OBSTETRICS & GYNECOLOGY

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- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)*

**The corresponding author has opted to make this information publicly available.*

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Date: Apr 19, 2022
To: "Olivia ANSELEM" [redacted]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-461

RE: Manuscript Number ONG-22-461

Cervical Dilators Concurrently with Misoprostol to Shorten Labor in Second-Trimester Terminations of Pregnancy: the DILATOP Randomized Controlled Trial

Dear Dr. ANSELEM:

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 May 10, 2022, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1:

This multi-center randomized-controlled trial compared labor duration in patients undergoing 2nd trimester induction termination using misoprostol and epidural analgesia concurrently with and without synthetic osmotic dilators. Primary outcome was proportion of women with a labor duration exceeding 12 hours with secondary outcomes including median duration of labor, proportion of women with labor exceeding 24 hours, time to amniotomy, length of delivery stay and hospitalization, rate of intra- and post-partum complications, and evaluation of pain and distress using validated scales. While no significant difference was seen in labor duration greater than 12 hours, this study found a significant difference in nulliparous patients for time to amniotomy with use of dilators. Time to amniotomy, however, did not decrease the proportion of patients with labor duration greater than 12 hours in this study.

I would recommend including why 3 hours was chosen for dilator placement and 12 hours for primary outcome, even if it was solely for ease of administration or cost of hospital stay. Line 269-270 indicates 3 hours was chosen for dilator placement because the duration is 2-3 hours before D&E. However, in the US, dilators are usually placed overnight prior to D&E, as indicated in the study cited in Lines 246-249, and very rarely only 2-3 hours usually for gestational ages between 15-18 weeks. Future studies may show benefit from leaving dilators in situ for a longer duration and including patients with cesarean section, as limiting prostaglandins for these patients with use of mechanical dilators may be beneficial. Also, please include that the fetal conditions necessitating termination did not contribute to increased fetal size which could extend labor duration, i.e. hydrocephalus.

I would ask clarification on the time course of pre-treatment mifepristone. Line 90 indicates it was given 2 days prior, but how many hours? Based on Society of Family Planning and American College of Obstetricians and Gynecologists guidelines, mifepristone should be given 24-48 hours prior to misoprostol.

Overall, this study was well designed and executed. It was also appropriately analyzed, especially given the changes necessary during the study period. I commend the authors for such an impressive study.

Reviewer #2:

This is an interesting study, and a very well-written manuscript. I do have a few questions and comments.
1. I'm very curious as to the reason why the ANSM decided to change the requirements for misoprostol route of administration and number of doses. My assessment of the available literature is not in line with this. I know you cannot speak to this - I am expressing curiosity.
2. Line 166: there should be a period after "administration".
3. Line 170: it is "level" not "livel".
4. Line 182: please explain why people without insurance were ineligible for the study - that was not listed as an exclusion criterion.
5. Line 191: I don't understand how the p=0.08 for the median Bishop score, when it was the same for both groups 1 (0-2).
6. Line 215: it should read "it healed" not "its healed".
7. Line 303: delete the word exceed.
8. In the conclusion you state correctly that the addition of dilators in the way used in this study was not additive. That said, there are a number of practices in this study that are not necessarily standardized across most second trimester medication abortion, including early AROM, epidural for everyone, etc. I am curious which of the many parts is now standard in your setting.

Reviewer #3:

The authors present a RCT of misoprostol +/- dilator use for TOP. This is an overall well done study with a cogent hypothesis which adds data to the literature in women undergoing TOP. While a negative study, the data is of clinical significance to CFP providers.

