Author’s response to reviews

Title: Cord Pilot Trial, comparing alternative policies for timing of cord clamping before 32 weeks gestation: follow-up for women up to one year

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Author’s response to reviews:

Dear Editor-in-Chief,

RE: Re-submission `Cord Pilot Trial, comparing alternative policies for timing of cord clamping before 32 weeks gestation: follow-up for women up to one year’

Thank you for the opportunity to respond to the reviewer comments on our revised manuscript. We have responded to the reviewer comments below and revised the manuscript. We would therefore like to resubmit our paper for consideration by BMC Pregnancy and Childbirth.
Response to Reviewer reports:

Zachary A. Vesoulis (Reviewer 1): Thank you for allowing me to review the revised manuscript. This is a very interesting project and highlights yet another of the often intangible benefits of DCC. The authors are to be commended for their efforts at revision and clarification. I had a couple of minor points.

-I am still a little concerned about including mothers of deceased infants. I worry that the mental anguish of infant mortality alters the scores of the surveys, falsing attributing an effect to delayed cord clamping. Perhaps the authors could do a limited analysis removing those infants to ensure that results are still similar?
Response:

Our work with Bliss (UK based charity for babies born prematurely or sick) prior to the trial with mothers whose babies died following preterm birth indicated that these mothers wanted the opportunity to continue to be involved and contribute to the findings. We agree that depression and anxiety scores and satisfaction with birth are likely to be affected by the baby death. However the numbers of mothers whose babies had died at the time questionnaire completion was small (5 for the first questionnaire and 4 for the second questionnaire, 3% of questionnaires completed at each time point). If these 5 mothers whose babies had died at the time of the first questionnaire completion are not included, the results are similar:

- the mean HADS score for depression in the clamp ≥2 minutes group is 5.0 (standard deviation (sd) 3.3) and 5.9 (sd 3.6) in the clamp ≤20 seconds group

- the mean HADS score for anxiety in the clamp ≥2 minutes group is 7.4 (sd 4.1) and 7.4 (sd 4.6) in the clamp ≤20 seconds group.

-I appreciate the inclusion of the "additional file" with more complete data about the included infants/mother, but I would like to repeat my request for statistical comparison between the groups. I do not think that it is sufficient to rely on a randomization design to ensure that the groups are balanced. For example, the infants with delayed cord clamping appear to have been born by c-section much more often (63% of cases) compared to those without delayed cord clamping (54% of cases) but I am unable to judge if that was statistically significant. The current table format makes statistical analysis difficult, as there are already multiple columns based on survey completion. The authors should add an additional table to "additional file" listing a baseline statistic comparison.
Response:

The aim of the manuscript is to report the follow-up of the women up to one year after the birth rather than perform any statistical testing. At baseline any imbalances between the groups will be due to chance due to randomisation so the clinical relevance of any imbalances is the most important thing to consider, which adding information on statistical significance may distract from. At follow-up, lost to follow-up may have introduced differences between groups in the baseline characteristics that are not due to chance. However due to the relatively small sample size, we feel that it is more important for readers to assess the clinical relevance of any imbalances on the descriptive statistics presented for anxiety, depression and satisfaction rather than adding a baseline statistical comparison. We have added a sentence to the results section describing the characteristics where there is imbalance between the groups for women who returned the questionnaires.

-I really like the ROC curve, nice depiction of the results! The table underneath may not be necessary and could be removed for space-conserving reasons, if needed.

Response:

Thank you. The table showing the number of participants included at each time point in the graph (“number at risk”) is recommended when presenting Kaplan-Meier curves (Altman et al., 1995) however we would be happy to remove it if the editor thinks it is preferable.

References