OBSTETRICS & GYNECOLOGY

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- Comments from the reviewers and editors (email to author requesting revisions)
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**Date:** Mar 26, 2021
**To:** "Uma M. Reddy" [redacted]
**From:** "The Green Journal" em@greenjournal.org
**Subject:** Your Submission ONG-21-335

RE: Manuscript Number ONG-21-335

Intrapartum resuscitation interventions for Category II fetal heart rate tracings and improvement to Category I

Dear Dr. Reddy:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Apr 16, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

The Maternal-Fetal Medicine Units Network published a randomized trial which evaluated the utilization of ECG ST-segment analysis in the New England Journal of Medicine in 2015. This is a secondary analysis of the data that was presented as a poster at the Society of Maternal-Fetal Medicine annual meeting in 2017. In this study they objectively identified category 2 fetal heart rate tracings treated with 1 of 4, or combination of 4 therapies, which include oxygen administration, IV fluids, amnioinfusion and tocolytic therapy using terbutaline. They desired to determine how often improvement the category 1 tracings occurred within the first 60 minutes of intervention, within 30 and 60 minutes after intervention, and compared neonatal morbidity rates between fetal heart rate tracings that improved and those that did not. The results provide new information on the success rates of these interventions using numbers of cases that are more robust than those that have been available in the literature. The following are my comments:

1. There is a worldwide movement to reducing cesarean section rates. This data gives us real life information on how likely the intervention chosen would be successful and within what period of time. They also give us information on its effect on the final product, the neonate. Regardless of the absence of controls this is still very clinically useful information for the intrapartum management/treatment of category 2 fetal heart rate tracings. The results show that with institution of these therapies and time or patience, improvement to category 1 fetal heart rate tracing status can be expected, with any real detriment to neonatal status.
2. I realize that software was used to objectively analyze the fetal heart rate tracings however the issue here is what type of decelerations were observed. Also, it is obvious that it was not standardize as to the therapies chosen, however this is how it is in reality. What would improve the study is what type of decelerations were observed; where they late or variable or late variable decelerations. Is it possible that the authors can go back and give us this information and the success rates of each treatment based on the type of deceleration? For example, revealing would be for resuscitation by reducing the frequency of the contractions especially when there is uterine tachysystole. I would also be quite effective when there a late decelerations. An amnioinfusion would certainly target variable decelerations but would not be indicated for treat late decelerations. Oxygen therapy may help resolve reflexive late decelerations but not variable decelerations. It would be most interesting if this could be provided I would certainly make this study more informative.

Reviewer #2:

Dr. Reddy and members of the MFMU Network present a secondary analysis of data collected as part of the STAN trial. The STAN trial was a multicenter randomized controlled trial of fetal ECG ST-segment analysis that was used as an adjunct to conventional electronic fetal heart rate monitoring. The objective of the study was to determine the proportion of subjects with fetal heart rate tracings classified as category II that had improvement to category I within 60 minutes of initiation of resuscitative efforts. The authors found that approximately 20% of women meeting study inclusion criteria had maternal resuscitative efforts conducted for a category II tracing. Maternal oxygen administration was the most common resuscitative tool utilized. The majority of women with category II tracings improved to category I tracings within 60 minutes. There were no differences in the rate of adverse neonatal outcomes for women whose category II tracings improved to category I compared to those whose tracings did not improve. The authors conclude that the majority of women with category II tracings have improvement to category I tracing with maternal resuscitation efforts. They acknowledge the lack of a control group, namely women with category II tracings who did not receive resuscitative efforts.

Comments and Questions for the authors.

1. ACOG Practice Bulletin Number 116 (Figure 1) guides practitioners on two different approaches for the management of a Category II tracing. Women with category II tracings that are characterized by "absent FHR accelerations and absent/minimal FHR variability" should be delivered if there is no improvement with resuscitation efforts while those women with category II tracings that are characterized by the presence of "FHR accelerations or moderate FHR variability" can continue under surveillance. It would be interesting to provide a subgroup analysis using your data. Are women whose category II tracing that are characterized by the former (absent accelerations and absent/minimal FHR variability) less likely to convert to a category I tracing with resuscitation that women whose category II tracing is characterized by presence of FHR accelerations or moderate variability? This data may help validate the ACOG-recommended treatment algorithm that is presented in Figure 1 of the Practice Bulletin Number 116.

