

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

Date: Jul 01, 2022
To: "Michelle Volovsky" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-1037

RE: Manuscript Number ONG-22-1037

A Bedside Test to Diagnose Miscarriage and Rule Out Ectopic Pregnancy

Dear Dr. Volovsky:

Thank you for sending us your work for consideration for publication in Obstetrics & Gynecology. Your manuscript has been reviewed by the Editorial Board and by special expert referees. The Editors would like to invite you to submit a revised version for further consideration.

If you wish to revise your manuscript, please read the following comments submitted by the reviewers and Editors. Each point raised requires a response, by either revising your manuscript or making a clear argument as to why no revision is needed in the cover letter.

To facilitate our review, we prefer that the cover letter you submit with your revised manuscript include each reviewer and Editor comment below, followed by your response. That is, a point-by-point response is required to each of the EDITOR COMMENTS (if applicable), REVIEWER COMMENTS, STATISTICAL EDITOR COMMENTS (if applicable), and EDITORIAL OFFICE COMMENTS below. Your manuscript will be returned to you if a point-by-point response to each of these sections is not included.

The revised manuscript should indicate the position of all changes made. Please use the "track changes" feature in your document (do not use strikethrough or underline formatting).

Your submission will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jul 22, 2022, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

General comments: This study aims to evaluate the use of a bedside test strip (ROM plus) to confirm the etiology of first trimester bleeding. The prospective cohort study utilized data from 3 groups of patients: positive and negative controls and patients presenting with first trimester bleeding. The study found that the ROM plus accurately diagnosed vaginal or uterine blood with embryonic or fetal blood.

1. Interest and Relevance: The topic is very interesting and relevant to the readers of the journal. First trimester bleeding evaluation is extremely common and poses a significant challenge to practitioners across the country.

2. Readability: The manuscript is very well written with good grammar and easy readability.

3. Materials and Methods: The authors clearly describes the rationale for the study design and describes the methods thoroughly

4. Discussion: The authors clearly lays out the clinical applicability of the test and the few limitations.

5. The authors clearly describes the ways this novel test could provide significant benefit to the medical community and patients through decreased healthcare burden, cost, and stress.

6. I appreciated the reflection on how the Covid-19 pandemic has affected the evaluation and management of first trimester bleeding and pregnancies of unknown location. Another benefit of this test to aid in earlier diagnosis of miscarriage to consider is the possible improvement in care for patients living in states with increasing abortion care restrictions. In states with harsh legislative restrictions, physicians often need to take extra or unnecessary steps to

definitively diagnose an early pregnancy loss. This bedside test could be used to expedite diagnosis and decrease barriers to treatment.

Reviewer #2: This is an evaluation of ROM Plus, the PROM detection kit, for ruling out ectopic pregnancies upon presentation with vaginal bleeding.

1. Title: I wouldn't say a bedside test to diagnose miscarriage because the test was negative for complete abortions.
2. Use of "ROM Plus": This will have to be changed to a generic name most likely, consult with the journal, perhaps, "Point of care test for the detection of Alpha-fetoprotein (AFP) and Insulin-like growth factor-binding protein 1 (IGFBP-1)".
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4. Methods: Was a sample size calculation performed?
5. Methods: Positive samples were refrigerated....how so? The cotton swab? A blood clot? You mention women bringing in dried bloody pads from home to be tested as a potential application, so is this how these samples were stored? We need to know the storage conditions.
6. Discussion: I would reposition this test as: If it is positive, then one can potentially rule out ectopic pregnancy (I believe a larger study is warranted) but if it is negative, it is not helpful in somebody with PUL. After all, you don't know still if they have had a miscarriage (complete) vs. ectopic with a negative test and still would need to do more workup. I would organize the discussion more about what to do in different scenarios.
7. Discussion: Regarding patients using this test at home...how would that work, it is not available over the counter. Please address this issue.
8. Discussion: What about cornual ectopics? Would they perform any different?

STATISTICAL EDITOR COMMENTS:

Table 1: The proportion of EFT (+) in this series is ~ 48%, which is not representative of the population. Although sens and spec are valid metrics for this series, PPV and NPV are not, especially since the (+) and (-) controls were not unknown. Should instead report LR(+) and LR(-), rather than PPV and NPV.

