

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)*
- Email correspondence between the editorial office and the authors*

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

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obgyn@greenjournal.org.

Date: Oct 26, 2018
To: "Jialin Mao" [REDACTED]
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-18-1783

RE: Manuscript Number ONG-18-1783

Longer-term Outcomes Following Hysteroscopic and Laparoscopic Sterilizations

Dear Dr. Mao:

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 Nov 16, 2018, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

REVIEWER #1:

This is an interesting manuscript with a purpose to "assess longer-term surgical outcomes following interval hysteroscopic sterilization and laparoscopic sterilization for women undergoing these procedures in New York State between 2005 and 2016 in a cohort of women with median follow-up of 7 years." This was a retrospective, cohort study using an administrative database.

1. The authors used an administrative database "New York State Department of Health Statewide Planning and Research Cooperative System (SPARCS)" How complete is the data in the SPARCS database? Do all hospitals, ambulatory surgical centers and doctors' offices (office based hysteroscopic sterilizations) in the state that perform hysteroscopic and laparoscopic procedures report to this database? What did the authors do if there was missing data? How valid is the data in this administrative database? Could the authors please supply the CPT and ICD-9-CM codes that they used to identify their cohorts? Could they add the codes they used to identify comorbidities in a table in the supplemental appendix?

2. In the footnotes for Table 2: *Additional tubal intervention was defined as undergoing additional hysteroscopic sterilization or tubal ligation or resection. However, the * is not linked to information provided in the table itself. Please clarify.

3. In the footnotes for the figure, the red and blue lines are very thin and difficult for me to tell which one is red or blue. Please thicken the lines in the footnote, similar to the thickness in the figure.

4. Lines 56 and 200: Could the authors use a semicolon between the dates and 'n'. eg 2005-2016; 10,143 and 53,206?

5. Please carefully review the references and make sure they confirm to the Green Journal's instructions for authors, esp for et al and journal abbreviations.

REVIEWER #2:

Thank you for submitting this manuscript.

1. 70. Authors state "continuous monitoring of long-term outcomes for women who received THE DEVICE is warranted. However, the specific "device" has not been defined/stated in the manuscript prior to this line.

2. 105. "there has been" needs to be corrected. There HAVE been consumer concerns.
3. 129. "reduced index procedures" are mentioned throughout the manuscript and "likely represent procedures that were aborted..." Perhaps explain what is meant by reduced index?
4. Does that mean down-coded? Does it mean a modifier was attached to the claim? Line 272 mentions "incomplete index procedures." Is this again referring to procedural coding with modifiers? Was modifier 52 the only code used to identify BOTH reduced and incomplete index cases?
5. 255. Advise clarification of "this study" to emphasize referring to the US study and not the submitted manuscript. Perhaps, "the study by Perkins et al..."
6. 286. "after stop marketing" needs to be corrected.

REVIEWER #3:

Some general comments:

- 1- I recommend the use of active voice throughout the manuscript.
- 2- I would consider less emphasis on the secondary outcome of cancer incidence, given your short follow-up period.
- 3- The background and methods sections are more tightly written than the results and discussion; these latter two sections may warrant review by a native English speaker, to address grammatical errors (such as dropped articles) and awkward phrasing.

In addition, I have questions and suggestions for clarification:

