OBSTETRICS & GYNECOLOGY

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

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Date: Oct 08, 2020
To: "Roy Lauterbach" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-2301

RE: Manuscript Number ONG-20-2301

Persistent breech presentation – A profound predictor of external cephalic version success

Dear Dr. Lauterbach:

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 14 days from the date of this letter. If we have not heard from you by Oct 22, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: This retrospective cohort study seeks to determine if persistent breech presentation in the second half of pregnancy is associated with a difference in success rate following ECV. This is an interesting study that provides a novel interpretation of antenatal US-determined fetal position that appears to correlate with ECV success. The association is biologically plausible to the extent that persistent breech presentation is a surrogate for either fetal or maternal factors that may not be overcome by ECV. Questions and suggested revisions are listed as they appear in the manuscript:

1) Line 64: The average number of ultrasound documented is 5 +/- 2 which would indicate an ultrasound every 3 weeks. This number of ultrasound exams would not be generalizable to many OB practices. An analysis that limits the # of included ultrasounds would be helpful in determining if an ultrasound every 3 weeks is necessary for this to be an effective marker and therefore if this study is generalizable to populations who have less ultrasounds during pregnancy. In other words, how few times does persistent breech discriminate the ECV outcome?

2) The manuscript points to several other factors that have been studied related to success of ECV. It would be helpful to compare how the new proposed risk factor of persistent antenatal breech performs in comparison to these classic risk factors - these could be done by a separate multivariable analysis or a composite variable construct.

3) Lines 192-195: In this section, the rate of success seems to be misrepresented in relation to the classic risk factors. It would seem that 100% of those in the group with composite favorable conditions for ECV ended up having a successful ECV, although less of the patients with favorable conditions for ECV had a PBP. Please clarify.

4) Table 1 / Lines 183-184- Since around half of patients did not even have an ECV attempt, it would be important to know if there was any selection bias. Thus, details of the non-ECV cohort should be provided including the rate of PBP.

5) In terms of mode of delivery, there seems to be excess focus on non-instrumental vaginal delivery. It would seem that primary outcome is best emphasized, namely "vaginal delivery" vs "cesarean delivery" as mechanistically, an instrumental vs non instrumental vaginal delivery is of interest relative to a breech presentation, but would have less relevance to patient counseling.

6) Line 200: It seems that the only indication for CS experienced in this population was arrest of descent- can you confirm or clarify? No FHR indications, no arrest of dilation in the active phase of labor? If true, is this something unique to this population and how does it compare to the rate of CS for arrest of descent among your overall population.

7) Lines 257-258: There are several limitations to the study- some are noted above and need to be articulated here. An example is the # of ultrasounds that may not be generalizable, as they are not usually done for otherwise low risk

pregnant women. Also, can you comment on whether you would use this fact prospectively in counseling and if so, how?

Reviewer #2: This paper is a retrospective cohort study by Lauterbach et al to evaluate a possible correlation between a new variable named "persistent breech presentation" (PBP) and the success rate of ECV. The authors examined all ECVs performed at or beyond 37 weeks of gestation, between January 2008 and January 2019 at their center, and concluded that among women with persistent compared to non-persistent breech presentation, the rates of successful external cephalic version and non-instrumental vaginal delivery were significantly lower. Although this paper has a potential to contribute to the ongoing discussion about external cephalic version and persistent breech presentations, this paper has some issues that merit comments by the authors.

General comments
1. Why would pregnant women get 5 or more ultrasounds during pregnancy? Were these all high risk pregnancies getting growth ultrasounds?

2. In women with non-PBP, did the authors attempt to look for causes of persistent breech presentations during the ultrasound evaluations, like uterine anomalies (septate uteri, bicornuate uteri), abnormal pelvices, and abnormal placentations?. This would be critical in defining PBP and during counseling as well.