Also, the title, abstract and Table 1 are actually showing discrimination between EFT and no EFT, not specifically for EP. There were 12 cases of EP, of which all 12 were correctly ascertained by the test. That is, the rate was 100%, but its 95% CI were 70% to 100%. A larger sample is required to demonstrate the test's utility for exclusion of EP. For example, to allow for an error rate of < 10% would require ~ 35/35 correct, while ~ 75/75 would be required to show a < 5% error rate would occur for the prospective diagnosis of EP with this test.

EDITORIAL OFFICE COMMENTS:

1. If your article is accepted, the journal will publish a copy of this revision letter and your point-by-point responses as supplemental digital content to the published article online. You may opt out by writing separately to the Editorial Office at em@greenjournal.org, and only the revision letter will be posted.
2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:
 - * Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and at the end of the abstract. For industry-sponsored studies, describe on the title page how the funder was or was not involved in the study.
 - * Include clinical trial registration numbers, PROSPERO registration numbers, or URLs at the end of the abstract (if applicable).
 - * Name the IRB or Ethics Committee institution in the Methods section (if applicable).

- * Add any information about the specific location of the study (ie, city, state, or country), if necessary for context.

3. Obstetrics & Gynecology's Copyright Transfer Agreement (CTA) must be completed by all authors. When you uploaded your manuscript, each coauthor received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please ask your coauthor(s) to complete this form, and confirm the disclosures listed in their CTA are included on the manuscript's title page. If they did not receive the email, they should check their spam/junk folder. Requests to resend the CTA may be sent to em@greenjournal.org.

4. ACOG uses person-first language. Please review your submission to make sure to center the person before anything else. Examples include: "People with disabilities" or "women with disabilities" instead of "disabled people" or "disabled women"; "patients with HIV" or "women with HIV" instead of "HIV-positive patients" or "HIV-positive women"; and "people who are blind" or "women who are blind" instead of "blind people" or "blind women."

5. The journal follows ACOG's Statement of Policy on Inclusive Language (<https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2022/inclusive-language>). When possible, please avoid using gendered descriptors in your manuscript. Instead of "women" and "females," consider using the following: "individuals;" "patients;" "participants;" "people" (not "persons"); "women and transgender men;" "women and gender-expansive patients;" or "women and all those seeking gynecologic care."

6. Your submission indicates that one or more of the authors is employed by a pharmaceutical company, device company, or other commercial entity. This must be included as a statement in the Financial Disclosure section on the title page.

7. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric 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.

8. Make sure your manuscript meets the following word limit. The word limit includes the manuscript body text only (for example, the Introduction through the Discussion in Original Research manuscripts), and excludes the title page, précis, abstract, tables, boxes, and figure legends, reference list, and supplemental digital content. Figures are not included in the word count.

Procedures and Instruments: 2,000 words

9. For your title, please note the following style points and make edits as needed:

- * Do not structure the title as a declarative statement or a question.
- * Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles.
- * Abbreviations, jargon, trade names, formulas, and obsolete terminology should not be used.
- * Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," "A Systematic Review," or "A Cost-Effectiveness Analysis" as appropriate, in the subtitle. If your manuscript is not one of these four types, do not specify the type of manuscript in the title.

10. Specific rules govern the use of acknowledgments in the journal. Please review the following guidelines and edit your title page as needed:

- * 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 or indicate whether the meeting was held virtually).
- * 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]."
- * Do not use only authors' initials in the acknowledgement or Financial Disclosure; spell out their names the way they appear in the byline.

11. Provide a précis for use in the Table of Contents. The précis is a single sentence of no more than 25 words that states the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use

commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."

12. Be sure that each statement and any data in the abstract are also stated in the body of your manuscript, tables, or figures. Statements and data that appear in the abstract must also appear in the body text for consistency. Make 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 manuscript.

In addition, the abstract length should follow journal guidelines. Please provide a word count.

Procedures and Instruments: 200 words

13. 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.

14. The journal does not use the virgule symbol (/) in sentences with words, except with ratios. 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.

15. 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.