Specific comments:
1) LIne 47-49; if data has shown this technique to be efficacious, why did you repeat this study? what is different about this RCT compared to others ?
2) LIne 79-82; Were none of these simply elective TOP for maternal desire?
3) Line 87- why were women with IUFD excluded?
4) The methods section is a bit verbose- i would move much of this to supplemental materials
5) Line 155 I am unclear why you added 55 patients after you did your power calculation please explain
6) Line 198-200; the statistical data is not presented well ; please include ORs 95% CIs and P values
7) The discussion s well written and not over reaching

STATISTICAL EDITOR COMMENTS:

Abstract: Need to change the format to conform to our RCT abstract format.

lines 11-12, 136-138, 149-157: The primary outcome was proportion of women with duration of labor > 12 hrs, requiring samples in the case and controls of 134 each, based on the usual criteria for alpha and beta and a relative difference of 50% vs a control rate of 30%. That calculation does not include smaller subsets (ie, based on parity). That is a secondary outcome and is also underpowered.

Table 1: The groups were randomized and there is no need to statistically compare the two groups. The column of p-values should be omitted. Any difference is due to random chance.

Table 2: The primary outcome, as defined earlier, should be clearly separated from all secondary ones.

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: "Patients with obesity" instead of "obese patients," "Women with disabilities" instead of "disabled women," "women with HIV" instead of "HIV-positive women," "women who are blind" instead of "blind women."

5. Clinical trials must include a data sharing statement. Please add the following questions and your answers to the end of the manuscript after the References section:

Authors' Data Sharing Statement
Will individual participant data be available (including data dictionaries)? No.
What data in particular will be shared? Not available.
What other documents will be available? Not available.
When will data be available (start and end dates)? Not applicable.
By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? Not applicable.

6. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines:

CHEERS: economic evaluations of health interventions
CHERRIES: studies reporting results of Internet e-surveys
CONSERVE: reporting trial protocols and completed trials modified due to the COVID-19 pandemic and other extenuating circumstances
CONSORT: randomized controlled trials
MOOSE: meta-analyses and systematic reviews of observational studies
PRISMA: meta-analyses and systematic reviews of randomized controlled trials
PRISMA for harms: PRISMA for harms
RECORD: observational studies using ICD-10 data
STARD: studies of diagnostic accuracy
STROBE: observational studies
SQUIRE 2.0: quality improvement in health care studies

Include the appropriate checklist for your manuscript type upon submission, if applicable, and indicate in your cover letter which guideline you have followed. Please write or insert the page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at www.equator-network.org/.

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.

Original Research: 3,000 words

9. 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.

10. 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.

Original Research: 300 words

11. Abstracts for clinical 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 at http://edmgr.ovid.com/ong/accounts/sampleabstract_RCT.pdf and edit your abstract as needed.

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

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

14. 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.

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

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

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

16. Line 235: 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.

17. 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.

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

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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 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 May 10, 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

Paris, April 27th, 2022

Editor, Obstetrics and Gynecology

Dear Dr. Schorge,

Thank you for considering the publication of our manuscript “Cervical Dilators Concurrently with Misoprostol to Shorten Labor in Second-Trimester Terminations of Pregnancy: the DILATOP Randomized Controlled Trial” (ONG-22-461) in Obstetrics & Gynecology.
Please find below a point-by-point response to the comments of the reviewers and editors, as required. We also join a revised version of our manuscript with changetrack changes tracked.

Please do not hesitate to contact me for any clarifications. It is possible that I will not be available in the future weeks, you can contact my colleague Dr. Tsatsaris [redacted]

Sincerely,

Olivia Anselem

REVIEWER COMMENTS:

Reviewer #1:

This multi-center randomized-controlled trial compared labor duration in patients undergoing 2nd trimester induction termination using misoprostol and epidural analgesia concurrently with and without synthetic osmotic dilators. Primary outcome was proportion of women with a labor duration exceeding 12 hours with secondary outcomes including median duration of labor, proportion of women with labor exceeding 24 hours, time to amniotomy, length of delivery stay and hospitalization, rate of intra- and post-partum complications, and evaluation of pain and distress using validated scales. While no significant difference was seen in labor duration greater than 12 hours, this study found a significant difference in nulliparous patients for time to amniotomy with use of dilators. Time to amniotomy, however, did not decrease the proportion of patients with labor duration greater than 12 hours in this study.

