OBSTETRICS & GYNECOLOGY

NOTICE: This document contains comments from the reviewers and editors generated during peer review of the initial manuscript submission and sent to the author via email.

Questions about these materials may be directed to the *Obstetrics & Gynecology* editorial office: obgyn@greenjournal.org.

Date: Apr 10, 2020
To: "John J. Byrne" john.byrne@utsouthwestern.edu
From: "The Green Journal" em@greenjournal.org
Subject: Your Submission ONG-20-556

RE: Manuscript Number ONG-20-556

Postpartum tubal ligation: Does BMI Impact Surgical Outcome?

Dear Dr. Byrne:

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).

Due to the COVID-19 pandemic, your paper will be maintained in active status for 30 days from the date of this letter. If we have not heard from you by May 10, 2020, we will assume you wish to withdraw the manuscript from further consideration.

REVIEWER COMMENTS:

Reviewer #1: Thank you for the opportunity to review your work. Given that no prior work examined the question of how BMI influences complications during PP BTL, this study is novel, so thank you for putting time and energy into this important topic that affects many women.

1. General comments:

2. Given that your hospital uses Parkland methods, how do you think your data might look different for modified Pomeroy?

Also, given that post-partum salpingectomy is gaining popularity, what is your take on this trend given your findings? Reference below or similar to those below address this point? It might help to add % PP sterilizations done via Pomeroy, Parkland, and salpingectomy in your hospital and nationally if that data is avail.

Lines 247-249. To me, it seems that it probably does not matter that type of BTL you do or if you do a salpingectomy or not as your minilap incision is the same, in terms of BMI effect. Can you pls elaborate on that? That would actually make your study more generalizable.

3. Powell CB, Alabaster A, Simmons S, et al. Salpingectomy for Sterilization: Change in Practice in a Large Integrated Health Care System, 2011-2016. Obstet Gynecol. 2017;130(5):961-9671

4. Danis RB, Della Badia CR, Richard SD. Postpartum Permanent Sterilization: Could Bilateral Salpingectomy Replace Bilateral Tubal Ligation? J Minim Invasive Gynecol. 2016;23(6):928-932

5. Are any salpingectomies being performed at your institution?

Introduction

6. First paragraph summarizes need for immediate PPTL.

7. Line 124. "99% effective." To me it seems that it would be of use to go into CREST numbers a bit more there, only because you dive into failure later in the paper and that still remains the landmark dataset. They looked at failures/5-10 years/1000 women along with ectopics as percent of those pregnancies.

8. Line 126-130 and reference 10. Since seems to be a direct precedent to your study, would it be possible to dive a little deeper as to why BMI might have been a barrier? Were authors of this study suggesting any reasons as to why that might be?

9. Aim of the study is clearly stated

Methods

10. Paragraph 1 provided useful detail for the setting

11. Time interval: how was it chosen? What was the reason for 2015-2019 time period?

12. Pls state if this was a convenience sample.

13. Inclusion and exclusion criteria are clearly stated

14. Paragraph 2 is helpful as it describes clinical workflow

15. Lines 154-156. Please clarify what you mean by "second review." Were all records reviewed twice for accuracy or only portion of the records?

16. Primary outcomes: how did it come up with those? Please explain why and how you chose those parameters and why you opted not to use one of the existing surgical complication scoring systems such as Clavien-Dindo.

17. Please state that study design was single institution retrospective chart review.

18. Line 246: In discussion, it is stated that follow up was 1-5 years, but it was not clear how this was carried out. Please describe.

19. Do you use wound retractors such as Alexis Applied Medical product? Some providers do, and that is thought to improve exposure and to decrease infection rates.

Results

20. Line 185.It seems like a figure there is missing, I assume it was a flowchart with inclusion/exclusion criteria and numbers by BMI?

21. Sample size and obese numbers are significant given that it a was a single institution. Addressing it in lines 240-242 was very helpful for the reader.

22. Line 203 and lines 232-236: would it be possible to specify time interval of follow up for this pregnancy rate in terms of years? That would make it compatible to CREST data. Otherwise, to me it seems that stating that your pregnancy rate is lower than CREST without specifying time interval of follow up or comparing fecundity of cohorts makes this comparison less meaningful. Same goes for ectopics.

