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Timing of Umbilical Cord Clamping in Term and Preterm Deliveries and Infant and Maternal Outcomes: *A Systematic Review of Randomized Controlled Trials*

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RELEVANCE

Active management of the third stage of labor (comprising administration of a uterotonic agent, cord clamping and cutting, and controlled cord traction) has supplanted the 'physiological' (non-interventionist) approach [1]; as a consequence the umbilical cord is usually clamped soon after delivery of the baby. The observation that the cord can contain up to 20 mL of blood [2] raised the possibility of delaying clamping to allow placental transfusion to the baby. One of the major advantages could be to increase the circulating volume and hemoglobin level. The benefits of the former include less respiratory distress and reduced need for later transfusions [3,4]. Increasing the hemoglobin level and iron stores is attractive because anemia in early infancy is a frequent problem, especially in developing countries. However these potential benefits need to be balanced against possible harmful effects, for the mother (postpartum hemorrhage and its consequences) [1,5,6] and infant (delayed resuscitation, hypothermia, polycythemia, hyperbilirubinemia and risk of intraventricular hemorrhage). The issue is complicated by the fact that term babies, preterm babies and very premature babies could behave as different cohorts, making it difficult to develop an empiric guideline for timing of cord clamping across all gestations.

This systematic review explores the question: Does delayed cord clamping (*intervention*) at delivery, improve maternal and infant (*population*), short-term and long-term outcomes (*outcome*), compared to early cord clamping (*comparator*)?

CURRENT BEST EVIDENCE

An exhaustive literature search was undertaken in September 2010, for randomized controlled trials (RCT) comparing delayed cord clamping (DCC) defined as >30 seconds following delivery, versus early cord clamping (ECC) defined as within 30 seconds of delivery; reporting maternal and/or infant outcomes. The final updated search on 16 December 2010 in the Cochrane Library (search term "*cord clamp*" and filter "*Record title*") yielded 3 Cochrane systematic reviews (CSR), 5 other systematic reviews, and 71 trials. Medline search on the same date (search term: *cord clamping*; limits: *randomized controlled trial, meta-analysis*) yielded 137 citations. The available systematic reviews [7-12] were either outdated and/or had methodological limitations.

A total of 57 publications were short-listed as potentially relevant. Thirty were excluded for the following reasons: not RCT comparing DCC *vs* ECC (*n*=6), RCT but intervention in either arm not according to definition of DCC or ECC (*n*=4), RCT but intervention in control arm not described (*n*=1), outcome not of interest (*n*=2), publications as editorials, correspondence or commentaries (*n*=6), outdated systematic reviews (*n*=6), only abstract available without data (*n*=5). Overall, 29 trial reports - 15 in term and 14 in preterm deliveries comprise current best evidence (***Table* I**); this includes two additional trials identified through searching of bibliography of short-listed publications [23] and recent conference proceedings [27].

