Hematological Status between Early and Delayed Cord Clamping after Normal Delivery in Term Infants at Damnoen Saduak Hospital

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ABSTRACT

Objective: To compare the hematological status between early and delayed cord clamping and determine adverse outcomes 48 hours after birth.

Material and method: 148 singletons uncomplicated term pregnancies were selected according to inclusion criteria of this study. They were randomized to either early (at fist 10 seconds) or delayed (at 120 seconds) cord clamping after normal vaginal delivery. The infant's venous hemoglobin, hematocrit and total mean serum bilirubin were measured at 48 hours after birth.

Results: 148 term infants were selected for this study. 72 were randomized to receive early cord clamping and 76 were delayed cord clamping. At baseline two groups had similar maternal demographic characteristics. At 48 hours after delivery, the infant's hemoglobin, and hematocrit were statistically significant higher in delayed cord clamping than early cord clamping (17.8 g/dl vs. 16.1 g/dl; p< 0.001 and 54.5% vs. 50.3%; p<0.001, respectively). The prevalence of neonatal anemia in early cord clamping was relative higher than delayed cord clamping but the difference was not statistical significant (N=11, 15.3% vs. N=4, 5.3%; p=0.08, respectively). Polycythemia and mean serum total bilirubin were relative higher in delayed cord clamping than early cord clamping however there were not statistically significant (4.0% vs. 1.4%; p=0.25 and 13.3 mg/dl vs. 12.7 mg/dl; p=0.21, respectively). There were no significant difference in Apgar score, phototherapy and maternal blood loss.

Conclusion: In Term infant delayed cord clamping at 2 minutes after birth resulted in significantly increase hemoglobin, and hematocrit measured at 48 hours after birth. No difference in adverse outcome was found among both groups.

Keywords: cord clamping, adverse outcomes, postpartum hemorrhage

Introduction

Iron deficiency anemia is the most common nutritional disorder worldwide. In developing countries up to 50% of children become anemia by 12 month of age[1]. Data from Demographic Health Surveys from 11 developing countries found that children 6-24 months of age became anemia 50%[2]. In Thailand, among young infants (4-6 months of age) in small survey areas, the prevalence is high as 32-62%[3].

Risk factors for iron deficiency include low birth weight, maternal iron deficiency during pregnancy and male sex[1,4]. Iron stores at birth are a major factor influencing growth and the occurrence of iron deficiency anemia during infancy[5]. Iron deficiency anemia in infancy and childhood is of particular concern because of potentially detrimental effects on physical and cognitive development, some of which might be irreversible even after iron treatment[6]. Lower level of neonatal hemoglobin and serum iron have been found related to higher levels of negative emotionality and lower level of alertness and soothability[7].

Strategies to reduce iron deficiency anemia in infants include iron supplementation and iron fortification. Although these measures have been shown to be clinically effective[8-10], they are either cost-ineffective or difficult to implement, especially in developing countries. Delayed cord clamping or placental transfusion could be cost-effective intervention to improve iron status of infants by enhancing their red cell mass. Physiologic study in term infants have shown that a transfer from the placenta of approximately 80 ml. of blood occurs by 1 minute after birth, reaching approximately 100 ml. at 3 minutes after birth[11-13]. This additional blood can supply extra iron amounting to 40-50 mg/kg of body weight. This extra iron combined with body iron (approximately 75 mg/kg of body weight) presents at birth in a full-term newborn, may help to prevent iron deficiency anemia during the first year of life[14]. In additional potential benefit of delayed cord clamping is increased in hamopoietic stem cells transferred to newborn which might play role in different blood disorders and immune conditions[15].

A 2008 Cochrane review assessed the effect of umbilical cord clamping in term infants on maternal and fatal outcomes that involved 2,989 women and their infants. Reviewers found that infant who underwent delayed cord clamping had significantly higher levels of hemoglobin compared with infants in early cord clamping. Infant ferritin levels remained higher in infants in delayed cord clamping compared with that of early cord clamping group until 6 months. There was no significant difference in postpartum hemorrhage within these two groups[16].

