NOTICE: This document contains correspondence generated during peer review and subsequent revisions but before transmittal to production for composition and copyediting:

- 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.

Personal or nonessential information may be redacted at the editor’s discretion.

Questions about these materials may be directed to the Obstetrics & Gynecology editorial office:

obgyn@greenjournal.org.
Dear Dr. Berghella:

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

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

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

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Oct 22, 2021, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

Thank you for opportunity to review this systematic review and meta-analysis on a very important topic. Appreciate the authors efforts to publish this compilation of data in a timely fashion given several RCTS on this topic have been published in the last 12 months.

84: Consider re-phrasing "limiting it utility in the outpatient setting." There is little data on misoprostol use in the outpatient setting so utility is unclear and there are safety concerns based on increased incidence of tachysystole when used inpatient.

182: I don't understand how it is possible to have no difference in vaginal birth rate, but significantly lower cesarean delivery rate (they should be directly correlated right? significantly lower CD rate should results in significantly higher VD rate). Can you please clarify?

200 and 327: Clarify comparison group throughout manuscript. Outpatient balloon ripening compared with inpatient balloon only, or in one study there was concurrent oxytocin administration. It is unknown if outpatient balloon ripening shortens time to delivery when compared to inpatient cervical balloon with concurrent misoprostol. Most hospitals now use misoprostol concurrently with cervical balloon and thus these results could not be extrapolated to know if outpatient balloon only ripening may reduce c-section rate or time from admission to delivery at these intuitions. This is a very significant limitations of this study and I think should be very clear to readers through out discussion.

248-251: Can you please provide rationale for including abstract-only and non-peer review data? Would primary outcomes be different if you excluded this data? (sensitivity analysis with and without this data would be nice)

Reviewer #2:

The authors present a systematic review and meta-analysis on outpatient cervical ripening with balloon catheter. The manuscript is well written and address a clinically relevant topic. They conclude that outpatient cervical ripening decreases
time in the labor and delivery unit without noted safety concerns.

Abstract:
Line 57-The tabulation, integration and results should note that only 571 were included in analysis of primary outcome.

Results:
Figure 1- the flow diagram should include data regarding studies excluded from primary outcome analysis as all 8 were not included in analyzing for time on labor and delivery.

Tables 1 and 2- The data in these tables should be cut down if at all possible?
Table 3, 4 and 5- These tables also provide interesting information, however they will need to be cut down to the most pertinent issues only (i.e. total time on LD and not include data on time from expulsion of catheter, time in hospital, bishop score data, oxytocin infusion rates etc). The tables can likely be condensed into one table.

Discussion:
Line 207- this paragraph reads more of a literature review and does not focus on the current study outcomes and can be condensed.
Line 219- again this is not included in the analysis and can be reduced to a more brief comment.
Line 261- The authors should note that a funnel lot assessing publication was not completed due to low number of studies in the methods section.

Overall the discussion should be cut down to focus more on the study findings.

STATISTICAL EDITOR COMMENTS:
The Statistical Editor makes the following points that need to be addressed:
General: Should include the funnel plots corresponding to fig 3A through 3G in supplemental material.
Since the studies had variable assessments of bias (fig 2), should include analysis of the primary outcome (Fig 3A), restricted to only those with low bias risk to corroborate that finding. Could be in supplemental material, if desired.
In Fig 3, should clearly demarcate the primary outcome (lines 129-130), ie, time on L&D unit as shown in Fig 3A, from all the other (secondary) ones.
Fig 3F and 3G: each of these outcomes (PPH and NICU admission) were infrequent, so the samples (actually the counts of adverse outcomes) are too few to generalize the NS findings, due to low stats power. This should be noted in limitations section. As an alternative, might simply report the overall rates of PPH and NICU admission in the two groups, along with their respective CIs.

EDITOR COMMENTS:
1. How is it possible to have no difference in the rate of vaginal birth between the groups yet the cesarean delivery rate differed and was lower in the outpatient group? Wouldn't one expect these two metrics to vary in tandem?
2. Please include the absolute rates of cesarean delivery and vaginal delivery in the Results and Abstract.
3. Please report the mean time on L&D and total time in the hospital for each group in the Results, not just the mean difference between groups.
4. There was a significantly shorter time between balloon expulsion and delivery for the in compared to outpatient groups. This should be reported in the Results section.
5. Please remove the reduction in cesarean delivery from the Precis and Abstract Conclusion. This should focus only on the primary outcome, time on labor and delivery.
6. Line 282 states 8.3 hours less spent in the hospital, Results and Tables report 8.1 and the confidence interval is
different. Please review.

