

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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obgyn@greenjournal.org.

Date: Dec 23, 2020
To: "Caroline Verhaeghe" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-3127

RE: Manuscript Number ONG-20-3127

Impact of manual rotation of occiput posterior fetal positions: The RMOS randomized controlled trial.

Dear Dr. Verhaeghe:

Your manuscript has been reviewed by the Editorial Board and by special expert referees. Although it is judged not acceptable for publication in Obstetrics & Gynecology in its present form, we would be willing to give further consideration to a revised version.

If you wish to consider revising your manuscript, you will first need to study carefully the enclosed reports submitted by the referees and editors. Each point raised requires a response, by either revising your manuscript or making a clear and convincing argument as to why no revision is needed. To facilitate our review, we prefer that the cover letter include the comments made by the reviewers and the editor followed by your response. The revised manuscript should indicate the position of all changes made. We suggest that you use the "track changes" feature in your word processing software to do so (rather than strikethrough or underline formatting).

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jan 15, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

This is an interesting study, which has some value. The primary objective of the study was to determine whether attempted manual rotation of occiput posterior positions affected the rate of spontaneous delivery. However, I have several concerns about the manuscript.

1. With regard to study design, it appears that an occiput posterior position was considered abnormal regardless of the existing circumstances, and therefore might benefit from rotation early in the second stage. I disagree with that premise. For example, I would consider an OP position to be normal and expected in a pelvis with predominantly anthropoid features. Moreover, I would expect the success rate of manual rotation to be much lower in that situation than if the pelvis were gynecoid. Do the authors have any data concerning the pelvic architecture of the cases? It would be very helpful in interpreting the results.
2. Spontaneous rotation from OP to OA usually does not occur until the head has entered the middle or inferior pelvic strait. Why attempt manual rotation before that time? Serious head trauma can occur in this maneuver. And by attempting rotation early in the second stage we have no way of knowing how many would have rotated spontaneously if they had been left alone.
3. Was there any control exerted over the indication for cesarean or operative vaginal delivery? If not, it is very difficult to interpret the results. In other words, if the criteria for cesarean or forceps/vacuum delivery differed among various practitioners who made the decision about mode of delivery, that could introduce bias.
4. Table 1.
Provide units for BMI and age. Was ethnicity observed or self-reported? Why is "France" an ethnicity? It seems to me people of many different ethnic backgrounds and races live in France. The last 2 lines in the legend should be footnotes below chart.
5. Table 3.
Provide units for time to delivery; define "right" episiotomy and shoulder dystocia. Do "LOSA 3 and 4" refer to third and fourth- degree lacerations?
6. Table 4. Provide units for lactate. What kind of hematoma do you refer to?
7. Only about 2/3 of the patients in the manual rotation group were successfully rotated. Why was this? Did it depend

on the operator (MD or Midwife), on the experience of the operator, or on some feature of the pelvis? How many of these successfully rotated OP fetuses returned to their OP position again prior to delivery? I assume that is 45 of the 71 rotations. This suggests to me that the rotation was attempted too early in labor or that the qualities of the pelvis that predisposed to OP positioning were not considered.

8. It is unclear why 22 rotations were attempted in the expectant management group. Were these done very late in labor when there seemed no other option, or were they done inadvertently in violation of protocol?

9. Although the authors' English is excellent there are a few instances in which they have translated a French term ambiguously into English. I recommend the following changes:

- Change "variety" to "position"
- Change "expectative" to "expectant"
- Line 96 Change "presentations" to "positions"

Reviewer #2:

The authors have presented a prospective randomized trial examining whether attempting rotation of the fetus from occiput posterior position to occiput anterior position will impact delivery type and lead to change in maternal outcomes. I appreciate the author's evaluation of this important subject.

Title

Appropriate for manuscript.

Precis

In the Precis and throughout the manuscript the authors use the term "posterior varieties" which I believe the authors mean as any of the occiput posterior positions (left occiput posterior, direct occiput posterior or right occiput posterior). If this is correct, I advise changing the term "posterior varieties" to simply "occiput posterior positions" here and throughout the manuscript to correspond to usage in the United States.

Abstract

Overall appropriate for manuscript.

Line 56: please delete "to."

Line 57: please change "expective" to "expectant" management here and throughout the manuscript.

Line 66: I suggest revising this sentence to read "....defined by conversion to an occiput anterior position as confirmed by ultrasound, was 68%."

Introduction

Line 86: I would define occiput posterior positions (LOP, OP, ROP) here.

Line 92: please change "lesions of the anal sphincter [LOSA]" to "obstetric anal sphincter injuries (OASIS)" which in the US means a 3rd or 4th degree sphincter laceration.

Line 105-106: please delete "should be abandoned as they" and just leave the part about "Instrumental rotations using forceps are potentially hazardous....."

Line 109: I am uncertain whether the authors are using the term "spatula" as a synonym for "forceps" or if they specifically mean Thierry or Teissier spatulas, which to my knowledge are not used in the US. My understanding is that these are non-articulating devices. Please define the term here and/or in the Methods section. Thank you. Also, you mention vacuum rotation here and in the Methods section. I assume you place the vacuum and allow passive rotation, and do not actively twist or turn the vacuum, which can lead to so-called "cookie cutter" scalp lacerations. I am uncertain what the sentence "Spatula and vacuum rotations are more often than not followed by an instrumental assistance" means. Are the authors implying that spatula and vacuum deliveries are often unsuccessful and require forceps? This is an unclear sentence. Please clarify.

Methods

Line 139: please report the actual age ranges of your participants.

Lines 144-151: how does your team determine fetopelvic disproportion? By fetal cardiac arrhythmia I assume you mean "abnormal fetal heart rate pattern" because you mention fetal scalp pH testing, but in any event please clarify. How do you define "hemorrhaging during the first phase of labor?" You can probably delete lines 149-151.

