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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)*
- Email correspondence between the editorial office and the authors*

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.

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

Date: Apr 26, 2019

To: "Han-Yang Chen"

From: "The Green Journal" em@greenjournal.org

Subject: Your Submission ONG-19-660

RE: Manuscript Number ONG-19-660

Neonatal and Maternal Morbidity among Low-Risk Parous Women at 39 to 41 Weeks of Gestation

Dear Dr. Chen:

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 May 17, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: The authors aim to compare neonatal and maternal morbidity related to delivery week-by-week from 39 to 41 weeks gestation among low-risk parous women. There are many typos throughout the manuscript. Will need a very careful proofread. I have the following additional comments:

Methods

- 1. Birth certificate data are typically reliable for race/ethnicity and gestational age at delivery. I am concerned about data validity for the morbidity endpoints. Can the authors provide references demonstrating the validity of these data for the selected outcomes?
- 2. Line 99. It is more common to see a morbidity measure of Apgar <7 at 5-minutes. Why did the investigators choose Apgar <5? Can a reference be provided?
- 3. Line 103. Did the authors include women with a history of cesarean delivery? The incidence of uterine rupture would be incredibly low in women with no prior cesarean. There are data regarding history of cesarean delivery and TOLAC on the 2003 version of the birth certificate so this information was available. Why was it not used to exclude women from the analysis?
- 4. How is "low risk" defined for the purposes of this analysis?
- 5. Was there a way to exclude women with a contraindication to vaginal delivery (eg previa, accreta)?
- 6. For the maternal morbidity composite, it appears that the authors chose to include everything available on the birth certificate under maternal morbidity except for 3rd/4th degree laceration (reference 13). Why was higher order laceration the only component of recorded maternal morbidity on the birth certificate that was not included?
- 7. The same is true for neonatal morbidity. Some of the available neonatal morbidity outcomes on the birth certificate were selected and others were not. It may be valuable for the authors to discuss why they selected the neonatal morbidity outcomes that they did.

Results

8. It seems like the majority of the morbidity difference stems from women beyond 41 weeks. I think we already know that we should not expectantly manage beyond 41 weeks so I am not sure how much this paper adds to the literature.

9. The authors adjusted for what was available to them on the birth certificate. Unfortunately, these data are largely incomplete when considering all the possible confounding variables related to gestational age at delivery and perinatal outcomes.

Discussion

- 10. Line 188. It is the Society for Maternal-Fetal Medicine. Not Society of...
- 11. Line 193. The authors call for a RCT to evaluate outcomes in parous women induced at 39 weeks vs expectant management. Such a trial would need to be huge given the adverse event difference between the groups was much less than 1 per 1000. Consider adding a sample size calculation for such a trial.

Reviewer #2: This is a population based retrospective study using birth certificate data. The aim of the study was to compare birth outcomes of multiparous women when delivered between 39-39 6/7 weeks vs. 40 - 40 6/7 and 41 - 41 6/7 weeks. The authors found that both neonatal and maternal complications rose with each successive week.

- 1. The authors excluded mothers with hypertensive disorders. As they noted, this is a risk with increasing gestational age. Could the authors do a secondary analysis including those mothers?
- 2. Given that the authors' conclusions are consistent with most studies, including the recent ARRIVE trial, one wonders why the conclusions seem milquetoast.
- 3. As the authors are aware, in the last decade, ACOG and SMFM have recommended not to perform elective deliveries before 39 weeks. In fact, many hospital and even Medicaid programs use this as a quality measure of obstetric care. I certainly agree with this practice guideline but the evidence for it was mainly retrospective. Much like the authors' submission.
- 4. Therefore, should the authors make a stronger case that the National recommendations should be delivery BETWEEN 39 and 40 6/7 weeks? Perhaps the authors can compare the complications they noted at 40 and 41 weeks with what has been reported at 38 and 37 weeks.

Reviewer #3: ONG-19-660

General:

1. This is an important study as almost 2/3 of births in the US occur to parous women. While the adjusted RR is small (<2.0) implying this may not be a statistically significant difference between groups, the trend increases as GA increases, and the "N" is extremely large, I feel the results are clinically important. As the authors state, a large RCT should be conducted to corroborate these results, but this remains an important starting point.

Abstract:

2. The abstract succintly states the rationale and methodology of the study. The primary and secondary outcomes to be investigated, and the results and conclusions are clearly elaborated.

Introduction:

3. The introduction clearly states the importance of the study. Although nulliparous women have been well studied (by the same authors and others), whether those findings apply equally as well to multiparous women, has not yet been thoroughly investigated in a large cohort. The primary (neonatal) and secondary (maternal) outcomes at 39 vs. 40-41 weeks are clearly reiterated.