Results:
Page 8-9, Lines 189-192: The authors state that "In total, 34 women out of 224 women in the PBP group and 239 women in the non-PBP group had a composite of favorable conditions for ECV success (multiparity, normal amniotic fluid volume, posterior placenta, no documented uterine activity, BMI<30). So, this means that 190 women had some form of 'unfavorable conditions for ECV' in the PBP group? Wouldn't these 'unfavorable factors' explain why ECV would fail in these women in the first place?.

Page 16, Table 1: Please remove the 'NS' and use numbers to indicate the P-values.

Reviewer #3: In this work, Lauterbach and colleagues report that women with persistent breech presentation (PBP) are significantly less likely to have a successful external cephalic version (ECV) compared to women with cephalic presentation documented at least once between the mid-trimester anatomic survey and 37 + 0 weeks. The following questions and comments are raised:

Introduction

What stimulated the authors to consider PBP as a new variable, given this was not a routine question asked prior to ECV in their study population?

Materials and Methods

The authors protocol for ECV allows up to 4 attempts. Was the number of attempted versions the same in the PBP and non-PBP groups?

The average number of ultrasound examinations performed was five. What were the major indications for the multiple ultrasounds? Were some of these pregnancies complicated by conditions which might have influenced fetal presentation?

Results

Is it known why ECV was attempted in only 53.8% of the 1271 women with breech presentation at 37 weeks or greater? Is there a difference in the population of women who chose to have attempted ECV versus those who did not?

Were the birth weights between the 10% and 90% for all newborns in both groups? If not, how many were LGA or SGA?

Table 1 is unclear. The individual favorable conditions for ECV success were the same for the PBP and non-PBP groups. The composite of favorable conditions ALONE prior to ECV attempt was significantly lower in the PBP group. What does this mean exactly? That ALL of the favorable conditions listed were present in 15.2 % (34/224) of the PBP group and 52.0% (239/460) of the non-PBP group? This should be clarified.

43.2% (19/44) of women in the PBP group had "emergency" cesarean delivery due to arrest of decent. Why were all of these emergent? Was there evidence of non-reassuring fetal status?

Discussion

Is PBP an independent predictor of unsuccessful ECV or a result of absence of a composite of conditions favoring ECV success?

Why is an instrumental vaginal delivery not considered a success, especially considering there were no differences in neonatal outcomes?

Given the fact that many women will have a mid-trimester anatomic survey but may not have multiple subsequent intervening ultrasound examinations, do the authors feel that in cases of breech presentations diagnosed near term, it would be worthwhile to correlate with the presentation at the mid-trimester ultrasound?

Was there any explanation or can the authors speculate on the etiology of PBP and is there any clinical significance beyond a decreased likelihood of successful ECV?

STATISTICAL EDITOR COMMENTS:

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

Table 1: Parity can only have integer values. Should format as median (range or IQR) or as categories, not as mean ± SD. Should include the number of U/S exams that documented PBP vs Non-PBP, since the former required "all" and the latter at least one non, need to assure the reader that the number of exams was equivalent for the two groups. The groups differed not only in PBP vs non-PBP, but in the proportion with favorable conditions for ECV success. Why is the conclusion necessarily that PCP vs non-PCP was determinative of success, rather than the proportion with favorable conditions for ECV? Need to provide more detail for the "Favorable conditions" allocation. The groups show no difference in mean values for parity, amniotic fluid index or BMI, nor for % posterior placenta. Yet the difference in % favorable could not be more different (87 % vs 13%). Need to show the proportions with no uterine activity and explain how this summary composite was obtained from the components listed.

lines 194-195: What is the statistical support for this statement, as compared to proportion of women with favorable conditions for ECV, for example? Put another way, if a woman had favorable conditions and was in the PBP group, what was the % with successful ECV (with CIs)? vs women with a favorable condition who was in the non-PBP group (% with CI)?

Table 2: The PBP group had N = 44, so the format of n(%) should be changed to integer values for %, rather than citing to 0.1% precision. The counts among the PBP group are too few to allow for adjustment for 5 variables. The models are likely over fitted. Again, this analysis does not adjust for the differences in "favorable conditions" for the PBP vs non-PBP groups.