Line 163: Was this a midwife intern or obstetrics intern? Please specify. You mention that the patients are randomized only after making sure that the obstetrics provider was experienced in manual rotation, but the screened patients are not mentioned in the flow chart (Figure 1). Also, did the intern ever perform the manual rotation, and, if so, was this followed by an attempt by someone more senior? Finally, in the discussion section (Lines 424-427) the authors mention that a

resident could also participate. Please add to Line 163.

Lines 169-183: I enjoyed the writeup of the technique.

Line 189: US readers will be unfamiliar with acupuncture to relieve OP positions.

Line 191: 3 hours seems like a long time to "labor down" prior to pushing. This is probably an uncommon practice in the US. More importantly, how long of a 2nd stage did the protocol allow before proceeding to cesarean delivery?

Line 203: please define "surgical lesions"

Line 204: vaginal vein thrombosis is a rare pregnancy complication.

Line 205: please define "poor scarring." Many of these complications are quite rare and I wonder why the team chose them. The study is very likely underpowered to identify many of these.

Line 253: can delete "The author(s) confirm" and start with "Institutional"

RESULTS

Line 267: Can delete "upon entry to the delivery room."

Lines 275-277: How do the authors explain the deviation from the protocol?

Discussion

Lines 417-439: While using a "real world" process where a midwife, intern, resident or attending obstetrician performs the attempted rotation maneuver, this has the potential to confound the results due to difference in operator experience. Did a more senior member of the team attempt rotation if the technique failed for the intern or resident? In line 422-423 you mention that diagnosing an OP position was simple, but later (lines 434-435) comment that the midwife may have missed some of the patients with an OP position. This is confusing. Also, please add a comment regarding whether or not you believe the study was powered appropriately to detect differences in the more uncommon maternal and neonatal outcomes.

Bibliography

Please change to References for journal formatting

These appear appropriate for the journal. I did not check formatting.

Reviewer #3:

A prospective RCT in a single center over 3 years (n=216) to evaluate the impact of manual rotation at full dilation of posterior varieties (confirmed by ultrasound in the early second stage) on the rate of spontaneous vaginal delivery
 Precis: I would change "Manual rotation of posterior varieties does not increase the rate of vaginal delivery without instrumental assistance" to "Manual rotation of posterior varieties does not increase the rate of spontaneous vaginal delivery" The latter is most consistent with your objective.

The Objective is very consistent

Abstract: well written,

line 53- "a suspected posterior variety" I would suggest an "ultrasound confirmed posterior variety"

line 56- I would add manual rotation at the start of second stage after ultrasound confirmation of posterior varieties.

Introduction well written, I would shorten the description of the two previous studies as you detail them in the discussion

Methods: It is not until the discussion that we learn that midwives, interns, residents and physicians all performed the manual rotation? This should be in the Methods. Was everyone educated on the procedure in a standardized curriculum?
 Lines 178-181 When describing the technique of a manual rotation by SOGC what do you mean by head slightly exposed?
 line 188-189 You state "The modification of postures, the introduction of oxytocin and the use of acupuncture allowed in the expectative group" Once an attempted rotation was completed were the same maneuvers allowed in the rotation group?

There is a very long list of secondary outcomes some of which are quite rare "death, fistula" were you powered to detect such complications? How was post partum stress syndrome defined and measured (line 206). I do not see some of the maternal complications reported on. There is a table devoted to neonatal complications

Results:

line 266-277 "Two hundred and thirty-eight patients agreed to participate in the study upon entry to the delivery room"
 "Please clarify when women were consented as this may be in part differences in language use. In the US most women are admitted to the "Delivery Room" and deliver in the room where they labor. Were women consented after a confirmed posterior variety on ultrasound, in the early second stage? I would change this sentence to capture the time in labor as opposed to a geographic time place as this has different meaning in different cultures and Units.

Lines 310-312 One hundred and sixty-eight primiparous patients were randomized, 83 to the manual rotation arm and 85 to the expectative management arm. Of these patients,
 47% had spontaneous vaginal delivery in the manual rotation group compared to 50.6% in the expectative management group. Were failed manual rotations more common in nullips vs multips?

Did an epidural make a difference in an ability to perform a manual rotation. Were there any episodes of fetal bradycardia

during the manual rotation or were any stopped because of intolerance by the woman

Discussion:

The two previous studies that have evaluated manual rotation are mentioned in both the Introduction and in the Discussion. Lines 354-398 are spent detailing the other two studies. This is almost two full pages. There is too much detail. I would only discuss the major differences and shorten considerably.

I would also shorten the description of these studies in the Introduction if you are going to detail in the Discussion.

I think the Discussion needs more detail about the study: generalizability, understanding differences between cultures and practices. Some examples:

Can you comment on the maternal BMI average of 26 and its generalizability?

Can you comment on the 30% instrumental delivery rate and whether this is generalizable?

Can you comment on when to do a manual rotation? Given that 18 women in the expectant group eventually had a manual rotation and 66% were successful, can you do it any time during second stage?

You try to get at the safety of this by looking at delivery outcomes. Many will be interested in the immediate complications that were encountered during the procedure if any. I think pertinent negatives can be very powerful. Was manual rotation abandoned because women did not tolerate?

70% of the women were nulliparous, although I know there were no significant differences in the final outcomes between the groups, was manual rotation more successful in multiparous women?

There is no information about epidurals in Methods or the Tables. Do women get epidurals during labor in your hospital, could this be a modifier on success or tolerance of the procedure?

Table 3: Time from randomization to delivery. I assume you mean hours? needs unit.

STATISTICS EDITOR COMMENTS:

Need to format the Abstract per our template for RCTs.

lines 221-223: This sentence is unclear.

lines 223-227: The criteria for sample size calculation is incomplete. Need to specify both rates, not just a 20% increase (in the reference cited, the rates were 20% vs 40% for sample size calculation).

