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Early vs. Delayed Cord Clamping at Full-Term Planned Cesarean Section: A Randomized Study

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Abstract

Objective: In cesarean section (CS), which, early vs. delayed cord clamping is better for neonatal and maternal hematocrit/hemoglobin level is not yet completely determined. This randomized controlled study attempted to determine this issue. **Methods:** Study population consisted of 64 full-term pregnant women/neonates undergoing planned CS: 32 received early cord clamping (ECC: 15 seconds after birth) and 32 delayed cord clamping (DCC: 90 seconds). We measured and analyzed 1) neonatal hematocrit at the first 24 - 48 hours, and 2) maternal-hemoglobin-change before and after CS. **Results:** Infants with ECC and DCC showed hematocrit (24 - 48 hours) of 57.47 ± 8.65 vs. 59.54 ± 7.67, showing no significant difference. Also, no significant differences were observed in the change in maternal hemoglobin in two groups. **Conclusions:** Cord clamping at 15 vs. 90 seconds did not yield neonatal hematocrit change or maternal hemoglobin change. As far as the present data (neonatal and maternal anemia) was concerned, cord may be clamped at 15 seconds in planned term CS.

Keywords

Umbilical Cord Clamping, Elective Cesarean Section, Neonatal Hematocrit, Neonatal Jaundice, Obstetric Hemorrhage

1. Introduction

It's known that adequate placental transfusion reduces the risk of iron deficiency in the neonate and could increase iron storage in late childhood [1]-[6].

Previous publications state that cesarean section is associated with reduced

placental transfusion and decreased iron storage in the newborn [7] [8], which can be attributed to early cord clamping, usually associated with fear of maternal complications during the surgical procedure. Thus, delayed clamping is sometimes recommended. However, which, early vs. late cord clamping, is better for neonatal hematocrit level, is not yet completely determined. We believe that institute-specific data for this issue may be of use. In consequence, we here attempted to determine the neonate hematocrit value between the first 24 - 48 hours of life of the newborn and change in maternal hemoglobin, comparing ECC (15 s) versus DCC (90 s), during elective cesarean sections performed at the Obstetrics Department of the Complejo Hospitalario CSS, in Panama City, Panama.

2. Methodology

2.1. Trial Design

This study was single-center, randomized clinical trial conducted to compare DCC versus ECC in neonates born through elective cesarean section. This study was approved by our Institutional Review Board (IRB-CHDrAAM-CSS). Written informed consent of study participants was obtained preoperatively followed by immediate randomization. There were no interventions by the investigators in the cesarean surgical approach.

2.2. Participants

All patients with full term pregnancies who would be taken to elective cesarean section in Complejo Hospitalario Dr. Arnulfo Arias Madrid were eligible to participate. Eligibility criteria included women ≥ 18 years of age, with a singleton pregnancy scheduled for cesarean section at ≥37 weeks gestation by LMP, proven by early USG, and who are not in labor. Indications for the cesarean section were: previous cesarean section, product in pelvic presentation, previous myomectomy or fetal macrosomia. Pregnant patients with structural fetal alterations and chromosomal abnormalities; with premature rupture of membranes or clinical data of maternal or neonatal infection, were excluded.

2.3. Procedure

Umbilical cord management was randomized before birth, at maternal admission in the hospital, between the ECC and DCC arm. In the operating room, immediately after birth, the timer was turned on, and the umbilical cord was clamped according to the randomization arm (within 15 s in the ECC and after 90 s in the DCC arm). We chose arbitrarily 15 seconds for ECC and 90 seconds for LCC, following the recommendation of the World Health Organization, where a cut-off point of 60 seconds for early clamping is established, after which it's understood by late clamping. We consider it prudent to exceed the time up to 90 seconds, allowing to guarantee that the cut-off point is exceeded. We consider 15 seconds a feasible cord clamping time in our institution, which doesn't interfere with the fluidity of the surgical technique.

The baby was positioned on the maternal abdomen (at the level of the placenta) and covered with sterile towels, dried and stimulated during the procedure. After cord management, the baby was given to the Neonatologist to be cared for according to the resuscitation guidelines.