EDITOR COMMENTS:

1. We are happy to consider a revised manuscript. However, our enthusiasm for it will depend on how you interpret the fact that those with persistent breech also had clinical profiles which are much more unfavorable for successful version. That is, does persistent breech provide clinically useful information over and above the clinical characteristics?

2. 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:
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Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

4. 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.

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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.

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 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.

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. Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title.

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

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* 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).

10. Provide a short title of no more than 45 characters, including spaces, for use as a running foot.

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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%").

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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 14 days from the date of this letter. If we have not heard from you by Oct 22, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Dwight J. Rouse, MD, MSPH

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

Reply to manuscript review:

Reviewer #1:

We thank the reviewer for their remarks. We hope you find our reply, additions and clarifications satisfactory.

1. "Line 64: The average number of ultrasound documented is 5 +/- 2 which would indicate an ultrasound every 3 weeks. This number of ultrasound exams would not be generalizable to many OB practices. An analysis that limits the # of included ultrasounds would be helpful in determining if an ultrasound every 3 weeks is necessary for this to be an effective marker and therefore if this study is generalizable to populations who have less ultrasounds during pregnancy. In other words, how few times does persistent breech discriminate the ECV outcome?"

   According to the Israeli society of obstetrics and gynecology low risk pregnancy follow-up guidelines, pregnant women are required to attend obstetric follow-up during the 2nd and 3rd trimesters once between 24-30 weeks` gestation and once between 30-36 weeks` gestation. Sonographic evaluation during these follow-up sessions is obligatory. The 5 US examinations performed during the study included the 2 for mentioned examinations in addition to the anatomic survey performed during the 2nd trimester and the US performed at 37 weeks` gestation prior to external cephalic version attempt. Thus, the additional US examinations were non obligatory and presumably were performed due to various patient complaints during random OBGYN visits. We added this limitation to the list of limitations in the discussion section.
2. "The manuscript points to several other factors that have been studied related to success of ECV. It would be helpful to compare how the new proposed risk factor of persistent antenatal breech performs in comparison to these classic risk factors - these could be done by a separate multivariable analysis or a composite variable construct."

Since we wish to perform a much more in-depth analysis of the impact of PBP on ECV success, we are currently in the midst of evaluating several success prediction models based on previous published models that incorporate PBP and weigh it`s impact on ECV. We feel that the prediction model was not the primary goal of the study but rather an interesting development that need be paid attention to in future studies and ECV attempts since it is a novel risk factor.

3. "Lines 192-195: In this section, the rate of success seems to be misrepresented in relation to the classic risk factors. It would seem that 100% of those in the group with composite favorable conditions for ECV ended up having a successful ECV, although less of the patients with favorable conditions for ECV had a PBP. Please clarify."

   We understand the confusion related to the percentage. We added a clarification in the results section.

4. Table 1 / Lines 183-184- Since around half of patients did not even have an ECV attempt, it would be important to know if there was any selection bias. Thus, details of the non-ECV cohort should be provided including the rate of PBP.

   The 587 women that compose the remaining women that were not included in the final analysis were excluded based on the specific exclusion criteria mentioned in the methods section, most of which refused an ECV attempt. Therefore, no selection bias was suspected. Due to the early exclusion based on ECV attempt (Yes or No) we did not obtain the information regarding this cohort except for the reason for exclusion which has been added to the results section as requested.

5. "In terms of mode of delivery, there seems to be excess focus on non-instrumental vaginal delivery. It would seem that primary outcome is best emphasized, namely "vaginal delivery" vs "cesarean delivery" as mechanistically, an instrumental vs non instrumental vaginal delivery is of interest relative to a breech presentation, but would have less relevance to patient counseling."

   We found that the "normal" analysis namely vaginal vs. cesarean delivery didn't emphasize enough the impact of PBP on mode of delivery. Though vacuum deliveries are considered vaginal deliveries, the rate of complications and the potential mental and psychological impact on the mother are substantial. As such, some women, after receiving a thorough

explanation regarding the risks of vacuum delivery including the risk of intracranial hemorrhage would prefer elective CS compared to ECV with PBP. Therefore, we found it extremely relevant to discuss these results with the patient before attempting ECV in situations with PBP.

