

# OBSTETRICS & GYNECOLOGY



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

**Date:** Mar 13, 2020  
**To:** "Abbey C Sidebottom" [REDACTED]  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-20-343

RE: Manuscript Number ONG-20-343

An examination of maternal and neonatal outcomes in hospital-based deliveries with water immersion

Dear Dr. Sidebottom:

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 Apr 03, 2020, we will assume you wish to withdraw the manuscript from further consideration.

#### REVIEWER COMMENTS:

Reviewer #1: The authors have done a retrospective study to look at the safety of water immersion in labour as well as the safety of giving birth in water ( water births) . The precis is that delivering in water or in the author's words, second stage water immersion is safe.

They have looked at a cohort of 603 women who entered the tub intending water birth. They have looked at the outcomes for the mother and the neonate and have compared with a similar population. They have also analysed the outcomes based on whether it was only water immersion or delivery and seen if there were any differences.

1. The study period has been over a few years from 2014- 2018. Did the authors notice any specific differences or impact because of this long period?
2. Out of 603 women who entered, 215 were only in first stage and the authors have said about maternal choice being the reason in 125. Was there any particular cause for so many exits as all were intending water birth at entry?
3. The authors have stratified the reasons for exit in the first stage. But there were 74 who exited in second stage. What was the reasons here? Was it patient or provider choice?
4. The authors have done a comparison with a similar group of 603 women who were selected from a bigger pool. They were comparable but there were differences in ethnicity and language preferences. Could this have any confounding effect? Were they a more motivated group or were a elite group with no problems at all?
5. Also the comparator group-what was the standard of care-the provider? As this can have a major effect on the need for labour interventions.
6. In the comparator group the epidural was 50% vs 17% in the water immersion group. This is a big difference compared to the Cochrane review where it was 43 vs 39%. Do the authors have any explanation for the same? The CS rates were however similar to the Cochrane evidence.
7. When they compared for the second stage immersion, how were the controls selected from the pool of 603. There is no matching shown for this group though given for the total.
8. The overall NICU rates were similar but in the first stage group who exited especially due to provider choice, it was higher and that is understandable. The second stage SCN rates were very low 2.5% compared to the controls, Cochrane etc. This is very heartening. But what do the authors feel could be the cause for this? Is it because they are a subgroup of

women who have not developed any risk factors at all and so possibly could explain this low rate of adverse outcome.

9. Cord avulsion is a very rare and recognised complication and the authors have adequately analysed that

10. There has been a significant effect on perineal tears in general and specifically severe ones with respect to second stage water immersion. Especially important as the Cochrane review has not been able to demonstrate any difference. Again could this be due to what we discussed in Point 8. How do the authors account for it?

11. There has been no mention of neonatal infection or temperature or fever.

12. What was the duration of immersion especially for those who delivered in water?

13. What was the average water temperature?

14. Was there any effect on the duration of labour- first and second?

15. What was the effect on EBL/ third stage?

16. And finally what about the maternal and caregiver satisfaction or perspective?

17. Though the above may not have been in the review agenda, these help to put the risks in perspective.

18. Did they have any emergencies while delivering in water? And what was the outcome? This becomes very important to both the caregivers as well as to the patients.

The study is very encouraging as it reflects the Cochrane review that there have been no evidences pointing to major adverse outcomes.

Reviewer #2: Thank you for your work.

Specific comments:

Abstract: can you mention maternal infectious complications in the abstract?

Introduction:

Is the previous waterbirth data hospital based, or does it include home based delivery?

Methods:

Please start with an IRB approval statement.

Lines 157-9: you state above all women were consented, but were all 5113 women consented for you to search their records and use them, or did you contact them after? Was this a blanket "your data might be used for research" statement and was this OK with IRB?

Lines 178-80: were c/S cases included in analysis? It seems they would have a different risk profile for your outcomes of interest.

Lines 206-9 how were these variables chosen?

Line 216: what variables were included in the logistic model to control for confounding and how were they chosen?

Can you include information on your sample size calculations? What effect difference did you expect to see? You are using a very low risk population, what was the baseline risk of the outcomes you are looking at?

It is not clear if you separately looked at those who delivered in the water versus those submerged. I think most of us would assume the risk comes in delivery in water, less from stage of submersion, though that is interesting too.

Results:

223-8: did you look at length of labor between the groups? Could this have impacted the differences in pain med and augmentation rates?

Lines 232-3 is this a significant difference? If so, did you look to see if these babies had higher NICU admit rates?

