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RESEARCH ARTICLE

Study of delayed cord clamping (DCC) versus physiological cord clamping (PCC) in management of child birth

Shrinivas N Gadappa, Sonali S Deshpande, Dhanashree R Lahane

Corresponding author: Dr. Dhanashree R Lahane, Assistant Professor, Department Of OBGY, GMCH, Aurangabad, India; Email: Dhanashrelahane7@gmail.com

ABSTRACT

Objectives: To compare the effect of delayed cord clamping (DCC) versus physiological cord clamping (PCC) on third stage of labour and fetal outcome. **Methodology:** This is arandomized controlled trial. Participants were randomly assigned to control group (DCC) receiving cord clamping after 1 minute of delivery of baby and the study group (PCC) receiving cord clamping after delivery of placenta. Maternal and early neonatal outcome was analyzed and compared between the two groups by appropriate statistical test. **Result:** Baseline maternal characteristics were comparable in both groups. The duration of third stage of labour was higher in PCC, but no significant increase in incidence of PPH, no need of additional uterotonic and no need for blood transfusion was observed. Average FHR was normal in both the groups with FHR at 1 minute higher in PCC group and FHR at 5 minutes higher in DCC group. The fetal temperature was comparable in both groups. The mean Apgar score was higher in PCC group than DCC. Fetal haemoglobin and hematocrit values were also higher in PCC group. **Conclusion:** PCC is safe, effective and cost-free intervention for neonatal health benefits and should be implemented in the term and pre term infants, even in resource poor settings, where it might offer a sustainable strategy to prevent transient tachypnia of new born (TTA), hypothermia and may prevent long term anemia in new born without increasing the maternal risk of third stage complication.

Keywords: Anaemia, delayed cord clamping, neonatal hypothermia, neonatal jaundice, physiological cord clamping, post partum haemorrhage.

There has been debate for centuries regarding, when to clamp and cut the umbilical cord of the newly born infant, practices have ranged from one extreme to the other. From the time of the ancient Greeks, midwives have described the value of waiting to clamp the cord until pulsations stop or until the placenta is delivered [1]. Committee on neonatal resuscitation recommended delayed cord clamping for infants who do not require immediate resuscitation [2], and the World Health Organization (WHO) has also reiterated their recommendation to delay cord clamping (DCC) for 1-3 minutes while initiating simultaneous essential newborn care [3]. Yet, all the current practice guidelines vary in their emphasis and details; but it should also be noted that all of them do suggest that delayed cord clamping may not be feasible or desirable in every situation, especially when immediate resuscitation is required. The Ministry of Health and Family Welfare, Government of India issued an advisory (dated November 6, 2019) on deferring cord clamping until delivery of placenta (known as physiological cord clamping) as a part of an initiative to promote physiological childbirth in healthy pregnant women, who have no identified risk factors for themselves or their babies [4].

Active management of labour involves prophylactic oxytocin administration (either IV or IM) followed by clamping the cord 1-3 minutes after birth and controlled cord traction [5]. The physiological care includes facilitating a comfortable, warm environment; encouraging an upright position to facilitate birth of placenta; refraining from fundal

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massage; paying close attention to signs of excessive blood loss; being mindful for direct and indirect signs of placental separation, facilitating immediate skin-to-skin contact with newborn and early breastfeeding [6]. Government Medical College and Hospital, Aurangabad has pioneered implementation of respectful maternity care services to all pregnant women. As a part of this initiative, one of the key interventions is to provide quality care with dignity and equity to every pregnant woman visiting the hospital. We started implementing physiological care to give mothers the joy of giving birth in a natural way, in a desirable position and in the presence of a birth companion of their choice, aiding early initiation of breast feeding with better fetal outcome physiologically with minimum medical intervention. The added benefits for the baby include increase in iron stores, more stem cells (resulting in stronger immune system), improved development and cognitive performance of the child along with better cardio-respiratory stability and a smoother transition to extra uterine life [4].

Our institution is a tertiary care center catering high as well as low risk pregnant women from nearby area. The available data from many studies compared beneficial effects of physiological cord clamping for new born health but concern remains regarding potential maternal complications (PPH, retained placenta) and excess placental transfusion. Furthermore, the physiological cord clamping advisory was for only for uncomplicated pregnancies. Hence, the present study was undertaken to compare the maternal and early neonatal outcome in early cord clamping versus physiological cord clamping in low risk as well as hemodynamically stable high-risk pregnancies.

Materials and methods

Study place: Department of obstetrics and gynaecology GMCH, Aurangabad.

Duration of study: 6 months (November 2019- May 2020).

Sample size: Sample size was calculated by using Open Epi software - PCC group (A) :1000; DCC group (B) : 1000.

