

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)*
- Email correspondence between the editorial office and the authors*

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obgyn@greenjournal.org.

Date: Aug 02, 2018
To: "Thomas Schmitz" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-1344

RE: Manuscript Number ONG-18-1344

Neonatal morbidity after management of vaginal noncephalic second-twin delivery by residents

Dear Dr. Schmitz:

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 Aug 23, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

REVIEWER #1:

In this multicenter, prospective observational cohort study, authors, sought to compare composite neonatal morbidity following non-cephalic second twin vaginal delivery between residents supervised by attending staff versus attending staff. They concluded that composite neonatal morbidity was similar between the 2 groups.

This is a well conducted practical, "as is" study and a well-written manuscript. However, certain clarifications are needed to strengthen the internal validity and improve the generalizability of their study.

1. Although authors have had 2 other publications from this cohort, it will be helpful to readers to further clarify the study settings (for context and repeatability). It would appear that the hospitals that participated were either teaching/major academic centers or non teaching hospitals?
 - a. What is the staffing model in these 2 broad settings especially in terms of staff experience in vaginal breech deliveries? What is the average number of attending staff vaginal breech deliveries per annum?
 - b. How were patients selected for vaginal breech deliveries versus elective CS and how were cases assigned to residents versus attending staff? (e.g., previous term vaginal deliveries, estimated fetal weights, etc) These selection criteria may be a key determinant of the reported outcomes (in spite of statistical adjustments made) and may actually improve the generalizability of the manuscript.
 - c. There are additional factors that may have influenced likelihood of vaginal delivery that aren't reported; of the labor induction group (44% of cohort), did methods of induction, timing or favorability of cervix at induction differ? How about grand multiparity (parity >4-5) given that the residents' group had more women born outside of France (presumably non white?) and may therefore have higher rates of grand multiparous women? And why was ethnicity (more relevant attribute) not captured?
 - d. How was the second twin delivery conducted in terms of - how long staff waited before initiating delivery after 1st twin delivery? Was artificial rupture of membranes routinely performed and when? Was Pitocin used and when? How about episiotomy rates?
2. Although authors adjusted for confounders by logistic regressions and propensity scoring, there are still elements of the analyses that need clarifying. That supervising consultants have higher CS rates and 5 birth injuries (vs. 0 for residents) likely reflects uncorrected confounding differences in the cohorts.

- a. Since authors were comparing outcomes in supervised residents and attending staff deliveries, why then were 108 deliveries performed by attending staff excluded because there were no residents at the deliveries? Inclusion of those in the analysis is still consistent with the study's objectives and will be useful.
 - b. Analysis by "per treatment protocol" - ie, residents versus attending staff regardless of initial delivery assignment will be useful in understanding how good the selection criteria was. A difference in outcomes in favor of residents validates the selection criteria and a difference in favor of attending staff may raise additional questions about the study's conclusions.
 - c. Analysis by center of delivery- tertiary center versus non-tertiary center (supervised residents in tertiary centers versus supervised residents in non-tertiary/ attending versus attending) may further validate the point authors made about volumes of deliveries and differences in expertise according to centers. It may also illuminate to what extent patients' risk factors are driving the outcomes.
 - d. Authors need to show sample size justification.
3. Composite neonatal outcomes are reasonable since event rates of individual morbidities are low; however, using composite rate is a limitation and should be acknowledged as such in the discussion since outcomes directly related to conduct of vaginal breech delivery would have been more relevant, for example, serious neonatal birth injuries, hypoxic ischemic encephalopathy rates. APGAR score is a poor surrogate and subject to bias (score inflation); cord pH values would have been more useful. It will be very useful to see a comparison of the severity of neonatal outcomes. What were the causes of 4 perinatal deaths? Finally, although not a primary outcome of interest, any data on maternal outcomes, for example, 3rd/4th degree perineal laceration rates, postpartum hemorrhage, maternal sepsis (Endometritis) and length of hospital stay will provide a balance and more complete understanding of the study.

REVIEWER #2:

The authors report on neonatal outcomes for noncephalic second twins according to training level of initial delivering obstetrician from a large national cohort of contemporary deliveries in France. They reassuringly show no difference in neonatal outcomes according to whether or not a resident or supervising obstetrician made the initial attempt at delivery and use this as evidence to support the hands on training for obstetricians for vaginal twin birth. This paper and the dataset from which it is derived is uniquely suited to address an important issue in contemporary obstetrics and would be of value to those with interest in twin delivery, operative obstetrics and medical education. I have a few questions for these authors:

1. Page 6, Lines 16-21: These two sentences are long and confusing, suggest rewording as this is the crux of your argument.
2. Page 7, Lines 4-5: The protocol information is published elsewhere, but I imagine the readers would be interested in a few more details of the obstetric climate in France. This is addressed later in the methods, but particular questions I had include: What does the Maternity ward level I, II, III designation mean (could address this here or in the footnote of Table 2)? For those deliveries begun by a senior obstetrician with a change in practitioner what are those criteria or who is that "backup" practitioner? What is the policy for attempted vaginal birth for cephalic presenting first twins (recognizing this is not the standard of care for many centers/countries)? Is there any information about how a senior OB makes the decision to allow the resident to try first—is this a product of hospital structure and staffing, or is there actual clinical decision making involved?
3. Page 8, Lines 3-6: It would be interesting to see the web-based questionnaire in the supplemental materials—such a terrific idea to make this study possible!
4. Page 10, Line 21: It is interesting that cesarean delivery rates for the second twin were lower in women managed by residents initially. This isn't the primary outcome of interest but is of great relevance considering the morbidity of a combined delivery. I would be eager to see this addressed in the Discussion?
5. Page 11, Line 18-20: I'm not necessarily sure this is true—part of the conclusion of this paper could easily be that having someone take over doesn't portend worse neonatal outcomes. Perhaps this is just a misperception? And remember 10% of the time another obstetrician took over the delivery from the "senior" obstetrician. I would be hesitant to feature this as a principle finding in the discussion.
6. Page 12, Line 6-8: Do we have any information available about how many twin vaginal births were performed by the supervising obstetrician?
7. Page 12, Line 14-19: I agree that volume and comfort with twin vaginal birth likely explains these findings. Explaining a bit of HOW the decision of who starts the delivery is made would go a long way to address confounding by indication—something that is difficult to address even with a well done propensity score matching analysis.
8. Page 12, Line 23-24: Avoid priority claim, or provide details of the literature review supporting this.

