

OBSTETRICS & GYNECOLOGY



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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

**The corresponding author has opted to make this information publicly available.*

Personal or nonessential information may be redacted at the editor's discretion.

Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office:
obgyn@greenjournal.org.

Date: Feb 22, 2022
To: "Steven L Clark" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-83

RE: Manuscript Number ONG-22-83

Category II intrapartum fetal heart rate patterns unassociated with recognized sentinel events – Castles in the Air

Dear Dr. Clark:

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).

Please be sure to address the Editor comments (see "EDITOR COMMENTS" below) in your point-by-point response.

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 Mar 15, 2022, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

This is a commentary on the current (and historical) state of the use of electronic fetal heart rate monitoring in labor management.

This manuscript argues that obstetric practice has become overly reliant on EFHRM to identify fetuses sustaining irreversible neurologic injury due to labor induced hypoxia-acidemia, with a resultant overuse of cesarean delivery for perceived fetal benefit, to the detriment of our patients.

This manuscript is persuasively and eloquently argued. It makes use of a combination of personal observation and deep knowledge of the evidence. In particular, it dissects well the fallacy of identifying timing of neurologic injury to intrapartum events, based on the understanding, among other things, of the chronicity of potential neurologic abnormalities. It also makes use of more recent evidence suggesting the low correlation between umbilical cord gas findings at time of delivery, Apgar scores, and long-term neurologic outcomes.

Weaving all this together, this manuscript makes the strong and defensible claim that bold and declarative moves need to be made to de-emphasize the role of EFHRM in clinical decision-making, at least until the time comes that the evidence supports that which we have been doing until now without evidence.

Specific suggestions are as follows, mostly of the stylistic variety:

Lines 37-39: This is a sentence fragment.

Lines 63-64: Also a sentence fragment. Consider combining with the prior sentence.

Line 97: This should be "hypoxia-inducing" instead of "hypoxia-induced."

Lines 92, 129, and 162: For the section headings, consider finding a more consistent language between the three.

"Abnormal babies have abnormal tracings" is fairly concrete, while the other two are figurative. Given that this section of the manuscript is the "key principles" section, I would err on the side of more concrete take-away points as headers.

Lines 129-136: I find the statements herein too strong. There is likely a larger subset than you give credit of current obstetricians who not only are have an eye to the shortcomings of EFHRM, but also practice in a manner that avoids over-reliance on EHFRM leading to non-indicated Cesareans. This reader is one of those obstetricians, and I credit that to being inculcated from the time of medical school with the opposite of a "religious belief" in the value of EFHRM.

Lines 146-152: I agree with this point, and I might add that current hospital protocols involve a great deal of education modules (forced upon nurses and obstetricians) that reinforce the perception that EHFRM is clinically valuable.

Lines 179-181: I agree with this point as well. It may be a good time to reference as an example specifically what is described on page 210 of the ACOG/AAP monograph you cited (ref 5), "Additional fetal heart rate patterns that develop after a Category I fetal heart pattern on presentation, which may suggested intrapartum timing of a hypoxic-ischemic

event, include tachycardia with recurrent decelerations and persistent minimal variability with recurrent decelerations." Lines 210-214: These sentences are redundant with the beginning of the paragraph and could be removed or combined with little loss to the argument.

Reviewer #2:

In this commentary, the author argues that category II intrapartum tracing on EFM unassociated with a sentinel event should be abandoned as a basis for obstetrical intervention -- namely cesarean section--as a means of preventing cerebral palsy. In making this argument the author presents the understood poor positive predictive value associated with EFM and the overall unchanged rate of cerebral palsy. The author argues that it is more likely that abnormal babies have abnormal tracings and that there is a fundamental confusion of cause and effect.

Many of the authors statements are broadly understood and accepted. Few would argue with the fact that intrapartum EFM as a means of preventing cerebral palsy has been a disappointment. And few would argue with the fact that the misuse of EFM medically and medico-legally is not a serious problem.