4. Line 121: You examined procedures in outpatient and ambulatory settings only--did this capture all hospital operating room settings? For instance, in a hospital with an ambulatory OR and a traditional "inpatient" OR, cases that can safely be performed in the ambulatory setting may be performed in the other due to scheduling issues. Essentially, do you think you captured all procedures?
5. Line 127-8: How did you define laparoscopic sterilization--were all methods (including complete salpingectomy) included in your analysis?
6. Line 152: Why were cancers grouped as gynecologic vs other, when sterilization has only been reported to reduce the incidence of ovarian cancer (and not endometrial, cervical, etc.)? Was it not possible to pull out ovarian cancer only by ICD-9 code?
7. Lines 216-217: I'm not following the results in this paragraph: It's unclear how the percentages were generated - is this of all women who had a subsequent procedure? The percentages in the text add up to 85.6% - what procedure did the other 14.4% of women undergo? Table 2 presents 479 women with an index hysteroscopic procedure and additional surgery, and the text states that 89 women had a reduced procedure, which should leave 390 women for the sensitivity analysis. But Appendix Table 2 lists 452 women.
8. Line 241: As in my query above, did you calculate the incidence of ovarian cancer in this time period?
9. Line 273: You discuss the possible reasons for reoperation for patients with an index hysteroscopic procedure, but do not discuss the possible reasons for reoperation for those women with an index laparoscopic procedure. Beyond procedure failure (and subsequent pregnancy, including ectopic pregnancy), did you find any evidence (in associated diagnosis codes) of other reasons, such as cancer prevention?
10. Lines 276-280: This commentary does not follow from your current investigation, and I would not include it here.
11. Lines 282-289: I would not repetitively call the Essure device a "controversial" device; this is commentary that does not follow from your current study.
12. Line 292: If you are going to allude to "potential ongoing risks" of the device, you should provide examples and citations.
13. Lines 315-316: You do not currently provide any evidence to support this assertion--the risk of reoperation decreases with time, and there is no increased risk of hysterectomy. What is your data to support this conclusion?
14. Table 1: it is not standard to report differences between groups, but to present p-values.

STATISTICAL EDITOR'S COMMENTS:

1. line 63: Should use the same format as for the earlier descriptions of HR, that is, include the respective %s for each cohort.
2. Methods and Table 1: Were there any missing data (besides race/ethnicity, which is indicated) in either the full data set or the matched set? If so, should enumerate all missing data.
3. Table 1: Should indicate whether the differences between cohorts in the complete set all became NS in the matched cohorts. If not, then indicate which remained significantly different.
4. Table 2: Was the inference threshold $p < .05$? Did the hysterectomy during follow-up HR meet the inference threshold or not? Need to indicate as footnote in Table.
5. Table 3: Should include the n along with the % for each year. Should also include the N at risk for each time period.
6. Fig 1: Should include a Table (could be supplemental material), indicating the number of adverse events for each cohort, along with the number remaining at risk for the time increments indicated along the x-axes.
7. I think that Figs 1 and 2 in the Appendix are important enough to include in the main text

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. Each author on this manuscript must submit a completed copy of our revised author agreement form (updated in the January 2018 issue). Please note:

a) Any material included in your submission that is not original or that you are not able to transfer copyright for must be listed under I.B on the first page of the author agreement form.

b) All authors must disclose any financial involvement that could represent potential conflicts of interest in an attachment to the author agreement form.

c) All authors must indicate their contributions to the submission by checking the applicable boxes on the author agreement form.

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AND

* Drafting the work or revising it critically for important intellectual content;

AND

* Final approval of the version to be published;

AND

* Agreement to be accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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3. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained."

*The manuscript's guarantor.

If you are the lead author, please include this statement in your cover letter. If the lead author is a different person, please ask him/her to submit the signed transparency declaration to you. This document may be uploaded with your submission in Editorial Manager.

4. 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 for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), and quality improvement in health care (ie, SQUIRE 2.0). Include the appropriate checklist for your manuscript type upon submission. 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 <http://ong.editorialmanager.com>. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, CHEERS, or SQUIRE 2.0 guidelines, as appropriate.

5. 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 will be transitioning as much as possible to use of the reVITALize definitions, and we encourage authors to familiarize themselves with them. The obstetric data definitions are available at <http://links.lww.com/AOG/A515>, and the gynecology data definitions are available at <http://links.lww.com/AOG/A935>.

6. 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 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and appendixes).

Please limit your Introduction to 250 words and your Discussion to 750 words.

7. 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.

8. 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.

9. 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.

10. 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.

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, that each author has given approval to the final form of the revision, and that the agreement form signed by each author and submitted with the initial version remains valid.