6. "Line 200: It seems that the only indication for CS experienced in this population was arrest of descent- can you confirm or clarify? No FHR indications, no arrest of dilation in the active phase of labor? If true, is this something unique to this population and how does it compare to the rate of CS for arrest of descent among your overall population."

   Indeed, the indication for all 19 patients that underwent emergent CS was arrest of descent. In our practice of 5000 deliveries per year, the rate of non-elective CS is 8.7%. The indications for non-elective CS are as following- 2.6% for arrest of descent, 4.3% for previous 1 CS or more in active labor that are not interested in a trial of labor, 1.5% for non-reassuring fetal heart rate and 0.3% for arrest of dilatation. We presume that the small number of patients with successful ECV and PBP is the cause for the possible bias for CS indication. We added this limitation to the list of limitations in the discussion section.

7. "Lines 257-258: There are several limitations to the study- some are noted above and need to be articulated here. An example is the # of ultrasounds that may not be generalizable, as they are not usually done for otherwise low risk pregnant women. Also, can you comment on whether you would use this fact prospectively in counseling and if so, how?"

   We added the number of ultrasounds to the list of limitations in the based on the 1st remark. Regarding the 2nd part of your remark, the study was born when the principal investigator was working in the obstetric emergency room and examining a patient that was considering ECV due to breech presentation. The patient was a perfect candidate with all the favorable ECV success factors on her side but several attempts to perform ECV failed. This situation repeated itself a couple of times and raised serious questions for all the physicians involved. After examining all the facts thoroughly, we hypothesized the PBP concept. Regarding future patient counseling, I think it is too early to change practice based on one study and therefore, except for prospectively documenting results of ECV attempts and US scans during

pregnancy, we are still far from counseling women against performing ECV based on PBP alone. We do counsel women with unfavorable factors for ECV success and PBP that the chances of ECV success are very low but do not discuss the possible impact on mode of delivery at this stage.

Reviewer #2:

We thank the reviewer for their remarks. We hope you find our reply, additions and clarifications satisfactory.

1. "Why would pregnant women get 5 or more ultrasounds during pregnancy? Were these all high-risk pregnancies getting growth ultrasounds?"
   According to the Israeli society of obstetrics and gynecology low risk pregnancy follow-up guidelines, pregnant women are required to attend obstetric follow-up during the 2nd and 3rd trimesters once between 24-30 weeks` gestation and once between 30-36 weeks` gestation. Sonographic evaluation during these follow-up sessions is obligatory. The 5 US examinations performed during the study included the 2 for mentioned examinations in addition to the anatomic survey performed during the 2nd trimester and the US performed at 37 weeks` gestation prior to external cephalic version attempt. Thus, the additional US examinations were non obligatory and presumably were performed due to various patient complaints during random OBGYN visits. We added this limitation to the list of limitations in the discussion section.
2. "In women with non-PBP, did the authors attempt to look for causes of persistent breech presentations during the ultrasound evaluations, like uterine anomalies (septate uteri, bicornuate uteri), abnormal pelvices, and abnormal placentations?. This would be critical in defining PBP and during counseling as well."
   At the end of the results section you can find that we examined possible causes for PBP including the rate of cord entanglement and uterine abnormalities detected during either an elective or an emergency CD, and found no significant difference between the PBP and the non-PBP groups. Regarding abnormal placentation, women with suspected abnormal placentation including placenta previa, accrete, increta, percreta or just a

low-lying placenta were excluded from the study. We added this to the exclusion criteria in the methods section.

3. “Page 8-9, Lines 189-192: The authors state that "In total, 34 women out of 224 women in the PBP group and 239 women in the non-PBP group had a composite of favorable conditions for ECV success (multiparity, normal amniotic fluid volume, posterior placenta, no documented uterine activity, BMI<30). So, this means that 190 women had some form of 'unfavorable conditions for ECV' in the PBP group? Wouldn't these 'unfavorable factors' explain why ECV would fail in these women in the first place?.”