The optimal timing for clamping the umbilical cord after birth has been a subject of controversy and debate. Several systematic reviews have suggested that clamping the umbilical cord in all birth should be delayed at least 30-60 seconds with the infant maintained at or below the level of placenta[17]. Immediate cord clamping after birth is common practice in Thailand including active management of the third stage of labour for prevention of postpartum hemorrhage as recommended in the guideline at Damnoen Saduak Hospital[18].

In view of above reviews, we performed a randomized controlled trial to determine the benefits and risks of timing of umbilical cord clamping. The main objective of this study was to compare the effect of early cord clamping and delayed cord clamping in term infants on hemoglobin, hematocrit status and possible adverse outcomes (as follow anemia, polycythemia, hyperbilirubinemia) at 48 hours after birth and maternal postpartum hemorrhage.

Material and Methods

This was randomized controlled trial performed in Department of Obstetrics and Gynecology, Damnoen Saduak Hospital between July 25, 2012 and December 15, 2012.

Ethical committee of Damnoen Saduak Hospital approved this protocol. Finally informed written consent was taken from all participant pregnant women after full explanation of the nature and purposed of the study. History taking and physical examination were taken and others data were taken via questionnaire to gather demographic and socioeconomic detail from pregnant women.

All pregnant women meeting the following selection criteria were included 1) Gestational age 37 to 42 weeks confirmed date by early ultrasound and certain LMP 2) Expected birth weight > 2500 grams 3) Singleton birth 4) Good antenatal care 5) Normal labour. Pregnant women also excluded if they had a diagnosis of any of following condition; Preeclampsia or eclampsia, gestational diabetes mellitus, renal disease, cardiopathies, connective tissue disease, antepartum hemorrhage, fetal congenital anomalies, malpresentation, nuchal cord, thick meconium stain, fetal distress and instrumental delivery.

After crowning of infant's head 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 labour room) to early cord clamping or delayed cord clamping. In the early cord clamping group, clamping was done at first 10 seconds after delivery whereas clamping was done at 120 seconds after birth in the delayed cord clamping group. The cord clamping technique was similar in both groups by using of two tonsil clamps. After delivery, the infant was kept between the legs of mother, at approximately the same level as placenta and Apgar score was checked. The infant was provided immediate newborn care using guidelines for neonatal resuscitation (i.e. 1. The infant is placed in warm environment, 2. The airway is cleared, 3. The infant dried, stimulated and wrapped in warm towel)[19]. Mother were also followed up by examining vital parameters and blood loss during deliveried were estimated. The infant's health was assessed every morning by pediatrician until 48 hours after birth. Infant's venous blood samples were collected in K3EDTA 1 ml for complete blood count (Hemoglobin and hematocrit) and in one capillary tube for mean serum total bilirubin at 48 hours after birth. Complete blood count was done using COULTER-HmX, Autometic cell counter and total serum bilirubin was estimated by APEL BR-5100 bilirubinometer. Polycythemia in neonate was defined as venous Hct > 65%[20] and anemia defined as venous Hct < 45%[21-22]. Phototherapy was considered on child by child basis in hospitalized infant of 35 or more weeks' gestation[23].

Sample size

Base on the result of the study by Emhamed et al[21], the difference of infant's mean hematocrit between the early cord clamping group (Hct = 49.3%) and on delayed cord clamping group (52.9%) is 3.6%, and the standard deviation in each group is 5.7 and 6.3 g/dl, respectively. On assumption with the power of 80% and confidence level of 95% a sample size of 43 infants was required in each group. From above reviews, the randomized control study about delayed cord clamping and early cord clamping base on small number of enrolled infants and the only one study in Thai population has only 90 sample. Moreover we will collect for the more number for unexpected exclusion sample. So we will enroll more sample than was calculated.

