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COMPARISON OF UMBILICAL CORD MILKING AND DELAYED CORD CLAMPING ON HAEMOGLOBIN AND HAEMATOCRIT LEVELS IN TERM NEONATES. A RANDOMIZED CONTROLLED TRIAL.

Pediatrics

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ABSTRACT

Background: Delayed umbilical cord clamping is an effective strategy and particularly relevant for infants living in low-resource settings with less access to iron-rich foods and thus are at greater risk of anaemia.

Objective: To compare the effect of umbilical cord milking (UCM) and delayed cord clamping (DCC) on haematological parameters (serum ferritin & hemoglobin) at birth and at 72 hours in term neonates.

Methods: This was an Open Label Randomized Controlled Trial conducted at Suvidha Mother and Child Nursing Home Talab Tillo Jammu over a period of 6 months. A total of 68 babies born at > 37 weeks of gestation were randomized in three groups, group I UCM alone (n=28) , Group II DCC alone (n=23) and Group III both UCC and DCC (n=17) using simple randomization technique . In milking group, Umbilical cord was milked 4 times towards the baby at a speed of 10 cm / sec . In Delayed Cord Clamping group cord was clamped and cut 2-3 cm distance from the umbilical stump after 3 minutes of birth. In Group III both procedures were done simultaneously.

Statistical analysis: ANOVA was used to compare mean difference of outcome between three intervention arms. Two tailed P value of <0.05 was taken as significant. SPSS version 20.0 was used for data analysis

Results: The baseline characteristics were mostly comparable in the all the groups. Maximum increase in Haemoglobin and PCV was seen in group II i.e delayed cord clamping . Mean haemoglobin and heamatocrit (PCV) levels at 72 hours of life neonates in group II (17.7g% and 55.4) and group III (17.3g% and 54) were comparable .

Conclusion: Both the interventions i.e Delayed cord clamping performed alone or in combination with umbilical cord milking had comparable effect on hematological status in term neonates.

KEYWORDS

Umbilical cord milking, Delayed cord clamping, Haemoglobin, Heamatocrit

INTRODUCTION

Anaemia, defined as haemoglobin concentration below established cut-off levels is a widespread public health problem with major consequences for human health, affecting and hindering social and economic development.[1] Children with iron deficiency anaemia are more likely to have delayed psychomotor development, impaired performance in tests of language skills, motor skills, and coordination, equivalent to a 5–10-point deficit in intelligence quotient. Both epidemiological and experimental data suggest that when these impairments occur at an early age, they may be irreversible, even after repletion of iron stores, thus reinforcing the importance of approaches (such as delayed cord clamping) that can prevent this condition.[2]

Optimal timing of umbilical cord clamping(UCC) has significant effect on level of blood volume and haemoglobin levels. “Early” cord clamping is generally carried out in the first 60 seconds after birth (most commonly in the first 15–30 seconds), whereas “delayed” (also referred to as “late”) cord clamping (DCC) is generally carried out more than 1 min after the birth or when the umbilical cord pulsation has ceased.[3]

In the early 19th century, the English physician, Erasmus Darwin mentioned “another thing very injurious to the child is the tying and cutting of the navel string too soon, which should always be left till the child has not only repeatedly breathed but till all pulsation in the cord ceases. As otherwise the child is much weaker”. [4][5]

There is growing evidence that delayed cord clamping is beneficial and can improve the infant's iron status for up to 6 months after birth. Clamping the umbilical cord at 2–3 min, or until cord pulsations cease, allows placental transfusion which provides sufficient iron reserves for the first 6–8 months of life, preventing or delaying the development of iron deficiency.

However more evidence is needed in this respect. Fifteen randomized controlled trials (738 infants) have evaluated the effects of umbilical cord clamping time in preterm neonates born predominantly in high-income countries .[6]

WHO recommends delayed umbilical cord clamping (not earlier than 1 min after birth) for improved maternal and infant health and nutrition outcomes and it is one of the essential intervention during postpartum period to protect mother from risk of postpartum haemorrhage and neonate from anaemia. However still it is not widely practised by obstetricians due to various reasons like heavy patient burden, shortage of time , insufficient staff and low doctor population ratio especially in settings like ours. The present study was contemplated to comapre the effects of umbilical cord milking, delayed cord clamping and combination of both procedures on neonatal haemoglobin and haematocrit (PCV) levels.

MATERIAL AN METHODS

The present study was open label, randomized controlled trial. Informed consent was obtained from all the participating mothers after explaining the purpose of study.