Study design: Randomized controlled trial, participants were randomly assigned to one of two parallel groups with a 1:1 ratio, with DCC group receiving cord clamping after 1 minutes of delivery of baby and the PCC group receiving cord clamping after delivery of placenta.

Inclusion criteria: All pregnant women coming to labour room with:

1. Gestational age >34 weeks.
2. Single live fetus.
3. Fetal heart rate between 120-160 beats/minute for normal delivery.
4. Willing to participate in the study.

Exclusion criteria: Maternal risk factors like:

1. Maternal haemodynamic instability,
2. Abnormal placentation (abruption / placenta previa/adherent placenta),
3. Rh negative blood group,
4. Mothers requiring blood transfusion during labour before delivery,
5. Sero - positive status of mothers,
6. Mothers undergoing caesarean section,
7. Gestational age < 34 weeks ,
8. Multiple gestation,
9. Need for immediate neonatal resuscitation,
10. Cord avulsion,
11. Congenital anomalies,
12. Still born babies,
13. Mother not willing to participate in study.

After approval from institution ethics committee and after applying inclusion and exclusion criteria, women were enrolled in the study. A written informed consent was obtained after explaining the purpose of the study. She was provided the desired quality care even though she denied participation in the study. All staff in the delivery unit where trained in the study procedures before the trial started. Baseline demographic parameters along with history, examination and laboratory parameters were noted. The course of labour was monitored by using partograph. Induced or spontaneous labor, duration of first stage, second stage of labour was noted. The method and labour monitoring was similar for all patients till the delivery of the baby. The principal investigator prepared a random list using random digit generator for randomization of pregnant women in two groups and upon delivery of the baby. The patient where divided in either of the group by randomization.

PCC group: Upon delivery, new-born was received by nurse/doctor with a warm towel and was transferred to the mother's abdomen immediately and established skin to skin contact while umbilical cord was still intact. The time of baby's delivery was noted. After immediate care and assessment, if the newborn was vigorously active and carrying, the baby was kept over mother's chest for skin to skin contact and put to nipple. Rapid evaluation of the newborn was done. The routine newborn care and resuscitation steps were followed as per the current NRP

guidelines. The placenta was allowed to deliver physiologically. The umbilical cord was clamped and cut only after delivery of placenta. Prophylactic injection oxytocin was given 10 units intramuscular to the mother only after placental delivery. Mother was looked for any sign of excess bleeding before or after delivery of placenta to note postpartum hemorrhage.

DCC group**:** Upon delivery, the newborn was placed on mother's abdomen, and immediate essential newborn care was initiated (thoroughly drying the baby and assessing breathing). Within1 minute of delivery, intramuscular oxytocin (10U) was given to mother. Umbilical cord was clamped after 1 minutes and cord was cut. Delivery of placenta was done with controlled cord traction and time was noted.

In both the group a stop watch was used to measure the time from delivery of the baby until the delivery of placenta. Uterine tone was assessed for early identification of uterine atony, and uterine massage was performed if atony was present. All other aspects of obstetric care were managed according to standard operative procedures at our institute. In any of the group, if the placenta was not delivered within 15 minutes of the newborn delivery or any signs of increased bleeding were noted, decision for manual separation of placenta was taken by doctor on duty.

Maternal outcome was noted in the form of duration of third stage of labour, complications of third stage like atonic PPH, retained placenta, uterine inversion, need for additional uterotonics to control atonic PPH and need of blood transfusion and compared in both groups.

Early neonatal outcome as birth weight, time required initiating breast feeding, oxygen saturation at 1,5,10 minutes, heart rate at 1, 5 minutes, temperature at 5 minutes, Apgar score at 5 minutes and neonatal complications like jaundice, need phototherapy, hypothermia, admission to NICU were recorded and compared in both groups.

Statistics: It is a randomized controlled trial to avoid selection bias. The sample size calculated by open Epi software was total of 2000. 1000 patients were randomly allotted in PCC group as cases and same number of patients were included in DCC group as control. Parameters to be studied were decided. The staff and doctors monitoring the labour were taught the method of recording the parameters and warning sign. The data was collected and all data will be entered in excel and analyzed by using SPSS software version 15. Chi square test and independent t test will be applied according to the type of parameter compared. The P value < 0.05 was considered significant.

Results

This randomized controlled study was conducted on 2000 expectant mothers. The baseline characteristics of both groups are expressed in table 1.

