

# 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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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:** "Daisuke Shigemi" [REDACTED]  
**From:** "The Green Journal" em@greenjournal.org  
**Subject:** Your Submission ONG-18-2317

RE: Manuscript Number ONG-18-2317

Laparoscopic versus open surgery for severe pelvic inflammatory disease and tubo-ovarian abscess

Dear Dr. Shigemi:

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: This paper is a retrospective cohort study using a large Japanese inpatient data base with a broad, vague objective - to compare surgical outcomes after laparoscopy versus laparotomy in patients with PID and TOA. Objective should be worded with stating more specific outcomes. Data base is limited in type of information provided and subject to coding and information entered. Study did not take into account experience of surgeon doing procedure, extent of disease, previous surgeries, adhesions, involvement of residents, type of hospital, patient selection for type of procedure, or any other factors that can influence quality of care and patient outcomes. Limitations, which authors acknowledge, are significant and limit the study.

1. Line 51 - please quantify "common"
2. Line 53-55 and 57-58 - please provide more recent data as references are over 20 years old
3. Line 58-59 - please back up with lit search, etc.
4. Line 63-64 - reference here and quantify
5. Line 67-70 - what about guidelines from other countries?
6. Line 72 - please back up this statement (lit search, etc)
7. Line 73-74 - reference here
8. Line 98-100 - this is a limitation of the data base
9. Line 112-117 - please provide some details about why this clinical score was included
10. Line 118-123 - why were these outcomes selected?
11. Line 162 - what types of minimally invasive drainage procedures?
12. Line 164-166 - were these diagnosis in addition to PID/TOA or were these patients initially diagnosed wrong and did not have PID/TOA? Please clarify.
13. Line 166 - please provide a number for 28.6% (n=?) and how many were laparotomy versus laparoscopy?

14. Line 168-169 - please clarify this sentence and again, how many laparotomy versus laparoscopy?
15. Line 171-183 - what is role or correlation of differences of baseline characteristics with postsurgical complications?
16. Line 204-206 - please back up this statement (lit search, etc)
17. Line 209-211 - again, old reference from 1991 here. More recent data required
18. Line 213 - reference here please
19. Line 231 - why were hysterectomies performed?
20. Line 232-233 - please back up this statement
21. Line 233-235 - reference here please
22. Line 242-246 - please expand and provide more information about patients who received hysterectomies, such as clinical indications, extent of disease, comorbidities, etc.

Reviewer #2: This is a retrospective cohort study using a large national database to determine whether there is benefit in laparoscopy over laparotomy in the treatment of pelvic inflammatory disease and tubo-ovarian abscess

#### Introduction:

1. Line 67-70: If you are trying to publish in an American journal, you should consider adding whether there are published guidelines from other large governing bodies, including ACOG, RCOG, etc, apart from Japanese Society of OBGYN.

#### Methods:

2. Line 124: Propensity Score matching does not account for unknown variables, which are perhaps the most likely to make differences in the observed outcomes, and which may make the unobserved variables effect stronger confounders in the matched comparison groups. For example, size of the TOA, a value that could not be retrieved from the database you used, may be the strongest predictor of whether a practitioner moved for laparotomy or laparoscopy initially, thus becoming more pronounced as a confounder when other variables are accounted for.

#### Discussion:

3. You have failed to mention, or it may be difficult or impossible to determine from the data set that you were using how many of the laparotomy cases started out as laparoscopic but were converted to laparotomy due to difficulty with adhesions or possible bowel injury during laparoscopy. If a case started as laparoscopic but converted due to injury or inability to complete surgery laparoscopically, it may give unfair bias against laparotomy cases if it was coded only as laparotomy.

#### Reviewer #3: To the Authors:

Well written paper with a figure and tables constructed in such a way that the average reader of this Journal can understand - as long as he/she understands "Propensity Score- Matched Analysis".

- 1- I would recommend adding "A Propensity Score Matched Analysis" to the Title.

2-As addressed as limitations in the Discussions section, I, too, have concerns that data from "about 1200 hospitals (only 82 academic), 27,841 patients is likely to be incomplete or in some cases incorrect and the retrospective comparison data that is presented is likely flawed by numerous factors. However, your presentation of that is of interest, and I feel that it should be left in.