Results of meta-analyses for 17 outcomes in

TABLE I SUMMARY OF INCLUDED RCTs

Setting [Ref]	Participants	DCC n, timing of clamping	ECC n, timing of clamping	Outcomes
Term Deliveries				
Argentina [13]	>37 wk	92, >150 sec; 91, 45-75 sec	93, <20 sec	Hct (6h,24-48h), PC, PC requiring ET, HB, Bil>16mg/dl, Maternal blood loss, Maternal Hct, multiple neonatal morbidities
Argentina [14]	>37 wk	83, >150 sec; 83, 45-75 sec	86, <20 sec	Ferritin at 6mo, Mean Hb, Hb<10.5g/dl
Mexico [15]	>37 wk	237, 2 min	239, <20 sec	Hct, clinical HB, Hb, PC, Hct (6mo, Ferritin (6mo), Total iron (6mo), maternal blood loss
Libya [16]	37-42 wk	58, ACCP	46, <10 sec	Hct, Hb, PC, HB, hyperviscosity, maternal Hct, maternal Hb
India [17]	>37 wk	59, APD + IP lower	48, ICC	Hb (3mo), ferritin (3mo), maternal Hb, maternal ferritin
Guatemala [18]	>37 wk, weight >2 kg	22, ACCP + IP lower; 22, ACCP + IP level	21, ICC	Hct, PC, Hct (2mo), Hb (2mo), ferritin (2mo), Maternal Hb, maternal ferritin, maternal iron indices(at delivery and follow-up)
India [19]	>37 wk born to anemic mothers	49, APD + IP lower	53, ICC	Hb (birth), ferritin (birth), Hb (3mo), ferritin (3mo), anemia (3 mo), breastfeeding, maternal Hb
Iran [20]	38-42 wk	34, 3 min +IP at level	34, <30 sec	Hct (2h, 18h), PC, clinical signs of PC (2h, 18, 5d)
Pakistan [21]	Term	100, ACCP + IP level	100, ICC	Hb, Bil
Sweden [22]	39-40 wk	15, 3 min + IP level	15, <10 sec	Hct (birth, 24 h, 5d), blood viscosity, rheological parameters
United Kingdom [23]	Term	483/480	DCC=ACCP or 5 min; ECC=ICC	Apgar (5min), NICU adm, PT need, breastfeeding, maternal PPH, maternal mean blood loss, maternal need for BT, MRP, length of third stage
United Kingdom [24]	37-42 wk	296, 3 min	256, ICC	Respiratory problems, clinical HB, PT need, birth weight, feeding, maternal PPH, MRP
Canada [25]	38-42 wk	15, 1 min + IP lower	15, <15 sec	Hct, RBC volume, plasma volume, Bil
Zambia [26]	Term	55, ACCP + IP lower	50, <20 sec	Hb, ET (1d), HB, birth weight, PT need, anemia (4mo), maternal blood loss
Sweden [27]	Term	200, >180 sec	200, <10 sec	Hb (2d), Hct (2d), Bil, respiratory symptoms, PC, PT need, Hb (4mo), ferritin (4mo), Transferrin saturation (4mo), reticulocyte Hb (4mo), anemia (4mo)

Contd.....

Setting [Ref]	Participants	DCC n, timing of clamping	ECC n, timing of clamping	Outcomes
Preterm Deliveries				
United Kingdom [28]	24-32 wk	23, 30-90 sec + IP lower	23, ICC	Hct, mean blood volume, CRIB score, transfusion requirement
Switzerland [29]	24-32 wk	15, 60-90 sec + IP lower	24, <20 sec	Mortality, Hct (4h, 24h, 72h), cerebral bood flow (4h, 24h), tissue oxygenation
South Africa [30]	<35 wk	24, 60 sec + IP NS ± ergometrine	14, ICC	Mortality, cerebral USG (6-72h), Apgar score, birth weight, SBP (5 min), cord blood gas
Israel [31]	24-35 wk	30, 30-45 sec + IP lower	35, 5-10 sec	Mortality, Hct, MBP, IVH, BT need, no. of BT, PT need, peak Bil, PDA, NEC
Israel [32]	24-35 wk	30, 30-45 sec + IP lower	35, 5-10 sec	Levels of IgG, IgM, C3, C4(at birth), sepsis, days of AB, infections in 1st mo.
Australia [33]	26-33 wk	23, 30 sec	23, ICC	Mortality, Hct (1h, 4h), Apgar score, temperature, MV need, BT volume, peak Bil, cerebral USG
USA [34]	24-32 wk	16, 30-45 sec + IP lower	16, 5-10 sec	MBP, glucose, no. of volume expanders, volume transfused, peak bil, IVH, suspected NEC
USA [35]	24-32 wk	36, 30-45 sec + IP lower	36, 5-10 sec	Mortality, no. transfused, volume transfused, IVH, BPD, suspected NEC, sepsis, LOS
USA [36]	24-32 wk	29, 30-45 sec + IP lower	29, 5-10 sec	Neurodevelopmental outcome among survivors at 7mo
United Kingdom [37]	24-28 wk	16, 30-45 sec + IP NS	17, ICC	Hct (4h), BT, resuscitation, Apgar score, BP (12 h), IVH, NEC, RoP, LOS, PDA
Germany [38]	<33wk	19, 45 sec + IP lower	20, <20 sec + IP at lower	No. of transfusions, volume transfused, Apgar score, BP, (1h,4h,24h), RD (1d), IVH, PDA, PT need, PT duration
USA [39]	30-36 wk	39/61	DCC=1 min + IP at lower; ECC=ICC	Hct, BT, Apgar score, SNAP score, MV need, Bil, PT need
USA [40]	30-36 wk	39, 1 min + IP lower	61, ICC	Mortality, IVH
Holland [41]	36-36 wk	21, 3 min	20, <30 sec	Hct (1h, 10 wk), Hb (1h, 10 wk), glucose, Bil, PC, PT need, ferritin (10wk)