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 Nov 16, 2018, 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

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

Manuscript Number ONG-18-1783

Re: Longer-term Outcomes Following Hysteroscopic and Laparoscopic Sterilizations

Dear editors and reviewers,

We appreciate the opportunity to respond to the comments and revise our manuscript. We provide below our replies in *italic*. Changes in accordance with the revisions have been made in the manuscript. In addition, we have revised our manuscript to meet editorial requirement.

I affirm that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Kind regards,

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Fax: 646-962-0281
jim2012@med.cornell.edu

REVIEWER COMMENTS:

REVIEWER #1:

This is an interesting manuscript with a purpose to "assess longer-term surgical outcomes following interval hysteroscopic sterilization and laparoscopic sterilization for women

undergoing these procedures in New York State between 2005 and 2016 in a cohort of women with median follow-up of 7 years." This was a retrospective, cohort study using an administrative database.

1. The authors used an administrative database "New York State Department of Health Statewide Planning and Research Cooperative System (SPARCS)" How complete is the data in the SPARCS database? Do all hospitals, ambulatory surgical centers and doctors' offices (office based hysteroscopic sterilizations) in the state that perform hysteroscopic and laparoscopic procedures report to this database? What did the authors do if there was missing data? How valid is the data in this administrative database? Could the authors please supply the CPT and ICD-9-CM codes that they used to identify their cohorts? Could they add the codes they used to identify comorbidities in a table in the supplemental appendix?

Response: *Thank you for your questions. SPARCS collects information from all acute hospitals and extended outpatient surgical services, certified ambulatory surgical centers, and emergency departments in New York State. We included procedures performed in outpatient or ambulatory surgical settings to maintain a clean comparison to outpatient laparoscopic procedures as some of the procedures performed in inpatient settings may be more complex. Office procedures were not recorded in the database. We have further clarified this in the manuscript.*

Missing race was handled using a missing category in analysis. Other demographic variables and comorbidities, which were identified based on codes, did not have missing value. We included procedure codes and comorbidities in the appendix (Appendix Table 1). Elixhauser comorbidity codes were obtained from Healthcare Cost and Utilization Project website. We included a link to the webpage in the appendix.

2. In the footnotes for Table 2: *Additional tubal intervention was defined as undergoing additional hysteroscopic sterilization or tubal ligation or resection. However, the * is not linked to information provided in the table itself. Please clarify.

Response: *We apologize for the confusion. This note was retained from earlier versions of the table where the first two outcomes were reported together. We have removed it.*

3. In the footnotes for the figure, the red and blue lines are very thin and difficult for me to tell which one is red or blue. Please thicken the lines in the footnote, similar to the thickness in the figure.

Response: *We have increase the thickness of the lines in the legend.*

4. Lines 56 and 200: Could the authors use a semicolon between the dates and 'n'. eg 2005-2016; 10,143 and 53,206?

Response: *We have rephrased these two sentences to avoid confusions.*

5. Please carefully review the references and make sure they confirm to the Green Journal's instructions for authors, esp for et al and journal abbreviations.

Response: *Thank you for your comments. We have revised the reference format to follow Green Journal's recommendation.*

REVIEWER #2:

Thank you for submitting this manuscript.

1. 70. Authors state "continuous monitoring of long-term outcomes for women who received THE DEVICE is warranted. However, the specific "device" has not been defined/stated in the manuscript prior to this line.

Response: *We have revised the sentence.*

"With limited evidence of outcomes following hysteroscopic sterilization beyond 7 years and existing reports of removals years after initial implantations, continuous monitoring of long-term outcomes for women who received the device is warranted."

2. 105. "there has been" needs to be corrected. There HAVE been consumer concerns.

Response: *Thank you. We have corrected this.*

3. 129. "reduced index procedures" are mentioned throughout the manuscript and "likely represent procedures that were aborted..." Perhaps explain what is meant by reduced index?

Response: *We have now further clarified "reduced index procedures" in methods section.*

"The presence of a CPT modifier code 52 (reduced service modifier) likely represented index sterilization procedures that were aborted or not completed due to patient conditions."