Table 1: Baseline characteristics (N=2000)

Characteristics		PCC (N=1000) Case		DCC (N=1000) Control		Statistical test
		No	%	No	%	
Gravida	Primigravida	449	44.9	406	40.6	X^2=3.77;
	Multigravida	551	55.1	594	59.4	df=1;P=0.06
Gestational weeks	≥34 -37	79	7.9	84	8.4	X^2=0.203;
	>37-40	876	87.6	873	87.3	df=1;P=0.90
	>40	45	4.5	43	4.3	
Type of delivery	Spontaneous	838	83.8	834	83.4	X^2=0.058;
	Induced	162	16.2	166	1.66	df=1;P=0.81
Associated high risk factors	HDP	53	5.3	56	5.6	X^2=0.95
	Anaemia	89	8.9	92	9.2	df=6
	Hypothyroidism	17	1.7	20	2.0	P=0.98
	GDM	12	1.2	14	1.4	
	Preterm	79	7.9	84	8.4	
	Breech	05	0.5	08	0.8	
	Previous CS	12	1.3	11	1.1	

There was no statistically significant difference observed in duration of first and second stage of labour. The mean duration required for expulsion of placenta in PCC group was 8.02 ±1.85 minutes as compared to 6.48 ± 1.35 minutes in DCC group and was found to be statistically significant (p<0.001). The mean drop in haemoglobin level after delivery was not found to be statistically significant (table 2).

Table 2: Duration of labor and placental delivery

Labor characteristics		PCC (N=1000) Mean	PCC (N=1000) Std. Deviation	DCC (N=1000) Mean	DCC (N=1000) Std. Deviation	Test statistics*
Duration of labor	Stage 1 in minutes	656.4	175.2	652	173.4	t=0.58; p=0.59
	Stage 2 in minutes	49.32	29.18	50.12	29.60	t=-0.61; p=0.54
Time required for expulsion of placenta (third stage of labour)		8.02	1.85	6.48	1.35	t=21.26; p<0.001
Drop in haemoglobin level (pre delivery & Post delivery)		0.62	0.44	0.65	0.52	t= 1.39 ; p = 0.16

*Test applied: Independent sample t-test

The placenta was delivered in DCC group by controlled cord traction (100%) and in PCC group was delivered spontaneously in 81.2%, with assistance in 6.8% and with the help of gravity in 12% cases. In PCC group, PPH was seen in 48 (4.8 %) women and in DCC group it was seen in 50 (5%) women. All the women with PPH were given additional uterotonics. The association between occurrence of PPH and method of cord clamping (PCC and DCC) was not found to be significant. No case of inversion of uterus or

manual removal of placenta was noted in both the groups (table 3).

Table 3: Maternal outcome in cases and control group (N=2000)

Maternal outcome		PCC(N=1000)		DCC (N=1000)		Test statistics†
		No	%	No	%	
Mode of delivery of placenta	CCT	00	00	1000	100	
	Self	812	81.2	00	81.2	
	Gravity	120	12.0	00	12.00	
	With assistance	68	6.8	00	6.8	
Complication during stage 3 of labor (PPH)		48	4.8	50	5	X^2= 1.71; df = 1; p = 0.19
Need for additional uterotonics		48	4.8	50	5	X^2= 1.71; df = 1; p = 0.19
Need for Blood transfusion		7	0.7	16	1.6	X^2= 1.71; df= 1; p = 0.19

† Test applied: Chi-square test

Table 4: Neonatal outcome in cases and control group

Neonatal outcome		PCC (N=1000)		DCC (N=1000)		Test statistics*
		Mean	Std. Deviation	Mean	Std. Deviation	
Time required to initiate breast feeding (min)		13.00	3.50	15.84	2.76	t= -20.079; p<0.001
SPO_2	1min	92.65	2.44	91.38	1.48	P > 0.001
	5 min	94.04	2.17	92.01	2.03	p>0.001
	10 min	95.51	2.39	93.56	2.79	p>0.001
Neonatal heart rate	1min	114.63	7.26	111.76	5.62	t= 9.88; p<0.001
	5 min	121.02	9.54	129	4.82	t= 7.18; p<0.001
Fetal temp (at 5 mins)		98.84	27.84	98.85	27.84	t= -0.009; p=0.99
APGAR score (at 5 minutes)		8.97	0.42	8.85	0.67	t= 4.8; p<0.001
Neonatal hemoglobin (day 3)		18.85	0.81	18.06	0.90	t= 20.66; p<0.001
Neonatal haematocrit (day 3)		56.58	2.42	54.20	2.73	t= 20.66; p<0.001
		PCC (N=1000)	%	ECC (N=1000)	%	Test statistics†
Neonatal jaundice		12	1.2%	15	1.5%	p> 0.001
Need of phototheray		4	33.3%	7	40%	P >0.001
NICU admission		18	1.8%	18	1.8%	X^2= 0.02; p=0.86

*Test applied: Independent sample t-test; † Test applied: Chi-square test

The mean time required to initiate breast feeding in PCC group was 13 ± 3.50 minutes and DCC group was 15.84 ± 2.76 minutes. The difference was found to be significant (p<0.001). The mean SPO_2 levels were higher in PCC group at 1, 5, 10, compared to DCC group (all p>0.001). Average neonatal heart rate was normal in both the groups, at 1 minute higher in PCC group and at 5 minutes higher in DCC group. The fetal temperature was comparable in both groups with an average of 98.84 ° F. The mean Apgar score was higher in PCC group than DCC (p<0.001). Fetal haemoglobin and hematocrit values were also higher in PCC group (p<0.001). The presence of neonatal jaundice and NICU admission were not influenced with method of cord clamping (p=0.69 and 0.86 respectively).

