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A study to compare umbilical cord milking and delayed cord clamping in term neonates and its effects on hemoglobin and haematocrit levels in a tertiary health care Centre – A randomized controlled trial.

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Abstract

Background: Children with anaemia are more likely to have delayed psychomotor development, impaired performance in tests of language skills, motor skills, and coordination. These impairments may be irreversible, even after repletion of iron stores, thus the importance of approaches (such as umbilical cord milking and delayed cord clamping) that can prevent this condition.

Objective: Comparison of umbilical cord milking (UCM) and delayed cord clamping (DCC) on Haematological parameters at birth and at 72 hours in term neonates.

Methods: This was an Open Label Randomized Controlled Trial conducted at Government medical college Jammu over a period of 6 months. A total of babies born at >37 weeks of gestation were randomized in three groups, group I UCM alone (n= 30), Group II DCC alone (n= 28) and Group III both UCC and DCC (n= 22) using simple randomization technique. In milking group, Umbilical cord was milked 5 times towards the baby. In Delayed Cord Clamping group cord was clamped and cut 2cm distance from the umbilical stump 2 min after birth. In group Ill both were done simul taneously.

Results: All the baseline characteristics were mostly similar and 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 haematocrit (PCV) levels al 72 hours of life of neonates in group in group II (17.5g% and 55.3) and group III (17.2g% and 53.4) were com parable.

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

Keywords: Cord Milking, Cord Clamping, Term Neo nates, Haemoglobin

Introduction

A worldwide public health problem in developing countries is anaemia which is commonly found in young children and pregnant women. Anaemia is defined as haemoglobin concentration 2SD below the mean for established age cut-off values with major consequences for human health, affecting and hindering social and economic development. [1] Children with anaemia are more likely to have delayed psychomotor development, impaired performance in tests of language skills, motor skills, and coordination. 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 that can prevent this condition. [2]

The evidences reveal that long-term ramification in cognitive brain effect comes from anaemia during infancy and young children. It has been found that iron stores at birth are greatly affected by trans-placental transfer of iron and blood from the placenta and cord at the time of delivery. The iron deficiency anaemia during infancy results from the iron stored during the period of delivery. [3-5]

Methods like umbilical cord milking and delayed cord clamping serve to potentially enhance neonatal blood volume and consequently iron stores after birth as well as provide sufficient iron reserves for the first 3 to 6 months of life; thus, preventing iron deficiency anaemia and irreversible neurological dysfunction due to iron deficiency.

Delayed cord clamping defined variably as clamping till cessation of pulsations or up to 60-180 seconds. [6]

Umbilical cord milking, involves milking the entire contents of the umbilical cord towards the baby. Cut umbilical cord milking (umbilical cord detached from placenta) limits the refilling of cord from placenta, so less blood is likely to be transfused when compared to intact umbilical cord milking (pushing the blood toward the infant at least four times before clamping the umbilical cord). [7-11]

The present study aims to establish the Haema to logical parameters in neonates after umbilical cord clamping, delayed cord clamping and combination of both these procedures.

Materials and methods

The present study was an open label randomized controlled trial done at our tertiary health care Centre, Government medical college Jammu. Informed consent was taken from all participating mothers after explaining the purpose of study.

Inclusion criteria

All neonates more than 37 weeks born either by vaginal route or via caesarean section in Government Medical College Jammu whose parents gave consent.

Exclusion criteria

1. Multiple gestation
2. Umbilical Cord anomalies
3. Rh-ve Mother
4. Major congenital malformation
5. Ante-partum Haemorrhage
6. Maternal blood transfusion for anaemia

Outcome

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%, the minimum sample size required in each arm was 20 at 5% level of significance and 80 % power of the test to detect difference of 1.2 gm% keeping dropout rate of 20% in mind we take a sample of size 80. Allocation sequence was concealed in sealed envelopes which were

to be opened by obstetrician just before delivery. There were three intervention arms. In Group I (n=30) only umbilical cord milking was done, Group II (n=28) had delayed umbilical cord clamping and Group III (n=22) had both procedures done i.e., both delayed cord clam ping and milking of umbilical cord.

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 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 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. Haemoglobin and PCV were measured two times one onday1 (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.

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. IBM SPSS version 21 was used for data analysis.

Results

220 mothers were eligible for the study out of which 40 were excluded from our study because of preterm delivery. Out of 180 eligible mothers, 100 mothers were excluded for reasons like not agreed to participate in the study and therefore didn't give consent (60 mothers), multiple gestation (8), Rh negative mothers (8), Placenta previa (12), Abruptio placenta (8) and (4) mothers received transfusion for anaemia.