The following are my questions for the author:

1. Can the author more clearly define the meaning and the means of diagnosis of a sentinel event -- while a cord prolapse or uterine rupture with a priori risk factors may be more or less obvious, an abruption may be more difficult to diagnose. What else does the author define as sentinel events and how best to inform the range of these events with a Category II tracing?
2. The author refers to subtle category II FHR patterns-- can the author better delineate the meaning of subtle? Are there less subtle Category II tracings which should inform decision-making in the absence of a sentinel event, or is the commentary about all category II FHR patterns?
3. The management paradigms around Category II tracing are complex and in part related to the progress of labor -- can the author better inform the commentary around labor management with this dimension? For example should higher doses of pitocin or other uterine stimulants be encouraged in the presence of a Category II tracing in order to advance the progress of labor?
4. Is it the author's position that all Category II tracings should not be acted on until they manifest as a Category III?
5. Given the arguments made regarding the poor positive predictive value of EFM generally and the argument that neurologically abnormal babies have abnormal tracings, what do the authors suggest should be done with a category III tracing absent a sentinel event? Why should this be managed any differently than a Category II tracing? Or should it not be managed any differently absent a sentinel event?

Reviewer #3:

The authors write a commentary about the lack of association of category II intrapartum fetal heart rate patterns and recognized sentinel events.

- The article discusses different aspects of intrapartum continuous electronic fetal heart rate (FHR) monitoring, a highly relevant topic of our routine obstetrical clinical practice. Specifically, the authors address the limitations of category II fetal heart tracing patterns.
- Even though the article mentions some limitations of intrapartum EFM well supported by existing literature, the provided information is mixed with personal views and conceptions making the article confusing and speculative on several instances.
- The article discusses the lack of efficacy of intrapartum electronic fetal monitor to reduce the rate of cerebral palsy. They present data about the stability of cerebral palsy rate between 1985 and 2005. They state that despite the progressive incorporation of EFM along the increasing rate of cesarean delivery the rate of cerebral palsy did not change during this time frame. The most likely explanation is that most cases of neurological injury resulting in cerebral palsy occur during the antepartum period.
- The authors missed the opportunity to cite in their article a systematic review and meta-analysis of randomized and quasi-randomized controlled trials by Alfirevic et al published in 2013 and updated in 2017 (with no new studies) with findings that are relevant for the topic and should be presented in the present article. A summary of findings of the systematic review and meta-analysis are: compared with intermittent auscultation, continuous cardiotocography did not reduce the rate of cerebral palsy (RR 1.75, 95% CI 0.84 to 3.63, n=13,252, two trials). On the other hand, there was a significant increase in the rate of cesarean delivery rate associated with continuous cardiotocography (RR 1.63, 95% CI

1.29 to 2.07, n = 18,861, 11 trials). Overall perinatal death did not change between the interventions, but the neonatal seizure rate was lower with continuous cardiotocography (RR 0.50, 95% CI 0.31 to 0.80, n = 33,513, 11 trials)

- The authors do not support with references the statement written in lines 65 to 67. ACOG Practice Bulletin No 70 states that normal category I tracing is highly predictive of normal fetal acid-base status but does not mention that normal FHR tracing presumes the fetus is neurologically intact as stated by the authors in this paragraph. Recommend adding references to support the statement.

- The authors mention the term "subtle category II FHR patterns" on several occasions in the article but the term is not well defined, and it is not a term used in current clinical practice guidelines in the US. Recommend using standardized definitions of normal and abnormal intrapartum FHR tracings.

- Furthermore, the authors associate "subtle category II FHR patterns" with "depletion of fetal reserve", another term that is not defined, neither supported by a reference(s). The narrative writing in the paragraph from line 78 to line 91 is difficult to follow and the statements don't have references.