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

A. OPT-IN: Yes, please publish my point-by-point response letter.
B. OPT-OUT: No, please do not publish my point-by-point response letter.

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

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

10. For studies that report on the topic of race or include it as a variable, authors must provide an explanation in the manuscript of who classified individuals' race, ethnicity, or both, the classifications used, and whether the options were defined by the investigator or the participant. In addition, the reasons that race/ethnicity were assessed in the study also should be described (eg, in the Methods section and/or in table footnotes). Race/ethnicity must have been collected in a formal or validated way. If it was not, it should be omitted. Authors must enumerate all missing data regarding race and ethnicity as in some cases, missing data may comprise a high enough proportion that it compromises statistical precision and bias of analyses by race.

Use "Black" and "White" (capitalized) when used to refer to racial categories. The nonspecific category of "Other" is a convenience grouping/label that should be avoided, unless it was a prespecified formal category in a database or research instrument. If you use "Other" in your study, please add detail to the manuscript to describe which patients were included in that category.

11. Authors of systematic reviews are encouraged to prospectively register their study in PROSPERO (https://www.crd.york.ac.uk/PROSPERO/), an international database of prospectively registered systematic reviews. If you already have a PROSPERO registration number, please note it in your submitted cover letter and include it at the end of the abstract.

12. 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.

13. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Review articles should not exceed 6,250 words. Stated word limits include the title page, précis, abstract, text, tables, boxes, and figure legends, but exclude references.

14. Specific rules govern the use of acknowledgments in the journal. Please note the following guidelines:
   * All financial support of the study must be acknowledged.
   * Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
   * All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form
verifies that permission has been obtained from all named persons.
* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).
* If your manuscript was uploaded to a preprint server prior to submitting your manuscript to Obstetrics & Gynecology, add the following statement to your title page: "Before submission to Obstetrics & Gynecology, this article was posted to a preprint server at: [URL]."

15. 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 Reviews is 300 words. Please provide a word count.

16. 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.

17. ACOG avoids using "provider." Please replace "provider" throughout your paper with either a specific term that defines the group to which are referring (for example, "physicians," "nurses," etc.), or use "health care professional" if a specific term is not applicable.

18. 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%).

19. 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.

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

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

If the reference you are citing has been updated and replaced by a newer version, please ensure that the new version supports whatever statement you are making in your manuscript and then update your reference list accordingly (exceptions could include manuscripts that address items of historical interest). If the reference you are citing has been withdrawn with no clear replacement, please contact the editorial office for assistance (obgyn@greenjournal.org). In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

21. Figures

Figures 1-2: Please upload as a figure file on Editorial Manager.

Figure 3: Please break into multiple figures, as this will not fit on a single printed page. Please upload as a figure file on Editorial Manager.

Figure 4: Please rename this as a box.

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

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

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

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

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

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

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Oct 22, 2021, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

Jason D. Wright, MD
Editor-in-Chief, Elect

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

In compliance with data protection regulations, you may request that we remove your personal registration details at any time. (Use the following URL: https://www.editorialmanager.com/ong/login.asp?a=r). Please contact the publication office if you have any questions.
October 19, 2021

Dear Obstetrics & Gynecology Editors,

Thank you for the opportunity to revise our manuscript entitled “Outpatient cervical ripening with balloon catheters: a systematic review and meta-analysis of randomized controlled trials” and resubmit for consideration for publication in Obstetrics & Gynecology.

We sincerely appreciate the referees and Editor’s comments. We have read the Instructions for Authors and have provided a point-by-point response to each comment, included in this letter, starting on the following page. We believe the edits made have strengthened our manuscript.

This meta-analysis was pre-planned and pre-registered (PROSPERO registration No.: CRD42019140503). This is original research, which has not been published elsewhere, nor is it under consideration for publication elsewhere. The findings were presented as a poster presentation at the Society for Maternal-Fetal Medicine’s 41st Annual Pregnancy Meeting, held virtually in January 2021. All authors have approved the publication and submission of this manuscript and report no conflict of interest. Please let us know if you have any additional questions or areas where we can provide further clarification. We again thank you for the opportunity to resubmit our manuscript.