   The composite means that all the favorable conditions listed were present in the patient. We understand how the presented data may be confusing. The composite of favorable conditions was only presented for the successful ECVs. The text does not state what is mentioned in the remark regarding 34 of 224. Of the 421 successful ECVs, 273 had a composite of favorable conditions for ECV. When considering this, one may say that the discrepancy in the rate of favorable conditions may explain the difference in ECV success. Of the failed ECVs (the remaining 263 patients of the 684 that underwent ECV), we did not present the rate of the composite of favorable conditions. Therefore, it would seem that there is a significant discrepancy between the 15% in the PBP group and the 52% in the non PBP group that may explain by itself the difference in ECV success. In light of this we added the composite of favorable conditions to the whole population of women that underwent ECV to show there was no difference between the groups (60.2% vs. 61.3%, P>0.05). This data was added to Table 1.

4. “Page 16, Table 1: Please remove the 'NS' and use numbers to indicate the P-values.”

   We changed the `NS` values to numerical values as requested.

Reviewer #3:

We thank the reviewer for their remarks. We hope you find our reply, additions and clarifications satisfactory.

1. “What stimulated the authors to consider PBP as a new variable, given this was not a routine question asked prior to ECV in their study population?”

The study was born when the principal investigator was working in the obstetric emergency room and examining a patient that was considering ECV due to breech presentation. The patient was a perfect candidate with all the favorable ECV success factors on her side but several attempts to perform ECV failed. This situation repeated itself a couple of times and raised serious questions for all the physicians involved. After examining all the facts thoroughly, we hypothesized the PBP concept.

2. "The authors protocol for ECV allows up to 4 attempts. Was the number of attempted versions the same in the PBP and non-PBP groups?"
   There were no significant differences in the number of ECV attempts between the PBP and non-PBP groups. We added these results to Table 1.
3. "The average number of ultrasound examinations performed was five. What were the major indications for the multiple ultrasounds? Were some of these pregnancies complicated by conditions which might have influenced fetal presentation?"
   According to the Israeli society of obstetrics and gynecology low risk pregnancy follow-up guidelines, pregnant women are required to attend obstetric follow-up during the 2nd and 3rd trimesters once between 24-30 weeks` gestation and once between 30-36 weeks` gestation. Sonographic evaluation during these follow-up sessions is obligatory. The 5 US examinations performed during the study included the 2 for mentioned examinations in addition to the anatomic survey performed during the 2nd trimester and the US performed at 37 weeks` gestation prior to external cephalic version attempt. Thus, the additional US examinations were non obligatory and presumably were performed due to various patient complaints during random OBGYN visits. We added this limitation to the list of limitations in the discussion section.
4. "Is it known why ECV was attempted in only 53.8% of the 1271 women with breech presentation at 37 weeks or greater? Is there a difference in the population of women who chose to have attempted ECV versus those who did not?"
   The 587 women that compose the remaining women that were not included in the final analysis were excluded based on the specific exclusion criteria mentioned in the methods section, most of which refused an ECV attempt. Therefore, no selection bias was suspected. Due to the early exclusion based

on ECV attempt (Yes or No) we did not obtain the information regarding this cohort except for the reason for exclusion which has been added to the results section as requested.

5. "Were the birth weights between the 10% and 90% for all newborns in both groups? If not, how many were LGA or SGA?"

   There were no significant differences in the neonatal birth weights between the PBP and non-PBP groups. We added these results to Table 1.

6. "Table 1 is unclear. The individual favorable conditions for ECV success were the same for the PBP and non-PBP groups. The composite of favorable conditions ALONE prior to ECV attempt was significantly lower in the PBP group. What does this mean exactly? That ALL of the favorable conditions listed were present in 15.2 % (34/224) of the PBP group and 52.0% (239/460) of the non-PBP group? This should be clarified."