9. Page 13, Line 15-16: I would not expect having a resident involved in your care to double your risk of adverse outcomes. It would be more instructive to either use their adverse outcome rates to report their actual power to detect a difference, or assume a more conservative or evidence-based estimate of "harm" (or improvement) from having a resident involved in your care. Given their findings this should be done as a two-tailed hypothesis.

10. This is a well-done study with findings of interest to clinicians and educators alike addressing an important issue in contemporary obstetrics. I agree generalizability is the greatest limitation to this study but I think a few more details and clarifications in the methods could help reassure the reader that these findings are generalizable to other countries or centers. The authors have demonstrated that resident involvement in noncephalic second twin vaginal birth is safe for babies and may even be safer for moms (lower cesarean rate...). These results suggest that a resident or other obstetrician uncertain with his or her skillset should be given first attempt to deliver the second twin under the watchful supervision of a "senior" obstetrician. ...). I would be most interested in seeing the Discussion focused to comment on how the findings of their study could be adapted to other environments. Regardless, this is practical and useful information for those interested in preserving twin vaginal birth for future generations of patients.

REVIEWER #3:

The manuscript is a prospective cohort observational study (JUMODA cohort) conducted in France . The study includes 176 maternity in France . The neonatal mortality after active management by supervised resident or senior obstetrician of noncephalic second-twin born after vaginal delivery (immediate total breech extraction for breech presentation and internal version and total breech extraction for transverse presentation) is analyzed. The objective of this manuscript is to compare the neonatal immediate complications for vaginal delivery after internal obstetrical maneuvers performed by senior obstetrician or by supervised resident for the second non-vertex twin after 32 weeks of gestation . The Authors suggest the lack of training is probably the factor for Cesarean deliveries and for neonatal complications. The Authors analyze 1376 twin pregnancy births by vaginal delivery of twin 1 and non-vertex twin 2 , after 32 weeks of gestation. 545 deliveries were performed by residents and 831 deliveries were performed by senior ob-gyn . The Authors found there is no statistically significant difference between neonatal complication found in the 2 groups . I suggest the Authors to clarify why/ if the need for future training applies only for residents or both- for residents and senior obstetricians.

Title :

1. Please clarify why the title mentioned only residents , if the neonatal mortality in the two groups (supervised residents vs senior) is found not to be statistically different ? This may indicate that level of training/ or practical skills has no significant impact in neonatal morbidity .

Precis :

2. Line 3 : The Authors recommend hands-on training for "future practitioners" ? I recommend to clarify if future generation refers only to residents ?

Materials and Methods :

3. Line 11 - Can the Authors explain why they used "mother"s country of birth " as a potential explanatory factor ?

4. Line 16-28 : I suggest to describe the propensity score method in a more friendly way , to be easily understood also by readers that do not have strong statistical background .

Results :

5. Line 13 : Why is important to mention the fact that residents managed deliveries for patients born abroad ?

Table 1 -

6. Monochorionic monoamniotic twins were vaginally delivered ?

7. In case of IUGR the delivery was spontaneous or induced ?

8. What does it mean "Change of practitioner during delivery" ?

STATISTICAL EDITOR'S COMMENTS:

1. As can be seen from Tables 1 and 2, there were many baseline differences between the two cohorts.

2. Table 3 attempts to adjust the RR with 12 variables, yet the number of adverse primary outcomes was only 13 vs 31. This is many fewer adverse outcomes than would be needed for such an adjustment model.
3. The proportion of adverse outcomes is low (2.4% vs 3.7%), which give little statistical power to discern a difference in rates. Given the sample sizes and proportions at hand, there was only ~ 14% power to discern a difference. Put another way, given the usual threshold for power and alpha of 80% and .05, the detectable alternative RRs (referenced to the observed 0.76) would be < 0.34 or > 1.93. A much larger sample would be required to discern a difference between the two cohorts.
4. The propensity score matching did a good job part of the analysis succeeded in matching for differences in baseline characteristics, which resulted in 511 in each cohort with a RR of 0.65. Unfortunately the same issues of low power were not overcome (power now ~ .24).
5. The problem of low power is exacerbated with the subset analyses of Appendices 3, 4, 5, 6 with smaller samples.

ASSOCIATE EDITOR' COMMENTS

Please reduce emphasis on sub-group analyses and be clear in Discussion that low statistical power for many of the comparisons is a limitation

EDITORIAL OFFICE COMMENTS:

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

1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

2. 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 web site 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.

3. 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. Variance is needed in the following sections:

The following text in the discussion section is taken nearly verbatim from a previous publication by the author. This needs to be rewritten. "First, despite the publication...as others have suggested." In addition, a very large percentage of the methods section is nearly verbatim from a previous publication (<https://doi.org/10.1016/j.ajog.2018.01.023>). While we understand that there will be overlap given that the papers are from the same study, the methods section should be updated to add variance and avoid self-plagiarism.