Sincerely,

Rebecca Pierce-Williams for all authors
REVIEWER COMMENTS:

Reviewer #1:

Thank you for opportunity to review this systematic review and meta-analysis on a very important topic. Appreciate the authors efforts to publish this compilation of data in a timely fashion given several RCTS on this topic have been published in the last 12 months.

84: Consider re-phrasing "limiting it utility in the outpatient setting." There is little data on misoprostol use in the outpatient setting so utility is unclear and there are safety concerns based on increased incidence of tachysystole when used inpatient.

Response: This was rephrased, now on lines 88-89 to state: “Due to these safety concerns and insufficient data on use in the outpatient setting, it cannot currently be recommended for this purpose.”

182: I don't understand how it is possible to have no difference in vaginal birth rate, but significantly lower cesarean delivery rate (they should be directly correlated right? significantly lower CD rate should results in significantly higher VD rate). Can you please clarify?

Response: We recognize here that a single “event” (i.e., cesarean delivery or vaginal delivery), should have been chosen. According to the Cochrane Handbook for Systematic Reviews of Interventions (Version 6.2, 2021), they recommend choosing one event in dichotomous outcomes (rather than event and non-event) when evaluating risk ratio. Events can be switched for odds ratio or risk difference without issue, as the effect size would be the same but in the opposite direction; however, this shouldn’t be done with RR as it can change the effect estimate and statistical significance. This is because RR differs between situations that are high or low risk. It is recommend using the less common state (or adverse event) as the event of interest. They refer to Deek et al (2002), in stating that there is “empirical evidence that risk ratios of the adverse event are more consistent than risk ratios of the non-event”. In our case, the less common state (or adverse event) would be cesarean rather than vaginal delivery. Therefore, our analysis could only have included the event of cesarean delivery only, and the risk ratio could not have been calculated for both dichotomous outcomes.

We suggest removing the information on RR of vaginal delivery (the non-event) and so removed “There was no difference in the rate of vaginal births (including operative vaginal deliveries), RR 1.07 (95% CI 0.98, 1.18)” from the results section (paragraph starting on line 203). This was also removed from table 4 and figure 3.

200 and 327: Clarify comparison group throughout manuscript. Outpatient balloon ripening compared with inpatient balloon only, or in one study there was concurrent oxytocin administration. It is unknown if outpatient balloon ripening
shortens time to delivery when compared to inpatient cervical balloon with concurrent misoprostol. Most hospitals now use misoprostol concurrently with cervical balloon and thus these results could not be extrapolated to know if outpatient balloon only ripening may reduce c-section rate or time from admission to delivery at these intuitions. This is a very significant limitations of this study and I think should be very clear to readers through out discussion.

Response:
In the discussion, formerly starting on line 200 (now 223), the first sentence was edited to state: “In this meta-analysis of mostly low-risk patients, outpatient cervical ripening with a balloon catheter is significantly associated with over 7-hours less time that patients spend on L&D (n=571), and with a 24% decreased risk of cesarean delivery (n=740), when compared to inpatient induction using a balloon catheter.”

Line 370 (final paragraph) now reads as: “In summary, compared to inpatient cervical ripening utilizing balloon catheters, outpatient balloon induction is associated with significantly shorter time on L&D by over 7 hours, and a significant 24% decreased risk of cesarean delivery.”

In the limitations section we edited lines 281-292 to read: “There was heterogeneity in the study designs, with some allowing simultaneous pharmacologic agents for the inpatient control group (i.e., balloon and oxytocin), others allowing subsequent cervical ripening agents (i.e., prostaglandins) in both groups (only once admitted), and others directly comparing only balloon use in each arm. The RCTs included in our meta-analysis included only balloon use outpatient, as the intervention group. Many institutions are now using concurrent balloon and misoprostol cervical ripening. None of the studies included in our analysis compared outpatient balloon to inpatient balloon with concurrent misoprostol. In a 2020 network meta-analysis by Orr et al, the time to vaginal delivery was not different when comparing Foley with prostaglandins to Foley with oxytocin (mean duration, 1.3 hours; 95% confidence interval, -2.0 to 4.7). Based on this, we could expect findings comparing outpatient balloon to inpatient balloon plus misoprostol to be similar to our findings, but more research, in the form of RCTs, is needed.