Methods:

4. This is a retrospective cohort study of low risk pregnancy in parous women using the revised (2003) birth certificate data available through federal registers. The revision of the criteria for assigning the GA enhances the validity of the ascertainment of GA, making the findings more credible in actual practice. The neonatal and maternal outcomes investigated are clearly delineated. The added detail of explaining the use of sensitivity analysis to address maternal PPH, probably not totally familiar to clinicians, is clearly explained.

Results:

5. The low cesarean birth rate is impressive, but not unexpected in this group of low risk multiparas. The overall rate of neonatal complications, while low in general, are clearly increased as GA advances, but the low aRR is still statistically significant in this very large cohort, but, as noted above, may be not be as clinically relevant. The maternal morbidity

clearly appears increased at 41 weeks, but again the aRR of <2.0 still raises doubts about the clinical significance.

Discussion:

6. This section nicely summarizes the results, acknowledging that the combined neonatal morbidity (5/1000) and maternal morbidity (2/1000) are low, but clinically and economically important due the large number of parous women and their infants involved (>1.2 million). This helps to remedy the knowledge gap about this large group of parturients, and likewise tends to acknowledge the significance of the findings despite the low aRR. The authors appropriately suggest that a large RCT, as was carried out with primiparous women, is indicated to confirm these observations. The strengths and limitations are well reviewed, and the fact that PPH and PEC were not well included in maternal outcomes is acknowledged.

References:

7. The references are adequate, including significantly smaller studies that nevertheless reflect the findings of this investigation.

Tables:

- 8. The tables are exceptionally thorough, and because they are so detailed, may make them a bit "overwhelming" for the clinician, and perhaps they could be simplified.
- 9. The Figure is also very clear and, I feel, helpful for clinicians.
- 10. The inclusion of the "STROBE Statement", likewise probably not very familiar to clinicians, is helpful, and demonstrates the attention to detail of the authors.

STATISTICAL EDITOR'S COMMENTS:

- 1. Table 2: Both the study samples and the numbers of adverse outcomes are large, justifying multiple variable adjustment. However, it would enhance the conclusions if additional corroboration were done by matching subsets of the 40 and 41 week cohorts to the 39 week referent cohort by the variables that differed at baseline. Also, the RR and aRR are useful and appropriate metrics, but it would also be useful for the reader if the rates per 1000 births (with CI) were included, along with the predicted differential rate of adverse neonatal morbidity per 1000 (or per 10,000) births if deliveries hypothetically occurred at 39 wks rather than at 40 or 41 wks.
- 2. Table 3: Same comments re: additional matching analysis and stating of absolute difference in rates of maternal morbidities. Also, the composite neonatal adverse outcome included mortality, while the adverse composite maternal does not. Likely the counts would have insufficient power and may have a NS difference, but it would be useful for the reader to separately show data re: maternal morbidity. Given the size of the data set, likely there are a non-trivial number of maternal mortalities in this series.
- 3. Table 4: Same suggestion for matching algorithm and stating results as absolute differences in rates per 1000 live births.

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, as well as subsequent author queries. 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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- 2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.
- 2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

3. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration

statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained." *The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

- 4. In order for an administrative database study to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.
- 5. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works. Variance is needed in the following sections:
- a. ABSTRACT: The entire abstract is nearly identical to the abstract of your April 2019 O&G article "Neonatal and Maternal Morbidity Among Low-Risk Nulliparous Women at 39–41 Weeks of Gestation." Please significantly modify the text of your abstract.
- b. LINES 73-5 ("These data, ascertained....within the first year").
- 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 and gynecology data definitions at https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize. 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.
- 8. 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).
- 9. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot.
- 10. 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 limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

- 11. 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.
- 12. 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.
- 13. 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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* * *

If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at http://ong.editorialmanager.com. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

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 May 17, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982

2017 IMPACT FACTOR RANKING: 5th out of 82 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.

5 5/13/2019, 10:46 AM

May 6, 2019

Nancy C. Chescheir, MD Editor-in-Chief Obstetrics & Gynecology 409 12th Street, SW Washington, DC 20024-2188

RE: Manuscript Number ONG-19-660

Neonatal and Maternal Morbidity among Low-Risk Multiparous Women at 39 to 41 Weeks of Gestation

Dear Dr. Chescheir:

Thank you kindly for considering the above-mentioned manuscript for publication in *Obstet Gynecol*.

Per your instructions, we have responded point-by-point to each of the suggestions by the reviewers and the statistical editor (please see below).

We are attaching:

- 1. Red ink copy of the revised manuscript and
- 2. Clean copy of the revised manuscript.

Please note that in our response to the reviewers and editors, the line number refers to the red ink version (and not the clean copy) of the revised manuscript.

The lead author affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained."

We truly appreciate your consideration of our manuscript and look forward to seeing it in print.