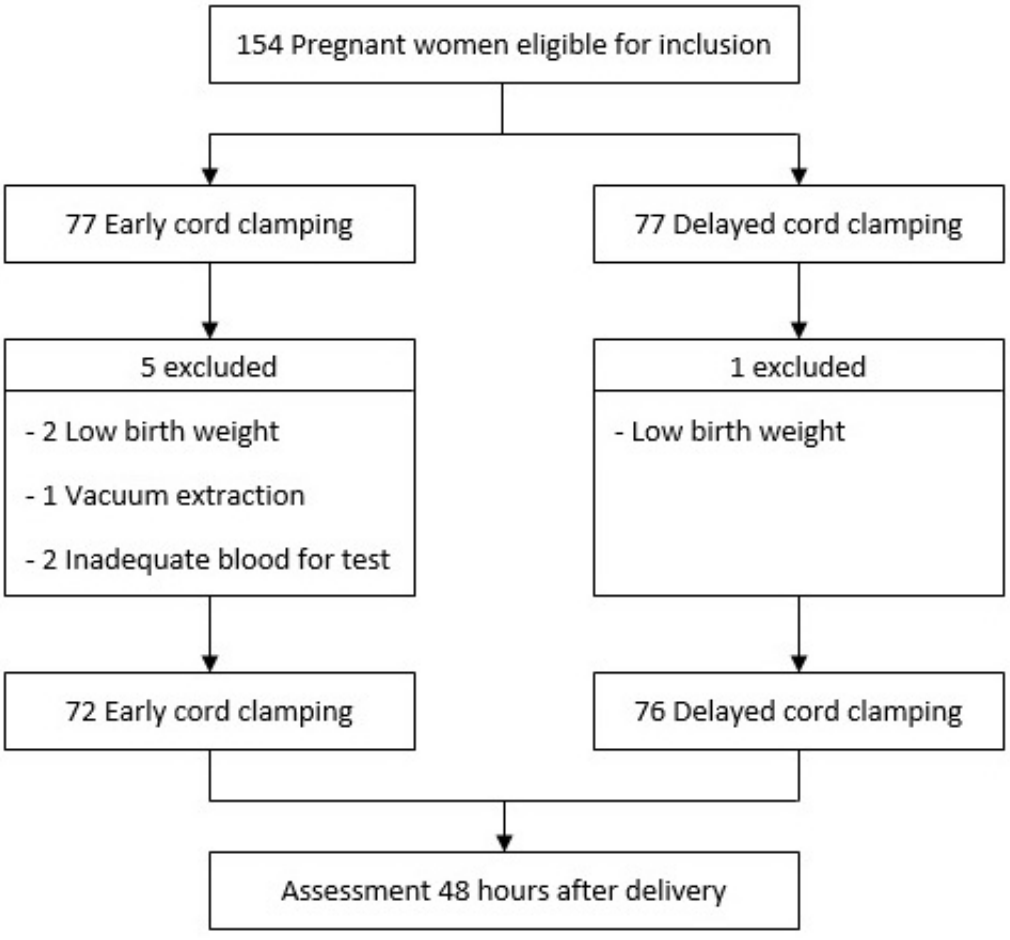

Fig 1. Recruitment into the study

Statistical analysis

The information collected from the data forms was analyzed by using SPSS version 11. The continuous variables were compared with the independent t-test and categorized variable with the Chi-square or Fisher's exact test as appropriate. The results were reported as means, stand deviations (SD) or percentages. The level of significance used was $p<0.05$.

Results

There were 154 term pregnant women eligible for inclusion. 77 were randomized to early cord clamping and 77 to delayed cord clamping. Six pairs were excluded from final analysis, following the reason as Fig. 1. Compliance with the allocated intervention was 93.5% (72 of 77 pairs) in early cord clamping and 98.7% (76 of 77) in delayed cord clamping.

Baseline characteristics of mother in early cord clamping and delayed cord clamping were comparable in term of maternal age, parity, gestational age, antenatal visit, iron supplement, maternal hematocrit in third trimester, maternal anemia, estimated blood loss and postpartum hemorrhage did not differ significantly. (Table 1.)