Table 1: Need units for BMI.

Table 2: Since CIs are included, no need to include p-values, they are redundant. Also, since the primary endpoint was defined as a difference in proportions, should format the primary endpoint as difference in proportions, rather than OR, even though the mathematical test yields equivalent results. Also, the primary endpoint was not posited as an adjusted OR, even though the OR and aOR are numerically almost identical (0.94 vs 0.92).

Table 3: Need units for time. Both times and blood loss appear to have non-normal distributions. If so, then should format as median(range or IQR) and test non-parametrically.

Table 4: Same comment re: number of phototherapy sessions or durations of hospitalization as possibly non-normally distributed.

EDITOR COMMENTS:

1. Thank you for submitting your work to Obstetrics and Gynecology. If you choose to submit a revision, please reduce the length of your Introduction by approximately 1/3. It can be refocused on why you did this study specifically with less review of the existing literature.

2. Line 144. How was "suspected fetopelvic disproportion" defined? Was this standardized in any way?

3. Please see instructions for authors for suggested format for your Discussion.

4. Please also provide a "per protocol" analysis for the secondary outcomes.

5. It is unclear why adjusted odds ratios are being presented. In a randomized trial, differences at baseline should be accounted for in the randomization process. What are the authors adjusting for, and why?

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. 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. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

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

3. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

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 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.

6. 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).

7. 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.

8. Abstracts for all randomized, controlled trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online here: http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf. Please edit your abstract as needed.

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.

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%).

12. 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 reference you are citing is still current and available. If the reference has been updated (ie, replaced by a newer version), please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript (exceptions could include manuscripts that address items of historical interest). All ACOG documents (eg, Committee Opinions and Practice Bulletins) may be found at the Clinical Guidance page at <https://www.acog.org/clinical> (click on "Clinical Guidance" at the top).

15. When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

When you submit your revision, art saved in a digital format should accompany it. Please upload each figure as a separate file to Editorial Manager (do not embed the figure in your manuscript file).

If the figures were created using a statistical program (eg, STATA, SPSS, SAS), please submit PDF or EPS files generated directly from the statistical program.

Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi for color or black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

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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 in a word processing format such as Microsoft Word. Your revision's cover letter should include the following:

* A confirmation that you have read the Instructions for Authors (<http://edmgr.ovid.com/ong/accounts/authors.pdf>), and

* A point-by-point response to each of the received comments in this letter. Do not omit your responses to the Editorial Office or Editors' comments.

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jan 15, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Torri Metz, MD
Associate Editor, Obstetrics

2019 IMPACT FACTOR: 5.524

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

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Torri Metz
Associate Editor, Obstetrics
Obstetrics & Gynecology

February 11, 2021.

Manuscript Number ONG-20-3127: “Impact of manual rotation of occiput posterior fetal positions: The RMOS randomized controlled trial”

Dear Editor,

Please find enclosed our manuscript, entitled “The Impact of manual rotation of occiput posterior fetal positions on the rate of spontaneous vaginal delivery: The RMOS randomized controlled trial” by Verhaeghe C *et al.*, which we are submitting for publication in *Obstetrics & gynecology*.

The lead author affirms that he had read the Instructions for author.

We would like to thank you for your email. We have carefully read the comments made by the reviewers. As recommended, we have responded point-by-point to the comments. Please find below the comments and our point-by-point response.

REVIEWER COMMENTS:

Reviewer #1:

This is an interesting study, which has some value. The primary objective of the study was to determine whether attempted manual rotation of occiput posterior positions affected the rate of spontaneous delivery. However, I have several concerns about the manuscript.

With regard to study design, it appears that an occiput posterior position was considered abnormal regardless of the existing circumstances, and therefore might benefit from rotation early in the second stage. I disagree with that premise. For

example, I would consider an OP position to be normal and expected in a pelvis with predominantly anthropoid features. Moreover, I would expect the success rate of manual rotation to be much lower in that situation than if the pelvis were gynecoid. Do the authors have any data concerning the pelvic architecture of the cases? It would be very helpful in interpreting the results.

We thank the reviewer for this insightful comment. Pelvic architecture is not routinely collected in our center and we did not include this evaluation in our study.

However, it is well documented that obstetrical outcomes are generally better in cases with gynecoid compared to anthropoid pelvic features. This parameter would have been difficult to include in our study due to the lack of an objective and reproducible method of evaluating pelvic architecture.

Indeed, a purely clinical evaluation of pelvic architecture is subjective, and several studies have raised concerns regarding its validity as a predictor of adverse obstetrical outcomes in cephalic presentation (1,2).

We have now included this limitation in the discussion section of the article:

« Also, the pelvic architecture of our patients, a factor that could influence obstetrical outcome, was not known” (Line 580).

Spontaneous rotation from OP to OA usually does not occur until the head has entered the middle or inferior pelvic strait. Why attempt manual rotation before that time? Serious head trauma can occur in this maneuver. And by attempting rotation early in the second stage we have no way of knowing how many would have rotated spontaneously if they had been left alone.

We agree with the reviewers: the spontaneous rotation of posterior fetal positions to an anterior fetal position generally occurs when the head has entered the pelvic cavity or plane of outlet. In our study design the "expectant management" control group allows for us to estimate how many fetuses would have spontaneously rotated without any intervention and therefore to conclude on the impact of systematic manual rotation of posterior fetal positions.

We chose to study the impact of manual rotation at full dilatation as it is well described in available literature that when manual rotation is performed in case of stagnation of dilatation or in case of non-engagement at full dilatation, the risk of failure of manual rotation is 4 times higher (ORa= 4.2, 95%CI 1.6-11.5) compared to when manual rotation is performed systematically at full dilatation prior to stagnation (3,4).