3-If feasible, I would like to know what percentage of the planned laparoscopic procedures were converted into laparotomies intraoperatively and why.

4-I would also like to see the data on the percentage of TOAs which were drained with US guidance.( successfully and Unsuccessfully)

#### STATISTICAL EDITOR'S COMMENTS:

1. Table 1: Need to indicate for the unmatched and the score-matched cohorts, whether the patient characteristics are statistically different.
2. Table 2: Need to show the statistical comparisons for these outcomes for laparotomy vs laparoscopy.
3. Table 3, lines 44-46: The text cites another comparison (the length of stay), so that should be included. For surgical complications, revision surgery and in-hospital deaths, the counts were low and there is low power to generalize any of these NS differences for those outcomes. So, the only conclusion of differences relates to proportion needing blood transfusions, duration of operation and length of stay. The others are not generalizable.

#### 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. 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. In order for an administrative database study to be considered for publication in Obstetrics & Gynecology, the database used must be shown to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.

5. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works. Variance is needed in the following sections:

\*Please rework lines 253-256 (several limitations...disease severity). This is nearly verbatim from work you previously published.

6. 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.

7. 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.

8. 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).

9. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot.

10. 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.

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. 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.

13. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.

14. 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).

15. 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/ifauth.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.

15 February, 2019  
Dr. Nancy C Chescheir, MD  
Editor-in-Chief  
*Obstetrics & Gynecology*

Dear Dr Chescheir,

We very much appreciate the opportunity to revise our manuscript, entitled “Laparoscopic versus open surgery for severe pelvic inflammatory disease and tubo-ovarian abscess: a propensity score-matched analysis”. We responded to the reviewers’ comments as point-by-point responses, below, and we revised the manuscript accordingly. All of the changes we made are shown using the "underline formatting" in the revised manuscript because the line numbers were not shown correctly with "track changes" feature.

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.

We hope our revised manuscript is now suitable for publication in *Obstetrics & Gynecology*.

Thank you very much for your time and effort in considering our manuscript for publication in *Obstetrics & Gynecology*.

Yours sincerely,  
Daisuke Shigemi

## **REVIEWER COMMENTS:**

**Reviewer #1: This paper is a retrospective cohort study using a large Japanese inpatient data base with a broad, vague objective - to compare surgical outcomes after laparoscopy versus laparotomy in patients with PID and TOA. Objective should be worded with stating more specific outcomes. Data base is limited in type of information provided and subject to coding and information entered. Study did not take into account experience of surgeon doing procedure, extent of disease, previous surgeries, adhesions, involvement of residents, type of hospital, patient selection for type of procedure, or any other factors that can influence quality of care and patient outcomes. Limitations, which authors acknowledge, are significant and limit the study.**

>We amended the objectives to state more specific outcomes, in the abstract.  
(Lines 28–30)

### **1. Line 51 - please quantify "common"**

>We added reported estimated numbers for PID and also added supporting references: new references #1 and #2. (Line 53)

### **2. Line 53-55 and 57-58 - please provide more recent data as references are over 20 years old**

>We added recent data on the prevalence of TOA and also added new reference #5. (Lines 55–57)

### **3. Line 58-59 - please back up with lit search, etc.**

>We added more recent data on the mortality rate associated with PID and added new reference #12. (Lines 61–63)

### **4. Line 63-64 - reference here and quantify**

>We changed the sentence as follows and referenced the sentence:



“A recent study reported clinical experience with laparoscopic surgery to treat PID with or without TOA.<sup>6</sup>” (Lines 66-67)

**5. Line 67-70 - what about guidelines from other countries?**

>We added the treatment guidelines for the Centers for Disease Control, Europe, UK, and Australia and added new references #15–18. (Lines 72–76)

**6. Line 72 - please back up this statement (lit search, etc)**

>We deleted the sentence because it was unclear.