INCLUSION CRITERIA:

All neonates more than 37 weeks born either by vaginal route or through Lower segment caesarean section (LSCS) in Suvidha Nursing Home , and whose parents gave consent for blood sampling at birth (Day 1) and after 72 hours of age were considered eligible for the study. Gestational age was calculated from ultrasound and if it was not available last menstrual period (LMP) was used.

EXCLUSION CRITERIA:

Mother fetus pair with following characteristics were excluded from the study

1. Multiple gestation,

2. Umblical cord anomalies like true knots or cord prolapse
3. Rh negative mother,
4. Major congenital malformation antenatal diagnosed or apparent at birth
5. Hydrops fetalis,
6. Placenta previa and abruption placenta
7. Maternal blood transfusion for anaemia.

Primary Outcome was to estimate the levels of haemoglobin and PCV at birth i.e on day 1 and at 72 hours(day 3).

SAMPLE SIZE:
The minimum blood haemoglobin at birth is around 11 gm% [7]. and to detect difference of 1.2 gm% with acceptable alpha as 0.05 and 80% power,the minimum sample size required in each arm keeping drop out rate of 20% in mind was 28. Randomisation was done using simple randomization technique by employing table of simple random numbers by indepenent biostatiscian. Allocation sequence was concealed in sealed envelopes which were to be opened by obstetrician just before delivery. Laboratory investigators were blinded to the intervention. Blinding of the doctors was not possible as they were aware of intervention which they were giving. There were three intervention arms. In Group I only umbilical cord milking was done, Group II had delayed umblical cord clamping and Group III had both procedures done i.e. both delayed cord clamping and milking of umbilical cord.

Interventions:
For all interventions after delivery, babies were positioned between the mother's abdomen (for babies delivered through vaginal route) or on the mother's thigh (for babies delivered by caesarean section)

a) Umbilical cord milking:
Umbilical cord was milked 4 times towards the baby at a speed of 10 cm / sec and cord was clamped and cut 2 – 3 cm from umbilical stump.

b) Delayed cord clamping:
Umbilical cord was clamped and cut 2-3 cm distance from the umbilical stump after 3 minutes of birth.

c) For both procedures, umbilical cord was milked 4 times towards the baby at a speed of 10 cm / sec and then cord was clamped and cut 2 – 3 cm from umbilical stump at 3 minutes of birth.

After delivery, intramuscular oxytocin was given to vaginally delivered mothers and intravenous oxytocin was given to mother who was delivered through caesarean section. All neonates were managed as per standard protocol. Early breast feeding was encouraged in all babies as per standard guidelines. Heamoglobin and PCV were measured two times one on day 1(Birth) and second after 72 hours of every neonate.

Baseline characteristics of mothers like gestational age, maternal weight and maternal haemoglobin,mode of delivery and use of oxytocin were noted. Birth weight, sex of neonates,initiation of breast feeding was recorded. Anaemia was classified using WHO classification.[8]

Results were presented using measures of descriptive statistics like mean and standard deviation . Intragroup results at birth and after 72 hours was compared using independent t test. ANOVA was used to compare mean difference of outcome between three intervention arms. Two tailed P value of <0.05 was taken as significant. SPSS version 20.0 was used for data analysis.

RESULTS
300 mothers were eligible for the study and out of which 140 were excluded for reasons like preterm delivery in 37 mothers and 103 patients went to government setup for delivery. Out of 160 eligible mothers, 92 mothers were excluded for reasons like not agreed to participate in the study and therefore didn't give consent (56 mothers), Multiple gestation (10), Rh negative mothers (8), Placenta previa (10), Abruptio placenta (5) and (3) mothers received transfusion for anaemia.

A total of 68 mothers were finally enrolled in the study. Group I had 28 mothers and received intervention Umblical Cord milking ,Group II had 23 mothers and received Delayed umbilical cord clamping and 17 mothers were enrolled in group III who received both the interventions i.e Umblical Cord milking and Delayed umbilical cord clamping.(Fig 1) Baseline characteristics were compared between all the groups ,Gestational age, maternal Hb and birth weight of babies was nearly comparable, p(<0.05). However maternal weight differed among all the groups and it was statiscally not significant (p>0.05)

We observed 16 (23.5%) mothers who were suffering from anaemia i.e <11 gm%. However out of them 11 (16.1%)were in category of mild anaemia and 5 (7.3 %) were suffering from moderate anaemia (1 in Group I and 3 in group II) as per WHO classification.