Table 1. Maternal baseline characteristics

Variable	Early cord clamping (N = 72)	Delayed cord clamping (N = 76)	p
Mean maternal age(year) (+SD)	24.3 ± 6.0	23.1 ± 6.0	0.23
Parity (mean) (+SD)	1.7 ± 0.9	1.8 ± 0.9	0.72
- Nulliparous (%)	37 (51.4)	39 (51.3)	
- Multiparous (%)	35 (48.6)	37 (48.7)	
Mean gestational age (weeks) (+SD)	38.9 ± 1.1	38.9 ± 1.1	0.86
Number of antenatal visit (times) (+SD)	9.9 ± 2.2	9.3 ± 2.4	0.13
Iron supplementation during pregnancy (%)	72 (100)	76 (100)	1.00
Mean maternal Hct in third trimester (%)(+SD)			
Maternal anemia (Hct<33%)(%)	36.8 ± 2.6	36.1 ± 2.6	0.08
Maternal blood loss (ml) (+SD)	17 (23.6)	24 (31.6)	0.37
Postpartum hemorrhage (%)	202.7 ± 18.6	201.3 ± 27.0	0.70
Postpartum hemorrhage (%)	1 (1.4)	2 (2.6)	0.52

N = number of infant, Hct=hematocrit

Infant baseline characteristics comparable in body weight, Apgar score, sex, length of stay in the hospital were not difference between early cord clamping group and delayed cord clamping group. (Table 2.)

Table 2. Infant base line characteristics

Variable	Early cord clamping (N = 72)	Delayed cord clamping (N = 76)	p 0.47
Variable	3182.4 ± 354.5	3138.0 ± 293.0	1.00
Mean birth weight (grams) (±SD)	10	10	0.73
Apgar score at 5 minute (point)			
Infant sex			
- Male (%)	40 (55.6)	39 (51.3)	
- Female (%)	32 (44.4)	37 (48.7)	
Mean length of stay in hospital (days) (±SD)	3.8 ± 3.1	3.9 ± 2.2	0.78

N = number of infant

Infant hemoglobin and hematocrit at 48 hours after birth in early cord clamping group were 16.1 g/dl, 50.3% and in delayed cord clamping group were 17.8 g/dl, 54.5% respectively. The difference between early cord clamping on hemoglobin and hematocrit were statistically significant (p<0.001).

Neonatal anemia which hematocrit < 45% in early cord clamping group was relatively higher than delayed cord clamping group (n = 11, 15.3% vs. n = 4, 5.3%: p=0.08, respectively) but the difference were not

statistically significant. There were no significant regarding to polycythemic infant which hematocrit > 65% between delayed cord clamping group and early cord clamping group (4.0% and 1.4%, respectively).

The mean serum total bilirubin at 48 hours in delay cord clamping group was slightly higher than early cord clamping group (13.3mg/dl vs. 12.7mg/dl, respectively). The proportion of neonatal hyperbilirubinemia indicated by the use of phototherapy[23] in delayed cord clamping were higher than early cord clamping group (n=33, 43.4% vs. n=23, 31.9%, respectively). There were no significant difference in mean serum total bilirubin and phototherapy between delayed cord clamping group and early cord clamping group. (Table 3.)

Table 3. Infant hematologic outcome 48 hours after birth

Variable	Early cord clamping (N = 72)	Delayed cord clamping (N = 76)	p
Mean Hb (g/dl) (± SD)	16.1 ± 1.7	17.8 ± 2.0	<0.001*
Mean Hct (%)(± SD)	50.3 ± 5.7	54.5 ± 6.0	<0.001*
Neonatal anemia (Hct < 45%) (%)	11 (15.3)	4 (5.3)	0.08
Polycythemia (Hct > 65%) (%)	1 (1.4)	3 (4.0)	0.25
Mean serum total bilirubin (mg/dl) (±SD)	12.7 ± 2.9	13.3 ± 3.5	0.21
Phototherapy (%)	23 (31.9)	33 (43.4)	0.20

* p<0.05 was significant, N=number of infant, Hematocrit=Hct, Hemoglobin=Hb

Discussion

The results of this study show that delayed cord clamping group had significant increase infant mean hematocrit than early cord clamping group (54.5% vs. 50.3%, respectively). This is similar to other studies on the early hematological effect of delayed cord clamping showing a higher mean infant hematocrit at 24-48 hours: Nelle 1993 (59.0% vs. 43.0%, respectively)[24] Emhamed 2004 (52.9% vs. 49.3%, respectively)[21], Abdel Aziz 1999 (59% vs. 43%, respectively)[25], Ceriani Cernadas 2006 (56.4% vs. 51.1%, respectively)[22], Mitra 2009 (49.4% vs. 46.7%, respectively)[26], Chapparo CM 2006 (62.0% vs. 59.5%, respectively)[27], and Thawinkarn 2008 (56.2% vs. 49.7%, respectively)[28].

