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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Date: Jan 04, 2022
To: "Loïc Sentilhes" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-21-2197

RE: Manuscript Number ONG-21-2197

Maternal and neonatal morbidity after attempted operative vaginal delivery: a propensity score analysis.

Dear Dr. Sentilhes:

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).

Please be sure to address the Editor comments (see "EDITOR COMMENTS" below) in your point-by-point response.

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 25, 2022, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: A pre specified secondary analysis of data collected from a prospective cohort study that took place from December 2008 to October 2013 at a French tertiary-care university hospital with more than 4,000 deliveries annually. Important to know that the original study was designed primarily to assess the effect of fetal head station on short-term maternal and neonatal morbidity and prospectively analyze maternal complications at 6 months: pelvic floors disorders, sexual dysfunction, and postpartum depressive symptoms. Published in 2015 Green journal and 2017 PLOS.

This secondary analysis objective includes both objectives of their most recent publications above. "To assess severe short-term maternal and neonatal morbidity and pelvic floor disorders at 6
12 months postpartum after attempted operative vaginal deliveries (OVD) according to type of instrument. (forcep/spatula and vacuum)

1.Objective is well stated

2. Well written

3.Methodology: applaud their use of propensity score matching much like your other studies for indication

4. Results: Table 2 Is the NICU hospitalization because of the OVD or are there other maternal characteristics (example GDM) that are causing the NICU hospitalization. What were the dominant reasons, the key drivers for each of the composite scores both maternal and neonatal in each group- It was hard for me to tell reading table 2. Is there a direct correlation between the instrument and the morbidity incurred?

5. Given that your original article found that station of head after propensity score matching was not significant and now you have found that the instrument of choice is not significant after propensity score matching, what is it do you think accounts for the severe morbidity?? This should be part of discussion. IS it the indication??

6. Do you think trying to isolate a single cause for a complex clinical situation as a cause of morbidity is worthwhile? could there be several causes that converge? This should be part of discussion

7. Discussion: Avoid saying "To our knowledge, our study is the first using a propensity score analysis to compare aOVD results among women with the same distribution of baseline covariates, that i..." Claiming to be the first requires yo to publish your search strategy in the bed of your paper.

Reviewer #2: This article attempts to add to the existing literature on the maternal and neonatal morbidity after operative vaginal delivery. there is quite bit of literature on this subject, but the authors of this paper feel their approach is more robust acknowledging that the ideal randomized trial will probably never be performed.

1. It is great that all of the cases of operative vaginal delivery that met criteria were included in the analysis and as one might expect from the available literature, forceps are associated with maternal morbidity. Although this finding is no longer significant after the propensity score is applied, the OR is still 1.5. This suggests a power issue that resulted from 2/3rd's of the cohort being eliminated from this part of the analysis.

2. This study does not appear to be powered enough to say as much about neonatal morbidity maternal morbidity.

3. In addition to the loss of cohort as a result of propensity scoring, the poor followup at 6 months further limits the power of the study for the variables measured.

4. A discussion of the advantages of propensity scoring versus logistic regression might be helpful. Does the use of propensity scoring truly make a difference as opposed to other adjustment techniques previously used to examine similar cohorts of patient's?

5. Overall an interesting study, but I am not convinced that it significantly adds to the existing literature. More discussion on how the study adds to what is already known is needed.

6. Spatula use is uncommon outside of France I think and might need to be explained for the readers of this journal.

STATISTICAL EDITOR COMMENTS:

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

lines 22-23, Fig 2: The study is powered to evaluate the difference in several maternal morbidity rates, but not for the difference in neonatal rates. The difference in baseline rates (8.4% vs 10.2% for adverse neonatal outcomes), based on the samples at hand, 80% power and alpha = 0.05, would have power ~ 30%. In order to discern a difference in that range (~ 1.2x the baseline rate) would require ~ 3x the sample sizes in this series. In other words, the difference in maternal adverse outcomes can be confirmed, while the difference in neonatal outcomes is underpowered.