2. Can you present mode of delivery data for those women whose category II tracing improved to category I compared to those whose tracings did not improve?

3. You acknowledge the limitation of not including a control group, namely women with category II tracings who did not receive intrapartum resuscitation. Given that you used the PeriCALM software to identify category II tracings, why not start by identifying all subjects with a category II tracing and then determine if resuscitation improved outcomes compared to those who did not receive resuscitation? You do state that this approach may not be possible as most MFMU sites likely would have initiated some type of resuscitation for a category II tracing but it is certainly possible that some women did not receive resuscitative efforts. I am not asking you to do this data analysis, but you may have this data given that the PeriCALM platform was used to analyze the strips. It would be important to determine what characteristics of a category II tracing would benefit from resuscitative efforts; this may be your next study.

4. Figure 1 shows that 806 women had an intervention for their category II tracing before the category II tracing persisted for at least 30 minutes. This group could also serve as an interesting subgroup. Were women whose intervention that started prior to their category II tracing being present for 30 minutes more likely (or less likely) to have recovery to category I compared to the women whose category II tracing persisted for at least 30 minutes before intervention? Did this group have lower (or higher) cesarean delivery rates or improved (or worse) outcomes? You may not have outcome data for this group but if you do, it would be an interesting analysis to present.

5. The last row in Table 2 is labeled, "Given in combination with another intervention". I was not sure what this referred to. Can you clarify in the table and text?

Reviewer #3:

Overall Comments: The authors present a retrospective cohort study from a secondary analysis of a MFMU network STAN trial, a large multicenter randomized controlled trial (RCT) of fetal ECG ST-segment analysis used as an adjunct to conventional electronic fetal monitoring in laboring patients with singleton pregnancies >36 weeks gestation. The aim of this secondary analysis was to evaluate intrapartum resuscitation interventions and improvement of Category II fetal heart rate tracings (FHRT) and the primary outcome was improvement to category I tracing within 60 minutes after intervention. Other outcomes included an improvement of FHRT to category I within 30-60 minutes and neonatal outcomes. Twenty percent of the RCT participants met inclusion criteria. In summary, approximately 2/3rds of category II's in this population improved to category I within 60 minutes and there was no difference in neonatal composite adverse outcome. Specific comments/queries below:

Specific Comments:
Title: ok
Short title: Perhaps, "Outcomes of" intrapartum resuscitation interventions
Précis: OK
Abstract: Good summary of study and results
Introduction: Please provide your hypothesis for this analysis.
Materials and Methods: Was this a planned secondary analysis (ie an aim of the protocol for the index trial)?
Results: Thank you for flow diagram. Of interest was also that the majority of subjects did not have a category II tracing to manage. Were there any differences in clinic-demographic characteristics in subjects of this report compared to those that did not have category II FHRTs? Would like to see the characteristics of the Improvement and Non-improvement groups in Table 1.
Discussion: Good discussion of the results with the current literature. Strengths and limitations provided. How can these findings provide implications for clinical care?
Tables/Figures: See above.

STATISTICS EDITOR COMMENTS:

Lines 87-90: Unfortunately, not only was there NS difference in incidence of composite neonatal adverse outcomes, but the sample was underpowered, given how infrequent the adverse outcome was. For example, given alpha = 0.05, power = 80%, the sample sizes at hand and a baseline rates of 2.8%, the rate among the without improvement group would have to exceed ~ 5.2%. Put another way, in order to have discerned an relative increase of 50% (from 2.8 % to 4.2%), there is only ~ 44% power to discern that difference, given the sample sizes at hand. So, the description of incidences of outcomes is OK, but should include CIs and not generalize that there is no difference in neonatal composite outcome.

Fig 1: Did those who were excluded from the analysis differ from the analyzed cohort (Table 1) in ways which could make the analyzed group not representative?

