

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)*

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Date: Jun 17, 2022
To: "Shelby Dickison" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-820

RE: Manuscript Number ONG-22-820

Reducing maternal morbidity through double balloon catheter management of cesarean scar and cervical pregnancies: a preliminary report.

Dear Dr. Dickison:

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 08, 2022, we will assume you wish to withdraw the manuscript from further consideration.

EDITOR COMMENTS:

We would be happy to consider a revision but ask, in addition to responding to the reviewers' comments, that you remove the comparison group and simply report on the outcomes for the balloon-treated patients with rates and 95% confidence intervals, since the two groups in your present manuscript were not randomly allocated to the treatment they received.

REVIEWER COMMENTS:

Reviewer #1:

In this case series, the authors compare outcomes before and after cervical double balloon catheter treatment for CSP/CXPs. They report higher rates of transfusion, hysterectomy, and ICU admission prior to CDBC. CDBC significantly decreased maternal morbidity as well.

Introduction

- Line 49: Is there a citation that the incidence is increasing

Methods:

- Line 62: What guidelines? This should be cited
- What was the standard treatment before CDBC was introduced - this should be defined clearly
- What CDBC performed exclusively as the SOC after 2018? This is unclear

Results:

- What was the time frame for this study in the pre CDBC era?
- The authors report in Line 74 that patients opted for CDBC - this was a patient decision? Or was it a uniform protocol? There is the potential for selection bias in these patients as well
- I am also curious about the exemption from IRB. This is an area that does not have a well-defined SOC. As this is testing a treatment, although retrospective, I'm not sure this falls into a QI as the study is not to look at uptake of CDBC but actual outcomes for efficacy which is usually outside of a QI scope
- It is hard to interpret the results without a description of what is included in the non-balloon treatment.

Discussion:

- Line 93-94: Without an assessment of how CSP/CXP are treated pre-balloon it is hard to interpret these findings; although it is not described in the table, for instance, if hysterectomy was the standard care, it would make sense that the morbidity is higher. It is also possible that those 5 hysterectomies were also associated with transfusion in a case that was emergent. Understanding the types of treatment and what was offered in the early era is integral to interpreting these findings

Reviewer #2:

I want to thank the authors for their work in furthering our understanding of the treatment options of this dangerous condition without clear best practices in treatment.

I thought the abstract distilled the major findings of the paper appropriately.

The introduction was appropriately brief for a research letter. If space allowed, a description of the current leading treatment options and the data we have about those options in the literature. What is a 'normal' baseline rate of complications for this condition? For contemporary management is transfusion/hysterectomy expected 5% of the time 50%?? The hypothesis/central question of the work was not quite articulated in the introduction.

In the methods section, I would have appreciated a bit more about the protocol used for the double balloon catheter treatments, or if similar to previous work, a link to a previously published protocol. Was this inpatient or outpatient treatment? How long were patients followed? Were there any balloon related complications-- unable to place properly/balloon ruptures? As currently described, it makes it quite hard to know how to replicate this work. I was hoping for more details about the recruitment and enrollment in this study. The authors mention that subsequent to 2018 they treated CSPs with the balloon catheter. It's not quite clear if every patient after 2018 received a balloon catheter or if there were some patients who were counseled and opted for a different treatment. Also unclear is how far back the study goes. Is the study design to study all CSP treatments before 2018 and compare to all after 2018-- and if so, when did the study begin, (usually studies will cite the range of years patients were included in each group)? Or is it to compare balloon catheter treatments to all other treatments? Or is it both? Clarity is needed here. And is there a reason the authors did not specify which treatments were included the non-balloon catheter group? One can't but wonder if a specific treatment (say, MTX alone) was responsible for the majority of the morbidity in the non-balloon group. Why compare a heterogeneous group of treatments to a homogenous treatment protocol. The inclusion of methotrexate is another confounding factor. I appreciate the inclusion of methotrexate administration in Table 1 so we can compare groups, but was it given the same way in both groups? There is no description of how the MTX was administered in the non-balloon treatment group (IM vs. local injection) which makes it harder to interpret the results.

Otherwise Table 1 and the results sections faithfully report the data. I would have included the EMV/AVM data in Table 1 for completeness.