AB=antibiotics; ACCP=at cessation of cord pulsations; APD=after placental descent; Bil=Bilirubin; BP=blood pressure; BPD=broncho-pulmonary dysplasia; BT=blood transfusion; DCC= delayed cord clamping; ECC = early cord clamping; ET=exchange transfusion; Hb=haemoglobin; HB=hyperbilirubinemia; Hct=hematocrit; ICC=immediate cord clamping; IP=infant position; IVH=intraventricular hemmorhage; LOS=late onset sepsis, MBP=mean blood pressure; MRP=manual removal of placenta; MV=mechanical ventilation; NEC=necrotizing enterocolitis; NICU=neonatal intensive care unit; NS=not specified; PC=polycythemia; PDA=patent ductus arteriosus; PP=post-partum hemmorhage; PT=phototherapy; RBC=red blood cell; RD=respiratory distress; RoP=retinopathy of prematurity; SBP=systolic blood pressure, USG=ultrasonography

TABLE II SUMMARY OF META-ANALYSIS OF DATA PERTAINING TO TERM DELIVERIES

Outcome	Trials (*N*)	Participants (*n*)	Effect size (95% CI)
Term Deliveries			
Initial hematocrit (%) at birth	6	1163	MD 2.38 (1.10, 3.67)
Initial hemoglobin (g/dL)	4	1059	MD 1.95 (0.81, 3.10)
Hematocrit (%) at longest follow-up	2	403	MD 1.72 (-2.00, 5.44)
Hemoglobin (g/dl) at longest follow-up	7	1318	MD 0.17 (-0.15, 0.49)
Anemia at follow-up	3	402	RR 0.85 (0.54, 1.35)
Ferritin level (mcg/L) at longest follow-up	4	857	MD 17.00 (12.15, 21.85)
Admission to NICU	2	1239	RR 0.96 (0.40, 2.33)
Respiratory distress	2	1008	RR 0.99 (0.35, 2.81)
Hyperbilirubinemia or jaundice	5	2210	RR 1.16 (0.92, 1.45)
Requirement of phototherapy	5	1974	RR 1.28 (0.48, 3.42)
Polycythemia	6	936	RR 1.22 (0.79, 1.87)
Maternal PPH >500 mL	4	1878	RR 0.82 (0.65, 1.04)
Severe Maternal PPH (>1000mL)	4	1684	RR 1.19 (0.67, 2.11)
Maternal blood loss (mL)	1	963	MD -6.36 (-47.66, 34.94)
Maternal hemoglobin (g/dL)	4	1175	MD 0.12 (-0.06, 0.30)
Maternal ferritin level (mcg/L)	2	154	MD -5.01 (-16.30, 6.28)
Need for manual removal of placenta	2	1315	RR 0.45 (0.22, 0.94)
Preterm Deliveries			
Mortality	9	503	RR 0.55 (0.21, 1.46)
Hematocrit at birth	9	457	MD 3.04 (2.58, 3.51)
Requirement for transfusions	6	358	RR 0.72 (0.54, 0.96)
Number of transfusions administered	4	144	MD -0.92 (-1.78, -0.05)
Peak serum bilirubin (mg/dL)	5	215	MD 0.91 (0.21, 1.60)
Requirement of phototherapy	3	180	RR 1.23 (0.94, 1.60)
Patent ductus arteriosus	4	183	RR 1.28 (0.62, 2.64)
Intraventricular hemmorhage	7	408	RR 0.49 (0.32, 0.74)
Respiratory distress syndrome	1	39	RR 1.84 (0.64, 5.30)
Requirement of ventilatory support	2	85	RR 1.09 (0.66, 1.81)
Mean blood pressure	2	97	MD 3.66 (0.74, 6.58)
Necrotizing enterocolitis	3	137	RR 0.47 (0.13, 1.69)
Hemoglobin at longest follow-up	1	34	MD 1.10 (0.35, 1.85)
Ferritin at follow-up	1	34	MD 19.00 (-60.93, 98.93)
Hematocrit at follow-up	1	34	MD 4.00 (0.53, 7.47)
Bronchopulmonary dysplasia	1	72	RR 1.33 (0.51, 3.46)

CI=confidence interval, MD=mean difference, RR=relative risk

term deliveries and 16 outcomes in preterm deliveries are detailed in ***Table* II**. The findings suggest limited clinically significant benefits of delayed cord clamping for term infants; however it resulted in significantly reduced incidence of intraventricular hemorrhage in preterm neonates. Delayed clamping neither increases complications nor provides benefits for mothers delivering at term; risks and benefits for mothers delivering prematurely have not been explored in the trials.