Sincerely yours,

Han-Yang Chen, Ph.D. Assistant Professor

REVIEWER COMMENTS:

Reviewer #1: The authors aim to compare neonatal and maternal morbidity related to delivery week-by-week from 39 to 41 weeks gestation among low-risk parous women. There are many typos throughout the manuscript. Will need a very careful proofread.

Response: We appreciate the reviewer's comments regarding the multiple typographical error throughout the manuscript. We have reviewed the manuscript and had an external proof reader review the revised manuscript.

I have the following additional comments:

Methods:

1. Birth certificate data are typically reliable for race/ethnicity and gestational age at delivery. I am concerned about data validity for the morbidity endpoints. Can the authors provide references demonstrating the validity of these data for the selected outcomes?

Response: We appreciate the reviewer's comments regarding the validity of the selected outcomes. We include this limitation the revised manuscript (lines 231-237): "Finally, since some health and medical items are likely underreported, research based on birth certificates has been criticized;²² however, studies evaluating birth certificate data have consistently shown that the demographic and selected medical and health items (i.e., method of delivery, birth weight, and plurality) are collected with a high degree of completeness and accuracy.²³ Although maternal morbidity measures have been added to the birth data files since 2011, there is a paucity of research assessing the validity of maternal morbidity measures.²⁴"

2. Line 99. It is more common to see a morbidity measure of Apgar <7 at 5-minutes. Why did the investigators choose Apgar <5? Can a reference be provided?

Response: We appreciate the reviewer's inquiry of why we used Appar < 5 at 5 minutes. According to ACOG workshop on neonatal encephalopathy (second edition; 2014), Appar score < 5 at 5 minutes (and at 10 minutes) is a neonatal sign consistent with acute intrapartum or peripartum event. We have added this reference in the manuscript (line 103).

3. Line 103. Did the authors include women with a history of cesarean delivery? The incidence of uterine rupture would be incredibly low in women with no prior cesarean. There are data regarding history of cesarean delivery and TOLAC on the 2003 version of the birth certificate so this information was available. Why was it not used to exclude women from the analysis?

Response: We appreciate the reviewer's request to clarify if in our analysis we included women who had prior cesarean delivery. In our analysis we consider low risk women as those who labored (vaginal delivery or labor with subsequent cesarean delivery) during the current delivery. Our original analysis did not exclude women with a history of cesarean delivery if they labored.

In the revision, we have conducted a second sensitivity analysis to exclude women with a prior cesarean, and our findings showed consistent results that the risk of composite neonatal and maternal morbidity increases, from 39 through 41 weeks' gestation, albeit modestly (lines 178-181, Table 5).

4. How is "low risk" defined for the purposes of this analysis?

Response: We appreciate the reviewer's request for clarification about what constituted low-risk pregnancy. Consistent with the definition in reference #2, low-risk pregnancy was defined as women who had "singleton, non-anomalous gestations, who did not have hypertensive disorders, pregestational or gestational diabetes, labored (vaginal delivery or labor with subsequent cesarean delivery) from 39 through 41 weeks, had cephalic presentations (lines 79-83)." we have conducted a second sensitivity analysis to exclude women with a prior cesarean delivery (see response to Q3 above)

5. Was there a way to exclude women with a contraindication to vaginal delivery (eg previa, accreta)?

Response: We appreciate the reviewer's request to clarify if we excluded women who had a contraindication to vaginal delivery, like abnormal placentation. Since the cohort consists of women who labored (line 81), women in whom vaginal delivery was contraindicated were excluded.

6. For the maternal morbidity composite, it appears that the authors chose to include everything available on the birth certificate under maternal morbidity except for 3rd/4th degree laceration (reference 13). Why was higher order laceration the only component of recorded maternal morbidity on the birth certificate that was not included?

Response: We appreciate the reviewer's inquiry of why we excluded 3rd and 4th degree lacerations from the composite morbidity. We excluded them because the National Quality Forum to ultimately withdraw their endorsement of OASIS as a quality indicator because it is not an appropriate measure of value (see details below). It should be noted that the composite morbidity is congruent with what is included in reference #2.

American College of Obstetricians and Gynecologists' Committee on Practice Bulletins—Obstetrics. Practice Bulletin No. 165: Prevention and Management of Obstetric Lacerations at Vaginal Delivery. Obstet Gynecol. 2016;128(1):e1-e15.

The Practice Bulletins states that ".....The Joint Commission included OASIS in its 2002 Pregnancy and Related Conditions Core Measure set. The Agency for Healthcare Research and Quality has proposed third-degree and fourth-degree lacerations as patient safety indicators, and the National Quality Forum adopted OASIS as a quality measure in 2003. Since adoption, however, the low rates of these injuries have not decreased. Unreliable data collection is cited as one of the reasons for the lack of reduction in OASIS because obstetrician—gynecologists and other obstetric care providers may be unlikely to code third-degree lacerations that do not extend through the anal sphincter complex.

