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The Effect of Umbilical Cord Clamping, Cutting and Milking in Term Infants Delivered by Cesarean Section: A randomized controlled trial

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ABSTRACT

Objectives: To investigate the effect of umbilical cord milking (UCM) and immediate umbilical cord clamping (ICC) in term infants delivered by cesarean section.

Materials and Methods: This investigation's design was a randomized controlled trial. One hundred and ten term pregnant women were recruited and allocated equally in the study and control groups. The study group (UCM) undertook umbilical cord milking toward the infant five times in 30 seconds after the umbilical cord was immediately clamped at a 20 cm. length from the newborn. The control group (ICC), by contrast, underwent immediate umbilical cord clamping without milking at 2 cm. from umbilicus as the standard manner. Neonatal outcomes such as neonatal hematocrit (Hct) at 48 hours after birth, microbilirubin level, respiratory rate and length of stay in hospital were recorded.

Results: Neither neonatal outcomes nor neonatal Hct at 48 hrs revealed statistical differences between the two groups. There were no serious maternal and fetal complications in either group. The two groups showed no significant differences in demographic and operative data.

Conclusion: UCM at a point 20 cm. from umbilicus had no effect in raising the Hct level at 48 hours following birth and no harmful effect in the term newborn delivered by cesarean section.

Keywords: umbilical cord milking, term pregnancy, cesarean section

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การศึกษาเปรียบเทียบประสิทธิผลของการรีดเลือดจากสายสะดือทารกแรกคลอดที่คลอดครบกำหนดโดยการผ่าตัดคลอดทางหน้าท้อง เทียบกับการหนีบตัดสายสะดือตามวิธีมาตรฐาน: การทดลองแบบสุ่ม

ศวัลยา ทิพย์วารี, จรินทร์ทิพย์ สมประสิทธิ์,ชำนาญ แท่นประเสริฐกุล, คมสันติ์ สุวรรณฤกษ์, กรณ์กาญจน์ ภมรประวัติธนะ

บทคัดย่อ

วัตถุประสงค์: *เพื่อศึกษาเปรียบเทียบประสิทธิผลของการรีดเลือดจากสายสะดือทารกแรกคลอดครบกำหนดที่คลอดโดยการผ่าตัดคลอดทางหน้าท้อง เปรียบเทียบกับการหนีบตัดสายสะดือโดยวิธีมาตรฐาน โดยการวัดระดับความเข้มข้นเลือดที่ 48 ชั่วโมงหลังคลอด*

วัสดุและวิธีการ: *เป็นการศึกษาวิจัยเปรียบเทียบแบบสุ่ม โดยทำการศึกษาวิจัย ณ ห้องผ่าตัดโรงพยาบาลธรรมศาสตร์เฉลิมพระเกียรติ ในสตรีตั้งครรภ์ครบกำหนดที่ได้รับการผ่าตัดคลอดทางหน้าท้อง ตั้งแต่วันที่ 1 กรกฎาคม 2557 ถึง 31 ธันวาคม 2557 โดยมีผู้เข้าร่วมวิจัยทั้งหมด 110 คน แบ่งเป็นกลุ่มทดลองคือหนีบตัดสายสะดือยาว 20 เซนติเมตร ห่างจากสะดือทารกและรีดเลือดจากสายสะดือสู่ทารก 5 ครั้ง หลังจากนั้นตัดสายสะดือ 2 เซนติเมตร ห่างจากสะดือทารก กลุ่มควบคุมคือหนีบตัดสายสะดือตามวิธีมาตรฐานห่างจากสะดือทารก 2 เซนติเมตร เก็บข้อมูลความเข้มข้นเลือดที่ 48 ชั่วโมงแรกของทารกหลังคลอดและภาวะแทรกซ้อนของทารก ได้แก่ อัตราการหายใจ ระดับไมโครบิลิรูบิน และระยะเวลานอนโรงพยาบาลของทารก*

ผลการศึกษา: *ข้อมูลพื้นฐานของ 2 กลุ่ม ได้แก่ อายุ น้ำหนักก่อนตั้งครรภ์ และส่วนสูงของสตรีตั้งครรภ์ ระยะเวลาการผ่าตัด ปริมาณเลือดที่เสียไประหว่างผ่าตัด และน้ำหนักแรกคลอดของทารกพบว่าไม่มีความแตกต่างกันอย่างมีนัยสำคัญ รวมทั้ง ความเข้มข้นเลือดที่ 48 ชั่วโมง และภาวะแทรกซ้อนของทารกไม่มีความแตกต่างกันอย่างมีนัยสำคัญ*