EDITOR COMMENTS:

1. The Editors of Obstetrics & Gynecology have increased 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. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
* Include your title page information in the main manuscript file. The title page should appear as the first page of the document. Add any previously omitted Acknowledgements (ie, meeting presentations, preprint DOIs, assistance from non-byline authors).
* Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.
* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
* Name the IRB or Ethics Committee institution in the Methods section (if applicable).
* Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

3. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. When you uploaded your manuscript, each co-author received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

4. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

6. 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.

7. 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).
* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

8. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

9. 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.

10. 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.

11. 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.

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%").

12. Line 260: Your manuscript contains a priority claim. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search

should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

13. 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.

14. Please review examples of our current reference style at http://ong.editorialmanager.com (click on the Home button in the Menu bar and then "Reference Formatting Instructions" document under "Files and Resources). Include the digital object identifier (DOI) with any journal article references and an accessed date with website references. Unpublished data, in-press items, personal communications, letters to the editor, theses, package inserts, submissions, meeting presentations, and abstracts may be included in the text but not in the reference list.

In addition, the American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the references you are citing are still current and available. Check the Clinical Guidance page at https://www.acog.org/clinical (click on "Clinical Guidance" at the top). If the reference is still available on the site and isn't listed as "Withdrawn," it's still a current document.

If the reference you are citing has been updated and 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.

15. Each supplemental file in your manuscript should be named an "Appendix," numbered, and ordered in the way they are first cited in the text. Do not order and number supplemental tables, figures, and text separately. References cited in appendixes should be added to a separate References list in the appendixes file.

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

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.

If you choose open access, you will receive an Open Access Publication Charge letter from the Journal's Publisher, Wolters Kluwer, and instructions on how to submit any open access charges. The email will be from publicationservices@copyright.com with the subject line, "Please Submit Your Open Access Article Publication Charge(s)." Please complete payment of the Open Access charges within 48 hours of receipt.

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If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded as a Microsoft Word document. Your revision's cover letter should include the following:

* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
* A point-by-point response to each of the received comments in this letter. Do not omit your responses to the Editorial Office or Editors' comments.

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jan 25, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Jason D. Wright, MD
Editor-in-Chief

2020 IMPACT FACTOR: 7.661
2020 IMPACT FACTOR RANKING: 3rd out of 83 ob/gyn journals

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time. (Use the following URL: https://www.editorialmanager.com/ong/login.asp?a=r). Please contact the publication office if you have any questions.

[redacted]

January 19th, 2022

Ref. Original Research: "Maternal and neonatal morbidity after attempted operative vaginal delivery: a propensity score analysis."

Dear Dr. Wright,

Thank you for your e-mail dated January 4th, 2022 and the useful comments by the two Reviewers, the Statistical Editor, and the Editorial team. The manuscript has now been completely revised in accordance with these comments. As recommended, we have responded point-by-point to each reviewer and editor's comments and return a copy of the revision, in which the changes have been made with the "track changes" feature.

Choice of instrument for assisted vaginal birth remains a controversial topic. Previous data have suggested a conflict between the interests of the mother and the fetus: forceps appear to be associated with maternal morbidity and vacuum with more frequent and severe neonatal complications. Moreover, previous research about maternal and neonatal complications after operative vaginal delivery comparing the type of instrument used had severe limitations, mainly because of their observational and retrospective design, without any control for indication bias.

We aimed to determine maternal and neonatal morbidity according to the type of instrument used — vacuum versus forceps or spatulas — from a large French prospective cohort of attempted operative vaginal deliveries that included details of the clinical situations affecting the decision to attempt such an instrumental birth (in particular, prenatally suspected macrosomia, fetal head station, and occiput position), which are often unavailable in large retrospective population-based studies. The primary endpoints were composite severe morbidity for mothers and, separately, for newborns. Propensity-score analysis was used to ensure comparability of women with the same distribution of baseline covariates and to minimize selection bias and the likelihood of incorrectly attributing any association to forceps/spatula.

Our results suggest that, after controlling for indication bias with a propensity score analysis, among women with singleton term pregnancies, attempted operative vaginal deliveries with forceps or spatulas compared with vacuums were not associated with a higher rate of severe maternal or neonatal morbidity or with our secondary endpoint, a higher rate of symptoms of urinary and anal incontinence at 6 months postpartum. These results support the

use of either vacuum or forceps or spatula, mainly according to the preference of the provider and the women.