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

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

Express all percentages to one decimal place (for example, 11.1%). Do not use whole numbers for percentages.

17. Line 208: Your manuscript contains a priority claim, which means you state your study is the first of its kind or the largest study to date. We discourage such claims, since they are often difficult to prove. If this is based on a systematic search of the literature, that search should be described in the text (search engine name, 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, please delete or rephrase this statement.

18. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available at http://edmgr.ovid.com/ong/accounts/table_checklist.pdf.

19. Please review examples of our current reference style at https://edmgr.ovid.com/ong/accounts/ifa_suppl_refstyle.pdf. 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 formal reference list. Please cite them on the line in parentheses.

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. In most cases, if an ACOG document has been withdrawn, it should not be referenced in your manuscript.

Please make sure your references are numbered in order of appearance in the text.

20. Figure 1 may be resubmitted as-is with the revision

21. 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 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 a point-by-point response to each of the received comments in this letter. Do not omit your responses to the EDITOR COMMENTS (if applicable), the REVIEWER COMMENTS, the STATISTICAL EDITOR COMMENTS (if applicable), or the EDITORIAL OFFICE COMMENTS.

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

Again, your manuscript will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Jul 22, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

John O. Schorge, MD
Deputy Editor, Gynecology

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.

Dear Dr. Schorge,

Thank you very much for the evaluation of our submission previously titled “A Bedside Test to Diagnose Miscarriage and Rule Out Ectopic Pregnancy”. We were very happy with the positive responses and appreciate all the reviewer suggestions and comments. We thank you for giving us an allowance on the word count, it was greatly appreciated and we believe this improves the quality of the work.

All comments made by the reviewers were addressed. Please see below our response to each query as well as the resubmitted manuscript with the tracked changes.

Thank you for your time and consideration. We look forward to hearing from you.

Kind regards,
Michelle Volovsky

Reviewer 1:

General comments: This study aims to evaluate the use of a bedside test strip (ROM plus) to confirm the etiology of first trimester bleeding. The prospective cohort study utilized data from 3 groups of patients: positive and negative controls and patients presenting with first trimester bleeding. The study found that the ROM plus accurately diagnosed vaginal or uterine blood with embryonic or fetal blood.

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4. Discussion: The authors clearly lays out the clinical applicability of the test and the few limitations.
5. The authors clearly describes the ways this novel test could provide significant benefit to the medical community and patients through decreased healthcare burden, cost, and stress.
6. I appreciated the reflection on how the Covid-19 pandemic has affected the evaluation and management of first trimester bleeding and pregnancies of unknown location. Another benefit of this test to aid in earlier diagnosis of miscarriage to consider is the possible improvement in care for patients living in states with increasing abortion care restrictions. In states with harsh legislative restrictions, physicians often need to take extra or unnecessary steps to definitively diagnose an

early pregnancy loss. This bedside test could be used to expedite diagnosis and decrease barriers to treatment.

Reply: Thank you very much for your thoughtful review of our paper. The suggestion in comment 6 is very valuable and has been incorporated into the discussion.

Reviewer 2:

This is an evaluation of ROM Plus, the PROM detection kit, for ruling out ectopic pregnancies upon presentation with vaginal bleeding.

1. Title: I wouldn't say a bedside test to diagnose miscarriage because the test was negative for complete abortions.
2. Use of "ROM Plus": This will have to be changed to a generic name most likely, consult with the journal, perhaps, "Point of care test for the detection of Alpha-fetoprotein (AFP) and Insulin-like growth factor-binding protein 1 (IGFBP-1)".
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6. Discussion: I would reposition this test as: If it is positive, then one can potentially rule out ectopic pregnancy (I believe a larger study is warranted) but if it is negative, it is not helpful in somebody with PUL. After all, you don't know still if they have had a miscarriage (complete) vs. ectopic with a negative test and still would need to do more workup. I would organize the discussion more about what to do in different scenarios.
7. Discussion: Regarding patients using this test at home...how would that work, it is not available over the counter. Please address this issue.
8. Discussion: What about cornual ectopics? Would they perform any different?