We do agree that the success rate of manual rotation is higher when the fetal presentation is engaged. However, our primary endpoint was to evaluate the impact of attempting systematic manual rotation at full dilation.

Concerning the risk of severe trauma to the fetal head, no data was found in available literature on this subject. The only risks that are documented in available literature are the occurrence or aggravation of fetal heart rate abnormalities (de 10 à 20 %)(3,5), and an extremely low risk of umbilical cord prolapse (5).

Was there any control exerted over the indication for cesarean or operative vaginal delivery? If not, it is very difficult to interpret the results. In other words, if the criteria for cesarean or forceps/vacuum delivery differed among various practitioners who made the decision about mode of delivery, that could introduce bias.

We thank the reviewer for this relevant comment. All cesarean or operative vaginal delivery indications followed the French obstetrical guidelines:

- http://www.cngof.asso.fr/data/RCP/cesarienne_2000 (6)

- http://gynerisq.fr/bibliotheque_docs/recommandation-du-cngof-sur-les-extractions-instrumentales/ (7)

The cesarean rate in our center (19.6% in 2019) is similar to the French national rate (19.7%) (8).

Indications for cesarean section were:

- Fetal rhythm anomalies +/- fetal scalp blood PH
- After 2-3 hours at full dilation without engagement
- Failure of an attempt of instrumental delivery

Indications for instrumental delivery were:

- Fetal heart rate abnormalities when the fetus was engaged in the pelvic cavity
- Ineffective efforts when bearing down

Table

1.

Provide units for BMI and age.

We have provided units for BMI and age in the table.

Was ethnicity observed or self-reported?

Ethnicity was self-reported.

Why is "France" an ethnicity? It seems to me people of many different ethnic backgrounds and races live in France.

We have corrected the table and the ethnicity "Caucasian" now features.

The last 2 lines in the legend should be footnotes below chart.

The table has been corrected accordingly.

Table 3.

Provide units for time to delivery;

We have included the units (hours) for the time to delivery in table 3.

define "right" episiotomy and shoulder dystocia.

We have provided the following definitions in footnotes:

- right episiotomy as: an episiotomy with incision at the vulva fork, at a 45° angle toward the right ischiatic region.
- shoulder dystocia as: the absence of shoulder clearance of the fetus after expulsion of the head, necessitating the use of obstetrical maneuvers other than gentle traction of the head or the return maneuver.

Do "LOSA 3 and 4" refer to third and fourth- degree lacerations?

We have corrected the manuscript and the table. LOSA 3 and 4 refer to OASIS 3 and 4 lacerations.

Table 4. Provide units for lactate.

We have now provided the units for the lactate parameter: mmol/L.

What kind of hematoma do you refer to?

We did a data check with respect to this parameter:

- One file was not found
- In two cases, the suspected lumbar hematoma was diagnosed as a cherry angioma

As there is an error, we have chosen to remove this item from the table.

Only about 2/3 of the patients in the manual rotation group were successfully rotated. Why was this? Did it depend on the operator (MD or Midwife), on the experience of the operator, or on some feature of the pelvis?

Among the manual rotation group (106 patients), 13/106 rotations were attempted by midwives, 32/106 by a senior resident and 55/106 by a MD, in 6/106 cases the operators' level of experience was not known.

Our data shows a higher rate of failure of manual rotations in the midwife group compared to the MD group or the senior resident group.

- 7/13 (53.8%) failure in the midwife group vs 8/32 (25%) failure in the senior resident group ($p=0.06$)
- 7/13 (53.8%) failure in the midwife group vs 16/55 (29.6%) in the MD group ($p=0.09$)
- 8/32 (25%) failure in the senior resident group vs 16/55 (29.6%) in the MD group ($p=0.68$)

However, our global success rate is close to the success rate described in previous publication (4,9,10).

How many of these successfully rotated OP fetuses returned to their OP position again prior to delivery? I assume that is 45 of the 71 rotations. This suggests to me that the rotation was attempted too early in labor or that the qualities of the pelvis that predisposed to OP positioning were not considered.

We thank the reviewer for this comment. Among the 71 successful manual rotations, 14 (19,7%) returned to their OP position. Indeed, this could be the consequence of pelvic architecture or because manual rotation was in fact performed too early in labor.

It is unclear why 22 rotations were attempted in the expectant management group. Were these done very late in labor when there seemed no other option, or were they done inadvertently in violation of protocol?

In fact, there were 22 deviations from protocol in the expectant management group. These manual rotations were carried out at a later stage in labor and when there was no other option according to the MD.

These manual rotations were not carried out inadvertently in violation of the study protocol.

Although the authors' English is excellent there are a few instances in which they have translated a French term ambiguously into English. I recommend the following changes:

- Change "variety" to "position"
- Change "expectative" to "expectant"
- Line 96 Change "presentations" to "positions"

We thank the reviewer for this comment, and we have corrected the manuscript accordingly.

Reviewer #2:

The authors have presented a prospective randomized trial examining whether attempting rotation of the fetus from occiput posterior position to occiput anterior position will impact delivery type and lead to change in maternal outcomes. I appreciate the author's evaluation of this important subject.

Title

Appropriate for manuscript.

Precis

In the Precis and throughout the manuscript the authors use the term "posterior varieties" which I believe the authors mean as any of the occiput posterior positions (left occiput posterior, direct occiput posterior or right occiput posterior). If this is correct, I advise changing the term "posterior varieties" to simply "occiput posterior positions" here and throughout the manuscript to correspond to usage in the United States.

We thank the reviewer for this comment, and we have accordingly replaced "varieties" to "positions" in the manuscript.

Abstract

Overall appropriate for manuscript.

Line 56: please delete "to."

Line 57: please change "expective" to "expectant" management here and throughout the manuscript.