We note that our secondary endpoints involved survey responses about medium-term urinary and anal incontinence and that the response rate was only 43.9%. We have, nonetheless, as recommended in section Q of the Instructions to Authors, carefully characterized and compared the respondents and nonrespondents and found that the nonrespondents differed mainly for severe neonatal morbidity, which is clearly a factor unrelated to incontinence at 6 months. We think under these circumstances — secondary but relevant outcomes, and detailed analysis of nonresponders — this paper should not be automatically rejected for not meeting the response requirements for a study based only on a survey.

The authors hereby confirm 1) that all authors have made a substantial contribution to the information or material submitted for publication; 2) that all have read and approved the final manuscript; 3) that they have reviewed and edited the submission to omit any identifying information; 4) that they have no direct or indirect commercial financial incentive associated with publishing the article; 5) that there was no source of extra-institutional funding, particularly that provided by commercial sources; 6) that the manuscript or portions thereof are not under consideration by another journal or electronic publication and have not been previously published; 7) that this study was approved by a National Institutional Review Board and informed consent was obtained from all study participants.

Each author fulfils the authorship criteria of the ICMJE Recommendations. The authors also agree to the inclusion of their names in the list of authors on the manuscript in the order shown on the title page.

We confirm that we have read carefully the Instructions for Authors. We provide below a point-by-point response to each of the received comments.

Thank you for considering our article for publication in *Obstetrics & Gynecology*.

Sincerely yours,

Loïc Sentilhes, M.D., PhD, FRCOG,
Corresponding author,
For and on behalf of all authors.

ONG-21-2197: Maternal and neonatal morbidity after attempted operative vaginal delivery: a propensity score analysis

Point by point responses to Reviewers' comments

We would like to thank both reviewers, the statistical editor, and the editor for their comments, which have helped us to improve the quality of our paper.

Reviewer #1

A pre specified secondary analysis of data collected from a prospective cohort study that took place from December 2008 to October 2013 at a French tertiary-care university hospital with more than 4,000 deliveries annually. Important to know that the original study was designed primarily to assess the effect of fetal head station on short-term maternal and neonatal morbidity and prospectively analyze maternal complications at 6 months: pelvic floors disorders, sexual dysfunction, and postpartum depressive symptoms. Published in 2015 Green journal and 2017 PLOS.

This secondary analysis objective includes both objectives of their most recent publications above. "To assess severe short-term maternal and neonatal morbidity and pelvic floor disorders at 6 months postpartum after attempted operative vaginal deliveries (OVD) according to type of instrument. (forcep/spatula and vacuum)

1. **Objective is well stated**

We thank the Reviewer for this comment.

2. **Well written**

We thank the Reviewer for this comment.

3. **Methodology: applaud their use of propensity score matching much like your other studies for indication**

We are grateful to the Reviewer for this comment.

4. **Results: Table 2 Is the NICU hospitalization because of the OVD or are there other maternal characteristics (example GDM) that are causing the NICU hospitalization. What were the dominant reasons, the key drivers for each of the composite scores both maternal and neonatal in each group- It was hard for me to tell reading table 2. Is there a direct correlation between the instrument and the morbidity incurred?**

We thank the Reviewer for his/her comment. We agree with the Reviewer that such information could have been very interesting.
We acknowledge we did not collect the data about the dominant reason for the NICU hospitalization. In fact, we made the choice, which is usual in studies assessing neonatal outcome, to report the overall NICU incidence, regardless of the reason (direct, indirect or unrelated to the operative vaginal delivery) that led caregivers to decide that the child required NICU admission and thus not to report the NICU incidence a priori related directly or

indirectly to OVD. In fact, determining whether a NICU admission is related, directly or indirectly, to operative vaginal delivery is subject to biases and may result in particular in an underestimate of the incidence of these admissions related to operative vaginal delivery. We did, however, provide readers with the incidence rates for each group for the following neonatal outcomes potentially related to OVD (see Table 2): the 5-min Apgar score < 7, pH < 7.00, NICU hospitalization > 24 h, respiratory distress syndrome, scalp laceration, scalp hematoma, pain necessitating drugs, neonatal trauma, intraventricular hemorrhage>grade 2, need for resuscitation or intubation, sepsis, seizures, and neonatal death.