Reviewer #3:

Abstract: Need to include the total N and N for each cohort

Table 1: Need units for age, BMI, GA, HCG, distance traveled. Since the 2 cohorts had N = 23 and N = 14, need to round all %s to nearest integer %, not to 0.1% precision and should include range, with median values, since the IQRs would have little precision, based again on the modest sample sizes. None of the maternal morbidity metrics have sufficient counts of adverse outcomes to allow for multivariable adjustment for two adjustors. The models are over fitted, so should omit all aORs. Also, give the small counts, should simply use Fisher's test rather than ORs and acknowledge that the

groups were not randomized in limitations section.

General: Although the baseline characteristics are numerically similar and statistically NS, based on the respective sample sizes, there is little stats power to discern or to generalize that NS difference exists between the populations these cohorts represent.

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."

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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

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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.

Research Letters: 600 words (do not include more than two figures and/or tables [2 items total])

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.

Research Letter: 125 words

11. 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.

12. 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.

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

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.

15. 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 Jul 08, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,
Dwight J. Rouse, MD
Deputy Editor, Obstetrics

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

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EDITOR

COMMENTS:

We would be happy to consider a revision but ask, in addition to responding to the reviewers' comments, that you remove the comparison group and simply report on the outcomes for the balloon-treated patients with rates and 95% confidence intervals, since the two groups in your present manuscript were not randomly allocated to the treatment they received.

We are happy to comply with this and report our results as a case series. The table and manuscript has been re-written to remove the comparison group.

However, knowledge regarding optimal treatment of CSP and CXPs are lacking, because there are no comparisons that currently exist in the literature between methods – and only other case series for the CDBC method. We did not perform a randomized controlled trial, so did not comment on the efficacy of this method over other methods. However, we can offer a historical comparison of outcomes associated with this treatment to non-CDBC treated outcomes at our same institution. *The intention of this retrospective cohort was to create a stepping stone in which other studies could build upon.* Although not randomized, there remains a clean “before and after” timepoint where all cases afterwards were treated with CDBC, removing some of the selection bias concerns present in other independently-presented case series. The difference in outcomes of maternal morbidity were significant, even for the small numbers that we have, and offers clinical equipoise for testing the CDBC method in future rigorous RCTs that could adequately address the questions of efficacy, which is currently unanswered for CSP and CXP treatments. Thus, we ask for consideration of the following line to be included in the discussion of the revised case series:

Line 88

When we reviewed all cases of CSPs and CXPs from 2013 through 2018 treated at our institution prior to introduction of the CDBC method (n=14, 13 with systemic methotrexate and intra-sac potassium chloride, 1 with dilation and curettage, Table), we found significantly higher complications with higher rates of transfusion (35.7%, $p=0.021$), hysterectomy (35.7%, $p=0.021$), and ICU admission (21.4%, $p=0.047$) when compared to the CDBC method.

We did include these patients in the Table for ease of reference, but could delete them out if the editors prefer.

REVIEWER COMMENTS:

Reviewer #1:

In this case series, the authors compare outcomes before and after cervical double balloon catheter treatment for CSP/CXPs. They report higher rates of transfusion, hysterectomy, and ICU admission prior to CDBC. CDBC significantly decreased maternal morbidity as well.

Introduction

- Line 49: Is there a citation that the incidence is increasing.

This citation was added. (line 49)

Methods:

- Line 62: What guidelines? This should be cited
- What was the standard treatment before CDBC was introduced - this should be defined clearly
- What CDBC performed exclusively as the SOC after 2018? This is unclear

Citation for original protocol added in line 53. We added pre-CDBC standard treatment to line 76-78. We added the explanation that all patients opted for CDBC treatment after 2018, which is now in line 70.

Results:

- What was the time frame for this study in the pre CDBC era? **This was 2013-2018, which is included in Line 89**

- The authors report in Line 74 that patients opted for CDBC - this was a patient decision? Or was it a uniform protocol? There is the potential for selection bias in these patients as well

We offered this to all eligible patients starting in 2018, using shared decision-making. All patients who presented with CSP/CXP during this time elected for CDBC management. This is reflected in the update in line 59.