Line 66: I suggest revising this sentence to read "....defined by conversion to an occiput anterior position as confirmed by ultrasound, was 68%."

The abstract has been corrected accordingly.

Introduction

Line 86: I would define occiput posterior positions (LOP, OP, ROP) here.

We thank the reviewer for this comment. We have provided definitions of occiput posterior positions (Line 113)

- Left occiput posterior (LOP)
- Occiput posterior (OP)
- Right occiput posterior (ROP)

Line 92: please change "lesions of the anal sphincter [LOSA]" to "obstetric anal sphincter injuries (OASIS)" which in the US means a 3rd or 4th degree sphincter laceration.

LOSA has been replaced by OASIS in the manuscripts text and tables.

Line 105-106: please delete "should be abandoned as they" and just leave the part about "Instrumental rotations using forceps are potentially hazardous....."

We have deleted this sentence.

Line 109: I am uncertain whether the authors are using the term "spatula" as a synonym for "forceps" or if they specifically mean Thierry or Teissier spatulas, which to my knowledge are not used in the US. My understanding is that these are non-articulating devices. Please define the term here and/or in the Methods section. Thank you.

We thank the reviewer for this comment.

We use Thierry spatulas which are commonly used in France. Thierry spatulas are non-articulating devices.

We have also added the following sentence (Line 144): "Thierry spatulas are non-articulating instruments, commonly used in France, that consist of two spoon shaped devices. They allow for the orientation of the fetal head and propel the fetal head through the maternal genital tract via contact points on the maternal perineum and the fetal malar bones (11).

Also, you mention vacuum rotation here and in the Methods section. I assume you place the vacuum and allow passive rotation, and do not actively twist or turn the vacuum, which can lead to so-called "cookie cutter" scalp lacerations.

Indeed, we did not actively twist or turn the vacuum. In order to provide greater clarity, we have added "passively assisted" in the manuscript (Line 147)

I am uncertain what the sentence "Spatula and vacuum rotations are more often than not followed by an instrumental assistance" means. Are the authors implying that spatula and vacuum deliveries are often unsuccessful and require forceps? This is an unclear sentence. Please clarify.

The idea that we would like to convey is that once the Thierry spatulas or vacuum cup are in place, to facilitate a passive rotation from a posterior position to an anterior position, the Thierry spatulas or vacuum cup remain in place most of the time and delivery is assisted.

We do not mean to convey that after rotation, the spatulas or vacuum cup is replaced by forceps.

For greater clarity this section has been rephrased (Line 147).

Methods

Line 139: please report the actual age ranges of your participants.

We have updated the manuscript with: « all patients over 18 years old » (Line 192)

Lines 144-151: how does your team determine fetopelvic disproportion?

The assessment of fetopelvic disproportion was left to the discretion of the physicians and was evaluated either only clinically, via a pelvic examination and the measurement of uterine height, or via the combination of a clinical exam and an ultrasound estimate of fetal weight.

By fetal cardiac arrhythmia I assume you mean "abnormal fetal heart rate pattern" because you mention fetal scalp pH testing, but in any event please clarify.

Yes, by fetal cardiac arrhythmia we refer to « abnormal fetal heart rate pattern". We have updated the manuscript (Line 199).

How do you define "hemorrhaging during the first phase of labor?"

We have corrected the manuscript and replaced “hemorrhaging” by “metrorrhagia” (Line 201).

You can probably delete lines 149-151.
We have deleted lines 149-151.

Line 163: Was this a midwife intern or obstetrics intern? Please specify.
A resident (obstetrics intern), we have corrected the manuscript (Line 222).

You mention that the patients are randomized only after making sure that the obstetrics provider was experienced in manual rotation, but the screened patients are not mentioned in the flow chart (Figure 1).
Unfortunately, the number of screened patients is unknown; this is one of the limitations of our study, that we acknowledge in the limitations part of the discussion (Line 576).

Also, did the intern ever perform the manual rotation, and, if so, was this followed by an attempt by someone more senior?
After randomizing, the physician on-call could authorize the on-call obstetrics resident or a midwife to perform the manual rotation, although only if they had previously been trained in the procedure. A given operator was allowed to perform three attempts at manual rotation, but in no case could there be more than one operator. Thus, for example, if the manual rotation was unsuccessful after three attempts by the obstetrics resident, the physician was not allowed, according to the study protocol, to attempt to perform the manual rotation.

Finally, in the discussion section (Lines 424-427) the authors mention that a resident could also participate. Please add to Line 163.
As mentioned above, only senior resident (4-5th year) could participate in the study.
We have added this to the manuscript (Line 222)

Lines 169-183: I enjoyed the writeup of the technique.
We thank the reviewer for this comment.

Line 189: US readers will be unfamiliar with acupuncture to relieve OP positions.
Due to insufficient evidence demonstrating that acupuncture can improve obstetrical outcomes, we have removed this section from the manuscript.

Line 191: 3 hours seems like a long time to "labor down" prior to pushing. This is probably an uncommon practice in the US. More importantly, how long of a 2nd stage did the protocol allow before proceeding to cesarean delivery?
In France, if circumstances allow for it, current guidelines recommend waiting for a third hour at complete dilation if the presenting part of the fetus has not fully passed through the pelvic inlet (French Haute Autorité de Santé – HAS and French National College of Gynecology and Obstetrics - CNGOF). The administration of oxytocin is recommended after two hours at full dilation if uterine dynamics are considered to be insufficient (12). Thus, the study protocol allowed for a maximum time of 3 hours at complete dilatation before cesarean section was considered. (Line 260)

Line 203: please define "surgical lesions"

Surgical lesions were defined as lesions of the: ureter (wound or section), intestines (wound), bladder (including wounds requiring or not a urinary catheter).

We have updated the manuscript to include the definition of the different surgical lesions (Line 291).