4. 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), and quality improvement in health care (ie, SQUIRE 2.0). 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, or SQUIRE 2.0 guidelines, as appropriate.

5. 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 will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at <http://links.lww.com>

/AOG/A515, and the gynecology data definitions are available at <http://links.lww.com/AOG/A935>.

6. 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 appendixes).

Please limit your Introduction to 250 words and your Discussion to 750 words.

7. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with 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 signature on the journal's author agreement 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).

8. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot.

9. 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.

10. 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.

11. 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.

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

13. Our readers are clinicians and a detailed review of the literature is not necessary. Please shorten the Discussion and focus on how your results affect or change actual patient care. Do not repeat the Results in the Discussion section.

14. 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.

15. The American College of Obstetricians and Gynecologists' (College) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite College 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. 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 a College document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All College documents (eg, Committee Opinions and Practice Bulletins) may be found via the Resources and Publications page at <http://www.acog.org/Resources-And-Publications>.

If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at

<http://ong.editorialmanager.com>. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

If you submit a revision, we will assume that it has been developed in consultation with your co-authors, that each author has given approval to the final form of the revision, and that the agreement form signed by each author and submitted with the initial version remains valid.

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 Aug 23, 2018, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,


The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982

2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

If you would like your personal information to be removed from the database, please contact the publication office.

Pr Thomas Schmitz



Paris, August 21st 2018

Dear Editors,

Thank you for your response on August 2nd 2018, concerning our manuscript ONG-18-1344 entitled “Neonatal morbidity after management of vaginal noncephalic second-twin delivery by residents” 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.

The National Data Protection Authority (DR-2013-528), the consultative committee on the treatment of information on personal health data for research purposes (13-298), and the committee for the protection of people participating in biomedical research (PP-13-014) approved this study.

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

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

Yours sincerely,

Thomas Schmitz



All line numbers refer to the revised version of the manuscript without the highlighted changes.

We realized by performing new analyses for Reviewer 1 that we made a mistake in the calculations for the primary outcome in the senior group. Two cases of necrotizing enterocolitis grade 1 were wrongly classified as grade 2 or 3. Therefore, it is not 31 morbid events in the senior group but only 29 that should have been taken into account. We modified the text and Tables all along the manuscript regarding this error.

RESPONSE TO REVIEWER COMMENTS:

REVIEWER #1:

In this multicenter, prospective observational cohort study, authors, sought to compare composite neonatal morbidity following non-cephalic second twin vaginal delivery between residents supervised by attending staff versus attending staff. They concluded that composite neonatal morbidity was similar between the 2 groups.

This is a well conducted practical, "as is" study and a well-written manuscript. However, certain clarifications are needed to strengthen the internal validity and improve the generalizability of their study.

1. Although authors have had 2 other publications from this cohort, it will be helpful to readers to further clarify the study settings (for context and repeatability). It would appear that the hospitals that participated were either teaching/major academic centers or non teaching hospitals?

The hospitals that participated to the JUMODA study were hospitals performing more than 1500 deliveries per year because they concentrate high twin delivery volumes, i.e more than 95% of the annual twin deliveries in France. As shown in the Tables below, the majority were public hospitals. In France, residents are employed in university public hospitals, in non-university public hospitals, in non-lucrative private hospitals but not in lucrative private hospitals. Because we feel that i) hospital delivery volume and level of care were more explicative variables, ii) hospital status (university public, non-university public, non-lucrative private and private) was closely correlated with delivery volume, and iii) enough variables were already included in the regression models, we did not include these data in Table 2. However, this could be performed according to the Editor wishes.

Hospital status in the JUMODA study

Hospital status	Maternity units (N=176)	Deliveries (N=8823)
University public	42 (23.9)	3935 (47.3)
Non-university public	104 (59.1)	3650 (43.9)
Lucrative private	20 (11.4)	416 (5.0)
Non-lucrative private	10 (5.7)	319 (3.8)

Hospital status in this study

Hospital status	Maternity units (N=149)	Deliveries (N=1376)
University public	42 (28.2)	688 (50.0)
Non-university public	96 (64.4)	632 (45.9)
Lucrative private	5 (3.4)	21 (1.5)
Non-lucrative private	6 (4.0)	35 (2.6)

a. What is the staffing model in these 2 broad settings especially in terms of staff experience in vaginal breech deliveries? What is the average number of attending staff vaginal breech deliveries per annum?

Because the JUMODA study involved 176 centers with 10 to 20 senior obstetricians and 5 to 10 residents (rotating every 6 months in different hospitals), the questionnaire did not include variables regarding number of vaginal breech delivery per senior or resident practitioners. We therefore cannot answer this question. However, we are aware of important differences in perinatal care organization between France and the United States that are of interest for the reader. This is the reason why we addressed this point in the discussion section by providing a rough estimate of the number of practitioner in the participating hospitals to enable an estimation of the number of deliveries managed each year by a senior practitioner. For instance, perinatal organization such as those described by Easter (ref 26) with 97 clinicians, 62 MFM sub-specialists and specialists in obstetrics and 35 clinicians from the private practice for 150 annual twin deliveries does not exist in France. Typically in France, for a level 3 maternity unit with 3000 deliveries per year, 120 twin pregnancies are managed for 10 to 15 practitioners. Therefore the number of twin deliveries performed each by a French practitioner is very likely to be far more important than in the United States. Because we did not collect the exact number of practitioners per center we did not provide these data in the Methods and Results sections and this point was only brought up in the Discussion section page 13, lines 16-20.

b. How were patients selected for vaginal breech deliveries versus elective CS and how were cases assigned to residents versus attending staff? (e.g., previous term vaginal deliveries, estimated fetal weights, etc) These selection criteria may be a key determinant of the reported outcomes (in spite of statistical adjustments made) and may actually improve the generalizability of the manuscript.