I would recommend including why 3 hours was chosen for dilator placement and 12 hours for primary outcome, even if it was solely for ease of administration or cost of hospital stay.
We have added the following sentence in the methods section to explain this choice in duration of dilator placement, line 115: “We chose 3 hours for the duration of dilators

placement because it has been demonstrated that dilators reach a diameter of 10 mm after 2 to 3 hours (15) and because we soughed to evaluate the shortest procedure reported".
We chose 12 hours to evaluate our primary outcome based on our preliminary study and because it seems to be an acceptable duration for women. We added this sentence in the methods section, line 153: "This cutoff was chosen because in our preliminary study labor lasted less than 12 hours for 70 % of the women (18) and because we hypothesized that women would find this duration acceptable."
Line 269-270 indicates 3 hours was chosen for dilator placement because the duration is 2-3 hours before D&E. However, in the US, dilators are usually placed overnight prior to D&E, as indicated in the study cited in Lines 246-249, and very rarely only 2-3 hours usually for gestational ages between 15-18 weeks.
We agree with this remark. We have deleted this sentence, which was incorrect.
Future studies may show benefit from leaving dilators in situ for a longer duration and including patients with cesarean section, as limiting prostaglandins for these patients with use of mechanical dilators may be beneficial. Also, please include that the fetal conditions necessitating termination did not contribute to increased fetal size which could extend labor duration, i.e. hydrocephalus.
We have added this information in the methods section, line 102: "Fetal condition that might prolong labor, such as hydrocephalus, were not included."

I would ask clarification on the time course of pre-treatment mifepristone. Line 90 indicates it was given 2 days prior, but how many hours? Based on Society of Family Planning and American College of Obstetricians and Gynecologists guidelines, mifepristone should be given 24-48 hours prior to misoprostol.
Mifepristone was given 48 hours before the induction of labor began. I have modified the sentence accordingly, line 103: "All women received 200 mg oral mifepristone 48 hours before induction began."

Overall, this study was well designed and executed. It was also appropriately analyzed, especially given the changes necessary during the study period. I commend the authors for such an impressive study.
Thank you very much.

Reviewer #2:

This is an interesting study, and a very well-written manuscript. I do have a few questions and comments.
1. I'm very curious as to the reason why the ANSM decided to change the requirements for misoprostol route of administration and number of doses. My assessment of the available literature is not in line with this. I know you cannot speak to this - I am expressing curiosity.
I assume they published this recommendation because misoprostol had until then been prescribed only off-label. The aim of this new temporary use recommendation was to provide a regulatory framework authorizing this use, which was nonetheless already widespread in France, with quite heterogeneous routes of administration and formulations. This new recommendation specified both the formulation and the route of administration.
2. Line 166: there should be a period after "administration".

We have corrected this mistake and we thank you.
3. Line 170: it is "level" not "livel".
We thank you for this correction, which we have made.
4. Line 182: please explain why people without insurance were ineligible for the study - that was not listed as an exclusion criterion.
French regulations concerning clinical research ban the inclusion of patients without health insurance. It is mentioned in the Methods section, line 83. We have added "without health insurance" to the following sentence on lines 97-101: " Women with a uterine surgical scar, known uterine malformation, multiple pregnancy, placenta previa, premature rupture of membranes, chorioamnionitis, psychiatric condition, Bishop score of 7 or more, *in utero* fetal death before induction, allergy to mifepristone or misoprostol, contraindication to epidural analgesia, mifepristone, or misoprostol, or without health insurance were excluded."
5. Line 191: I don't understand how the p=0.08 for the median Bishop score, when it was the same for both groups 1 (0-2).
This result has been already checked by our statistician because we had the same question: the p-value is obtained by a Mann-Whitney test with the null hypothesis that the distribution of the variable is the same in both groups. For this reason, even though the quartiles are the same, the p-value is small.
6. Line 215: it should read "it healed" not "its healed".
Thank you, we have corrected this mistake.
7. Line 303: delete the word exceed.
We have deleted it.
8. In the conclusion you state correctly that the addition of dilators in the way used in this study was not additive. That said, there are a number of practices in this study that are not necessarily standardized across most second trimester medication abortion, including early AROM, epidural for everyone, etc. I am curious which of the many parts is now standard in your setting.
Thank you for this comment. We agree that practices are quite heterogenous in second trimester medical abortion. In our center, we recommend early AROM and epidural analgesia. Most of the centers changed their practices after the study and implemented epidural anesthesia for all women. This can be considered a great improvement in minimizing women's discomfort.