Line 204: vaginal vein thrombosis is a rare pregnancy complication.

Yes, vaginal vein thrombus is a rare complication, since its incidence is approximately 1/1000 births. We chose to record this complication because it occurs primarily after the straining of maternal tissue and instrumental extraction is a known risk component for vaginal vein thrombus.

We therefore wished to explore whether or not manual rotation could also have an impact on the incidence of vaginal vein thrombosis.

Line 205: please define "poor scarring." Many of these complications are quite rare and I wonder why the team chose them. The study is very likely underpowered to identify many of these.

"Poor scarring" has been used to describe a problem with scar tissue of the episiotomy. We have updated the manuscript with the term "problematic scarring" (Line 293)

We fully agree with the reviewer that all these complications are very rare and the analyses relating to them are purely exploratory. Under no circumstances will any conclusions be drawn relative to an association or causal link. We have chosen to record these complications for observational purposes.

Line 253: can delete "The author(s) confirm" and start with "Institutional"

We have deleted "The author(s) confirm" and now include "Institutional Review Board approval (IRB) was obtained".

RESULTS

Line 267: Can delete "upon entry to the delivery room."

We have deleted "upon entry to the delivery room"

Lines 275-277: How do the authors explain the deviation from the protocol?

In fact, there were 22 deviations from protocol in the expectant management group. These manual rotations were carried out at a later stage in labor and when there was no other option according to the MD.

These manual rotations were not carried out inadvertently in violation of the study protocol.

This bias was taken into account by carrying out both an ITT and per-protocol analysis.

Discussion

Lines 417-439: While using a "real world" process where a midwife, intern, resident or attending obstetrician performs the attempted rotation maneuver, this has the potential

to confound the results due to difference in operator experience. Did a more senior member of the team attempt rotation if the technique failed for the intern or resident? After randomizing, the physician on-call could authorize the on-call obstetrics resident or a midwife to perform the manual rotation, although only if they had previously been trained in the procedure. A given operator was allowed to perform three attempts at manual rotation, but in no case could there be more than one operator. Thus, for example, if the manual rotation was unsuccessful after three attempts by the obstetrics resident, the physician was not allowed, according to the study protocol, to attempt to perform the manual rotation.

We agree with the reviewer that allowing a midwife, a resident or a physician to do the manual rotation may cause a bias. We did not classify operators into experienced and inexperienced operators as no official definition of an experienced operator is available, to our knowledge, in literature.

In our maternity ward, before the implementation of this research protocol, midwives were allowed to perform manual rotation during labor, without prior authorization from a physician. Allowing for midwives, residents and physicians to perform the maneuver seemed to be a good way of ensuring that we did not miss any inclusions.

In line 422-423 you mention that diagnosing an OP position was simple, but later (lines 434-435) comment that the midwife may have missed some of the patients with an OP position. This is confusing.

We thank the reviewer for this comment. We have moderated the fact that diagnosing an OP position was simple. Indeed, in cases with caput succedaneum, the diagnosis of position can be difficult.

Also, please add a comment regarding whether or not you believe the study was powered appropriately to detect differences in the more uncommon maternal and neonatal outcomes.

The study is not powerful enough to detect rare maternal and neonatal complications. We state in the methods section that the secondary analyses are all exploratory and that it is impossible to conclude on any association or any causal link.

Although, we fully agree with the reviewer, we are unable to provide additional insight as the power calculation was only carried out for the primary judgment criterion.

Bibliography

Please change to References for journal formatting

These appear appropriate for the journal. I did not check formatting.

We have updated the section for journal formatting.

Reviewer #3:

A prospective RCT in a single center over 3 years (n=216) to evaluate the impact of manual rotation at full dilation of posterior varieties (confirmed by ultrasound in the early second stage) on the rate of spontaneous vaginal delivery

Precis: I would change "Manual rotation of posterior varieties does not increase the rate of vaginal delivery without instrumental assistance" to " Manual rotation of posterior varieties does not increase the rate of spontaneous vaginal delivery" The latter is most consistent with your objective.

We have changed this section as recommended.

The Objective is very consistent

Abstract:

well written,

line 53- "a suspected posterior variety" I would suggest an "ultrasound confirmed posterior variety"

We have written "suspected posterior ..." because the patients eligible for inclusion into the study were those with a clinical suspicion of posterior position (after vaginal examination), while the patients definitely included in the study were those with a clinical suspicion of posterior position and confirmed by an ultrasound examination. Confirmation of posterior position with ultrasound was only required for definitive inclusion into the study.

line 56- I would add manual rotation at the start of second stage after ultrasound confirmation of posterior varieties.

We have now included "at the start of second stage" in the abstract.

Introduction well written,

I would shorten the description of the two previous studies as you detail them in the discussion

We have reduced in the introduction section, as advised, the description of the two studies detailed in the discussion section.

Methods:

It is not until the discussion that we learn that midwives, interns , residents and physicians all performed the manual rotation? This should be in the Methods.

We have included in the Methods section that a midwife, an obstetrics resident or a physician could carry out the manual rotation. The operator had up to three attempts. However, there could never be more than one operator (Line 222).

Was everyone educated on the procedure in a standardized curriculum?

No, there was no standardized training in the manual rotation maneuver. This is why it was not possible for us to categorize the operators as an "experienced operator" or an "inexperienced operator". Nevertheless, untrained personnel were not allowed to perform the manual rotation.

Lines 178-181 When describing the technique of a manual rotation by SOGC what do you mean by head slightly exposed?

Usually the fetal head is slightly flexed, and constant gentle pressure exerted.

line 188-189 You state "The modification of postures, the introduction of oxytocin and the use of acupuncture allowed in the expectative group" Once an attempted rotation was completed were the same maneuvers allowed in the rotation group ?

Patients in both groups received the same standard labor care.