**7. Line 73-74 - reference here**

>We changed the sentences as follows and added new references #20 and #21:

“However, previous observational reports could not adequately adjust for patients’ background characteristics including severity, pre-existing comorbidities, and hospital characteristics.<sup>6,20,21</sup>” (Lines 78–80)

**8. Line 98-100 - this is a limitation of the data base**

>We described the limitations in the discussion, in the manuscript. (Lines 275–278)

**9. Line 112-117 - please provide some details about why this clinical score was included**

>We included this clinical score because the database included information on consciousness level only as the Japan Coma Scale score, and the presence of alert consciousness was important to estimate patients' disease severity. We added a sentence to explain why we used this score in our study. (Lines 120–121)

**10. Line 118-123 - why were these outcomes selected?**

>We selected these outcomes because they are important as short-term perioperative outcomes. These outcomes are objective because they can be measured quantitatively. However, the database does not include long-term

outcomes such as the rate of infertility, ectopic pregnancy, and chronic pelvic pain.

We added sentences to explain our reasons for selecting these outcomes.

(Lines 129–132)

**11. Line 162 - what types of minimally invasive drainage procedures?**

> Percutaneous or transvaginal drainage procedures were included. We added sentences to clarify. (Lines 172–173)

**12. Line 164-166 - were these diagnosis in addition to PID/TOA or were these patients initially diagnosed wrong and did not have PID/TOA? Please clarify.**

> These diagnoses were in addition to PID/TOA. We added sentences to clarify. (Line 178)

**13. Line 166 - please provide a number for 28.6% (n=?) and how many were laparotomy versus laparoscopy?**

> We added the required number (n=1,262) (Line 179). The numbers and rates of hysterectomy in the laparotomy and laparoscopy groups are shown in Table 1.

**14. Line 168-169 - please clarify this sentence and again, how many laparotomy versus laparoscopy?**

> We changed the sentences to clarify and added the rate of TOA complication in both groups. (Lines 183–185)

**15. Line 171-183 - what is role or correlation of differences of baseline characteristics with postsurgical complications?**

> After propensity-score matching, the rate of postsurgical complications decreased from 6.6% to 3.9% in the laparotomy group, indicating that patients who underwent laparotomy had higher severity regarding their baseline condition before surgical treatment. In addition, propensity-score matching allowed us to adjust for patients' background characteristics to compare perioperative outcomes.

We added sentences to explain the role of propensity-score matching in Table 2. (Lines 225–227)

**16. Line 204-206 - please back up this statement (lit search, etc)**

>We changed the sentence as follows:

“Our results also showed significantly better surgical outcomes for laparoscopic surgery vs laparotomy, and we were able to adjust for differences in patients' baseline characteristics and disease severity using propensity-score matching. In Table 2, the rate of postsurgical complications decreased (from 6.6% to 3.9%) in the laparotomy group after propensity-score matching, indicating that patients undergoing laparotomy had higher preoperative PID severity.” (Lines 222–227)

**17. Line 209-211 - again, old reference from 1991 here. More recent data required**

>We added references from 1993 and 2014. (new reference #3 and #6) (Lines 228–230)

**18. Line 213 - reference here please**

>We added new references #3, and #6–8). (Line 232)

**19. Line 231 - why were hysterectomies performed?**

>We could not identify reasons or indications for hysterectomy from the database. However, 95% of the patients who underwent hysterectomy were  $\geq 40$  years of age ( $n=1,196/1,262$ ). In addition, approximately half of the patients undergoing hysterectomy had concurrent gynecological benign comorbidities, and approximately 25% had TOA on admission. These patients' background characteristics including age, gynecological benign comorbidities, and the presence of TOA were assumed to be related to the high hysterectomy rate. We added sentences to show detailed results and explain our assumed reasons for hysterectomy. (Lines 248–257).

**20. Line 232-233 - please back up this statement**

> We changed the sentence and added a reference from 2014 (new reference #6), and compared the hysterectomy rate. (Lines 258–260)

**21. Line 233-235 - reference here please**

> We added references, as recommended. (Line 262, new reference #3 and #34)

**22. Line 242-246 - please expand and provide more information about patients who received hysterectomies, such as clinical indications, extent of disease, comorbidities, etc.**

> We expanded the discussion and added more information about patients who underwent hysterectomy. (Lines 248–257)

**Reviewer #2: This is a retrospective cohort study using a large national database to determine whether there is benefit in laparoscopy over laparotomy in the treatment of pelvic inflammatory disease and tubo-ovarian abscess**