สรุป: *การรีดเลือดจากสายสะดือทารกที่ถูกหนีบตัดยาว 20 เซนติเมตรสู่ทารก ในทารกแรกคลอดครบกำหนดที่คลอดโดยการผ่าตัดคลอดทางหน้าท้องไม่เพิ่มความเข้มข้นเลือดที่ 48 ชั่วโมงแรกของทารก และไม่มีภาวะแทรกซ้อนต่อมารดาและทารก*

คำสำคัญ: *การรีดเลือดจากสายสะดือ, ครรภ์ครบกำหนด, การผ่าตัดคลอดทางหน้าท้อง*

Introduction

Anemia is a global public health problem, especially in developing countries. It occurs at all stages of the life cycle, but is more prevalent in pregnant women and young children. In a report on neonatal anemia in Thailand by Chaiteeyanonin and colleague in year 2006 (unpublished data), neonatal anemia was found in 10% of newborns who had been delivered at gestational age (GA) less than 35 weeks. Anemia during infancy and early childhood has a long-term effect in cognitive brain function. Iron stored at times of birth is the factor influencing iron-deficiency anemia during the period of infancy, which can be affected by transplacental transfer of blood from the placenta and umbilical cord at the time of delivery. Delayed cord clamping (DCC), in which the cord was clamped between 30 to 180 seconds after birth, and umbilical cord milking (UCM), in which blood from cord or placenta was squeezed toward the baby, have been shown to incur an increase in hemoglobin in preterm and term infants[1-6].

A recent meta-analysis from Al-Wassia et al, Backes et al and Ghavam et al, demonstrated the efficacy and safety of placental transfusion by UCM or DCC in preterm neonate[2, 7, 8]. Subject's gestational age in studies of Backes and Ghavam were in very preterm (GA 28-30 weeks) and extremely low birth weight groups. The study from Al-Wassia in 2015 concluded that UCM had no adverse effect in the immediate postnatal period in infants with GA less than 33 weeks. Furthermore, this method resulted in higher initial levels of hemoglobin, diminished oxygen requirement and intraventricular hemorrhage (IVH) in this infant group. Their study also presented higher hemoglobin levels in the first 48 hours and 6 weeks after birth in newborns who had been delivered with GA over 33 weeks without an increased risk for hyperbilirubinemia[7]. However, the clinician had concerns regarding maternal bleeding from delayed uterine or perineal suturing and also delayed resuscitation and hypothermia in preterm newborns caused by DCC. Recent studies have shown that UCM and DCC result in comparable increases in Hb in premature babies[9]. However, there were different techniques in the UCM procedure that have been described in the literature. Nowadays there is insufficient data concerning the effects of different technique of UCM.

This investigation was designed from the research question that whether UCM by immediate clamping, cutting and then milking the umbilical cord in term infants delivered by cesarean section will have a different result in neonatal outcomes including neonatal hematocrit, microbilirubin level and length of stay in the hospital as compared with the standard procedure by immediate clamping after delivery.

Materials and Methods

The randomized controlled trial was conducted from July 2014 to December 2014 in the Department of Obstetrics and Gynaecology, Thammasat University Hospital, Thailand. The study was approved by the Institutional Review Board of Faculty of Medicine, Thammasat University. The inclusion criteria involved women within the age group 18-45 years, who had singleton term pregnancies (37-42 weeks of gestation, as documented by their last menstruation periods or antenatal ultrasonograms during their first trimesters) and who were planned to deliver their infants by cesarean section. The exclusion criteria were fetal congenital anomaly, death fetus in utero (DFIU), gestational diabetes mellitus (GDM), severe maternal anemia (Hb less than 9 g/dl), placenta previa, unstable maternal hemodynamic condition and abnormal fetal tracing (severe fetal bradycardia, fetal distress and non-reassuring fetal heart rate). Demographic data consisted of maternal age, body weight, height and maternal Hct. Operative data were operative times, estimated blood loss and neonatal birth weight.