- It is well known that the use of intrapartum EFM is associated with increased cesarean delivery, but it is important to mention that cesarean delivery is not immediately indicated in the setting of category II fetal heart tracing in current clinical guidelines in the US. Several interventions such as discontinuation of any labor stimulant such as oxytocin, cervical exam, optimization of maternal blood pressure and maternal positioning should be first taking in place.

- The authors make a good point about the need for a revision of the classification of intrapartum EFM, specifically a better understanding of the implications of category II FHR tracing. This is not an easy task given the ambiguity of the FHR patterns that belong to this category and the poor correlation with adverse perinatal and neonatal outcomes.

- The authors do not go in deep detail about the high interobserver and intraobserver variability interpreting intrapartum FHR tracings neither on the importance of appropriate training and education on the interpretation of intrapartum FHR patterns and management of abnormal FHR patterns.

STATISTICS EDITOR COMMENTS:

The article submitted reports to a very important thematic regarding labor practices and ideologies. It states a strong opinion, scientifically based and looks very important to raise questions regarding the utility of FHR monitoring. It is provocative, but science and innovation needs to be in order to produce any change,

There are some things I would like to be made more clearer:

Line 37. - the reference reports to the results of one study, of one center in the USA; it may not reflect all the USA data and as so I would not make that generalization in the article (it should not be half of 1 million...)

Line 45 - I would not call as recent a systematic review from almost 10 years ago

Line 47 - it should be made more clearer in the article that FHR intends to reduce the incidence of <10% of the cerebral palsy which are truly (apparently) the result of labor; it is difficult to prove the efficacy of any intervention when we are dealing with incidences of <10% of 2/1000; also when we are able to deal more effectively with premature infants (sometimes also from 23 weeks of gestation!), it may be difficult to reduce the totality of cerebral palsy cases. I understand it is an opinion, but readers should be more adequately driven towards that opinion

Line 76 - there is a task force from ACOG in 2014 that should replace reference 22 (out of date)

Line 85 - there should be made a more clearer explanation of subtle category II patterns - readers should clearly understand what is being commented here

Line 107 - reference 28 does not look suitable . the results presented are from reference number 2, a study published in 2021

Line 120 - reference 29 is incorrect I guess; I also suggest looking at the paper from Graham published in 2016 in Nature reviews

Line 124 - I am not sure that all cases of uterine rupture and major placental abruption are detected by FHR auscultation alone; something that should be made more clearer in the article is that, although cerebral palsy rates have not changed With electronic FHR, mortality is virtually inexistent nowadays

Line 139 - not sure if reference 30 is correct

Line 186 . I would add the FIGO recommendations regarding FHR monitoring

I am not sure if it is possible, but I would add a comment towards training; there is some evidence that with more training

results are better with FHR monitoring; a part of the excess of morbidity and interventions (cesarean section or instrumental deliveries) is driven by the inexperienced doctors, even when they look wiser as stated in the text

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased 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.
- B. OPT-OUT: No, please do not publish my point-by-point response letter.

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:

- * Include your title page information in the main manuscript file. The title page should appear as the first page of the document. Add any previously omitted Acknowledgements (ie, meeting presentations, preprint DOIs, assistance from non-byline authors).
- * Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.
- * Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
- * Name the IRB or Ethics Committee institution in the Methods section (if applicable).
- * Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

3. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. When you uploaded your manuscript, each co-author received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

4. 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.

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Current Commentary articles should not exceed 3,000 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

6. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:

- * All financial support of the study must be acknowledged.
- * 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]."

7. Provide a *précis* on the second page, for use in the Table of Contents. The *précis* is a single sentence of no more than 25 words that states the conclusion(s) of the report (ie, the bottom line). The *précis* should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the *précis*. Please avoid phrases like "This paper presents" or "This case presents."

8. 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 Current Commentary articles is 250 words. Please provide a word count.

9. 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.

10. 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.

11. Please review examples of our current reference style at <http://ong.editorialmanager.com> (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources"). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the references you are citing are still current and available. Check the Clinical Guidance page at <https://www.acog.org/clinical> (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document.