4. Does that mean down-coded? Does it mean a modifier was attached to the claim? Line 272 mentions "incomplete index procedures." Is this again referring to procedural coding with modifiers? Was modifier 52 the only code used to identify BOTH reduced and incomplete index cases?

Response: *We apologize for the confusion. The "incomplete index procedures" also meant index procedures that were not completed. This corresponds to the definition of "reduced index procedures" in our cohort. We have unified them to be "reduced index procedures".*

5. 255. Advise clarification of "this study" to emphasize referring to the US study and not the submitted manuscript. Perhaps, "the study by Perkins et al..."

Response: *Thank you for the suggestion. We have revised the sentence.*

6. 286. "after stop marketing" needs to be corrected.

Response: *Thank you. We have corrected this.*

REVIEWER #3:

Some general comments:

1- I recommend the use of active voice throughout the manuscript.

Response: *We have revised the manuscript to use mostly active voice.*

2- I would consider less emphasis on the secondary outcome of cancer incidence, given your short follow-up period.

Response: *Thank you for the suggestion. We have removed secondary outcome reporting from abstract and de-emphasized the cancer outcomes.*

3- The background and methods sections are more tightly written than the results and discussion; these latter two sections may warrant review by a native English speaker, to address grammatical errors (such as dropped articles) and awkward phrasing.

Response: *We have revised the manuscript and asked colleagues to help review the writing.*

In addition, I have questions and suggestions for clarification:

4. Line 121: You examined procedures in outpatient and ambulatory settings only--did this capture all hospital operating room settings? For instance, in a hospital with an ambulatory OR and a traditional "inpatient" OR, cases that can safely be performed in the ambulatory setting may be performed in the other due to scheduling issues. Essentially, do you think you captured all procedures?

Response: *Thank you for the questions. Procedures performed in ORs in extended outpatient surgical settings of hospitals were captured as outpatient surgical procedures. We only included procedures performed in outpatient or ambulatory surgical settings to maintain a clean comparison to outpatient laparoscopic procedures as some of the procedures performed in inpatient settings may be more complex. Because this study was of comparative context and aimed at comparing sterilization procedures performed among patients that were eligible of receiving both hysteroscopic and laparoscopic procedures, it was not necessary to include all procedures. We have further clarified these in our manuscript.*

5. Line 127-8: How did you define laparoscopic sterilization--were all methods (including complete salpingectomy) included in your analysis?

Response: *Thank you for the question. Laparoscopic sterilization was defined as laparoscopic ligation or occlusion of fallopian tubes, using ICD and CPT procedure codes. We have included the codes in the appendix file now. Salpingectomy was not included in the same group because*

it's a more aggressive procedure compared to tubal ligation or occlusion. We have addressed the limitation of not including salpingectomy in the discussion.

6. Line 152: Why were cancers grouped as gynecologic vs other, when sterilization has only been reported to reduce the incidence of ovarian cancer (and not endometrial, cervical, etc.)? Was it not possible to pull out ovarian cancer only by ICD-9 code?

Response: *We examined the incidence of ovarian cancer only. But due to the low occurrence, the incidence of ovarian cancer only was not able to yield to valid statistical estimates. Therefore, gynecologic cancer incidences were aggregated. We have clarified this in the methods section.*

“Due to the low occurrence, individual cancer incidence, such as ovarian cancer, was not able to yield valid statistical estimates. Therefore, cancer outcomes were aggregated to be reported as gynecologic and non-gynecologic cancer incidences.”

7. Lines 216-217: I'm not following the results in this paragraph: It's unclear how the percentages were generated - is this of all women who had a subsequent procedure? The percentages in the text add up to 85.6% - what procedure did the other 14.4% of women undergo? Table 2 presents 479 women with an index hysteroscopic procedure and additional surgery, and the text states that 89 women had a reduced procedure, which should leave 390 women for the sensitivity analysis. But Appendix Table 2 lists 452 women.