All parturient who met criteria were briefly counseled at antenatal care clinic at GA 36 weeks. Previous counseled parturient who met criteria and planned for cesarean section was recruited for eligibility. Complete informed, written consent was signed by parents after repeated thorough counseling prior to delivery. Subjects were randomized and divided

into two groups: a control group and a study group.

For randomization, we used computer-generated random numbers in blocks of 4. Allocation concealment was maintained by identify each group by a written slip kept in a serially numbered opaque sealed envelope. The sealed envelope was opened by the staff on duty, who was not involved during intervention after ensuring that all parturient met criteria. The control group was defined by the application of immediate umbilical cord clamping (ICC). Following birth, the babies were held on the maternal thighs. The umbilical cord was clamped (within 5 seconds) and cut at a point two centimeters from the fetal umbilicus as in usual standard manner. The study group was defined by the application of UCM. The umbilical cord was immediately clamped (within 5 seconds) at 20 cm from the fetal umbilicus. The baby was then immediately transferred to a radiant warmer to prevent neonatal hypothermia. At radiant warmer, the umbilical cord was then milked toward the infant five times within a 30-second interval by nurse who learned UCM technique. After finished milking, the umbilical cord was then cut at a point two centimeters from the umbilical stump as standard procedure. Neonate from either group was transferred to the newborn unit and underwent routine standard management. Data collection was composed of demographic data, hematocrit (Hct) at 48 hours after birth, Apgar score, the newborn's respiratory rate, microbilirubin level (MB) at 48 hours after birth and length of stay in the hospital (LOS).

Phototherapy was performed in term and low risk neonate who had MB level more than 15 mg/dL. The risk factor consisted of isoimmune hemolytic disease, G6PD deficiency, asphyxia, significant lethargy and sepsis. In term and high risk neonate, phototherapy was started when MB level was more than 13 mg/dL.

The sample size was calculated by STATA program version 12 on the basis of Upadhyay's trial[10]. The trial revealed a mean ± standard deviation (SD) of hematocrit level among the term neonate in intervention and control arm were 41.2±6.3 and 37.2±6.0%, respectively. The effect size was calculated by absolute difference of mean between two groups divided by pooled SD. By this formula, the effect size was 0.8. A two-tailed study was undertaken, with a value of 0.05 and power of 95% assigned to the study. The study required the participation of at least 51 infants in each group.

Because of a 10% attrition rate that typically follows such a study, it was decided to augment the sample size to 55 infants in each group. Analysis of the data continuum was performed through the unpaired t test. Comparison of categorical data was performed through either the chi square or Fischer's exact test, according to which method was more applicable. Any P value < 0.05 was understood as significant.

Results

During the study period, 110 cases were enrolled. Participants were randomized and divided into two groups, a study group (UCM after clamping and cutting) and a control group (ICC). Each group comprised 55 cases. Demographic data consisted of maternal age, body weight, height and maternal Hct. Operative data were operative times, estimated blood loss and neonatal birth weight. Both groups revealed no significant differences in baseline characteristics, as shown in Table 1. Both groups revealed no statistically significant differences in baseline characteristics, except umbilical cord length which was found longer in the study group (50.7 vs. 47.7 cm; p<0.01) (Table 1).

Neonatal outcomes consisted of Hct (48 hr), MB, Apgar score, respiratory rate and length of stay in hospital. There were no statistical differences between the two groups, as presented in Table 2.

From the subgroup analysis, the MB level in small infants seemed to be affected by UCM. The MB levels in babies above and below 2,800 gm in body weight were 9.1 and 8.2 mg/dL, respectively. However, the difference was not significant.

There were no serious maternal and neonatal complications in the study group. Most babies had an Apgar score of 9 at 1 minute. Only one case in the control group had an Apgar score of 7 at 1 minute. Ultimately, this case had gotten an Apgar score of 10

at 5 minutes. One case in the control group had contracted?? tachypnea of newborn (TTNB); this infant needed only oxygen supplementation in an oxygen box without resorting to endotracheal tube intubation or respirator support. Moreover, one case in the control group had been diagnosed neonatal jaundice from ABO incompatibility. Complete recovery was achieved and the baby was discharged from the hospital eight days after diagnosis. *(Hospitalization occurred four days following a 24 hr single phototherapy)*