23. Lines 208-209 information about additional operative time was helpful.

24. Table 1. For women with umbilical hernia, how was this addressed during BTL?

25. Table 2. Aborted procedures-would it possible to state the reason?

26. I am wondering if it is possible to look at risk of complications by controlling an increase in OR time? Might be too small of a sample.

Discussion

27. Line 228-229. Composite morbidity of 1.3% found in this study-how does this compare to CREST? What was their composite morbidity? Was their patient populations differnet from yours? When looking at composite morbidity from CREST, did you separate post-partum BTLs from other sterilizations in the data set (ex. interval)?

28. From your dataset, was it possible to identity which women planned to have a BTL but did not get it and why, like in ref 10? It would be interesting to compare factors and identify barriers. Do you think anesthesia teams are more likely to cancel tubals because of BMI? Or because there is no dedicated team and space to perform them, so that acuity of L+D is the main factor?

Discussion/intro:

29. Is there a reason as to why studies below were not cited in this work for comparison?

Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of pregnancy after tubal sterilization: findings from the U.S. Collaborative Review of Sterilization. Am J Obstet Gynecol. 1996;174(4):1161-1168; discussion 1168-1170

Peterson HB, Xia Z, Hughes JM, Wilcox LS, Tylor LR, Trussell J. The risk of ectopic pregnancy after tubal sterilization. U.S. Collaborative Review of Sterilization Working Group. N Engl J Med. 1997;336(11):762-767.

30. I am not sure ref 15 is of much use here since most of the women in that study had their BTL done via large (over 5 cm) laparotomy incision and this was an interval, not PP BTL. Reference 16 had 0.39% incidence of major complications, which differs a bit from this cohort. Can that be discussed?

31. Please address small number in BMI >40 group in table 2 in terms of lack of power. P value in Table 2 is close to 0.05. I personally agree that BMI should not impede access to BTL, but we can't say that risk is the same in morbidly obese due to small size of the sub-group in this cohort.

32. What are next steps?

Reviewer #2: This study addresses an important topic in obstetrics and family planning - how BMI impacts the safety of performing BTL after vaginal delivery. The authors discuss the barriers to BTL in general and based on BMI and the importance of access to contraception in the postpartum period. Given the increasing rates of obesity, this is becoming even more relevant to our care. Strengths include large sample size and provider pool, which helps with generalizability.

I have some questions regarding the statistical analysis of the primary outcome and about using a composite that should be addressed (see below). Also, the retrospective nature of this study excludes those who had intended BTL, but did not get it - which will inherently affect their findings (the highest risk patients were excluded). The paper needs copy editing for some typos (see examples below.) There are also a few other limitations/discussion points that I would recommend the authors consider. See line-by-line comments.

Line 101: Although not statistically different, there was a trend to increased complications with the highest BMI group. Since complications are rare and your p value is approaching 0.05, do you think there would be a difference with an even larger sample?

Line 101-103: For clarity, might change to "Twelve cases of incomplete transection were noted on pathology reports; however, none of these accounted for the 6 subsequent pregnancies that occurred. Otherwise it reads as 6/12 incomplete transections became pregnant.

Line 104: was difference in time statistically significant?

Line 106: change "risk of pregnancy" to "risk of method failure with subsequent pregnancy"

Line 117: Do 48% of all women receive contraception or only 48% of those attending postpartum visits?

Line 123 and 153: add partial to "mid-segment partial salpingectomy" to be clear that this is not a complete salpingectomy

Line 131: This presumption is based on assuming complication rates from other surgeries with BMI as a risk factor. What is the documented risk of BMI for operative complications in general?

Line 160: how is documentation standardized in regards to incision length, is this typically documented? How often do providers document if the incision is extended? This is a limitation in a retrospective study.

Line 165: I understand using a composite score given rare outcomes, but there is some bias in counting any complication as equal. Certainly a wound complication requiring return to OR is a more significant complication than a wound complication not requiring a return to the OR. What does "surgical complication" on your table refer to? In the abstract you say surgical complication is blood transfusion, aborted procedure, or extension of incision - the first 2 of which are separately listed in your table.

Line 197: Which BMI categories had multiple events?

Line 199: add (n=11) after "super-morbid obese category."