Table 2,3: For all columns with N < 100, should round all %s to nearest integer %, not cite to nearest 0.1% precision.

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
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4. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Race/ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

5. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at http://ong.editorialmanager.com. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

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* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).
* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology,

add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

9. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

10. Only standard abbreviations and acronyms are allowed. A selected list is available online at http://edmgr.ovid.com /ong/accounts/abbreviations.pdf. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

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12. ACOG is moving toward discontinuing the use of "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

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If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

14. Your manuscript contains a priority claim. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

15. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

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17. Figure 1: Please upload as a figure file on Editorial Manager.

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* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and

* A point-by-point response to each of the received comments in this letter. Do not omit your responses to the Editorial Office or Editors' comments.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors and that each author has given approval to the final form of the revision.

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Apr 16, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

John O. Schorge, MD
Associate Editor, Gynecology

2019 IMPACT FACTOR: 5.524
2019 IMPACT FACTOR RANKING: 6th out of 82 ob/gyn journals

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RE: Manuscript Number ONG-21-335
Intrapartum resuscitation interventions for Category II fetal heart rate tracings and improvement to Category I

Dear Dr. Schorge:

We appreciate the careful and thoughtful reviews of our manuscript. We have done our best to address the comments in our responses below. We have revised the manuscript accordingly using track changes.

Sincerely,
Uma Reddy

REVIEWER COMMENTS:

Reviewer #1:

The Maternal-Fetal Medicine Units Network published a randomized trial which evaluated the utilization of ECG ST-segment analysis in the New England Journal of Medicine in 2015. This is a secondary analysis of the data that was presented as a poster at the Society of Maternal-Fetal Medicine annual meeting in 2017. In this study they objectively identified category 2 fetal heart rate tracings treated with 1 of 4, or combination of 4 therapies, which include oxygen administration, IV fluids, amnioinfusion and tocolytic therapy using terbutaline. They desired to determine how often improvement the category 1 tracings occurred within the first 60 minutes of intervention, within 30 and 60 minutes after intervention, and compared neonatal morbidity rates between fetal heart rate tracings that improved and those that did not. The results provide new information on the success rates of these interventions using numbers of cases that are more robust than those that have been available in the literature. The following are my comments:

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Response: Thank you

2. I realize that software was used to objectively analyze the fetal heart rate tracings however the issue here is what type of decelerations were observed. Also, it is obvious that it was not standardize as to the therapies chosen, however this is how it is in reality. What would improve the study is what type of decelerations were observed; where they late or variable or late variable decelerations. Is it possible that the authors can go back and give us this information and the success rates of each treatment based on the type of deceleration? For example, revealing would be for resuscitation by reducing the frequency of the contractions especially when there is uterine tachysystole. I would also be quite effective when there a late decelerations. An amnioinfusion would certainly target variable decelerations but would not be indicated for treat late decelerations. Oxygen therapy may help resolve

reflexive late decelerations but not variable decelerations. It would be most interesting if this could be provided I would certainly make this study more informative.

Response:
Although we agree with the reviewer that this type of analysis would be interesting, we are concerned that dividing up the cases by type of deceleration and then by type of intervention (with multiple intervention being applied) will result in small sample sizes being analyzed and may not yield meaningful results. However, in an attempt to address this issue please refer to response to reviewer 2, comment #2 to subcategorize Category II tracings according to ACOG Practice Bulletin Number 116 (Figure 1) algorithm.

Reviewer #2:

Dr. Reddy and members of the MFMU Network present a secondary analysis of data collected as part of the STAN trial. The STAN trial was a multicenter randomized controlled trial of fetal ECG ST-segment analysis that was used as an adjunct to conventional electronic fetal heart rate monitoring. The objective of the study was to determine the proportion of subjects with fetal heart rate tracings classified as category II that had improvement to category I within 60 minutes of initiation of resuscitative efforts. The authors found that approximately 20% of women meeting study inclusion criteria had maternal resuscitative efforts conducted for a category II tracing. Maternal oxygen administration was the most common resuscitative tool utilized. The majority of women with category II tracings improved to category I tracings within 60 minutes. There were no differences in the rate of adverse neonatal outcomes for women whose category II tracings improved to category I compared to those whose tracings did not improve. The authors conclude that the majority of women with category II tracings have improvement to category I tracing with maternal resuscitation efforts. They acknowledge the lack of a control group, namely women with category II tracings who did not receive resuscitative efforts.