Additionally, a number of OASIS risk factors are not modifiable, many of which may be due to childbirth itself or actions necessary to facilitate safe childbirth, and are not necessarily reflective of the routine practice of obstetrician—gynecologists and other obstetric care providers. These factors led the National Quality Forum to ultimately withdraw their endorsement of OASIS as a quality indicator because it is not an appropriate measure of value."

7. The same is true for neonatal morbidity. Some of the available neonatal morbidity outcomes on the birth certificate were selected and others were not. It may be valuable for the authors to discuss why they selected the neonatal morbidity outcomes that they did.

Response: We appreciate the reviewer's request for clarification about how we selected some but not all of the morbidity available in the birth-certificate. We selected these outcomes because respiratory support was a component of the primary outcome of ARRIVE trial, because low Apgar score and neonatal seizure are associated with long term sequelae, and because we wanted to be consistent with outcomes noted in reference #2.

Results

8. It seems like the majority of the morbidity difference stems from women beyond 41 weeks. I think we already know that we should not expectantly manage beyond 41 weeks so I am not sure how much this paper adds to the literature.

Response: The reviewer suggests that most of the composite maternal and neonatal morbidity occurs beyond 41 weeks, which we should avoid. Additionally, the reviewer thinks that our manuscript may not add much to the literature.

For the following three reasons, we respectfully disagree with this comment of reviewer #1. First, as noted in Tables 2 to 4, the composite maternal and neonatal morbidities, along with several of their components, are significantly higher at 40 weeks than 39 weeks. Even though the absolute rate of the morbidity is low at 40 weeks, since one-third of low-risk women deliver at 40 weeks, the adverse outcomes have noticeable burden of disease. Second, we provided the data at 41 weeks and not beyond 41 weeks. Third, about 1 in 10 low-risk pregnancies that met the inclusion criteria delivered at 41 weeks, providing that women and clinicians do continue to delivery beyond 40 weeks.

9. The authors adjusted for what was available to them on the birth certificate. Unfortunately, these data are largely incomplete when considering all the possible confounding variables related to gestational age at delivery and perinatal outcomes.

Response: We concur, to some extent, with the reviewer and included that in the limitation (lines 215-217). Nonetheless, our results were consistent with prior studies and data from these certificate do provide opportunities to identify factors associated with adverse outcomes.

Discussion

10. Line 188. It is the Society for Maternal-Fetal Medicine. Not Society of...

Response: The reviewer is quite correct that it is the Society of Maternal-Fetal Medicine and not Society for... The revised manuscript has the correct verbiage (line 200).

11. Line 193. The authors call for a RCT to evaluate outcomes in parous women induced at 39 weeks vs expectant management. Such a trial would need to be huge given the adverse event difference between the groups was much less than 1 per 1000. Consider adding a sample size calculation for such a trial.

Response: The reviewer requests a sample size for a potential randomized trial comparing the outcomes with induction vs. expectant management of low-risk parous women at 39 weeks. In the revised manuscript we clarify that the trial we propose should have a primary outcome similar to ARRIVE (lines 241-242) and not the composite we delineated here.

Reviewer #2: This is a population based retrospective study using birth certificate data. The aim of the study was to compare birth outcomes of multiparous women when delivered between 39-39 6/7 weeks vs. 40 - 40 6/7 and 41 - 41 6/7 weeks. The authors found that both neonatal and maternal complications rose with each successive week.

1. The authors excluded mothers with hypertensive disorders. As they noted, this is a risk with increasing gestational age. Could the authors do a secondary analysis including those mothers?

Response: We appreciate the reviewer's comment. Since our study focuses on low risk women, a secondary analysis including high risk mothers (with hypertensive disorders) contradicts our study goal.

2. Given that the authors' conclusions are consistent with most studies, including the recent ARRIVE trial, one wonders why the conclusions seem milquetoast.

Response: We appreciate the reviewer's comment. Although our results were consistent with most studies, we acknowledge that our results were from an observational (retrospective cohort) study and the rate of composite neonatal and maternal morbidity increases, albeit modestly, from 39 through 41 weeks of gestation.

3. As the authors are aware, in the last decade, ACOG and SMFM have recommended not to perform elective deliveries before 39 weeks. In fact, many hospital and even Medicaid programs use this as a quality measure of obstetric care. I certainly agree with this practice guideline but the evidence for it was mainly retrospective. Much like the authors' submission.

Response: We concur with the reviewer about the retrospective nature of the studies which promulgated the "39-week" rule and our study.

