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EFFECT OF EARLY AND DELAYED CORD CLAMPING ON HEMOGLOBINAND HEMATOCRIT AMONG FULL TERM NEONATES

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Abstract:

Anemia is common disorder in pediatric population. In developing countries, prevalence of iron deficiency anemia (IDA) is highest among children aged below five years. In Pakistan, overall 62.3% children are anemic out of which 4.1% are severely anemic. IDA is associated with impaired physical growth and cognitive development in children less than five years of age.

Objective: *To compare the mean hemoglobin levels and frequency of polycythemia in full term neonates after early and delayed cord clamping*

Study Design: *Randomized Controlled Trial*

The sample size was calculated by the WHO sample size calculator, with consecutive non probability Sample size = 95 in each group, total sample size = 190, using power of test 80% ,level of significance 5% ,anticipated population proportion 1=5%, Anticipated population proportion 2=16%.

Setting: *The study was conducted in DHQ Hospital, Faisalabad*

Duration Of Study: *Six month from the date of approval of synopsis from board of study (December 2018 to June 2019)*

Methodology: *One hundred and ninety full term neonates were selected after fulfilling inclusion and exclusion criteria. All the participants were divided into two equal groups randomly. One group was subjected to early cord clamping after delivery while other group was subjected to late cord clamping. Two hours after clamping the venous blood samples were taken for the hemoglobin and hematocrit levels. SPSS version 17 for windows was used for statistical analysis. Mean and standard deviation were calculated for gestational age, birth weight, hemoglobin and hematocrit. Frequency and proportions were calculated for gender and polycythemia. Effect modifiers like gestational age, gender and birth weight were controlled by stratification. Independent sample t test and Chi square tests were applied before and after stratification appropriately. A p value of ≤ 0.05 was considered significant.*

Results: *Mean gestational age of the mothers was 39.27 ± 1.50 weeks (mean ±SD). Out of 190 neonates, 91 (47.9%) were males while the 99 (52.1%) were females. The mean birth weight was 3.64 ± 0.72 kg (mean ± SD) while mean Hb and HCT levels were 16.07 ± 2.30 g/dl and 63.26 ± 5.32% respectively.Keeping cut off value of 13.5 g/dl of Hb to label anemia or no, my study showed that 35 (18.4%) neonates were anemic. The polycythemia (HCT >65%) was present in 72 (37.9%) of neonates. There was no difference between groups in terms of gender, anemia, gestational age and birth weight (p values 0.663, 0.852, 0.700 and 0.491 respectively). The distribution of polycythemia was different among groups (p value 0.007). The mean hemoglobin level in group A was 15.52 ± 1.90 g/dl while in group B it was 16.62 ± 2.53 g/dl (p value 0.001). Similarly, the mean hematocrit level was different among groups (62.09 ± 4.75 and 64.43 ± 5.62 for group A and B respectively, p value 0.002). The stratification results showed the results showed that mean Hb levels are statistically not different among some of the groups (gestational age <40 weeks, birth weight <4 kg) while HCT levels are significantly different among male group and category of birth weight >4 kg.Rest of the stratification groups showed significant difference.*

CONCLUSION: *The delayed cord clamping in neonates results in increased mean hemoglobin and hematocrit levels with increased frequency of polycythemia as compared to early cord clamping.*

KEYWORDS: *Infant, Newborn, Hemoglobins, Umbilical Cord, Polycythemia, Prognosis,*

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INTRODUCTION:

Anemia is common disorder in pediatric population. In developing countries, prevalence of iron deficiency anemia (IDA) is highest among children aged below five years. In Pakistan, overall, 62.3% children are anemic out of which 4.1% are severely anemic. IDA is associated with impaired physical growth and cognitive development in children less than five years of age. [1] A study in India showed that delayed cord clamping is safe, simple and low-cost procedure in reducing IDA in infants. Mean hemoglobin measured in early cord clamping group was 17.75 ± 1.56 g/dl while it was 19.97 ± 1.511 g/dl in late cord clamping group. [2]