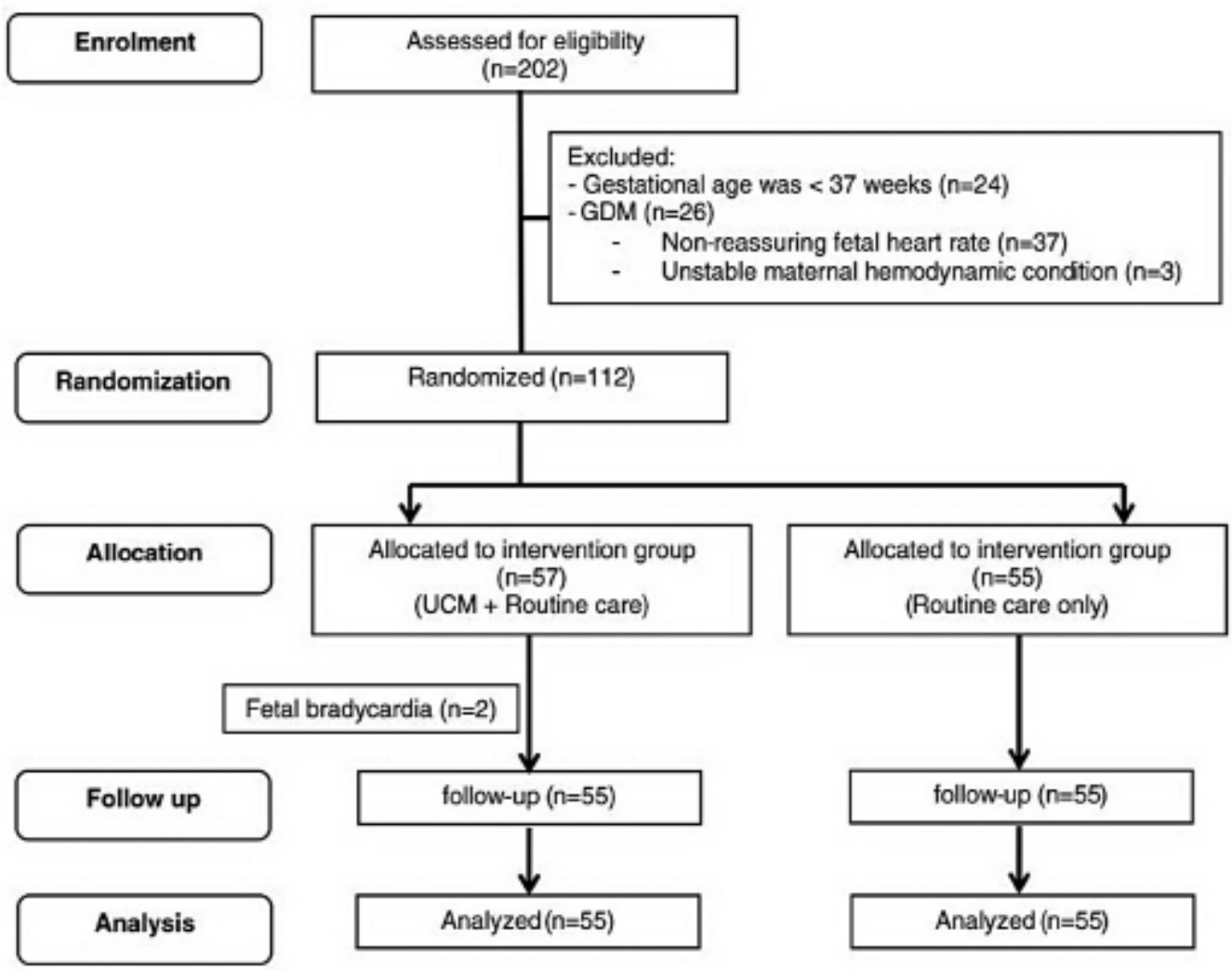

Fig. 1. Flow diagram of study participants.

Table 1. Demographic and clinical characteristics of the participants.