   The composite means that all the favorable conditions listed were present in the patient. We understand that the presented data may be confusing. The composite of favorable conditions was only presented for the successful ECVs. Of the 421 successful ECVs, 273 had a composite of favorable conditions for ECV. When considering this, one may say that the discrepancy in the rate of favorable conditions may explain the difference in ECV success. Of the failed ECVs (the remaining 263 patients of the 684 that underwent ECV), we did not present the rate of the composite of favorable conditions. Therefore, it would seem that there is a significant discrepancy between the 15% in the PBP group and the 52% in the non PBP group that may explain by itself the difference in ECV success. In light of this we added the composite of favorable conditions to the whole population of women that underwent ECV to show there was no difference between the groups (60.2% vs. 61.3%, P>0.05). This data was added to Table 1.

7. "43.2% (19/44) of women in the PBP group had "emergency" cesarean delivery due to arrest of decent. Why were all of these emergent? Was there evidence of non-reassuring fetal status?"

   The CDs were emergent due to prolonged 2nd stage and arrest of descent and not non reassuring fetal heart tracings.

8. "Is PBP an independent predictor of unsuccessful ECV or a result of absence of a composite of conditions favoring ECV success?"

We refer you to our reply for remark 6 that is repeated here in short and to the addition in table 1. There was no difference between the groups regarding the composite of favorable conditions (60.2% vs. 61.3%, P>0.05). Therefore, PBP is apparently the responsible party for the extremely low ECV success rate.

9. "Why is an instrumental vaginal delivery not considered a success, especially considering there were no differences in neonatal outcomes?"
   We found that the "normal" analysis namely vaginal vs. cesarean delivery didn't emphasize enough the impact of PBP on mode of delivery. Though vacuum deliveries are considered vaginal deliveries and the neonatal outcomes were similar, the rate of complications and the potential mental and psychological impact on the mother are substantial. As such, some women, after receiving a thorough explanation regarding the risks of vacuum delivery including the risk of intracranial hemorrhage would prefer elective CS compared to ECV with PBP. Therefore, we found it extremely relevant to discuss these results with the patient before attempting ECV in situations with PBP.
10. "Given the fact that many women will have a mid-trimester anatomic survey but may not have multiple subsequent intervening ultrasound examinations, do the authors feel that in cases of breech presentations diagnosed near term, it would be worthwhile to correlate with the presentation at the mid-trimester ultrasound?"
    Since the fetus may change presentation multiple times between the mid-trimester anatomical survey and ECV attempt at term, the correlation between the 2 scans seems to be random at best. PBP was defined based on the continuity of fetal presentation and an attempt to generalize the results of 2 scans almost 20 weeks apart negates the whole definition of PBP.
11. "Was there any explanation or can the authors speculate on the etiology of PBP and is there any clinical significance beyond a decreased likelihood of successful ECV?"
    We thought that uterine malformations of cord entanglement could explain the unsuccessful ECVs but we found no difference between the groups. We have no speculation regarding the etiology of PBP and further studies are required before any conclusions may be reached.

Statistical Editor:

We thank the statistical editor for their remarks. We hope you find our reply, additions and clarifications satisfactory.

1. "Table 1: Parity can only have integer values. Should format as median (range or IQR) or as categories, not as mean ± SD. Should include the number of U/S exams that documented PBP vs Non-PBP, since the former required "all" and the latter at least one non, need to assure the reader that the number of exams was equivalent for the two groups. The groups differed not only in PBP vs non-PBP, but in the proportion with favorable conditions for ECV success. Why is the conclusion necessarily that PCP vs non-PCP was determinative of success, rather than the proportion with favorable conditions for ECV? Need to provide more detail for the "Favorable conditions" allocation. The groups show no difference in mean values for parity, amniotic fluid index or BMI, nor for % posterior placenta. Yet the difference in % favorable could not be more different (87 % vs 13%). Need to show the proportions with no uterine activity and explain how this summary composite was obtained from the components listed."
   We changed the means to medians where relevant as suggested. This was an honest mistake that was missed by all the authors. The number of scans performed for each group was similar as can be seen in Table 1. Regarding the number of scans in which the fetal presentation was non-breech, we feel that the relevance of this data is limited since we determined that we are interested in the study group that consists of patients with breech presentation in all scans compared to the definition of non-PBP which was non-breech presentation in at least one scan (with no regard to the number of scans during which the fetus was non-breech). Regarding our conclusions and the somewhat confusing presentation of the rate of favorable conditions for ECV success, we added an additional line to the table that referred to the rate of favorable conditions for ECV from the whole study population as oppose to the final line in the table that refers to the rate of ECV success and favorable conditions for ECV among the population of women with successful ECV. Thus, though a bit confusing, it was important for us to show that even in the setting of favorable conditions for ECV the success rate for ECV was extremely low compared to non-PBP. Since we wish that

