Evidence tables for review question: What is the optimum position for the baby during delayed cord clamping (including after instrumental and caesarean birth)?

Jain, 2020

Bibliographic Reference	Jain, R.; Jain, A.; Devgan, V.; Sekhar, J.; Effect of alternative positions of neonates prior to delayed cord clamping on placental transfusion: a randomized control trial; Journal of Maternal-Fetal and Neonatal Medicine; 2020; vol. 33 (no. 9); 1511-1516

Study details

Country/ies where study was carried out	India
Study type	Randomised controlled trial (RCT)
Study dates	Not reported
Inclusion criteria	• term pregnancy • uncomplicated antenatal period • informed written consent
Exclusion criteria	• Women with medical complications including eclampsia, heart disease, anaemia (Hb <10 g/dl), hypothyroidism, antepartum haemorrhage, abnormal antenatal ultrasound, multiple pregnancies, and Rh-negative blood group
Patient characteristics	<u>Maternal age - mean ± standard deviation</u> • Abdominal Level group: 23.9 ± 3.4 • Below vaginal Level group: 23.3 ± 3.5 <u>Gestational age - median (Inter Quartile Range)</u> • Abdominal Level group: 39 (2) • Below vaginal Level group: 38 (3)

	Primiparous - number - (%) Abdominal Level group: 52 (53.6) Below vaginal Level group: 59 (57.8)
Intervention(s)/control	• Abdominal Level (above level of introitus): newborns were placed on the mother's abdomen for 90 seconds. The cord was clamped at 90 seconds. • Below vaginal Level (below level of introitus): newborns were held at 20cm below the introitus for 90 seconds. The cord was clamped at 90 seconds.
Duration of follow-up	• 3 - 4 months
Sources of funding	• Not reported

Sample size	Randomised N= 248
	
	• Abdominal Level group: 124 (excluded n= 1 maternal medical disease)
	• Below vaginal Level group: 124 (excluded n= required resuscitation)
	
	Received intervention
	
	• Abdominal Level group: 123
	  ○ Excluded n= 3 (1 withdrew consent)
	  ○ Errors in processing blood samples n= 7
	  ○ Lost to follow up n= 16
	• Below vaginal Level group: 123
	  ○ Excluded n= 1 (major congenital abnormality)
	  ○ Errors in processing blood samples n= 5
	  ○ Lost to follow up n= 15
	
	Included in analysis
	
	• Abdominal Level group: 97
	• Below vaginal Level group 102

Other information	2 unaccounted for exclusions in AL group

Outcomes

Outcome	**AL group, , N = 97**	**BL group, , N = 102**
Jaundice requiring phototherapy Lower values are better No of events	n = 3	n = 2
Infant haemoglobin at 3-4 months Higher values are better Mean (SD)	12 (0.9)	12.3 (1.1)
Fall in haemoglobin from birth Lower values are better Mean (SD)	4.2 (0.9)	4 (0.9)
Exclusive breastfeeding at 3-4 months No of events	n = 89	n = 95
Neonatal admission Lower values are better No of events	n = 0	n = 2

Critical appraisal

Section	**Question**	**Answer**
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Allocation was computer generated and concealed in opaque envelopes and opened just prior to delivery. No baseline imbalances to suggest problems with randomisation.)*

Section	Question	Answer
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Risk of bias judgement for deviations from the intended interventions (effect of adhering to intervention)	Some concerns *(Participants and people delivering the intervention were aware of their assigned intervention. Analysis was by per protocol as loss to follow up was excluded. Reasons for loss to follow up are unclear and is possible that it is because of non-adherence to assigned intervention.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Low *(Outcome data available for most participants, there was loss to follow up but it was balanced between groups so unlikely that missingness in the outcome depended on its true values)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Some concerns *(Method of outcome measurement was not inappropriate, blinding of the investigator was not possible and is likely that this could have affected some of the outcome measurements. The laboratory technicians that processed blood sample for haemoglobin outcomes were not aware of the assigned intervention. Breastfeeding data was collected at follow up appointment, NICU admission is an objective measure data was collected in the hospital)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(A pre-specified protocol was not available to determine bias in selected reporting.)*
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	No variation between outcomes.