A total of 80 mothers were finally enrolled in the study. Group I had 30 mothers and received intervention Umbilical Cord milking, Group II had 28 mothers and received Delayed umbilical cord clamping and 22 mothers were enrolled in group III who received both the interventions i.e., Umbilical Cord milking and Delayed umbilical cord clamping as shown in Table 1. Baseline characteristics were compared between all the groups, Gestational age, maternal Hb and birth weight of babies was statistically non-significant (p>0.05). However maternal weight differed among all the groups was statistically significant (p<0.05)

Table 1: comparison of baseline chara cteristics of mothers and neonates in three groups

Characteristic	Group I (milking) (n=30)		Group II (Delayed Cord Clamping) (n=28)		Group I (Both) (n=22)		p-value
	Mean	Sd	Mean	Sd	Mean	Sd	
Gestational age	38.1	1.10	37.5	1.12	37.8	0.98	0.112 (N.S)
Maternal weight	68.6	8.66	72.4	9.54	80.2	12.23	0.001 (S)
Maternal Hb	11.3	0.84	11.2	1.04	11.6	0.76	0.28 (N.S)
Birth weight of babies	3.2	0.43	3.3	0.34	3.2	0.32	0.52 (N.S)

Table 2: comparison of three intervention groups accor ding to various characteristics

Mode of delivery	Group I (Milking)	Group II (Delayed Cord Clam ping)	Group I (Both)	P-value
Vaginal	6	2	3	0.364 (N.S)
LSCS	24	26	19	
Total	30	28	22	80
Sex of baby				
Male	16	15	14	0.714 (N.S)
Female	14	13	8	
Total	30	28	22	80

Table 3: Intergroup and Intragroup comparison of Hb and PCV at birth and after 72 hours

Outcome assessed	Group I (Milking)		Group II (Delayed Cord Clamp in)		Group I (Both)		Significance
	Mean	Sd	Mean	Sd	Mean	Sd	
Hb (at birth)	13.8	1.36	14.6	1.56	15.3	1.83	0.004 (S)
Hb (after 72 hours)	15.6	2.11	17.5	1.65	17.2	1.91	0.001 (S)
Significance	0.0002 (S)		0.001 (S)		0.001 (S)		
PCV (at birth)	42.5	4.66	48.3	5.4	47.3	5.91	0.004 (S)
PCV (after 72 hours)	48.3	5.12	55.3	5.9	53.4	6.22	0.001 (S)
Significance	0.001 (S)		0.001 (S)		0.001 (S)		

We observed 15 (18.75%) mothers who were suffering from anaemia i.e., <11gm%. However out of them 10 (12.5%) were in category of mild anaemia and 5 (6.25 %) were suffering from moderate anaemia (2 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 (45 i.e. 56. 25%) and females babies delivered (35 i.e., 43. 75%) with M:F ratio of 1.28:1. However the results were not statistically significant (p>0.05) as shown in 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 Haemo globin and PCV was seen in group II i.e., delayed cord clamping. The results were statistically significant in all the groups (p <0.05) as shown in 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 statistically significant. Regarding PCV, baseline levels (at birth) of group II and group III were almost similar and correspo ndingly 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 maxi mum increase in Hb and PCV was seen in neonates of group II mothers. The findings were statistically significant. Similarly Mean haemo globin and heama to crit (PCV) levels at 72 hours of neonates in group II (17.5g% and 55.3) and III (17.2g% and 53.4) were comparable as shown in table 3.

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. The lower limit of age group of childhood anaemia is kept at 6 months as up to 6 months infant has sufficient iron stores in the body.

In industrialized countries, Iron deficiency anaemia is prevented by good nutrition and iron supple mentation. 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.

Though Government of India has scaled up various interventions like Iron supple mentation, deworming, manage ment 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. Delay in cord clamping at birth leads to an additional 80-100ml of blood from placenta to the infant's circulation.[12]

Hemo globin 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) haemo globin of neonates at birth was com paratively 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 hemo globin concentration and improved iron status up to six months after birth, thus decreasing 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, haemo globin at 3 months of life was significantly higher in delayed cord clamping group when compared to immediate cord clamping group. Rabe et al also com pared these two techniques of delayed cord clamping and umbilical cord milking and concluded milking the cord four times achieved a similar amount of placen to-fetal blood transfusion compared with delaying clamping the cord for 30 seconds. [23].But the study was conducted in pre term infants.

Various authors like Cernades et al [24] and Amit Upadh yay [25] reported lower mean haemoglobin levels with

early cord clamping as compared to milking and delayed cord clamping.

Rabe et al. [23] reported a higher hemo globin levels than reported by Upadhyay et al.[25] 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 haemo globin and hematocrit level during the initial 48 hrs of life in both the groups were comparable [26]. Similar results observed in previous studies. [19] [20]. Piyadi gama etal also report ed there were no significant differences between the UCM and DCC groups with regard to mean neonatal Hb. [27]

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. [28]

The American Congress of Obstetricians and Gyneco logy proposed that the routine practice of umbilical cord clamping should not be altered for the collection of cord blood for banking. [29] 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. [30][31]

According to Hutch on, 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. [32]

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 under five 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. [33] 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 follow up 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 .

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