

# OBSTETRICS & GYNECOLOGY



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

- Comments from the reviewers and editors (email to author requesting revisions)
- Response from the author (cover letter submitted with revised manuscript)\*
- Email correspondence between the editorial office and the authors\*

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

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

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

[obgyn@greenjournal.org](mailto:obgyn@greenjournal.org).

**Date:** Jan 29, 2019  
**To:** "Deborah Hawkins" [REDACTED]  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-18-2263

RE: Manuscript Number ONG-18-2263

Sustained effectiveness of laparoscopic transabdominal cerclage in subsequent pregnancies

Dear Dr. Hawkins:

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

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

Your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Feb 19, 2019, we will assume you wish to withdraw the manuscript from further consideration.

#### REVIEWER COMMENTS:

Reviewer #1:

ONG-18-2263

TITLE: Sustained effectiveness of laparoscopic transabdominal cerclage in subsequent pregnancies

Article type: Original Research

Precis: In this observational cohort series, laparoscopic transabdominal cerclage was found to have sustained effectiveness for more than one pregnancy.

Overall:

The objective of this study is to evaluate obstetric outcomes of subsequent pregnancies in women who had a laparoscopic transabdominal cerclage.

Abstract:

No comments.

OTHER:

Disclosures: none.

Human subjects: Ethics approval from the Royal Women's Hospital in Melbourne Australia.

Introduction:

1. Thorough description of the problem and literature review.

Methods:

No comments

Results:

No comments

Discussion:

2. Major limitation of this study (very small sample size) is appropriately discussed. Reviewer appreciates thorough review

of all limitations.

References:

No comments.

TABLES AND FIGURES:

No comments

Reviewer #2: Abstract: Well written, the objective, results and conclusions are clear

Introduction: The objective is clear, adequate background for why this topic is important in obstetrics

Materials and Methods:

1. Line 126: What type of progesterone would be prescribed? Were these women given IM 17 OHP or vaginal progesterone? This could introduce bias into the cohort.

2. Line 131: Telephone interviews were conducted with the patients, how much information was obtained from the patients? This could introduce recall bias

3. Results are clear, easy to follow and read. It would be important to define short cervix or the cervical lengths for women presented in table 1.

Discussion

4. Line 197-203: Is there a conclusion to be drawn among these women?

5. Limitations: how many women received progesterone? What form of progesterone?

Reviewer #3: The authors in their manuscript clearly outline the strengths and limitations of their paper and the need for ongoing research. The manuscript is wordy and can be truncated by having the authors refer to their tables in the Results section. The strengths and limitations section and the future research should be incorporated in the Discussion section and not have separate titles.

In Lines 121 and 122, the authors outline that suction cerclage can be performed without disturbing the cerclage; however, if the cerclage has closed the internal loss it would be technically difficult to enact a suction cerclage and the authors should address this in their manuscript.

STATISTICAL EDITOR'S COMMENTS:

1. lines 63-72: The various proportions cited should include 95% CI, since the sample sizes are modest. Likewise, the means and medians should include SD and range or IQR, respectively to give context.

2. lines 132: Suggest a diagram to summarize the pregnancy outcomes. The more detailed Table 1 could be cited as on-line material.

3. lines 248-250: The sample size is so limited ( $n = 3$ ), that this statement has no statistical foundation, as would be seen by addition of CIs for all proportions. e.g., for 3 success out of 3 tries, the 100% estimate has a lower 95% bound of 21%.

ASSOCIATE EDITOR'S COMMENTS:

Please in your revision

1) In abstract, provide actual numbers and report percentages to whole numbers only

2) Frame your findings as associations-an uncontrolled study can not demonstrate effectiveness

EDITORIAL OFFICE COMMENTS:

1. The Editors of Obstetrics & Gynecology are seeking to increase transparency around its peer-review process, in line with

efforts to do so in international biomedical peer review publishing. If your article is accepted, we will be posting this revision letter as supplemental digital content to the published article online. Additionally, unless you choose to opt out, we will also be including your point-by-point response to the revision letter, as well as subsequent author queries. If you opt out of including your response, only the revision letter will be posted. Please reply to this letter with one of two responses:

1. OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.
2. OPT-OUT: No, please do not publish my response letter and subsequent email correspondence related to author queries.

2. As of December 17, 2018, Obstetrics & Gynecology has implemented an "electronic Copyright Transfer Agreement" (eCTA) and will no longer be collecting author agreement forms. When you are ready to revise your manuscript, you will be prompted in Editorial Manager (EM) to click on "Revise Submission." Doing so will launch the resubmission process, and you will be walked through the various questions that comprise the eCTA. Each of your coauthors will receive an email from the system requesting that they review and electronically sign the eCTA.

