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

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Potential competing interests: No potential competing interests to declare.

What is already known – the authors must refer to the preterm data that shows a convincing reduction in mortality and IVH

What this study adds : This states “Infant morbidities like RDS, NEC, and IVH were not significantly different between DCC and ECC. Incidence of jaundice requiring phototherapy and symptomatic polycythemia was not increased significantly by DCC.” This is too strongly worded. They should state that they found no evidence of a difference, the study is too small and under powered to definitively exclude a difference.

Background

The statements made in the first paragraph of page 3 cannot be justified based on the reference given (reference 2) and are probably incorrect. I suggest that the latest Cochrane review and meta -analysis is referenced and a more accurate description of the benefits of DCC provided, based on this.

Method

Design is well described and appropriate to the study.

The randomisation process is good.

There is no primary outcome defined.

The aims and objectives of the study are not clear.

The sample size calculation doesn’t make sense. What is the primary outcome? What is the incidence of the primary outcome in the population? What reduction in this frequency is being looked for? And what is the justification for this magnitude of reduction?

There is no description of the statistical methods used. This needs to be added in.

Results

Table 1.

There is inappropriate use of p values. P values don't tell us whether 2 populations are different, they tell us what is the probability of the difference we can observe arising by chance. As these groups have been selected at random, the only explanation for nay difference could be chance. Significance testing of demographic differences in a randomised controlled trial should never be performed .

What values are shown for gestation, wt, OFC, length ? They should show median and range (these are not normally distributed data)

Table 2.

The authors should to define what each abbreviation means and also provide definitions or diagnostic criteria for diagnoses such as NEC, IVH, RDS. There should also be a description of phototherapy thresholds, transfusion thresholds etc.

For continuous variables, median and range should be given. What statistical test of significance was applied?

What does "p, X2" mean as the title of the final column?

"Hb at birth" would be better labelled as "Hb at 49 to 72 hours"

Figure 4. Needs some further explanation. Does "Exp" mean expired (ie dead)? And are the words following that the cause of death? This should be explained in more detail (with more consistent use of brackets). The term "anaemia" requires a definition.

Figure 5. This is a repeat of information already given. It is redundant, it doesn't add anything and should be removed.

Discussion

The authors refer to the "Cochrane report " and reference a systematic review of DCC in term babies (ref 6). As their study has been conducted in the preterm population, they should reference the relevant Cochrane review: RabeH, GyteGML, Díaz-RosselloJL, DuleyL. E ect of timing of umbilical cord clamping and other strategies to influence placental transfusion at preterm birth on maternal and infant outcomes. Cochrane Database of Systematic Reviews 2019, Issue 9. Art. No.: CD003248.

Tarnow-Mordi is mis-spelt as "Modi" in the final paragraph of the discussion. Also in the last sentence, the authors state that Duley et al found evidence of improved developmental outcome in reference 14. This is entirely incorrect and must be removed.

Overall the review of the literature provided in the Discussion is poor. Random results from a very incomplete sample of

the available literature is presented. A description of the outcomes gleaned from the Cochrane 'preterm' review of DCC (see above) would cover all of this much more completely and accurately.

The study is very small and does not have the statistical power to make any definitive statement about the incidence of most of the outcomes reported – eg, although there was no statistical difference in the rate of mortality between the 2 groups, ¾ of the deaths occurred in the ECC group, which is entirely consistent with the published data, There was 50% more RDS in the ECC group and 50 more phototherapy in the DCC group – neither was statistically significant, the study is too small to allow a meaningful conclusion to be reached. This should be discussed.

Overall - this is a well conducted study and the results are interesting. But, it is not publishable in its current form and requires some rewriting.