Reply: Thank you for your thoughtful and helpful suggestions, they are appreciated and each point has been addressed. Please see below:

1. The title has been changed to be more specific to our findings.
2. The name ROM plus was replaced in many areas, such as the abstract and conclusion. The rationale for the choice of this product was explained in the introduction, as it is currently the only FDA approved product of this nature. And so, after this explanation appears, we maintained the use of ROM plus in the text. If the journal prefers us to change the name throughout the whole manuscript, please advise and we can certainly do so.

3. Missed abortions were included in the D&C group (n=9) along with D&C for TOP. This has been clarified in the text. AFP is very high in the yolk sac as early as 4-5 weeks gestation and, therefore, it will be detected in the vaginal blood of both scenarios (D&C for missed miscarriage or for termination of pregnancy as long as EFT is present). This has been shown in the references below:
 - a. Mor A, Tal R, Haberman S, Kalgi B, Nasab SH, Minkoff H. Same-day confirmation of intrauterine pregnancy failure in women with first-and early second-trimester bleeding. *Fertil Steril*. 2018;109:1060.
 - b. Mor A, Gardezi M, Jubanyik K, Simsek B, Seifer DB, Patrizio P et al. Miscarriage determination in first trimester based on alpha-fetoprotein extracted from sanitary pads. *Fertil Steril* 2021;116:462-9.
4. A sample size calculation has been performed and added to the methods section. Our study samples exceeded the minimum number needed in each group. An online sample size calculator was used: <https://www.statskingdom.com/proportion-sample-size-calculator.html>.
5. Sample storage has been clarified in the text as either the patient's pad, gauze sample, or cotton swab were placed into a specimen container and stored.
6. We thank the reviewer for this important point. The discussion has been amended to reflect this suggestion.
7. A caveat that this would only be possible if the test were to become available over the counter has been added.
8. There were no cornual ectopic pregnancies in our study and this is therefore a potential limitation, which has been added to the discussion.

STATISTICAL EDITOR COMMENTS:

Table 1: The proportion of EFT (+) in this series is ~ 48%, which is not representative of the population. Although sens and spec are valid metrics for this series, PPV and NPV are not, especially since the (+) and (-) controls were not unknown. Should instead report LR(+) and LR(-), rather than PPV and NPV.

Also, the title, abstract and Table 1 are actually showing discrimination between EFT and no EFT, not specifically for EP. There were 12 cases of EP, of which all 12 were correctly ascertained by the test. That is, the rate was 100%, but its 95% CI were 70% to 100%. A larger sample is required to demonstrate the test's utility for exclusion of EP. For example, to allow for an error rate of < 10% would require ~ 35/35 correct, while ~ 75/75 would be required to show a < 5% error rate would occur for the prospective diagnosis of EP with this test.

Reply: Thank you very much for these comments. We have replaced the predictive values with the likelihood ratios. We also replaced the prior table with 2 separate tables: Table 1 now presents the raw numbers. Table 2 presents the test's performance. Lastly, we changed the title of our manuscript (removing 'ectopic pregnancy') to better reflect the clinical meaning of our results.

EDITORIAL OFFICE COMMENTS:

Reply: Thank you very much for your comments and suggestions, please see our responses below each point where changes were applicable.

1. If your article is accepted, the journal will publish a copy of this revision letter and your point-by-point responses as supplemental digital content to the published article online. You may opt out by writing separately to the Editorial Office at em@greenjournal.org, and only the revision letter will be posted.

2. When you submit your revised manuscript, please make the following edits to ensure your submission contains the required information that was previously omitted for the initial double-blind peer review:

- * Funding information (ie, grant numbers or industry support statements) should be disclosed on the title page and at the end of the abstract. For industry-sponsored studies, describe on the title page how the funder was or was not involved in the study.
- * 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.

This was completed. There was no funding and IRB numbers appear within the text.

3. Obstetrics & Gynecology's Copyright Transfer Agreement (CTA) must be completed by all authors. When you uploaded your manuscript, each coauthor received an email with the subject, "Please verify your authorship for a submission to Obstetrics & Gynecology." Please ask your coauthor(s) to complete this form, and confirm the disclosures listed in their CTA are included on the manuscript's title page. If they did not receive the email, they should check their spam/junk folder. Requests to resend the CTA may be sent to em@greenjournal.org.