- I am also curious about the exemption from IRB. This is an area that does not have a well-defined SOC. As this is testing a treatment, although retrospective, I'm not sure this falls into a QI as the study is not to look at uptake of CDBC but actual outcomes for efficacy which is usually outside of a QI scope

We consulted with our IRB regarding this project. The purpose of this project was to collect retrospective information to evaluate the outcomes of the CDBC method as an internal quality review, given the change in our practice. We did not evaluate efficacy, as no trials were performed, and we do not consider our outcomes as generalizable knowledge, given the small scope of this project and single center experience. Thus, this work was classified as non-human QI.

- It is hard to interpret the results without a description of what is included in the non-balloon treatment.

Non-balloon treatment included systemic methotrexate and intrasac potassium chloride injection. This was added in the Table and in line 90-91.

Discussion:

- Line 93-94: Without an assessment of how CSP/CXP are treated pre-balloon it is hard to interpret these findings; although it is not described in the table, for instance, if hysterectomy was the standard care, it would make sense that the morbidity is higher. It is also possible that those 5 hysterectomies were also associated with transfusion in a case that was emergent. Understanding the types of treatment and what was offered in the early era is integral to interpreting these findings

Due to the word limit of a research letter, we did not include this information. A sentence is now included in line 90-91 and in the Table addressing this. In our pre-balloon treatment group, most (13) patients were treated with intramuscular methotrexate +/- intrafetal KCl. One had a D&C. Two required hysterectomy due to complications arising from treatment.

Reviewer #2:

I want to thank the authors for their work in furthering our understanding of the treatment options of this dangerous condition without clear best practices in treatment.

I thought the abstract distilled the major findings of the paper appropriately.

The introduction was appropriately brief for a research letter. If space allowed, a description of the current leading treatment options and the data we have about those options in the literature. What is a 'normal' baseline rate of complications for this condition? For contemporary management is transfusion/hysterectomy expected 5% of the time 50%??

Thank you for this suggestion. Given the predominance of case series for treatment of CSP and CXPs, this is a difficult question to answer succinctly. There is a large range depending on the treatment modality; one review of 751 patients and 31 non-CDBC treatment methods reported an overall complication rate of 44%. Complications were defined as the immediate or delayed need for a secondary treatment, and included unplanned surgery, transfusion, hysterectomy, and uterine artery embolization. Complications by treatment modalities ranged from 0% (n=1, vaginal hysterotomy) to 66.7% (n=33, D&C and Shirodkar cerclage). Due to word count, we could not include all of this but have added this sentence:

Line 51-52: “the optimal management is unknown, and complications following treatment have been reported as high as 44%.”

- 1. Timor-Tritsch IE, Monteagudo A. Unforeseen consequences of the increasing rate of cesarean deliveries: early placenta accreta and cesarean scar pregnancy: a review. Am J Obstet Gynecol 2012;207: 14–29. doi: 10.1016/j.ajog.2012.03.007.**

The hypothesis/central question of the work was not quite articulated in the introduction. **Our central question of evaluating complications and morbidity following balloon treatment is stated in lines 55-56.**

In the methods section, I would have appreciated a bit more about the protocol used for the double balloon catheter treatments, or if similar to previous work, a link to a previously published protocol. Was this inpatient or outpatient treatment? How long were patients followed? Were there any balloon related complications-- unable to place properly/balloon ruptures? As currently described, it makes it quite hard to know how to replicate this work.

We have added the citation for original protocol on line 63; we did not detail this protocol due to word count limits. All patients who were offered placement opted for placement, all placements were successful (line 69-71).

I was hoping for more details about the recruitment and enrollment in this study. The authors mention that subsequent to 2018 they treated CSPs with the balloon catheter. It's not quite clear if every patient after 2018 received a balloon catheter or if there were some patients who were counseled and opted for a different treatment. Also unclear is how far back the study goes. Is the study design to study all CSP treatments before 2018 and compare to all after 2018-- and if so, when did the study begin, (usually studies will cite the range of years patients were included in each group)? Or is it to compare balloon catheter treatments to all other treatments? Or is it both? Clarity is needed here.