The mean infant hemoglobin at 48 hours of our study was also significant increase in delayed cord clamping group than early cord clamping group as found by Emhamed 2004 (18.5 g/dl vs. 17.1 g/dl, respectively)[21], Mitra 2009 (16.3 g/dl vs. 15.6 g/dl, respectively)[26], Chapparo CM 2006 (19.9 g/dl vs. 19.3 g/dl, respectively)[27], Thawinkarn 2008 (18.7 g/dl vs. 16.8 g/dl, respectively)[28], and Deeba 2009 (15.2 g/dl vs. 14.1 g/dl, respectively)[29] which measure infant hemoglobin at 6 hours after birth. But the other studies found no significant difference in hemoglobin at 2-3 months[5, 30, 31] or 4-6 months of age[27, 32].

The proportion of anemic infant (Hct <45%) in early cord clamping group was relatively higher than delayed cord clamping group (15.3% vs. 5.3%; p=0.08, respectively) but not significant difference in statistically. Same as result of Emhamed 2004 (6.9% vs. 4.3%; p=0.58, respectively)[21] and Mitra 2009 (16.0% vs. 6.3%; p=0.13, respectively)[26]. The reason of no statistical significant in decrease number of fetal anemia in this study may be due to proportion of anemic mother in both groups was higher than another studies[21, 28, 31].

In some studies found the prevalence of anemic infant were statistically higher in early cord clamping group than delayed cord clamping group[22,28]. But long term follow up in Chaparro CM 2006 there were similar

portion of anemic infant in 6 months of age[27].

Polycythemia in this study was higher in delayed cord clamping group than early cord clamping group, but not significant in statistic (4.0% vs. 1.4%, respectively). Same as many studies Van Rheenen 2004(33), Linderkam 1922[12], Oxford Midwives Research group 1991[34], Mitra 2009[26], and Emhamed 2004[21].

No significant difference between early cord clamping group and delayed cord clamping group regarding to the mean serum total bilirubin and phototherapy in which was compatible with other studies[19-20, 28-30, 33-35]. But there were relative higher in delayed cord clamping group.

However the more number of polycythemia, mean serum total bilirubin and phototherapy were found in delayed cord clamping than early cord clamping must be mention in this study.

Another outcome in this study were Apgar score and length of stay in the hospital which not difference in early cord clamping group and delayed cord clamping group.

In some studies observed risk of developing either neonatal tachypnea or respiratory grunting between two group but no significant difference was found[22,35,36].

In 2002, early cord clamping was included as a part of active management of the third stage of labour to prevent postpartum hemorrhage[18], although more recent reference do not include early cord clamping as a component of this protocol[37]. As far as we are aware there is no evidence that early cord clamping, independently from other active manage techniques (administration of oxytocin drug before delivery placenta and control cord traction) is associated with less maternal hemorrhage, or delayed cord clamping would be contraindication when other active management techniques are used. Maternal blood loss in our study not difference between early cord clamping group and delayed cord clamping group same as Chaparro CM 2006[27], and Thawinkarn 2008[28]. But limitation of this study was that we assessed maternal blood loss by estimation rather than quantitatively which may have resulted in nonsignificant difference between both groups.

The aim of this study was compare hematological status between early and delayed cord clamping in term infants that results in statistically significant. The difference of mean hematocrit and hemoglobin level at 48 hours after delivery in favor of the delayed cord clamping group is possibly of clinical importance. Iron stores in term newborn are normally adequate to maintain iron sufficiency for approximately four months of postnatal growth[38]. Improved iron status from these additional red cells might increase the stores sufficiently to cover the first 5-6 month. But this study can follow up hematocrit and hemoglobin 48 hour after birth.Thus multicenter, large scale study and long term follow up are needed.