Mansaray, 2015

Bibliographic Reference	Mansaray A; Yetman R; Berens P; Effect of Delayed Cord Clamping Above Versus Below the Perineum on Neonatal Hematocrit: A Randomized Controlled Trial.; Breastfeeding medicine : the official journal of the Academy of Breastfeeding Medicine; 2015; vol. 10 (no. 10)

Study details

Country/ies where study was carried out	US
Study type	Randomised controlled trial (RCT)
Study dates	March 2012 - October 2013
Inclusion criteria	• Singleton intrauterine pregnancy • ≥ 37 weeks gestation • Anticipated vaginal birth
Exclusion criteria	• Hypertension • Diabetes mellitus • Renal disease • Medically managed seizure disorders • Pre-eclampsia • Intrauterine growth restriction • Chromosomal/anatomical abnormalities • Placental abruption.
Patient characteristics	Maternal age - years - mean ± standard deviation • Group A: 26.3 ±1.86 • Group B: 26.5 ±2.01 Gestational age - weeks - mean ± standard deviation • Group A: 39.0 ±0.38 • Group B: 39.4 ±0.39
Intervention(s)/control	Group A: babies were placed on the mother's abdomen Group B: babies were held below the perineum (at least 10 cm) In both groups the cord was clamped at 60-75 seconds

Duration of follow-up	Not reported
Sources of funding	Not reported
Sample size	Randomized N= 101 • Group A: 53 o Excluded: 26 o Caesarean birth n= 7 o Meconium n=4 o Nurse failure to collect blood sample n= 4 o Physician failure to delay clamping n= 2 o Tight nuchal n=3 o Operative delivery n= 2 o Bradycardia n= 1 o Sample clotted n= 2 o Intra-amniotic infection n=1 • Group B: 48 o Excluded: 22 o Caesarean birth n= 7 o Meconium n= 5 o Nurse failure to collect blood sample n= 2 o Physician failure to delay clamping n= 2 o Tight nuchal n= 1 o Operative delivery n= 2 o Bradycardia n= 2 o Sample clotted n= 1 o Intra-amniotic infection n= 0 Included in analysis

	• Group A: 27 • Group B: 26
Other information	Breastfeeding rates at discharge were low at an average of 27.8% with a monthly low rate of 19% and high rate of 40%. The study cohort would not have been expected to have different initiation rates.

Outcomes

Outcome	Group A, , N = 27	Group B, , N = 26
Jaundice requiring phototherapy Lower values are better No of events	n = 3	n = 1
Jaundice requiring transfusion Lower values are better No of events	n = 0	n = 0
Apgar score <7 at 1 min Higher values are better Mean (SD)	8.5 (0.24)	8.3 (0.22)
Apgar score <7 at 5 min Higher values are better Mean (SD)	9 (0.07)	9 (0)
NICU admission Lower values are better No of events	n = 3	n = 2

Critical appraisal

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Allocation was randomly generated via an online program research randomiser. No baseline imbalances to suggest problems with randomisation.)*
Domain 2a: Risk of bias due to deviations from the intended interventions (effect of assignment to intervention)	Risk of bias for deviations from the intended interventions (effect of assignment to intervention)	Low *(Blinding of midwives and women was not possible, but no evidence that assignment to intervention affected implementation. No evidence that ITT protocol not followed.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	*Low* *(Outcome data available for all participants. 48 participants were removed post randomisation. Reasons for removal were specified and exclusions were balanced across groups)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Method of outcome measurement was not inappropriate, blinding of the medical staff (outcome assessors) was not possible but it is not deemed to have affected outcome measurement. The staff collecting the newborn haemoglobin and haematocrit samples were blinded to group assignment. Jaundice requiring photo therapy or transfusion was obtained by a review chart after discharge, Apgar score and NICU admission are standardised measures)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Some concerns *(A pre-specified protocol was not available to determine bias in selected reporting.)*
Overall bias and Directness	Risk of bias judgement	Some concerns
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	No variation between outcomes.