As stated in the Methods section, in France, total breech extraction is recommended for breech second twins and for transverse second twin after internal version. Furthermore, as explained in the discussion section, the breech presentation of the second twin is considered as the most favorable presentation and noncephalic second twin presentation is not an indication for planned cesarean delivery. As shown in the Table below, only 25 (1.4%) cesareans were performed only because of noncephalic second twin presentation. Therefore, decision of planned cesarean is not based on second presentation in France. Similarly, only 12 (0.7%) cesareans were planned because of a second twin larger than the first twin. Finally, cesareans were planned mostly because of noncephalic first twin presentation and pregnancy complications. To clarify this point, thanks to the Reviewer, we changed the flow chart. The numbers of planned cesareans and of cesareans during labor are now provided only for noncephalic second twin presentations. Furthermore, we added a sentence in the results section, page 10, lines 9-12, providing major indications for planned cesarean and stating that only 25 (1.4%) of the planned cesarean were performed for noncephalic second twin presentations. This point is also addressed in the discussion section page 12, lines 3-4.

Indications for planned cesarean delivery	1712 (100%)
Noncephalic first twin	588 (34.4)
Previous cesarean	205 (12.0)
IUGR for either twin	166 (9.7)
Preeclampsia	154 (9.0)
Abnormal pelvis	75 (4.4)
Placenta praevia	28 (1.6)
PPROM	27 (1.6)
Noncephalic second twin	25 (1.5)
Second twin larger than first twin	12 (0.7)
Other	432 (25.2)

c. **There are additional factors that may have influenced likelihood of vaginal delivery that aren't reported; of the labor induction group (44% of cohort), did methods of induction, timing or favorability of cervix at induction differ? How about grand multiparity (parity >4-5) given that the residents' group had more women born outside of France (presumably non white?) and may therefore have higher rates of grand multiparous women? And why was ethnicity (more relevant attribute) not captured?**

The methods of induction, Bishop score and parity ≥ 4 are provided in the Table below.

	Residents N=545	Seniors N=831	P
Onset of labor			
Spontaneous	300 (55.1)	468 (56.3)	0.019
Oxytocin	148 (27.2)	263 (31.7)	
Prostaglandins	85 (15.6)	87 (10.5)	
Balloon	12 (2.2)	13 (1.6)	
Bishop score (mean \pm SD)	5.6 \pm 1.9	6.0 \pm 1.8	0.021
Parity ≥ 4	25 (4.6)	57 (6.9)	0.084

As shown in the above Table, Bishop scores were lower in the resident group, induction with prostaglandins and balloons more frequent and parity ≥ 4 less frequent than in the senior group. Therefore, it is very unlikely that these additional factors have influenced the likelihood of vaginal delivery and the primary outcomes in favor of the resident group. We did not modify the manuscript regarding this point raised by the Reviewer.

Ethnicity was not captured because it is against the law in France. We used country of birth as a surrogate.

d. **How was the second twin delivery conducted in terms of - how long staff waited before initiating delivery after 1st twin delivery? Was artificial rupture of membranes routinely performed and when? Was Pitocin used and when? How about episiotomy rates?**

We cannot provide any data regarding artificial rupture of membranes after first twin delivery because it was not part of the questionnaire. The intertwin delivery interval (ITDI) was already provided in Table 2 and median ITDI was one minute shorter (4 versus 5) in the resident group compared to the senior group. As shown in the Table below, there was no difference for episiotomy rates. Stopping the oxytocin perfusion after delivery of the first twin, as recommended in the French guidelines to facilitate obstetric maneuvers, was more frequent in the resident group. This last point likely reflects the greater expertise for twin deliveries of the centers where residents are working. Because practices depend on center in France and all analyses are adjusted on the center, we did not modify the text regarding this point raised by the reviewer.

	Residents N=545	Seniors N=831	P
Episiotomy	120 (22.1)	164 (19.7)	0.298
Stopping oxytocin perfusion after 1st twin delivery	288/377 (76.4)	323/563 (57.4)	<.001

2. **Although authors adjusted for confounders by logistic regressions and propensity scoring, there are still elements of the analyses that need clarifying. That supervising consultants have higher CS rates and 5 birth injuries (vs. 0 for residents) likely reflects uncorrected confounding differences in the cohorts.**

a. **Since authors were comparing outcomes in supervised residents and attending staff deliveries, why then were 108 deliveries performed by attending staff excluded because there**

were no residents at the deliveries? Inclusion of those in the analysis is still consistent with the study's objectives and will be useful.

These 108 deliveries were not excluded because there was just no resident at delivery but because there was no resident at all working in these hospitals. Because we intended to compare neonatal outcomes according to the first practitioner managing noncephalic second twin delivery in centers where residents can benefit from hands-on training, these deliveries were indeed excluded. We did not modify the text regarding this point raised by the reviewer.

b. Analysis by "per treatment protocol" - ie, residents versus attending staff regardless of initial delivery assignment will be useful in understanding how good the selection criteria were. A difference in outcomes in favor of residents validates the selection criteria and a difference in favor of attending staff may raise additional questions about the study's conclusions.

As shown in the Table below, results were similar in a "per protocol analysis". Therefore, we did not modify the text regarding this point raised by the Reviewer; however the following Table could be added in the Appendix section if it is the Editor wish.