Line 206-207: This sentence is not clear. Was there a difference in EBL by groups? Otherwise would just say "The mean EBL was 10.2mL (SD) overall and did not vary by BMI category. The "up to..." in the parenthesis is confusing. Same for line 209-210.

Paragraph starting line 211: Would move to follow paragraph starting on line 195. It appears that your first analysis (primary outcome) compared the 5 BMI categories (table 2) and the second analysis compared just 2 categories - obese/nonobese (table 4). Was any regression analysis performed?

Line 220-222: Prior surgery as a risk factor - I did not see this analysis reported in the results, only on the graph in figure 1.

Line 222: change "across categories" to "with increasing BMI" Also, I think a doubling of operative time from ~20 to 40 minutes based on your figure (from lowest to highest BMI) is clinically significant. Maybe just say that there was variability in operative time in all BMI categories, with significant overlapped. Also line 238-239.

Limitations:
You discuss that BMI is a risk factor for not having a planned BTL postpartum and your cohort is limited to those who were able to have the procedure. Comment on how this limitation impacts your findings. Presumably the obese women that did not receive a BTL postpartum were a higher risk group? Although BMI is an objective marker, some surgeons may make decisions based on adipose distribution.

Do you have estimates of how many women desired BTL and then did not get it?

Retrospective - limitations in provider documentation.

Other topics for discussion:
How does reported complication rates compare to complications with interval surgical permanent contraception? Is there data of obesity as a risk factor for surgical complications for laparoscopic BTL or laparoscopy in general?

There are benefits of complete salpingectomy - lower method failure and ovarian cancer risk reduction. These are probably more challenging after vaginal deliveries and BMI is likely a risk. However, PP BTL has the benefit of providing contraception during hospitalization, since patients have barriers to follow up. Just something to consider - when would an interval procedure be better?

Other comments:
Needs some copy editing for typos. Recommend avoiding passive language. Examples:
Line 116: "has been shown" or change to "is reported as low as..."
Line 185: Figure 1
Line 187: add kg/m2
Line 223-224: change to , Figure 2. or (Figure 2). Currently has comma and end parenthesis.

Recommend more specific titles for tables and figures

Although the term "sterilization" is still used in ACOG documents and in the literature, the term "permanent contraception" is preferred.

Reviewer #3: Outstanding methods and interpretation of the data. This will be a solid addition to the family planning literature.

STATISTICAL EDITOR COMMENTS:

The Statistical Editor makes the following points that need to be addressed:

lines 230-204: Should include CIs for this rate.

Table 1: Should cite parity as median(range), not as mean (range), since parity can only have integer values.

Table 2: Should include CIs for the primary composite outcome %s.

Table 4: Should include CIs for the composite major outcome %s. Cannot generalize the conclusion of NS difference, since the study is under powered. Although the samples are large, the counts of adverse outcomes are rare. For example, given the non-obese rate of 19/1307 (1.45%), the sizes of the two cohorts and the usual criteria of 80% power and an alpha =0.05, the discernible rate of the obese cohort would have to be outside the range 0.5% to 2.9%. Since the rate among obese was 30/2363 (1.27%), the conclusion is not generalizable. Put another way, in order to detect a rate 1.5x

that of the non-obese (or 0.67x times their rate), one would need about 3x the samples in this series, assuming a baseline proportion of 1.45% and the same relative sizes of cases:controls. So, should just cite the %s and their CIs, but not conclude that there could be no difference in major composite outcome rates.

Figs 1, 2: Should provide concise summary in legend for these figures. For Fig 1, although the association between BMI and operative times is not random, the relationship is by no means close enough to be predictive. Should include overlay of CI (for individual outcomes, not for the mean of the model prediction.) Also, the proportion with prior abd surgery (Table 1) appears to increase with Obese Class, so would need to adjust operative time for hx of prior abd surgery, or do a separate sensitivity analysis.

EDITOR'S COMMENTS:

We no longer require that authors adhere to the Green Journal format with the first submission of their papers. However, any revisions must do so. I strongly encourage you to read the instructions for authors (the general bits as well as those specific to the feature-type you are submitting). The instructions provide guidance regarding formatting, word and reference limits, authorship issues ad other relevant topics. Adherence to these requirements with your revision will avoid delays during the revision process by avoiding re-revisions on your part in order to comply with formatting.