Characteristics	ICC (n=55)	UCM (n=55)	P
Age (yr)	30.94±6.27	31.40±5.02	0.68
Body weight (kg)	57.30±14.07	57.27±10.00	0.99
Height (cm)	159.49±6.10	157.58±5.88	0.10
Maternal Hct (%)	35.30±2.95	35.18±2.85	0.82
Operative times (min)	38.18±10.77	40.63±11.58	0.25
Blood loss (ml)	370.00±124.20	365.45±143.33	0.86
Birth weight (g)	3207.05±365.71	3228.63±301.70	0.74
CL (cm)	47.74±3.64	50.74±2.54	< 0.01

ICC: immediate umbilical cord clamping, UCM: umbilical cord milking,
Hct: hematocrit, CL: umbilical cord length
Categorical data analyzed using Fischer's exact test, continuous data analyzed using unpaired t-test

Table 2. Neonatal outcomes.

	ICC (n=55)	UCM (n=55)	P
Hct at 48 hr (%)	50.56±5.50	50.12±4.78	0.66
MB (mg/dL)	8.23±1.65	8.33±1.92	0.77
Apgar at 1 min	8.96±0.26	9±0.00	0.32
Apgar at 5 min	10±0.00	10±0.00	1.00
RR (bpm)	47.20±4.12	46.69±3.03	0.46
LOS (day)	3.1±0.68	3.0±0.19	0.26

ICC: immediate umbilical cord clamping, UCM: umbilical cord milking
Hct: hematocrit, MB: microbilirubin, RR: respiratory rate, LOS: length of stay, bpm: beat per minutes
Categorical data analyzed using Fischer's exact test, continuous data analyzed using unpaired t-test

Discussion

This study focused on UCM in a full-term infant who had been delivered by cesarean section. The UCM in our study was defined as milking five times after the cord was immediately clamped and cut approximately at 20 cm. of length from the umbilical stump. Our data showed that milking of blood pooled in the umbilical cord after cord was clamped had no effect in the raising of the hematocrit level at 48 hours after birth in the term of the newborn. Although this UCM procedure was somewhat similar to a recent study by Upadhyay et al[10], their data demonstrated significantly high hemoglobin levels in the UCM group as compared with the control group both in term and near-term infants at 12 hours, 48 hours and 6 weeks after birth. The difference between our study and Upadhyay's study was the length of cord clamped and times of UCM. The umbilical cord in their study was clamped at 25 cm. of length and milked three times. Another difference was that our study enrolled only women who had delivered by cesarean section, while Upadhyay's study included all methods of delivery.

Upadhyay's work showed the benefit of UCM in increasing Hct level, while this study reported indifferent Hct level in UCM and ICC groups. GA of subjects in Upadhyay and the present study were more than 35 and 37 weeks, respectively. Average birthweight was 2,700 and 3,200 grams in Upadhyay and this study, respectively. The time of umbilical cord clamping in Upadhyay was longer than in the present study (within 30 and 5 seconds). The umbilical cord length before milking of Upadhyay was 25% longer

than present study (25 and 20 cm). The more blood volume in umbilical cord and the lesser neonatal birth weight may result the increment of Hct level in Upadhyay's work compare to this study.

Most previous studies showed the positive effect on hemoglobin or hematocrit level in full-term and preterm infants from placental transfusion strategies, whether it is DCC or UCM without maternal and neonatal complications. Three studies from the US and one study from India were conducted on preterm babies[3, 10-12]. Only one study from Erickson et al[13] was conducted in a full-term pregnancy. Hematocrit in UCM was higher than in ICC group. Comparative data of previous literature are presented in Table 3.

A Cochrane review showed a lower hemoglobin concentration in infants at 24-48 hours and lower iron stores at 3-6 months with the early cord clamping group, as compared with the delayed cord clamping group[4]. Although our study did not demonstrate the raising of hematocrit at 48 hours after birth, we did not follow the iron storage at a later point in life that might have been affected by the procedure[4, 14].

The UCM technique differed in various studies. Milking three times from inward to fetus was mentioned in a study by Patel, March and Upadhyay[3, 10, 12]. In our study, we milked the umbilical cord five times, as described in Erickson's study[13]. Length of milking in the literature varied from 20 cm, 25 cm and total umbilical cord length[10-12]. Our study relied on the 20 cm length, as from Kantheria's work[11]. The major factor that had an effect on hematocrit levels might have been the placental blood pool prior to cord milking. Most studies of UCM performed cord milking 2-5 times, and then clamped and cut the umbilical cord. Erickson's study was milking total cord length and then clamping in term infants delivered by cesarean section. Although, Erickson's study was limited by a sample size too small to detect potential neonatal complications. It was only in our study and Upadhyay's study[10], that the cord was clamped before cord milking. However, the results of these two studies still differed. The difference technique was summarized in Table 3.