Conclusion

In term infants delayed cord clamping at 2 minutes after birth resulted in significantly increase hemoglobin and hematocrit values measured at 48 hours after birth. No difference in adverse outcome was found between 2 group. But long term follow-up, large scale studies are needed.

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การเปลี่ยนแปลงทางโลหิตวิทยาในทารกคลอดครบกำหนดทางช่องคลอดระหว่างกลุ่มหนีบสายสะดือเร็วและช้าที่โรงพยาบาลดำเนินสะดวก

นวลพรรณ แทนม้วน

วัตถุประสงค์: *ศึกษาเปรียบเทียบผลทางด้านโลหิตวิทยาของทารก ระหว่างกลุ่มหนีบสายสะดือเร็วและกลุ่มหนีบสายสะดือช้า และผลเสียที่อาจเกิดขึ้นได้ที่ 48 ชั่วโมงหลังคลอด*

สถานที่ทำวิจัย: *กลุ่มงานสูติ-นรีเวชกรรม โรงพยาบาลดำเนินสะดวก ระหว่างวันที่ 25 กรกฎาคม ถึง 15 ธันวาคม พ.ศ.2555*

วัสดุและวิธีการ: *สตรีตั้งครรภ์เดี่ยวครบกำหนด และไม่มีภาวะแทรกซ้อนจำนวน 148 คน แบ่งเป็น 2 กลุ่ม โดยการสุ่ม คือกลุ่มหนีบสายสะดือเร็ว โดยหนีบสายสะดือที่ 10 วินาที และกลุ่มหนีบสายสะดือช้า โดยหนีบสายสะดือที่ 120 วินาที หลังคลอดปกติทางช่องคลอด เมื่อทารกอายุได้ 48 ชั่วโมง จะได้รับการตรวจระดับฮีโมโกลบิน, ระดับความเข้มข้นของเลือด และระดับสารเหลืองในหลอดเลือดดำ*

ผลการวิจัย: *สตรีตั้งครรภ์ครบกำหนดจำนวน 148 คน แบ่งเป็นกลุ่มโดยการสุ่ม โดยเป็นกลุ่มหนีบสายสะดือเร็ว 72 คน และกลุ่มหนีบสายสะดือช้า 76 คน โดยทั้ง 2 กลุ่มไม่มีความแตกต่างกันทางด้านข้อมูลพื้นฐานทั่วไป เมื่อทารกอายุได้ 48 ชั่วโมงหลังคลอด พบว่า ระดับฮีโมโกลบิน และระดับความเข้มข้นของเลือดในกลุ่มหนีบสายสะดือช้า มีค่ามากกว่ากลุ่มหนีบสายสะดือเร็ว อย่างมีนัยสำคัญทางสถิติ คือ 17.8 g/dl กับ 16.1 g/dl (p< 0.001) และ 54.5% กับ 50.3% (p<0.001) ตามลำดับ พบสัดส่วนของภาวะโลหิตจางในทารกแรกเกิด ของกลุ่มหนีบสายสะดือเร็วมากกว่ากลุ่มหนีบสายสะดือช้า แต่ไม่มีนัยสำคัญทางสถิติ คือร้อยละ 15.3 และ 5.3 (p=0.08) ตามลำดับ พบภาวะเลือดข้นและสารเหลืองในหลอดเลือดดำในกลุ่มหนีบสายสะดือช้า มากกว่ากลุ่มหนีบสายสะดือเร็วคือ 4.0% กับ 1.4% (p=0.25) และ 13.3 mg/dl กับ 12.7 mg/dl (p=0.21) ตามลำดับ ไม่พบความแตกต่างอย่างมีนัยสำคัญทางสถิติของระดับคะแนนแอปการ์, การส่องไฟรักษา และปริมาณเลือดที่เสียระหว่างคลอดของทั้ง 2 กลุ่ม*

สรุป: *ในทารกคลอดครบกำหนด การหนีบสายสะดือที่ 2 นาที สามารถเพิ่มระดับฮีโมโกลบิน และระดับความเข้มข้นของเลือดได้อย่างมีนัยสำคัญ และไม่พบภาวะแทรกซ้อนระหว่างมารดาและทารกเพิ่มขึ้น*