

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)*

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

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

Date: Jan 02, 2020
To: "Diane Korb" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-19-2281

RE: Manuscript Number ONG-19-2281

FIRST TWIN IN BREECH PRESENTATION: NEONATAL MORTALITY AND MORBIDITY ACCORDING TO PLANNED MODE OF DELIVERY

Dear Dr. Korb:

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 Jan 23, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

1. Given that the French guidelines do not call for cesarean delivery of the breech first twin, the authors should give more details for why only 20% of eligible subjects had planned vaginal delivery. Why did the obstetrician performing the delivery (see line 130) choose to ignore the guidelines 80% of the time (see lines 209-10)?
2. In lines 112-3, the authors should state whether they are referring to clinical or X-ray pelvimetry.
3. The words "when carefully selected" should be added somewhere in the sentence in lines 244-6.

Reviewer #2: This is a secondary analysis of a prospective multicenter national population-based observational study of twin deliveries in France. In this subset cohort, the authors assessed the composite neonatal morbidity and mortality up to 28 days of neonatal life between an intended attempt at vaginal birth vs. planned elective Cesarean section in twins after 32 weeks when the first presenting fetus is a breech. The cohort was of healthy twins diamniotic after 32 weeks with EFW between 1500-4000 gm, with second twin not "substantially larger" than first twin in patients without a contraindication for vaginal birth. The authors adjusted for potential confounders such as parity, previous CS, gestational age at birthing, and number of twin deliveries by center, using Poisson multivariate regression analysis. They also tried to control for "indication bias" using a "propensity Score". The authors concluded that planned vaginal delivery was not associated with increased neonatal morbidity and mortality than with planned caesarean section.

I have the following comments:

1. This is a very important paper that adds to our literature in management of twins in an era of high rates of abdominal deliveries. It adds new knowledge to our perception of risks for fetal and neonatal harm in planned vaginal delivery of twins when the first twin is a breech. Delivering a breech particularly in twins is a lost art amongst the newer generations of obstetricians especially on this continent. This paper should alleviate many fears regarding vaginal delivery in pregnancy when twin A is a breech.
2. Given that the cohort under study here is part of a larger group of patients from the JUMODA study and given that

many readers are not familiar with that particular study, the authors have to elaborate more on certain particulars so that this current study report can stand alone. In the Material and Methods section for example, the authors refer to certain criteria for appropriateness of a planned vaginal delivery in a twin breech. Many need some elaboration:

- a. Normal pelvimetry: is this by clinical assessment of the pelvis or radiologic pelvimetry?
 - b. Hyperextension of the neck: is this done on day of planned delivery or before? If so by how long?
 - c. Estimated fetal weight of <3800 gm: how is this done, given inaccuracy of US measurements at term?
 - d. Twin B not substantially larger than Twin A: how is that defined? AC centiles >20% or some other measurement?
3. The hypothesis should be clearly stated as it is not
4. I remain uncertain what Type of breech presentations for twin A were enrolled in the planned vaginal delivery group? Were only frank or complete breeches allowed to be in the planned Vaginal delivery group? Please clarify and offer distribution of types of breeches for the planned vaginal delivery group and for the elective CS group (may be shown in Table 2)
5. I am not familiar with "propensity score" and how it was used to control for "indication bias". A review by a statistician is in order.
6. Please comment whether any of the patients in the planned vaginal delivery group were induced and or augmented. A sub-analysis of the primary outcomes of those who were induced and those who went into spontaneous labor should be included and compared to those who were in the elective CS group, even though the numbers (n) will be smaller.
7. It appears that most patients in the planned delivery group had a CS for intrapartum complications. What was the compliance rate with the Intention to treat category and the actual execution of that planned pathway? For example, did the 11 patients of the 113 patient who had a CS in the planned vaginal delivery group (Table 3) undergo an elective CS for a change of mind? Equally, what was the reason for the 4 patients in the elective CS group to have delivered vaginally? Did they come in with active labor and a decision was made to let them attempt to deliver vaginally?
8. It appears that 22% of those in the planned vaginal delivery group and 15 % of those in elective CS group delivered before 35 weeks. While the neonatal composite morbidity was low in both groups, was there a predisposition for these neonatal complications to occur as a result of prematurity rather than method of delivery especially for complications of intubation, neonatal sepsis, BPD, or IVH?
9. Interlocking twins is a rare but a very serious risk with adverse outcomes and dire consequences. It happened once in this study in the cohort of 298 planned for vaginal delivery. Was the second twin cephalic at the onset of labor?
10. Even though I note that the Twin Study selection criteria include only "low risk" women, yet I note that up to 20-26 % of patients in this cohort had preeclampsia or gestational hypertension, fetal growth restriction, diabetes or twin to twin transfusion. Would the authors not consider those as possible confounders for the primary outcome that need to be controlled in the multivariate regression analysis? Please comment.
11. I was surprised that there was no calculation of sample size at the onset of this endeavour based on a clinically significant difference in the primary outcome by mode of delivery. The authors do comment in the Discussion section that the sample they had had an 80% power to show a 2.6-fold increase in risk of the primary outcome. Perhaps include that sentence in the Methods and Analysis section earlier in the paper. I fairness though, as this work is not a randomized clinical trial, but a prospective observational study, the authors have to use the cohort size they have. It is obvious that the sample size was small and the confidence intervals wide. Hence it is prudent for the authors to indicate that these results are suggestive and not confirmatory of the safety of a planned vaginal delivery in twins when twin A is a breech. The results of this study should be considered preliminary.