If the reference you are citing has been updated and replaced by a newer version, please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

12. Authors whose manuscripts have been accepted for publication have the option to pay an article processing charge and publish open access. With this choice, articles are made freely available online immediately upon publication. An information sheet is available at <http://links.lww.com/LWW-ES/A48>. The cost for publishing an article as open access can be found at <https://wkauthorservices.editage.com/open-access/hybrid.html>.

If your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

If you choose open access, you will receive an Open Access Publication Charge letter from the Journal's Publisher, Wolters Kluwer, and instructions on how to submit any open access charges. The email will be from publicationservices@copyright.com with the subject line, "Please Submit Your Open Access Article Publication Charge(s)." Please complete payment of the Open Access charges within 48 hours of receipt.

If you choose to revise your manuscript, please submit your revision through Editorial Manager at <http://ong.editorialmanager.com>. Your manuscript should be uploaded as a Microsoft Word document. Your revision's cover letter should include the following:

- * 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 Mar 15, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,
Dwight J. Rouse, MD
Deputy Editor, Obstetrics

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd out of 83 ob/gyn journals

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: <https://www.editorialmanager.com/ong/login.asp?a=r>). Please contact the publication office if you have any questions.

3/6/2022

Dear Dr. Rouse:

Please find attached the revised article ***Category II intrapartum fetal heart rate patterns unassociated with recognized sentinel events – Castles in the Air***. All requested changes have been addressed and changed when feasible, as outlined in the Response to Reviewers. I'm happy to make additional modifications if requested.

Sincerely,

Steven L. Clark, MD

Responses to reviewers

Reviewer #1:

This is a commentary on the current (and historical) state of the use of electronic fetal heart rate monitoring in labor management.

This manuscript argues that obstetric practice has become overly reliant on EFHRM to identify fetuses sustaining irreversible neurologic injury due to labor induced hypoxia-acidemia, with a resultant overuse of cesarean delivery for perceived fetal benefit, to the detriment of our patients.

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Weaving all this together, this manuscript makes the strong and defensible claim that bold and declarative moves need to be made to de-emphasize the role of EFHRM in clinical decision-making, at least until the time comes that the evidence supports that which we have been doing until now without evidence. **NO CHANGES REQUESTED**

Specific suggestions are as follows, mostly of the stylistic variety:

Lines 37-39: This is a sentence fragment. **I AM UNCERTAIN TO WHICH LINES THE REVIEWER IS REFERRING AS MY LINE NUMBERING MAY BE DIFFERENT. ALL SENTENCES IN THIS MANUSCRIPT HAVE A SUBJECT AND A PREDICATE, A NOUN AND A VERB. I HAVE OCCASIONALLY DELIBERATELY USED CORRECT, BUT UNUSUAL SYNTAX FOR EMPHASIS (SUCH AS LINE 70 AND LINE 94) I'D LIKE TO KEEP THESE AS WRITTEN, BUT WILL CHANGE THEM IF THE EDITOR FEELS IT MORE APPROPRIATE TO DO SO.**

Lines 63-64: Also a sentence fragment. Consider combining with the prior sentence. **SEE ABOVE**

Line 97: This should be "hypoxia-inducing" instead of "hypoxia-induced." **CHANGED AS REQUESTED**

Lines 92, 129, and 162: For the section headings, consider finding a more consistent language between the three. "Abnormal babies have abnormal tracings" is fairly concrete, while the other two are figurative. Given that this section of the manuscript is the "key principles" section, I would err on the side of more concrete take-away points as headers. **CHANGED AS REQUESTED**

Lines 129-136: I find the statements herein too strong. There is likely a larger subset than you give credit of current obstetricians who not only are have an eye to the shortcomings of EFHRM, but also practice in a manner that avoids over-reliance on EHFRM leading to non-indicated Cesareans. This reader is one of those obstetricians, and I credit that to being inculcated from the time of medical school with the opposite of a "religious belief" in the value of EFHRM. **THE "VIRTUALLY EVERY" HAS BEEN SOFTENED TO "MOST."**