Comments and Questions for the authors.

1. ACOG Practice Bulletin Number 116 (Figure 1) guides practitioners on two different approaches for the management of a Category II tracing. Women with category II tracings that are characterized by "absent FHR accelerations and absent/minimal FHR variability" should be delivered if there is no improvement with resuscitation efforts while those women with category II tracings that are characterized by the presence of "FHR accelerations or moderate FHR variability" can continue under surveillance. It would be interesting to provide a subgroup analysis using your data. Are women whose category II tracing that are characterized by the former (absent accelerations and absent/minimal FHR variability) less likely to convert to a category I tracing with resuscitation that women whose category II tracing is characterized by presence of FHR accelerations or moderate variability? This data may help validate the ACOG-recommended treatment algorithm that is presented in Figure 1 of the Practice Bulletin Number 116.

Response: We appreciate this excellent suggestion by the reviewer and performed the analyses as suggested above. We added the table below and the following text in the Methods section on pages 7-8 of the paper: “In a post-hoc analysis, we further analyzed category II tracings according to ACOG Practice Bulletin Number 116 (Figure 1) which provides two different approaches for the management of a Category II tracing. For people with category II tracings characterized by "absent FHR accelerations and absent/minimal FHR variability" delivery should be considered if there is no improvement with

resuscitation efforts while those with tracings that are characterized by the presence of "FHR accelerations or moderate FHR variability" can continue surveillance and intrauterine resuscitative measures. (2) We compared these two subcategories of Category II tracing for the rate of improvement to Category I following each intervention, except for tocolytic administration due to its small numbers." We added the following to the Results section on page 9 "In the post-hoc analysis, of the 2,251 participants, 14.7% (n=332) were in the "absent FHR accelerations and absent/minimal FHR variability" subgroup; oxygen was administered in 75.9% of these cases (252/332) (Table 4). After oxygen administration, the "absent FHR accelerations and absent/minimal FHR variability" subgroup was more likely to convert to Category I tracing within 60 minutes than the "FHR accelerations or moderate FHR variability subgroup", (77.0% vs. 63.0%, OR 2.0, 95%CI 1.4, 2.7) due to improvement in variability. After IVF bolus the "absent FHR accelerations and absent/minimal FHR variability" subgroup was also more likely to convert to Category I tracing within 60 minutes than the "FHR accelerations or moderate FHR variability subgroup", (77% vs. 65.4%, OR 1.8, 95%CI 1.1, 2.9). Amnioinfusion was not associated with a difference in conversion to Category I tracing within 60 minutes for the two category II FHRT subgroups."

**Table 4: Intervention characteristics and improvement of FHR tracing to Category I within 60 minutes by ACOG category II tracing type**

| | N | Accelerations or moderate variability* | Absent accelerations and absent/ minimal variability* | p-value |
|---|---|---|---|---|
| Any intervention | 2,251 | 1,189/1,919 (62.0) | 244/332 (73.5) | <0.001 |
| Oxygen | 1,698 | 911/1,446 (63.0) | 194/252 (77.0) | <0.001 |
| IVF bolus | 659 | 366/560 (65.4) | 76/99 (77) | 0.03 |
| Amnioinfusion | 240 | 108/207 (52.2) | 17/33 (52) | 0.94 |

IVF = intravenous fluid
Data are proportion (%)

* ACOG category II tracing type in the 30 minutes immediately before the intervention

2. Can you present mode of delivery data for those women whose category II tracing improved to category I compared to those whose tracings did not improve?
Response: We did provide this information in the results at the end of the first paragraph on page 9: "When excluding those 169 participants, cesarean delivery occurred in 30.8% (441/1433) of those that improved to Category I within 60 minutes and 28.5% (185/649) that did not improve and were still at risk of cesarean delivery."