248-251: Can you please provide rationale for including abstract-only and non-peer review data? Would primary outcomes be different if you excluded this data? (sensitivity analysis with and without this data would be nice)

Response: Abstract-only and non-peer reviewed data were included to limit reporting bias from unpublished studies. The primary outcome, and relative risk of cesarean delivery (another significant outcome found in the meta-analysis), were still significantly different when excluding the unpublished studies.

On lines 189-193 of the results section the following was added: “When excluding the two unpublished studies13,16, the mean difference in time on L&D remained significantly different (-7.02 hours, 95% CI -11.19– -2.85, n=544). The primary outcome of time on
L&D also remained significantly different when only analyzing those studies of low risk of bias (MD -7.06 hours, 95% CI -12.30 – -1.30, n=496).9,11,12,14

On lines 199-202 of the results section the following was added: “The RR of cesarean delivery remained significantly lower in the outpatient group when excluding unpublished studies13,16 (RR 0.76, 95% CI 0.58 – 0.99, n=651) and when including only studies of low risk of bias (RR 0.71, 95% CI 0.53 – 0.95, n=496).9,11,12,14

In the discussion section, on lines 278-281, we added: “These studies were included to decrease non-reporting bias. With exclusion of these studies the primary outcome of difference in time on L&D remained significantly different, and the RR of cesarean delivery remained significantly lower.”

Reviewer #2:

The authors present a systematic review and meta-analysis on outpatient cervical ripening with balloon catheter. The manuscript is well written and address a clinically relevant topic. They conclude that outpatient cervical ripening decreases time in the labor and delivery unit without noted safety concerns.

Abstract:
Line 57-The tabulation, integration and results should note that only 571 were included in analysis of primary outcome.

Response: This detail was added in the abstract on line 57-58, “Eight trials, (740 patients) were included; 6 studies (571 patients) reported on our primary outcome.”

Results lines 160-162 now read: “Eight RCTs, including 740 patients, were eligible for inclusion9–16; 6 studies (571 patients) reported on our primary outcome.9–14”

Results:
Figure 1- the flow diagram should include data regarding studies excluded from primary outcome analysis as all 8 were not included in analyzing for time on labor and delivery.

Response: Figure 1 was edited to include a box showing the exclusion of 2 studies from meta-analysis of the primary outcome. The figure includes a footnote: “*n=2 studies excluded from meta-analysis of primary outcome due to non-reporting on this outcome.15,16 These studies were included in meta-analysis of secondary outcomes.”

Tables 1 and 2- The data in these tables should be cut down if at all possible?

Response: Wording in these tables were cut down. Please advise if more should be omitted.
Table 3, 4 and 5- These tables also provide interesting information, however they will need to be cut down to the most pertinent issues only (i.e. total time on LD and not include data on time from expulsion of catheter, time in hospital, bishop score data, oxytocin infusion rates etc). The tables can likely be condensed into one table.

Response: The tables were cut down significantly, with several rows deleted; however, they were left separate. If preferred, we can condense further. Outcomes removed were added to a supplementary table at the end of the manuscript.

Discussion:
Line 207- this paragraph reads more of a literature review and does not focus on the current study outcomes and can be condensed.

Response: This paragraph was condensed, now lines 231-246.

Line 219- again this is not included in the analysis and can be reduced to a more brief comment.

Response: This paragraph was condensed, now starting on line 247.

Line 261- The authors should note that a funnel plot assessing publication was not completed due to low number of studies in the methods section.

Response: Upon review, and suggestion from the statistical editor, we did include funnel plots in figures 3 and 4.

Overall the discussion should be cut down to focus more on the study findings.

Response: The discussion was condensed. Please let us know if this is adequate.

STATISTICAL EDITOR COMMENTS:

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

General: Should include the funnel plots corresponding to fig 3A through 3G in supplemental material.

Response: Funnel plots were included with the forest plots in Figures 3 and 4, as these were split into two separate figures due to the large size of the figure.