Lines 146-152: I agree with this point, and I might add that current hospital protocols involve a great deal of education modules (forced upon nurses and obstetricians) that reinforce the perception that EHFRM is clinically valuable. **MENTION OF EDUCATIONAL MODULES HAS BEEN ADDED**

Lines 179-181: I agree with this point as well. It may be a good time to reference as an example specifically what is described on page 210 of the ACOG/AAP monograph you cited (ref 5), "Additional fetal heart rate patterns that develop after a Category I fetal heart pattern on presentation, which may suggested intrapartum timing of a hypoxic-ischemic event, include tachycardia with recurrent decelerations and persistent minimal variability with recurrent decelerations." **THIS ENTIRE QUOTE HAS BEEN ADDED – LINES 171-175 IN THE REVISED MANUSCRIPT.**

Lines 210-214: These sentences are redundant with the beginning of the paragraph and could be removed or combined with little loss to the argument. **DELETED**

Reviewer #2:

In this commentary, the author argues that category II intrapartum tracing on EFM unassociated with a sentinel event should be abandoned as a basis for obstetrical intervention -- namely cesarean section-- as a means of preventing cerebral palsy. In making this argument the author presents the understood poor positive predictive value associated with EFM and the overall unchanged rate of cerebral palsy. The author argues that it is more likely that abnormal babies have abnormal tracings and that there is a fundamental confusion of cause and effect. **NO CHANGE IS REQUESTED. HOWEVER, I HAVE NOT ARGUED THAT THIS PRACTICE SHOULD BE ABANDONED, BUT RATHER THAT WE SIMPLY HAVE TO BITE THE BULLET AND CONDUCT THE APPROPRIATE CLINICAL TRIALS IF WE ARE TO CONTINUE IT. THIS SHOULD BE CLEAR IN THE FINAL SENTENCE OF THE MANUSCRIPT.**

Many of the authors statements are broadly understood and accepted. Few would argue with the fact that intrapartum EFM as a means of preventing cerebral palsy has been a disappointment. And few would argue with the fact that the misuse of EFM medically and medico-legally is not a serious problem.

The following are my questions for the author:

1. Can the author more clearly define the meaning and the means of diagnosis of a sentinel event -- while a cord prolapse or uterine rupture with a priori risk factors may be more or less obvious, an abruption may be more difficult to diagnose. What else does the author define as sentinel events and how best to inform the range of these events with a Category II tracing? **THIS HAS BEEN CLARIFIED IN THE REVISED MANUSCRIPT.**
2. The author refers to subtle category II FHR patterns-- can the author better delineate the meaning of subtle? Are there less subtle Category II tracings which should inform decision-making in the absence of a sentinel event, or is the commentary about all category II FHR patterns? **THIS HAS BEEN CLARIFIED IN THE REVISED MANUSCRIPT.**
3. The management paradigms around Category II tracing are complex and in part related to the progress of labor -- can the author better inform the commentary around labor management with this dimension? For example should higher doses of pitocin or other uterine stimulants be encouraged in the presence of a Category II tracing in order to advance the progress of labor? **A COMMENT REGARDING PROGRESS OF LABOR HAS BEEN ADDED IN THE REVISED MANUSCRIPT.**
4. Is it the author's position that all Category II tracings should not be acted on until they manifest as a Category III? **NO. IN FACT THE MANUSCRIPT MAKES CLEAR THE VALUE OF ACTING ON SOME CATEGORY II PATTERNS.**
5. Given the arguments made regarding the poor positive predictive value of EFM generally and the argument that neurologically abnormal babies have abnormal tracings, what do the authors suggest should be done with a category III tracing absent a sentinel event? Why should this be managed any differently than a Category II tracing? Or should it not be managed any differently absent a sentinel event? **OF COURSE, NO ONE KNOWS, WHICH IS THE POINT OF THE PAPER. HOWEVER, I HAVE ADDED A SENTENCE TO THIS EFFECT IN THE REVISED MANUSCRIPT – LINES 231-232**

Reviewer #3:

The authors write a commentary about the lack of association of category II intrapartum fetal heart rate patterns and recognized sentinel events.

