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 10, 2020
To: "Yasser Yehia El-Sayed" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-460

RE: Manuscript Number ONG-20-460

Patient characteristics and adverse outcomes in low- risk nulliparas induced or expectantly managed

Dear Dr. El-Sayed:

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).

Due to the COVID-19 pandemic, your paper will be maintained in active status for 30 days from the date of this letter. If we have not heard from you by May 10, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: This is a secondary analysis of a large randomized trial of elective induction versus expectant management (ARRIVE trial - 6096 deliveries) among low-risk nulliparous women. Outcomes included a composite of perinatal mortality and severe morbidity. 5007 pregnancies were included in this secondary analysis (those with fetal anomalies, those who did not adhere to the study protocol and those with labor, induction or cesarean section that began before 39 weeks 0 days even if actual delivery was at 39 weeks 0 days or later were excluded) and a multivariable model was built. It was found that elective induction at 39 weeks was associated with a reduced risk of the perinatal composite outcome while BMI was associated with increased risk.

Human subjects: IRB approvals were obtained from 41 participating sites, written informed consent was obtained prior to randomization.

Abstract:
1. The abstract is specific and representative of the article. Clinical trial registration is included.

Introduction:
2. This section summarizes the methods and findings of the primary analysis in which composite primary outcome did not differ significantly between groups however a lower frequency of cesarean section was significant in the induction group.

Methods:
3. Methods are well described.

Results:
4. The data answer the question. The large sample size adds confidence in the precision of the estimates.

Discussion:
5. The discussion clearly describes the analysis included a group of women for whom the intervention was more truly actionable.

References:
6. Pertinent references are cited.

Tables/Figures:

7. Figure 1: Very minor suggestion: add "included in the secondary analysis" to the last box in the flow diagram. Also may want to indicate either in the text or in the flow diagram how many of the 5007 analyzed were in each of the 2 randomized groups.

Reviewer #2: This is a secondary analysis of the comparison group's primary outcome of the ARRIVE trial.

Abstract: the objective is clear

Introduction: clear objective

Methods:
- Inclusion and exclusion criteria are clear and appropriate
- Outcomes are well defined including PPH (although broad criteria, it is well defined)

Results:
- Clearly presented (tables and graphs support results)

Discussion:
Line 235-237: "additionally..." This is a very relevant finding and the authors may want to move this earlier in the discussion
I'd be interested in the author's opinion on the association between increasing BMI and decreased third and fourth degree lacs, same with increased PPH in hispanic women in their cohort

Reviewer #3: Thanks for the opportunity to review.
Interesting per protocol analysis of data generated by ARRIVE.
Explanation of difference in findings between primary ARRIVE analysis and this analysis would be relevant. ie no difference in perinatal composite vs a difference in this analysis
Reporting of the CS rates between the two study groups would also be of interest.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

1. Should include a flow diagram to show the various subsets and final groups analyzed.

2. Table 1: Although the number excluded is modest (6% of total), what would the analysis of the primary outcome be similar if ITT were applied to the entire cohort of 5327?

3. Table 2: Suggest a smaller increment for referent index of change in composite vs BMI. Using increments of 10 kg/m² seems too coarse grain. Also, the primary outcome of interest (perinatal composite) should be more clearly separated from the others. Should include in footnote to Table the adjustors included in the multivariable model. Many of the subsets have small counts and potentially are over fitted models (eg, N= 4, 11, 9, 14). Suggest simply reporting the overall 3rd/4th laceration and PPH aRRs and the relationship of laceration rates to BMI, including the crude rates and not attempting to quantify aRRs by most racial subsets.

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:
A. OPT-IN: Yes, please publish my point-by-point response letter.
B. OPT-OUT: No, please do not publish my point-by-point response letter.

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.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

3. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

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); Case Reports should not exceed 8 typed, double-spaced pages (2,000 words); Review articles should not exceed 25 typed, double-spaced pages (6,250 words); Current Commentary articles should not exceed 12 typed, double-spaced pages (3,000 words); Clinical Practice and Quality articles should not exceed 22 typed, double-spaced pages (5,500 words); Procedures and Instruments articles should not exceed 8 typed, double-spaced pages (2,000 words); Personal Perspectives essays should not exceed 12 typed, double-spaced pages (3,000 words); Clinical Conundrums articles should not exceed 6 pages (1,500 words); Questioning Clinical Practice articles should not exceed 6 pages (1,500 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. 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; Reviews, 300 words; Case Reports, 125 words; Current Commentary articles, 250 words; Executive Summaries, Consensus Statements, and Guidelines, 250 words; Clinical Practice and Quality, 300 words; Procedures and Instruments, 200 words. Please provide a word count.

7. 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.

The journal does not use "EIOL" for "elective labor induction" or "EM" for "expectant management." Please expand these terms in your paper.

8. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

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

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

8. 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 through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded in a word processing format such as Microsoft Word. 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.

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 30 days from the date of this letter. If we have not heard from you by May 10, 2020, we will assume you wish to withdraw the manuscript from further consideration..

Sincerely,

The Editors of Obstetrics & Gynecology

2018 IMPACT FACTOR: 4.965
2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

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