Since the studies had variable assessments of bias (fig 2), should include analysis of the primary outcome (Fig 3A), restricted to only those with low bias risk to corroborate that finding. Could be in supplemental material, if desired.
Response:
In the results section starting on lines 191-193, the following was added: “The primary outcome of time on L&D also remained significantly different when only analyzing those studies of low risk of bias (MD -7.06 hours, 95% CI -12.30 – -1.30, n=496).”

In the results on lines 199-202, the following was added: “The RR of cesarean delivery remained significantly lower in the outpatient group when excluding unpublished studies (RR 0.76, 95% CI 0.58 – 0.99, n=651) and when including only studies of low risk of bias (RR 0.71, 95% CI 0.53 – 0.95, n=496).”

The following was added to discussion lines 296-299: “When analyzing only those studies with low risk of bias, the primary outcome of time on L&D, as well as the RR of cesarean delivery, remained significantly different between groups.”

In Fig 3, should clearly demarcate the primary outcome (lines 129-130), ie, time on L&D unit as shown in Fig 3A, from all the other (secondary) ones.

Response: Figure 3A relabeled as: Primary Outcome: Time on Labor & Delivery, hours

Fig 3F and 3G: each of these outcomes (PPH and NICU admission) were infrequent, so the samples (actually the counts of adverse outcomes) are too few to generalize the NS findings, due to low stats power. This should be noted in limitations section. As an alternative, might simply report the overall rates of PPH and NICU admission in the two groups, along with their respective CIs.

Response:
The results section (lines 206-208) was edited to state: “Maternal adverse outcomes including intrapartum fever, chorioamnionitis (also called Triple I, for intrauterine infection, inflammation, or both), endometritis or PPH occurred infrequently in each group (Table 4).”

Lines 215-216 were also edited: “Adverse neonatal outcomes including 5-minute Apgar scores <7, NICU admission, umbilical cord arterial pH <7.1 and birth injuries were also infrequent in both groups.”

In the discussion (lines 233-235) we added: “…however, in our analysis rates of adverse maternal and neonatal outcomes occurred infrequently and therefore, there was inadequate power to find a significant difference between groups.”

EDITOR COMMENTS:

1. How is it possible to have no difference in the rate of vaginal birth between the groups yet the cesarean delivery rate differed and was lower in the outpatient group? Wouldn't one expect these two metrics to vary in tandem?
Response: We recognize here that a single “event” (i.e., cesarean delivery or vaginal delivery), should have been chosen. According to the Cochrane Handbook for Systematic Reviews of Interventions (Version 6.2, 2021), they recommend choosing one event in dichotomous outcomes (rather than event and non-event) when evaluating risk ratio. Events can be switched for odds ratio or risk difference without issue, as the effect size would be the same but in the opposite direction; however, this shouldn’t be done with RR as it can change the effect estimate and statistical significance. This is because RR differs between situations that are high or low risk. It is recommend using the less common state (or adverse event) as the event of interest. They refer to Deek et al (2002), in stating that there is “empirical evidence that risk ratios of the adverse event are more consistent than risk ratios of the non-event”. In our case, the less common state (or adverse event) would be cesarean rather than vaginal delivery. Therefore, our analysis could only have included the event of cesarean delivery only, and the risk ratio could not have been calculated for both dichotomous outcomes.

We suggest removing the information on RR of vaginal delivery (the non-event) and so removed “There was no difference in the rate of vaginal births (including operative vaginal deliveries), RR 1.07 (95% CI 0.98, 1.18)” from the results section. This was also removed from table 4 and figure 3.

2. Please include the absolute rates of cesarean delivery and vaginal delivery in the Results and Abstract.

Response: The rates of cesarean delivery (21% outpatient vs 27% inpatient) were added to the abstract and results.

Abstract line 62-64 reads: “The outpatient group was significantly less likely than the inpatient group to undergo a cesarean delivery (21% vs 27%), RR 0.76 (95% CI 0.59 – 0.98).”

Results lines 197-199 reads: “The outpatient group was significantly less likely than the inpatient group to undergo a cesarean delivery (21% vs 27%), with a RR of 0.76 (95% CI 0.59, 0.98).”

Rates of vaginal delivery (79% outpatient and 73%) can be added if preferred; however, due to the changes described above recommending reporting of only one of 2 dichotomous events, this has not yet been added.

3. Please report the mean time on L&D and total time in the hospital for each group in the Results, not just the mean difference between groups.