3. You acknowledge the limitation of not including a control group, namely women with category II tracings who did not receive intrapartum resuscitation. Given that you used the PeriCALM software to identify category II tracings, why not start by identifying all subjects with a category II tracing and then determine if resuscitation improved outcomes compared to those who did not receive resuscitation? You do state that this approach may not be possible as most MFMU sites likely would have initiated

some type of resuscitation for a category II tracing, but it is certainly possible that some women did not receive resuscitative efforts. I am not asking you to do this data analysis, but you may have this data given that the PeriCALM platform was used to analyze the strips. It would be important to determine what characteristics of a category II tracing would benefit from resuscitative efforts; this may be your next study.

Response: We thank the reviewer for this excellent suggestion. We are not able to do this for this paper but will explore as the topic for a future paper.

4. Figure 1 shows that 806 women had an intervention for their category II tracing before the category II tracing persisted for at least 30 minutes. This group could also serve as an interesting subgroup. Were women whose intervention that started prior to their category II tracing being present for 30 minutes more likely (or less likely) to have recovery to category I compared to the women whose category II tracing persisted for at least 30 minutes before intervention? Did this group have lower (or higher) cesarean delivery rates or improved (or worse) outcomes? You may not have outcome data for this group but if you do, it would be an interesting analysis to present.

Response: In the table below, we present the length of tracing before intervention. Of these 806 cases, in 265 (33%) of them no category II tracing was observed using the PeriCalm algorithm. A priori the decision was made to analyze cases when there was a Category II FHR tracing for at least 30 minutes prior to the intervention. We do not feel that analysis of this subgroup of patients with either no category II or less than 30 minutes of category tracing II will contribute meaningful information.

| Length of tracing before intervention | Number of women |
|---|---|
| 0 to <10 mins | 396 |
| 10 to <20 mins | 223 |
| 20 to <30 mins | 187 |

5. The last row in Table 2 is labeled, "Given in combination with another intervention". I was not sure what this referred to. Can you clarify in the table and text?

Response: This has been further clarified in the footnote for Table 2 and in the text.

Reviewer #3:

Overall Comments: The authors present a retrospective cohort study from a secondary analysis of a MFMU network STAN trial, a large multicenter randomized controlled trial (RCT) of fetal ECG ST-segment analysis used as an adjunct to conventional electronic fetal monitoring in laboring patients with singleton pregnancies >36 weeks gestation. The aim of this secondary analysis was to evaluate intrapartum resuscitation interventions and improvement of Category II fetal heart rate tracings (FHRT) and the primary outcome was improvement to category I tracing within 60 minutes after intervention. Other outcomes included an improvement of FHRT to category I within 30-60 minutes and neonatal outcomes. Twenty percent of the RCT participants met inclusion criteria. In summary, approximately 2/3rds of category II's in this population improved to category I within 60 minutes and there was no difference in neonatal composite adverse outcome. Specific comments/queries below:

Specific Comments:
Title: ok

Short title: Perhaps, "Outcomes of" intrapartum resuscitation interventions

Response: This has been changed accordingly.

Précis: OK

Abstract: Good summary of study and results

Introduction: Please provide your hypothesis for this analysis
Response: As we explained in the introduction since the data are very limited, this was purely a descriptive study of the frequency of use of standard intrapartum resuscitation interventions for category II tracings, conversion to category I tracings 60 minutes post-intervention, and neonatal morbidity rates in Category II tracings.

Materials and Methods: Was this a planned secondary analysis (ie an aim of the protocol for the index trial)?
Response: This was not a planned secondary analysis of the index trial. However, there was a plan to use FHR pattern-recognition software post trial for FHR tracing interpretation.

Results: Thank you for flow diagram. Of interest was also that the majority of subjects did not have a category II tracing to manage. Were there any differences in clinic-demographic characteristics in subjects of this report compared to those that did not have category II FHRTs?