Any author agreement forms previously submitted will be superseded by the eCTA. During the resubmission process, you are welcome to remove these PDFs from EM. However, if you prefer, we can remove them for you after submission.

3. 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 and gynecology data definitions at <https://www.acog.org/About-ACOG/ACOG-Departments/Patient-Safety-and-Quality-Improvement/reVITALize>. If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

4. Because of space limitations, it is important that your revised manuscript adhere to the following length restrictions by manuscript type: Original Research reports should not exceed 26 typed, double-spaced pages (6,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and print appendixes) but exclude references.

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

- \* All financial support of the study must be acknowledged.
- \* Any and all manuscript preparation assistance, including but not limited to topic development, data collection, analysis, writing, or editorial assistance, must be disclosed in the acknowledgments. Such acknowledgments must identify the entities that provided and paid for this assistance, whether directly or indirectly.
- \* All persons who contributed to the work reported in the manuscript, but not sufficiently to be authors, must be acknowledged. Written permission must be obtained from all individuals named in the acknowledgments, as readers may infer their endorsement of the data and conclusions. Please note that your response in the journal's electronic author form verifies that permission has been obtained from all named persons.
- \* If all or part of the paper was presented at the Annual Clinical and Scientific Meeting of the American College of Obstetricians and Gynecologists or at any other organizational meeting, that presentation should be noted (include the exact dates and location of the meeting).

6. The most common deficiency in revised manuscripts involves the abstract. Be sure there are no inconsistencies between the Abstract and the manuscript, and that the Abstract has a clear conclusion statement based on the results found in the paper. Make sure that the abstract does not contain information that does not appear in the body text. If you submit a revision, please check the abstract carefully.

In addition, the abstract length should follow journal guidelines. The word limits for different article types are as follows: Original Research articles, 300 words. Please provide a word count.

7. 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.

8. The journal does not use the virgule symbol (/) in sentences with words. Please rephrase your text to avoid using "and/or," or similar constructions throughout the text. You may retain this symbol if you are using it to express data or a measurement.

9. Please review the journal's Table Checklist to make sure that your tables conform to journal style. The Table Checklist is available online here: [http://edmgr.ovid.com/ong/accounts/table\\_checklist.pdf](http://edmgr.ovid.com/ong/accounts/table_checklist.pdf).

10. 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 <http://edmgr.ovid.com/acd/accounts/ifaauth.htm>.

Please note that 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.

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If you choose to revise your manuscript, please submit your revision via Editorial Manager for Obstetrics & Gynecology at <http://ong.editorialmanager.com>. It is essential that your cover letter list point-by-point the changes made in response to each criticism. Also, please save and submit your manuscript in a word processing format such as Microsoft Word.

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

Again, your paper will be maintained in active status for 21 days from the date of this letter. If we have not heard from you by Feb 19, 2019, we will assume you wish to withdraw the manuscript from further consideration.

Sincerely,

The Editors of Obstetrics & Gynecology

2017 IMPACT FACTOR: 4.982

2017 IMPACT FACTOR RANKING: 5th out of 82 ob/gyn journals

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In compliance with data protection regulations, please contact the publication office if you would like to have your personal information removed from the database.

February 14, 2019

Dear Editor and Reviewers,

Thank you for the opportunity to revise our paper and for your constructive feedback. I have responded directly to all of the comments below and have used the track changes feature to highlight all changes to the text of the paper.

Thank you again,



Dr Deborah Hawkins

#### REVIEWER COMMENTS:

Reviewer #1:

ONG-18-2263

TITLE: Sustained effectiveness of laparoscopic transabdominal cerclage in subsequent pregnancies

Article type: Original Research

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No comments.

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No comments.

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No comments

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Materials and Methods:

1. Line 126: What type of progesterone would be prescribed? Were these women given IM 17 OHP or vaginal progesterone? This could introduce bias into the cohort.

- Thank you for bringing up this important point about possible co-intervention. In Australia, the vast majority of women who require progesterone are prescribed vaginal suppositories. We have now included all of the known progesterone treatments for all of the patients in Table 2.

2. Line 131: Telephone interviews were conducted with the patients, how much information was obtained from the patients? This could introduce recall bias.

- As added to the paper, the majority of the information was gathered from chart review and the patients' obstetricians. The main purpose of the phone conversations was to find out if the patient had any pregnancies that had not yet

been captured in the database so the detailed information could be gathered from the charts and treating obstetricians.

3. Results are clear, easy to follow and read. It would be important to define short cervix or the cervical lengths for women presented in table 1.