All patients after 2018 were offered and elected for CDBC. Prior to this, we collected data on all CXP/CSPs diagnosed since 2013. This includes all available data in the electronic medical record. This is clarified in lines 69-71, and 90-91.

And is there a reason the authors did not specify which treatments were included the non-balloon catheter group? One can't but wonder if a specific treatment (say, MTX alone) was responsible for the majority of the morbidity in the non-balloon group. Why compare a heterogeneous group of treatments to a homogeneous treatment protocol.

We have clarified the pre-balloon treatments (90-91). 13 received systemic methotrexate and intrasac KCl, which was standard of care for CSP and CXPs at the time; 1 received a D&C.

The inclusion of methotrexate is another confounding factor. I appreciate the inclusion of methotrexate administration in Table 1 so we can compare groups, but was it given the same way in both groups? There is no description of how the MTX was administered in the non-balloon treatment group (IM vs. local injection) which makes it harder to interpret the results.

We have clarified the pre-balloon treatments (90-91). 13 received systemic methotrexate and intrasac KCl, which was standard of care for CSP and CXPs at the time; 1 received a D&C. All patients who received methotrexate with balloon treatment received it systemically (line 63).

Otherwise Table 1 and the results sections faithfully report the data. I would have included the EMV/AVM data in Table 1 for completeness.

We chose not to include EMV as an *a priori* complication from the treatment group since it has been shown to occur in 20% of expectantly managed CSPs (doi: 10.7863/ultra.34.4.601), so it is unknown if this is related to balloon treatment or the underlying pathophysiology. The patient who developed the EMV was included as a complication in the CBDC group due to bleeding requiring admission. This was added in line 77-79.

Reviewer #3:

Abstract: Need to include the total N and N for each cohort

We have included the Ns to reflect the balloon group (line 28).

Table 1: Need units for age, BMI, GA, HCG, distance traveled.

The table has been updated.

Since the 2 cohorts had N = 23 and N = 14, need to round all %s to nearest integer %, not to 0.1% precision and should include range, with median values, since the IQRs would have little precision, based again on the modest sample sizes. None of the maternal morbidity metrics have sufficient counts of adverse outcomes to allow for multivariable adjustment for two adjusters. The models are over fitted, so should omit all aORs. Also, give the small counts, should simply use Fisher's test rather than ORs and acknowledge that the groups were not randomized in limitations section.

We have removed the statistical comparison between the groups from the Table per the Editor's request, rounded all %s to the nearest integer, and included the range. Fisher's test was used where appropriate, when n<5. We make it clear that these groups were not randomized in the methods section and the Table footnote.

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.

We agree to this.

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:

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- * 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.

The IRB information is included. The remainder of this information is not applicable.

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We have notified our coauthors to complete this form.

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We have reviewed our letter to reflect the above suggested language.

5. The journal follows ACOG's Statement of Policy on Inclusive Language (<https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2Fclinical-information%2Fpolicy-and-position-statements%2Fstatements-of-policy%2F2022%2Finclusive-language&data=05%7C01%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWlloiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=NIP1GD9zgFcA3vTZ4HQGfMKgmqgPO0b6dOG7xMtRVps%3D&reserved=0>). 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."

We appreciate and applaud the journal's commitment to inclusive language, and have used "patients" instead of "women" throughout the letter.

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 <https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fwww.equator-network.org%2F&data=05%7C01%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWlloiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6IklhaWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=>

JmK7v%2FUYdnwT5ipVC9H%2B5ehnUoTeQLhxb4AgHISRQ5Y%3D&reserved=0

We have included the SQUIRE 2.0 checklist with this quality improvement research letter.