Reviewer #3: This is a planned secondary analysis of the JUMODA study, a prospective cohort study of mode of delivery in 8,800 twin pregnancies that was conducted in 176 maternity units across France in 2014-2015. The current analysis compares neonatal morbidity and mortality in twins with breech presentation of the first twin, according to mode of delivery. The paper is beautifully written. Comments and questions follow.

1. Abstract. Overall this is an excellent summary. The following are minor.
 - a. Would consider a sentence conveying that planned breech delivery of presenting twins is performed in France (but that data are limited, etc). Reader might not be expecting this.
 - b. Lines 56-58. The authors mention "all the inclusion criteria of the Twin Birth Study," but readers probably won't know what these are. Also, women with twin pregnancies are not considered low-risk (by the readership), so might rephrase how this content is presented in the manuscript.
 - c. Line 62. Minor, but might add "breech" to convey that all 1,467 twin pregnancies had breech-presenting twins.
 - d. Line 65. Approximately 80% had a planned cesarean delivery. Here or elsewhere in the manuscript, would try to give the reader a sense of why.

e. Minor: Please write out JUMODA the first time you use the abbreviation.

2. Introduction. This section is also well written. The following are minor.

- a. Lines 78-80. The authors might mention that e.g. in the absence of a contraindication, it is recommended that all women in whom the presenting twin is cephalic be offered vaginal delivery, provided personnel with appropriate training and experience are available. As presented the tone may not fully convey the degree of caution exercised when considering vaginal twin delivery.
- b. Lines 84-87. In the discussion, might address morbidity in vaginal singleton breech delivery compared with vaginal twin breech delivery more fully. Is there a rationale for why morbidity would be lower in a multiple gestations?

3. Methods. The content is clearly presented.

- a. Line 115. Would include something about the risks quoted to study participants as part of informed consent.
- b. Line 120. Do the authors mean birth weight (as stated) or estimated fetal weight? It would be reasonable if the authors want to analyze pregnancies with birth weight >4000g separately, but trial exclusion criteria should be based on criteria known prior to delivery.
- c. Line 122. Please define "second twin substantially larger than the first twin." Might mention that presentation of the second twin was not a consideration (this may not be intuitive to readership).
- d. Line 129-130. When was the planned mode of delivery planned? The authors write that it was defined prospectively by the obstetrician, but when did that occur?

4. Results.

- a. Lines 204-208. The authors acknowledge differences between cohorts in a way that encourages providers considering vaginal breech delivery to have safeguards in place (nicely done).
- b. Lines 209-210. The main indication for planned cesarean was breech presentation of the first twin (>60%). But, all in this series had breech presentation.
- c. Table 1. Weren't pregnancies with placenta previa excluded? What was the rationale for including a pregnancy with TTTS in the (low-risk?) study group?

5. Discussion.

- a. Lines 244-246. Might include a few more sentences in the opening paragraph to highlight study findings. For example, likelihood of successful vaginal twin delivery with breech presenting twins when carefully selected, and low incidence of mortality, birth asphyxia, and interlocking heads. Is there evidence that interlocking heads is a true risk, or perhaps is this something that need not be a significant concern any longer, now that ultrasound can reliably evaluate fetal position in labor?
- b. Were outcomes equivalent because of careful patient selection, or because women delivering vaginally were at lower risk?
- c. Lines 287-291. This appears to be the concluding take-home message. Might want to end the manuscript with these 2 sentences (short paragraph).
- d. Lines 291-295. Here the authors compared the findings from their current study with JUMODA cohort results for planned vaginal delivery when the presenting twin is cephalic. This may be the primary question that readers have after reading the results text. It would be reasonable for the authors to include a paragraph with more information about their prior study results (for comparison), such as any areas in which the individual morbidities differed. Might move this paragraph to after the paragraph that ends in line 256, where the authors review other work on this topic, right before the strengths of their study.

STATISTICAL EDITOR COMMENTS:

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

This is an important topic and the analysis is well done. Unfortunately, the study is under powered and the NS findings cannot be generalized. For example, using the samples at hand, a baseline rate of 1.9% adverse outcomes, using the standard power of 80% and $\alpha = .05$, the detectable alternative would have to be > 5.0% or = 0%. Put another way, to have the usual power of 80% and to establish that the rate could not be > double the control group rate, the samples would have to be ~ 700 and ~ 2700, or more than double the present samples. The Authors do acknowledge this (lines 273-278), but it needs more emphasis. That is, the NS difference in adverse rates cannot be generalized, for the above reasons, along with those clinical issues named by the Authors.

The math is similar for the 2nd twin analysis.

Should report the adverse outcome rates with 95% CIs.

Fig 2: The wide CIs for RRs imply how few the counts are for adverse events. That is, CD rates could plausibly be 2x those after vaginal delivery.

EDITOR'S COMMENTS:

We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues, and other things. Adherence to these requirements with your revision will avoid delays during the revision process, as well as avoid re-revisions on your part in order to comply with the formatting. Please use the STARD guidelines, as specified in the instructions for authors for reports of diagnostic testing.