Reviewer #3:

The authors present a RCT of misoprostol +/- dilator use for TOP. This is an overall well done study with a cogent hypothesis which adds data to the literature in women undergoing TOP. While a negative study, the data is of clinical significance to CFP providers.

Specific comments:
1) Line 47-49; if data has shown this technique to be efficacious, why did you repeat this study? what is different about this RCT compared to others ?
We understand this remark. We explained the aim of our study on lines 53-68. Those studies calculated labor duration without treating dilator insertion as the beginning of induction — a methodologically questionable choice. Moreover, most of the previous studies involved dilator insertion the evening before prostaglandin placement, which has several

disadvantages: it extends the length of stay, and painful insertion can increase women's discomfort overnight. The aim of our study was to evaluate a different strategy, one that does not increase women's pain, by inserting the dilators under epidural analgesia and using them for the shortest period reported possible.

2) Line 79-82; Were none of these simply elective TOP for maternal desire?

French law authorizes second- (and third-) trimester abortions only in case of either a high probability of an incurable and severe fetal disease, or a maternal condition causing continued pregnancy to threaten maternal health. It is not allowed for maternal desire only after 14 weeks.

3) Line 87- why were women with IUFD excluded?

We chose to exclude IUFD because we assumed that labor could be shorter in this situation, depending on the time between IUFD and its diagnostic which is difficult to precise.

4) The methods section is a bit verbose- i would move much of this to supplemental materials

I moved much of the Methods section in supplementary material as requested.

5) Line 155 I am unclear why you added 55 patients after you did your power calculation please explain

We added 55 women after the ANSM alert modifying misoprostol administration from vaginal to oral and from 8 tablets to 6 tablets maximum, to have a homogeneous protocol comprising at least 280 women, with no loss of power, as this was the number of patients we initially estimated would demonstrate a difference between groups.

6) Line 198-200; the statistical data is not presented well ; please include ORs 95% CIs and P values

This sentence does not include ORs, because we compared medians, this sentence is the following one to be sure I did not misunderstood:

"The overall median duration of labor was 8.5 hours (IQR 6.1-13.6) in the dilator group vs 9.2 hours (IQR 6.1-13.7) in the control group (*P*=.65), and 10.5 hours (IQR 7.3-15.6) and 11.8 hours (IQR 8.5-16.5) respectively, among nulliparous women (*P*=.33)."

7) The discussion s well written and not over reaching

Thank you.

STATISTICAL EDITOR COMMENTS:

Abstract: Need to change the format to conform to our RCT abstract format.

We have corrected the format of the abstract.

lines 11-12, 136-138, 149-157: The primary outcome was proportion of women with duration of labor > 12 hrs, requiring samples in the case and controls of 134 each, based on the usual criteria for alpha and beta and a relative difference of 50% vs a control rate of 30%. That calculation does not include smaller subsets (ie, based on parity). That is a secondary outcome and is also underpowered.

We agree with this comment: the sample was calculated to demonstrate a difference for our primary outcome and not for secondary outcomes, such as comparison in nulliparas.
We have added in the discussion section, line 420: “Moreover, our study was underpowered to assess differences in secondary outcomes and in the subgroup of nulliparas.”