But, to attempt to clarify the point raised by the Reviewer #1, we can confirm that all of the 138 newborns hospitalized in NICU met our composite criterion of severe neonatal morbidity (5-minute Apgar score<7, umbilical artery pH < 7.00, need for resuscitation or intubation, neonatal trauma, intraventricular hemorrhage > grade 2, admission to the NICU (neonatal intensive care unit) for >24 hours, convulsions, sepsis, or neonatal death), although it was not possible to determine the dominant reason(s) that led to the decision to transfer the newborn to the NICU. This information has been now added as a footnote in Table 2.

5. **Given that your original article found that station of head after propensity score matching was not significant and now you have found that the instrument of choice is not significant after propensity score matching, what is it do you think accounts for the severe morbidity?? This should be part of discussion. IS it the indication??**

We thank the Reviewer for his/her comment and for the interest in our previous work and we agree that discussing the determinants related to operative vaginal delivery could be interesting.
However, our initial study was designed to determine whether the fetal head station (mid-pelvic compared with low-pelvic operative vaginal delivery) affected severe neonatal or maternal morbidity. This study was designed to determine whether the instrument (forceps/spatula versus vacuum) increased severe neonatal or maternal morbidity.
That is, neither study was designed for an exploratory analysis. In both studies, the multivariate analysis was designed to evaluate the association between the exposures (station of fetal head in our original article and the choice of instrument in this study) and the neonatal and maternal morbidity outcomes, with adjustment for potential confounders of this particular association with an etiologic objective, as described in Appendix 3. Thus, other covariates, such as the indication for the OVD, were adjustment variables for this relationship and cannot be interpreted as potential risk factors.
In Appendix 3, we report the adjusted OR (aOR) of each adjustment covariate. Interestingly, we found that the aOR of the indication for OVD was significant, as in the original article. Nevertheless, due to the limitations described above, we chose not to highlight this point to avoid confusing readers, as this work was not designed for an exploratory analysis.
However, we agree with Reviewer #1 that exploratory analyses are needed to examine the potential risk factors for severe maternal and neonatal morbidity when an OVD is performed, and we plan to perform this analysis in the future.

As suggested by the Reviewer, we have clarified this point by modifying the following sentence in the Discussion section, subsection Clinical and research implications, lines 312-315, page 15: "Future **exploratory** studies should determine whether some circumstances or subgroups of women might benefit from one instrument or the other, **and which**

determinants are associated with severe maternal and neonatal morbidity when OVDs are performed."

6. **Do you think trying to isolate a single cause for a complex clinical situation as a cause of morbidity is worthwhile? could there be several causes that converge? This should be part of discussion.**

We agree with the Reviewer that there is probably no single cause of severe morbidity in case of OVD. In our study and in our original article, we found that neither the choice of the instrument nor the fetal head station appear to be the dominant reason for severe maternal or neonatal morbidity. Only further exploratory studies can determine what determinants are associated with severe maternal and neonatal morbidity when an OVD is performed. We plan to perform this analysis in the future. As described in the previous answer, we have modified the following sentence to the Discussion section, subsection Clinical and research implications, lines 312-315, page 15: "Future **exploratory** studies should determine whether some circumstances or subgroups of women might benefit from one instrument or the other, **and which determinants are associated with severe maternal and neonatal morbidity when OVDs are performed**"

7. **Discussion: Avoid saying "To our knowledge, our study is the first using a propensity score analysis to compare aOVD results among women with the same distribution of baseline covariates, that i..." Claiming to be the first requires yo to publish your search strategy in the bed of your paper.**

We apologize for this assumption.

We have modified the following sentence, in the subheading 'Results' of the Discussion section, lines 299-301, page 14: "**Unlike most studies, ours has the advantage of** using a propensity score analysis to compare aOVD results among women with the same distribution of baseline covariates, that is, the same probability of forceps-assisted delivery."

Reviewer #2:

This article attempts to add to the existing literature on the maternal and neonatal morbidity after operative vaginal delivery. there is quite bit of literature on this subject, but the authors of this paper feel their approach is more robust acknowledging that the ideal randomized trial will probably never be performed.