Line 52: Delete "Our primary objective"" thus leaving a "to" statement.

Results and Conclusion section of abstract will need to be adjusted related to comments by statistical editor regarding the underpowered status of your paper for the negative results.

Line 83: Change "is associated" to "are associated".

Line 101-106: one of your reviewers asked for more information about the JUMODA trial. I think this is sufficient as written.

Line 119: I was expecting Figure 1 to be the inclusion and exclusion criteria. Could you provide these? You have a list of exclusion criteria lines 120-124. Are the only inclusion criteria the presence of twins by EGA and weight limits?

Line 121: Could you edit to "a fetal anomaly affecting either twin"?

Line 123: Any myoma or only one in the lower uterine segment?

Methods section is very well written—thank you.

Line 213: Not sure you need a sentence here. You can just say "No fetus died intrapartum" The rate of composite.....

Line 216 and throughout results (including tables, abstract):

P Values vs Effect Size and Confidence Intervals

While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, the preferred citation should be in terms of 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.

This is true for the abstract as well as the manuscript, tables and figures.

Please provide absolute values for variables, in addition to the assessment of statistical significance.

We ask that you provide crude OR and RR's followed by adjusted values for all variables.

Line 275: Please put the power analysis (Presumably post hoc, but make that clear) in the methods section. In the discussion section, please include the information provided in the statistical editor's comments regarding the power of your study, and the number needed for adequate power.

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. All studies should follow the principles set forth in the Helsinki Declaration of 1975, as revised in 2013, and manuscripts should be approved by the necessary authority before submission. Applicable original research studies should be reviewed by an institutional review board (IRB) or ethics committee. This review should be documented in your cover letter as well in the Materials and Methods section, with an explanation if the study was considered exempt. If your research is based on a publicly available data set approved by your IRB for exemption, please provide documentation of this in your cover letter by submitting the URL of the IRB website outlining the exempt data sets or a letter from a representative of the IRB. In addition, insert a sentence in the Materials and Methods section stating that the study was approved or exempt from approval. In all cases, the complete name of the IRB should be provided in the manuscript.

4. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works.

Please add some variance to the Methods section to distinguish this paper from previous papers on this study.

5. Please submit a completed STROBE checklist with your submission.

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), 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, 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 and gynecology data definitions at <https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

7. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

8. 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:

- * 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).

10. Provide a précis on the second page, for use in the Table of Contents. The précis is a single sentence of no more than

25 words that states the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."

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

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.

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.

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%).

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.

16. 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>.

17. Figures 1 and 2 may be resubmitted as-is with your revision.

18. 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 <http://edmgr.ovid.com/acd/accounts/ifauth.htm>.

Please note that if your article is accepted, you will receive an email from the editorial office asking you to choose a publication route (traditional or open access). Please keep an eye out for that future email and be sure to respond to it promptly.

19. 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 21 days from the date of this letter. If we have not heard from you

by Jan 23, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2018 IMPACT FACTOR: 4.965

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

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: <https://www.editorialmanager.com/ong/login.asp?a=r>). Please contact the publication office if you have any questions.



Paris, January 17th 2020

Dear Editor,

Thank you for your response on January 2nd 2020, concerning our manuscript ONG-19-2281 entitled “First twin in breech presentation: neonatal mortality and morbidity according to planned mode of delivery” informing us you would be willing to give further consideration to a revised version.

The authors are very grateful to the Reviewers and Editors for their constructive help. We think the paper has been much improved. Our revised version has taken into account all the following points raised by the Reviewers and Editors.

All the authors have read and approved the revised version of the paper.

We hope our manuscript now meets the standards of *Obstetrics & Gynecology*.

Yours sincerely,

Diane Korb

All line numbers refer to the revised version of the manuscript with the highlighted changes.

Response to the Reviewers

Reviewer #1:

1. Given that the French guidelines do not call for cesarean delivery of the breech first twin, the authors should give more details for why only 20% of eligible subjects had planned vaginal delivery. Why did the obstetrician performing the delivery (see line 130) choose to ignore the guidelines 80% of the time (see lines 209-10)?

The French guidelines do not recommend systematic planned cesarean delivery but they do neither recommend planned vaginal delivery. The 2 options are possible due to the lack of solid evidences. Although this study took place in a country where systematic planned cesarean delivery is not recommended in case of first twin in breech presentation, and where obstetricians are trained in and accustomed to the management of vaginal breech delivery, the rate of planned cesarean delivery is high in this situation. This reflects the apprehension of the majority of the practitioners to perform a planned vaginal delivery, as it is observed in other countries having guidelines recommending a planned cesarean delivery.

We now state in the introduction section that the two options are possible in France, lines 103-104.

2. In lines 112-3, the authors should state whether they are referring to clinical or X-ray pelvimetry.

The manuscript has been modified as suggested by the Reviewer. We have now specified that pelvimetry is referring to computed tomographic (CT) pelvimetry, line 130.

3. The words "when carefully selected" should be added somewhere in the sentence in lines 244-6.

The discussion has been modified as suggested by the Reviewer. We have added to the discussion the fact that our conclusions apply to first twin in breech presentation in carefully selected patients, line 289.