2.4. Outcome Measures

The primary outcomes were the neonatal hematocrit between the first 24 - 48 hours of life, obtained from a capillary blood sample and the change in maternal hemoglobin. Change in maternal hemoglobin was calculated using the difference between maternal hemoglobin on admission and 12 hours after surgery. Secondary outcomes included: obstetric hemorrhage and neonatal jaundice. Obstetric hemorrhage was defined as the presence of hemodynamic changes associated to bleeding during the cesarean section and immediate post-partum period, and neonatal jaundice as the amount of neonatal bilirubin necessary to receive phototherapy, according neonatology guidelines.

2.5. Sample Size

The sample size calculation was based on the primary outcome (neonatal hematocrit between the first 24 - 48 hours of life), and the effect size was chosen accordingly to a previous publication [9].

A sample size of 54 participants (27 per arm) was required to have a 0.80 chance of detecting – significant at the 0.05 level – a mean difference of 6% (with a standard deviation [SD] of 6%) in the primary outcome measure between the two arms. The sample size was increased to 64 subjects to take into account a possible dropout of 20%.

2.6. Randomization

Once the eligible patient signed the informed consent, they were assigned into two groups. Participants randomly chose a properly sealed and opaque envelope, inside which were the numbers 15 (for ECC) or 90 (for DCC). These envelopes were in a box, in the custody of the main investigator. The surgeons were informed by the investigator in which group the patient was found. Neither the researchers nor the patients were blind. The health caregivers who measured the neonatal hematocrit and maternal hemoglobin were unaware of the group to which the patient was assigned.

2.7. Data Collection

Information on maternal (age, weight, height, parity, hemoglobin at admission) and neonatal characteristics (sex, weight, height, head and chest circumference, Apgar score at 1 and 5 minutes) were obtained by the investigators from the clinical record. Likewise, the laboratory parameters after surgery such as neonatal hematocrit and maternal hemoglobin and complications such as obstetric hemorrhage and neonatal jaundice were extracted from the clinical record.

2.8. Statistical Analysis

A database will be made by using the Epi-Info program, in which the results of the different variables to be analyzed will be tabulated. Statistical analysis was conducted as an intention-to-treat analysis. The results obtained in this study will be presented through figures and tables, using statistical measures such as average, median, mean and percentages.

The first analysis to be carried out in the study is to compare the treatment groups (their demographic characteristics, anthropometric measures and conditions inherent to their clinical status), presenting summary measures (means, medians) in continuous variables and percentages and numbers for categorical variables. Epi-Info statistical software will be used to measure the differences between the two groups.

To evaluate the maternal impact of the waiting process to clamp the umbilical cord, the difference (delta Δ) between the maternal hemoglobin value at admission and the post-cesarean maternal hemoglobin value was used (maternal hemoglobin on admission—post caesarean maternal hemoglobin = Δ maternal hemoglobin).

Neonatal hematocrit between 24 and 48 hours of live and the change of maternal hemoglobin will be expressed as mean and SD and was compared between the two arms using the Student *t* test. The results from the regression models are reported as regression coefficient (β) with 95% confidence interval (CI). All tests were two-sided, and a p value < 0.05 was considered statistically significant. Secondary variables and additional results will also be expressed as means and standard deviations and will be compared between the two groups in a Student t test.

3. Results

A total of 64 patients were included in the study, randomly admitted, who met the inclusion criteria, who were also interested in participating in the study and signed the informed consent. Of these patients, 32 underwent DCC (90 s) and the other 32 ECC (15 s).

Both arms had similar maternal and neonatal characteristics such as: maternal age, gestational age, number of previous pregnancies, maternal pathologies, maternal BMI, neonatal APGAR at one minute and at 5 minutes, sex, weight, head circumference, thoracic circumference and neonatal height. (Table 1)

The mean neonatal hematocrit between 24 - 48 h after birth was 57.47 ± 8.65 in the ECC arm and 59.54 ± 7.67 in DCC arm, this difference wasn't statistically significant (p 0.34).

The Δ maternal hemoglobin in the ECC arm resulted in 1.17 ± 0.76, and in the DCC arm resulted in 1.0 ± 0.75, without achieving statistical significance (p = 0.38). (Table 2)

There were no cases of obstetric hemorrhage in either of the two arms. Similarly, neonatal jaundice didn't develop in newborns that underwent ECC, neither in newborns that underwent DCC. (Table 2)

Table 1. Baseline participant characteristics.