**Introduction:**

**1. Line 67-70: If you are trying to publish in an American journal, you should consider adding whether there are published guidelines from other large governing bodies, including ACOG, RCOG, etc, apart from Japanese Society of OBGYN.**

> We added the treatment guidelines for the Centers for Disease Control, Europe, UK, and Australia, and added new references #15–18. (Lines 72–76)

**Methods:**

**2. Line 124: Propensity Score matching does not account for unknown variables, which are perhaps the most likely to make differences in the observed outcomes, and which may make the unobserved variables effect**

**stronger confounders in the matched comparison groups. For example, size of the TOA, a value that could not be retrieved from the database you used, may be the strongest predictor of whether a practitioner moved for laparotomy or laparoscopy initially, thus becoming more pronounced as a confounder when other variables are accounted for.**

>We added sentences to explain the unobserved variables as follows:

“However, unobserved variables such as size of the TOA, laboratory data including blood testing, severity of intrapelvic adhesions, and surgeons' skill were not included when estimating propensity scores because the database we used did not include these variables.” (Lines 144–148)

### **Discussion:**

**3. You have failed to mention, or it may be difficult or impossible to determine from the data set that you were using how many of the laparotomy cases started out as laparoscopic but were converted to laparotomy due to difficulty with adhesions or possible bowel injury during laparoscopy. If a case started as laparoscopic but converted due to injury or inability to complete surgery laparoscopically, it may give unfair bias against laparotomy cases if it was coded only as laparotomy.**

>From the database, we could identify patients who initially underwent laparoscopic surgery but then underwent laparotomy to repair bowel or ureteral injury, and we confirmed there were no such patients. However, we could not identify patients for whom initial laparoscopic surgery was converted to laparotomy because of adhesions without bowel or ureteral injury; such patients were recorded as undergoing laparotomy.

We agree that laparotomy cases may have been associated with greater surgical difficulty.

We added sentences to explain this limitation as follows:

“Fourth, selection bias is possible secondary to intraoperative conversion of surgical procedures. The database allowed us to identify patients who initially underwent laparoscopic surgery but then underwent laparotomy to repair bowel

or ureteral injury. We confirmed there were no such patients. However, we could not identify patients for whom initial laparoscopic surgery was converted to laparotomy because of adhesions, without bowel or ureteral injury; these patients were recorded as undergoing laparotomy.” (Lines 286–292)

**Reviewer #3: To the Authors:**

**Well written paper with a figure and tables constructed in such a way that the average reader of this Journal can understand - as long as he/she understands "Propensity Score- Matched Analysis".**

**1- I would recommend adding "A Propensity Score Matched Analysis" to the Title.**

>We changed the title as follows:

“Laparoscopic versus open surgery for severe pelvic inflammatory disease and tubo-ovarian abscess: a propensity score-matched analysis”

**2-As addressed as limitations in the Discussions section, I, too, have concerns that data from "about 1200 hospitals (only 82 academic), 27,841 patients is likely to be incomplete or in some cases incorrect and the retrospective comparison data that is presented is likely flawed by numerous factors. However, your presentation of that is of interest, and I feel that it should be left in.**

>We thank Reviewer #3 for these comments.

**3-If feasible, I would like to know what percentage of the planned laparoscopic procedures were converted into laparotomies intraoperatively and why.**

>From the database, we could identify patients who initially underwent laparoscopic surgery but then underwent laparotomy for repairing bowel or ureteral injury, and we confirmed there were no such patients. However, we could not identify patients for whom initial laparoscopic surgery was converted to

laparotomy because of adhesions without bowel or ureteral injury; these patients were recorded as undergoing laparotomy.

We added the following sentences to explain this limitation:

“Fourth, selection bias is possible secondary to intraoperative conversion of surgical procedures. The database allowed us to identify patients who initially underwent laparoscopic surgery but then underwent laparotomy to repair bowel or ureteral injury. We confirmed there were no such patients. However, we could not identify patients for whom initial laparoscopic surgery was converted to laparotomy because of adhesions, without bowel or ureteral injury; these patients were recorded as undergoing laparotomy.” (Lines 286–292)

**4-I would also like to see the data on the percentage of TOAs which were drained with US guidance.( successfully and Unsuccessfully)**

>Forty-three percent (1,017/2,463) of the patients underwent minimally-invasive drainage to treat TOA. We added this sentence to the results (Lines 175–176).