Table 1: The groups were randomized and there is no need to statistically compare the two groups. The column of p-values should be omitted. Any difference is due to random chance.
We have deleted the column of p-values in Table 1 and in the manuscript in the Results section.

Table 2: The primary outcome, as defined earlier, should be clearly separated from all secondary ones.
We have separated the primary outcome from the secondary ones in Table 2.

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.
I agree.

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.
All of this information is included.

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.
I agree.

4. ACOG uses person-first language. Please review your submission to make sure to center the person before anything else. Examples include: "Patients with obesity" instead of "obese patients," "Women with disabilities" instead of "disabled women," "women with HIV" instead of "HIV-positive women," "women who are blind" instead of "blind women."
The manuscript follows ACOG guidelines.

5. Clinical trials must include a data sharing statement. Please add the following questions and your answers to the end of the manuscript after the References section:

Authors' Data Sharing Statement
Will individual participant data be available (including data dictionaries)? No.
What data in particular will be shared? Not available.
What other documents will be available? Not available.
When will data be available (start and end dates)? Not applicable.
By what access criteria will data be shared (including with whom, for what types of analyses, and by what mechanism)? Not applicable.

Data sharing statement is included.

6. Responsible reporting of research studies, which includes a complete, transparent, accurate and timely account of what was done and what was found during a research study, is an integral part of good research and publication practice and not an optional extra. Obstetrics & Gynecology supports initiatives aimed at improving the reporting of health research, and we ask authors to follow specific guidelines:

CHEERS: economic evaluations of health interventions
CHERRIES: studies reporting results of Internet e-surveys
CONSERVE: reporting trial protocols and completed trials modified due to the COVID-19 pandemic and other extenuating circumstances
CONSORT: randomized controlled trials
MOOSE: meta-analyses and systematic reviews of observational studies
PRISMA: meta-analyses and systematic reviews of randomized controlled trials
PRISMA for harms: PRISMA for harms
RECORD: observational studies using ICD-10 data
STARD: studies of diagnostic accuracy
STROBE: observational studies
SQUIRE 2.0: quality improvement in health care studies

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page numbers where each item appears in the margin of the checklist. Further information and links to the checklists are available at https://nam12.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.equator-network.org%2F&data=05%7C01%7C%7C3830ecb3410a4b6019d108da28373ed6%7C84df9e7fe9f640afb435aaaaaaaaaaaa%7C1%7C0%7C637866514991488400%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=tVTcrPfou9wZE9rHgKoPJAnE2VuFcmpfB5QpBvkc7d0%3D&reserved=0.

The CONSORT checklist is included.

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://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2Fpractice-management%2Fhealth-it-and-clinical-informatics%2Frevitalize-obstetrics-data-definitions&data=05%7C01%7C%7C3830ecb3410a4b6019d108da28373ed6%7C84df9e7fe9f640afb435aaaaaaaaaaaa%7C1%7C0%7C637866514991488400%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=UfGlUukurPtwFTSXRg7evbaiFc45IKn%2FpHUUdChuVNM%3D&reserved=0 and the gynecology data definitions at https://nam12.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2Fpractice-management%2Fhealth-it-and-clinical-informatics%2Frevitalize-gynecology-data-definitions&data=05%7C01%7C%7C3830ecb3410a4b6019d108da28373ed6%7C84df9e7fe9f640afb435aaaaaaaaaaaa%7C1%7C0%7C637866514991488400%7CUnknown%7CTWFpbGZsb3d8eyJWIjoiMC4wLjAwMDAiLCJQIjoiV2luMzIiLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=wCwxtLan0EjfiXaZYC9IMT484ZyG7KPhWalcfPpWTk8%3D&reserved=0. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

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Original Research: 3,000 words

The number of word has been reduced.

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Original Research: 300 words

The abstract length is 289 words.

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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 May 10, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

John O. Schorge, MD
Deputy Editor, Gynecology