Table 3. Comparing data the umbodical cord milking from previous literature.

Characteristics	Patel et al[3] (UCM/ICC)	Kantheria et al[11] (UCM/ICC)	March et al[12] (UCM/ICC)	Upadhyay et al[10] (UCM/ICC)	Erickson et al[13] (UCM/ICC)	Present study (UCM/ICC)
Year	2014	2014	2013	2013	2011	2015
Place	USA	USA	USA	India	USA	Thailand
GA (wk)	< 30	23 - < 32	24 - 28	> 35	37 - < 42	37 - 42
Route of deliver	CS, Vg	CS, Vg	CS, Vg	CS, Vg	CS	CS
Casea (n)	318	60	113	200	24	110
Age (yr)	27.6/27.7		26.9/29.5	18-40	34.7/32	31.4/30.9
Body weitht (kg)				46.8/47.2		57.2/57.3
Height (cm)						157.6/159.3
Maternal Hct (%)			33.1/32.2			35.2/35.3
Operative times (min)						40.6/38.2
EBL (ml)						365.5/370.0
Distant length (cm)	Total	20	20	25	Total	20
Milking (time)	3	2	3	3	5	5
Newborn						
Birth weight (g)	960/880	1170/1131	755/770	2750/2640	3662/3524	3228.6/3207.1
Apgar at 1 min	4/5	5/6	4/4		8/8	9/8.9

Table 3. Comparing data the umbodical cord milking from previous literature. (Cont.)

Characteristics	Patel et al[3] (UCM/ICC)	Kantheria et al[11] (UCM/ICC)	March et al[12] (UCM/ICC)	Upadhyay et al[10] (UCM/ICC)	Erickson et al[13] (UCM/ICC)	Present study (UCM/ICC)
Apgar at 5 min	7/7	7/7	6.5/7		9/9	10/10
Hct at 12 hr (%)			43.3/40.8*	45.7/41.2*		
Hct at 24 hr (%)	49.9/45.1*	47/42*				
Hct at 48 hr (%)				41.2/37.2*	57.5/50.0*	50.1/50.6
MB (mg/dL)		8/7		7.4/6.6	12.4/11.8	8.3/8.2
RR (bpm)				41.9/42.2		46.7/47.2
LOS (day)	93/97					3.0/3.1
Complications						
IVH	15/27*	2/4	9/20*			
NEC	18/32*		6/10			
Death	22/40*	2/1				

GA: gestational age, Vg: vaginal delivery, CS: cesarean section, EBL: estimate blood loss, Distant length: length from fetal umbilicus to clamping site, MB: microbilirubin, RR: respiratory rate, Bpm: beatperminutes, LOS: length of stay, IVH: intraventicular hemorrhage, NEC: necrotizing enterocolitis, *: P value < 0.05

Phototherapy is usually indicated in infants who had low birth weights, high MB and lower gestational age. MB levels in this study showed no differences between the UCM and control groups. MB level of low birth weight babies (< 2,800 gm) were higher than those babies who had birth weights greater than 2,800 gm. It was not statistically different because of the low number of cases. An investigation into the cause jaundice and hyperbilirubinemia in low birth weight newborns who received UCM should be conducted for more strongly supported conclusions.

The limitation of this study was timing of follow up. The newborn hematocrit should be followed 3-6 months after birth in order to monitor iron storage and anemia over the long term.

As shown in many literatures, UCM resulted in good postnatal hematocrit and reducing neonatal complications in the preterm group. There is currently insufficient data to corroborate any supposed benefits from the UCM for infants born in resource-rich surroundings. It is firstly true that umbilical cord clamping extending to 60 seconds has the potential of augmenting total body iron stores. Indeed, this augmentation could benefit infants born in iron-deficient populations. Nonetheless, such unestablished but possible benefits must be juxtaposed against an increase in risk level of neonatal phototherapy[9]. However, further studies and a longer follow-up should be conducted to collect more data for full term newborns in the country in areas with high prevalence of iron-deficiency anemia.

Conclusion

Twenty centimeters of UCM after the cord was clamped could not raise the neonatal hematocrit and neonatal complication. Our study suggested that UCM on full-term babies was a safe procedure.

Potential conflicts of interest

The authors declare no conflict of interest.

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