Maximum deliveries were LSCS in all the groups and overall there were nearly equal males(35 i,e 51.4%) and females babies delivered (33i.e 48.5%) with M:F ratio of 1.06:1. However the results were not statiscally significant p>0.05.(Table 2)

There was intragroup increase in mean haemoglobin and PCV in all the three groups from birth and 72 hours after particular intervention . Maximum increase in Haemoglobin and PCV was seen in group II i.e delayed cord clamping .The results were significant in all the groups p(<0.01).(Table 3)

Mean haemoglobin levels at birth of neonates in group II and III were comparable. However in group I it was nearly 1 gm/dl lower as compared to other two groups. The results were not statistically significant. Regarding PCV, baseline levels (at birth) of group II and group III were almost similar and correspondingly PCV of group I was lower as compared to both groups.

When intergroup results were compared , it was seen that after 72 hours of intervention, there was significant increase in Hb and PCV in all the groups but the maximum increase in Hb and PCV was seen in neonates of group II mothers.The findings were statistically significant. Similarly Mean haemoglobin and heamatocrit (PCV) levels at 72 hours of neonates in group II(17.7g% and 55.4) and III(17.3g% and 54) were comparable (Table 4)

DISCUSSION
Iron deficiency anaemia is a highly prevalent and public health problem in India. It is most common in women of reproductive age group and children under 5 years of age in low and middle income countries. As per National Health and Family Survey 4 (NFHS 4) in India conducted in 2015-2016, prevalence of anaemia in pregnant women and among 6 months to 5 years children was 50 % and 58% respectively.[9] The lower limit of age group of childhood anaemia is kept at 6 months as upto 6 months infant has sufficient iron stores in the body.

In industralized countries, Iron deficiency anaemia is prevented by good nutrition and iron supplementation. In low resource settings especially India, children have high risk of developing anaemia especially iron deficiency anaemia as their feeding practices are not optimum, intake of diet deficient in iron , frequent infection and there are lower coverage rates of Iron supplementation. We undertook a study in 2014-15 where we reported infant and young child feeding practices among children aged 0 to 23 months in block RS Pura of district Jammu using set of core and optional indicators given by WHO. The results revealed lower overall intake of iron. Only 22 % of infants and children were having iron rich/iron fortified food. [10]

Though Government of India has scaled up various interventions like Iron supplementation, deworming, management of infections, addressing undernutrition through various health programmes like Rashtriya Bal Swasthya Karyakaram(RBSK),Reproductive Maternal ,Neonatal, child health and Adolescent(RMNCHA) and many more. Much needs to be done to see the visible results at ground level.

Various studies have confirmed that delayed umbilical cord clamping at birth enhances red cell mass and improves iron status during infancy. In term infants, one-minute and three minute delay in cord clamping after birth leads to an additional 80 mL and 100 ml of blood from the placenta to the infant's circulation respectively. [11][12]

Baseline characteristics like gestational age, maternal haemoglobin and birth weight of neonates were comparable in three groups .However maternal weight differed among all the groups. The reasons may be the entry of women in study at different gestational ages.
Hemoglobin level is higher at birth than at any other period of life and reduces from approximately 17 gm/dl at birth to a low of about 11.2 gm/dl in the first two months of life.[13]

Initial (Baseline) haemoglobin of neonates at birth was comparatively on lower side in our study , indicating lower body iron stores .This could be due to poor maternal health and high prevalence of maternal anaemia in developing countries. Though we have observed anaemia in nearly 23.5 % of women , the percentage of moderate anaemia was 7.4%. Iron

store in a neonate is largely determined by maternal iron status, gestational age of and birth weight of the neonate.[14] . Maternal anaemia during pregnancy is associated with anaemia during infancy.[15-17]

These children were at more risk of developing anaemia especially if they were not fed properly or suffer from concurrent infections in future. We observed significantly higher levels of intergroup haemoglobin and PCV levels after 72 hours in all the intervention arms. Maximum increase was seen in group II. However increase in group II and III were comparable as compared to group I, That means both procedures like Delayed cord clamping done in group II and combined Delayed cord clamping and umbilical cord milking done in group III produced nearly comparable levels of haemoglobin and PCV as compared to procedure cord milking when done in isolation. The reason may be with delayed cord clamping, there is more passage of blood through cord as it has more connectivity to bigger pool of blood in placenta as compared to milking done alone and the effect is sustained when both procedures are performed in combination. The second reason may be due to the fact that in group III the sample size was comparatively less as compared to both the groups and thus it was not adequate enough to detect the difference in outcome.

Delayed cord clamping and umbilical cord milking to some extent have raised their haemoglobin levels from initial levels, which can only be sustained further if proper IYCF practices and care is being practiced..