- The article discusses different aspects of intrapartum continuous electronic fetal heart rate (FHR) monitoring, a highly relevant topic of our routine obstetrical clinical practice. Specifically, the authors address the limitations of category II fetal heart tracing patterns. **NO CHANGE REQUESTED**
- Even though the article mentions some limitations of intrapartum EFM well supported by existing literature, the provided information is mixed with personal views and conceptions making the

article confusing and speculative on several instances. **PERSONAL VIEWS ARE WHY IT IS SUBMITTED AS A COMMENTARY RATHER THAN ORIGINAL RESEARCH.**

- The article discusses the lack of efficacy of intrapartum electronic fetal monitor to reduce the rate of cerebral palsy. They present data about the stability of cerebral palsy rate between 1985 and 2005. They state that despite the progressive incorporation of EFM along the increasing rate of cesarean delivery the rate of cerebral palsy did not change during this time frame. The most likely explanation is that most cases of neurological injury resulting in cerebral palsy occur during the antepartum period.

NO CHANGE REQUESTED

- The authors missed the opportunity to cite in their article a systematic review and meta-analysis of randomized and quasi-randomized controlled trials by Alfievic et al published in 2013 and updated in 2017 (with no new studies) with findings that are relevant for the topic and should be presented in the present article. A summary of findings of the systematic review and meta-analysis are: compared with intermittent auscultation, continuous cardiotocography did not reduce the rate of cerebral palsy (RR 1.75, 95% CI 0.84 to 3.63, n=13,252, two trials). On the other hand, there was a significant increase in the rate of cesarean delivery rate associated with continuous cardiotocography (RR 1.63, 95% CI 1.29 to 2.07, n = 18,861, 11 trials). Overall perinatal death did not change between the interventions, but the neonatal seizure rate was lower with continuous cardiotocography (RR 0.50, 95% CI 0.31 to 0.80, n = 33,513, 11 trials) **REFERENCE AND DISCUSSION ADDED- LINES 83-85 OF REVISED MANUSCRIPT**

- The authors do not support with references the statement written in lines 65 to 67. ACOG Practice Bulletin No 70 states that normal category I tracing is highly predictive of normal fetal acid-base status but does not mention that normal FHR tracing presumes the fetus is neurologically intact as stated by the authors in this paragraph. Recommend adding references to support the statement. **WE DO NOT CLAIM THAT ACOG SAYS THIS.**

- The authors mention the term "subtle category II FHR patterns" on several occasions in the article but the term is not well defined, and it is not a term used in current clinical practice guidelines in the US. Recommend using standardized definitions of normal and abnormal intrapartum FHR tracings. **ONE OF THE MAIN POINTS OF THIS DISCUSSION, MADE SEVERAL TIMES THROUGHOUT THE TEXT IS THAT CURRENT TERMINOLOGY IS INSUFFICIENT AND MISLEADING – WE CANNOT USE SUCH “STANDARD” TERMINOLOGY TO DESCRIBE THE NON-UTILITY OF SUCH TERMINOLOGY. WE HAVE CLEARLY OUTLINED WHAT WE MEAN WHEN WE SAY “SUBTLE PATTERNS” AND THE OTHER REVIEWERS UNDERSTOOD THIS. FURTHER, WE HAVE CLEARLY SUGGESTED A REMEDY – PLACE THE DRAMATIC DECELERATION/SENTINAL EVENT TRACINGS IN THE CATEGORY III GROUP, AND LEAVE THE LESS WELL DEFINED SUBTLE CHANGES IN A CATEGORY II GROUP WHILE STATING THERE IS NO EVIDENCE-BASED STANDARD OF CARE FOR THIS GROUP OF TRACINGS.**