Response: We compared 7,032 patients with no intervention for Category II FHRT to 2,251 patients included in our analysis in the table below. Although the participants in the no intervention group were earlier in gestational age, had lower BMI, more likely to be non-Hispanic white, less likely to be nulliparous and greater cervical dilation at randomization compared with the analyzed group, these differences other than parity are small and are not clinically significant. We defer to the editor on whether addition of this information to the paper will be of value to the reader.

| | No intervention for Category II tracing (N=7,032) | Analysis cohort (N=2,251) | p-value |
|---|---|---|---|
| Age, years | 27.3 ± 5.8 | 27.1 ± 6.0 | 0.09 |
| Gestational age at time of randomization, weeks | 39.3 ± 1.2 | 39.5 ± 1.2 | <0.001 |
| Race and ethnicity | | | <0.001 |
| Non-Hispanic Black | 22.7% | 23.4% | |
| Non-Hispanic White | 45.2% | 36.0% | |
| Asian | 2.0% | 3.1% | |
| Hispanic | 28.8% | 35.4% | |
| Other or not recorded | 1.3% | 2.1% | |

| | | | |
|---|---|---|---|
| Body mass index, kg/m$^2$ | 32.5 ± 6.9 | 33.5 ± 7.0 | <0.001 |
| Education level, years | 12.9 ± 2.7 | 12.8 ± 2.5 | 0.20 |
| Nulliparous | 37.5% | 59.4% | <0.001 |
| Cervical dilation at randomization, cm | 5.0 ± 1.3 | 4.6 ± 1.3 | <0.001 |
| Induced labor | 58.4% | 60.6% | 0.08 |

Would like to see the characteristics of the Improvement and Non-improvement groups in Table 1.
Response: Although interesting, our objective is to examine the result of interventions on Category II tracings. By introducing the patient characteristics of those who may or may not show improvement in the FHR tracing, our concern is that the focus of the paper will be shifted toward a different question. Therefore, we prefer to maintain Table 1 in its current format.

Discussion: Good discussion of the results with the current literature. Strengths and limitations provided. How can these findings provide implications for clinical care?
Response: We believe that the current findings demonstrate that the overall risk of the neonatal composite outcome was low for category II tracings in either group: Improvement within 60 minutes - Rate 2.8% (95% CI 2.0% to 3.8%) and No improvement within 60 minutes - Rate 3.2% (95% CI 2.1% to 4.6%). However, these results reinforce the need for trials and further study of these interventions, particularly oxygen administration.
Tables/Figures: See above.

STATISTICS EDITOR COMMENTS:

Lines 87-90: Unfortunately, not only was there NS difference in incidence of composite neonatal adverse outcomes, but the sample was underpowered, given how infrequent the adverse outcome was. For example, given alpha = 0.05, power = 80%, the sample sizes at hand and a baseline rates of 2.8%, the rate among the without improvement group would have to exceed ~ 5.2%. Put another way, in order to have discerned a relative increase of 50% (from 2.8 % to 4.2%), there is only ~ 44% power to discern that difference, given the sample sizes at hand. So, the description of incidences of outcomes is OK, but should include CIs and not generalize that there is no difference in neonatal composite outcome.

Response: The CIs for incidences of outcomes has been added to the manuscript: Improvement within 60 minutes - Rate 2.8% (95% CI 2.0% to 3.8%) and No improvement within 60 minutes - Rate 3.2% (95% CI 2.1% to 4.6%). We have removed the statement that that there is no difference in neonatal composite outcome. Further, we have added the following sentence on page 11 as part of the limitations: “Lastly, because the incidences of the neonatal composite morbidity were relatively low in the subgroups of category II tracings, this study is likely underpowered to detect a difference in this low frequency outcome.”

Fig 1: Did those who were excluded from the analysis differ from the analyzed cohort (Table 1) in ways which could make the analyzed group not representative?
Response: We compared participants in the analyzed cohort to those who were excluded due to less than 30 minutes of FHRT before the first intervention (n=806). The included participants in the analysis

cohort were more likely to be later in gestational age, more likely to be non-Hispanic white and less likely to be Hispanic, have higher BMI, more likely to be nulliparous and less cervical dilation at randomization compared with those excluded due to insufficient FHRT before intervention. These small absolute differences are likely of not clinical significance, but we added the table below as a supplemental Table.