	ECC (15 s)	DCC (90 s)	*P* value
Maternal age (years)	29.21 ± 5.88	29.25 ± 5.78	0.983
Gestacional age (weeks)	38.87 ± 0.67	39.08 ± 0.77	0.25
Number of pregnancies	2.84 ± 1.05	2.71 ± 1.11	0.64
Severe preeclampsia	0.0 (0)	2.0 (6.25)	0.47
Gestacional Diabetes	1.0 (3.13)	1.0 (3.13)	1.00
Maternal BMI	34.98 ± 9.32	31.79 ± 5.13	0.09
APGAR (1 min)	8.96 ± 0.17	9.00 ± 0.00	0.32
APGAR (5 min)	9.00 ± 0.00	9.00 ± 0.00	1.00
Male Gender	16 (50)	19 (59.38)	0.61
Newborn weight (g)	3335.93 ± 388.26	3354.28 ± 462.88	0.86
Newborn Head Circunference (cm)	35.46 ± 1.05	35.21 ± 1.18	0.37
Newborn Thoracic Circunference (cm)	33.53 ± 5.59	34.53 ± 1.999	0.34
Newborn Height (cm)	64.87 ± 2.60	78.36 ± 3.55	0.59

Data are expressed as number (%) or mean (SD). DCC, delay cord clamping; ECC, early cord clamping.

Table 2. Study outcomes.

Outcomes	ECC (15 s)	LCC (90 s)	*P* Value
Primary outcomes	*mean* (*SD*)	*mean* (*SD*)	
Neonatal hematocrit	57.47 (±8.65)	59.54 (±7.67)	0.34
Δ maternal hemoglobin	1.17 (±0.76)	0.99 (±0.75)	0.38
Secondary outcomes			
Obstetric hemorrhage	0.0 (0)	0.0 (0)	
Neonatal jaundice	0.0 (0)	0.0 (0)	

4. Discussion

Currently three studies have been published regarding the effect of the timing of umbilical cord clamping in elective cesarean sections. The first of these was published in 1975, there were no statistically significant differences between early and late cord clamping comparing the residual placental blood volume when performing a cesarean section. Our results correlate with this investigation, showing that the delay in cord clamping makes no differences in the supply of blood components to the neonate. However, our study didn't measure the placental residual blood volume value.

A recent publication with casuistry of 80 patients, affirms the benefit in terms of neonatal hematocrit level, of clamping up to 60 seconds [9]. This study compared 10 vs 60 seconds and they concluded that delaying cord clamping beyond 60 s increases the hematocrit at day 2 in neonates born through elective cesarean section. Previous studies on vaginal deliveries have reached the same conclusion

[10]. Our results don't correlate with these publications.

Other results observed in our research are that there's no impact on change in maternal hemoglobin and the presence of complications like obstetric hemorrhage, according to the delay of cord clamping. In 2013, McDonald *et al.* demonstrated that there is no statistically significant difference between early vs late cord clamping in terms of severe postpartum vaginal bleeding [11] More recent publications performed in elective cesarean sections, show that delaying cord clamping beyond 60 s has no effect over maternal blood losses [9].

Delayed cord clamping was associated with an increase in the need for phototherapy in a study published in 2013, which compared the time of cord clamping in vaginal delivery [11]. However, in our study no neonate reported jaundice. These results correlate with more recent studies carried out in cesarean sections in which increasing cord clamping time has no effect over neonatal bilirrubin [9] [12] [13] [14].

As a limitation of our research, we can mention that the primary objectives are short-term results (neonatal hematocrit and change in maternal hemoglobin). Studies are needed where long-term neonatal results are evaluated.

Among the strengths of our study we can mention its design (randomized clinical study), as well as that it is easily reproducible in other institutions and countries. The population to which the study is oriented; patients undergoing elective caesarean section, the number of which has been in considerable increase in recent years worldwide and represents a population that has not been the subject of numerous investigations.

5. Conclusion

Cord clamping at 15 vs. 90 seconds in elective cesarean sections is the same, when comparing the neonatal hematocrit value. A prolonged time of placental transfusion isn't capable of guaranteeing an improvement in the neonatal hematological status in patients who undergo elective cesarean section. Also the cord clamping time isn't related to changes in postoperative maternal hemoglobin and appearance of obstetric hemorrhage. Thus, it's not justified to establish regulations on cord clamping on the above.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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