	Residents N=420	Seniors N=796	P	aRR 95% CI
Composite morbidity	11 (2.6)	26 (3.3)	0.532	0.91 (0.33-2.13)

c. Analysis by center of delivery- tertiary center versus non-tertiary center (supervised residents in tertiary centers versus supervised residents in non-tertiary/ attending versus attending) may further validate the point authors made about volumes of deliveries and differences in expertise according to centers. It may also illuminate to what extent patients' risk factors are driving the outcomes.

	Tertiary N=444	Non Tertiary N=101	P	cRR 95% CI
Residents				
Composite morbidity	12 (2.5)	1 (1.4)	0.563	1.77 (0.22-13.9)
Attending	N=414	N=417		
Composite morbidity	20 (4.8)	9 (2.2)	0.036	2.25 (1.05-4.86)

We agree with the Reviewer. As shown in the above Table, analysis by center of delivery – tertiary versus non tertiary – shows that composite morbidity is driven by patients' risk factors, the high risk patients delivering in tertiary center more frequently. Because level of care is closely correlated with delivery volume and university status, we did not add this variable into the regression models. Therefore, we did not modify the text regarding this point raised by the reviewer.

d. Authors need to show sample size justification.

The justification for sample size calculation is provided in response to Reviewer 2 point 9 and to the Statistical Reviewer point 3and in the discussion section page 13, lines 22-27.

3. Composite neonatal outcomes are reasonable since event rates of individual morbidities are low; however, using composite rate is a limitation and should be acknowledged as such in the discussion since outcomes directly related to conduct of vaginal breech delivery would have been more relevant, for example, serious neonatal birth injuries, hypoxic ischemic encephalopathy rates. APGAR score is a poor surrogate and subject to bias (score inflation); cord pH values would have been more useful. It will be very useful to see a comparison of the severity of neonatal

outcomes. What were the causes of 4 perinatal deaths? Finally, although not a primary outcome of interest, any data on maternal outcomes, for example, 3rd/4th degree perineal laceration rates, postpartum hemorrhage, maternal sepsis (Endometritis) and length of hospital stay will provide a balance and more complete understanding of the study.

The composite outcome in the JUMODA study is the same as in the Twin Birth Study (TBS), the reference study in the field. The composite structure of this outcome is explained by the fact that as in the TBS, we included preterm deliveries from 32 weeks of gestation justifying the integration of neonatal complications of prematurity in the composite outcome. Furthermore, the numbers of individual morbid events were low enough to justify a composite outcome. The individual morbidities are provided, however, in Table 3.

It was not planned to collect cord pH because missing values were expected to be too high for correct interpretation.

There were only 2 cases of perinatal death, not 4, one in each group both due to congenital malformations.

Finally, we believe that maternal morbidity i) is far beyond the scope of this study, and ii) unlikely to be impacted by the first practitioner at second twin delivery. Therefore, we did not modify the text regarding this point raised by the reviewer.

REVIEWER #2:

The authors report on neonatal outcomes for noncephalic second twins according to training level of initial delivering obstetrician from a large national cohort of contemporary deliveries in France. They reassuringly show no difference in neonatal outcomes according to whether or not a resident or supervising obstetrician made the initial attempt at delivery and use this as evidence to support the hands on training for obstetricians for vaginal twin birth. This paper and the dataset from which it is derived is uniquely suited to address an important issue in contemporary obstetrics and would be of value to those with interest in twin delivery, operative obstetrics and medical education. I have a few questions for these authors:

1. Page 6, Lines 16-21: These two sentences are long and confusing, suggest rewording as this is the crux of your argument.

We modified the text page 6, lines 17-22, as suggested by the reviewer.

2. Page 7, Lines 4-5: The protocol information is published elsewhere, but I imagine the readers would be interested in a few more details of the obstetric climate in France. This is addressed later in the methods, but particular questions I had included: What does the Maternity ward level I, II, III designation mean (could address this here or in the footnote of Table 2)? For those deliveries begun by a senior obstetrician with a change in practitioner what are those criteria or who is that "backup" practitioner? What is the policy for attempted vaginal birth for cephalic presenting first twins (recognizing this is not the standard of care for many centers/countries)? Is there any information about how a senior OB makes the decision to allow the resident to try first—is this a product of hospital structure and staffing, or is there actual clinical decision making involved?

In Table 2, maternity ward level I, II, III is an inadequate wording, we meant Hospital Level I, II, III and referred to NICU associated with maternity unit. We corrected this point in Table 2 page 19.

For changes of practitioner when delivery was first managed by a senior, the back-up practitioner was another senior (45%), a resident or a midwife (55%). These changes are complex to interpret because they likely correspond to 2 distinct situations: in the first case the delivery was difficult, in the second case, the delivery was easy enough to let the resident ending it.

We don't understand the following question: What is the policy for attempted vaginal birth for cephalic presenting first twins (recognizing this is not the standard of care for many centers/countries)? We believe the reviewer meant NONcephalic first twin. Among the 1645 twin pregnancy with a first twin in breech presentation at 32 weeks and more, 1311 (79.7%) had planned cesarean and only 344 (20.3%) planned vaginal delivery of whom 209 (62.5%) delivered both twin vaginally. These data will be presented at the 2019 SMFM meeting in Las Vegas. Planned vaginal delivery is possible in France as long as the same criteria as for a singleton breech delivery are fulfilled i.e normal pelvis and EFW less than 3800g. However, because of the lack of large reassuring series, most of the French practitioners prefer planning a cesarean.

Finally, we did not collect in the questionnaire the reasons or conditions leading the supervising practitioner to allow second delivery by the resident.

3. Page 8, Lines 3-6: It would be interesting to see the web-based questionnaire in the supplemental materials—such a terrific idea to make this study possible!

The questionnaire is longer than 20 pages. Because of its length, we are afraid it is not possible to provide these data as supplementary file.