Discussion

In the era of modern obstetric, positive pregnancy experience is our motto. Interventions can be lifesaving when properly implemented but can sometime have adverse effect [7]. By this study we aim to study physiological approach of delivery for its fetal benefits and possible effect on labour.

In present study, the baseline characters of pregnant women coming to labour room were comparable. In third stage of labour, time required for expulsion of placenta in PCC (8.02±1.85 minutes) was significantly higher as compare to DCC as in PCC placenta was allowed to deliver physiologically without any cord traction or cord pull empowering mother to control her delivery. Though duration of 3rd stage of labour is increased but it is important as mother is closely observed for that duration by the medical staff, breastfeeding gets initiated earlier and newborn is also under observation without any adverse risk to the mother.

There were cases of PPH noted in PCC, but no case of massive PPH, but it was in comparison with that of in control group and no significant difference in incidence of PPH was noted. Need for additional uterotonics and need for blood transfusion in both groups was also comparable. The safety of deferring oxytocin was also documented by various studies. Similar study conducted suggested that prophylactic administration of oxytocin after delivery of shoulder or baby prior to placental delivery can cross placenta and exposes the newborn to oxytocin inadvertently also effect and safety aspects of synthetic oxytocin on the newborn with exposure around birth is not yet documented [8]. Multiple studies comparing prophylactic administration of uterotonic before

and after placental delivery didn't find significant difference in the risk of PPH and need for blood transfusion.

The mean drop in haemoglobin level after delivery was comparable in both groups. This also assured that there was no increase in the blood loss during third stage of labour in PCC due to increase time required to spontaneously deliver placenta and administration of oxytocin after delivery of placenta. Similar result was observed in a study from Turkey documented no statistically significant differences in severe haemorrhage among low-risk pregnant women when oxytocin within first minute of delivery was compared with after placental expulsion [9]. Indian study also reported no increase in incidence of PPH [10].

In present study, mean time required for initiation of breast feeding in PCC was 13±3.5 mins, which was significantly lower as compared to DCC group was (15.84 ± 2.76 minutes) as baby was kept on mother`s chest immediately after birth umbilical cord was still intact in PCC group. But though value is significant, but it does not impact initiation and continuation of breast feeding in long term.

The studies from India [10], Netherlands [11] and Nepal [12] practicing cord clamping after placental delivery documented higher oxygen saturation and smooth cardiopulmonary transition in neonates during initial 5-10 minutes after birth. Similar result was observed in present study.

In present study, PCC resulted in significant health benefits to infants delivered after 34 weeks of gestation. The SPO_2 level were observed higher, smooth transition to extra-uterine life, better Apgar score, fetal haemoglobin and hematocrit and was not associated with any clinically significant in incidence of neonatal jaundice requiring phototherapy or NICU admission. This was comparable with study where DCC was compare with PCC [13].

In present study, new born temperature at end of 5 min was comparable in both the groups with not a single case of hypothermia as skin to skin contact was practised as per departmental standard operative procedures.

Limitation of study: In study immediate benefits of PCC were assessed. Anemia in infants required follow up of 1 year.

Conclusion

The government advisory proved PCC safe and of fetal benefit in low risk uncomplicated pregnancy but the present study compared the maternal and early neonatal outcome in physiological cord clamping in low risk as well as hemodynamically stable high-risk pregnancies with increasing the maternal risk.

Cardio-respiratory stabilization of new-born was more effective with physiological cord clamping than delayed cord clamping without increasing the maternal risk of third stage complication. We recommend, PCC as a safe, effective and cost-free intervention for smooth transition of circulation and should be implemented in the term and pre term infants, even in resource poor settings, which might offer a sustainable strategy to prevent TTN, hypothermia and can be practiced for prevention of anaemia up to 1 year in newborn.

Conflict of interest: None. **Disclaimer:** Nil.

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Shrinivas N Gadappa [1], Sonali S Deshpande [2], Dhanashree R Lahane [3]

[1] Professor and Head, Department Of OBGY, GMCH, Aurangabad, India; [2] Academic Professor, Department Of OBGY, GMCH, Aurangabad, India; [3] Assistant Professor, Department Of OBGY, GMCH, Aurangabad, India.