Response: *We apologize for the confusion. Among the 10,143 women undergoing hysteroscopic sterilization, 438 (4.3%) had at least one subsequent procedures. The reason why numbers in Table 2 added up to 479, exceeding 438, was because some patients had multiple reoperations, for example, an additional tubal ligation and later on a hysterectomy. Among the 438 patients, for the first reoperation, 82 (18.7%) had another hysteroscopic sterilization procedure and 293 (66.9%) had a tubal ligation or resection. The remaining 63 (14.4%) women had a hysterectomy. We have clarified this in the manuscript. We also revised appendix Figure 2 to make it clearer. Unfortunately, we are not able to include all exact numbers of breakdowns in Appendix Figure 2 due to the restriction of DUA, which prohibited reporting of numbers <11 or numbers that can be used to estimate cells of <11. We have noted this in the figure legend.*

8. Line 241: As in my query above, did you calculate the incidence of ovarian cancer in this time period?

Response: *We examined the incidence of ovarian cancer only. But due to the low occurrence, the incidence of ovarian cancer only was not able to yield to valid statistical estimates. Therefore, gynecologic cancer incidences were aggregated. We have clarified this in the methods section.*

9. Line 273: You discuss the possible reasons for reoperation for patients with an index hysteroscopic procedure, but do not discuss the possible reasons for reoperation for those women with an index laparoscopic procedure. Beyond procedure failure (and subsequent pregnancy, including ectopic pregnancy), did you find any evidence (in associated diagnosis codes) of other reasons, such as cancer prevention?

Response: *Thank you for the question. For the laparoscopic group, apart from some patients who appeared to have undergone reoperation related to procedure failure, many of them had diagnosis of other gynecologic conditions associated with the readmission for reoperation, such as endometriosis, menstrual disorder or fallopian tube inflammatory disease. Due to the limitation of administrative data, it cannot be ascertained whether these diagnoses were the cause of reoperation. Therefore, we used comparative methods so that the laparoscopic group provided the baseline estimate of reoperation. The goal of the study was to assess whether patients undergoing hysteroscopic sterilization had excessive reoperations after accounting for these baseline rates.*

10. Lines 276-280: This commentary does not follow from your current investigation, and I would not include it here.

Response: *We have removed that.*

11. Lines 282-289: I would not repetitively call the Essure device a "controversial" device; this is commentary that does not follow from your current study.

Response: *We have revised these sentences.*

“However, patient recruitment for the study has been slow and the length of study is long.”

12. Line 292: If you are going to allude to "potential ongoing risks" of the device, you should provide examples and citations.

Response: *Thank you for the suggestion. Recent publications have reported Essure removal years after implantation. A single-site study from Netherlands (ref) reporting 93 cases of device remove had 27% of the removal procedures occurring >5 years after implantation. The longest time to removal in their study was 10 years (125 months). We have added this reference in the manuscript.*

Ref: Maassen LW, van Gastel DM, Haveman I, Bongers MY, Veersema S. Removal of Essure((R)) sterilization devices: a retrospective cohort study in the Netherlands. J Minim Invasive Gynecol 2018 Oct 16.

13. Lines 315-316: You do not currently provide any evidence to support this assertion--the risk of reoperation decreases with time, and there is no increased risk of hysterectomy. What is your data to support this conclusion?

Response: *Our study showed a time-varying risk profile of the hysteroscopic sterilization procedure. When compared with laparoscopic sterilization, the increased reoperation risk following hysteroscopic sterilization was most prominent within the first one and two years. Reoperation risks after 3 years of initial procedure were comparable between the two groups until the end of 7-year follow-up. Currently very long-term outcome is unknown. There have been case-series or single-site reports of device complications and removal in longer-term as mentioned above. Therefore, we think it is more appropriate to suggest continuous monitoring than concluding that the 7-year reoperation risk can be extrapolated to longer terms. We have further clarified this.*

“There have been reports of device removal in longer-terms (up to 10 years) after the initial hysteroscopic sterilization. The manufacturer estimated that over 750,000 women received the device. For the hundreds of thousands of women with the device already implanted, continuous monitoring of the long-term outcomes following hysteroscopic

sterilization is crucial given the limited evidence of the risks of the device beyond 7 years.”