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://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2Fpractice-management%2Fhealth-it-and-clinical-informatics%2Frevitalize-obstetrics-data-](https://nam10.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%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWIjojMC4wLjAwMDAiLCJQIjojV2luMzliLCJBTiI6lk1haWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&sdata=TBv4tBfJI%2FcAMNLnKVXQmEg2qK5HIYw1hX6hACyrqPE%3D&reserved=0)

[definitions&data=05%7C01%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWIjojMC4wLjAwMDAiLCJQIjojV2luMzliLCJBTiI6lk1haWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&sdata=TBv4tBfJI%2FcAMNLnKVXQmEg2qK5HIYw1hX6hACyrqPE%3D&reserved=0](https://nam10.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%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWIjojMC4wLjAwMDAiLCJQIjojV2luMzliLCJBTiI6lk1haWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&sdata=TBv4tBfJI%2FcAMNLnKVXQmEg2qK5HIYw1hX6hACyrqPE%3D&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-](https://nam10.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%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWIjojMC4wLjAwMDAiLCJQIjojV2luMzliLCJBTiI6lk1haWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&sdata=oeb7ZgSLMrUvr19HgzkHOXTe2aVgv4aMHristsrKYwE%3D&reserved=0)

[definitions&data=05%7C01%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWIjojMC4wLjAwMDAiLCJQIjojV2luMzliLCJBTiI6lk1haWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&sdata=oeb7ZgSLMrUvr19HgzkHOXTe2aVgv4aMHristsrKYwE%3D&reserved=0](https://nam10.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%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWIjojMC4wLjAwMDAiLCJQIjojV2luMzliLCJBTiI6lk1haWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&sdata=oeb7ZgSLMrUvr19HgzkHOXTe2aVgv4aMHristsrKYwE%3D&reserved=0). If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

The reVITALize definition of ectopic pregnancy is consistent with our use of this terminology in our 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.

Research Letters: 600 words (do not include more than two figures and/or tables [2 items total])

Our research letter complies with the above word limit. The current word count is

544.

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.

We have included all applicable acknowledgements according to the above guidelines.

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.

Research Letter: 125 words

The word count of the abstract is 83.

11. Only standard abbreviations and acronyms are allowed. A selected list is available online

at <https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fedmgr.ovid.com%2Fong%2Faccounts%2Fabbreviations.pdf&data=05%7C01%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWlloiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6IjEhaWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&sdata=rdbhcHnHDAFNt8jnARg3VONBkHqFKj5DbCINoJ7cquA%3D&reserved=0>. Abbreviations and acronyms cannot be used in the title or précis. Abbreviations and acronyms must be spelled out the first time they are used in the abstract and again in the body of the manuscript.

We use “CSP” and “CXP” throughout this paper, but these abbreviations are not included in the title, and are spelled out in their first use.

12. 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.

We have removed the virgule symbol from our text (removed from line 48, line 81, and line 88).

13. 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.

We have removed the term provider and replaced with “physician” (line 82, 88).

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

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.

Our data has been reported to reflect the above guidelines.

15. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available at https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fedmgr.ovid.com%2Fong%2Faccounts%2Ftable_checklist.pdf&data=05%7C01%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWljojMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6Ikl1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=Fr%2BMA4t%2FT%2FQd6HqeAck9P2%2F4tXhx1leYgzCJUEfJp2k%3D&reserved=0.

We have reviewed the guidelines to ensure our tables conform to the journal style.

16. Please review examples of our current reference style at https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fedmgr.ovid.com%2Fong%2Faccounts%2Ffifa_suppl_refstyle.pdf&data=05%7C01%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWljojMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6Ikl1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=iLI%2Fe%2BwSZQnSY%2FoKc%2BipiFfqvFdOOotGXUSSHwMwGIY%3D&reserved=0. 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://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.acog.org%2Fclinical&data=05%7C01%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWljojMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6Ikl1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=tnUHs7VAUkrSjL%2Bx%2BIP%2Fou17O3Va0NRbbDCxbQFbS0%3D&reserved=0> (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.

Our references reflect the above guidelines.

17. Figure 1: Please remove the A, B, and C labels. These will be added back in per journal style. Please upload as a figure file on Editorial Manager.

We have removed the A, B, and C labels and will upload as a figure file.

