The **E**ffect of **Ti**ming of **C**ord **C**lamping on the **O**utcome **A**mong **T**erm *(ETiC-COAT)* delivered at a Tertiary Government Hospital

: A Double Blind Randomize Control Trial

Project Description (1):

- The American Academy of Pediatricians (AAP) in 2004

- red blood cells can improve the infant's iron stores,

- also has the potential of overwhelming the newborn's metabolism, thus, leading to increased levels of bilirubin and in very severe cases, severe jaundice and later kernicterus.

- The AAP, therefore, recommends that the potential benefits or harm against DCC should be weighed by clinicians in the context of their settings.

Project Description (2):

WHO, 2007

> ➤ "the cord should not be clamped earlier than necessary"
> ➤ Noted that this would take around 3 minutes

> ➤ Weak recommendation, with low quality evidence

EINC

GRADE Working Group grades of evidence

High quality: Further research is very unlikely to change our confidence in the estimate of effect.

Moderate quality: Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.

Low quality: Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.

Very low quality: We are very uncertain about the estimate.

Further research is VERY likely to have an important impact on the confidence in the estimated Effect and likely to change the estimate

Objectives:

GENERAL:

To determine the effect of timed of cord clamping on the following neonatal outcomes among Term Neonates delivered in a tertiary hospital

SPECIFIC

- T o determine the effect of ECC on the neonatal outcomes among newborns delivered at the tertiary hospital
- To determine the effect of DCC on the neonatal outcomes among newborns delivered at tertiary hospital
- To compare the effect of early cord clamping and delayed cord clamping on the following neonatal outcomes:
- To determine the optimum time of cord clamping among newborns delivered at the tertiary hospital

Methodology (1):

Research Design

      : Prospective Single blinded, Randomized Controlled Trial Design

Subject Selection

- *Inclusion Criteria*
  - Term neonates who were between 37-42 weeks AOG by Ballard Score at the time of delivery
  - Neonates delivered in tertiary government hospital from January to May of 2013

Methodology (2):

- **Sample Size**:
  - As a result, the total number of respondents included in the analysis of the study was 199 which was above the computed size of 184.
- **Randomization and Study Treatment**
  - computer-generated table of random numbers
- **Data Analysis and Statistical Treatment**
  - Chi-square: for the categorical outcomes (tachypnea, jaundice, plethora, admission need for PET and disposition).
  - Independent Sample T-Test: for continuous outcome variables of hematocrit, and length of hospital stay
  - Logistic Regression Analyses: Subgroup Analysis of Categorical Outcomes (Kramer Classification, specific timing)
  - ANOVA: for the hematocrit levels in different periods of time.

Results (1): **Neonatal Outcomes according to Type of Cord Clamping**

Table 2: Summary table comparing neonatal outcomes between two group, 2013

	Neonatal Outcomes	Total N= 199 n (%)	Type of Cord Clamping		p- value
			ECC N= 96 n (%)	DCC N= 103 n (%)	
Hematocrit	Risk for Anemia at 4-6 months of age (hct ≤0.46)	12 (6)	11 (12)	1 (1)	*0.011*
	Polycythemia (hct ≥ 0.65)	15 (7.5)	1 (1)	14 (13.5)	*0.013*
Plethora	At 6 hours of life	67 (33.7)	12 (12.5)	55 (53.4)	*<0.001*
	At 12 hours of life	39 (19.6)	4 (4.2)	35 (34)	*<0.001*
	At 24 hours of life	25 (12.6)	2 (2.1)	23 (22.3)	*<0.001*
Jaundice	At 24 hrs of life	31 (15.6)	6 (6.3)	24 (24.3)	*<0.001*
Classification of Jaundice	Kramer-1	24 (12.1)	6 (6.3)	18 (17.5)	*0.010*
	Kramer-2	11 (5.5)	2 (2.1)	9 (8.7)	*0.035*
	Kramer-3**	4 (2)	1 (1)	3 (2.9)	*0.27*
Tachypnea	At birth*	10 (5)	1 (1)	9 (8.7)	*0.013*
	At 6 hrs of life	4 (2)	1 (1)	3 (2.9)	*0.347*
	At 12 hrs of life	3 (1.5)	1 (1)	2 (1.9)	*0.603*
	At 24 hrs of life	1 (0.5)	0	1 (1)	*0.333*

*after cord clamping
** too small for comparison

Results (2): **Effect on central hematocrit**

Table 3a: Mean and range of central hematocrit (mean, range) at 6 hours of life classified according to cord clamping time, 2013

Time	N	Mean Hct	Range of Hct	SD
ECC1 (5 sec)	31	0.5135	0.38-0.60	.054
ECC2 (15 sec)	35	0.5237	0.36-0.66	.068
ECC3 (25 sec)	30	0.5263	0.40-0.62	.049
DCC1 (1 min)	32	0.5644	**0.46-0.63**	.055
DCC2 (2 min)	35	0.5969	0.45-0.71	.074
DCC3 (3 min)	36	0.6031	0.36-0.74	0.55

Note:

- ECC – risk of anemia
- 2 and 3 mins – risk of polycythemia
- 1 min- no unwanted finding as far as hematocrit level

Results (3):

Table 5: Number and Percentage of admissions with corresponding diagnosis and DAMA According to type of cord clamping, 2013

Admissions/ DAMA	Total N	Type of Cord Clamping		p-value
		ECC n (%)	DCC n (%)	
WITH Intravenous Hydration (due to polycythemia)	18	3 (16)	15 (83)	**0.005**
TTNB	2	0	2 (100)	0.17
Pneumonia	6	2 (33.3)	4 (66.6)	0.45
Sepsis	6	3 (50)	3 (50)	0.93
DAMA	5	0	5 (100)	**0.029**

Note:

- Significant number of admissions under DCC group
  - Polycythemia (p <.005)
- Significant number of those who went on DAMA under DCC

Conclusion & Recommendation:

Conclusion:

- ECC: risk for developing anemia at 4-6 months of age.
- DCC (2 and 3 mins): more significant polycythemia

  : Plethora and jaundice

  : number of admissions

  : tachypnea

- No significance : incidence of n. pneumonia, n sepsis and TTNB.
- Optimum time for cord clamping: one minute- barring any undesirable neonatal outcome

Recommendation:

- to use one minute as a time for cord clamping from the delivery of both shoulders especially in our EINC implementation.
- further study is recommended