Reviewer #2:

This is a secondary analysis of a prospective multicenter national population-based observational study of twin deliveries in France. In this subset cohort, the authors assessed the composite neonatal morbidity and mortality up to 28 days of neonatal life between an intended attempt at vaginal birth vs. planned elective Cesarean section in twins after 32 weeks when the first presenting fetus is a breech. The cohort was of healthy twins diamniotic after 32 weeks with EFW between 1500-4000 gm, with second twin not "substantially larger" than first twin in patients without a contraindication for vaginal birth. The authors adjusted for potential confounders such as parity, previous CS, gestational age at birthing, and number of twin deliveries by center, using Poisson multivariate regression analysis. They also tried to control for "indication bias" using a "propensity Score". The authors concluded that planned vaginal delivery was not associated with increased neonatal morbidity and mortality than with planned caesarean section.

I have the following comments:

1. This is a very important paper that adds to our literature in management of twins in an era of high rates of abdominal deliveries. It adds new knowledge to our perception of risks for fetal and neonatal harm in planned vaginal delivery of twins when the first twin is a breech. Delivering a breech particularly in twins is a lost art amongst the newer

generations of obstetricians especially on this continent. This paper should alleviate many fears regarding vaginal delivery in pregnancy when twin A is a breech.

We thank the Reviewer for his/her comment.

2. Given that the cohort under study here is part of a larger group of patients from the JUMODA study and given that many readers are not familiar with that particular study, the authors have to elaborate more on certain particulars so that this current study report can stand alone. In the Material and Methods section for example, the authors refer to certain criteria for appropriateness of a planned vaginal delivery in a twin breech. Many need some elaboration:

We provided in the Methods section the criteria used in France to accept a planned vaginal delivery in case of breech presentation, in singleton or twin pregnancy with a breech presenting first twin. This information was provided to the reader for understanding the French management of breech delivery.

However, this observational study, in a pragmatic approach, didn't aim to verify how these criteria were respected. We rephrased this paragraph, lines 126-134.

a. Normal pelvimetry: is this by clinical assessment of the pelvis or radiologic pelvimetry?

The manuscript has been modified as suggested by the Reviewer. We have now specified that pelvimetry is referring to CT pelvimetry, line 130.

b. Hyperextension of the neck: is this done on day of planned delivery or before? If so by how long?

The French guidelines recommend checking for the absence of hyperextension of the fetal head before accepting a planned vaginal delivery. The timing of the checking is not defined in the guidelines. However, the decision to accept or refuse a planned vaginal delivery was let to the investigators in each center. The questionnaire didn't collect information about this specific criterion needed for the decision of the planned mode of delivery. We are unable to provide information about the frequency or timing of the checking of the absence of hyperextension of the fetal head.

Therefore, we didn't modify the manuscript regarding this point raised by the Reviewer.

c. Estimated fetal weight of <3800 gm: how is this done, given inaccuracy of US measurements at term?

The French guidelines recommend performing a cesarean in case of EFW greater than 3800g in case of breech presentation. However, the decision to accept or refuse a planned vaginal delivery was let to the investigators in each center. The questionnaire didn't collect information about this specific criterion needed for the decision of the planned mode of delivery. We are unable to provide information about the frequency or timing of the EFW. Therefore, we didn't modify the manuscript regarding this point raised by the Reviewer.

d. Twin B not substantially larger than Twin A: how is that defined? AC centiles >20% or some other measurement?

The French guidelines do specify the threshold above which a cesarean has to be performed, due to the lack of strong evidences allowing such recommendations. The threshold depends on the center and practitioners. This is the reason why the questionnaire, in a pragmatic approach, only asked if a cesarean had been decided because of a «fetal estimated weight discrepancy considered as important when choosing the mode of delivery ».

3. The hypothesis should be clearly stated as it is not

As previously reported in French retrospective studies (references 7 and 8 of the manuscript), we hypothesized that planned vaginal delivery will not be associated with a significant increase in neonatal mortality and morbidity as compared with planned cesarean delivery. We added this sentence at the end of the introduction section, lines 108-115.

4. I remain uncertain what Type of breech presentations for twin A were enrolled in the planned vaginal delivery group? Were only frank or complete breeches allowed to be in the planned Vaginal delivery group? Please clarify and offer distribution of types of breeches for the planned vaginal delivery group and for the elective CS group (may be shown in Table 2)

The French guidelines do not take into account the type of breech presentation for the decision of the planned mode of delivery. In the planned vaginal delivery group, 132 (44.7%) of breech were complete, and 163 (55.3%) were frank. We added in the manuscript that the type of breech presentation is not taken into account for the decision of the planned mode of delivery in our country, lines 134-136.

We agree with the reviewer that it would have been interesting to know if the complete breech presentations were over-represented in the planned cesarean delivery group. Unfortunately, we do not have this information available for the planned cesarean delivery group, this is that why we did not add this information in Table 2.

5. I am not familiar with "propensity score" and how it was used to control for "indication bias". A review by a statistician is in order.

6. Please comment whether any of the patients in the planned vaginal delivery group were induced and or augmented. A sub-analysis of the primary outcomes of those who were induced and those who went into spontaneous labor should be included and compared to those who were in the elective CS group, even though the numbers (n) will be smaller.