CRITICAL APPRAISAL

Risk of bias: The 29 trials included in the two components of this systematic review comprise current best evidence from published literature. However, only 4 trials in term deliveries [13,14,20,24] and 7 in preterm deliveries [31,32,34-36,39,40] could be classified as having low risk of bias based on criteria in the Cochrane Risk of Bias tool; the remainder had moderate or high [16,18,21,22,25,27] risk of bias. **Web *Table* I** summarizes the assessment of risk of bias in the included trials. Data in term deliveries was too limited for sensitivity analysis to assess impact of low(er) quality trials. Among preterm deliveries, risk of mortality and intraventricular hemorrhage were comparable among trials with low risk of bias (RR 0.25, 95% CI=0.04-1.45, 4 trials, *n*=308) and (RR 0.52; 95% CI=0.28-0.98, 4 trials, *n*=308) respectively, suggesting robust results.

Participant characteristics: All the trials included fairly stable pregnant women and used several exclusion criteria prior to randomization. Similarly, babies likely to be at risk of adverse outcomes were generally excluded. Therefore, the results pertain to a fairly well-filtered cohort of mothers and babies; raising the problem of distinguishing between efficacy and effectiveness of interventions. The trials among preterms did not describe the indication/cause of preterm delivery. This is important because antepartum hemorrhage, fetal distress, etc could be contributory; in such situations DCC cannot be considered.

Procedural differences in trials: Although the definition of ECC was fairly uniform across trials, DCC was defined in multiple ways (time ranging from 30 seconds to 5 minutes). This implies that trials with different DCC definitions could be heterogeneous enough to warrant caution in interpreting results.

Further, besides the timing of cord clamping, the position of the infant following delivery could independently affect placental transfusion to the baby. Since there is no clear recommendation on the ideal infant position following delivery [42], trials in term babies positioned babies either lower than the introitus [17,19,25,26], or at the same level [20-22] in the DCC arm. Position was not specified in the ECC arm. One trial [18] had two DCC arms with position lower and at level. Among preterms, the majority of trials used lower position with DCC [28,29,31,32,34-36,39,40]. Only one trial [38] used the lower position for both arms. The impact of position could not be ascertained in this systematic review.

It is customary to administer an uterotonic drug during the active management of the third stage; some trials included this component in either or both arms. The relative impact of this also cannot be established through this systematic review. Most trials included vaginal deliveries; some included Caesarean section deliveries as well. The relative differences (if any) between the two modes of delivery could not be explored in this review.

Conflict of maternal and neonatal interest: The current standard of care is to manage the third stage of labor actively (rather than expectantly) [43]; hence DCC is not the preferred method from the Obstetricians' perspective. However, many Units are shifting to a policy of DCC in term deliveries, expecting benefit for infants. Waiting for DCC in a stable baby (not requiring resuscitation) does not pose a problem from the pediatricians' viewpoint. However, since DCC has limited clinical benefits in term babies, this could create an apparent 'conflict' between maternal and neonatal interest, which can be resolved through joint appraisal and application of current best evidence. Unfortunately, none of the trials examined preferences of (maternal and neonatal) personnel in the delivery team.

EURECA CONCLUSIONS IN THE INDIAN CONTEXT

- For infants delivered at term, delayed cord clamping results in very limited clinically significant, short and long-term benefits; it neither increases maternal complications nor provides maternal benefit.
- Among preterm deliveries, delayed cord clamping results in significantly reduced risk of intraventricular hemorrhage and marginal hemodynamic benefits in neonates. The risks and benefits for mothers are not known.

EXTENDIBILITY

Most of the trials among term deliveries were conducted in developing country populations, including two from India. However, all were conducted in settings with facilities for management of potential adverse maternal and neonatal consequences at the point-of-care; these facilities are consistent with services at level II (and above) neonatal care facilities. Limitations of manpower and/or material resources across various delivery settings could preclude application of the evidence in this systematic review.

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