There is a very long list of secondary outcomes some of which are quite rare "death, fistula" were you powered to detect such complications?

The study is not powerful enough to detect rare maternal and neonatal complications. We state in the methods section that the secondary analyses are all exploratory and that it is impossible to conclude on any association or any causal link.

How was post-partum stress syndrome defined and measured (line 206).

Initially, postpartum stress was to be measured using two standardized questionnaires (IES scale and PDEQ scale). Unfortunately, only a few questionnaires were distributed in the post-natal ward and the rate of response was therefore very low. We are therefore unable to report the results of postpartum stress. As a result, we have deleted this passage.

I do not see some of the maternal complications reported on. There is a table devoted to neonatal complications.

When no maternal complications were observed in any of the groups, we did not report this, although in the case of neonatal complications, we did report events that did not occur in our study.

Below is the table of maternal complications, it shall be included in the supplemental data should section.

	Expectant management	Manual rotation	p
n	119	117	
Cervical lesions (%)	0 (0.0)	0 (0.0)	NA
Vaginal vein thrombosis (%)	0 (0.0)	0 (0.0)	NA
Surgical wound (%)	0 (0.0)	0 (0.0)	NA
Postpartum endometritis (%)	0 (0.0)	0 (0.0)	NA
Postpartum fever (%)	0 (0.0)	0 (0.0)	NA
Problematic episiotomy scarring (%)	0 (0.0)	1 (0.9)	0.993
Deep vein Thrombosis (%)	0 (0.0)	0 (0.0)	NA
Pulmonary Embolism (%)	0 (0.0)	0 (0.0)	NA
Intestinal occlusion (%)	0 (0.0)	0 (0.0)	NA
Fistula (%)	0 (0.0)	0 (0.0)	NA
Transfer to ICU (%)	0 (0.0)	0 (0.0)	NA
Death (%)	0 (0.0)	0 (0.0)	NA

Results:

line 266-277 "Two hundred and thirty-eight patients agreed to participate in the study upon entry to the delivery room "Please clarify when women were consented as this may be in part differences in language use. In the US most women are admitted to the "Delivery Room" and deliver in the room where they labor. Were women consented after a confirmed posterior variety on ultrasound, in the early second stage? I would change this sentence to capture the time in labor as opposed to a geographic time place as this has different meaning in different cultures and Units.

We thank the reviewer for this comment, and we have further clarified this point: Inclusion of patients was done after ultrasound confirmation of the posterior position and not upon entry into the labor room.

238 patients agreed to participate in the study and signed a consent form after the posterior position was confirmed by ultrasound examination at full dilation.

Two patients withdrew their consent.

Lines 310-312 One hundred and sixty-eight primiparous patients were randomized, 83 to the manual rotation arm and 85 to the expectative management arm. Of these patients, 47% had spontaneous vaginal delivery in the manual rotation group compared to 50.6% in the expectative management group. Were failed manual rotations more common in nullips vs multips?

It is described in literature that primiparity is a risk factor for the failure of manual rotation (3,10). This is why we stratified randomisation on parity.

In our study:

Among the 117 patients randomized in the manual rotation group, 83 were primiparous (70.9%) and 34 were multiparous (29.1%).

Among the 71 successful manual rotations: 48 (67.6%) were primiparous and 23 (32.4%) were multiparous.

Among the 34 failed manual rotations: 27 (79.4%) were primiparous and 7 were multiparous (20.6%) (p value = 0.210).

We found there to be no difference between primiparous and multiparous patients on the rate of failure of manual rotation.

Bertholdt et al in 2019 also found no association between parity and success or failure of manual rotation (4).

Did an epidural make a difference in an ability to perform a manual rotation?

This question is interesting unfortunately our research protocol does not provide us with an answer to this question. In fact, only patients with epidural analgesia were included in the study.

All patients were therefore under epidural analgesia.

Were there any episodes of fetal bradycardia during the manual rotation or were any stopped because of intolerance by the woman.

Although a very good question, we do not have this data. Should we have recorded this information, it may have allowed us to explain some of the 34 failures of manual rotation.

Discussion:

The two previous studies that have evaluated manual rotation are mentioned in both the Introduction and in the Discussion

Lines 354-398 are spent detailing the other two studies. This is almost two full pages, There is too much detail. I would only discuss the major differences and shorten considerably

I would also shorten the description of these studies in the Introduction if you are going to detail in the Discussion

We have reduced in the introduction section, as advised, the description of the two studies also detailed in the discussion section.

We have also shortened the discussion to include only major differences.

I think the Discussion needs more detail about the study: generalizability understanding differences between cultures and practices. Some examples: Can you comment on the maternal BMI average of 26 and its generalizability Can you comment on the 30% instrumental delivery rate and whether this is generalizable

Can you comment on when to do a manual rotation? Given that 18 women in the expectant group eventually had a manual rotation and 66% were successful, can you do it any time during second stage?

We have added a paragraph on the external validity of our study in which we discuss our population, delivery and outcomes (caesarean section and instrumental delivery rates) (Line 584).

You try to get at the safety of this by looking at delivery outcomes many will be interested in the immediate complications that were encountered during the procedure if any, I think pertinent negatives can be very powerful. Was manual rotation abandoned because women did not tolerate?

The point raised by the reviewer is highly relevant.

No manual rotation attempts were interrupted due to poor maternal tolerance: indeed, all patients included in our study had effective epidural analgesia.

However, unfortunately we do not have any data on fetal tolerance. It would have been of great value to investigate whether certain maneuvers were interrupted due to fetal heart rate anomalies for example. We could also have collected data on the reasons behind assisted births: non-engagement, fetal heart rate anomalies, fetal stagnation, etc. Unfortunately, we did not collect this information.

70% of the women were nulliparous although I know there were no significant differences in the final outcomes between the groups, was manual rotation more successful in multiparous women?