4. Page 10, Line 21: It is interesting that cesarean delivery rates for the second twin were lower in women managed by residents initially. This isn't the primary outcome of interest but is of great relevance considering the morbidity of a combined delivery. I would be eager to see this addressed in the Discussion?

The reasons likely to explain the lower cesarean for the second twin rate in the resident group are addressed in the discussion page 11, lines 25-28 and page 12, lines 1-20.

5. Page 11, Line 18-20: I'm not necessarily sure this is true—part of the conclusion of this paper could easily be that having someone take over doesn't portend worse neonatal outcomes. Perhaps this is just a misperception? And remember 10% of the time another obstetrician took over the delivery from the "senior" obstetrician. I would be hesitant to feature this as a principle finding in the discussion.

As suggested by the Reviewer, we deleted this result as a principal finding.

6. Page 12, Line 6-8: Do we have any information available about how many twin vaginal births were performed by the supervising obstetrician?

We do not have these data. As explained in the response to point 1a of Reviewer 1, the number of noncephalic second twin delivered by a senior practitioner each year in France is likely to be greater than in the United States due to different perinatal organization, involving much fewer practitioners in France than in the US.

7. Page 12, Line 14-19: I agree that volume and comfort with twin vaginal birth likely explains these findings. Explaining a bit of HOW the decision of who starts the delivery is made would go a long way to address confounding by indication—something that is difficult to address even with a well done propensity score matching analysis.

We now acknowledge in the discussion section page 13, line 9 that confounding by indication might persist even though we used propensity score matching analysis. However, considering that the population of the resident group was at higher risk than in the senior group, we do believe this is unlikely to explain the trend toward lower morbidity rates in the resident group. Furthermore, factors like pregnancy complications, gestational age, nulliparity, chorionicity, IVF, or previous cesarean that might have influenced the supervisor not to let the resident perform the delivery have been included in the propensity score.

8. Page 12, Line 23-24: Avoid priority claim, or provide details of the literature review supporting this.

As suggested by the Reviewer, we deleted this sentence.

9. Page 13, Line 15-16: I would not expect having a resident involved in your care to double your risk of adverse outcomes. It would be more instructive to either use their adverse outcome rates to report their actual power to detect a difference, or assume a more conservative or evidence-based estimate of "harm" (or improvement) from having a resident involved in your care. Given their findings this should be done as a two-tailed hypothesis.

We agree with the Reviewer that we did not expect resident to double the risk of adverse neonatal outcomes. However, as hypothesized and stated in the introduction, fear of such clinically significant increases might be the reason why senior obstetrician could be reluctant to pursue hand-on training for residents. This is the reason why, although we now acknowledge page X, line Y that our study lacks statistical power to evidence small statistically significant differences between the two groups, i.e a 1.1% absolute and 31% relative decrease, it still has the statistical power to show a doubling of the primary outcome in the resident group compared to the senior group from 3.5% to 7.0%. We modified the text regarding this point raised by the reviewer, page 13, lines 22-27.

10. This is a well-done study with findings of interest to clinicians and educators alike addressing an important issue in contemporary obstetrics. I agree generalizability is the greatest limitation to this study but I think a few more details and clarifications in the methods could help reassure the reader that these findings are generalizable to other countries or centers. The authors have demonstrated that resident involvement in noncephalic second twin vaginal birth is safe for babies and may even be safer for moms (lower cesarean rate...). These results suggest that a resident or other obstetrician uncertain with his or her skillset should be given first attempt to deliver the second twin under the watchful supervision of a "senior" obstetrician. ...). I would be most

interested in seeing the Discussion focused to comment on how the findings of their study could be adapted to other environments. Regardless, this is practical and useful information for those interested in preserving twin vaginal birth for future generations of patients.

We thank the reviewer for its comment however we don't know how our results could apply to other environments. We believe it is the role of the reader to appropriate our data for adapting its practice. The best we can do is describing as accurately as possible the perinatal organization in our country. This is what we tried to do in the Methods section page 7, lines 18-28 and page 8, lines 1-2 and in the discussion section, page 11, lines 25-28, page 12, lines 1-20 and page 13, lines 15-20.

REVIEWER #3:

The manuscript is a prospective cohort observational study (JUMODA cohort) conducted in France. The study includes 176 maternity in France. The neonatal mortality after active management by supervised resident or senior obstetrician of noncephalic second-twin born after vaginal delivery (immediate total breech extraction for breech presentation and internal version and total breech extraction for transverse presentation) is analyzed. The objective of this manuscript is to compare the neonatal immediate complications for vaginal delivery after internal obstetrical maneuvers performed by senior obstetrician or by supervised resident for the second non-vertex twin after 32 weeks of gestation. The Authors suggest the lack of training is probably the factor for Cesarean deliveries and for neonatal complications.

The Authors analyze 1376 twin pregnancy births by vaginal delivery of twin 1 and non-vertex twin 2, after 32 weeks of gestation. 545 deliveries were performed by residents and 831 deliveries were performed by senior ob-gyn. The Authors found there is no statistically significant difference between neonatal complications found in the 2 groups.

I suggest the Authors to clarify why/ if the need for future training applies only for residents or both- for residents and senior obstetricians.

We agree that the need for future training should also apply to senior obstetricians. However, our data do not allow any conclusion about that since we only compared resident to senior obstetricians.

Title:

1. Please clarify why the title mentioned only residents, if the neonatal mortality in the two groups (supervised residents vs senior) is found not to be statistically different? This may indicate that level of training/ or practical skills has no significant impact in neonatal morbidity.

It is common practice in a title to only refer to the “experimental group” and not to the reference group, therefore we did not modify the title.