#### **STATISTICAL EDITOR'S COMMENTS:**

**1. Table 1: Need to indicate for the unmatched and the score-matched cohorts, whether the patient characteristics are statistically different.**

>We explained these statistical differences in the main text (Lines 188–193).

**2. Table 2: Need to show the statistical comparisons for these outcomes for laparotomy vs laparoscopy.**

>We added statistical comparisons for outcomes following laparotomy vs laparoscopy, in Table 2.

**3. Table 3, lines 44-46: The text cites another comparison (the length of stay), so that should be included. For surgical complications, revision**

**surgery and in-hospital deaths, the counts were low and there is low power to generalize any of these NS differences for those outcomes. So, the only conclusion of differences relates to proportion needing blood transfusions, duration of operation and length of stay. The others are not generalizable.**

>We added data on median length of hospital stay and p-values for the Mann–Whitney U test, in Table 3 (risk difference and its 95% CI cannot be calculated).

We changed the sentence in the abstract and discussion as follows:

“...regarding surgical complications, blood transfusion, operation duration, and length of hospital stay....” (Lines 48–49)

“...regarding surgical complications, number of blood transfusions, operation duration, and length of hospital stay.” (Lines, 298–300)

#### **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.

> We choose #1 (OPT-IN).

**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. 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. In order for an administrative database study to be considered for publication in Obstetrics & Gynecology, the database used must be shown**

**to be reliable and validated. In your response, please tell us who entered the data and how the accuracy of the database was validated. This same information should be included in the Materials and Methods section of the manuscript.**

> We discussed the database used in the current study in the Materials and Methods section.

Briefly,

- Attending physicians are encouraged to record diagnoses accurately by linking data entries with reimbursement for health care costs. (Lines 106–107)
- A previous study showed that the validity of the diagnostic records in the DPC database is generally high, and that the sensitivity and specificity of the primary diagnoses are 50%–80% and 96%, respectively. The specificity and sensitivity of procedures were found to exceed 90%. (Lines 107–110)

**5. All submissions that are considered for potential publication are run through CrossCheck for originality. The following lines of text match too closely to previously published works. Variance is needed in the following sections:**

**\*Please rework lines 253-256 (several limitations...disease severity). This is nearly verbatim from work you previously published.**

> We changed the sentences as follows:

“However, our study has several limitations. First, we used a retrospective and observational design, which precluded randomization. Even though propensity-score matching was performed to balance patients' background characteristics and adjust for confounding factors,...” (Lines 271–275)

**6. 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-a>**

[nd-Quality-Improvement/reVITALize](#). If use of the reVITALize definitions is problematic, please discuss this in your point-by-point response to this letter.

**7. 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.**

**8. 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).**

**9. Provide a short title of no more than 45 characters (40 characters for case reports), including spaces, for use as a running foot.**

**10. 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.**

**11. Only standard abbreviations and acronyms are allowed. A selected list is available online at <http://edmqr.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. 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 rephrased sentences containing this symbol.**

**13. We discourage claims of first reports since they are often difficult to prove. How do you know this is the first report? If this is based on a systematic search of the literature, that search should be described in the text (search engine, search terms, date range of search, and languages encompassed by the search). If on the other hand, it is not based on a systematic search but only on your level of awareness, it is not a claim we permit.**

>We deleted the phrase “first report” in the revised manuscript.

**14. 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).**

>We reviewed the Table Checklist.

**15. 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.**

## Daniel Mosier

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**From:** Daisuke Shigemi [REDACTED]  
**Sent:** Tuesday, March 5, 2019 5:43 AM  
**To:** Daniel Mosier  
**Subject:** Re: Manuscript Revisions: ONG-18-2317R1  
**Attachments:** 18-2317R1 ms (3-4-19v2)\_revised.docx

Dear Mr. Mosier,

I appreciate your positive response.

I have completed my revision on the manuscript (ONG-18-2317R1).

Please find the attached file (file name "18-2317R1 ms (3-4-19v2)\_revised").