Similar pattern of findings were observed by other studies as well .A number of systematic reviews (Anderson O et al ; 2011, McDonald et al., 2008, Hutton et al., 2007, Mathew et al., 2007) have examined the risks and benefits of delayed cord clamping in healthy term infants. These have found an increase in hemoglobin concentration and improved iron status up to six months after birth, thus decreasing the risk of early neonatal anemia and iron deficiency.[18-21]

Balaji S also observed that neonates allocated to milking group had nearly similar haemoglobin values at 2 months compared with delayed clamping group , indicating a similar amount of placental blood transfer in both groups.[22] . In a study by Gupta and Ramji in 2002, haemoglobin at 3 months of life was significantly higher in delayed cord clamping group when compared to immediate cord clamping group . Rabe et al also compared these two techniques of delayed cord clamping and umbilical cord milking and concluded milking the cord four times achieved a similar amount of placento-fetal blood transfusion compared with delaying clamping the cord for 30 seconds. [24].But the study was conducted in pre term infants.

Various authors like Cernades etal [25] and Amit Upadhyay [26] reported lower mean haemoglobin levelswith early cord clamping as compared to milking and delayed cord clamping.

Rabe et al.[24] reported a higher hemoglobin levels than reported by Upadhyay et al.[26] ,which was possibly related to the milking technique. Rabe et al. milked, when the cord was still attached to the placenta while Upadhyay et al milked after cutting the cord. So in Rabe et al study the baby got more blood due to subsequent refilling of cord from placenta.

Jaiswal P in 2015, also reported that the mean haemoglobin and hematocrit level during the initial 48 hrs of life in both the groups were comparable.[27] Similar results observed in previous studies .[19][20]. Piyadigama etal also reported there were no significant differences between the UCM and DCC groups with regard to mean neonatal Hb .[28]

Earlier there were concerns that with delayed cord clamping, there can be a delay in carrying out timely resuscitation if needed; it may interfere with attempts to collect cord blood for banking purposes; may increase the potential for excessive placental transfusion leading to neonatal polycythemia, especially in pregnancies with risk factors such as maternal diabetes, severe intrauterine growth restriction, and living in high altitudes. Yet the benefits outweigh these concerns. As we know, sick and preterm infants are likely to benefit most from additional blood volume derived from a delay in cord clamping as per recommendations of European expert consensus.[29]

The American Congress of Obstetricians and Gynecology proposed that the routine practice of umbilical cord clamping should not be altered for the collection of cord blood for banking.[30]. Neonatal polycythemia has not been observed at higher frequencies among infants in the delayed cord clamping group in several systematic reviews, and in large randomized controlled studies.[31][32]. According to Hutchon, a delayed cord clamping (40 seconds has been a standard in their unit) and additional placental transfusion can be immensely beneficial for infant born with a history of fetal distress from umbilical cord compression; this should be deemed as the first step of neonatal resuscitation.[33] .

Large scale multicentric clinical trials are needed to compare milking of umbilical cord with delayed cord clamping. The simple and yet efficient intervention of clamping the cord at 2-3 minutes of life thus can be very useful in low-resource settings specially like ours where more than half of underfive children suffer from anaemia and particularly take diet which is deficient in iron. Delayed umbilical cord clamping (not earlier than 1 min after birth) is recommended by WHO for improved maternal and infant health and nutrition outcomes.[34]. Ideally, it should be implemented as part of an integrated programme for childbirth and postnatal care. The **appropriateness** of delayed umbilical cord clamping must be fully explained to the target population (health workers and women/ families), emphasizing the relevance and the benefits of the intervention.

Strengths of study

1. Most suitable study design that is Randomized Controlled Trial was used to compare the outcome between different intervention arms.
2. Standardized methodology was employed in conducting procedures like delayed umbilical cord clamping and cord milking by expert obstetricians and paediatricians.

Limitations

1. It was an open label trial as blinding was not possible due to nature of interventions.
2. The period of followup of neonate was very short. The results would have been more promising if infants were observed again at the age of 6 and 12 months to see if the initial increase in Hb through these procedures , sustains later in infancy or not. It was difficult to follow them up at 6 months and 12 months of age due to limited resources in terms of manpower, money and time.
3. Measurement of serum ferritin would have been better as it is indicator of infant's body iron stores as compared to Hb and PCV.
4. Circulating blood volume was not measured as it was expensive and time consuming.
5. We could have subjected some neonates to early cord clamping group to see the effects of delayed versus early cord clamping or milking but it has already been established that delayed cord clamping is more beneficial. So it was unethical on our part to randomize some neonates to early cord clamping group.
6. Power of study was less as sample size in group III was comparatively low to detect minor differences in outcome.