As compared to early clamping, a delay of one to three min in cord clamping provides an additional blood of 20-35 ml/kg body weight. This additional amount of blood can supply extra iron amounting to 40-50 mg/kg body weight. A new born has 75 mg/kg body weight of iron stores which may reach up to 115-125 mg/kg when this additional volume of blood is added due to late cord clamping. This may help to prevent IDA. Moreover, late cord clamping is associated with increased serum ferritin levels at four months of age. [3] However, a very recent study conducted in India showed that delayed cord clamping has no significant effects on hemoglobin and iron stores in infants. [4]

A recent study conducted in Spain showed that frequency of polycythemia in full term newborns in which cord clamping was delayed is higher. Out of 80 patients exposed to early cord clamping 4 (5%) developed polycythemia whereas out of 131 neonates exposed to delayed cord clamping 21 (16%) developed polycythemia. [5]

The rationale of this study is to compare the effect of early and delayed cord clamping on neonatal hemoglobin and hematocrit with reference to anemia and polycythemia as there is limited research regarding frequency of polycythemia. The results of my study would help to adapt a cord clamping technique that has an advantage of improved hematological profile and decreased risk of complications.

MATERIAL AND METHODS:

This research was conducted in Department of Paediatrics, DHQ hospital Faisalabad, six months after approval from the hospital ethical review committee. Patients of both genders male and female including full term neonates, neonates having APGAR score of 8/10 or above at one minute and mothers with Hb ≥ 10 g/dl at time of delivery were included the study.

Early cord clamping is defined as umbilical cord clamping within 15 seconds after delivery. Delayed cord clamping is defined as umbilical cord clamped at 60-180 seconds after birth or immediately after cessation of cord pulsations. Full term neonate is defined as neonate with gestational age of 37-41 weeks. Anemia is defined as central venous hemoglobin level ≤ 13.5 g/dl measured at two hours of life.

Polycythemia central venous hematocrit of > 65% measured at two hours of life. Patients including neonates born to mothers with pregnancy induced hypertension, gestational diabetes, poly or oligohydramnios, heart disease, anemia or preterm labor, neonates with any congenital or acquired illness were excluded from the study.

190 mothers going to deliver were selected from Obstetrics labor room of DHQ Hospital, Faisalabad after fulfilling the inclusion and exclusion criteria. Mothers were divided into two equal groups by table of random numbers. Hospital registration numbers and informed written consent was taken from all mothers. In group A after delivery the cord clamping was done early while in group B the late cord clamping was done. The researcher was kept blind of the group identity. Hemoglobin and hematocrit were measured at two hours of life in the laboratory that was verified by hematologist. All the data was entered on specially designed proforma.

Data was analyzed using SPSS version 17 for windows. Quantitative data like gestational age, birth weight, hemoglobin, hematocrit, and qualitative data like gender and frequency of polycythemia was analyzed. Mean and standard deviation were calculated for quantitative data. Frequency and percentages were calculated for analysis of qualitative data. Both groups were compared each other in terms of mean hemoglobin levels, hematocrit levels (independent sample t test) and frequency of polycythemia (Chi square test). Effect Modifiers like gestational age, gender and birth weight were controlled by stratification. Post-stratification independent sample t test and Chi square test were applied. A p-value of ≤ 0.05 was considered significant.

RESULTS:

I conducted study on 190 neonates after fulfilling inclusion and exclusion criteria.

Table 1: Gender distribution among groups (n=190)

Parameter		**Group**		Total	P value
		A	B		
Gender	Male	44	47	91	0.663[a]
	Female	51	48	99	
Total		95	95	190	

Table 2: Anemia among groups (n=190)

Parameter		**Group**		Total	P value
		A	B		
Anaemia	Yes	18	17	35	0.852**Error! Bookmark not defined.**
	No	77	78	155	
Total		95	95	190	

Table 3: Polycythemia among groups (n=190)

Parameter		**Group**		Total	P value
		A	B		
Polycythaemia	Yes	27	45	72	0.007**Error! Bookmark not defined.**
	No	68	50	118	
Total		95	95	190	

[a] Chi square test

Both groups, A and B were compared among each other in terms of various quantitative variables. The results have been shown in the following table. The results showed that both the Hb and hematocrit are significantly different among groups.