Lines 291-300: did you look at the parity distribution in the laceration data? Also while the overall groups were the same

for many demographic features, did those who delivered in water differ?

Lines 303: did you look at maternal post partum infection? What is your general choriamnionitis / endometritis rate?

Can you comment on whether you were powered to find maternal differences?

Discussion:

Lines 329-34: this doesn't need to be stated twice, would remove it either here or results.

Lines 351-3: did you consider excluding from the study women who had "medical concerns"? Also, did you look at the non water immersion group to see what percent of them had "medical concerns" identified during labor (which could skew toward favorable water birth numbers)? This is concurrent with the UK study that found the 1st stage folks who left water had risks, so maybe comparing folks who had an uncomplicated enough labor to stay in the water to folks who didn't enter water, therefore may have had undetected (by you) risks is what is skewing your result?

Reviewer #3: An examination of maternal and neonatal outcomes in hospital-based deliveries with water immersion

The manuscript is well-written, with a succinct summary of guidelines and shortcoming of the published reports on water birth, an uncommon occurrence. Use of propensity score provides panache which is uncommon.

While revising the manuscript, please address the following:

1. In the title, inform the reader that it's a multi-center study, which is one of the strengths of the analysis.
2. The abstract and the introduction are well-written and provide a nice summary of the literature.
3. A flow-diagram of total deliveries during the study period, total women eligible, women excluded (along with their indications), and included in the analysis is needed.
4. The fact that HealthPartner contributed data on water immersion but not control is potential source of bias. I was unable to ascertain how many cases were derived from HealthPartner. Hopefully, the flow-diagram can clarify this.
5. Please provide rationale for the independent variables that were matched for propensity score. I am surprised that epidural, and IV pain medication were not matched for.
6. Please provide the rate of SGA (birth weight < 10th percentile for GA) and LGA (birthweight > 90th percentile GA) in the two groups. Admittedly, antepartum suspicion of abnormal growth are reasons to exclude water immersion. Since, the majority of the newborns with aberrant growth are undetected before birth, there must be SGA and LGA in the two groups.
7. What were the criteria for admission to SCN/NICU? Could there be bias in that newborns after water immersion were considered "healthier" and not admitted to SCN/NICU though they met other criteria.
8. What is the possible biological plausibility of severe lacerations among women who had immersion in the 2nd stage of labor?
9. In the Tables 2 and 3, please bold the findings that were significantly different. This will allow for the busy clinician to discern what differed significantly.
10. Please comment on the generalizability of the finding.
11. The Appendix exemplifies the nuanced thought process of the researchers.

STATISTICAL EDITOR COMMENTS:

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

Table 2: Should more clearly separate the primary from all secondary outcomes. I believe the primary was comparison of NICU or SCN admission rates in the immersion cohorts vs their matched comparison groups. Also, since the comparisons were between the matched comparison (control) and (1) water immersion in 1st Stage only and (2) water immersion in 2nd Stage, the inference threshold should be .025, not .05, since two hypotheses were being tested. The secondary

outcomes (Apgars, cord avulsion rates, maternal outcomes etc should all include CIs for their proportions, not p-values and should be in a separate Table or clearly separated from the primary outcome. Also, many of the events had low frequency and the NS stats comparisons had insufficient power to generalize those NS conclusions beyond these data. For example, Apgars < 7, cord avulsion, composite measure of adverse outcomes, 3rd/4th degree lacerations or chorioamnionitis).

General: Should include a Table similar to Table 1 comparing the matched control vs 1st stage and control vs 2nd stage immersion cohorts in order to demonstrate for the reader how closely the groups were matched. Could be on-lines supplemental material.

Table 3: The p-values are not needed, since CIs are included. However, the inference testing for the primary outcome (if now there are three comparisons, should have CIs corresponding to  $p < .017$ , which would make all three of the primary outcomes NS. Again, need to clarify which is the primary outcome.

#### EDITOR'S COMMENTS:

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

#### PRESENTATION OF STATS INFORMATION (P Values vs Effect Size and Confidence Intervals)

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

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

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

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

Please limit p values to 3 decimal places.

Line 38: avoid abbreviations in the precis. Conversely, spell out all abbreviations on first use (Line 44)

Line 44: The objective of the abstract should be a simple "To" statement without background information. This could be "To compare neonatal intensive or special care nursery admission for in-hospital deliveries with water immersion compared to a clinically similar population without water immersion".

