

Review of: "Delayed vs Early Umbilical Cord Clamping in 100 Preterm Infants: an RCT from Bhavnagar, Gujarat"

Paula Sanchez-Thevenet¹

¹ Universidad Cardenal Herrera-CEU

Potential competing interests: No potential competing interests to declare.

Qeios ID: YZHQXI

Delayed vs Early Umbilical Cord Clamping in 100 Preterm Infants: an RCT from Bhavnagar, Gujarat-

Minesh S Bhikadiya, Shivani G Shah, Jayendra Gohil¹

General comments

It is an interesting study that confirms the efficacy of performing a delayed clamping of the umbilical cord (DCC) in preterm births, from a specific health system. The results of the study regarding that DCC improves hematological measures and reduces the need for blood transfusion, coincide with those reported in previous studies. Also, adds evidence on some morbidity outcomes, i.e neurodevelopmental impairment, and it extends the follow-up time to 4 months after birth. However, before proceeding with the processing of the document, it is necessary to rewrite, clarify and modify several points, in order to specify and give greater comprehensibility to the information and findings it reports. The manuscript has messy and unconnected messages. For example, you have information in the Introduction that should be in the Methodology or Discussion sections. Also, it has information in the conclusions that should be in the Discussion section.

I believe that it is important that the authors register their trial on the Clinical Trials (<https://beta.clinicaltrials.gov/>) data base, to guarantee compliance with international standards for this type of experimental research with human beings.

In general, I strongly recommend that authors follow the CONSORT (Consolidated Standards of Reporting Trials, <http://www.consort-statement.org/>) guide (and checklist: <http://www.consort-statement.org/checklists/view/32--consort-2010/66-title>) to prepare and reports the trial findings. This will facilitate their complete and transparent reporting.

Introducción

1. The topic should be more focused on what is known and what is unknown about the efficacy of the use of DCC in preterm birth. For this purpose, the authors should review the most up-to-date bibliography such as the following:

- Seidler AL, Gyte GML, Rabe H, Díaz-Rossello JL, Duley L, Aziz K, Testoni Costa-Nobre D, Davis PG, Schmölzer GM, Ovelman C, Askie LM, Soll R; INTERNATIONAL LIAISON COMMITTEE ON RESUSCITATION NEONATAL LIFE

SUPPORT TASK FORCE. Umbilical Cord Management for Newborns <34 Weeks' Gestation: A Meta-analysis.

Pediatrics. 2021 Mar;147(3):e20200576. doi: 10.1542/peds.2020-0576. PMID: 33632931; PMCID: PMC7924139.

- Gomersall J, Berber S, Middleton P, McDonald SJ, Niermeyer S, El-Naggar W, Davis PG, Schmölzer GM, Ovelman C, Soll RF; INTERNATIONAL LIAISON COMMITTEE ON RESUSCITATION NEONATAL LIFE SUPPORT TASK FORCE. Umbilical Cord Management at Term and Late Preterm Birth: A Meta-analysis. Pediatrics. 2021 Mar;147(3):e2020015404. doi: 10.1542/peds.2020-015404. PMID: 33632933.
- Fogarty M, Osborn DA, Askie L, Seidler AL, Hunter K, Lui K, Simes J, Tarnow-Mordi W. Delayed vs early umbilical cord clamping for preterm infants: a systematic review and meta-analysis. Am J Obstet Gynecol. 2018 Jan;218(1):1-18. doi: 10.1016/j.ajog.2017.10.231. Epub 2017 Oct 30. PMID: 29097178.
- Jasani B, Torgalkar R, Ye XY, Syed S, Shah PS. Association of Umbilical Cord Management Strategies With Outcomes of Preterm Infants: A Systematic Review and Network Meta-analysis. JAMA Pediatr. 2021 Apr 1;175(4):e210102. doi: 10.1001/jamapediatrics.2021.0102. Epub 2021 Apr 5. PMID: 33683307; PMCID: PMC7941254.

2. The following statement needs a bibliographic reference to support it: *"During the first 5 to 15 seconds after the delivery, blood volume increases by 5 to 15 ml/kg as a result of uterine contractions."*

3. The term "immediately" requires specification: Do you mean less than 5 seconds after birth?

4. The following statement needs a bibliographic reference to support it: *"The time to umbilical cord clamping may have an important impact on a population's health. Even small effects on each individual may have a great impact when multiplied in a large population..."* It is even better to remove this statement and therefore focus on the background of DCC, following the recommendation detailed above (item 1).

5. The following statement is not appropriate in the Introduction, because readers have not yet accessed the results of the study: *"...as shown by the results of this study..."*

6. Figures 1 and 2 are not of our own elaboration and are unnecessary. The information they show is very basic and does not provide a higher quality to the introduction.

Primary Objective

1. The "primary objective" is different from the objective stated in the Abstract section. The objective stated in the Abstract is more appropriate.

Methods

1. Figures 3 and 4 should be summarized in a single figure. For this, it is recommended to use standardized diagrams

such as the consort flowchart (<http://www.consort-statement.org/consort-statement/flow-diagram>)

Results

1. This section needs to be rewritten, incorporating paragraphs that integrate the contents of the quantitative results shown in the tables. It is impossible to understand the logical sequence of presentation of the findings, considering the way they are presented. The authors can analyze numerous examples of how to present this section, in the original studies that they themselves report in the bibliography.
2. Table 2:, Birth Weight, Birth Length, and 1 Min Apgar Score are baseline characteristics? Especially, birth weight and 1 min Apgar might be affected by DCC or ECC. Consequently, both should be considered as outcomes and not as independent variables or baseline characteristics.
3. Table 2: Please specify the title, including the time of monitoring or measurement of each parameter. The use of the term "various" is unspecific and ambiguous.

Discussion

1. This section needs to be rewritten. In particular, authors should compare their findings with more recent studies. For this purpose, please revise recommended systematic reviews above. The limitations of the study should be included in this section. In this way, the authors should consider as a serious limitation the fact that it was the parents who recorded numerous clinical variables up to the fourth month of life. The parents are not health personnel with technical qualifications to carry out these measurements.

Conclusions

This section needs to be rewritten taking in account all the above mentioned. The following statement is not part of the conclusion, but of the discussion *"In the population studied in this trial, preterm infants born after an uncomplicated pregnancy by healthy mothers, delayed cord clamping improved iron stores as inferred from MCV level at 4 months of age. The requirement of blood transfusion was reduced with delayed cord clamping upto 4 months of age significantly. Infant morbidity was not affected between delayed as compared to early cord clamping, either during the neonatal period (hyperbilirubinemia/ jaundice, respiratory symptoms, polycythemia) or at the 4-month of life (infection symptoms, gastrointestinal problems, contact with doctors)."*

References

1. There are a lot of superscripts whose meaning is not understood.

Other observations

What this study adds

1. It is not clear what the authors mean by the following statement: *For a premature infant between 28 to <37 weeks gestation*. Taking into account recent systematic reviews on the subject, there are numerous RCTs on the efficacy of DCC in newborn less than 37 weeks, and even 34 weeks gestation.

Key words

I recommend removing non-standard abbreviations such as DCC and ECC. And instead of, adding key terms that reflects the contribution of the study, such as: *neurodevelopmental*, *necrotizing enterocolitis*.

Final recommendation: for a better revision of the manuscript and feedback from the reviewers, it is advisable to add the line numbers in the text.