4. Therefore, should the authors make a stronger case that the National recommendations should be delivery BETWEEN 39 and 40 6/7 weeks? Perhaps the authors can compare the complications they noted at 40 and 41 weeks with what has been reported at 38 and 37 weeks.

Response: The reviewer suggests that based on this analysis if we would consider making a national recommendation of delivery between 39 and 40 weeks. Though the suggestion is tantalizing, we rather not for two reasons. First, whenever feasible national guidelines should be based on randomized trials. Second, the trial by Grobman et al (reference # 1) has already prompted recommendations by SMFM and ACOG (reference # 18).

Reviewer #3: ONG-19-660

General:

1. This is an important study as almost 2/3 of births in the US occur to parous women. While the adjusted RR is small (<2.0) implying this may not be a statistically significant difference between groups, the trend increases as GA increases, and the "N" is extremely large, I feel the results are clinically important. As the authors state, a large RCT should be conducted to corroborate these results, but this remains an important starting point.

Response: We truly appreciate that the reviewer's nod that the results are potentially "clinically important."

Abstract:

2. The abstract succinctly states the rationale and methodology of the study. The primary and secondary outcomes to be investigated, and the results and conclusions are clearly elaborated.

Response: We truly appreciate reviewer's remarks about our abstract.

Introduction:

3. The introduction clearly states the importance of the study. Although nulliparous women have been well studied (by the same authors and others), whether those findings apply equally as well to multiparous women, has not yet been thoroughly investigated in a large cohort. The primary (neonatal) and secondary (maternal) outcomes at 39 vs. 40-41 weeks are clearly reiterated.

Response: We truly appreciate reviewer's remarks about our introduction.

Methods:

4. This is a retrospective cohort study of low risk pregnancy in parous women using the revised (2003) birth certificate data available through federal registers. The revision of the criteria for assigning the

GA enhances the validity of the ascertainment of GA, making the findings more credible in actual practice. The neonatal and maternal outcomes investigated are clearly delineated. The added detail of explaining the use of sensitivity analysis to address maternal PPH, probably not totally familiar to clinicians, is clearly explained.

Response: We truly appreciate reviewer's remarks about our methods, particularly the use of sensitivity analysis.

Results:

5. The low cesarean birth rate is impressive, but not unexpected in this group of low risk multiparas. The overall rate of neonatal complications, while low in general, are clearly increased as GA advances, but the low aRR is still statistically significant in this very large cohort, but, as noted above, may be not be as clinically relevant. The maternal morbidity clearly appears increased at 41 weeks, but again the aRR of <2.0 still raises doubts about the clinical significance.

Response: We truly appreciate reviewer's remarks about our results. We acknowledge that the rate of composite neonatal and maternal morbidity increases, albeit modestly, from 39 through 41 weeks of gestation, but these results are "clinically important."

Discussion:

6. This section nicely summarizes the results, acknowledging that the combined neonatal morbidity (5/1000) and maternal morbidity (2/1000) are low, but clinically and economically important due the large number of parous women and their infants involved (>1.2 million). This helps to remedy the knowledge gap about this large group of parturients, and likewise tends to acknowledge the significance of the findings despite the low aRR. The authors appropriately suggest that a large RCT, as was carried out with primiparous women, is indicated to confirm these observations. The strengths and limitations are well reviewed, and the fact that PPH and PEC were not well included in maternal outcomes is acknowledged.

Response: We truly appreciate reviewer's remarks about our discussion.

References:

7. The references are adequate, including significantly smaller studies that nevertheless reflect the findings of this investigation.

Response: We truly appreciate reviewer's remarks about references.

Tables:

8. The tables are exceptionally thorough, and because they are so detailed, may make them a bit "overwhelming" for the clinician, and perhaps they could be simplified.

Response: We truly appreciate reviewer's remarks about tables being exceptionally thorough. We believe that the information we provided are necessary for the clinicians and future researchers who appreciate granular information.

9. The Figure is also very clear and, I feel, helpful for clinicians.

Response: We truly appreciate reviewer's remarks about the figure.

10. The inclusion of the "STROBE Statement", likewise probably not very familiar to clinicians, is helpful, and demonstrates the attention to detail of the authors.

Response: We truly appreciate reviewer's remarks about "STROBE Statement." Since this required document for reporting an observational study is mainly for reviewing process in the green journal, we choose not to include it in the main text.

STATISTICAL EDITOR'S COMMENTS:

1. Table 2: Both the study samples and the numbers of adverse outcomes are large, justifying multiple variable adjustment. However, it would enhance the conclusions if additional corroboration were done by matching subsets of the 40 and 41 week cohorts to the 39 week referent cohort by the variables that differed at baseline. Also, the RR and aRR are useful and appropriate metrics, but it would also be useful for the reader if the rates per 1000 births (with Cl) were included, along with the predicted differential rate of adverse neonatal morbidity per 1000 (or per 10,000) births if deliveries hypothetically occurred at 39 wks rather than at 40 or 41 wks.