Line 48: can you tell us a bit about clinical eligibility (Singleton? Term? No prior CS? Any parity? Etc)

Line 56-58: I'm not clear how many were in each group. Please present the data so it's clear how many had only first stage, only 2nd stage, both 1st and 2nd stage only, delivery in the water w 1st but not 2nd; 2nd but not 1st and all stages. The way it is written (12.3% exited), the reader has to do the math to figure out how many remained.

Line 59: when you say admissions were lower for second stage water immersion, does that exclude women who delivered in the water?

Line 66: provide the fever data in results if you are going to include in conclusions. Are these maternal or infant fevers?

Line 65: Please edit conclusion to be consistent w/ comments by statistical editor .

Line 114: Please specify if 2nd stage could be 2nd stage AND 1st stage or 2nd only? Also please specify your inclusion or exclusion of those who actually DELIVERED in the water. You've set up the reason for your study to address 2nd stage immersion)Lines 76-110) and commented on lack of clarity in prior studies of the actual details of water immersion. I have to admit by line 114, I'm unclear who you are comparing. Based on the abstract, it seems that you are including women with water births and 2nd stage immersion as well as those with 2nd stage immersion only. That seems to muddy the waters a bit related to your goal.

Line 133: Please include Appendix Table IA in the body of the table rather than as an appendix.

Lines 141-145 clearly states your groups and may be used in the appendix and elsewhere and be clearer than currently written.

Line 178: Journal style is "cesarean birth" or "cesarean delivery" not "cesarean section".

Line 198: how were fetal distress and fetal placental problems defined?

Line 215: unclear—is "total water immersion"=603—in other words, any degree of immersion or is "total water immersion" referring to women with 1st +2nd stage + water delivery?

Line 222: Please see note above about how to present your data.

Line 232: Is there a difference in CS rates? Doesn't look like it but please provide evidence on this question.

Line 235: we don't use subheadings like this.

Line 243: "total immersion group"=see need for clarity around line 215.

Line 247: please note the lack of power for these non significant results.

Line 298+ Please provide 95% CI's in lieu of p values.

Line 307: in your discussion, please focus on your primary outcome first followed by secondary outcomes.

Line 343: We do not allow authors to describe variables or outcomes in terms that imply a difference (such as the terms "lower", "Higher", "trend" or "tendency" or "marginally different") unless there is a statistical difference. Please edit here and throughout to indicate that there is no difference.

#### EDITOR COMMENTS:

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

- A. OPT-IN: Yes, please publish my point-by-point response letter.
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2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

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

3. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author\* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained."  
\*The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

4. In order for a database study to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.

5. 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: 12% of the article is based on another published source with Sidebottom as author. Appendix 1 and App. 1 Table is almost verbatim copied from this other source. Please rewrite these sections or obtaining permission may be necessary.

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When you submit your revised manuscript, please upload 1) the permissions license and 2) a copy of the original source from which the material was reprinted, adapted, or modified (eg, scan of book page(s), PDF of journal article, etc.).

6. Please submit a completed STROBE checklist with your revision.

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

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

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

9. 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.

10. 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).

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

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

12. Only standard abbreviations and acronyms are allowed. A selected list is available online at <http://edmgr.ovid.com/ong/accounts/abbreviations.pdf>. Abbreviations and acronyms cannot be used in the title or *précis*. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

13. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

14. In your Abstract, manuscript Results sections, and tables, the preferred citation should be in terms of an effect size, such as odds ratio or relative risk or the mean difference of a variable between two groups, expressed with appropriate confidence intervals. When such syntax is used, the P value has only secondary importance and often can be omitted or noted as footnotes in a Table format. Putting the results in the form of an effect size makes the result of the statistical test more clinically relevant and gives better context than citing P values alone.

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

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

15. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: [http://edmgr.ovid.com/ong/accounts/table\\_checklist.pdf](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).

16. The American College of Obstetricians and Gynecologists' (ACOG) documents are frequently updated. These documents may be withdrawn and replaced with newer, revised versions. If you cite ACOG documents in your manuscript, be sure the reference you are citing is still current and available. If the reference you are citing has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance ([obgyn@greenjournal.org](mailto:obgyn@greenjournal.org)). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found via the Clinical Guidance & Publications page at <https://www.acog.org/Clinical-Guidance-and-Publications/Search-Clinical-Guidance>.

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

- \* A confirmation that you have read the Instructions for Authors (<http://edmgr.ovid.com/ong/accounts/authors.pdf>), and
- \* A point-by-point response to each of the received comments in this letter.

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Apr 03, 2020, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Nancy C. Chescheir, MD  
Editor-in-Chief

2018 IMPACT FACTOR: 4.965  
2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

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