In the planned vaginal delivery group, 195 (66.1%) of women have a spontaneous labor and 100 (33.9%) an induction of labor (61 by oxytocin, 33 by prostaglandins and 6 by balloon). The association between the planned mode of delivery and the neonatal morbidity of first and second twin was not modified according to the onset of labor (table below).

Table: Neonatal morbidity according to the planned mode of delivery and the onset of labor

	Planned vaginal delivery n/N (%)	Planned cesarean delivery n/N (%)	p
Spontaneous labor			
Neonatal morbidity of 1 st twin	3/195 (1.5)	22/1169 (1.9)	0.741
Neonatal morbidity of 2 nd twin	7/195 (3.6)	28/1169 (2.4)	0.329
Induction of labor			
Neonatal morbidity of 1 st twin	2/100 (2.0)	22/1169 (1.9)	0.934
Neonatal morbidity of 2 nd twin	0	28/1169 (2.4)	0.118

We do not believe these analyses provide crucial information. We did not modify the manuscript regarding this point raised by the Reviewer.

7. It appears that most patients in the planned delivery group had a CS for intrapartum complications. What was the compliance rate with the Intention to treat category and the actual execution of that planned pathway? For example, did the 11 patients of the

113 patient who had a CS in the planned vaginal delivery group (Table 3) undergo an elective CS for a change of mind? Equally, what was the reason for the 4 patients in the elective CS group to have delivered vaginally? Did they come in with active labor and a decision was made to let them attempt to deliver vaginally?

Among the 298 women of the planned vaginal group, none had an elective cesarean without a trial of labor. This applies also to the 11 women with a cesarean during labor for “other reason”, a very heterogeneous group with 11 different indications (arm prolapse, leg prolapse of the second twin below the first twin presentation, and other odd indications).

Concerning the 4 patients in the planned cesarean delivery group who delivered vaginally, the planned mode of delivery has been modified when the woman arrived in labor before the date of the planned cesarean.

8. It appears that 22% of those in the planned vaginal delivery group and 15 % of those in elective CS group delivered before 35 weeks. While the neonatal composite morbidity was low in both groups, was there a predisposition for these neonatal complications to occur as a result of prematurity rather than method of delivery especially for complications of intubation, neonatal sepsis, BPD, or IVH?

We agree with the reviewer that prematurity could impact the rate of the primary outcome. However, it is very unlikely that it could explain the non-significant differences observed in our study since morbidity rates were lower in the planned vaginal delivery group although preterm delivery rates were higher. The rate of neonatal morbidity varied according to the gestational age at delivery, but the association between the planned mode of delivery and the neonatal morbidity stratified on the gestational age at delivery remained non significant (Table below).

Table: Neonatal morbidity according to the planned mode of delivery and the gestational age at delivery

	Planned vaginal delivery n/N (%)	Planned cesarean delivery n/N (%)	p
<35 weeks			
Neonatal morbidity of 1 st twin	4/68 (5.9)	16/177 (9.0)	0.419
Intubation	2 (2.9)	7 (4.0)	
Neonatal sepsis	2 (3.1)	9 (5.2)	
BPD	0	0	
IVH	2 (3.1)	5 (2.9)	
Neonatal morbidity of 2 nd twin	5/68 (7.4)	17/177 (9.6)	0.581
Intubation	4 (5.9)	11 (6.2)	
Neonatal sepsis	0	6 (3.5)	
BPD	0	2 (1.2)	
IVH	2 (3.1)	9 (5.2)	
≥ 35 weeks			
Neonatal morbidity of 1 st twin	1/230 (0.4)	6/992 (0.6)	0.758
Intubation	0	1 (0.1)	
Neonatal sepsis	0	2 (0.7)	
BPD	0	2 (0.7)	
IVH	1 (1.1)	1 (0.3)	
Neonatal morbidity of 2 nd twin	2/230 (0.9)	11/992 (1.1)	0.750
Intubation	1 (0.4)	6 (0.6)	
Neonatal sepsis	1 (1.2)	2 (0.6)	
BPD	0	2 (0.6)	

IVH	0	1 (0.3)
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Because we do not believe these analyses provide crucial information and because of the even smaller number of events in this subgroup analysis according to gestational age than in the primary analysis, we did not modify the manuscript regarding this point raised by the Reviewer.

9. Interlocking twins is a rare but a very serious risk with adverse outcomes and dire consequences. It happened once in this study in the cohort of 298 planned for vaginal delivery. Was the second twin cephalic at the onset of labor?

This information was not available in the questionnaire. We only collected second twin presentation at delivery because second twin presentation is not an issue to decide the planned mode of delivery in our country, and there is no specific recommendation in the French guidelines regarding the choice of the planned mode of delivery according to second twin presentation, whatever the first twin presentation.

10. Even though I note that the Twin Study selection criteria include only "low risk" women, yet I note that up to 20-26 % of patients in this cohort had preeclampsia or gestational hypertension, fetal growth restriction, diabetes or twin to twin transfusion. Would the authors not consider those as possible confounders for the primary outcome that need to be controlled in the multivariate regression analysis? Please comment.

To avoid an overfitted model, we limited the adjustment model on 3 covariates, because there is a sparse number of composite adverse events (n=27); because it is classically admitted that the ratio of events per variable in regression analysis should not exceed 10 in order to avoid biasing the coefficients.