Precis:

2. Line 3: The Authors recommend hands-on training for "future practitioners"? I recommend to clarify if future generation refers only to residents?

As suggested by the reviewer, we clarified the Precis by stating that “future practitioners” refers to residents, page 4, line 3.

Materials and Methods:

3. Line 11 - Can the Authors explain why they used "mother"s country of birth" as a potential explanatory factor?

Collecting data about ethnicity is forbidden in France, this is the reason why country of birth is used as a proxy for ethnicity.

4. Line 16-28: I suggest to describe the propensity score method in a more friendly way, to be easily understood also by readers that do not have strong statistical background.

We described the propensity score method as friendly as possible.

Results:

5. Line 13: Why is important to mention the fact that residents managed deliveries for patients born abroad?

Again, country of birth is used as a proxy for ethnicity.

Table 1 -

6. Monochorionic monoamniotic twins were vaginally delivered?

Yes, some of them were vaginally delivered. It is an accepted practice in France as long as the first twin is in cephalic presentation. Since this point raised by the reviewer concerned only one woman, we did not modify the text.

7. In case of IUGR the delivery was spontaneous or induced?

We provided in the Table below the percentages of labor induction in each group for IUGR.

	Residents	Seniors	P
Induction for IUGR	36/75 (48.0)	43/75 (57.3)	0.252

Because the onset of labor (spontaneous or induction) and pregnancy complications were taken into account into the regression models and in the propensity score, we did not modify the text regarding this point raised by the Reviewer.

8. What does it mean "Change of practitioner during delivery"?

It means, in the resident group, that the supervising practitioner took over the resident the second twin delivery because he felt the resident was not performing well enough, and in the senior group that the practitioner called one of his colleague for help. Because this point seems to have been clearly understood by all the other Reviewers, we did not modify the text regarding this point raised by the Reviewer.

STATISTICAL EDITOR'S COMMENTS:

1. As can be seen from Tables 1 and 2, there were many baseline differences between the two cohorts.

We agree and it was expected.

2. Table 3 attempts to adjust the RR with 12 variables, yet the number of adverse primary outcomes was only 13 vs 31. This is many fewer adverse outcomes than would be needed for such an adjustment model.

We agree that the numbers of adverse outcomes might have been fewer than expected for adjustment with 12 variables. It is classically admitted that the ratio of events per variable (EPV) in regression analysis should not exceed 10 in order to avoid biasing the coefficients.¹ However, some authors, based on simulation studies, found that biases were within acceptable levels despite less than 10 EPV.²

Furthermore, we performed adjustments with models integrating only 4 to 6 variables only and the results were very similar. Finally, the aRR is close to the cRR and to the RR obtained after propensity score matching. Therefore, we believe these concordant results are accurately presented.

3. The proportion of adverse outcomes is low (2.4% vs 3.7%), which give little statistical power to discern a difference in rates. Given the sample sizes and proportions at hand, there was only ~ 14% power to discern a difference. Put another way, given the usual threshold for power and alpha of 80% and .05, the detectable alternative RRs (referenced to the observed 0.76) would be < 0.34 or > 1.93. A much larger sample would be required to discern a difference between the two cohorts.

We agree with the Reviewer that our study lack power to detect as small statistically significant difference as those measured herein, i.e a 1.1% absolute and 31% relative difference. This is now acknowledged in the weaknesses section of the Discussion page 13, lines 22-27. To demonstrate such a difference, more than 3500 women in each group would be needed. Such a study is very unlikely to be performed one day. Therefore, our data are helpful. Furthermore, we do believe that since we had the power to exclude a clinically significant increase in neonatal morbidity such as a doubling from 3.5% in the senior group to 7.0% in the resident group, this could reassure the reader and encourage them to pursue hands-on training of residents.

4. The propensity score matching did a good job part of the analysis succeeded in matching for differences in baseline characteristics, which resulted in 511 in each cohort with a RR of 0.65. Unfortunately the same issues of low power were not overcome (power now ~ .24).

See response to point 3.

5. The problem of low power is exacerbated with the subset analyses of Appendices 3, 4, 5, 6 with smaller samples.

We now acknowledge the lack of power especially for the subgroup analyses, page 13, lines 24-25, and state they should only be considered exploratory. Therefore, if it is the wish of the editor we could present these results without the aRR columns or even delete these Appendixes.

Reference

1. Peduzzi P, Concato J, Kemper E, Holford TR, Feinstein AR. A simulation study of the number of events per variable in logistic regression analysis. J Clin Epidemiol 1996;49:1373–9.
2. Vittinghoff E, McCulloch CE. Relaxing the rule of ten events per variable in logistic and Cox regression. Am J Epidemiol 2007;165:710–8.

ASSOCIATE EDITOR'S COMMENTS

Please reduce emphasis on sub-group analyses and be clear in Discussion that low statistical power for many of the comparisons is a limitation

We deleted from the first sentence of the discussion “regardless of gestational age and type of noncephalic second twin presentation” to avoid emphasizing on sub-group analyses. We have now clarified in the discussion section that our study was underpowered to show small statistically significant differences between the two groups, page 13, lines 22-27. This is now part of the Weaknesses section of the discussion. However, we believe important to state that we had the sample size to reject a doubling of the neonatal morbidity in the resident group compared to the senior group, as such a clinically significant increase could be the reason why senior obstetrician might be reluctant to provide hands-on training to residents.

EDITORIAL OFFICE COMMENTS:

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

1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.

2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

We opt IN.

2. 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 web site 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 ethics committee approval of the JUMODA study is documented both in the cover letter and in Methods section of the manuscript.