- Because the TAC is most often performed for either a history of mid trimester loss and/or a history of cervical procedures, many of the women with TAC do not have a "short cervix" at the time of insertion by any definition. What we are trying to illustrate is that the TAC is associated with term pregnancy in the first and subsequent pregnancies in our cohort irrespective of whether they had a short cervix at the time of insertion, or not.

## Discussion

4. Line 197-203: Is there a conclusion to be drawn among these women?

- The conclusion is that this is a complex issue and that it is difficult to predict who will make it to term or not. However, the vast majority in our cohort did make it to term, which can provide some basis for physicians to support women who want to pursue a subsequent pregnancy.

5. Limitations: how many women received progesterone? What form of progesterone?

- Thank you for bringing up this important point about possible co-intervention. In Australia, the vast majority of women who require progesterone are prescribed vaginal suppositories. We have now included all of the known progesterone treatments for all of the patients in Table 2.

Reviewer #3: The authors in their manuscript clearly outline the strengths and limitations of their paper and the need for ongoing research. The manuscript is wordy and can be truncated by having the authors refer to their tables in the Results section.

- Thank you. I have summarized the results in Table 2 and removed some of the text.

The strengths and limitations section and the future research should be incorporated in the Discussion section and not have separate titles.

- Thank you, I have made this change.



In Lines 121 and 122, the authors outline that suction cerclage can be performed without disturbing the cerclage; however, if the cerclage has closed the internal loss it would be technically difficult to enact a suction cerclage and the authors should address this in their manuscript.

- Thank you. This is an important point. I have edited the paper and added that, due to the technique we use, the internal os remains not too tightly closed to preclude curettage if it becomes necessary. Indeed, Dr Ades performs this procedure for his TAC patients who also choose to have obstetrical care with him and who have a miscarriage.

#### STATISTICAL EDITOR'S COMMENTS:

1. lines 63-72: The various proportions cited should include 95% CI, since the sample sizes are modest. Likewise, the means and medians should include SD and range or IQR, respectively to give context.

- Thank you, I have added the 95% CI (using adjusted Wald interval), SDs and IQRs.

2. lines 132: Suggest a diagram to summarize the pregnancy outcomes. The more detailed Table 1 could be cited as on-line material.

- Thank you. Results summarized in Table 2.

3. lines 248-250: The sample size is so limited ( $n = 3$ ), that this statement has no statistical foundation, as would be seen by addition of CIs for all proportions. e.g., for 3 success out of 3 tries, the 100% estimate has a lower 95% bound of 21%.

- Thank you, I have changed the paragraph to better reflect the small sample size.

#### ASSOCIATE EDITOR'S COMMENTS:

Please in your revision

1) In abstract, provide actual numbers and report percentages to whole numbers only

- Thank you, I have made these changes.

2) Frame your findings as associations-an uncontrolled study can not demonstrate effectiveness

- Thank you, that is an important point and I have changed the wording throughout the paper to reflect this point.

## Daniel Mosier

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**From:** Dr D Hawkins [REDACTED]  
**Sent:** Sunday, March 10, 2019 12:06 AM  
**To:** Daniel Mosier  
**Subject:** Manuscript Revisions: ONG-18-2263R1  
**Attachments:** 18-2263R1 ms (3-1-19v2).docx

Dear Daniel,

Thank you for the opportunity to do more revisions. I have attempted to address points 2-7. I think all information in the abstract is presented in either the body or the tables.

We are grateful and happy to accept all of the minor edits and deletions.

Thank you,  
Deborah

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**From:** Daniel Mosier  
**Sent:** Friday, March 1, 2019 12:57 PM  
**To:** [REDACTED]  
**Subject:** Manuscript Revisions: ONG-18-2263R1

Dear Dr. Hawkins,

Thank you for submitting your revised manuscript. It has been reviewed by the editor, and there are a few issues that must be addressed before we can consider your manuscript further:

1. Please note the minor edits and deletions throughout. Please let us know if you disagree with any of these changes.
2. LINE 36: Please revise "and/or" to mean either "and" or "or." Be sure this is done throughout your paper.
3. LINE 40: Please provide the study period
4. LINE 45: Please be sure this is stated in the body of your paper, tables, or figures. Statements and data that appear in the Abstract must also appear in the body text for consistency.
5. LINE 81: Please spell out "TAC" throughout your paper.

6. LINE 109: ?Meand, ? median-please specify
7. LINE 114: Please be sure this is stated in the body of your paper, tables, or figures. Statements and data that appear in the Abstract must also appear in the body text for consistency.

When revising, use the attached version of the manuscript. Leave the track changes on, and do not use the "Accept all Changes"

Please let me know if you have any questions. Your prompt response to these queries will be appreciated; please respond no later than COB on **Tuesday, March 5<sup>th</sup>**.

**Daniel Mosier**

Editorial Assistant

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