When we added as confounder a variable "pregnancy complications" defined by the occurrence of preeclampsia or gestational hypertension, fetal growth restriction, diabetes or twin to twin transfusion, the RR remained similar (adjusted RR=0.69 (0.25-1.90)) as those reported in our primary analysis (adjusted RR=0.71 (0.23-1.86)).

Furthermore, pregnancy complications were included in the model of the propensity score, for the matching and IPTW analyses, which provided similar adjusted RR than in the multivariate regression.

Finally, we performed a sensitivity analysis in which woman of the planned cesarean group were even at smaller risk by selecting only patients who had a cesarean only because the first was in breech presentation. The results of this sensitivity analysis were similar to the results of the primary analysis.

Therefore we didn't modify the manuscript according to this point raised by the reviewer.

11. I was surprised that there was no calculation of sample size at the onset of this endeavour based on a clinically significant difference in the primary outcome by mode of delivery. The authors do comment in the Discussion section that the sample they had had an 80% power to show a 2.6-fold increase in risk of the primary outcome. Perhaps include that sentence in the Methods and Analysis section earlier in the paper. I fairness though, as this work is not a randomized clinical trial, but a prospective observational study, the authors have to use the cohort size they have. It is obvious that the sample size was small and the confidence intervals wide. Hence it is prudent for the authors to indicate that these results are suggestive and not confirmatory of the safety of a planned vaginal delivery in twins when twin A is a breech. The results of this study should be considered preliminary.

We didn't make any power calculation since we had no idea about the rate of planned vaginal delivery in this population of woman with a breech presenting first twin. Our power analysis is post hoc and has been performed after the study completion.

The manuscript has been modified as suggested by the Reviewer. We have now specified the power calculation in the Methods section, lines 224-228.

Reviewer #3:

This is a planned secondary analysis of the JUMODA study, a prospective cohort study of mode of delivery in 8,800 twin pregnancies that was conducted in 176 maternity units across France in 2014-2015. The current analysis compares neonatal morbidity and mortality in twins with breech presentation of the first twin, according to mode of delivery. The paper is beautifully written. Comments and questions follow.

1. Abstract. Overall this is an excellent summary. The following are minor.

a. Would consider a sentence conveying that planned breech delivery of presenting twins is performed in France (but that data are limited, etc). Reader might not be expecting this.

We modified the Abstract as suggested by the reviewer, lines 54-55.

Furthermore, French policy for managing the choice of the mode of delivery in twin pregnancies with a breech presenting first twin has been clarified in the introduction section, lines 103-104.

b. Lines 56-58. The authors mention "all the inclusion criteria of the Twin Birth Study," but readers probably won't know what these are. Also, women with twin pregnancies are not considered low-risk (by the readership), so might rephrase how this content is presented in the manuscript.

The abstract has been modified as suggested by the Reviewer. We have now specified the inclusion criteria of the Twin Birth Study, lines 61-62.

c. Line 62. Minor, but might add "breech" to convey that all 1,467 twin pregnancies had breech-presenting twins.

The abstract has been modified as suggested by the Reviewer. We have now specified that 1,467 twin pregnancies had a breech presenting first twin, line 65.

d. Line 65. Approximately 80% had a planned cesarean delivery. Here or elsewhere in the manuscript, would try to give the reader a sense of why.

The French guidelines do not recommend systematic planned cesarean delivery but they do neither recommend planned vaginal delivery. The 2 options are possible due to the lack of solid evidences. The high rate of planned cesarean delivery reflects the apprehension of the majority of the practitioners to perform a planned vaginal delivery, as it is observed in other countries having guidelines recommending a planned cesarean

We now state in the introduction section that the two options are possible in France, lines 103-104.

e. Minor: Please write out JUMODA the first time you use the abbreviation.

The abstract has been modified as suggested by the Reviewer. We have now specified the abbreviation of JUMODA, line 56.

2. Introduction. This section is also well written. The following are minor.

a. Lines 78-80. The authors might mention that e.g. in the absence of a contraindication, it is recommended that all women in whom the presenting twin is cephalic be offered

vaginal delivery, provided personnel with appropriate training and experience are available. As presented the tone may not fully convey the degree of caution exercised when considering vaginal twin delivery.

The introduction has been modified as suggested by the Reviewer. We have now specified that in the absence of contraindications, it is recommended that all women in whom the presenting twin is cephalic be offered vaginal delivery, provided personnel with appropriate training and experience are available, lines 88-90.

b. Lines 84-87. In the discussion, might address morbidity in vaginal singleton breech delivery compared with vaginal twin breech delivery more fully. Is there a rationale for why morbidity would be lower in a multiple gestations?

As our study population consists only of twin pregnancies, and because we have not made any comparison with singleton pregnancies, we have not discussed this point in the manuscript. The rate of neonatal morbidity observed for the first twin in breech presentation in our study was similar to the rate observed in the PREMODA study, an observational prospective study conducted in France and Belgium and conducted to describe neonatal outcomes according to the planned mode of delivery for singleton term breech births (reference 20 of the manuscript).

3. Methods. The content is clearly presented.

a. Line 115. Would include something about the risks quoted to study participants as part of informed consent.