Sincerely,  
Daisuke Shigemi

2019年3月5日(火) 6:10 Daniel Mosier <[dmosier@greenjournal.org](mailto:dmosier@greenjournal.org)>:

Dear Dr. Shigemi,

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. Drs. Matsui, Fushimi, and Yasunaga will need to complete our electronic Copyright Transfer Agreement, which was sent to them through Editorial Manager.
3. TABLE 1:
  - a. What is this? Please clarify in the Table and the text
  - b. Please be consistent in the term used here and throughout the text
  - c. Please remove this variable from the Table and the text
  - d. Please remove this variable from the Table and the text
  - e. This level of detail is not necessary given the study objectives – please take out of Table for purposes of brevity
4. TABLE 2: This variable is so low and so peripheral, it can be removed

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 **Thursday, March 7<sup>th</sup>**.

Sincerely,

-Daniel Mosier

**Daniel Mosier**

Editorial Assistant

*Obstetrics & Gynecology*

The American College of Obstetricians and Gynecologists

409 12<sup>th</sup> Street, SW

Washington, DC 20024

Tel: 202-314-2342

Fax: 202-479-0830

E-mail: [dmosier@greenjournal.org](mailto:dmosier@greenjournal.org)

Web: <http://www.greenjournal.org>

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[Redacted signature block]

Daisuke Shigemi, M.D, MPH  
Department of Obstetrics and Gynecology  
Department of Clinical Epidemiology & Health Economics,  
School of Public Health, the Graduate School of Medicine  
and Faculty of Medicine at the University of Tokyo





## Eileen Chang (Temp)

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**From:** Daisuke Shigemi [REDACTED]  
**Sent:** Tuesday, March 5, 2019 11:28 AM  
**To:** Eileen Chang (Temp)  
**Subject:** Re: O&G Figure Revision: 18-2317

Dear Ms. Chang,

I appreciate your response.  
There was no additional comment on the figure.

Also, it was my pleasure.

Sincerely,  
Daisuke Shigemi

2019年3月6日(水) 1:22 Eileen Chang (Temp) <[echang@greenjournal.org](mailto:echang@greenjournal.org)>:

Hello,

Thank you for catching those mistakes. I have attached the edited version for your review.

And I apologize for the last email! It was indeed for another manuscript. Thank you for letting me know.

Best,

Eileen

**From:** Daisuke Shigemi [REDACTED]  
**Sent:** Tuesday, March 5, 2019 11:01 AM  
**To:** Eileen Chang (Temp) <[echang@greenjournal.org](mailto:echang@greenjournal.org)>  
**Subject:** Re: O&G Figure Revision: 18-2317

Dear Ms. Chang,

I appreciate your positive response.

I have commented on the figure.

Please find the attached file (file name "figure\_revision\_18-2317").

By the way, I think a previous e-mail from you was not for me. ("We have some author queries for you as well. Please see below:...")

Please check it.

Sincerely,

Daisuke Shigemi

2019年3月6日(水) 0:44 Eileen Chang (Temp) <[echang@greenjournal.org](mailto:echang@greenjournal.org)>:

Hello,

We have some author queries for you as well. Please see below:

In Figure 1, when all the exclusions are subtracted from 1,938, the total is 1,156. Is this correct? If so, are the percentages in the exclusion box correct?

In Figure 2, is this wording, "Hours after birth of first expression" correct? Should it instead read, "Hours after birth **and** first milk expression?"

In the legend for Figure 3, your description does not match the figure. Should there be a part A and part B to figure 3, or should we note information in the figure using symbols (in this case, we would use an asterisk [\*] and a dagger [†] instead of "A" and "B"?)

If you could get back to us on these queries by the 3/7 deadline we would appreciate it.

Thank you!

Eileen

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**From:** Eileen Chang (Temp)  
**Sent:** Tuesday, March 5, 2019 10:22 AM  
**To:** [REDACTED]  
**Subject:** O&G Figure Revision: 18-2317

Good Morning,

Your figure and legend has been edited, and they are attached for your review. Please review the figure and legend CAREFULLY for any mistakes.

PLEASE NOTE: Any changes to the figures must be made now. Changes made 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 appreciate a reply no later than Thursday, 3/7. Thank you for your help.

Best,

Eileen

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