Response: In Methods, we added the following to lines 150-152: “Means and standard deviations were compared between groups using combined means and standard deviations.”
Abstract lines 58-61 now reads: “Compared to the inpatient group, outpatient balloon cervical ripening was associated with significantly less time on L&D (outpatient 16.3 ± 9.7 hours vs. inpatient 23.8 ± 14.0 hours; mean difference -7.24 hours, 95% CI -11.03 – -3.34).”

Results lines 184-187: Regarding the primary outcome, duration of time on L&D, there was a significant difference, with the outpatient group spending 16.3 ± 9.7 hours on L&D versus the inpatient group spending 23.8 ± 14.0 hours (mean difference -7.24 hours, 95% CI -11.03 – -3.34).”

4. **There was a significantly shorter time between balloon expulsion and delivery for the in compared to outpatient groups. This should be reported in the Results section.**

Response: The following was added to the results, lines 203-205: “There was shorter duration of time from balloon expulsion to delivery in the inpatient group, based on 3 studies including 283 patients (MD 5.19 hours, 95% CI 1.22– 9.17).12–14

In discussion the following was added (lines 226-228) “There was shorter duration of time from balloon expulsion to delivery in the inpatient group, which could potentially be attributed to more frequent adjustments and evaluation for balloon expulsion while inpatient (see Table 1).”

5. **Please remove the reduction in cesarean delivery from the Precis and Abstract Conclusion. This should focus only on the primary outcome, time on labor and delivery.**

Response: This was removed from both the Precis and abstract conclusion.

**Précis:** Outpatient balloon cervical ripening is associated with decreased time on labor and delivery compared to inpatient ripening.

**Abstract conclusion:** “Outpatient balloon cervical ripening in low-risk patients is associated with a decreased amount of time from admission to delivery. Outpatient balloon cervical ripening is a safe alternative for low-risk patients, with the potential for significant benefits to patients and labor and delivery units.”

6. **Line 282 states 8.3 hours less spent in the hospital, Results and Tables report 8.1 and the confidence interval is different. Please review.**

Response: The RevMan file data and analysis was reviewed for accuracy and the result is mean difference mean difference -8.12 hours (95% CI -16.60–0.36). We apologize for any confusion.

Results line 194-195: “The total duration of hospital admission did not differ significantly between groups (MD -8.12 hours (95% CI -16.60–0.36)).”
Discussion lines 324-326: “While our meta-analysis showed that the outpatient group spent 8.12 hours less time in the hospital for the entire admission, this analysis did not reach statistical significance (95% CI -16.60–0.36).”

Table 4 reports a mean difference of -8.12, 95% CI -16.60–0.36.

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

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* Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
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12. 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://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2Fpractice-management%2Fhealth-it-and-clinical-informatics%2FreVitalize-obstetrics-data-definitions&amp;data=04%7C01%7Cvincenzo.berghella%40jefferson.edu%7C7C49c7f2fc5d44c53770208d984db2270%7C55a89906c7104366b444c590cb67c4a%7C0%7C0%7C637686899012103877%7CUnknown%7C7CTWFpbGZsb3d8eyJWJioiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6Ik1haWwiLCJXVC16Mn0%3D%7C1000&amp;reserved=0 and the gynecology data definitions at https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2Fpractice-management%2Fhealth-it-and-clinical-informatics%2FreVitalize-gynecology-data-definitions&amp;data=04%7C01%7Cvincenzo.berghella%40jefferson.edu%7C7C49c7f2fc5d44c53770208d984db2270%7C55a89906c7104366b444c590cb67c4a%7C0%7C0%7C637686899012103865%7CUnknown%7C7CTWFpbGZsb3d8eyJWJioiMC4wLjAwMDAiLCIjoiV2luMzliLCJBTiI6Ik1haWwiLCJXVC16Mn0%3D%7C1000&amp;reserved=0. If use of the
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21. Figures

Figures 1-2: Please upload as a figure file on Editorial Manager.

Response: Completed.

Figure 3: Please break into multiple figures, as this will not fit on a single printed page. Please upload as a figure file on Editorial Manager.

Response: Some outcomes, including vaginal delivery, and outcomes removed from tables, were removed from the figure and the figure was split into figures 3 and 4.

Figure 4: Please rename this as a box.

Response: Completed, renamed as Box 1.

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