3. 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. Variance is needed in the following sections:

The following text in the discussion section is taken nearly verbatim from a previous publication by the author. This needs to be rewritten. "First, despite the publication...as others have suggested." In addition, a very large percentage of the methods section is nearly verbatim from a previous publication (<https://doi.org/10.1016/j.ajog.2018.01.023>). While we understand that there will be overlap given that the papers are from the same study, the methods section should be updated to add variance and avoid self-plagiarism.

We modified the Discussion and Methods sections as much as possible to avoid self-plagiarism, however this was not possible everywhere, especially for the description of the primary outcome.

4. 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), and quality improvement in health care (ie, SQUIRE 2.0). 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, or SQUIRE 2.0 guidelines, as appropriate.

We now provide the STROBE checklist.

5. 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 will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at <http://links.lww.com/AOG/A515>, and the gynecology data definitions are available at <http://links.lww.com/AOG/A935>.

The revitalize definitions have been respected.

6. 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 appendixes).

Our manuscript is only 21 pages and 5111 words.

7. Specific rules govern the use of acknowledgments in the journal. Please edit your acknowledgments or provide more information in accordance with 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 signature on the journal's author agreement 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).**

Not applicable

8. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot.

A short title is provided Page 3, line 10.

9. 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.

The Abstract has carefully checked.

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 length of the Abstract is 298 words.

10. 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.

Not applicable

11. 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.

Not applicable

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

Such claims have been deleted.

13. Our readers are clinicians and a detailed review of the literature is not necessary. Please shorten the Discussion and focus on how your results affect or change actual patient care. Do not repeat the Results in the Discussion section.

The discussion has been shortened.

14. 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 our Tables were conforming to journal style.

15. The American College of Obstetricians and Gynecologists' (College) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite College 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. 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 a College document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All College documents (eg, Committee Opinions and Practice Bulletins) may be found via the Resources and Publications page at <http://www.acog.org/Resources-And-Publications>.

We checked our references were still current and available.

Daniel Mosier

From: SCHMITZ Thomas [REDACTED]
Sent: Wednesday, August 29, 2018 3:12 AM
To: Daniel Mosier
Subject: RE: Manuscript Revisions: ONG-18-1344R1
Attachments: 18-1344R1 ms (8-28-18v2) ts.docx

Dear Daniel,

I accept all the editorial changes.

Christophe Vayssière and Nicolas Sananès confirmed their authorship yesterday night, French time. Norbert Winer did not because he didn't receive your mail as I provided you a wrong address. The correct address is as follow:

[REDACTED]

There is no discrepancy between the abstract and the Result section. In the Abstract, we provide the adjusted relative risk (RR) and in the Result section the crude RR. In the Result section, page 12, the adjusted RR is also provided. Therefore, both data are correct and need to be presented to the reader.

Sincerely,

Pr Thomas SCHMITZ
Université Paris Diderot
Service de Gynécologie Obstétrique
Hôpital Robert Debré

[REDACTED]


De : Daniel Mosier [mailto:dmosier@greenjournal.org]
Envoyé : mardi 28 août 2018 20:06
À : SCHMITZ Thomas
Objet : Manuscript Revisions: ONG-18-1344R1

Dear Dr. Schmitz,

Thank you for submitting your revised manuscript. It has been reviewed by the editor, and there are a few issues that must be addressed before we can consider your manuscript further:

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.
2. LINE 4: The following authors need to respond to his/her authorship confirmation email. We emailed him/her at the addresses listed below. The email contains a link that needs to be clicked on. The sender of the email is EM@greenjournal.org.

Nicolas Sananès
Christophe Vayssière
Norbert Winer

- 
3. LINE 99: Page 12 says « 0.68, 95% CI 0.36-1.30.” Which data are correct?
 4. LINE 247: The abstract says 0.78, 95% CI -0.35-1.74.

Each of these points are marked in the attached manuscript. Please respond point-by-point to these queries in a return email, and make the requested changes to the manuscript. When revising, please leave the track changes on, and do not use the “Accept all Changes” function in Microsoft Word.

Please let me know if you have any questions. Your prompt response to these queries will be appreciated; please respond no later than COB on **Thursday, August 30th**.

Sincerely,
-Daniel Mosier

Daniel Mosier

Editorial Assistant

Obstetrics & Gynecology

The American College of Obstetricians and Gynecologists

409 12th Street, SW

Washington, DC 20024

Tel: 202-314-2342

Fax: 202-479-0830

E-mail: dmosier@greenjournal.org

Web: <http://www.greenjournal.org>

From: [REDACTED]
To: [Stephanie Casway](#)
Subject: RE: O&G Figure Revision: 18-1344
Date: Wednesday, August 29, 2018 10:02:08 AM

Hello Stephanie,

There is a mistake in the last right box. The right number is 831 and not 813. Otherwise, everything is OK for me.

Regards

Pr Thomas SCHMITZ

[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]
[REDACTED]

De : Stephanie Casway [mailto:SCasway@greenjournal.org]
Envoyé : mercredi 29 août 2018 14:47
À : SCHMITZ Thomas
Objet : O&G Figure Revision: 18-1344

Good Morning Dr. Schmitz,

Your figure has been edited, and a PDF of the figure is attached for your review. Please review the figure CAREFULLY for any mistakes.

PLEASE NOTE: Any changes to the figures must be made now. Changes made at later stages are expensive and time-consuming and may result in the delay of your article's publication.

To avoid a delay, I would be grateful to receive a reply no later than Friday, 8/31. Thank you for your help.

Best wishes,

Stephanie Casway, MA
Production Editor
Obstetrics & Gynecology
American College of Obstetricians and Gynecologists
409 12th St, SW
Washington, DC 20024
Ph: (202) 314-2339
Fax: (202) 479-0830
scasway@greenjournal.org