We included in the manuscript: " In our study, as is described by Bertholdt et al., multiparity is not associated with an increased success rate of the manual rotation maneuver».

There is no information about epidurals in Methods or the Tables. Do women get epidurals during labor in your hospital, could this be a modifier on success or tolerance of the procedure?

We thank the reviewer for this comment. We did not mention in the Methods section that only patients with epidural analgesia were eligible for inclusion. We have added this point to the manuscript (Line 194)

Table 3: Time from randomization to delivery I assume you mean hours? needs unit
We have added the unit for time from randomization to delivery: "hours".

STATISTICS EDITOR COMMENTS:

Need to format the Abstract per our template for RCTs.
We have redrafted the abstract according to the template.

lines 221-223: This sentence is unclear.
We have removed it from the manuscript.

lines 223-227: The criteria for sample size calculation is incomplete. Need to specify both rates, not just a 20% increase (in the reference cited, the rates were 20% vs 40% for sample size calculation).

We thank the reviewer for this pertinent comment. Although, we had specified the two rates in the protocol previously published (13), they were not included in the manuscript. This has been amended and we have now also added them to the manuscript.

The following was published in the study protocol : According to the hypothesis of Le Ray et al.'s study in 2013, 214 patients are required to show a 20% increase in the percentage of spontaneous vaginal delivery (60% without manual rotation vs 80% with manual rotation) with a power of 90% and an alpha risk of 5% (107 per group).

Table 1: Need units for BMI.

We have added the units for the BMI (Kg/m²).

Table 2: Since CIs are included, no need to include p-values, they are redundant.

We have removed the p-values from Table 2.

Also, since the primary endpoint was defined as a difference in proportions, should format the primary endpoint as difference in proportions, rather than OR, even though the mathematical test yields equivalent results. Also, the primary endpoint was not posited as an adjusted OR, even though the OR and aOR are numerically almost identical (0.94 vs 0.92).

Rather than a OR, we have now included in the abstract, the manuscript and in table II a difference in risk with a 95% confidence interval.

Table 3: Need units for time.

We have added the units of time: "hours".

Both times and blood loss appear to have non-normal distributions. If so, then should format as median(range or IQR) and test non-parametrically.

We have checked all the distributions: Time has a normal distribution and blood loss has a non-normal distribution.

Indeed, a non-parametric test was used for the analysis.

We have modified Table 3 by specifying the median and interquartile ranges relative to blood loss.

Table 4: Same comment re: number of phototherapy sessions or durations of hospitalization as possibly non-normally distributed.

The number of phototherapy sessions does not have a normal distribution. Indeed, we did carry out a non-parametric test.

We have modified table 4 to include the median and the interquartile range relative to the number of phototherapy sessions.

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. 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.
- A. [OPT-IN: Yes, please publish my point-by-point response letter.](#)

2. Obstetrics & Gynecology uses an "electronic Copyright Transfer Agreement" (eCTA). When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

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

[We have checked disclosures with all coauthors.](#)

3. Clinical trials submitted to the journal as of July 1, 2018, must include a data sharing statement. The statement should indicate 1) whether individual deidentified participant data (including data dictionaries) will be shared; 2) what data in particular will be shared; 3) whether additional, related documents will be available (eg, study protocol, statistical analysis plan, etc.); 4) when the data will become available and for how long; and 5) by what access criteria data will be shared (including with whom, for what types of analyses, and by what mechanism). Responses to the five bullet points should be provided in a box at the end of the article (after the References section).

[We have answered these 5 questions. These answers can be found at the end of the article after the references section.](#)

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 used of the revitalize definitions.](#)

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 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

[The revised manuscript adheres well to the length restrictions.](#)

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

* All financial support of the study must be acknowledged.

[We have no financial support.](#)

* 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.

[We had no assistance in the preparation of the manuscript.](#)

* 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.

[No one, other than the cited authors, contributed to the manuscript.](#)

* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

[The results will be presented on 13th of January 2021 at the French congress: Paris Santé Femme.](#)

7. 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 carefully checked the abstract and modified it where necessary.](#)

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

[The length of the abstract is 290 words](#)

8. Abstracts for all randomized, controlled trials should be structured according to the journal's standard format. The Methods section should include the primary outcome and sample size justification. The Results section should begin with the dates of enrollment to the study, a description of demographics, and the primary outcome analysis. Please review the sample abstract that is located online

here: http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf. Please edit your abstract as needed.

The abstract was written and has been edited according to the journal's guidelines.

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 checked all abbreviations.

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 changed the only place where we used the (/) was the mention primiparous / multiparous that has been changed to primiparous or multiparous.

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.

We checked the manuscript and adjusted the format accordingly.

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

Not applicable.

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%).

We have standardized the presentation of data throughout the manuscript.

12. 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.

We did not conduct a systematic literature review. We have therefore removed the statement that this is to our knowledge the first randomized trial on this topic.

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 reviewed the checklist and have corrected the tables, numbering and symbols

used for the footnotes where necessary. The checklist is attached.

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. We reviewed the reference list and have corrected it.

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

15. When you submit your revision, art saved in a digital format should accompany it. If your figure was created in Microsoft Word, Microsoft Excel, or Microsoft PowerPoint formats, please submit your original source file. Image files should not be copied and pasted into Microsoft Word or Microsoft PowerPoint.

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If the figures were created using a statistical program (eg, STATA, SPSS, SAS), please submit PDF or EPS files generated directly from the statistical program.

Figures should be saved as high-resolution TIFF files. The minimum requirements for resolution are 300 dpi for color or black and white photographs, and 600 dpi for images containing a photograph with text labeling or thin lines.

Art that is low resolution, digitized, adapted from slides, or downloaded from the Internet may not reproduce.

Flow Chart included.

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>.

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