1. **It is great that all of the cases of operative vaginal delivery that met criteria were included in the analysis and as one might expect from the available literature, forceps are associated with maternal morbidity. Although this finding is no longer significant after the propensity score is applied, the OR is still 1.5. This suggests a power issue that resulted from 2/3rd's of the cohort being eliminated from this part of the analysis.**

We thank the Reviewer for this comment. We agree with the Reviewer that the use of propensity score matching to limit the effects of confounding on estimates of the impact of instrument choice on maternal and neonatal outcomes results in eliminating the unmatched women of the cohort, and therefore in decreasing the study power.

To clarify this point for the readers, we have modified the following sentence in the Discussion section, lines 347-349, page 16: “Moreover, we must note that our results show a trend to higher rates of short- and long-term maternal morbidity, possibly obscured by the loss of power **due to the propensity score matching and the exclusion of the unmatched women from that analysis**.”

2. **This study does not appear to be powered enough to say as much about neonatal morbidity maternal morbidity.**

We thank the Reviewer for this comment.

We had previously highlighted this limitation in the initial Discussion section; it can currently be found on lines 342-344, page 16:
“Third, the infrequency of neonatal morbidity such as scalp hematoma, trauma or seizures, limited our statistical power to detect potentially clinically meaningful differences between vacuum and forceps or spatulas.”

Concerning the maternal morbidity, we cannot rule out the possibility that the propensity score matching resulted in a loss of power. Therefore, we have now highlighted this point still more strongly in the Discussion section as described above, in lines 347-349, page 16: “Moreover, we must note that our results show a trend to higher rates of short- and long-term maternal morbidity, possibly obscured by the loss of power **due to the propensity score matching and the exclusion of the unmatched women from that analysis**.”

However, our post-hoc calculation found that for severe maternal morbidity the univariate logistic regression would have detected an OR > 2.1. The ability or our study to detect this difference could be considered sufficiently relevant to physicians and patients.

3. **In addition to the loss of cohort as a result of propensity scoring, the poor follow-up at 6 months further limits the power of the study for the variables measured.**

We agree with the Reviewer.

Nonetheless, outcomes of pelvic floor disorders at 6 months are provided as secondary outcomes, and the response rate of 50% is similar to that in other studies assessing similar postpartum outcomes by postal questionnaires after birth. In addition, symptoms of urinary and anal incontinence are common postpartum events. Accordingly, our post hoc analysis determined that with a sample size of 245 patients, 19% of deliveries with adverse pelvic floor disorders outcomes at 6 months in the unexposed group (OVD with vacuum), there would have been a power of 80% and an alpha risk of 0.05, so that an OR > 2.3 would have been detected in univariate logistic regression. This result seems sufficiently relevant for the readers to recognize strong associations between the use of forceps/spatulas compared with vacuum and symptoms of urinary or anal incontinence.
To avoid complicating the comprehension of our results, we have chosen not to detail this post hoc analysis of our secondary endpoints.

Nevertheless, we modified the following sentence to highlight this limitation for the follow-up of 6 months secondary outcomes in the Discussion section, lines 347-351, page 16:

“Moreover, we must note that our results show a trend to higher rates of short- and long-term maternal morbidity, possibly obscured by the loss of power **due to the propensity score matching and the exclusion of the unmatched women from that analysis**. **This may be aggravated for the maternal secondary outcomes assessed at 6 month, by loss to follow-up.** Nonetheless, this increase appears moderate.”

4. **A discussion of the advantages of propensity scoring versus logistic regression might be helpful. Does the use of propensity scoring truly make a difference as opposed to other adjustment techniques previously used to examine similar cohorts of patient's?**

We chose not to detail the scientific argument for the use for our main analysis the propensity score versus logistic regression, but we provided the following references, which argue the value of its use for reducing the effects of confounding in observational studies:

31. Rosenbaum PR, Rubin DB. The central role of the propensity score in observationnal studies for causal effects. Biometrika. 1983;70:41-55.
32. Austin PC. An Introduction to Propensity Score Methods for Reducing the Effects of Confounding in Observational Studies. Multivar Behav Res. 2011;46(3):399-424.

