**Reviewer’s report**

**Title:** Using fetal scalp stimulation with Doppler ultrasonography to enhance intermittent auscultation in low-resource settings: A diagnostic trial from Tanzania

**Version:** 0  **Date:** 13 Nov 2018

**Reviewer:** Andrew Weeks

**Reviewer’s report:**

This is a relatively large study, with midwives using this technique in Africa for the first time. Low cost techniques for improving fetal monitoring during labour are understudied and potentially have huge impact on perinatal morbidity and mortality worldwide, which is currently unacceptably high. Furthermore, improving fetal monitoring during labour in LMIC has been highlighted as a research priority by experts. The authors' finding, that FSST enhanced intermittent auscultation improved the detection of significant acidaemia (pH< 7.0) from 27% to 70% is potentially of significance as a low cost, simple technique. I would therefore consider this topic area to be of great importance, and understudied. However, I do have concerns about this study:

**MAJOR CONCERNS**

1. It would be important to explain why cord gases were chosen for the diagnosis of "intrapartum fetal distress", whilst other important neonatal outcomes e.g. death, NICU admissions and APGARS were not recorded. Low pH does correlate well with poor outcomes long term, but the cut-off of 7.2 correlates very poorly with adverse neonatal outcome (mean arterial cord pH at birth is 7.24-7.26, so 7.2 is a very common outcome). A cut-off of 7.0 or 7.05 would be more appropriate and relate more to significant adverse outcomes. Furthermore, cord pH readings are expensive (and so rarely available in low resource settings outside of research) and of limited clinical value in the management of newborns in this setting. Thus, a standard local method would have been more appropriate, especially given the ethical need to continue the supply of any research intervention after the end of the study (was this done?).

2. There are no details of consent methods for the woman - please could these be provided?

3. The protocol for routine IA monitoring is not provided. In the IA and FSST group, how often were the women monitored if they had no risk factors? i.e. was the fetal heart only listened too once on admission and once when 9-10cm? The same detail is needed for the IA alone group.

**MINOR CONCERNS**
4. The abstract is not very clear about the methods and should be reworded to make clear the sequential process for recruitment of the patients.

5. The abstract should mention that this was a pre- and post-intervention observational study.

6. The setting of a referral centre in Tanzania is clear, but it would be useful to know the usual practice for fetal monitoring and if emergency CS is performed purely for fetal indications. The CS rate is 41% - how many of these are emergency CS?

7. The authors should provide information on the selection process for participants. What were the inclusion/exclusion criteria for the initial 50 patients? Were these the same as for the second study?

8. Line 26 - typo - must "of" a means.

9. The methods should be clear that the FSST is done vaginally. Some would do this using the 'Paulik's grip', so best to be clear in the text. It may also be worth mentioning this as an alternative in the discussion, given the invasive nature and infective risks of repeated vaginal examinations in labour.

10. It is important to know how many high-risk patients there are in each group (e.g. PPROM, APH, postdates, pre-eclampsia, etc) in order to compare them, not just whether a CS was indicated. However, no details are given. Furthermore, there is no mention of differing fetal monitoring for high and low risk patients, so we would have to assume that all are included and treated the same. Is this correct?

11. Only one obstetrician interpreted the CTG - it is well documented that there is often significant inter/intra observer error in CTG interpretation. Given that this is the Gold Standard in this study, can the authors provide detail on his / her experience or training, and what guidelines were followed for interpretation?

12. It is not clear how soon after birth the gases were taken.

13. The pH outcome measure should be made clearer. It looks as if the main outcome was pH 7.2 with a BE of over -12. Is this correct? So if the pH was 6.9 with a BE of -11 this would not be an adverse outcome. Correct?

14. Why was audible decelerations under 110 chosen? Would baseline rate under 110 AND any decelerations auscultated be more in line with international guidelines?

15. Fig 1 - the standard methods for presenting diagnostic comparisons is in a 2x2 table. This would provide complete transparency of their data. The term 'fetal distress' is also not a good academic (or lay) term in my opinion. Better to use '34 with abnormal IA', etc which is less emotionally laden.
16. The process for fetal monitoring and intervention is not clear. I had assumed that woman were admitted, underwent a triage with FSST to either regular FSST or routine IA (maybe every 30-60 minutes?). Then if further FSST tests were abnormal, then the woman has a CS / operative vaginal birth. Is this correct?

17. Figure 1 presents in its legend (for the first time) that 'fetal distress' includes the presence of meconium-stained liquor. The grade of meconium for this definition should be provided as surely low-grade meconium is normal for a post-dates fetus? I would not have this as part of the diagnosis of 'fetal distress' but maybe just as an indication for FSST. I would also include accelerations and decelerations in this definition. Surely if decelerations were heard then this would be considered abnormal...?

18. Given the increased use of vaginal examination, fetal infective outcomes should be provided.

19. At the end of the first CTG vs Doppler study, the authors should mention the outcomes for all patients - there is one missing in whom there was no agreement.

20. In table 1, the term 'referral' is unclear (are they referred in or out?). The term 'spontaneous labour' should be 'spontaneous onset of labour without need for augmentation'.

21. The 60% rate of augmentation of spontaneous onset labour requires comment, and a section in the methods to explain the reasons for use of augmentation.

22. In table 2 'asphyxia' is not defined.

23. References 2 and 5 are the same.

24. There are differences in the number of recruits from the published protocol and the paper. The authors should explain the difference.

**Are the methods appropriate and well described?**
If not, please specify what is required in your comments to the authors.

No

**Does the work include the necessary controls?**
If not, please specify which controls are required in your comments to the authors.

No

**Are the conclusions drawn adequately supported by the data shown?**
If not, please explain in your comments to the authors.

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