- Furthermore, the authors associate "subtle category II FHR patterns" with "depletion of fetal reserve", another term that is not defined, neither supported by a reference(s). The narrative writing in the paragraph from line 78 to line 91 is difficult to follow and the statements don't have references. **YES THEY DO HAVE REFERENCES – REFS 19-22 ARE CLEARLY REFERENCED NEAR THE END OF THIS PARAGRAPH. FOR OBVIOUS REASONS, THE “DEPLETION OF FETAL RESERVE” CANNOT BE REFERENCED SINCE IT IS A NON-EVIDENCED BASED MYTH WITH NO REFERENCES; BUT ANY READER OF THIS JOURNAL WILL BE FAMILIAR WITH THIS CONCEPT.**

- It is well known that the use of intrapartum EFM is associated with increased cesarean delivery, but it is important to mention that cesarean delivery is not immediately indicated in the setting of category II fetal heart tracing in current clinical guidelines in the US. Several interventions such as discontinuation of any labor stimulant such as oxytocin, cervical exam, optimization of maternal blood pressure and maternal positioning should be first taking in place. **TRUE, BUT WE NEVER CLAIM OTHERWISE. A DETAILED DISCUSSION OF CONSERVATIVE MEASURES WOULD MAKE THIS MANUSCRIPT TOO LONG FOR THE 3000 WORD LIMIT.**

- The authors make a good point about the need for a revision of the classification of intrapartum EFM, specifically a better understanding of the implications of category II FHR tracing. This is not an easy task given the ambiguity of the FHR patterns that belong to this category and the poor correlation with adverse perinatal and neonatal outcomes. **NO CHANGE CALLED FOR**
- The authors do not go in deep detail about the high interobserver and intraobserver variability interpreting intrapartum FHR tracings neither on the importance of appropriate training and education on the interpretation of intrapartum FHR patterns and management of abnormal FHR patterns. **I DO NOT GO INTO DEEP DETAIL DUE TO JOURNAL MANDATED SPACE LIMITATIONS AND THE FACT THAT SUCH VARIABILITY IS WELL RECOGNIZED. HOWEVER, I HAVE ADDED MENTION OF THIS IN THE REVISED MANUSCRIPT; REFERENCE 35 ALSO HIGHLIGHTS THIS PROBLEM.**

STATISTICS EDITOR COMMENTS:

The article submitted reports to a very important thematic regarding labor practices and ideologies. It states a strong opinion, scientifically based and looks very important to raise questions regarding the utility of FHR monitoring. It is provocative, but science and innovation needs to be in order to produce any change, **THANK YOU. NO CHANGE CALLED FOR**

There are some things I would like to be made more clearer:

Line 37. - the reference reports to the results of one study, of one center in the USA; it may not reflect all the USA data and as so I would not make that generalization in the article (it should not be half of 1 million...)**CHANGED TO READ "APPROXIMATELY HALF..."**

Line 45 - I would not call as recent a systematic review from almost 10 years ago **WHEN YOU ARE AS OLD AS I AM, 10 YEARS SEEMS PRETTY RECENT. BUT I HAVE ELIMINATED THE WORD "RECENT" IN THE REVISED MANUSCRIPT.**

Line 47 - it should be made more clearer in the article that FHR intends to reduce the incidence of <10% of the cerebral palsy which are truly (apparently) the result of labor; it is difficult to prove the efficacy of any intervention when we are dealing with incidences of <10% of 2/1000; also when we are able to deal more effectively with premature infants (sometimes also from 23 weeks of gestation!), it may be difficult to reduce the totality of cerebral palsy cases. I understand it is an opinion, but readers should be more adequately driven towards that opinion **THIS HAS BEEN EMPHASIZED WITH CITATION OF THE 10% ESTIMATION IN THE REVISED MANUSCRIPT, LINES 97-98**