Table 4: Quantitative variables among groups (n=190)

Parameter	Group		P value
	A	B	
Gestational age (weeks)	39.23 ± 1.49	39.32 ± 1.52	0.700[b]
Birth weight (kg)	3.68 ± 0.74	3.61 ± 0.71	0.491[b]
Hemoglobin (g/dl)	15.52 ± 1.90	16.62 ± 2.53	0.001[b]
Hematocrit (%)	62.09 ± 4.75	64.43 ± 5.62	0.002[b]

[b] Independent sample t test

The data was stratified according to gestational age, neonatal gender and birth weight as shown as below. The following table shows the comparison between groups for mean Hb levels after stratification. The results showed that mean Hb levels are statistically not different among some groups (gestational age <40 weeks, birth weight <4 kg).

Table 5: Hb comparison after stratification

Parameter		Group		P value
		A	B	
Gestational age	<40 weeks	15.58 ± 1.83	16.16 ± 2.46	0.131[c]
	>40 weeks	15.34 ± 2.08	17.57 ± 2.43	<0.0001[c]
Gender	Male	15.85 ± 1.86	16.90 ± 2.53	0.027[c]
	Female	15.23 ± 1.90	16.34 ± 2.52	0.015[c]
Birth weight	< 4 kg	15.84 ± 1.74	16.50 ± 2.48	0.097[c]
	> 4 kg	15.05 ± 2.03	16.841 ± 2.65	0.002**Error! Bookmark not defined.**

[c] Independent sample t test

The following table shows the comparison between groups for mean HC levels after stratification. The difference is not statistically significant among male group and category of birth weight >4 kg.

Table 6: Hematocrit comparison after stratification

Parameter		Group		P value
		A	B	
Gestational age	<40 weeks	61.97 ± 4.96	64.11 ± 5.17	0.017[d]
	>40 weeks	62.41 ± 4.25	65.10 ± 6.48	0.071[d]
Gender	Male	62.95 ± 4.93	62.87 ± 5.59	0.941[d]
	Female	61.35 ± 4.50	65.96 ± 2.26	<0.0001[d]
Birth weight	< 4 kg	61.91 ± 4.68	64.43 ± 5.56	0.009[d]
	>4 kg	62.36 ± 4.90	64.44 ± 5.83	0.107[d]

The following table shows the comparison between groups for polycythemia prevalence after stratification.

Table 7: Polycythemia comparison after stratification

Parameter		Polycythemia	Group		P value
			A	B	
Gestational age	<40 weeks	Yes	20	28	0.087[e]
		No	48	36	
	>40 weeks	Yes	07	17	0.026[e]
		No	20	14	
Gender	Male	Yes	17	18	0.974[e]
		No	27	29	
	Female	Yes	10	27	<0.0001[e]
		No	41	21	
Birth weight	< 4 kg	Yes	15	29	0.037[e]
		No	41	34	
	>4 kg	Yes	12	16	0.143[e]
		No	27	16	

DISCUSSION:

Clamping of the umbilical cord in fundamental step during the third stage of labor. The discussion over the timing of clamping of the cord has been controversial. Initial attempts to quest for this are in the literature since start of the nineteenth century but insufficient results are available. The residual blood in the placenta is the focus in this issue. In 1977 a study showed that Analysis of data from this study combined with data from a previous study shows that after 40 seconds the net flow between placenta and infant reverses and that cord clamping delayed beyond this point is accompanied by a rise in RPBV (residual placental blood volume) back to the level found when the cord was clamped before 20 seconds.[6] Later on when the timing of cold clamping was studied on larger scale with more variables in focus then it came to recognition that cord clamping timing in normal deliveries may have no significant effect but late clamping in premature neonates is beneficial because it reduces the incidence of respiratory distress syndrome.[7] In 2005 a literature review showed almost similar observations i.e. late cord clamping for full term neonates has no extra advantage.[8] The late cord clamping increases the blood viscosity by 40% initially which may revert to near normal after 24 hours.[9]Van Rheenen, P. and B. J. Brabin (2004) concluded that delayed cordclamping in term infants, especially those with anemic mothers, increases hemoglobin concentration in infants at 2-3 months of age and reduces the risk of anemia, without an associated increased risk of perinatal complications. In developing countries where fetal anemia is common, the advantages of delayed cord-clamping might be especially beneficial.[10] In 2008, Jahazi, A., et al.[11] showed that there is no difference between the early and late clamping groups in terms of HCT levels (61 ± 4.9 versus 61.6 ± 4.5% for early and later groups respectively, p value >0.05). This is contrary to my results as my study showed that HCT in early and late clamping group is 62.09 ± 4.75 and 64.43 ± 5.62% respectively with p value of 0.002. These conflicting results may have arisen due to two major differences. First the sample size of my study was 190 in total while above mentioned study had sample size of 64 only. Second difference was the timing of clamping. For my study, the early clamping was done at 15 seconds while in this study the early clamping was done at 30 seconds. In the same year another study had similar results as compared to my study. This study showed that late cord clamping coincides with an increased placental transfusion, expressed by higher hematocrit and emoglobin values, and larger left ventricle diameter at the end of the diastole, with no changes in peripheral perfusion or oxygen metabolism.[12] Role of late cord clamping is more elaborated in many recent studies which showed that the late cord clamping is associated with an increase in hematocrit, hemoglobin and ferritin at 48 hours of life, as well as an increased risk of polycythemia present with symptoms. There is no effect of late cord clamping on the APGAR score and duration of third stage of labor.[5, 13] A study by Chien, P. C., et al. (2015) supported that late umbilical cord clamping does not increase the risk of maternal postpartum hemorrhaging or neonate jaundice.[14] The results were validated by a recent study in 2017 which concluded that There were no significant differences in the risk of postoperative hemorrhage, manual removal of placenta, or maternal or neonatal morbidity between early cord clamping. In my study, I was limited to only single time hematological measurements in the immediate postnatal time, but the late cord clamping may have the beneficial effects later also. One study by Andersson, O., et al. (2011) showed the delayed cord clamping, compared with early lamping,resulted in improved iron status and reduced prevalence of iron deficiency at 4 months of age, and reduced prevalence of neonatal anemia, without demonstrable adverse effects.[3] Another recent study showed that serum ferritin levels are raised in late cord clamping group even at the end of six months of life.[15] Somewhat conflicting results were shown by Agarwal, S., et al. (2016).[4] It showed that at the end of one year there was no difference between groups in terms of iron stores, hemoglobin levels or growth parameters. These conflicting results may be due to the selection of participants as in 2017, Kc, A., et al. showed that delayed cord clamping reduces anemia at 8 and 12 months of age in a high-risk population, which may have major positive effects on infants' health and development. [16] So for low risk infants the early or late clamping might have no impact. The oxidant capacity is greater with early cord clamping than with delayed clamping or cord milking. Delayed cord clamping or milking are beneficial in neonatal care, and we suggest that they be performed routinely in all deliveries.[17] In my study, I stratified the data to counteract the effect of confounders. The stratification results showed the results showed that mean Hb levels are statistically not different among some of the groups (gestational age <40 weeks, birth weight <4 kg) while HCT levels are significantly different among male group and category of birth weight >4 kg.

CONCLUSION:

The delayed cord clamping in neonates results in increased mean hemoglobin and hematocrit levels

with increased frequency of polycythemia as compared to early cord clamping. The results should be ascertained on large scale to establish as protocol for late clamping of cord.

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