Supplement Table: Characteristics of Analyzed cohort compared to participants not included in the analysis

| | Included participants (N=2,251) | Insufficient FHR tracing before intervention (N=806) | p-value |
|---|---|---|---|
| Age, years | 27.1 ± 6.0 | 27.4 ± 6.0 | 0.31 |
| Gestational age at time of randomization, weeks | 39.5 ± 1.2 | 39.3 ± 1.2 | 0.001 |
| Self-Identified Race and ethnicity | | | 0.008 |
| Non-Hispanic Black | 23.4% | 24.8% | |
| Non-Hispanic White | 36.0% | 34.4% | |
| Asian | 3.1% | 1.6% | |
| Hispanic | 35.4% | 38.5% | |
| Other or not recorded | 2.1% | 0.7% | |
| Body mass index, kg/m$^2$ | 33.5 ± 7.0 | 32.5 ± 6.9 | <0.001 |
| Education level, years | 12.8 ± 2.5 | 12.7 ± 2.7 | 0.29 |
| Nulliparous | 59.4% | 45.4% | <0.001 |
| Cervical dilation at randomization, cm | 4.6 ± 1.3 | 5.1 ± 1.2 | <0.001 |
| Induced labor | 60.6% | 58.4% | 0.29 |

Table 2,3: For all columns with N < 100, should round all %s to nearest integer %, not cite to nearest 0.1% precision.
Response: This has been done

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

A. OPT-IN: Yes, please publish my point-by-point response letter.
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Response: We OPT-IN

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Response: This has been done

3. If your study is based on data obtained from the National Center for Health Statistics, please review the Data Use Agreement (DUA) for Vital Statistics Data Files that you or one of your coauthors signed. If your manuscript is accepted for publication and it is subsequently found to have violated any of the terms of the DUA, the journal will retract your article. The National Center for Health Statistics may also terminate your access to any future vital statistics data.
Response: N/A

4. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Race/ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.
Response: “Self-identified race and ethnicity” has been added to Table 1.

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.
Response: This has been done.

5. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), observational studies using ICD-10 data (ie, RECORD), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at
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amp;data=04%7C01%7Cuma.reddy%40yale.edu%7Cae880cdc6f22462e0ba708d8f08462d1%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C1%7C637523798679084625%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=6SsPw6SeNTvCoc5yLa%2FJCKGnR5K3eK3v0E4wh9JXfvs%3D&reserved=0. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, RECORD, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

Response: The STROBE checklist has been submitted.

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2Fpractice-management%2Fhealth-it-and-clinical-informatics%2Frevitalize-obstetrics-data-definitions&data=04%7C01%7Cuma.reddy%40yale.edu%7Cae880cdc6f22462e0ba708d8f08462d1%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C1%7C637523798679094623%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=v1GeqZtiVUmtcQQFJq1vP3dACqSZ7ouPpcsZ8Tpp940%3D&reserved=0 and the gynecology data definitions at https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2Fpractice-management%2Fhealth-it-and-clinical-informatics%2Frevitalize-gynecology-data-definitions&data=04%7C01%7Cuma.reddy%40yale.edu%7Cae880cdc6f22462e0ba708d8f08462d1%7Cdd8cbebb21394df8b4114e3e87abeb5c%7C0%7C1%7C637523798679094623%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C1000&sdata=lOrYDgN0C4zfNeYmefAqD5BpHGwAHDUbp1Uz9zT0C00%3D&reserved=0. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

Response: Terminology used in paper is compliant with ReVitalize Obstetric definitions

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

Response: The paper is within word limits. Current word count without references= 3,158 words. Word count with references= 3,681 words

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Response: The above guidelines have been followed.

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Response: The abstract has been carefully reviewed and is within the word count: 297 words

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Response: This has been done.

11. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

Response: This has been done.

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Response: “Provider” has been replaced with “health care professional” in the manuscript.

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Response: The above has been addressed throughout the manuscript.

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Response: We do not make a priority claim in the manuscript. We state there is a paucity of data on the topic and provide references and clinical trials.gov search in the discussion.

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Response: We will follow the above instructions.