In addition, we have previously highlighted the rationale for the propensity score approach in several parts of the manuscript:
- Introduction :
Lines 95-96, page 5 : “Propensity score analyses ensure the comparability of the study groups while minimizing indication bias.”
- Material and Methods :
Lines 195-197, page 9 : “Because instrument choice was probably guided by characteristics of the women and their pregnancy and labor, rather than chance, we used a propensity score as a sensitivity analysis to limit potential indication bias.”
- Discussion :
Lines 299-301, page 14 : “Unlike most studies, ours has the advantage of using a propensity score analysis to compare aOVD results among women with the same distribution of baseline covariates, that is, the same probability of forceps-assisted delivery.”
Lines 292-296, page 14: “Observational studies have reported discordant results regarding the association between maternal and neonatal morbidity and forceps-, spatula- and vacuum-assisted deliveries. They also were limited by methodological flaws —sample size, retrospective designs, limited data quality and availability, and absence of propensity score analysis to limit the indication bias affecting choice of instrument.[4,35-39] Any statistical approaches were limited to multivariable analyses controlling for some potential confounders.”
Lines 327-335, pages 15-16: “Fourth, to control for indication bias (which would otherwise be this study's major limitation), we performed propensity score analysis and rigorously adjusted for confounding factors, specifically maternal and obstetric characteristics (including prenatally suspected macrosomia, fetal head station, occiput position, physician experience with aOVD, and its indications) to minimize the likelihood of incorrectly attributing an association to forceps or spatulas. Our univariate analysis showed that forceps or spatulas were used in the most difficult conditions, and vacuum for less complicated, lower-risk, deliveries.”

However, we have now added the following sentence to emphasize the interest of the use of a propensity score method compared to logistic regression, in the Discussion section, Lines 327-334, pages 15-16: “Fourth, to control for indication bias (which would otherwise be this study's major limitation), we performed propensity score analysis, **which appears to perform better than logistic regression in reducing the effects of confounding in observational studies.**[31,32] We rigorously adjusted for confounding factors, specifically maternal and obstetric characteristics (including prenatally suspected macrosomia, fetal head station, occiput position, physician experience with aOVD, and its indications) to minimize the likelihood of incorrectly attributing an association to forceps or spatulas.”

5. **Overall an interesting study, but I am not convinced that it significantly adds to the existing literature. More discussion on how the study adds to what is already known is needed.**

We thank the Reviewer for this comment.

We have already highlighted how the study adds to what is already known in several parts of the manuscript in the Discussion section :
- Lines 299-301, page 14: “Unlike most studies, ours has the advantage of using a propensity score analysis to compare aOVD results among women with the same distribution of baseline covariates, that is, the same probability of forceps-assisted delivery”.
- Lines 292-295, page 14 : “Observational studies have reported discordant results regarding the association between maternal and neonatal morbidity and forceps-, spatula- and vacuum-assisted deliveries. They also were limited by methodological flaws —sample size, retrospective designs, limited data quality and availability, and absence of propensity score analysis to limit the indication bias affecting choice of instrument.[4,35-39]”
- Lines 309-311, page 15: “Our study, using propensity score analysis to limit indication bias, shows no difference between vacuum and forceps or spatulas in maternal and neonatal morbidity until hospital discharge or in pelvic floor disorders at 6 months.”
- Lines 317-331, pages 15-16: “Our study presents several strengths. First, the data come from a large prospective cohort in a center with a policy of planned vaginal delivery, demonstrated indirectly by its OVD (13.6%) and cesarean (20%) rates. These prospectively collected data, often unavailable in retrospective population-based studies, include maternal and obstetric characteristics, notably during the second stage of labor, and describe clinical situations affecting aOVD decisions (e.g., prenatally suspected macrosomia, fetal head station, and occiput position). Second, these data are robust: a collector bag was routinely used to estimate blood loss after delivery, neonatal arterial blood gases were systematically measured, and a qualified neonatologist examined all neonates. Our previous results were consistent with other well-established findings, especially for short- and mid-term maternal morbidity and short-term neonatal morbidity after vacuum or forceps deliveries.[14,15,22] Third, we studied all attempted OVDs, including failures, because their exclusion might mask a negative effect.[3] Fourth, to control for indication bias (which would otherwise be this study's major limitation), we performed propensity score analysis, **which appears to perform better than logistic regression in reducing the effects of confounding in observational studies.[31,32] ”**

However, to underline this point, we have now added the following sentence to the Discussion section, subsection Results, lines 301-303, page 14: “Moreover, our study provides prospective and longitudinal information about maternal outcomes, with detailed characteristics about several potential confounders to ensure appropriate adjustment.”.