The method section has been modified as suggested by the Reviewer. We have now specified that the woman's informed consent was obtained after the explanation about the benefits and risks of both planned mode of delivery, lines 133-134.

b. Line 120. Do the authors mean birth weight (as stated) or estimated fetal weight? It would be reasonable if the authors want to analyze pregnancies with birth weight >4000g separately, but trial exclusion criteria should be based on criteria known prior to delivery.

For the inclusion criteria we have chosen the birth weight because there are less missing data than for estimated fetal weight and because the fetal weight estimation could have been performed far from the term of delivery.

c. Line 122. Please define "second twin substantially larger than the first twin." Might mention that presentation of the second twin was not a consideration (this may not be intuitive to readership).

The French guidelines do not specify the threshold above which a cesarean has to be performed, due to the lack of strong evidences allowing such recommendations. The threshold depends on the center and the practitioners. This is the reason why the questionnaire, in a pragmatic approach, only asked if a cesarean had been decided because of a «fetal estimated weight discrepancy considered as important when choosing the mode of delivery ».

We have now specified that the presentation of the second twin was not a criterion for exclusion, line 135.

d. Line 129-130. When was the planned mode of delivery planned? The authors write that it was defined prospectively by the obstetrician, but when did that occur?

The date of the decision of the planned mode of delivery was not available in the JUMODA database.

4. Results.

a. Lines 204-208. The authors acknowledge differences between cohorts in a way that encourages providers considering vaginal breech delivery to have safeguards in place (nicely done).

We thank the Reviewer for his/her comment.

b. Lines 209-210. The main indication for planned cesarean was breech presentation of the first twin (>60%). But, all in this series had breech presentation.

Indeed, all first fetuses in this series had breech presentation and this was the only indication for cesarean for 60% of the planned cesarean delivery group.

c. Table 1. Weren't pregnancies with placenta previa excluded? What was the rationale for including a pregnancy with TTTS in the (low-risk?) study group?

We excluded the placenta previa overlying the internal os and responsible of a planned cesarean delivery as specified in the Methods section, line 158.

We didn't exclude TTTS because the occurrence of this complication doesn't modify the choice of the planned mode of delivery. In addition, it was not an exclusion criterion of the Twin Birth Study. And finally, due to the smaller case of TTTS (6 cases that is 0.3% and 0.6 % in compared groups), our results would be unchanged in case of exclusion.

5. Discussion.

a. Lines 244-246. Might include a few more sentences in the opening paragraph to highlight study findings. For example, likelihood of successful vaginal twin delivery with breech presenting twins when carefully selected, and low incidence of mortality, birth asphyxia, and interlocking heads. Is there evidence that interlocking heads is a true risk, or perhaps is this something that need not be a significant concern any longer, now that ultrasound can reliably evaluate fetal position in labor?

The opening paragraph is a summary of the principal findings of the study. Our primary outcome was a recognized composite of neonatal mortality and severe morbidity. Due to the small number of events for the primary outcome in the planned vaginal delivery group, we do not think reasonable to discuss some particular events separately. Furthermore, birth asphyxia was not one of these events. Only one case of interlocking heads occurred, preventing us to draw definitive conclusions. This case is described precisely enough in the Results section. Finally, we discussed this point in the discussion section, lines 317-319.

b. Were outcomes equivalent because of careful patient selection, or because women delivering vaginally were at lower risk?

We performed analysis with propensity score to control for indication bias related to confounding factors that might influence both the choice of the planned mode of delivery and the occurrence of neonatal mortality and morbidity, which allows obtaining two groups of comparison with similar characteristics as in a randomized trial. Due to the variables included in the propensity score corresponding to maternal, obstetrical, and neonatal characteristics, the women of the planned vaginal group were at similar risk than the women of the planned cesarean group.

To control for this potential bias, we also performed a sensitivity analysis restricted to women for which the indication of cesarean was only the presentation of the first twin. The results were similar as in the primary analysis.

c. Lines 287-291. This appears to be the concluding take-home message. Might want to end the manuscript with these 2 sentences (short paragraph).

We modified the structure of the discussion, and now these two sentences are in the end of the manuscript.

d. Lines 291-295. Here the authors compared the findings from their current study with JUMODA cohort results for planned vaginal delivery when the presenting twin is cephalic. This may be the primary question that readers have after reading the results text. It would be reasonable for the authors to include a paragraph with more information about their prior study results (for comparison), such as any areas in which the individual morbidities differed. Might move this paragraph to after the paragraph that ends in line 256, where the authors review other work on this topic, right before the strengths of their study.

The manuscript has been modified and we moved the paragraph as suggested by the Reviewer, lines 301-308.

STATISTICAL EDITOR COMMENTS:

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

This is an important topic and the analysis is well done. Unfortunately, the study is under powered and the NS findings cannot be generalized. For example, using the samples at hand, a baseline rate of 1.9% adverse outcomes, using the standard power of 80% and $\alpha = .05$, the detectable alternative would have to be $> 5.0\%$ or $= 0\%$. Put another way, to have the usual power of 80% and to establish that the rate could not be $>$ double the control group rate, the samples would have to be ~ 700 and ~ 2700 , or more than double the present samples. The Authors do acknowledge this (lines 273-278), but it needs more emphasis. That is, the NS difference in adverse rates cannot be generalized, for the above reasons, along with those clinical issues named by the Authors.