Line 76 - there is a task force from ACOG in 2014 that should replace reference 22 (out of date) **CHANGED. SEE REFERENCE 9**

Line 85 - there should be made a more clearer explanation of subtle category II patterns - readers should clearly understand what is being commented here **THIS HAS BEEN EXPANDED/CLARIFIED IN THE REVISED MANUSCRIPT**

Line 107 - reference 28 does not look suitable . the results presented are from reference number 2, a study published in 2021 **REFERENCE 28 DOES IN FACT ADDRESS THIS ISSUE, BUT WE HAVE ADDED REFERENCE 2 TO THIS STATEMENT, SINCE IT APPLIES AS WELL.**

Line 120 - reference 29 is incorrect I guess; I also suggest looking at the paper from Graham published in 2016 in Nature reviews **REFERENCE CORRECTED**

Line 124 - I am not sure that all cases of uterine rupture and major placental abruption are detected by FHR auscultation alone; **WE JUST SAID THAT IN GENERAL, SUCH EVENTS WOULD BE MANIFEST AND DETECTED BY SUCH FINDINGS. WE DID NOT SAY THEY ALL WERE.** something that should be made more clearer in the article is that, although cerebral palsy rates have not changed With electronic FHR, mortality is virtually inexistent nowadays **THIS IS CLEARLY STATED IN THE SECOND LINE OF THE INTRODUCTION.**

Line 139 - not sure if reference 30 is correct **THIS HAS BEEN CORRECTED**

Line 186 . I would add the FIGO recommendations regarding FHR monitoring **ADDED, NEW REFERENCE 34**

I am not sure if it is possible, but I would add a comment towards training; there is some evidence that with more training results are better with FHR monitoring; a part of the excess of morbidity and interventions (cesarean section or instrumental deliveries) is driven by the inexperienced doctors, even when they look wiser as stated in the text **SPACE LIMITATIONS PRECLUDE ADDITIONAL DISCUSSION. FURTHER, I DON'T KNOW THAT THIS IS TRUE – THIS IS PART OF MY THESIS – NO MATTER HOW WELL WE TRAIN PEOPLE TO RECOGNIZE IRRELEVANT PATTERNS, SUCH RECOGNITION WILL NOT IMPROVE OUTCOMES.**

EDITORIAL OFFICE COMMENTS:

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4. 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://urldefense.proofpoint.com/v2/url?u=https-3A_www.acog.org_practice-2Dmanagement_health-2Dit-2Dand-2Dclinical-2Dinformatics_revitalize-2Dobstetrics-2Ddata-2Ddefinitions&d=DwIGaQ&c=ZQs-KZ8oxEw0p81sggiaRA&r=bj-F4_TD3UcNPgiMcU9uKBTy7VAns4bhcw4DK1QA8O4&m=zyqPKM5oOxMW1MYlwndnw346EjYquc7DIOSceVQIGW0Okcm0BZi183MX38nyNDQN&s=k7Slzj88tHwkht5CwQhSUMK4UM9sP-dT5wHdqpmDV3Q&e= and the gynecology data definitions at https://urldefense.proofpoint.com/v2/url?u=https-3A_www.acog.org_practice-2Dmanagement_health-2Dit-2Dand-2Dclinical-2Dinformatics_revitalize-2Dgynecology-2Ddata-2Ddefinitions&d=DwIGaQ&c=ZQs-KZ8oxEw0p81sggiaRA&r=bj-F4_TD3UcNPgiMcU9uKBTy7VAns4bhcw4DK1QA8O4&m=zyqPKM5oOxMW1MYlwndnw346EjYquc7DIOSceVQIGW0Okcm0BZi183MX38nyNDQN&s=lq1Su62TSu0it3SThcdJcdqzjR5DLM7johReZBZ2g_w&e= . If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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