Vain, 2014

Bibliographic Reference	Vain, Nestor E.; Satragno, Daniela S.; Gorenstein, Adriana N.; Gordillo, Juan E.; Berazategui, Juan P.; Alda, M. Guadalupe; Prudent, Luis M.; Effect of gravity on volume of placental transfusion: a multicentre, randomised, non-inferiority trial; Lancet (London, England); 2014; vol. 384 (no. 9939); 235-40

Study details

Country/ies where study was carried out	Argentina
Study type	Randomised controlled trial (RCT)
Study dates	August 18th, 2011 - August 31st 2012
Inclusion criteria	• >37 weeks gestation • Uncomplicated vaginal birth
Exclusion criteria	• Placenta praevia • Postpartum haemorrhage • Multiple gestation • Intrauterine growth restriction • Major congenital malformations diagnosed before delivery • Maternal diseases (eg, eclampsia, Rh incompatibility, congestive heart failure) • Request by the parents for cord blood banking • Need for resuscitation of newborn • Short umbilical cord or tight nuchal cord that prevented the the newborn being placed according to randomisation were initially randomised were not included in the analyses
Patient characteristics	<u>Maternal age - mean – standard deviation</u> • Introitus group: 27 (6.8) • Abdomen group: 26.9 (6.9)

	Gestational age - mean - standard deviation • Introitus group: 39.1 (0.9) • Abdomen group: 39.1 (0.9) Parity - mean – standard deviation • Introitus group: 1.3 (1.6) • Abdomen group: 1.4 (1.7)
Intervention(s)/control	Introitus group: newborns were held by the investigator at the vaginal level Abdomen group: newborns were placed on the mother's abdomen or chest, dependent on the length of the umbilical cord In both groups the cord was clamped at 2 minutes All newborn babies were weighed immediately after birth at the level of the vagina
Duration of follow-up	Not reported
Sources of funding	Not industry funded

Sample size	Randomised N= 546
	
	• Introitus group n= 274
	  ○ 77 not eligible for primary analysis
	  ○ 42 caesarean section or forceps
	  ○ 19 short umbilical cord or nuchal cord
	  ○ 7 need for resuscitation
	  ○ 6 team became unavailable
	  ○ 2 weight scale malfunctioned
	  ○ 1 parent withdrew consent
	
	• Abdomen group n= 272

	○ 78 not eligible for primary analysis ○ 41 caesarean section or forceps ○ 16 short umbilical cord or nuchal cord ○ 10 need for resuscitation ○ 7 team became unavailable ○ 2 weight scale malfunctioned ○ 2 parents withdrew consent • Introitus group n= 197 included in analysis • Abdomen group n= 194 included in analysis

Outcomes

Outcome	Introitus group, , N = 197	Abdomen group , , N = 194
Bilirubin concentration Mean (SD)	8.4 (3)	8.7 (3)
Apgar score <7 at 5 min higher values are better Mean (SD)	9.5 (0.5)	9.4 (0.5)
NICU admission Lower values are better No of events	n = 1	n = 1

Critical appraisal

Section	Question	Answer
Domain 1: Bias arising from the randomisation process	Risk of bias judgement for the randomisation process	Low *(Randomised in a 1:1 ratio with computer-generated allocation sequence in block sizes of four to eight (created by a statistician who was not involved again in the trial until statistical analysis of the results). Allocation was concealed by sequentially numbered sealed opaque envelopes. There were no differences between groups at baseline.)*
Domain 2b: Risk of bias due to deviations from the intended interventions (effect of adhering to intervention)	Risk of bias judgement for deviations from the intended interventions (effect of adhering to intervention)	Some concerns *(Participants and people delivering the intervention were aware of their assigned intervention. Analysis was by per protocol as participants were excluded after randomisation. Reasons for ineligibility were: caesarean or forceps birth; short umbilical cord or nuchal cord; need for resuscitation; team became unavailable; weight scale malfunctioned and parents withdrew consent.)*
Domain 3. Bias due to missing outcome data	Risk-of-bias judgement for missing outcome data	Some concerns *(Outcome data was not available for most participants, there was loss to follow up but it was balanced between groups so unlikely that missingness in the outcome depended on its true values)*
Domain 4. Bias in measurement of the outcome	Risk-of-bias judgement for measurement of the outcome	Low *(Blinding of the outcome assessors (nurses and obstetricians) was not possible but it is not deemed to have affected outcome measurement.) Method of outcome measurement was not inappropriate. Bilirubin concentration obtained by blood sample, Apgar score and NICU admission are standardised measures)*
Domain 5. Bias in selection of the reported result	Risk-of-bias judgement for selection of the reported result	Low *(Outcomes reported as in the specified protocol. Unlikely to have been selected.)*
Overall bias and Directness	Risk of bias judgement	High
Overall bias and Directness	Overall Directness	Directly applicable
Overall bias and Directness	Risk of bias variation across outcomes	No variation between outcomes.