Response: We appreciate this comment and we agree that the RR and aRR are useful and appropriate metrics for our analyses, since they are easy to understand and comparable to the results of prior randomized trial and observational studies. In the revision, we have included the CI of the rates in the Tables 2-5 as suggested. However, since reviewer 3 has commented that our current tables with detailed information may overwhelm the clinicians, we believe that adding additional predictive differential rate would cause more confusion. Although we agree that a propensity score approach may enhance our conclusions, we did not use a propensity score method in our analysis, because this method highly depends on "measured" variables. Since birth certificate data were limited in various clinical variables as we stated in the manuscript, we would very likely not be able to generate an appropriate propensity score due to data limitation. Therefore, if permitted, we choose not to use this method in our current analysis. In addition, due to limited space allowed in the journal, it would be difficult to add additional analyses and explanations.

2. Table 3: Same comments re: additional matching analysis and stating of absolute difference in rates of maternal morbidities. Also, the composite neonatal adverse outcome included mortality, while the adverse composite maternal does not. Likely the counts would have insufficient power and may have a NS difference, but it would be useful for the reader to separately show data re: maternal morbidity. Given the size of the data set, likely there are a non-trivial number of maternal mortalities in this series.

Response: We appreciate this comment. We include neonatal mortality (death within 27 days) as a component of neonatal morbidity, as it is widely accepted in research that it may capture some morbidity that was not documented due to neonates died shortly after being born. On the other hand, since the birth certificate data have no information on maternal death, we were not able to assess its potential effect on maternal morbidity. Please also see our response for comment 1 regarding propensity score analysis.

3. Table 4: Same suggestion for matching algorithm and stating results as absolute differences in rates per 1000 live births.

Response: Please see our response for comment 1 regarding propensity score analysis.

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, as well as subsequent author queries. 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:
- 1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.

Response: We would like to OPT-IN.

- 2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.
- 2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

3. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained." *The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

Response: We have included the statement in the cover letter.

4. In order for an administrative database study to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.

Response: In the Materials and Methods section, we included this information as "This was a population-based retrospective cohort study using the Period Linked Birth-Infant Death Data Files of U.S. Vital Statistics Data from 2012-2016. These data, including all live births and were linked to infant deaths within the first year, were assembled by the National Center for Health Statistics and reported annually by the Centers for Disease Control and Prevention (CDC)."

- 5. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works. Variance is needed in the following sections:
- a. ABSTRACT: The entire abstract is nearly identical to the abstract of your April 2019 O&G article "Neonatal and Maternal Morbidity Among Low-Risk Nulliparous Women at 39–41 Weeks of Gestation." Please significantly modify the text of your abstract.

Response: We have revised the verbiage of the abstract.

b. LINES 73-5 ("These data, ascertained....within the first year").

Response: We have revised the main text as suggested.

- 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 and gynecology data definitions at https://urldefense.proofpoint.com/v2/url?u=https-3A www.acog.org About-2DACOG ACOG-2DDepartments Patient-2DSafety-2Dand-2DQuality-2DImprovement reVITALize&d=DwlGaQ&c=bKRySV-ouEg AT-w2QWsTdd9X KYh9Eq2fdmQDVZgw&r=g0KBmu4L8mRx06UXFuOsesN5wMV8B9z0e7XV-X2GHnE&m=ozaQc2V3F6I9hOyKeaF4vTe818is1JUggkuw CkvRpc&s=KAR5shMToMfjgddhJlhSKwSwltjaSkMTJEMmpNrB9PA&e="If">https://urldefense.proofpoint.com/v2/url?u=https-3A www.acog.org About-2DACOG ACOG-2DDepartments Patient-2DSafety-2Dand-2DQuality-2DImprovement reVITALize&d=DwlGaQ&c=bKRySV-ouEg AT-w2QWsTdd9X KYh9Eq2fdmQDVZgw&r=g0KBmu4L8mRx06UXFuOsesN5wMV8B9z0e7XV-X2GHnE&m=ozaQc2V3F6I9hOyKeaF4vTe818is1JUggkuw CkvRpc&s=KAR5shMToMfjgddhJlhSKwSwltjaSkMTJEMmpNrB9PA&e="If">https://urldefense.proofpoint.com/v2/url?u=https-3A www.acog.org About-2DACOG ACOG-2DDepartments Patient-2DSafety-2Dand-2DQuality-2DImprovement reVITALize&d=DwlGaQ&c=bKRySV-ouEg AT-w2QWsTdd9X KYh9Eq2fdmQDVZgw&r=g0KBmu4L8mRx06UXFuOsesN5wMV8B9z0e7XV-X2GHnE&m=ozaQc2V3F6I9hOyKeaF4vTe818is1JUggkuw CkvRpc&s=KAR5shMToMfjgddhJlhSKwSwltjaSkMTJEMmpNrB9PA&e="If">https://urldefense.proofpoint.com/v2/url?u=https-3A www.acog.org About-2DACOG ACOG-2DDepartments Patient-2DSafety-2Dand-2DQuality-2DImprovement reVITALize&d=DwlGaQ&c=bKRySV-ouEg AT-w2QWsTdd9X KYh9Eq2fdmQDVZgw&r=g0KBmu4L8mRx06UXFuOsesN5wMV8B9z0e7XV-X2GHnE&m=ozaQc2V3F6I9hOyKeaF4vTe818is1JUggkuw CkvRpc&s=KAR5shMToMfjgddhJlhSKwSwltjaSkMTJEMppNrB9PA&e="If">https://urldefense.proofpoint.com/v2/url?u=https-3A www.acog.org About-2DACOG ACOG-2DQuality-2DACOG ACOG-2DQuality-2DACOG ACOG-2DQuality-2DACOG ACOG-2DQuality-2DACOG
- 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.
- 8. 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).
- 9. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot.