6. **Spatula use is uncommon outside of France I think and might need to be explained for the readers of this journal.**

We thank the Reviewer for his comment.
To clarify this point, we modified the following sentence in the Introduction section, lines 72-75, page 5 :
"OVD rates range from 3% to 15% worldwide,[1,6-9] and its practice patterns vary widely, especially instrument choice among the vacuum, forceps, or spatulas **(consisting of two independent solid blades not connected to each other, i.e. without a fixed or sliding lock mechanism, and with a rounded cephalic curve).[10]"**

STATISTICAL EDITOR COMMENTS:

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

1. **lines 22-23, Fig 2: The study is powered to evaluate the difference in several maternal morbidity rates, but not for the difference in neonatal rates. The difference in baseline rates (8.4% vs 10.2% for adverse neonatal outcomes), based on the samples at hand, 80% power and alpha = 0.05, would have power ~ 30%. In order to discern a difference in that range (~ 1.2x the baseline rate) would require ~ 3x the sample sizes in this series. In other words, the difference in maternal adverse outcomes can be confirmed, while the difference in neonatal outcomes is underpowered.**

We agree with the Statistical Editor with this comment.
We modified the following sentence in the Discussion section, lines 342-347, page 16:
"Third, the infrequency of neonatal morbidity such as scalp hematoma, trauma or seizures, limited our statistical power to detect potentially clinically meaningful differences between vacuum and forceps or spatulas. **In addition, considering the small difference between the rates of severe neonatal morbidity (8.4% versus 10.2%), we acknowledge that our study is underpowered to confirm an absence of difference in neonatal adverse outcomes.**".

EDITOR COMMENTS:

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

A. OPT-IN: Yes, please publish my point-by-point response letter.
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2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:

*** Include your title page information in the main manuscript file. The title page should appear as the first page of the document. Add any previously omitted Acknowledgements (ie, meeting presentations, preprint DOIs, assistance from non-byline authors).**
*** Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and in the body text. For industry-sponsored studies, the Role of the Funding Source section should be included in the body text of the manuscript.**
*** Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).**
*** Name the IRB or Ethics Committee institution in the Methods section (if applicable).**
*** Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.**

We have followed these instructions.

3. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA), which must be completed by all authors. When you uploaded your manuscript, each co-author received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please check with your coauthors to confirm that they received and completed this form, and that the disclosures listed in their eCTA are included on the manuscript's title page.

We have followed these instructions.

4. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-obstetrics-data-definitions and the gynecology data definitions at https://www.acog.org/practice-management/health-it-and-clinical-informatics/revitalize-gynecology-data-definitions. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

We have followed these instructions.

5. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 5,500 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

We have followed these instructions.

6. 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.

We have followed these instructions.

7. 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).**
*** If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."**

We have followed these instructions.

8. 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.

We have followed these instructions.

In addition, the abstract length should follow journal guidelines. The word limit for Original Research articles is 300 words. Please provide a word count.

We have followed these instructions.

9. 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.

We have followed these instructions, but have assumed that OVD for operative vaginal delivery is a standard abbreviation despite its absence from the list (and accordingly, aOVD for attempted). Similarly UI is included, and it appears strange to abbreviate urinary incontinence but not anal incontinence, when they consistently appear together.

10. 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 have followed these instructions.

11. 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.

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

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We apologize for this assumption.

As suggested by the Reviewer#1, we modified the following sentence, in the Results section, line 299-301, page 14: "**Unlike most studies, ours has the advantage of** using a propensity score analysis to compare aOVD results among women with the same distribution of baseline covariates, that is, the same probability of forceps-assisted delivery".

13. 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 have followed these instructions.

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We have followed these instructions.

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