14. Table 1: it is not standard to report differences between groups, but to present p-values.

Response: *We have added p values to Table 1. The reason to keep difference is because when assessing balances in covariates before and after matching, p value is subject to sample size. In studies with large sample size, such as ours, difference or standardized difference to assess balances in covariates is often used.*

STATISTICAL EDITOR’S COMMENTS:

1. line 63: Should use the same format as for the earlier descriptions of HR, that is, include the respective %s for each cohort.

Response: *We have revised this.*

2. Methods and Table 1: Were there any missing data (besides race/ethnicity, which is indicated) in either the full data set or the matched set? If so, should enumerate all missing data.

Response: *Thank you for the question. Race/ethnicity was the only one that had missing data. Information for patient age and insurance were complete. Comorbidities were identified based on codes, which were collected for everyone.*

3. Table 1: Should indicate whether the differences between cohorts in the complete set all became NS in the matched cohorts. If not, then indicate which remained significantly different.

Response: *We have added p values to Table 1. The reason to keep difference is because when assessing balances in covariates before and after matching, p value is subject to sample size and our cohort has a large sample size.*

4. Table 2: Was the inference threshold $p < .05$? Did the hysterectomy during follow-up HR meet the inference threshold or not? Need to indicate as footnote in Table.

Response: *The p value for the estimate was 0.053 (upper bound of confidence interval was 1.004). We have clarified the p value in Table 2.*

5. Table 3: Should include the n along with the % for each year. Should also include the N at risk for each time period.

Response: *Thanks for the suggestion. We have added N at risk and N events to Table 3.*

6. Fig 1: Should include a Table (could be supplemental material), indicating the number of adverse events for each cohort, along with the number remaining at risk for the time increments indicated along the x-axes.

Response: *Number at risk and number of events at each time increment is now reported in Table 3. Due to DUA restriction to protect patient privacy, which prohibits the reporting of rare events, we are not able to report the number of events at each time increment for cancer outcomes and additional hysteroscopic sterilization procedures.*

7. I think that Figs 1 and 2 in the Appendix are important enough to include in the main text

Response: *Thanks for the suggestion. We have moved them to the main manuscript.*

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:

Response: *OPT-IN: Yes, please publish my response letter and subsequent email correspondence related to author queries.*

2. Each author on this manuscript must submit a completed copy of our revised author agreement form (updated in the January 2018 issue).

Response: *We have submitted author agreement forms signed by all co-authors. Disclosures are made on the title page.*

3. Our journal requires that all evidence-based research submissions be accompanied by a transparency declaration statement from the manuscript's lead author. The statement is as follows: "The lead author* affirms that this manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained." *The manuscript's guarantor.

Response: *The lead author has included this in the cover letter.*

4. 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 for reporting randomized controlled trials (ie, CONSORT), observational studies (ie, STROBE), meta-analyses and systematic reviews of randomized controlled trials (ie, PRISMA), harms in systematic reviews (ie, PRISMA for harms), studies of diagnostic accuracy (ie, STARD), meta-analyses and systematic reviews of observational studies (ie, MOOSE), economic evaluations of health interventions (ie, CHEERS), and quality improvement in health care (ie, SQUIRE 2.0). Include the appropriate checklist for your manuscript type upon submission. Please write or insert the page numbers where each item appears in the margin of the checklist. In your cover letter, be sure to indicate that you have followed the CONSORT, MOOSE, PRISMA, PRISMA for harms, STARD, STROBE, CHEERS, or SQUIRE 2.0 guidelines, as appropriate.

Response: *We have included a STROBE checklist.*

5. 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 22 typed, double-spaced pages (5,500 words). Stated page limits include all numbered pages in a manuscript (i.e., title page, précis, abstract, text, references, tables, boxes, figure legends, and appendixes). Please limit your Introduction to 250 words and your Discussion to 750 words.