Numbers below refer to line numbers.

88 and Title: It is an idiosyncratic fact that at the Journal we tend to avoid the use of the word impact to imply the result of a change, preferring to limit "impact" to mean a physical blow.

92: is the composite morbidity your primary outcome?

97: Instead of dash, substitute a colon. "…3670 women were studied: 263 were underweight…."
Sentence structure 97-100 and 182-185: is a little tricky. As written it says the "women were ..obesity" (1371 were class 1 obesity). Maybe "1371 were class 1 obese" or "had class 1 obesity"? Change here and throughout, including in manuscript (not just abstract).

112: Even more likely is that an unintended pregnancy adds financial and logistical stress to families.

114: Seems like there are some words missing in this sentence. Do you have a reference for this statement?

119: What percent of women use sterilization as their contraceptive?

127: do you have date about how many who want BTL don't get it at time of delivery hospitalization after vaginal birth?

139, 182: Please note that your study was conducted from date 1 to date 2, not between those dates. As written, it would exclude the dates given.

137: How were these women identified? Did you review electronic medical record? You never tell us the source of your data.

148: Where are preferences recorded?

155: Was this a 100% second review or a sampling? As written, I think you are saying that everyone extracted some of the charts, 3 of you redid the extraction on all ~3700 women and for the 1.3% with some morbidity, 2 of you reviewed those. Is that correct?
Was this a retrospective study?

173: Do you measure the height on all women admitted to L&D?

187: add units.

190: Does this # of births include the delivery at which the BTL is performed?

197: Perhaps clearer as (2 events occurred in 10 women; 3 events occurred in 1).

202: Transected instead of transection?

203: in discussion, please comment on the likelihood that a woman with a pregnancy subsequent to BTL would get her care within the Parkland system to allow for identification. (Ie, the rate of subsequent pregnancies might be higher than this).

Do you have any data related to type of anesthesia and if this altered by BMI?

Please note comments regarding low power to generalize conclusions of non significance.

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. 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:
A. OPT-IN: Yes, please publish my point-by-point response letter.
B. OPT-OUT: No, please do not publish my point-by-point response letter.

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.

Please check with your coauthors to confirm that the disclosures listed in their eCTA forms are correctly disclosed on the manuscript's title page.

3. Please submit a completed STROBE checklist for your revision.

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), quality improvement in health care studies (ie, SQUIRE 2.0), and studies reporting results of Internet e-surveys (CHERRIES). 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, SQUIRE 2.0, or CHERRIES guidelines, as appropriate.

4. 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.

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 print appendixes) but exclude references.

6. Please edit your title so that it does not pose a question.

7. 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).

8. Provide a précis on the second page, for use in the Table of Contents. The précis is a single sentence of no more than 25 words that states the conclusion(s) of the report (ie, the bottom line). The précis should be similar to the abstract's conclusion. Do not use commercial names, abbreviations, or acronyms in the précis. Please avoid phrases like "This paper presents" or "This case presents."

9. 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.

10. 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.

11. 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.

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

If appropriate, please include number needed to treat for benefits (NNTb) or harm (NNTh). When comparing two procedures, please express the outcome of the comparison in U.S. dollar amounts.

Please standardize the presentation of your data throughout the manuscript submission. For P values, do not exceed three decimal places (for example, "P = .001"). For percentages, do not exceed one decimal place (for example, 11.1%").

13. 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.

14. Figures 1-2: Please upload as figure files on Editorial Manager. There is a figure cited within the manuscript that does not have a number, please update.

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.

16. If you choose to revise your manuscript, please submit your revision through Editorial Manager at http://ong.editorialmanager.com. Your manuscript should be uploaded in a word processing format such as Microsoft Word. Your revision's cover letter should include the following:

* A confirmation that you have read the Instructions for Authors (http://edmgr.ovid.com/ong/accounts/authors.pdf), and
* A point-by-point response to each of the received comments in this letter.

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 30 days from the date of this letter. If we have not heard from you by May 10, 2020, we will assume you wish to withdraw the manuscript from further consideration..

Sincerely,

Nancy C. Chescheir, MD
Editor-in-Chief

2018 IMPACT FACTOR: 4.965
2018 IMPACT FACTOR RANKING: 7th out of 83 ob/gyn journals

_____