The math is similar for the 2nd twin analysis.

Should report the adverse outcome rates with 95% CIs.

Fig 2: The wide CIs for RRs imply how few the counts are for adverse events. That is, CD rates could plausibly be 2x those after vaginal delivery.

In the manuscript and in the tables, we replace the p values by the unadjusted RR.

We emphasize the limitation due to the small size of the planned vaginal group, lines 325-327, and in the last line of the Abstract. Finally, we added in Table 4 the 95% CI of the rate of the primary outcome.

EDITOR'S COMMENTS:

We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues, and other things. Adherence to these requirements with your revision will avoid delays during the revision process, as well as avoid re-revisions on your part in order to comply with the formatting. Please use the STARD guidelines, as specified in the instructions for authors for reports of diagnostic testing.

1. Line 52: Delete “Our primary objective” thus leaving a “to” statement.

The objective section of the Abstract has been modified as suggested by the Editor, line 53.

2. Results and Conclusion section of abstract will need to be adjusted related to comments by statistical editor regarding the underpowered status of your paper for the negative results.

We added in conclusion that our study was underpowered, line 84.

3. Line 83: Change “is associated” to “are associated”.

The manuscript has been modified as suggested, line 94.

4. Line101-106: one of your reviewers asked for more information about the JUMODA trial. I think this is sufficient as written.

We didn't modify the information about the JUMODA study.

5. Line 119: I was expecting Figure 1 to be the inclusion and exclusion criteria. Could you provide these? You have a list of exclusion criteria lines 120-124. Are the only inclusion criteria the presence of twins by EGA and weight limits?

The confusion comes from the fact that the source population of JUMODA is all the twin deliveries at or after 22 weeks of gestation during the study period without exclusion criteria. It is different to the population of the Twin Birth Study, a randomized trial, which was constituted with inclusion and exclusion criteria. So to select a study population similar to the population of the Twin Birth Study, we had to make exclusions as reported in Figure 1. We modified the manuscript to highlight the fact that we have made only exclusions from the population source of JUMODA, line 139-157.

6. Line 121: Could you edit to “a fetal anomaly affecting either twin”?

The manuscript has been modified as suggested, line 156.

7. Line 123: Any myoma or only one in the lower uterine segment?

The manuscript has been modified as suggested, line 158.

8. Methods section is very well written—thank you.

Line 213: Not sure you need a sentence here. You can just say “No fetus died intrapartum” The rate of composite.....

The manuscript has been modified as suggested, line 251.

9. Line 216 and throughout results (including tables, abstract):

P Values vs Effect Size and Confidence Intervals

While P values are a central part of inference testing in statistics, when cited alone, often the strength of the conclusion can be misunderstood. Whenever possible, the preferred citation should be in terms of 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.

This is true for the abstract as well as the manuscript, tables and figures.

Please provide absolute values for variables, in addition to the assessment of statistical significance.

We ask that you provide crude OR and RR's followed by adjusted values for all variables.

We now provide crude RR. The manuscript has been modified as suggested, lines 254, 274, 280 and 281 and in Table 4.

10. Line 275: Please put the power analysis (Presumably post hoc, but make that clear) in the methods section. In the discussion section, please include the information provided in the statistical editor's comments regarding the power of your study, and the number needed for adequate power.

The manuscript has been modified as suggested in the Methods section lines 224-228, and in the discussion section lines 325-327.

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.

We have checked that the eCTA forms are correctly disclosed on the manuscript's title page.

3. All studies should follow the principles set forth in the Helsinki Declaration of 1975, as revised in 2013, and manuscripts should be approved by the necessary authority before submission. Applicable original research studies should be reviewed by an institutional review board (IRB) or ethics committee. This review should be documented in your cover letter as well in the Materials and Methods section, with an explanation if the study was considered exempt. If your research is based on a publicly available data set approved by your IRB for exemption, please provide documentation of this in your cover letter by submitting the URL of the IRB website outlining the exempt data sets or a letter from a representative of the IRB. In addition, insert a sentence in the Materials and Methods section stating that the study was approved or exempt from approval. In all cases, the complete name of the IRB should be provided in the manuscript.

The ethical approvals are mentioned lines 230-233.

4. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works.

Please add some variance to the Methods section to distinguish this paper from previous papers on this study.

Not applicable

5. Please submit a completed STROBE checklist with your submission.

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), 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, CHEERS, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

We submitted a completed STROBE checklist.

6. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric and gynecology data definitions at <https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

Not applicable

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 total length of the paper is 4421 words.

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 has been carefully checked and does not exceed 100 words

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).**

This recommendation has been applied.

10. Provide a précis on the second page, for use in the Table of Contents. The précis is a single sentence of no more than 25 words that states the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."

We added a précis.

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

The abstract has been carefully checked. A word count is provided for the Abstract.

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 use of abbreviations has been checked.

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.

We modified the text according to these comments.

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%).

This recommendation has been applied.

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.

We checked the table's style.

16. 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>.

Not applicable.

17. Figures 1 and 2 may be resubmitted as-is with your revision.

We resubmitted figures 1 and 2 with our revisions.