10. 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 limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

11. Only standard abbreviations and acronyms are allowed. A selected list is available online at https://urldefense.proofpoint.com/v2/url?u=http-

3A edmgr.ovid.com ong accounts abbreviations.pdf&d=DwlGaQ&c=bKRySV-ouEg AT-w2QWsTdd9X KYh9Eq2fdmQDVZgw&r=g0KBmu4L8mRx06UXFuOsesN5wMV8B9z0e7XV-X2GHnE&m=ozaQc2V3F6l9hOyKeaF4vTe818is1JUggkuw CkvRpc&s=ZxjPexXqyAM5uin1ntwjNw87eumJSVQkCrY3B1-2CzM&e=. 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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Please note that 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 to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at https://urldefense.proofpoint.com/v2/url?u=http-3A ong.editorialmanager.com&d=DwlGaQ&c=bKRySV-ouEg AT-w2QWsTdd9X KYh9Eq2fdmQDVZgw&r=g0KBmu4L8mRx06UXFuOsesN5wMV8B9z0e7XV-X2GHnE&m=ozaQc2V3F6l9hOyKeaF4vTe818is1JUggkuw CkvRpc&s=Z4nwCwPW2e1Qlf10sl2ZpqpWtRR fzaaoBj9TNg-d9BQ&e=. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

If you submit a revision, we will assume that it has been developed in consultation with your coauthors 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 May 17, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982

2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

RE: Manuscript Revisions: ONG-19-660R1

Chen, Han-Yang	
Fri 5/17/2019 4:06 PM	
To:Daniel Mosier <dmosier@greenjournal.org>;</dmosier@greenjournal.org>	
Cc:Chauhan, Suneet P	
Importance: High	
1 attachments (87 KB)	
9-660R1 ms (5-16-19v3) 05.17.19 Chen edit.docx;	

Hi, Daniel

Sorry for this version confusion.

Dr. Rouse has a phone discussion with Dr. Chauhan regarding the revision yesterday. Based on that discussion, I revised the manuscript again.

Please see attached manuscript with my edits. Thank you.

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.

Please see my comments and edits. We agree and revise accordingly.

- LINE 35: or delivered?
 I changed it to "delivered"
- LINE 36: Please make this change throughout including Tables, etc.
 Please see my comment. Based on the discussion with the editor, I replaced the word "morbidity" with "adverse outcome".

I made this change throughout including <u>Title</u>, <u>Text</u>, <u>& Tables</u>.

- 4. LINE 120: Please cite here the references you had I added references 16-18.
- 5. TABLE 4: Please move this table and the next one to the Appendix. Please renamed those tables "Appendix 1" and "Appendix 2," respectively, and amend all citations in the manuscript.

 I renamed the tables to "Appendix 1" and "Appendix 2," and revised them in the manuscript (page 12).

Han-Yang Chen, PhD

Assistant Professor



Department of Obstetrics, Gynecology & Reproductive Sciences



From: Daniel Mosier [mailto:dmosier@greenjournal.org]

Sent: Friday, May 17, 2019 1:38 PM

To: Chen, Han-Yang

Subject: RE: Manuscript Revisions: ONG-19-660R1

Importance: High

**** EXTERNAL EMAIL ****

Dr. Chen,

There seems to be a big version control problem with your edits. I received your revision (version 3, attached) on Tuesday May 14th. Dr. Chauhan sent a version of the manuscript (version 4, attached) to our office on Thursday evening, May 16th. Some of the edits and responses are conflicting, and there seems to be disagreement between you and Dr. Chauhan.

Please resolve the discrepancies and send me the version of the manuscript that you would like reviewed by the editors.