4. ACOG uses person-first language. Please review your submission to make sure to center the person before anything else. Examples include: "People with disabilities" or "women with disabilities" instead of "disabled people" or "disabled women"; "patients with HIV" or "women with HIV" instead of "HIV-positive patients" or "HIV-positive women"; and "people who are blind" or "women who are blind" instead of "blind people" or "blind women."

This was addressed where relevant and possible.

5. The journal follows ACOG's Statement of Policy on Inclusive Language (<https://www.acog.org/clinical-information/policy-and-position-statements/statements-of-policy/2022/inclusive-language>). When possible, please avoid using gendered descriptors in your manuscript. Instead of "women" and "females," consider using the following: "individuals;" "patients;" "participants;"

"people" (not "persons"); "women and transgender men;" "women and gender-expansive patients;" or "women and all those seeking gynecologic care."

This was addressed where relevant and possible.

6. Your submission indicates that one or more of the authors is employed by a pharmaceutical company, device company, or other commercial entity. This must be included as a statement in the Financial Disclosure section on the title page.

No authors are employed by a pharmaceutical company. Two authors have a patent regarding the use of AFP in early pregnancy loss, which has been mentioned in the title page.

7. Standard obstetric and gynecology data definitions have been developed through the reVITALize initiative, which was convened by the American College of Obstetricians and Gynecologists and the members of the Women's Health Registry Alliance. Obstetrics & Gynecology has adopted the use of the reVITALize definitions. Please access the obstetric 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.

This was addressed where relevant and possible.

8. Make sure your manuscript meets the following word limit. The word limit includes the manuscript body text only (for example, the Introduction through the Discussion in Original Research manuscripts), and excludes the title page, précis, abstract, tables, boxes, and figure legends, reference list, and supplemental digital content. Figures are not included in the word count.

Procedures and Instruments: 2,000 words

This was discussed with the editor and we are very grateful for the additional word allowance.

9. For your title, please note the following style points and make edits as needed:

- * Do not structure the title as a declarative statement or a question.
- * Introductory phrases such as "A study of..." or "Comprehensive investigations into..." or "A discussion of..." should be avoided in titles.
- * Abbreviations, jargon, trade names, formulas, and obsolete terminology should not be used.
- * Titles should include "A Randomized Controlled Trial," "A Meta-Analysis," "A Systematic Review," or "A Cost-Effectiveness Analysis" as appropriate, in the subtitle. If your manuscript is not one of these four types, do not specify the type of manuscript in the title.

The title has been changed.

10. Specific rules govern the use of acknowledgments in the journal. Please review the following guidelines and edit your title page as needed:

- * 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 or indicate whether the meeting was held virtually).
- * 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]."
- * Do not use only authors' initials in the acknowledgement or Financial Disclosure; spell out their names the way they appear in the byline.

This has been addressed in the title page.

11. Provide a précis for use in the Table of Contents. The précis is a single sentence of no more than 25 words that states the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."

This has been added beneath the abstract.

12. Be sure that each statement and any data in the abstract are also stated in the body of your manuscript, tables, or figures. Statements and data that appear in the abstract must also appear in the body text for consistency. Make 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 manuscript.

In addition, the abstract length should follow journal guidelines. Please provide a word count.

Procedures and Instruments: 200 words

The abstract and paper are consistent in information.

13. 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.

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14. The journal does not use the virgule symbol (/) in sentences with words, except with ratios. 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.

This was changed throughout the manuscript.

15. 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.

This was changed throughout the manuscript.

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

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

Express all percentages to one decimal place (for example, 11.1%). Do not use whole numbers for percentages.

Percentages were changed throughout the manuscript.

17. Line 208: Your manuscript contains a priority claim, which means you state your study is the first of its kind or the largest study to date. We discourage such claims, since they are often difficult to prove. If this is based on a systematic search of the literature, that search should be described in the text (search engine name, 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, please delete or rephrase this statement.

This was removed from the manuscript.

18. Please review the journal's Table Checklist to make sure that your tables conform

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This was reviewed.

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This was reviewed.

20. Figure 1 may be resubmitted as-is with the revision