the information be displayed in a clear fashion, we changed the data in the last line of table 1 to reflect the success rate of ECV with favorable conditions from the whole population.

2. "lines 194-195: What is the statistical support for this statement, as compared to proportion of women with favorable conditions for ECV, for example? Put another way, if a woman had favorable conditions and was in the PBP group, what was the % with successful ECV (with CIs)? vs women with a favorable condition who was in the non-PBP group (% with CI)?"

   In continuation to our previous reply for remark 1, we show that of the total patients with PBP and favorable conditions only 25.2% of ECVs succeeded compared to 91.2% among non-PBP patients with favorable conditions.

3. "Table 2: The PBP group had N = 44, so the format of n (%) should be changed to integer values for %, rather than citing to 0.1% precision. The counts among the PBP group are too few to allow for adjustment for 5 variables. The models are likely over fitted. Again, this analysis does not adjust for the differences in "favorable conditions" for the PBP vs non-PBP groups."

   The % integers were changed as suggested. Regarding the analysis of the differences in favorable conditions, the adjustment was based on the total number of successful ECVs and not the slightly lower number of successful ECVs under favorable conditions. The bias due to the small group of patients analyzed in the mode of delivery analysis is substantial enough without minimizing the groups even more. Regarding the analysis of favorable conditions, this was addressed in our reply to remark 1+2.

Editor:

Thank you for your remarks. We hope you find our reply, additions and clarifications satisfactory.

1. "We are happy to consider a revised manuscript. However, our enthusiasm for it will depend on how you interpret the fact that those with persistent breech also had clinical profiles which are much more unfavorable for successful version. That is, does persistent breech provide clinically useful information over and above the clinical characteristics?"

   In light of the reviewers` remarks we added the composite of favorable conditions for the whole population of women that underwent ECV to

show there was no difference between the groups (60.2% vs. 61.3%, P>0.05). This data was added to Table 1. <u>The previous data only showed the rate of the composite from the population of successful ECVs, which was confusing.</u> Thus, the rate of ECV success among patients with PBP and favorable conditions was only 25.2% compared to 91.2% among non-PBP patients with favorable conditions. These results have been corrected in both table 1 and the text.

2. "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:

   OPT-IN: Yes, please publish my point-by-point response letter.

3. "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."

   I have confirmed with my coauthors the validity of their disclosures.

4. "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."

I have added the transparency declaration to my cover letter.

5. "Please submit a completed STROBE checklist. 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."

   The STROBE checklist has been filled and uploaded as a separate word file.

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 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."

After reviewing the reVITALize site we found no discrepancies between the manuscript text and the terms summarized in the site.

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."

   The body of text is comprised of 2828 words. The length of the manuscript is 19 pages including the references.

8. "Titles in Obstetrics & Gynecology are limited to 100 characters (including spaces). Do not structure the title as a declarative statement or a question. Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles. Abbreviations, jargon, trade names, formulas, and obsolete terminology also should not be used in the title. Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," or "A Systematic Review," as appropriate, in a subtitle. Otherwise, do not specify the type of manuscript in the title."

   The title does not contain any of the for mentioned statements. It is comprised of 90 characters including spaces.

9. "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).”

The financial disclosure appears after the conclusion section and the only acknowledgement is regarding the 39th SMFM presentation as a poster. The work on the study and manuscript were performed by the authors alone.

10. “Provide a short title of no more than 45 characters, including spaces, for use as a running foot.”