Please note that, as you the corresponding author, I am only allowed to communicate with you on this matter. You should send me the completed version of the manuscript, not Dr. Chauhan.

When revising, use the attached version of the manuscript. Leave the track changes on, and do not use the "Accept all Changes" function prior to re-submission.

Please let me know if you have any questions or concerns.

Sincerely, -Daniel Mosier

Daniel Mosier

Editorial Assistant Obstetrics & Gynecology

Tel: 202-314-2342

From: Chen, Han-Yang

Sent: Tuesday, May 14, 2019 4:59 PM

To: Daniel Mosier < dmosier@greenjournal.org>

Cc: Chauhan, Suneet P

Subject: RE: Manuscript Revisions: ONG-19-660R1

Hi, Daniel

Please see attached manuscript with my edits. Thank you.

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.

Please see my comment. Some change is not correct. See Q3.

LINE 35: or delivered?
 Please see my comment. It should be "labored".

- LINE 36: Please make this change throughout including Tables, etc.
 Please see my comment. The change is incorrect. I remove it. I would not make this change throughout including Tables.
- 4. LINE 120: Please cite here the references you had ladded references 16-18.
- 5. TABLE 4: Please move this table and the next one to the Appendix. Please renamed those tables "Appendix 1" and "Appendix 2," respectively, and amend all citations in the manuscript.

 I renamed the tables to "Appendix 1" and "Appendix 2," and revised them in the manuscript (page 11).

Han-Yang Chen, PhD

Assistant Professor



Department of Obstetrics, Gynecology & Reproductive Sciences

From: Daniel Mosier [mailto:dmosier@greenjournal.org]

Sent: Tuesday, May 14, 2019 2:37 PM

To:

Subject: Manuscript Revisions: ONG-19-660R1

**** EXTERNAL EMAIL ****

Dear Dr. Chen,

Thank you for submitting your revised manuscript. It has been reviewed by the editor, and there are a few issues that must be addressed before we can consider your manuscript further:

- 1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.
- 2. LINE 35: or delivered?
- 3. LINE 36: Please make this change throughout including Tables, etc.
- 4. LINE 120: Please cite here the references you had
- 5. TABLE 4: Please move this table and the next one to the Appendix. Please renamed those tables "Appendix 1" and "Appendix 2," respectively, and amend all citations in the manuscript.

When revising, use the attached version of the manuscript. Leave the track changes on, and do not use the "Accept all Changes"

Please let me know if you have any questions. Your prompt response to these queries will be appreciated; please respond no later than COB on **Thursday, May 16th.**

Sincerely,

-Daniel Mosier

Daniel Mosier

Editorial Assistant

Obstetrics & Gynecology

The American College of Obstetricians and Gynecologists
409 12th Street, SW

Washington, DC 20024

Tel: 202-314-2342

Fax: 202-479-0830

E-mail: dmosier@greenjournal.org
Web: http://www.greenjournal.org

From:
To:

Denise

Denise Shields

Subject: RE: figure in your Green Journal manuscript (18-660R1)

Date: Wednesday, May 15, 2019 2:42:30 PM

Attachments: image003.png

image001.png

Hi, Denise

It looks fine. Thank you.

Han-Yang Chen, PhD



From: Denise Shields [mailto:DShields@greenjournal.org]

Sent: Wednesday, May 15, 2019 1:16 PM

To: Chen, Han-Yang <

Subject: RE: figure in your Green Journal manuscript (18-660R1)

**** EXTERNAL EMAIL ****

Here is the corrected figure. Does this look okay?

From: Chen, Han-Yang

Sent: Monday, May 13, 2019 1:04 PM

To: Denise Shields < DShields@greenjournal.org>

Subject: RE: figure in your Green Journal manuscript (18-660R1)

Hi, Denise

There are some errors in the figure that needs correction.

Please see attached figure with my comments.

Thank you

Han-Yang Chen, PhD

Assistant Professor





From: Denise Shields [mailto:DShields@greenjournal.org]

Sent: Monday, May 13, 2019 11:41 AM

To: Chen, Han-Yang

Subject: figure in your Green Journal manuscript (18-660R1)

**** EXTERNAL EMAIL ****

Re: "Neonatal and Maternal Morbidity Among Low-Risk Parous Women at 39 to 41 Weeks of Gestation"

Dear Dr. Chen,

Your figure has been edited and is attached for your review. Please review the attachment CAREFULLY for any mistakes.

PLEASE NOTE: Any changes to the figure must be made now. Changes made at later stages are expensive and time-consuming and may result in the delay of your article's publication.

To avoid a delay, I would appreciate a reply no later than Wednesday, 5/15. Thank you for your help.

Best,

Denise

Denise Shields Senior Manuscript Editor Obstetrics & Gynecology

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