18. 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 [https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Flinks.lww.com%2FLLWW-](https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Flinks.lww.com%2FLLWW-ES%2FA48&data=05%7C01%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWlloiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTil6lk1haWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&sdata=dThSq0LxfKUVYDF%2Fd%2ByAhC9altI91uajimx68FBhl%2Fg%3D&reserved=0)

[ES%2FA48&data=05%7C01%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWlloiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTil6lk1haWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&sdata=dThSq0LxfKUVYDF%2Fd%2ByAhC9altI91uajimx68FBhl%2Fg%3D&reserved=0](https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Flinks.lww.com%2FLLWW-ES%2FA48&data=05%7C01%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWlloiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTil6lk1haWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&sdata=dThSq0LxfKUVYDF%2Fd%2ByAhC9altI91uajimx68FBhl%2Fg%3D&reserved=0). The cost for publishing an article as open access can be found at <https://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwkauthorservices.edmgr.com%2Fopen-access%2Fhybrid.html&data=05%7C01%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWlloiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTil6lk1haWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&p;sdata=tPYkwbD94i%2FloiCxWVWRL8pKUzgtSTjHkfpAd8K4XyA%3D&reserved=0>.

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.

We will be sure to respond promptly to this email.

If you choose to revise your manuscript, please submit your revision through Editorial Manager

at <https://nam10.safelinks.protection.outlook.com/?url=http%3A%2F%2Fong.edmgr.com%2F&data=05%7C01%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWlloiMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTil6lk1haWwiLCJXVCi6Mn0%3D%7C3000%7C%7C%7C&p;sdata=tPYkwbD94i%2FloiCxWVWRL8pKUzgtSTjHkfpAd8K4XyA%3D&reserved=0>

910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWljojMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=TTK47YSW%2BWe4vZRYzeyUWNMaPbNc5a01mS4YngfOMAY%3D&reserved=0. 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 08, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,
Dwight J. Rouse, MD
Deputy Editor, Obstetrics

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://nam10.safelinks.protection.outlook.com/?url=https%3A%2F%2Fwww.editorialmanager.com%2Fong%2Flogin.asp%3Fa%3Dr&data=05%7C01%7Cdickisons%40wustl.edu%7C75e250327e5d4fe3861908da506cad51%7C4ccca3b571cd4e6d974b4d9beb96c6d6%7C0%7C0%7C637910725095411133%7CUnknown%7CTWFpbGZsb3d8eyJWljojMC4wLjAwMDAiLCJQIjoiV2luMzliLCJBTiI6Ik1haWwiLCJXVCI6Mn0%3D%7C3000%7C%7C%7C&sdata=VFFsDKLZXM%2FH2omldz%2B6ZLa35S0FNdKhyo aYqKlh%2FL4%3D&reserved=0>). Please contact the publication office if you have any questions.

Date: Jul 21, 2022
To: "Shelby Dickison" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-22-820R1

RE: Manuscript Number ONG-22-820R1

Maternal morbidity following double balloon catheter management of cesarean scar and cervical pregnancies: a preliminary report

Dear Dr. Dickison:

Your revised manuscript was reviewed by the editors. We are requesting further revisions.

As we indicated in our letter offering you the opportunity to revise your manuscript, we are interested in a descriptive study of your experience with the double balloon method. We are not interested in the historical comparison group. So please:

1. Report only those patients treated with the double balloon;
2. Remove any reference to patients treated with other methods including in the Table and the Discussion.

That you treated so many patients with the double balloon method and had good outcomes will be a valuable contribution to the literature, the lack of a comparison group notwithstanding.

Also, please supply 95% CI intervals for your observed rates of complications. (To show that with your sample size, e.g., a rate of 0% is compatible with a rate of 0-X%).

Denise Shields will send you the version of your manuscript that you should use for editing. Please also address the following:

1. The following co-author will need to complete our electronic Copyright Transfer Agreement, which was sent to them by email through Editorial Manager. Please note their email address and make sure it is correct. Once the form is complete, please add their disclosures to the "Financial Disclosure" section.

Ashley E Veade [REDACTED]

2. Please check with Dr. Eisenberg about how to best word the Financial Disclosure text that pertains to him, which is from his Copyright Transfer Agreement.

3. In the Financial Disclosure paragraph, please note the sentence about off-label use, which was in David Eisenberg's section of the Copyright Transfer Agreement. Please edit as needed.

4. Did your study receive IRB approval or exemption? Please add text to the Methods section to explain.

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 Aug 04, 2022, we will assume you wish to withdraw the manuscript from further consideration.

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 Aug 04, 2022, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

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.