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: Dec 04, 2020
To: "Alon Ben-David" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-2946

RE: Manuscript Number ONG-20-2946

Colonization with Group B Streptococcus and The Risk for Infection after Cervical Ripening with Transcervical Foley Catheter

Dear Dr. Ben-David:

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 Dec 28, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: ONG 20-2946

In the manuscript under review, Ben-David et al present the results on of a retrospective analysis of their local data evaluating the impact of GBS colonization on neonatal infection among women undergoing IOL with transcervical foley balloon. The authors identified 3636 women that were included, 20% GBS positive. They found that the rate of infection was similar among the groups.

A few comments on the manuscript are as follows:

1. ABSTRACT - overall no major comments, some abbreviations are not approved by the journal.
2. INTRODUCTION - Makes the argument for the need for this analysis, however no hypothesis is stated.
3. METHODS - Line 121-123 one assumes that only women with fetuses in cephalic presentation were included
4. How was a sample size calculated? What was the effect size that the authors planned to detect?
5. Line 177 - what variables were included in the multivariate logistic regression.
6. Were the STROBE guidelines followed?
7. RESULTS - Line 186 patients included in the analysis cannot meet exclusion criteria
8. Table 1 - do the authors have any data on race? Bishop score and cervical dilation on admission? Time from admission to delivery? Length of labor is a known risk factor for infectious morbidity.
9. Table 2 - do the authors have any data on Number of cervical exams? Length of second stage?
10. Table 3 - it would be useful for the reader to see the actual rate of the complications by group as well as the unadjusted risk.
11. DISCUSSION - One additional imitation of the analysis is the possibility of a type I error specially given the low rate of the primary outcome.

Reviewer #2:

Thank you for your submission.
Abstract- This area nor the manuscript state your hypothesis about your study. Please state your hypothesis.
Methods- Extra-amniotic saline infusion is not a universal technique and you should consider explaining this technique for

clarification.
Results- Please italicize proper names of bacterial species

Overall I feel that this manuscript demonstrates the objective which was to determine the rates of early onset disease in newborns in women undergoing foley balloon cervical ripening with and without GBS colonization, but it would be further strengthened by addition of a control group of women not undergoing foley balloon induction (with sub-groups of GBS positive and negative women) as the relevance of this paper is to determine whether it is safe to use foley balloon devices in women with GBS positive cultures.

Reviewer #3:

The aim of this study was to determine whether women with proven GBS colonization undergoing cervical ripening with transcervical Foley cathether (TCFC) are at higher risk for maternal and neonatal infection.
Eligible participants included women at 37 weeks of gestation or greater who had a living, singleton, nonanomalous fetus in cephalic presentation, and intact membranes.

The study addresses an important topic to clinical obstetric practice.
I have general and specific comments and suggestions.

General comments
1. Suggest consistent use of "maternal infection(s)" rather than "maternal bacteremia" throughout the manuscript!
2. Suggest analysis of maternal infection(s) by mode of delivery (i.e., vaginal versus cesarean delivery).

Study design: Retrospective cohort
Major strengths: Significance to clinical obstetric practice

Major weaknesses: Retrospective cohort
The timing and duration of intrapartum antibiotic prophylaxis for women colonized with GBS undergoing mechanical cervical ripening has not been addressed.

Specific comments by page and lines
3. TITLE: Suggest change to, "Maternal Colonization with Group B Streptococcus and the Risk for Infection after Cervical Ripening with Transcervical Foley Catheter"

ABSTRACT
4. Page 3 lines 60-63. (See general comments above)
5. Page 3 lines 70-73. (See general comments above)

METHODS
6. Page 6 lines 139-141. Clarify. Do you stratify women whose reported penicillin allergy indicates a low-risk versus high-risk of anaphylaxis? If yes, how about use of cephalosporin in women with low-risk of anaphylaxis?

7. Page 7 lines 146-150. Clarify timing of transcervical Foley catheter insertion. Before or after intrapartum antibiotic prophylaxis administration?

RESULTS
8. Page 10 lines 212-218. (See general comments above)

DISCUSSION
9. Page 11 lines 236-238. (See general comments above)
10. Page 12 lines 266-269. (See general comments above)
11. Page 12 lines 269-271. Agreed!
12. Page 17. Table 2.
Suggest analysis of maternal infection(s) by mode of delivery (i.e., vaginal versus cesarean delivery).

STATISTICS EDITOR COMMENTS:

Table 1 and figure 1: There are a large proportion of women with unknown GBS status. That cohort should be compared

with the others in terms of both baseline characteristics and outcomes, in order to address potential selection bias and generalizability.

Table 2: The primary outcome had proportions of 5.4% of 754 vs 5.3% of 2882. The outcome is relatively uncommon and there is limited power to discern a difference. Using the usual criteria of $p < .05$ and 80% power and the sample sizes given, the discernable rate among the GBS(+) would have to be ~ 8.0% or higher. In other words, the result is NS, but underpowered. For the various secondary outcomes that were NS, the rates are lower and the math is worse in terms of statistical power. Need units for BW. Don't understand why the p-value for comparison of rates of neonatal sepsis is omitted; it can be calculated with Fisher's test as $p = 0.59$.

Table 3: Should include a footnote citing the variables retained in the aOR models. The column of p-values is redundant, since CIs are included. Should include columns of unadjusted ORs for context. The number of cases of maternal bacteremia (11+15 = 26) dictates that no more than 3 adjustors are feasible in the aOR model. If there are more than 3, then the model is likely over fitted.

EDITOR COMMENTS: Thank you for submitting your work to Obstetrics and Gynecology. We discussed this manuscript on the editor's conference call, and we are interested in having you submit a revised manuscript in the format of a research letter. The research letter would need to be focused only on the group of participants who were GBS positive. There should not be comparisons made to the GBS negative group as the study is underpowered to make such comparisons given the rate of the primary and secondary outcomes. We would like you to simply report rates of your primary outcome and the secondary outcome of early onset neonatal GBS sepsis with 95% confidence intervals around the point estimates. Please also include if antibiotics for GBS prophylaxis are started prior to transcervical Foley catheter placement per your institutional protocol.

EDITORIAL OFFICE COMMENTS:

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

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

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: 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 limit for Original Research articles is 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. 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%").

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

12. 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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* 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 Dec 28, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,
Torri Metz, MD
Associate Editor, Obstetrics

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

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