OBSTETRICS & GYNECOLOGY

NOTICE: This document contains comments from the reviewers and editors generated during peer review of the initial manuscript submission and sent to the author via email.

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

Date: Apr 18, 2019
To: "Rachel G Sinkey" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-522

RE: Manuscript Number ONG-19-522

Elective Induction of Labor Versus Expectant Management in Low-risk Multiparous Women

Dear Dr. Sinkey:

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 09, 2019, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Thank you for your hard work. Specific comments follow:

1. Introduction: Lines 49-51 is overly simplistic (need to expand on what that population looked like and how generalizable this result truly is).

2. Lines 64-5: was there previous data showing this or any other outcome? Need to review previous publications including multiparas (or lack of data).

3. Methods: You look at "resource utilization" by EM patients, but did you compare the inpatient time and L&D time like the ARRIVE trial did? Was perineal injury examined (likely low in multiparous group, but not impossible)?

Results:

4. Line 123: these 4 could reasonably excluded as they are not eligible for SVD (or would have been excluded in IOL group). Would this change your outcomes? Worth looking.

Discussion:

5. Lines 165-74: did you repeat your analysis excluding the shoulder dystocia numbers? This would give an idea of how much this alone drove your results.

6. Line 199-200: you need to characterize your center more thoroughly to allow for comparison and decisions about generalizability (residents, yes or no, academic? Hospitalists?, etc…)

7. Lines 211-2 this is an important point as there was significantly more time on L&D in the ARRIVE trial and this can be a large expense as well as a burden at busy L&D units.

Reviewer #2: This thoughtfully written article by Sinkey and colleagues examines the impact of elective induction of labor (e.g. the ARRIVE protocol) on multiparous women in a retrospective cohort. This manuscript is timely as it examines a question that many providers are wrestling with in terms of the applicability of the ARRIVE trial to multiparous women. The writing and methodology are appropriate and the manuscript notes it limitations in sample size and lack of true randomization. The two largest challenges to this publication that may not be able to be remedied are: 1. The relatively

small sample size and 2. Is this paper truly novel compared to prior similar publications that use an appropriate control group? The following suggestions are designed to strengthen the publication:

1* Though stylistically prefer I short introductions, the authors infer that the casual reader is aware of the novelty of the ARRIVE trial and the reason for the controversies (control group of labor vs. expectant management). A sentence adding clarity to this issue would be helpful.

2* Shoulder dystocia is a major driver of morbidity but clarity about the definition is not clearly defined? Were cases reviewed? Did they require secondary maneuvers? As their rate is several fold greater than nationally reported numbers it would be helpful to have more confidence in the data set.

3* Sensitivity analyses by parity and obesity should be considered

4* The study derives from an obstetrical registry. It would be helpful to have some level of attestation that the data is validated in some fashion.

5* Page 7 line 105 "obstetric triage visits and office visits at > 39 weeks" should be placed in parentheses following line "resource utilization" in line 100 and then eliminated.

6* Would consider eliminating the discussion on page 10 line 141 about the various gestational ages. This suggests that there is a graded approach to this issues and only encourages providers to go into scope creep and protocol non-adherence.

Reviewer #3: The authors have submitted a retrospective cohort study of multiparous women, comparing elective (non-medically indicated) induction at and just after 39 weeks with a comparison group of patients who were managed expectantly. I appreciate the authors' evaluation of this issue. As the authors mention, there are few analyses of outcomes of low risk, multiparous women.

Abstract:
Appropriate for the study indication, design, findings and conclusion.

Introduction:
The introduction is well-written and concise. Nicely frames the reason for conducting the study.

Materials and Methods:

1. Line 68: How robust is the institutional database? Did the authors perform any audits of the data to assure accuracy? If there is a significant risk of either missing patients who qualify for study analysis, or obtaining incorrect diagnoses, then the authors should discuss this as a possible study limitation.

Results:
Overall well-written.

2. Line 154: I would not expect that patients undergoing labor induction would have a similar number of triage visits >39 weeks than those managed expectantly. If the authors' institution requires patients undergoing induction to undergo evaluation in triage first, this may have altered their findings and they should mention this.

Discussion:

3. Line 164: Prior to publication of the ARRIVE trial, many hospitals had policies either discouraging or forbidding inductions without a medical indication. It appears this is the case at the author's institution.

4. Line 169: please delete "unique" as, unfortunately, there are many regions of the country with a relatively high percentage of overweight or obese pregnant patients.

5. Line 173: Please clarify this sentence, as your findings of no difference in neonatal respiratory support between groups is a notable difference than found in the ARRIVE study.

6. Line 182-184: I understand what the authors are getting at here but this sentence could be reworded for clarity. Perhaps a brief mention of why it is appropriate to compare induction versus expectant management (and not just spontaneous labor or vaginal delivery).

7. Lines 192 and 202: In the ARRIVE trial the protocol recommended cervical ripening for Bishop scores of <5 at admission, but the induction method was left up to the clinicians managing the patient. The authors may wish to mention

this difference since much of their study was modeled after the ARRIVE study.

8. Lines 199-212: This is a nicely written and honest assessment of the study limitations, which should allow readers to contemplate the study findings in the context of both strengths and weaknesses.

9. Line 206: please see prior comments regarding data mining.

10. Lines 213-291: Appropriately worded to reflect study findings, advise caution, and the need for future RCT.

References:

11. Appropriate and contemporaneous.

Tables and Figures:

12. In lines 155-156 the authors mention that women undergoing EM had significantly more office visits than those in the induction group, but the table (page 17) does not report this (category: number of prenatal visits)

STATISTICAL EDITOR'S COMMENTS:

1. Table 2: Should include a separate column for crude ORs to contrast with aORs. Including the crude ORs would then eliminate the need for the column of p-values (except for the comparison of death rates or $Apgar_5 < 3$ with 0 entries), which could be noted with footnotes. Many of the aORs have too few counts of adverse outcomes to justify adjustment of ORs with 3 covariates. (eg, perinatal composite, neonatal resp support, $Apgar_5 \leq 3$, shoulder dystocia, chorioamnionitis, preeclampsia, operative vaginal delivery). Should clearly separate the primary from the secondary outcomes.

2. Would it be possible to match the eIOL cohort by age, Hispanic ethnicity and first pregnancy wgt to the control group? This would avoid the need for adjustment of those variables and could corroborate the conclusions? Otherwise, the baseline differences in this non-random allocation of eIOL and the relatively rare adverse outcomes weakens the argument.

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.
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. 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.

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 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.

5. 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.

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).

7. 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.

8. 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.

9. 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.

10. 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.

11. 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 reference you are citing is still current and available. If the reference you are citing has been updated (ie, 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 (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found via the Clinical Guidance & Publications page at https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance.

12. The Journal's Production Editor had the following comments about the figures in your manuscript:

"Please upload Figure 1 as a separate file in Editorial Manager, rather than embedding it in the manuscript. "

When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate file to Editorial Manager (do not embed the figure in your manuscript file).

If the figures were created using a statistical program (eg, STATA, SPSS, SAS), please submit PDF or EPS files generated directly from the statistical program.

Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi for color or black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

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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 09, 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

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