Response: *Our manuscript now has a total word count of 4,271 and page count of 21. Introduction and Discussion are within the limits.*

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.

Response: *We have made sure that abstract is consistent with the main manuscript. Current word count of abstract is 296.*

7 . 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.

Response: *We have made sure that "/" is not used in the text.*

Daniel Mosier

From: Jialin Mao [REDACTED]
Sent: Monday, November 26, 2018 1:46 PM
To: Daniel Mosier
Subject: RE: Manuscript Revisions: ONG-18-1783R1
Attachments: 18-1783R1 ms (11-26-18v2)_JM.docx

Good afternoon,

Thank you for getting in touch. Attached is the updated manuscript.

1. We agree with the changes.
2. Dr. Pfeifer misread the form. She will fill in a new form and sign. And I will email her form and Dr. Sedrakyan's form later.
3. Date has been added.
4. This has been added in the main text.
5. It's referring to Figure 3 (revised in the manuscript).

Please let me know if there is anything else that needs my attention.

Best,
Jialin

Jialin Mao, MD, MSc

Instructor in Healthcare Policy and Research

Weill Cornell Medicine

Department of Healthcare Policy & Research
[REDACTED]
[REDACTED]
[REDACTED]



mdepinet.org

From: Daniel Mosier <dmosier@greenjournal.org>
Sent: Monday, November 26, 2018 9:00 AM
To: Jialin Mao [REDACTED]
Subject: [EXTERNAL] Manuscript Revisions: ONG-18-1783R1

Dear Dr. Mao,

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 3:
 - a. Each author must meet four criteria to be an author. On the Author Agreement form, Samantha Pfeifer did not indicate that she either made substantial contributions to the conception of the work or substantial contributions to the acquisition, analysis, or interpretation of the work. She also did not indicate that she gave final approval of the version to be published; nor did she indicate that she agrees to be held accountable for all aspects of the work. If these omissions were errors, submit a new form with the appropriate boxes checked. If they were not errors, remove the author's name from the byline and add it to the acknowledgment ("The authors thank...).
 - b. Please submit an Author Agreement form for Art Sedrakyan with both the "Disclosure of Potential Conflicts of Interest" and "Authorship" sections completed.
3. LINE 43: Please add the dates of the meeting.
4. LINE 61: Please be sure this is stated in the body of your paper. Statements and data that appear in the Abstract must also appear in the body text for consistency.
5. LINE 233: To which figure are you referring?

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 **Wednesday, November 28th**.

Sincerely,
-Daniel Mosier

Daniel Mosier

Editorial Assistant

Obstetrics & Gynecology

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From: [REDACTED]
To: [Stephanie Casway](#)
Subject: RE: O&G Figure Revision: 18-1783
Date: Tuesday, November 27, 2018 11:00:31 AM

Hi Stephanie,

Thanks for getting in touch. The figures look good.

AQ1: for figure 1, can you add to exclusion box 1:

Excluded

Reintervention records

Procedures performed via laparotomy or concurrent to other abdominal procedures

N=3,008

Best,
Jialin

Jialin Mao, MD, MSc

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]



mdepinet.org

From: Stephanie Casway <SCasway@greenjournal.org>
Sent: Monday, November 26, 2018 3:41 PM
To: Jialin Mao [REDACTED]
Subject: [EXTERNAL] O&G Figure Revision: 18-1783

Good Afternoon Dr. Mao,

Your figures and legend have been edited, and PDFs of the figures and legend are attached for your review. Please review the figures CAREFULLY for any mistakes. In addition, please see our query below.

AQ1: Would you like to add any additional information to the first exclusion box in Figure 1?

PLEASE NOTE: Any changes to the figures must be made now. Changes at later stages are expensive and time-consuming and may result in the delay of your article's publication.

To avoid a delay, I would be grateful to receive a reply no later than Thursday, 11/5. Thank you for your help.

Best wishes,

Stephanie Casway, MA
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