CONCLUSION

Umbilical cord milking and delayed cord clamping resulted in comparable levels of haemoglobin and hematocrit(PCV) at72 hours of life implying that similar amount of placental transfusion in both the groups .

TABLE 1 : Comparison of Baseline characteristics of Mothers and neonates in groups

Characteristic	Group I (Milking) Mean±SD	Group II (Delayed Cord Clamping) Mean±SD	Group III (Delayed Cord Clamping plus milking) Mean±SD	One Way ANOVA
Gestational age	38.2 ± 1.01	37.6 ± 0.78	37.7±0.77	F(2,65)=4.71 P<0.05 (S)
Maternal weight	68.9 ± 8.78	75.6 ± 10.84	80.05±16.53	F(2,65)=5.07 P<0.05 (S)
Maternal Hb	11.2 ± 0.63	11.3 ± 1.02	11.6±0.51	F(2,65)=1.45 P=0.74 (NS)
Birth weight of babies	3.1 ± 0.38	3.3 ± 0.36	3.3±0.43	F(2,65)=2.6 P=0.08(NS)

Iron deficiency anaemia assessment, prevention, and control. A guide for programme managers. Geneva: World Health Organization; 2001. (WHO/NHD/01.3; http://www.who.int/nutrition/ publications/en/ida_assessment_prevention_control.pdf, accessed 18 June 2014).

TABLE 2 Comparability of three intervention groups according to various characteristics

Mode of delivery				**Fisher Exact test**
Vaginal	4	1	2	P=0.53(NS)
LSCS	24	23	15	
Sex of baby				P=0.16(NS)
Male	18	11	6	
Females	10	12	11	

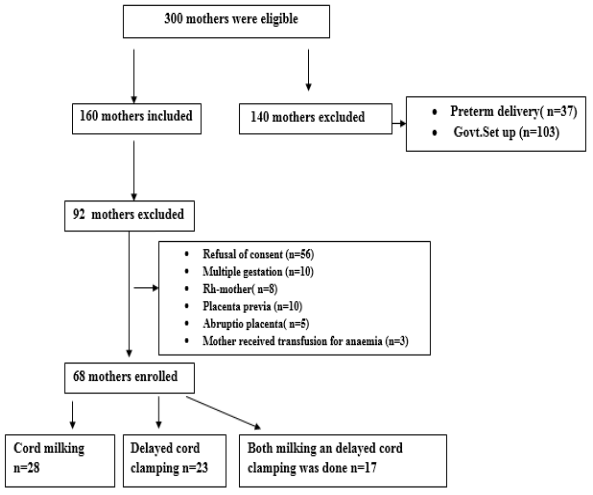
TABLE 3 Intragroup Comparison Of Hb and PCV at birth and after 72 hours

Intervention	**At birth**	**After 72 hours**	**Mean difference**	**t**	**p value**
Group I (Milking only)	**Mean±SD**	**Mean±SD**			
Hb	13.9±1.36	15.8±1.3	1.8	8.8	<0.01
PCV	43.4±5.05	48.9±4.14	5.3	6.61	<0.01
Group II (Delayed Cord Clamping)					
Hb	14.9±1.76	17.7±1.6	2.8	7.4	<0.01
PCV	47.6±5.6	55.4±5.8	7.7	4.6	<0.01
Group III (Delayed Cord Clamping plus milking)					
Hb	15.1±1.93	17.3±1.94	2.3	4.8	<0.01
PCV	47.8±5.39	54±6.17	6.1	4.1	<0.01

TABLE NO.4 Comparison of Hb and PCV among three intervention groups

Outcome assessed	**Group I (Milking only)**	**Group II (Delayed Cord Clamping)**	**Group III (Delayed Cord Clamping plus milking)**	**Statistical Inference One way ANOVA**	**Post hoc intergroup comaparisons (Tukey's test)**
	Mean ± SD	**Mean ± SD**	**Mean ± SD**		
Hb(At birth)	13.9 ± 1.36	14.9±1.76	15.1±1.93	F(2,65) = 3.31	p=0.042(NS)
Hb (After 72 hours)	15.8 ± 1.3	17.7±1.6	17.3±1.94	F(2,65) = 10.68	p<0.001(S)
PCV(At birth)	43.4 ± 5.05	47.6±5.6	47.8±5.39	F(2,65) = 5.52	p<0.001(S)
PCV (After 72 hours)	48.9 ± 4.14	55.4±5.8	54±6.17	F(2,65) = 11.59	p<0.001(S)

Fig 1 Flow of patients



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