    A short title has been provided as a running foot.

11. “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.”

    We reviewed the abstract in light of the revised manuscript and found no discrepancies. An abstract word count has been added on the title page (290 words).

12. “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 abbreviations in the manuscript are spelled out the first time they appear in both the abstract and body of the manuscript.

13. “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.”

The virgule symbol is used in the manuscript only when expressing data or a measurement.

14. **“**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%").”
    The manuscript was adjusted according to these remarks.
15. **“**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.”

    The tables adhere to the journal`s table checklist.

16. “Please review examples of our current reference style at http://ong.editorialmanager.com (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.
    In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the 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 at the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top)."

All relevant manuscript references adhere to the journal`s current reference style.

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

    The authors are not interested in publishing open access.

Date: Oct 26, 2020
To: "Roy Lauterbach" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-2301R1

RE: Manuscript Number ONG-20-2301R1

Persistent breech presentation – A profound predictor of external cephalic version success

Dear Dr. Lauterbach:

Your revised manuscript has been reviewed by the Statistical Editor. The Editors would like you to address these additional comments.

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 7 days from the date of this letter. If we have not heard from you by Nov 02, 2020, we will assume you wish to withdraw the manuscript from further consideration.

STATISTICAL EDITOR:

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

Table 1: The entry for composite of favorable conditions for ECV for non-PBP group is 262/460. That proportion is not 61.3%, but rather 57.0%. Need to clarify whether the n or the % is incorrect. The number of US exams is entered as 5±2, but the format is cited as median (range). Need to clarify.

I remain confused about the definition of composite for favorable conditions for ECV. This is comprised (lines 193-195) of multiparity, normal amniotic fluid volume, posterior placenta, no documented uterine activity and BMI < 30). According to Table 1, the proportion nulliparous was 63.8 % and 66.9% in PBP and non-PBP groups, respectively. Since the rates of favorable conditions were 60.2% and 57% for those PBP subsets, then the definition of composite favorable must not be all 5 of the variables, but rather one or more of them. Need to provide more information re: the determination of the composite (which could be supplemental material) and need to add a row in Table 1 re: uterine activity.

Need to more clearly separate the primary (ECV success rate) from all secondary outcomes

***

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. 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 7 days from the date of this letter. If we have not heard from you by Nov 02, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

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

_____

2nd Reply to manuscript review:

Statistical Editor:

We thank the statistical editor for their remarks. We hope you find our reply, additions and clarifications satisfactory.

1. "Table 1: The entry for composite of favorable conditions for ECV for non-PBP group is 262/460. That proportion is not 61.3%, but rather 57.0%. Need to clarify whether the n or the % is incorrect. The number of US exams is entered as 5±2, but the format is cited as median (range). Need to clarify."
   Regarding the composite, there was an error in the %. It is 56.9% as you remarked. We changed the % appropriately. Regarding the number of US exams, the median was 5 and the range was 2-7. We changed the values accordingly in table 1 and in the results section in the body of the text.
2. "I remain confused about the definition of composite for favorable conditions for ECV. This is comprised (lines 193-195) of multiparity, normal amniotic fluid volume, posterior placenta, no documented uterine activity and BMI < 30). According to Table 1, the proportion nulliparous was 63.8 % and 66.9% in PBP and non-PBP groups, respectively. Since the rates of favorable conditions were 60.2% and 57% for those PBP subsets, then the definition of composite favorable must not be all 5 of the variables, but rather one or more of them. Need to provide more information re: the determination of the composite (which could be supplemental material) and need to add a row in Table 1 re: uterine activity."
   We understand the problem. Indeed, the composite did not include all the parameters mentioned to be favorable for ECV success but rather a combination of at least 3 out of 5 parameters. We clarified this in the results section and added a clarification in the appendix of table 1. In addition, we added a row for uterine activity as suggested.
3. "Need to more clearly separate the primary (ECV success rate) from all secondary outcomes."
   Upon your suggestion we decided to display the primary outcome-ECV success rate, in a graphical manner. We appreciate your input.